PERSPECTIVE ARTICLE

Stakeholder Perspectives on the Current and Future of Additive Manufacturing in Healthcare

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Abstract: Additive manufacturing (AM) technologies have disrupted many supply chains by making new designs and functionalities possible. The opportunity to realize complex customized structures has led to significant interest within healthcare; however, full utilization critically requires the alignment of the whole supply chain. To offer insights into this process, a survey was conducted to understand the views of different medical AM stakeholders. The results highlighted an agreement between academics, designers, manufacturers, and medical experts, that personalization and design control are the main benefits of AM. Interestingly, surface finish was consistently identified as an obstacle. Nevertheless, there was a degree of acceptance that post-processing was necessary to achieve appropriate quality control. Recommendations were made for extending the use of *in situ* process monitoring systems to support improved reproducibility. Variations in the future vision of AM were highlighted between stakeholder groups and areas of interest for development noted for each stakeholder. Collectively, this survey indicates that medical stakeholders agree on the capabilities of AM but have different priorities for its implementation and progression. This highlights a degree of disconnection among the supply chain at a ground level; thus, collaboration on AM specific standards and enhancement of communication between stakeholders from project inception is recommended.

Keywords: Additive manufacturing; Survey; Healthcare

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1. Introduction

By 2015 the term "The Fourth Industrial Revolution" had spread past industry-specific conferences and entered general use[1]. It was becoming a catch-all phrase encompassing the growing automation in manufacturing, the Internet of Things, and an increased reliance on digital communication. The Fourth Industrial Revolution also relies heavily on the preceding three decades of development in three-dimensional (3D)-printing to enable highly customizable, decentralized, and on-demand manufacturing typically without many of the constraints of conventional processes. There has been a sustained interest in additive manufacturing (AM) since these technologies enable the production of complex, fully-dense and functional components directly from computer-aided design (CAD), and organically inspired and topologically optimized designs that are not achievable through subtractive machining. Initially, a simple prototyping technique, AM has evolved to become one of the most potentially disrupting processes across multiple sectors, particularly healthcare[2].

The quick evolution of AM within healthcare has led to different stages of adoption; polymer 3D printing is nearing the plateau of productivity while bioprinting continues to climb the peak of inflated expectations[3,4]. During the early stages of AM adoption, polymer based

technologies were rapidly implemented to develop surgical models for pre-operative planning and surgical teaching[5]. These derived further use in ophthalmology[6], medical instruments[7], and spinal surgery[8]; nevertheless, some of these polymer based techniques have been criticized for their resolution, deposition rates and low mechanical properties[9]. Since then, metal AM has captured the imagination of individuals and companies while retaining a general perception of being an emerging fringe technology, despite commercial systems being available for almost 20 years[10]. Developments by system manufacturers themselves have understandably revolved around increasing the industrial presence of AM by tackling what is generally referred to as the "barriers to entry." **Figure 1** shows a timeline of key announcements from metal AM system producers over the past 5 years that, while not exhaustive, provide insight into what the manufacturers perceive as the main barriers to entry. As one of the leaders pushing through the next industrial revolution[11], it is necessary to bring together all stakeholders to guide the future evolution of these techniques and their implementation across all sectors.

Figure 1 highlights the areas that these metal AM system producers want the industry to see as their key developments and, although it is difficult to draw firm conclusions, there are some clear points to note. Universally these producers have championed features that increase production (i.e., more extensive systems, lasers, and full automation) and emphasized a move toward systems that enable serialized production. Supporting this drive to large-scale production has been a secondary focus on quality assurance revolving around process simulation to ensure a "first-time-right" approach and process monitoring. More telling, however, are the areas that feature less prominently. The topic of part finishing is rarely mentioned in significant press releases, and the often highly manual methods used are regarded by those in the AM field as a "dirty secret" of the process. Likewise, system safety measures tend to make marketing material; however, these improvements rarely headline in press releases. Finally, aside the addition of more lasers to improve productivity, these metal processes remain largely unchanged technically since they first emerged with minor incremental improvements to print resolution.

Some similarities can be found in the case of prominent polymer 3D printing manufacturers that have favored the requirements of large enterprises in aerospace and automotive. The selective laser sintering P770, P500, and P810 series announced by EOS between 2016 and 2018, aimed to provide high efficiency, larger chambers, automatization and increased print speed while recently presenting their LaserProFusion technology with significant raise in laser number[16]. Similarly, 3D systems launched the MultiJet ProJet MJP 5600 in 2017 only announcing a next generation high speed fusion 3D printing system on February of last year[17], while Stratasys offered Fortus 900MC in 2016 and F770 in May of 2021[18]. It must be mentioned however that

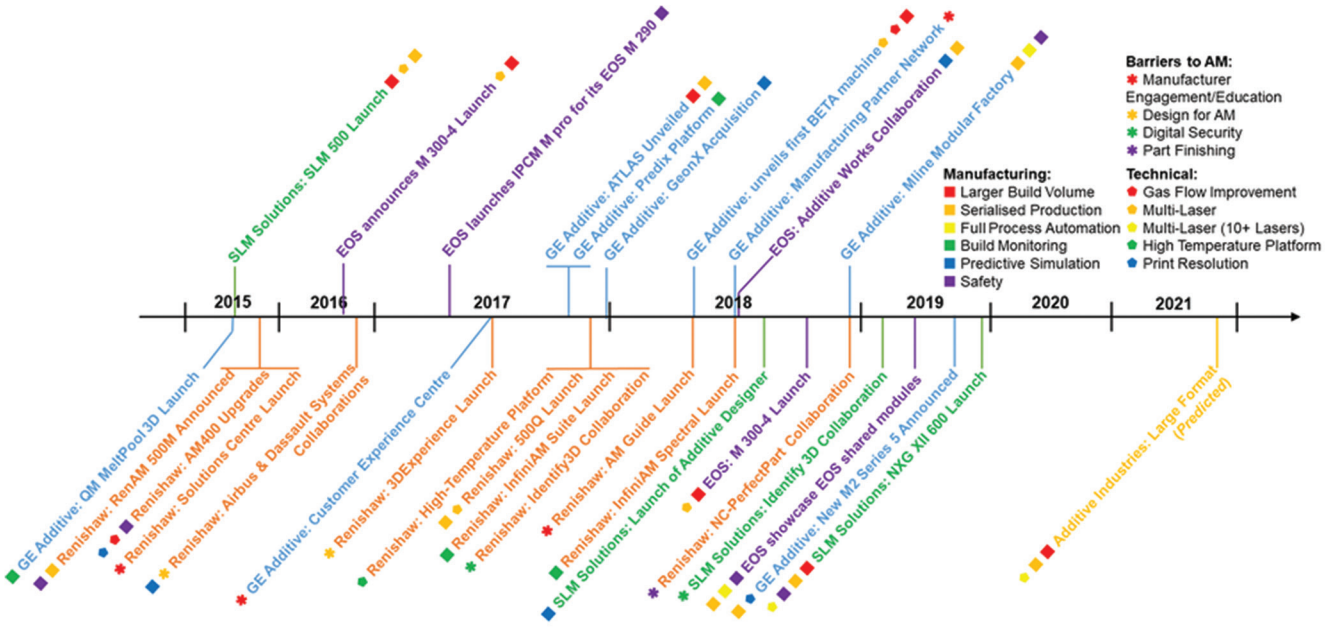

Figure 1. Timeline of key metal AM announcements by system producers with symbols denoting what specific technical, manufacturing, or entry barrier they are related to (Note: Dates relate to news article releases rather than in-service dates). Compiled using various sources[12-16].

polymer printers are generally more affordable and have been adopted early in health-care settings, which coupled with the rising of numerous 3D startups has led to an interest in reasonably prized, user friendly, and compact machines (i.e., FabPro™ 1000, **Figure 2**™, J35 Pro Compact or Formiga P110 Velocis)[16-18]. Nonetheless, it is still clear that system manufacturer advancements tend to favor engagement with larger scale industries such as automotive or aerospace yet align less closely with the medical device market. Conversely, medical implants and devices are a good fit with the benefits of AM in general, often needing to be patient specific and with biologically complementary geometries. In particular, the dental industry has embraced metal AM in the production of customized implants[19]. Likewise, the highly customized nature of maxillofacial implants has been enabled by AM[20] and the ability to form complex integrated lattice geometries has led to AM implants for spinal interbody fusion procedures[21].

From a research perspective, the medical sector has also embraced the unique capabilities of AM. Engineered porosity and lattice structures have been shown to enhance osseointegration and implant stability when applied in orthopedic implants[22,23]. Further novel functionalities such as sustained drug delivery[24], MRI artifact reduction[25], and bone modulus matching[26] have all been proven feasible by AM in fundamental research. Biomedical research has also begun to investigate how the often-overlooked AM surface interacts with both cells and bacteria[27,28] in as-fabricated and surface treated conditions. Hence, where AM system manufacturers have made little notable advance in this region, academic interest indicates that the interface between part and patient is critical in the device's effectiveness.

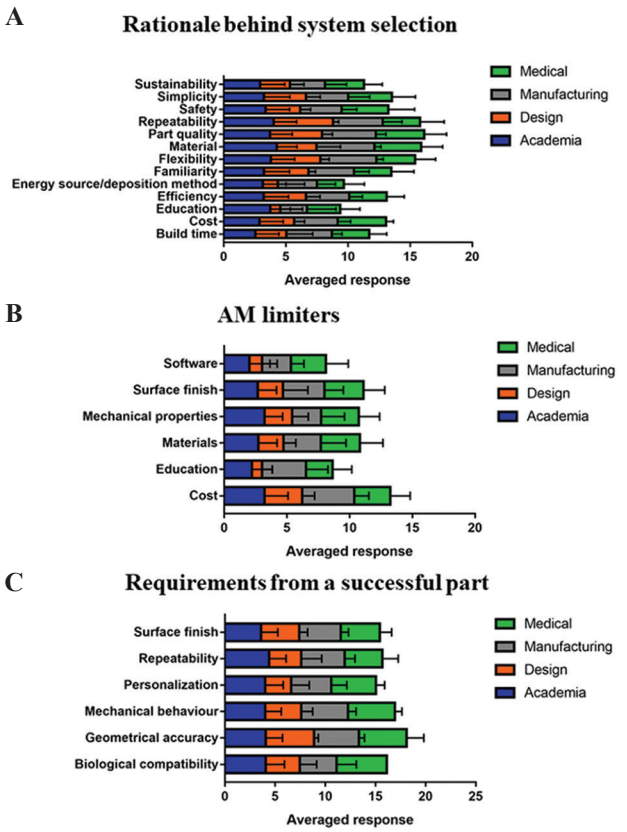

Figure 2. Classification of (A) main motivators behind system selection, (B) reasons that constrain 3D printing, and (C) most important features considered for the success of a printed part with 0 being not at all and 5 being very significantly.

It could broadly be suggested that the advances made by system manufacturers and the direction of biomedical research for AM metal implants has some shared goals but differ in key regions. The drive for part quality, 1st time-right, and process monitoring are areas that manufacturers have been working toward and are necessary for medical implants to satisfy regulatory standards. However, the scale-up efforts of manufacturers are not necessarily a priority in the medical implant market, particularly when considering patient customization. Health-care applications of AM are highly focused on the ease of modification to meet specific requirements in a case by case scenario[29], further suggesting a disconnection between stakeholders. This is compounded by the complexity inherent to the supply chain in medical device development. Instead of a direct relationship between supplier and customer, bespoke implants require inputs from designers, manufacturers, clinicians, and then the end user (i.e., patient) to be brought together while accounting for new technological developments by researchers. Thus, to fully realize the potential of AM in healthcare, it is paramount to ensure a clear alignment between all contributors to the supply chain.

Most available reviews have focused on the present and future uptake of AM based on their ability to produce complex geometries, rapid lead times, the flexibility of the design process, and the potential to create already assembled, movable parts[29-32]. However, limited attention has been focused on understanding mismatches between AM specialists in different application areas. To this backdrop, the following survey was undertaken to better clarify how AM is being used by various stakeholders in healthcare, the barriers to further uptake, and the perceived strengths and weaknesses. Through these findings, it is hoped that system manufacturers, device designers, researchers, and health-care experts may better collaborate and meet the demands of end users.

2. Methods

A questionnaire covering current affiliations, expertise, AM use, positioning, and vision (Questionnaire provided

in Supplementary File) were created using Jisc Online Surveys platform. The survey was circulated through more than 120 AM professionals and clinicians from the UK and overseas based on both scientific publications and news centered on the use of AM in medical settings, resulting in 37 respondents. These experts had to be focused on the application of AM in healthcare and actively working in this area, although it was accepted that they may be part of larger organizations with other areas of interest. As a selection criterion, the terms and agreement section was included stating the purpose of the survey, the use of the collected data, and the respondents' role in the current paper. From this, 36 responses were collected, subdivided between academia, design, manufacturing, and medical specialists and analyzed. A scale from 0 to 5 was provided in questions requiring valuation, with 0 being "not at all" and 5 being "very significant." In the remaining questions, percentages were calculated by dividing each category (e.g., academia) by the total responses of that same group instead of normalizing through the whole dataset. This was performed to facilitate comparison between each professional group.

Statistical analysis was conducted using SPSS (IBM Corp. IBM SPSS Statistics for Windows, Version 27.0) with a base alpha level of 0.05. Categorical data were assessed using Fisher's exact test followed by a Bonferroni-corrected z-test *post hoc*[33]. For the non-categorical data, the similarity of variances was verified using Levene's test and, if not violated, ANOVA-I test was performed, followed by Tukey's *post hoc*. When the similarity of variances could not be assumed, the mean comparison was performed through Welch's test and Games-Howell's *post hoc* test.

3. Results and discussion

3.1. Participant demographics

A total of 36 responses were collected from experts in academia, design, manufacturing and medicine (44.4%, 13.9%, 16.7%, and 25%, respectively) who were "working, researching, and/or implementing" AM devices in healthcare. Initial analysis (**Figure 3A**, **B and Tables S**1, **S2**) revealed that academia, manufacturing, and medical respondents are based in large institutions, either publicly funded or evenly distributed between the public and private sectors. In contrast, design firms appear to be small organizations generally privately funded, although some larger institutions can be found. AM seems to have been used for more than 5 years in all cases (**Figure 3C and Table S3**). However, the state of implementation appears to be further consolidated in academia and manufacturing with designers stating different usage rates depending on the technology used (**Figure 3D**, **E and Tables S4, S5**). Similarly, AM technologies are generally employed daily for academia and manufacturing, with mostly weekly production rates for medical professionals or monthly/bimonthly for designers. Medical professionals tend to split almost equally between using AM directly (**Figure 3F and Tables S6, S7**), or outsourcing the process. This seems to be linked to experience on AM use (**Table S8**), with 44.4% of medical experts being neither sporadic nor regular users while all remaining respondents are mostly regular users (81.3%, 100%, and 83.3% for Academia, Design and Manufacturing, respectively).

3.2. Area of interest and process selection

All stakeholders surveyed consistently listed prototyping, end-use parts, and concept verification as the main purpose for their AM produced devices (**Figure 4A and Table S9**). However, a prevalence for finished parts arises from the medical experts, 38.1%. Regarding materials (**Figure 4B and Table S10**), all seem to have a presence in academia, manufacturing and medical applications; however, polymers and metallic alloys were dominant for design respondents. The overall trend shows that polymers, followed by metals, are generally the most used sources in the academic, design, and medical sectors, which is in line with existing literature[7,9]. In contrast, metallic alloys are more prevalently used by participants within manufacturing. Historically, the use of AM in medicine began with the development of anatomically biosimilar or 3DGraphy models for surgical planning and education of healthcare professionals and students[5]. Since then, the scope of these technologies has grown to include the preparation of patient specific tools or jigs, implantable devices and bioprinting[5,34], although the previous reports still consider rapid prototyping as the main application area for AM[35-37]. The obtained responses in **Figure 4**, support the predominant use of AM to produce polymer prototypes or verify novel concepts, with a notable shift toward end use parts and tool production.

The pooling of all respondents indicates that the main systems used to process these raw materials depend on the area of expertise (**Figure 4C and Table S11**). A general prevalence for powder bed fusion seems to arise in all areas, although design and medical experts focus on a smaller range of techniques. Thus, it is clear that both academia and manufacturing are fully exploring the capabilities of AM, while design and medical are heavily focused on their raw materials and systems. At the same time, it must be mentioned that statistical analysis of the categorical data presented in **Figure 4** did not provide enough basis to suspect an influence of expertise on the aforementioned areas; nevertheless, differences in response rates make a proper estimation of these effects

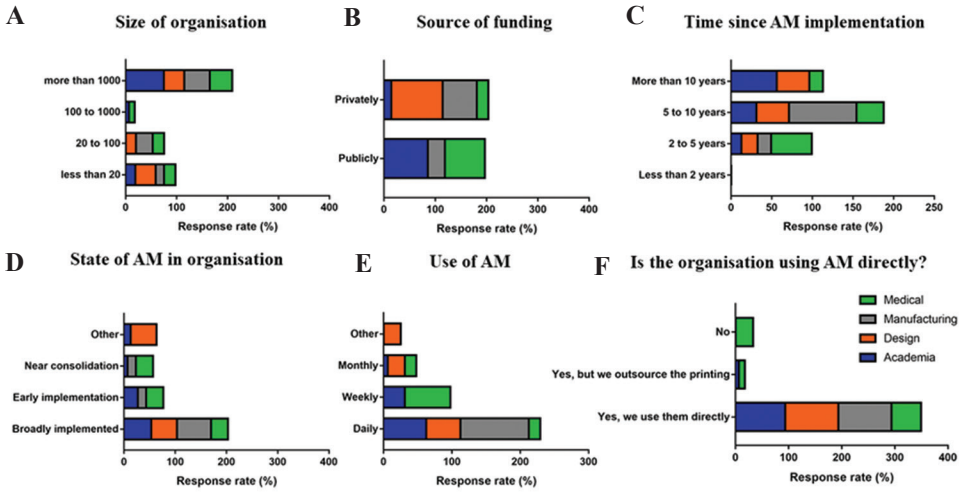

Figure 3. Respondent's demographic analysis showing (A) size of organization, (B) funding source, (C) time since AM implementation, (D) state of AM in the organization, (E) machine scheduling, and (F) use mode of AM in organization.

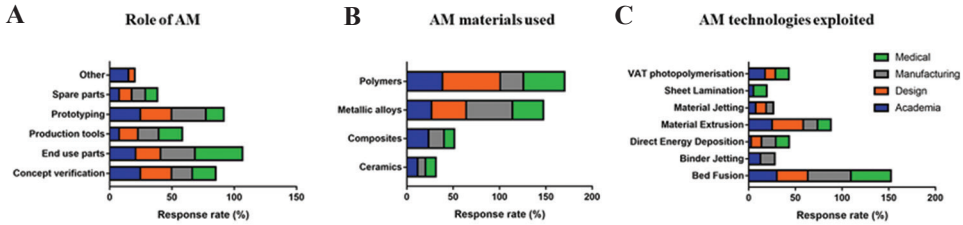

Figure 4. Percentage of responses per area of expertise regarding the (A) role, (B) material, and (C) system used in additive manufacturing.

difficult. These results indicate that design firms use AM in diverse applications but heavily specialize in materials and technologies.

3.3. Rationale for AM implementation

To understand the main drivers behind AM selection, respondents were asked to rank different reasons that influenced their decision (**Figure 2A and Table S12**). From the pooled responses, technology selection was mainly motivated by repeatability, part quality, material and flexibility while energy source/deposition method and education did not have a substantial impact. Statistical analysis indicated the significant difference in overall responses occurred between education/materials, energy source/materials, energy source/part quality, and energy source/repeatability ($P > 0.05$). Group-wise, small differences can be seen between experts, with academia, design, and manufacturing generally following the overall trend albeit slight shifting on their relevance. More interesting are the responses given by the medical specialists, who almost completely alter the general trend by focusing on cost (3.9 ± 0.6), part quality (3.9 ± 1.8), materials (3.8 ± 1.7), and safety (3.8 ± 2.1). Interestingly, the statistical analysis only indicated significant differences ($P > 0.05$) between designers and academia for education. This suggests that expertise has a limited influence on the reasons behind system choice.

In terms of barriers to entry (**Figure 2B and Table S13**), cost was considered the main obstacle alongside surface finish, mechanical properties, and materials. ANOVA II test indicated that statistical differences exist driven by expertise (designers and all other professionals) and barrier (cost/software). Thus, it is suggested that there is a disconnection within the supply chain. Of specific note is the high regard of education as an important barrier for manufacturing responders, 3.5 ± 1.8, while mechanical properties, 2.3 ± 1.9, of the finished part do not pose a high obstacle in modern AM.

To further understand the barriers to entry, it is necessary to evaluate the requirements of a successful AM device. From **Figure 2C and Table S14**, it seems clear that overall geometrical accuracy and, to a lesser degree, mechanical behavior is the top characteristic defining a successful part, with personalization ranked lowest of all the surveyed options. Nevertheless, statistical analysis indicates that there is no basis for saying which characteristics are the main discriminant of a successful part. In contrast, statistical significance was found due to expertise between designers and medical experts. A detailed comparison between perspectives for each group indicates that repeatability (4.4 ± 1.7) and surface

finish (3.6 ± 1.7) or mechanical behavior (4.7 ± 0.8) and biological compatibility (3.7 ± 2.0) are the highest and lowest priorities for academia and manufacturing, respectively. As expected, biological compatibility overshadows all other requirements from a medical perspective (5.0 ± 0.0), with repeatability ranked lowest (3.8 ± 1.6).

From the point of view of academic, design and manufacturing experts, simplicity, repeatability, part quality, and flexibility are some of the most desirable features (**Figure 2A**) and are heavily needed for a successful part (**Figure 2C**) while less sought for by medical practitioners. Decoupling of customization and cost is often regarded as a fundamental driver to the growth of AM in healthcare, allowing to bypass traditional economies of scale coining the term "economy of one"[38]. Personalization is highly desirable in complex clinical cases where the surgeon can control the design, although it poses a heavy burden on regulations. Since the advent of AM, it has become clear that each process can be significantly influenced by numerous input manufacturing parameters, which can result in products that do not meet quality control (QC) requirements[29,39]. Combining this with limited standardization and regulatory advice resulted in an initial preference of AM in non-critical parts that do not require regulatory approval and the use of in house specifications[40]. Over the last decade, new standards resulting from ASTM and ISO collaborations encompassing AM has supported increased confidence in their adoption[41-43]. Nevertheless, certification is still considered one of the main constraints of modern AM[29,40,44], which may explain the required features for success mentioned in this survey.

3.4. Advantages, limitations, and future perspectives of AM

To expand our understanding on the vision of AM as seen by different specialists, specific details were asked on the main advantages and disadvantages in healthcare (**Figure 5A, B and Tables S15, S16**). Based on the obtained data, it is clear that personalization, prototyping, design control, and lead times are the main benefits for academics and designers, although the latter indicated prototyping and personalization (23.1%) as the most valued characteristics. Manufacturers follow this trend highly rating prototyping and design control (21.7%), although other advantages were indicated (i.e., batch size and manufacturing of assembled parts). Similarly, medical experts focus on personalization followed by batch size, design control, entry cost, and lead times. The consequence of these valued properties of AM could reveal that the technology, currently sold as a highly versatile process capable of complex bespoke designs, is in agreement with how most specialists currently view these techniques.

The main disadvantages of modern AM as perceived from the obtained data (**Figure 5B**) seem to come from the expertise needed to use the systems, the achievable

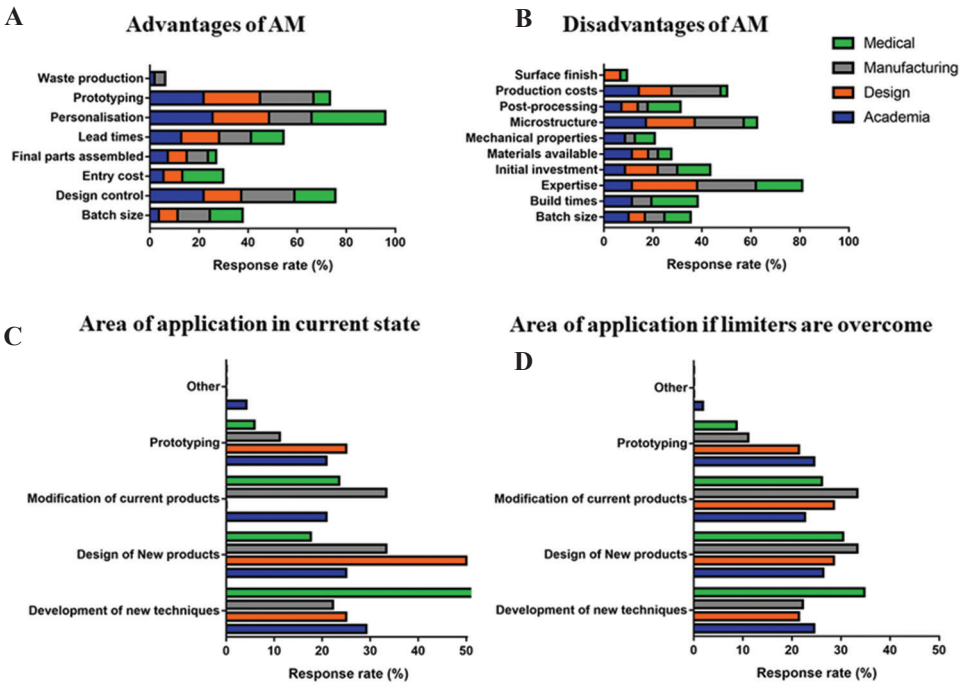

Figure 5. Additive manufacturing (A) advantages and (B) disadvantages as seen by each profession and areas where these processes would be of interest to further apply (C) currently or (D) if their main disadvantages are overcome.

microstructure, production costs, and initial investment. Notably, the limited rating for post-processing and mechanical properties may indicate that some stakeholders are not completely aware of their importance. Alternative, this may also suggest that old, well-known AM limiters are either being subsided by the advances of the technology or accepted as an inevitable part of these processes. Other barriers mentioned during the survey include limited standardization, few materials available, software reliability, complex machine certification or the manual labor involved in de-powdering (specific to metal AM processes), and post-processing.

Current and future perspectives were analyzed by surveying the likelihood of further incorporating or increasing the presence of AM given the state of the technologies as of now (**Figure 5C and Table S17**) or in a hypothetical future (**Figure 5D and Table S18**) where the previously mentioned limitations were eased. While similar core interests are shared in both scenarios, differences can be observed between respondent groups. The state of existing processes seems to be a tool to design new products and develop new techniques, although the latter varies with expertise. In the case of design respondents, the design of new products, 50%, should be the main area of focus for this technology; however, the pursuit of product modification, designing new products and development of new techniques through AM is shared between manufacturing (33.3%, 33.3%, and 22.2%, respectively) and medical (23.5%, 17.6%, and 52.9%, respectively). Specific areas where 3D printing could be effectively used included: Introduction of novel structures, research, and any field where customization is required or desired.

The general trend undergoes a slight shift in the hypothetical case that current limitations are subsided with the design of new products being the main focus area, followed by a similar interest in product modification and technique development. Small variations in interest take place in academia, manufacturing and medical experts; however, a more radical shift occurs in design. For once, these professionals did not consider the use of AM to modify products in the current state of the technology; nevertheless, 28.6% agree that this should be the main avenue alongside the design of new products and prototyping. Nevertheless, the Fisher exact test did not reveal a significant link between expertise or these fields.

Based on this survey, the main potential observed in medicine seems to be consistently focused on personalization and control of the final design (**Figure 4A and 5A)**. Similarly, lead time reduction is clearly perceived as a benefit for the uptake of AM. Thus, it is likely that all experts agree with the general trends reported in literature; nevertheless, it appears that personalization is not likely critical to the success of the part (**Figure 2C**). This is emphasized when the desired application of the technologies in its current state (**Figure 5C**) or if their main shortcomings are overcome (**Figure 5D**) is considered. The development of new products only increases in the medical field once the current issues are addressed, while design only considers the use of AM to modify existing products in the same scenario. Consequently, although personalized medicine is the main initiator of AM uptake, enhancement of the technological state of AM may lead to new opportunities.

Materials and mechanical properties were shown to be critical for the success of the device and may constrain the use of 3D printing (**Figure 2B and C**); however, these are not perceived as a huge disadvantage, with only microstructure mentioned as a constraint (**Figure 5B**). Feedstock for most systems is highly specialized, which requires specific manufacturing processes and control. As the technology is still emerging, the limited demand for bulk feedstock and poor guidance on quality management and traceability has reduced the number of suppliers and materials, resulting in material availability being critical to AM expansion[2,9,40]. Based on this survey, it seems likely that the respondents are mainly concerned about material processing rather than raw feedstock availability. Partly, this may have been caused by the specificity of the medical field where there has been a preference for the use of a reduced number of base materials considered as gold standards (i.e., Titanium alloys or PEEK)[45]. In contrast to material availability and given the intrinsic connection between microstructure and mechanical properties is thus, surprising to see the disconnection showed between these two parameters in the current survey. Nevertheless, much work has been done by the research community on the link between system inputs and final part properties for powder bed fusion[39,46,47] and material extrusion[48,49], two of the most used systems by the respondents. Regardless of the advances indicated by the academic community, it seems likely that concerns about anisotropy, delamination, or variations in mechanical behavior from well-established traditional techniques[29,50] are still affecting the uptake of these technologies.

Numerous reviews on AM state waste reduction and sustainability as main advantages over conventional processes, generally, as a result of reduced waste material, less energy intensive and polluting manufacturing processes, efficient designs and decentralization of the supply chain, which could result in significant cost savings[3,4,38,51-53]. While interest in using sustainability as a marker for system selection has been shown (**Figure 2A**), waste reduction was not considered an advantage (**Figure 5A**), with cost selected as the most consistent AM concern throughout the questionnaire. In this regard, it must be said that current AM technologies are still classed as emerging and perhaps lack the infrastructure

capable of supporting their full potential. Such is the case for the limited pool of suppliers, usually constrained to AM machine manufacturers[54,55]. Similarly, although technological advances on AM systems are common in the academic field[56], systems currently in use are limited by bed size, build time, technical expertise, and post processing requirements[40]. The previous surveys have mentioned the scalability of AM as a constraint to cost reduction and future implementation, with numerous machines required to attain a comparable rate of production to traditional processes[36,57]. While this may be true for AM to fully penetrate all production markets, it is necessary to recognize that AM has its own natural drawbacks and, as any other manufacturing process, it should be used where its inherent benefits can be exploited. The main advantages of AM come in the form of rapid production of low volume, highly complex on demand devices, indicating its preferential use for devices customized to the individual[39,58]. Thus, AM should be considered from a different standpoint and, similarly to the necessity of developing new standards, costs should be observed from a new perspective instead of applying previously used mass production models. For instance, machinery costs are expected to account for high shares (45 – 75%), raw materials are costly, but are amortized due to efficiency and design optimization, and processes are highly automated while reducing the need for imports/exports of specific components[3,51]. Consequently, while costs are currently an issue in medical applications, these are linked to the early state of the technology. Likewise, scalability as traditionally considered should be reviewed, clearly demonstrated by the limited evaluation of batch size as a disadvantage of current AM (**Figure 5B**).

As a result of limited regulations, manufacturing firms were required to develop their own capabilities and specific know-how highly regarded as an asset to ensure competitiveness during early AM implementation[36]. Similarly, the new change in paradigm brought from conventional manufacturing seeps into the basic tools commonly used in these applications. CAD software operations are heavily reminiscent of conventional subtractive manufacturing operations[50,59], but contrast with the complex structures desired from AM. This has led to a need of specialized know-how, clearly recognized as a disadvantage by the surveyed experts (**Figure 5B**). However, this recognition contrasts with the low score on education and software obtained from all except manufacturing experts (**Figure 2B**). Part of this may be a result of AM evolution; nevertheless, partnership between academic and external institutions could have influenced it. A senior manager of an aerospace firm that have adopted AM who was recently interviewed by Moradlou *et al*.[55] indicated that "the technology itself is not seen as a core competency, prompting the company to partner with external organizations," resulting in increased University Technology Centers, business lead collaborations with research (e.g., Catapult centers) or a supplier driven product and process design. Nevertheless, important differences between manufacturing experts and the rest of the surveyed professionals are still observed, suggesting that limited influence of these structures may take place in healthcare.

3.5. Optimization of AM parts

One of the fundamental aspects of any manufacturing process comes from understanding the main influencers in both successful and failed products. When asked about the main aspects affected by a printed part when the process was not optimized (**Figure 6A and Table S19**), the overall responses indicated that, geometrical accuracy, mechanical behavior, repeatability, and surface finish would be mostly affected. Small variations between respondents could be observed, although statistical analysis suggested that similar points of view are shared between experts. It is worth noting that there is a lack of correlation between biological compatibility and surface finish, which are known to be heavily interrelated[28].

Optimization of system parameters is reported for each build by 45.2% of the respondents (46.7%, 40%, 33.3% or 60% for academic, design, manufacturing, and medical, respectively). Nevertheless, it was clear that standard or master settings are commonly used with variations only applied when new materials, processes, or parametric research is undertaken. In all cases, parameters are mostly selected based on the technician's experience or manufacturer recommendations, followed by parametric analysis or the use of software tools (**Figure 6B and Table S20**). This is especially the case for designers and medical experts, while academics, manufacturers and medical experts are open to implement different protocols for AM optimization. Academics and manufacturing respondents heavily rely on parametric analysis, although the latter also relies on process feedback. Consequently, it seems clear that albeit an increased interest in process monitoring[60,61], AM is still heavily reliant on experienced staff and parametric analysis on simple geometries.

The limited process monitoring performed supports this heavy reliance on experience and previous work (**Figure 6C and Table 21**). When asked how the AM processes were supervised, only 29.5% of all respondents indicated that they possessed an in-built monitoring system, while 34.1% referred to system readings and 11.4% did not perform any monitoring. The lack of reliance on such systems is especially noticeable in design where no AM process monitoring was done by 20% of respondents and mostly using calibration master references or previous builds. In contrast, manufacturing firms always monitored the printing parameters, either

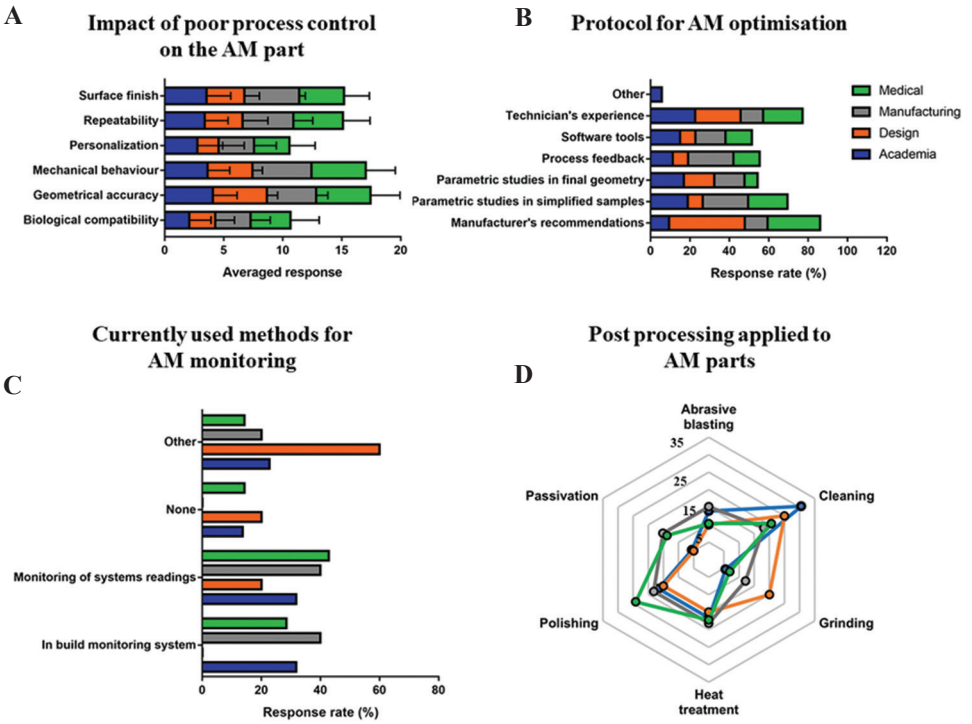

Figure 6. Analysis of system optimization including (A) impact quantification of poor machine control, (B) method for input setting selection, (C) techniques used to monitor 3D printing, and (D) post processing steps used on the printed part.

using an in-built system (40%), through system readings (40%) or other means. Only two medical experts report *in situ* process monitoring, with 42.9% using system readings, 14.3% depending on manual inspection and the last neglecting parameter control. Other monitoring tools included visual and manual inspection, experience or fundamental characterization of specifically designed specimens.

All respondents, regardless of expertise, recognized the importance of parameter control to ensure the quality of the finished part (**Figure 6A**). However, there seems to be a clear disconnection between control and biological compatibility. Manipulation of these inputs is critical for part production and compliance with clinical needs; however, their selection seems to be commonly based on the producer's recommendations, previous experience, or simple parametric analysis (**Figure 6B**). In 2012, the UK AM special interest group showcased the limited robustness of available systems, which coupled with the reduced guidance on QC had caused reticence and doubts on AM adoption[60,62,63]. More mature processes have well established practices with statistical models and controlled sampling, ensuring the viability of each batch. In contrast, AM is an emerging technology focused on personalization, which complicates implementation of traditional QC processes[41,50,64]. As a response to this gap in manufacturing control, *in situ* monitoring systems have been arising to control process deposition, energy source and raw material[60,65]. Commercially available systems have recently started to be available from companies such as Renishaw PLC, SLM Solutions GmbH or Velo 3D Inc., however, most methods function in an open loop where information is processed and evaluated afterwards[65]. An ideal *in situ* monitoring system should be able to detect and correct any deviations from the optimal process in a closed loop to prevent waste of time, materials, and energy due to failed production. Nevertheless, the datasets involved are normally too extensive to enable real time processing, limiting AM uptake[60,65]. Thus, the limited presence of such systems in the surveyed firms seems reasonable, with greater uptake in manufacturing and academia while of great interest for medical experts (**Figure 6C**).

In the previous paragraphs, parameter optimization and monitoring was questioned; however, poor surface finish, porosity, and heterogeneous microstructures of as printed parts are still the main limitations of modern AM processes. A critical example of their influence comes from the hand of fatigue performance, which even today still challenges the use of metal AM parts. Anisotropic properties arising from microstructural orientation due to complex thermal history and the mesostructure naturally occurring from the layer-by-layer processing of the base material weaken the dynamic resistance of as build parts. Moreover, these heavily synergize with defects in the form of unmelted particles and inner porosity to

provide areas for stress concentration and subsequent crack initiation[66,67]. Although some of these defects can be constrained through build optimization, numerous processing parameters influence the end part at different length scales. In addition, still today there is a limited understanding on how these affect static and dynamic behavior, thus, the direct application of as build AM parts is rare[67]. These are normally treated through the use of post processing for which cleaning, polishing, and heat treatment seem to be the most relied on, followed by abrasive blasting, grinding, and passivation (**Figure 6D and Table S22**). Similarly to previous questions, academia seems to follow the overall trend, although reliance on other techniques (e.g., coatings, vibro-polishing, and post-curing) depending on the manufacturing material and part purpose is relatively high (11.1%). The main post manufacturing processes designers use are cleaning and grinding with other equally ranked techniques. In contrast, the manufacturing sector seems to align with academia, similarly favoring cleaning, heat treatments, and polishing (18.2%) with an increased interest in abrasive blasting and passivation (15.2%). Finally, the most used treatment by medical specialists comes in the form of polishing (24.1%), followed by cleaning (20.7%) and heat treatment and passivation (17.2% and 13.8%, respectively) This intense use of post processing methods suggest that all professionals accept that these steps may be inevitable to subside AM disadvantages. This is further emphasized by the lack of statistical differences suggesting similar positioning between professionals (**Figure 6B-D**).

As with any other manufacturing technique, current AM processes are not perfect, with inherent drawbacks stemming from their approach to material conformation. While the layer-by-layer processing results in highly customizable and complex structures, the interaction between coatings naturally creates a rough surface[68-70]. This can be compounded in some AM technologies such as powder bed fusion, where part of the incident energy dissipates from the contour melt pool into the surrounding powder, leading to their partial melting and sintering[71-73]. Parameter optimization and careful part planning can reduce this effect; however, post processing is still the preferred manufacturing step alongside heat treatment for structural refinement[74-76]. For general AM applications, surface processing aims to eliminate crack initiation sites and reduce friction between reciprocating elements, although esthetics, and customer preferences still play a fundamental role. Jirsák *et al*.[36] reported that aerospace AM manufacturers needed to increase operational costs due to post processing to match surface requirements obtained through previous "traditional" techniques. In medical devices, the rationale for surface treatment is heavily based on the potential cytotoxic effect of unprocessed materials or surface modifications to enhance cell adhesion[27,28]. Further benefits can be obtained by chemical treatments to modify the topology and simultaneously enhance biological compatibility, for example by increasing the natural oxide layer of some metals (i.e., TiO_2). Nevertheless, these increase lead times and manual labor while potential contaminants may compromise biocompatibility[27]. At the same time, it must be mentioned that the push for complex and functionalized devices achievable only by AM could cause a shift in the use of these techniques. Most materials used in implantable devices have a significantly higher Young's modulus than native bone, resulting in most loads being supported by the artificial component. Following Wolf's law, this can lead to bone resorption with the subsequent weakening of tissue at the implant interface. Known as "stress shielding," this phenomenon has been one of the main drivers of AM in healthcare, where porosity and latticed structures enable a more even stress distribution while providing anchoring for new bone formation and delivery of complementary therapies[77-79]. Despite their advantages over bulk parts, latticed structures still require post processing to limit potential mechanical failure and cytotoxicity. However, methods requiring tool and visual access (e.g., polishing) that is heavily relied upon by some experts nowadays may be pushed aside for some of the other aforementioned techniques.

In this survey, all experts are aware of these benefits, with most post processing involving, at least, cleaning, heat treatments, and polishing/grinding (**Figure 6D**). On the other hand, passivation is less common in academia and design, which may be caused by the specialization in R&D for the former and the prominent use of polymers for the latter. Based on the potential effects of poorly treated surfaces, it is clear why the surface finish was so highly regarded by the experts surveyed; however, surface finish and post processing were not regarded as one of the main drawbacks of AM (**Figure 5B**). While roughness and post processing are common themes in the literature, this suggests that experts start to accept that this is an inherent defect of printed parts and complementary steps need to be added as with conventional manufacturing processes.

3.6. Functionalization of AM parts

Although AM has opened new avenues in medical device development, it is interesting that 80.6% of specialists questioned desire further functionalization of current parts. Group wise, all respondents for design, and a large majority for academia (81.3%) and manufacturing (83.3%) support the addition of novel approaches while this dwindles for medical professionals (66.7%). In general, it seems that latticed structures, antimicrobial coatings/loads, increased porosity, or growth factors/ osseoinductive loading/coatings are the most desired

improvements over conventional parts (**Figure 7 and Table S23**). From these responses, it seems likely that both academics and manufacturers are open to a large array of modifications. In contrast, design experts would mostly consider structural alterations, while medical experts favor antimicrobial modifications (29.4%) while growth or osseoinductive treatments ranked equally to physical functionality (17.6%). This suggests differences may arise due to expertise, although statistical analysis failed to link field and supplementary functionality.

Future directions of the AM field depend on the specific need, but it is clear that the main focus overall areas surveyed revolve around the exploitation of complex functional geometries (**Figure 7**). As previously mentioned, latticed and porous structures are becoming of high interest in healthcare due to their ability to limit aseptic loosening caused by the mismatch in mechanical properties between device and native tissue while providing space to deliver complementary therapies[77-79]. Alongside these benefits, latticed structures make it possible to maintain mechanical stability with further weight, waste and cost savings, resulting in an overall interest from all fields. Comprehensibly, more biologically centered strategies, such as antimicrobial loading or growth factors, are mostly sought for in academia and research. These seem to indicate that the current research landscape agrees with the current and future needs of AM stakeholders[29].

The results shown in this research have shed light on the current perspectives and future needs of AM experts in academia, manufacturing, design, and medicine. It must be said that the participants only represent a small proportion of knowledge with bias possibly subjected to each professional context. Furthermore, generalization of the conclusions presented in this study may be difficult due to the limited pool of participants. Regardless of these limitations, this manuscript gives confidence on the path taken by AM in healthcare while showcasing areas of interest for future development throughout the field.

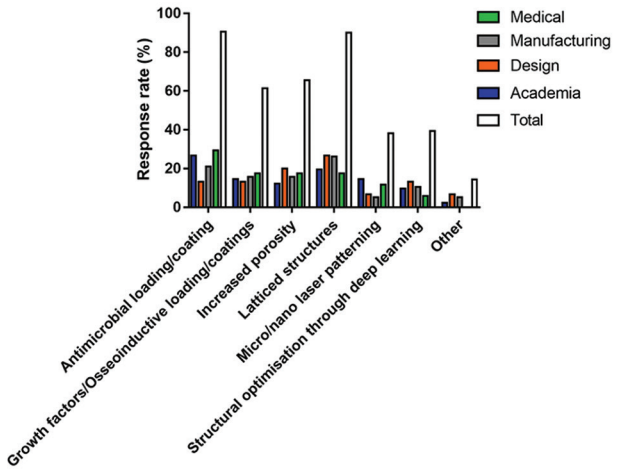

Figure 7. Supplementary functionality over conventional AM parts desired per area of expertise.

4. Conclusion

Herein, a survey was conducted to understand the state of AM in healthcare through the lens of academics, manufacturers, designers, and medical professionals. Repeatability, surface finish, mechanical behavior, cost, and biocompatibility are some of the main points cited as obstacles for using these technologies, although differences between their role and impact on the success of a printed part exist between professionals. This leads to slight variations on the future vision of AM in healthcare where manufacturing and medical experts would accept its use in both productions of new goods and modification of old ones. In contrast, designers were more focused on using AM for only new products, preferring to maintain their old capabilities to produce previous designs. All experts agree on the importance of process control to ensure the quality of the part; however, *in situ* monitoring systems are rare, with most optimization based on recommendations of manufacturers and technical experts. Interestingly, there seems to be an agreement that some defects of these processes (i.e., anisotropy or surface finish) are natural constraints with the necessity to apply post processing techniques that are not being highly valued as AM limitations. Personalization and design control are heavily regarded as the main advantages over conventional processes, further indicated by structural optimization being the central functionality desired over conventional devices. All these points indicate that most experts agree on the capabilities of AM, however, misconceptions and different visions still exist in the field. While AM has great potential in healthcare, all experts must work in tandem and understand the needs and constraints of each step in the supply chain. Thus, it is critical that all stakeholders must collaborate, ensuring that AM is used not as a magic bullet but as another manufacturing process properly selected when appropriate.

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Conflict of interest

The authors declare no conflict of interest.

Author contributions

The survey was developed by V.M.V., L.N.C., J.W.A., and S.C. with data collection and analysis performed by V.M.V. and supervised by J.W.A. The manuscript was written by V.M.V., L.N.C., J.W.A., S.A., A.G.A, and S.C. The project was supervised and funded by S.C.

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