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Innovating the supply chain in health-related crises: some evidence from ISINNOVA case

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Abstract

Purpose – Additive manufacturing (AM) technologies, also known as three-dimensional printing (3DP), is a technological breakthrough that have the potential to disrupt the traditional operations of supply chains. They open the way to a supply chains innovation that can significantly benefit hospitals and health-related organizations in dealing with crises or unexpected events in a faster and more flexible way. In this study the authors identify the boundary of this potential support.

Design/methodology/approach – The authors adopt a case study approach to understand the dynamics behind a well-known best practice to identify the main opportunities and the main pitfalls that AM may pose to health-related organizations wanting to leverage them.

Findings – The case highlights that it is possible to increase hospital flexibility using AM and that by leveraging the Internet it is possible to spread the benefits faster than what it would be normally possible using traditional supply chain processes. At the same time the case highlights that leveraging these technologies needs buy-in from all the relevant stakeholders.

Originality/value – The paper is one of the first, to the best of the authors' knowledge, to highlight the main opportunities and difficulties of implementing 3DP technologies in hospital supply chain management.

Keywords Supply chain innovation, Additive manufacturing, 3D printing, Open innovation, Spare parts, Covid-19

Paper type Research paper

1. Introduction

Supply chain innovation represents the possibility for manufacturing firms to enhance their competitiveness by changing their supply chain network, technology, process or a combination of these (Arlbjørn *et al.*, 2011).

Additive manufacturing (AM), also referred to three-dimensional printing (3DP) is a new way of producing goods adding materials (such as polymers, ceramics and metal) to an empty surface in layers to build an object from a digital-blue print (Holmström and Partanen, 2014; Achillas *et al.*, 2017). Even if this technologies were created in the late 80s (Ghobadian *et al.*, 2020), they have been recently considered as key innovations (Caputo *et al.*, 2016; Durach *et al.*, 2017; Steenhuis and Pretorius, 2017) that may have profound strategic effects in several industries (Mellor *et al.*, 2014; Beltagui *et al.*, 2020) as they may help in innovate the way companies will design, produce and market their goods (Achillas *et al.*, 2015; Schröder *et al.*, 2015) both complementing traditional manufacturing processes (Holmström *et al.*, 2010; Rylands *et al.*, 2016) or driving companies to transform them more deeply (D'Aveni, 2015; Luomaranta and Martinsuo, 2019).

In some previous studies AM has been found to have a slower production rate (Khajavi *et al.*, 2014) and without fewer economies of scale (Baumers and Holweg, 2019) than a traditional manufacturing process, and it requires specially pre-processed raw materials (Khajavi *et al.*, 2014). At the same time other studies have focused on AM's advantages in creating supply-chain innovations by reducing the supply-chain complexity (Rogers *et al.*, 2016; Candi and Beltagui, 2019) and improving its flexibility (Delic and Eyers, 2020), with positive effect on reducing wastes (Huang *et al.*, 2013), and more in general improving the whole supply chain sustainability (Despeisse *et al.*, 2017; Beltagui *et al.*, 2020). Furthermore, according to some studies it may be more cost-effective than traditional manufacturing in low-volume productions (Baumers *et al.*, 2016) as they help in de-centralizing the production process (Berman, 2012; Holmström and Partanen, 2014; Chan *et al.*, 2018), and in reducing the logistic costs (Bogers *et al.*, 2016; Schniederjans *et al.*, 2017), leveraging its digital nature.

3DP has been successfully used in several industries such as the automotive industry (Yin *et al.*, 2018), those related to cultural heritage (Chatzikonstantinou *et al.*, 2014), the fashion industry (Sun and Zhao, 2017) and the medical appliances (Durach *et al.*, 2017), even if in many cases they have been used for experiments and prototypes (Yin *et al.*, 2018).

Even if there is evidence that these technologies have been useful during the COVID-19 pandemic (Singh *et al.*, 2020; Nazir *et al.*, 2021), still little is known about how it may be used to deal with the main difficulties in emerging situations. Although AM allows health-care supply chain to be innovated enabling point-of-care manufacture of life-saving medicines, implants, equipment and devices within the vicinity of an outbreak or disaster (Phillips *et al.*, 2019), the effects of this type of technology in emergency situations is an area that still receives limited attention in the current literature. From a practical standpoint, this phenomenon becomes even more relevant in the aftermath of the COVID-19 pandemic, which has highlighted the need to develop and deploy technologies at a faster rate than in the past (Secundo *et al.*, 2021).

This paper sheds light on these topics and provides an in-depth analysis of best practice: the case of the creation of the Charlotte Valve, a valve for and emergency respiratory, by Isinnova srl. The paper uses a case study approach – a common research approach in the study of AM (De Jong and De Bruijn, 2013; D'Aveni, 2015; Laplume *et al.*, 2016; Caviggioli and Ughetto, 2019). We explore the dynamics that have helped Isinnova to develop and distribute, their Charlotte Valve during the COVID-19 Pandemic, to understand the main elements that have helped the diffusion of their valves so quickly during a health crisis. We also explore the main difficulties that the company had to overcome to distribute it on a global scale in a sector that is usually considered as a difficult one to implement AM (Sirichakwal and Conner, 2016). This paper is organized as follows: Section 2 highlights the literature review focusing on AM role in supply-chain innovations and their advantages. The research design is discussed in Section 3, while in Section 4 we present the Isinnova case. In Section 5 we outline the main discussion and the theoretical and managerial implications, while Section 6 concludes the paper including the suggestions for further research.

2. Literature review

According to several scholars, AM is seen as a technological transformation that has the potential to change the way things are produced and marketed (Berman, 2012; Achillas *et al.*, 2015; D'Aveni, 2015). At the same time, some studies show that these technologies help to change the way the global market works as they help to avoid the geographic restriction on production, with a lower ecological impact with less waste (Huang *et al.*, 2013; Beltagui *et al.*, 2020). According to some scholars (Bogers *et al.*, 2016; Hankammer and Kleer, 2018; Caviggioli and Ughetto, 2019), adopting these technologies may lead to a more consumer-centric logic, involving them in both the design and the manufacture of the products.

AM have several shortcomings limiting their diffusion such as accuracy and replicability of the productions, characteristics of the materials used and functional requirements of the model (Gibson *et al.*, 2014). The barriers to the adoption of 3DP include the costs of materials, the relative speed of production as well as the technical quality of equipment and output (Chan *et al.*, 2018; Chekurov *et al.*, 2018; Heinze and Heinze, 2020). Another constraint is related to the complexity of Computer-Aided Design software (Shukla *et al.*, 2018).

Several scholars have found various advantages in using 3DP in manufacturing According to Holmström *et al.* (2010) there are seven broad advantages of: no tooling (Eyers *et al.*, 2018; Araujo *et al.*, 2019); fast design changes (Holmström *et al.*, 2010); custom design (Son *et al.*, 2021); more function-oriented optimized products (Baumers and Holweg, 2019); shorter lead times with lower inventories (Pérès and Noyes, 2006; Grzesiak *et al.*, 2011; Achillas *et al.*, 2017); and waste reduction (Huang *et al.*, 2013; Baumers and Holweg, 2019; Luomaranta and Martinsuo, 2019). Last, but not least, AM enables companies to re-define their supply chains in order to manufacture at very low volumes, potentially down to even a single unit, letting them adopt mass-customization strategies (Tuck *et al.*, 2008; Berman, 2012; Eyers *et al.*, 2018). These technologies could allow real-time on-demand production (Huang *et al.*, 2013; Achillas *et al.*, 2015; Attaran, 2017) on a "glocalized" supply chain, the combination of the globalization of production in more localized facilities close to the consumers (Bogers *et al.*, 2016).

These technologies help companies exploit the digital nature of 3DP enabling small firms to share resources and shorten the supply chain (De Jong and De Bruijn, 2013; D'Aveni, 2015), as the goods will be manufactured directly on-site, while the 3D design would be transferred over the Internet, drastically reducing the distribution costs (Gao *et al.*, 2015), improving resource efficiency (Liu *et al.*, 2014) and fostering innovation processes (Schniederjans *et al.*, 2017).

They can be considered as a source of supply chain innovation (Lee *et al.*, 2011) as these new technologies are useful to create collaborative relationships in the supply chain in order to get the most out of their characteristics (Martinsuo and Luomaranta, 2018; Strong *et al.*, 2018).

Several studies have linked AM technologies and supply chain innovations (e.g. Holmström *et al.*, 2010; Steenhuis and Pretorius, 2017). The nature of AM can drive companies to adopt innovative supply chains (Achillas *et al.*, 2017), shifting from the "push supply chains" to "pull supply chains", where the actual customer drives the process and the design of the supply chain as a whole (Christopher and Ryals, 2014; Attaran, 2017).

According to Delic and Eyers (2020), AM can help supply chain to become more effective by improving their flexibility, allowing companies to compete more effectively in the modern dynamic environment (Seebacher and Winkler, 2015) adopting a more decentralized supply chain model (Bogers *et al.*, 2016; Caviggioli and Ughetto, 2019) and, as a consequence, they will help to reduce the impact of demand uncertainty on supply chain effectiveness (Khajavi *et al.*, 2014).

Manufacturers will be able to get the most out of the 3DP context, and of the related ecosystem, only if they are able acquire specific manufacturing capabilities (namely collaborative manufacturing flexibility, rapid thriftiness ability, self-customization and co-evolved design capability) to leverage on two key success factors, namely platform openness and solution diversity (Rong *et al.*, 2020). Ren *et al.* (2017) defined this approach as cloud manufacturing – i.e. a "smart networked manufacturing model" that supports product individualization, greater global collaboration, knowledge-intensive innovation and a quicker ability to respond to market trends. Thames and Schaefer (2016), describe cloud manufacturing as a networked manufacturing system, which uses free access to common, diverse and varied collection of manufacturing resources. They explain that these resources enable temporary cyber-physical production lines, which are more effective and more efficient, in satisfying the customer demands (Siderska and Jadaan, 2018).

Cloud manufacturing may leverage the open design approach (Raasch *et al.*, 2009), as the company may give the other actors in this innovation networks all the information on their new design to start a process of collaborative development on a limited number of related designs (Dalenogare *et al.*, 2018).

At the same time, using this approach companies can support firms to overcome resource constraints, but they will have to pursue the private-collective model and, as a consequence, they will have less control over these intellectual properties (Lakhani and von Hippel, 2003; West and Kuk, 2016). According to Beltagui *et al.* (2020), when companies successfully sidestep the issues related to correctly manage the new design intellectual properties, they may be more effective at leveraging an open innovation (OI) approach. In fact, the very same digital nature of AM enable small companies to share resources, both among themselves (D'Aveni, 2015), and with their customers (Chan *et al.*, 2018; Halbinger, 2018) helping to create more effective innovation processes (Schniederjans *et al.*, 2017).

OI is a new model for innovation (Chesbrough, 2003; Elmquist *et al.*, 2009; Santoro *et al.*, 2020) that has become widespread in several industries (Chesbrough and Brunswicker, 2014; Remneland-Wikhamn and Wikhamn, 2014; Spender *et al.*, 2017).

OI is based on the cooperative creation of ideas, and on applying them outside and inside the boundaries of any single participating firm (Chesbrough *et al.*, 2006). The company boundaries are seen as permeable, improving the potential for organizational learning (Peris-Ortiz *et al.*, 2018; Steiber *et al.*, 2020), and moving the locus of innovation from the single company to a network of actors (Gassmann and Enkel, 2004; Fichter, 2009; Bogers and West, 2012).

Adopting the OI approach, organization can share their knowledge resources with partners, suppliers and customers to leverage complementary assets (West and Bogers, 2014; West and Kuk, 2016) in accelerating innovation processes as they can all exploit a broader set of knowledge resources in more creative ways closing the link in the C-K-I triangle (Palmieri and Giglio, 2013, 2014).

Using the 3DP companies to frame the Makers' Movement (Anderson, 2012; Beltagui *et al.*, 2020; Halbinger, 2018) as a partner is a *coupled OI* process– i.e. an OI process that can be considered at the same time both an inbound and an outbound one – to integrate their competences and knowledge with those of the company and its partners in the traditional value chain (Gassmann and Enkel, 2004).

One of the first areas where AM has been effectively used is in enabling a cost-effective, low-volume production of spare parts (Li *et al.*, 2017; Chekurov *et al.*, 2018). Pérès and Noyes (2006) highlighted that AM enables the supply chains to produce the spare parts closer to where, and when, they are really needed. On the same page some scholars (Liu *et al.*, 2014; Sirichakwal and Conner, 2016; Muir and Haddud, 2018) found that 3DP spare parts can even reduce the inventory management costs, and the manufacturing downtime as well (Chekurov *et al.*, 2018). According to Frandsen *et al.* (2020), these technologies may be even more economically attractive when the low-volume spare parts production is taken into account.

Sirichakwal and Conner (2016) pointed out that in several industries (aero-space, defense and medical devices) companies need qualifications and certification to produce spare-parts and these cannot be easily obtained in a distributed production scenario. Furthermore, Holmström *et al.* (2010), hold that 3DP does not always produce consistent quality. Li *et al.* (2017), studying several different configurations of spare parts supply chains, showed that distributed deployment of AM machines does not always guarantee a quick response.

Another "industry" where 3DP has proven to be a viable alternative, is the humanitarian one where it has helped a quick response to unpredictable events in spite of significant resource constraints (da Costa *et al.*, 2012). AM has been used in several humanitarian applications from creating appliances for water management and sanitation (Corsini *et al.*, 2020) and in health-care (Durach *et al.*, 2017). Other studies examine 3DP during emergencies such as Bassett *et al.* (2015), that studied 3D printed wind turbines for disaster relief and rural electrification, Rodríguez-Espíndola and Beltagui (2018), who analyzed the possibility to build temporary shelters for disaster relief, or De la Torre *et al.* (2016), who investigated their viability to produce locally vehicle spare-parts in a disaster setting.

3. Research design

The literature review highlights that 3DP technologies may be a viable approach in dealing with innovating the supply chain (Holmström *et al.*, 2010; Bogers *et al.*, 2016; Ren *et al.*, 2017) and they can be useful to spare-parts management (Liu *et al.*, 2014; Sirichakwal and Conner, 2016; Khajavi *et al.*, 2014; Li *et al.*, 2017; Muir and Haddud, 2018). These two elements are critical factors to manage during emergency such as those occurring during the COVID-19 pandemic. These technologies have been shown to be more efficient than traditional technologies for two main reasons: they are more flexible than traditional production processes (Berman, 2012; Achillas *et al.*, 2017; Eyers *et al.*, 2018), and the production can easily leverage the OI paradigm (Chesbrough, 2003; Gassmann and Enkel, 2004).

AM technologies become effective when they can leverage their flexibility to produce a small batch of standard components (Berman, 2012; Holmström *et al.*, 2010; Eyers *et al.*, 2018; Beltagui *et al.*, 2020), or when they can enhance these components with customization (Petrick and Simpson, 2013; Bogers *et al.*, 2016; Steenhuis and Pretorius, 2016). Moreover, these technologies can be useful in developing an OI process in order to quickly improve a given design (Raasch *et al.*, 2009; Bogers *et al.*, 2016; Steenhuis and Pretorius, 2016; Dalenogare *et al.*, 2018) as they create an open-source design that may be improved by other such as users, printing companies and competitors as well. At the same time our literature review has highlighted that 3DP may have a significant flaw in the quality and certifiability of the replicas (Sirichakwal and Conner, 2016; Li *et al.*, 2017). In fact, the 3DP process may require several changes to the original procedure – to accommodate for different printer setting and to customize the design itself – in order to get the best product as possible (Holmström *et al.*, 2010).

According to these results, in this paper we explore the following research questions:

RQ1. Which are the main advantages and disadvantages of using 3DP technologies in dealing with an emergency?

RQ2. Do both companies and the hospitals carrying out these processes benefit from an OI approach?

To address these research questions, we examined the role of 3DP in dealing with the COVID-19 pandemic as a way to establish the viability and strengths of these technologies. We used a case study, as it allows us to analyze the items identified in our literature review in a real-life context (Saunders and Lewis, 2012). This approach is considered functional for an explorative purpose, following both a "constructivist", a "qualitative" and an "inductive" logic.

This study focuses on the "Charlotte Valve", a valve that Isinnova, an Italian innovation consultancy company, has developed to use Decathlon Easy-breath snorkeling mask as a ventilator mask for sub-intensive therapy. The case is a relevant one as it lets us analyze best practice in the medical devices industry. This industry requires high quality level and certification–both factors identified as potential short-comings of AM adoption (Holmström *et al.*, 2010; Sirichakwal and Conner, 2016). The case was studied in three phases. In the first phase we studied the case as it was presented in the press, in order to learn its main characteristics. We also looked at the Isinnova website to understand their general attitude toward the project. This phase required reading more than 200 articles and interviews presenting the Isinnova case or discussing it with managers from Isinnova, and other companies printing the valves, on both the Italian media (e.g. LaRepubblica, Corriere della Sera, IlGiornale), the International one (e.g. BBC, NY Times, Forbes, Reuters and Bloomberg) and in blogs and websites specialized on innovation and/or on start-ups (e.g. EconomyUp, Plastix, DeZeen and StartUpItalia).

The information gathered during the first phase was used to get a clearer picture of the case evolution. It provided useful background data for interviewing the Isinnova managers directly involved in designing, producing and later helping to distribute the Charlotte Valve. These interviews were used to comprehend how Isinnova management perceived its actions, and to further define the main difficulties that the project had to overcome to become a viable global solution. Moreover, the interview let us get the company's perception on using an OI approach in dealing with these issues.

Finally, we interviewed five doctors and three nurses working in big and small hospitals in the Lombardy Region, the Italian region most affected by the first COVID-19 wave, to get a different perspective, mostly focused on the potential issues, and to highlight their difficulties in dealing with the valve itself.

4. The Isinnova case

Isinnova is a research center in the Lombardy Region, located in the city of Brescia. It was created in 2014 by the engineer Cristian Fracassi and a local consultant, Alvise Mori, after the invention of a simple tool to notify customers if their frozen food was spoiled. The center's main activities are focused on developing processes for products by others. Isinnova carry out the preliminary research needed to patent the related innovations, design and create the needed prototypes, run tests and, last but not least, support their clients in searching for other companies willing to market the resulting products and/or in finding business angels' or venture capitalists' support. Over the last few years, they have worked with more than 350 inventors, to create 80 new products and to obtain 51 new patents.

During early March 2020, Brescia Area was the first European City, together with the nearby Bergamo, to be affected by the COVID-19 virus. The virus quickly overwhelmed the local hospital organizations that were not ready to deal with such a high number of patients needing intensive care medicine. In particular, the hospitals needed to use continuous positive airway pressure (C-PAP) therapy, a procedure needing that a machine would increase the air pressure in the throat, to help COVID-19 patients to breath more easily.

In particular, a local hospital (Ospedale Mellini di Chiari) was in need of the valves needed to connect the C-PAP masks to the machine; these valves adopted the Venturi's principle to automatically regulate the airflow. A local journalist, after discovering that the hospital managers had unsuccessfully tried to sanitize and re-use these valves, got the idea to have them 3D printed and started asking Fab-lab Italia, a nation-wide association of fab-labs [1], that if they could be produced using 3DP technologies.

Massimo Temporelli, used the Fab-Lab Italia network to identify a partner to help local hospitals to print more valves. Isinnova CEO Cristian Fracassi and one of the company engineers, Alessandro Romaioli, were ready to answer the request. They visited the Hospital, got a valve sample, replicated it and started printing some copies to deal with the emergency, providing several valves in just a few hours. The owner of the original file for the specific machine the hospital used is an American company that was unable to share the design due to existing company policies, and so Isinnova had to reverse engineer it. A few days later, Isinnova was contacted by Renato Favero, a doctor and ex-consultant of the Hospital in Gardone Val Trompia, to respond to this hospital shortage of C-PAP masks, a widespread problem linked to the COVID-19 diffusion. Favero proposed to adapt a snorkeling mask, produced by the French multinational company Decathlon, as a substitute for the whole mask (i.e. the Easy-breath snorkeling mask). The French multinational was ready to provide the needed CAD files for the mask, and later they decided to donate 10.000 masks to the Italian hospitals. A few days later, Isinnova designed a new ventilator connector, called the Charlotte valve that was able to connect a slightly modified mask to a ventilator unit. The prototype was tested on a healthy volunteer at the Chiari Hospital, proving to be effective.

Moreover, the design of the Charlotte valve is a relatively simple one that can be printed with the common 3D printers. As a consequence, both makers and 3DP laboratories were able to print it as needed by local hospitals. To foster this wide-spread participation, Isinnova created a section on their website where on one side the makers and the fab-labs could offer their printing-time to print the valves, and, on the other, the hospitals were able to communicate their needs to local "producers". The actual masks were then distributed by the civil protection. At the same time, they involved two other companies Lonati and idea factory to provide the first batch of these valves to the local hospitals as needed.

Isinnova decided to patent the new connector and to distribute it online as an open-source project to help other people, and other companies as well, to replicate it and to improve on it, if needed, in line with the usual behavior in the maker community. The initial project has been improved more than 20 times both by common people and professionals; the most famous one is the modifications developed by the Italian luxury carmaker Ferrari. The response from Italian makers has been astounding, more than 15,000 makers, fab-labs, and 3DP services as well, contacted Isinnova and, in less than a week, they were able to provide locally printed Charlotte valves to the civil protection.

The valve has been used in more than 50 hospitals in Italy, mostly small ones, where people in need have got access to these ventilators after signing a responsibility waiver to acknowledge that they knew the mask had been produced with safe material, such as PLA (Polylactic acid, or polylactide – a biocompatible bio-plastic material derived by typically made from fermented plant starch usually from corn, sugarcane or sugar beet pulp), and that they lacked the needed healthcare-related certifications.

In the following months the valve has been used in many countries over the world, in particular in Asian countries, and in South America. The files of the valve project have been downloaded more than 2.5 million times during the first COVID-19 wave, and it has been commonly used in several countries such as Brazil, Canada, France, Morocco, the Philippines and the US. For example, in Brazil the mask has been used more than 35,000 times or in France, the Charlotte valve has been printed more than 30,000 times.

This case highlights several interesting elements linked to how 3DP technologies may be used in managing crises in healthcare. For ease of discussion, we have divided the discussion into sub-paragraphs.

4.1 Supply chain flexibility and manufacturing quick response

This case highlights that 3DP technologies can be useful in providing hospitals and other health-related organizations with the needed flexibility to answer the rising needs related to a crisis without having to rely on the usual supply-chain channels that may be not able to satisfy their needs as quickly as needed. As highlighted by the project manager of Isinnova, AM leveraged their own competences and capabilities, allowing them to provide 10 copies of the existing valves in a matter of hours, in spite of the refusal of the original design owners to provide them a CAD file of the connector as, according to Fracassi, they feared for potential lawsuits linked to producing copies of the valve that were not certified under the European regulation.

An Isinnova engineer told us that:

> Using 3DP, after some hours spent measuring, designing and setting up the printer for the job, you can have a new valve ready in a matter of hours. If we used the usual injection molding technology, it would have arrived too late as the whole process may require even a couple of months.

At the same time, the more traditional technologies, once ready, can produce the valves at a higher speed with less cost and fewer defects. Isinnova realized that there was a stable need for their valves asked a local company, Oldrati Group, to create a mold for producing the valves using the traditional approach. Moreover, an Isinnova engineer explained to us that:

> Injection molding is still the preferred production technology when you have the time to produce the molds and to ship the final products to the hospital needing them, as it lets you produce a given object in a standard way with few differences between each copy, and with a higher success rate than the usual 3DP technologies.

At the same time, he held that:

> "In time of crisis you do not have the time needed to start the production with the traditional technologies, so 3DP is the only way to deal with these time-based requests" *even if* "one of the disadvantages of 3DP is the replicability of the project as using some 3DP technologies such as the fused deposition modeling, is that the various prints of a given design may be slightly different, in part as the results of the printing process, and in part as different printers may have small differences in their setting".

A doctor operating in a hospital in Lombardy Region highlighted that the:

> Charlotte valves proved to be useful to pass the direst days of the first wave in the COVID-19 pandemic as [they] did not have the respiratory masks to accommodate all the patients in sub-intensive therapy, and that [their] normal supply-chain was not able to provide them fast enough.

Another advantage of using 3DP technologies in distributing a given object is that the related projects are just files that can be easily shared over the Internet and then printed locally to accommodate the various hospitals' requests. Isinnova distributed the file of the project both on their website and on its social media. Regarding this, Fracassi argued that:

> "More than 2600 companies from all over the world has registered on [their] website and the list was public and it can be consulted by any hospital" *and* "many other companies have moved independently, teaming up directly with the hospitals. [They] shared the file on purpose not to be a filter; we would have been a bottleneck. Free sharing, on the other hand, has allowed [them] to create nodes and ramifications not necessarily passing through Isinnova. To date [they] have obtained over 2.5 million downloads of the file".

Similarly, a doctor in a small hospital confirmed that they were able to get the Isinnova kits from a local resident that had used the Isinnova map to contribute its printers to them.

4.2 Different technologies and needed competences

Another potential pitfall in 3DP, when dealing with the specific needs of some industries, is related to the different technologies that can be used to "print" and their specific characteristics. Isinnova designers considered three different rapid prototyping processes to create their first valves, each with different advantages and disadvantages. They initially used Stereolithography (SLA) printing for the first functional tests. This technology has the advantage to produce better prints, without jagged surfaces, but the vapors of the resins used in these printers are not biocompatible, so the company decided that the increased quality was not able to justify potential health-risks, so they were not used in the final production.

After that, Isinnova used the Fused Deposition Modeling (FDM) technology to create a functioning valve, but they discovered that the small tolerance of the original design was not compatible with the jagged, uneven, surface of the objects produced using this technology. Finally, they used selective laser sintering (SLS) which is slower than the previous two technologies but provides a smoother surface, needed to let the valve work normally, and is made using a biocompatible material.

This first approach highlighted the relevance of the various competences with 3DP that Isinnova has. As explained by a manager at Isinnova,

> We are not a fab-lab or a 3DP technology company, but we work as consultants in creating products for inventors and companies. We use these technologies for almost all of our prototypes and so we have to be competent in designing the objects and we have to know which 3DP technology is best for a given task.

Isinnova leveraged these competences in designing their patented Charlotte valve as they wanted to have a connector for the snorkeling mask that could be easily printed using a normal FDM printer, to exploit a technology that is far more widespread in the maker community and, as a consequence, it would have been more useful during emergencies.

4.3 Biomedical certification and product quality

One of the main difficulties in using 3DP for the health industry is the need to certify the production processes, the materials and the final products as well.

According to Isinnova management, there are two main issues in dealing with these certifications: the time and the production variance. The process of certification for a given product for biomedical use usually lasts more than one year. As a consequence, it is not possible to adopt it during a crisis. This potential pitfall was highlighted by the Isinnova Project Manager during our interview,

> It was a risk to provide these valves as, even if the material used was really hypoallergenic and not toxic as it is just a biocompatible plastic material derived from corn, it would have been a problem if our valve were related to some people dying as it was impossible to have them certified.

Another manager told us that

> Some people think our valves may go under the mandatory need regulations, but this was not really the case. In any case, we urged hospitals to use our valves only when the regular ones were not available and, moreover, to subject its use to a signed declaration of acceptance of using an uncertified biomedical device.

Another factor limiting these valves certifiability was related to the production process that may be carried out with different printers, from different vendors and, potentially, using different materials so they were not able to pass the strict legal requirements linked to the health regulations. According to a number of nurses and doctors we have interviewed, the lack of certification was less relevant for the smaller hospitals than for bigger ones, as usually the smaller hospitals are able to work a little less formally. In particular, a nurse told us

> Our hospital is a small one, so we were able to use these masks more freely, but [she] doubted that a bigger structure, with the spotlight on them, have been able to make full use of these valves. In any case, even if we got the valves from the Civil Protection, we asked all the potential users to sign an authorization.

On the contrary, in a bigger hospital a doctor told us

> We received the sealed valves but most colleagues were reluctant to use them as they feared the potential law-suits that could result if something went really wrong while using them.

However, managers at Isinnova told us that the Charlotte valve was:

> Fairly widespread in countries such as Brazil but even Uzbekistan and some of the countries of North Africa where there was less bureaucracy.

4.4 Open innovation and open sourcing

The Charlotte valve is an example of the OI approach advantages. The idea of using the mask came from an independent consultant, and Isinnova was able to design the valve quickly as Decathlon itself accepted to share the design of their snorkeling mask, so they were able to focus on the connectors.

From the beginning, Isinnova sought to create a project that could have been easily printed by the maker-community so the valves should have been printable using the more common FDM technology and so the project should take into account this technology characteristic rough surface. Isinnova patented the valve in order to prevent other people to use their design commercially but, at the same time, they decided to provide the design freely and to give support to the community by creating a website where the makers, could be informed of which hospitals near them needed valves. This initiative attracted several 3DP services such as Weerg, a 3DP online service, that was able to print more than 500 valves using the Nylon PA12 (a bio-medical approved plastic material), or the 3D systems of Pinerolo that not only printed the valves in Nylon PA12, but were able to develop a process to pack them in single-use sterile packaging that increased the security of the valves.

Other companies participated to help the campaign success. E.g. the 3DP World of Como asked a local radio to start a campaign to raise public awareness in the local area to donate people Easybreath masks in order to convert them into emergency ventilator masks using the ISINNOVA approach; or the Dallara Automobili, that urged one of its supplier, Roboze, to use its high precision printers to produce more than 150 Charlotte valve to distribute in several hospitals in Italy. Another example is the one of CRP-Energica, a company specialized in car and motorcycle racing technologies, that used their competence to provide more than 100 masks and, moreover, to improve the original project air flows and the connector effectiveness.

According to Cristian Fracassi, during the first few months, the original project of the Charlotte valve was modified at least 20 times. According to Romaioli, one notable, and really invasive, modification had been developed in Morocco, as a group of local makers modified the design of the valve to transform it, when coupled with the Easybreath mask, into an effective PPE with connectors to install several filters.

5. Discussion

In this paper we have presented the case of the Charlotte valve designed by Isinnova to connect a snorkeling mask to a ventilator for sub-intensive care during the COVID-19 pandemic. This case is an example of best practice on how the 3DP technologies may be effectively used in dealing with the difficulties in a health-related emergency such as the COVID-19 pandemic by re-designing the medical-devices spare parts supply chain.

The case highlights how the unexpected requests of ventilator masks linked to the COVID-19 pandemic showed the pitfall of traditional supply chains (da Costa *et al.*, 2012) and, at the same time, the opportunity to experiment using the adoption of 3DP products in many different parts of the world with a glocalized approach (Bogers *et al.*, 2016) to create a new, decentralized, supply-chain engaging the Makers' Movement (Anderson, 2012; Halbinger, 2018; Beltagui *et al.*, 2020) and several other companies in a real open design approach (Raasch *et al.*, 2009).

Isinnova was able to leverage its engineers' 3DP-related competences, developed helping their clients with rapid prototyping for their innovations, not only to replicate an existing valve but to design a completely new connector that could be easily printed with the common FDM printers' makers all over the world normally use reducing the issue related to printing quality (Sirichakwal and Conner, 2016; Li *et al.*, 2017).

At the same time the case is a classic example of a coupled OI process. The first idea to use these technologies to replicate an existing valve did not come to an expert in the rapid prototyping field but it came from a Doctor in the Ospedale Mellini di Chiari, that asked FabLab Italia for some support when their usual supply-chain failed to provide the needed number of ventilators. In a similar way, the idea to adapt the Easybreath mask as a ventilator came from Renato Favaro, a doctor rather than an inventor. Both are classic cases of inbound OI (Gassmann and Enkel, 2004).

In this process, Isinnova could leverage their own competences as innovation hub to quickly design the parts to be printed in order to move from the idea to the concept, first, and to the product, later. After producing the first prototypes, Isinnova asked a local hospital to make a quick test to see if their project worked.

Finally, even if the valve was quickly patented, Isinnova decided to rely on the Internet to diffuse their design, and to create a network where the hospitals needing these emergency valves and the community of the makers (Van Abel *et al.*, 2011; West and Kuk, 2016) or the companies, having the printing devices could be in contact in order to create a "*smart networked manufacturing model*" (Ren *et al.*, 2017). This opened the way to the outbound part of the coupled OI process adopted by Isinnova (Gassmann and Enkel, 2004). This has been pursued not for mere economic or strategic reasons, but for creating the social impact and value for communities in different countries in difficulty due to the pandemic.

Isinnova adopted the open design (Raasch *et al.*, 2009; Dalenogare *et al.*, 2018) approach as shown by the improvement to the project provided by Ferrari, CRPEnergica, and 3D systems, sharing the project itself over social media, paving the way to further improving the project, or its distribution in order to reduce the potential risks for the users of the masks. Moreover, as Isinnova shared the project files, it fostered the creation of other innovations such as the PPE that a group of Moroccan makers were able to derive from the original projects.

At the same time this case highlights that in case of emergency the 3DP technologies may be used to solve several supply chain issues as the products did not need to be shipped but they can be created on the spot according to the hospital needs (Durach *et al.*, 2017; Corsini *et al.*, 2020).

This case study highlights three main difficulties in using these technologies in healthcare, and how to overcome them. A first limitation is related to the printing process slow speed (Campbell *et al.*, 2012), especially for the FDM one. A single valve, on a normal 3D printer, can be printed in up to ten hours, limiting the potential of these technologies to absorb peaks of demands. Isinnova has used the concept of cloud manufacturing (Thames and Schaefer, 2016) for this project, distributing their design and the related instruction through social media and creating an interactive map to connect the hospitals, all over the world, with the local makers and printing service companies. Using these network power, Isinnova was able to multiplicate the "printers" each hospital might have access to increasing the effectiveness of the whole system without reducing its flexibility (Lakhani and von Hippel, 2003; West and Kuk, 2016). At the same time, the need to refer to a broad set of printers, coupled with the tight specification needed for the Charlotte valve to work correctly, put under the spotlight the second limit of these 3DP processes, the lack of standardization and the replicability of the design (Holmström *et al.*, 2010). Isinnova used its competence in 3DP technologies to create a valve, the Charlotte one, that could be easily printed by the most common 3D printers without asking for other machining on the printed pieces as for the original valve that required drilling two holes by hand.

Despite these efforts, aimed at creating a viable process, the main issue was that of not being able to certify the product itself for bio-medical applications, a problem mainly relevant in the more bureaucratic countries (Shirichakwal and Conner, 2016). On one side, Isinnova was not able to get the product certified as, during the pandemic, the usual 14 months process needed to certify a bio-medical product is too slow to get the product out timely; on the other side there was no possibility to standardize the printers used and the material as well.

Isinnova solved this issue in part by highlighting in all their communications that the valve was not certified under the EU regulations, and in part preparing a responsibility waiver; at the same time, they choose the 3DP technology in order to reduce the health-related risks and decided to recommend using a material, Nylon Pa12, that is normally used in bio-medical products.

5.1 Theoretical implications

The Isinnova case confirms the theoretical approach that sees AM technologies as a source of supply chain flexibility (Huang *et al.*, 2013; Eyers *et al.*, 2018; Delic and Eyers, 2020) and that they can be advantageous in the humanitarian operation and in the management of crisis (da Costa *et al.*, 2012). Using these technologies for humanitarian efforts can overcome temporary supply-chain shortages as the files needed to print them can be distributed worldwide in the same way of an MP3 file in a faster and cheaper way (Cagliano and Spina, 2000; Campbell *et al.*, 2012; Holmström and Partanen, 2014; Mellor *et al.*, 2014; Achillas *et al.*, 2017).

Furthermore, adopting AM may help to leverage existing local "resources" as these printers are today fairly common in many places and so organizations like hospitals, or other humanitarian ones, may leverage the distributed resources to produce the needed devices (Huang *et al.*, 2013; Tatham *et al.*, 2018). Although the various printers can use different technologies, they share the capability or reading a standardized digital file enabling a quite instant diffusion of the production on a global scale if the original project has not been tailor-suited to some specific, and rare, characteristics of high-end printers such as multi-filament approaches in the FDM, or the multi-color screens used in some SLA printers (Chekurov *et al.*, 2018).

The case highlights that AM may be seen as a central technology in creating a coupled OI process (Gassmann and Enkel, 2004). In fact, the case shows that a broad set of competences was not only needed in the first part of the project, the one on defining the concept and producing, and testing, the design, but it has been central to improve the project as well. This finding is consistent with existing research that these projects can be easily adapted, or modified, using some free and easy to use software without a deep knowledge of CAD software, companies may leverage local communities not only to produce the final component, but they may be functional in improving the project or in adapting it to some specific situations (Anderson, 2012; Rayna *et al.*, 2015; Halbinger, 2018; Beltagui *et al.*, 2020). All in all, the paper adds to the body of knowledge on OI, shedding light on how to create value for communities through outbound OI processes, often neglected by the literature, which mostly focused on inbound OI (Chesbrough and Brunswicker, 2014).

The case-study is consistent with the theoretical model by Tatham *et al.* (2018), when correctly managed, as in the Isinnova case, these characteristics help to create a "hub and spoke" supply chain model, where design and testing take place in a central facility (the hub) and the product is locally manufactured in-field (the spokes). Adopting this model, companies may overcome these technologies limitations that, when compared with conventional subtractive manufacturing or with the conventional injection molding production process (Atzeni and Salmi, 2012; Petrick and Simpson, 2013; Gao *et al.*, 2015).

5.2 Managerial implications

The Isinnova case gives some interesting suggestions to both managers of design and consultant services and to hospital management as well. This technology has proven to be a viable alternative for producing small batches of some standard components (Petrick and Simpson, 2013; Shukla *et al.*, 2018).

Cristian Fracassi's idea to open source the design and to distribute it freely over the Internet to overcome the company's production bottleneck, shows the importance to leverage the power of the network. If leveraging this power is potentially easy in humanitarian crises (da Costa *et al.*, 2012; Behl and Dutta, 2019), adopting an open-source approach can prove to be useful even in other situations as the original company may offer ancillary services in order to create a "better" offer while still getting the benefits of a standard distribution.

A second managerial implication of the Isinnova case is the importance of the various certifications, at least in the biomedical industry. Marco Romaioli, project manager at Isinnova, highlighted that these technologies may prove quite impossible to certify under the normal regulations. As a consequence, Isinnova has launched a donation-crowdfunding campaign to standardize the printers and the components. According to Marco Ruocco this project, called *ISI-3D 4 The Future* aims to create a standard package (3D printer and materials) to certify and to distribute to hospitals before new crises. In this way, Isinnova could potentially obtain the certification for their design-printer-filament combination to further reduce this barrier to hospitals' adoption of 3DP. Having these certified printers could prove to be useful to create hybrid-production processes that share the best of both worlds, leveraging the faster and cheaper traditional technologies when the products are standard and can be procured in advance, and using the 3DP replicas to satisfy the peaks of demand or when the components should be customized before the use.

6. Conclusion, limitations and further research

This paper presents an exploratory case study to highlight a best practice in adopting the 3DP technologies in the hospital to reduce the problems of the COVID-19 pandemic by re-designing the spare-parts supply chain. It has shown that, when coupled with an OI approach, and when the company is able to leverage the power of the networks and social media, this technology may become a viable alternative to the traditional supply chain not only for the price of the components, but for the production yield as well.

At the same time, we must acknowledge that this study has two main shortcomings that could be solved with further investigation. On one side, the exploratory nature of our research has driven us to use a case study approach. Our case, even if it deals with a best practice, may not reveal a generally viable path in other situations; to verify this, we propose to further test the other initiatives developed to solve procurement issues during the COVID-19 pandemic. Confronting these cases, the academic community may understand the main drivers behind their success, or their failure, to get a more complete understanding of their processes.

On the other side, in our research we have not investigated the motivation behind the participation of the maker in the project itself. Being able to "activate" the network of the makers and the fab-labs may become, in the future, a really significant factor just as being able to activate independent programmers was fundamental in the development and in the diffusion of the Linux operating systems at the end of the 90s. These aspects should be investigated with a quantitative, survey-based approach, to comprehend them to help managers in choosing to adopt these technologies when they are really useful.

Moreover, the case hints at a possible potential "third way" where the design company offers a service to the hospitals. Using certified printers, the hospital will be able to produce locally the components designed and customized by the company as needed by each specific case. Obviously this new, blended, business model should be tested to understand its real viability.

Note

1. Fab-labs – digital fabrication laboratories – are workshops equipped with many different technologies related to digital manufacturing such as 3D printing, CNC machining, Laser Engraving. They help entrepreneurs and inventors to turn their ideas into new products and prototypes.

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