Additive manufacturing and injection molding process for mass-production of face shields during COVID-19 pandemic: A comparative study

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Abstract

Face shield is a personal protective equipment required for healthcare professionals to decrease the risk of contamination during the COVID-19. Fused deposition modeling (FDM) is the most applied process of additive manufacturing due to its usability and low-cost. The injection molding (IM) is the fastest process for mass industrial production. The comparison between the FDM and IM process to produce plastic parts is well known, but this study is the first to perform a qualitative comparison of these processes for mass-production and distribution of face shields in a pandemic. The design of the face shield was developed in three prototyping cycles based on requirements of medical, Brazilian regulatory standards, manufacturing, and production. The FDM manufacturing of 35,000 face shields was carried out by a volunteer network using low-cost 3D printer and the IM manufacturing of 80,000 was carried out by partner companies. With the production of face shields through the FDM process, it was possible to make daily deliveries of small batches to local hospitals. A total of 80,000 face shields was produced in larger batches by the IM process and delivered to remote regions in Brazil. Considering the manufacturing resilience of the processes (quality, costs, and production time), in a situation such as the current COVID-19 pandemic with disturbances and uncertainties, both FDM and IM processes are suitable for mass production of face shields. The FDM process promotes a fast-daily production once a committed network of volunteers is formed in strategic regions. The IM process was the best option for large scale production of face shields and delivery to remote regions without the availability of 3D printers.

1. Introduction

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) or Coronavirus Disease 2019 (COVID-19) is a life-threatening disease caused by the novel coronavirus that has caused a large global outbreak [1]. The transmission of this disease occurs at human-to-human level, when droplets are generated close to the eyes, nose, or mouth and reach the respiratory system or through direct contact with contaminated surface followed by the touching of the eyes, nose, or mouth [2]. The most common symptoms are fever, pneumonia, and cough, but the severe cases progress to respiratory and death [3]. The COVID-19 infection began in Wuhan, China, in December 2019, and it has rapidly spread across several other countries. In February 2020, after 43,000 confirmed cases in 28 countries, COVID-19 was characterized as a pandemic, and after eight months 46,000,000 cases and over 1,2 million deaths were registered globally [4]. In Brazil, the number of COVID-19 cases grew fast, and currently, this is the second country with the highest number of infected individuals, with a total of 5,523,352 cases, and 159,668 deaths [5].

Brazil has a hybrid health system. Every citizen has free access to the National Health System, but a private system offers services covered out of payments and insurance plans [6]. About 80% of the Brazilian population rely exclusively on the public system [7]. Public health policies and infection control measures were required to limit virus spread and decrease the damage associated with the COVID-19 outbreak [2,8]. In all countries affected by the new coronavirus, the increased number of cases is associated with an overwhelmed health system, resulting in shortages of personal protective equipment (PPE) such as gloves, face masks, goggles, face shields, N95 masks, and gowns [9-10]. Healthcare workers are at the front line of the COVID-19 outbreak, as they are submitted to hazards that put them at risk of high pathogen exposure. To reduce the infection risk among workers, minimum contact with spread respiratory secretions using PPE is essential. Worldwide, there is no systematic and standardized reliable data regarding the number of healthcare workers that were infected or have died due to COVID-19 and PPE shortage. The International Council of Nurses (ICN) estimated that at least 230,000
healthcare workers have been COVID-19 infected and more than 600 nurses died around the world [11]. In Brazil, until the beginning of July 2020, about 83,100 healthcare workers were diagnosed with COVID-19, resulting in 316 nurse's dead [12].

The use of barriers that block respiratory droplets seems to prevent COVID-19 transmission, among which face masks and shields are the two primary options [13]. Face shields are used for the protection of the facial area and mucous membranes (eyes, nose, mouth) from splashes, sprays, and body fluid spatter [14-15]. Face shields significantly reduce the amount of inhalation of the influenza virus, providing a transparent physical barrier that covers the face and can be used in conjunction with face masks and goggles [16-17]. For optimal protection, the shield should cover the forehead, extend below the chin, and wrap around the side of the face, and there should be no exposed gap between the forehead and the shield frame [12,15]. Non-use of face shields by nurses during high-risk aerosolizing procedures on patients with respiratory infections resulted in greater than three-folds increased risk of infection. Face shields are efficient in reducing viral exposure by 97% on a contaminated surface [18].

On 23 March 2020, the Brazilian Health Surveillance Agency (ANVISA) simplified the PPE product regulation process during the COVID-19 pandemic. The requirements for face shields production were simplified, enabling the development of alternative models [19]. Some solutions have been created using different manufacturing methods such as additive manufacturing, popularly known for 3D printing [20]. This technology allows the manufacture of physical models through the addition of materials in layers in a cost-effective and fast approach based on computer aided design (CAD). Fused Deposition Modelling (FDM) is the most accessible 3D printing process for product development in the medical field due to its usability, availability of low-cost 3D printers, and a broad range of thermoplastic material [21-23]. FDM process has been used to produce face shields using open-access models to supply the demand of hospitals in the COVID-19 pandemic [24-26]. Injection Moulding (IM) is a manufacturing process that transforms raw thermoplastic material into designed parts of a particular shape. It is the most important process for mass production of identical items through the melting and injection of plastic at high pressure into a mold [27].

Some studies indicate that the production of face shields can be accomplished through the manufacturing processes FDM or IM [28-29]. However, which of the methods is the most suitable for mass production and rapid distribution of face shields in a pandemic situation? This study carried out in Brazil during the COVID-19 pandemic, is the first one to compare the FDM and IM processes through the production of 115,000 face shields that were distributed to support the healthcare system.

2. Material And Methods

The Higia project was conceived to support Brazilian public hospitals with face shields during the COVID-19 pandemic. In the next sections, the process of design, manufacture and distribution of face shields will be described. Finally, a comparison between the two methods is provided.

2.1 Design and prototyping cycles of the Higia face shield

The process of the Higia face shield design, development, testing, and improvement was carried out in 3 prototyping cycles. It was inspired by the open-source model of the face shield Prusa RC1 [30]. The face shield consists of a frame, produced by 3D-printing FDM in a polymeric material, a visor (transparent plastic sheet), and a rubber band. Despite its functionality, the Prusa RC1 face shield model requires long 3D-printing time (about 5
hours) and the use of a considerable amount of material. In the Higia model, some features of the Prusa RC1 model were adapted to suit a list of requirements that was created considering medical needs, 3D printing, ANVISA standards and production logistics [19] (Fig. 1).

The first version of the Higia frame was created with Fusion 360® 3D modeling software (Autodesk, USA) and saved in an STL file (standard tessellation) for additive manufacturing. In the prototyping cycles, the STL file was converted into a G-code file using Simplify3D® slicing software (Simplify3D, USA). The polylactic acid (PLA) filament (Material 3D, China) was used to manufacture the frame in a 3D printer Stella 2 (Boa Impressão 3D, Brazil) with the FDM process. The G-code language communicates with the 3D printer information of quality control such as printer's speed, which affects the production time, printer settings (nozzle diameter and position), printing settings (3D printed layer height and piece dimensions) and filament settings (type, color, diameter, and density).

### 2.2 Manufacturing of the Higia face shield using the fused deposition modeling (FDM) and the injection molding (IM) processes

To produce the Higia face shields using the additive manufacturing process, an FDM type 3D printer was required, with a minimum printing area of 200 x 200 mm, filament (PLA), acrylonitrile butadiene styrene (ABS) or similar, transparent Polyethylene Terephthalate (PET) sheet or similar with a thickness between 0.3 and 0.5 mm, and elastic bands. The setup FDM parameters were 5% full honeycomb infill, 0.3 mm layer height, 3 top solid layers, 3 bottom solid layers, 3 outline/perimeter shells, and 50 mm/s printing speed.

The metal mold of the frame produced for the IM process was based on the design previously created for the AM process. But the frame design was changed to allow the melted polypropylene to flow during the injection process in the mold. Some parameters of the Higia model such as strips to adjust the frame on the user's head were changed to adapt to the molding production. The mold is a structure of two parts: the cavity half of the mold and the ejector half of the mold. The melted material enters through a feed channel in the mold's cavity half and then it is hard-pressed, flowing through the machined ducts (guides) in cavity and ejector molds halves to form the desired part. After forming, the two parts of the molds are separated, the frame is attached to the second mold and ejected from there, falling freely inside a collecting container in the machine. The qualitative comparison of both face shield production processes FDM and IM was based on Franchetti and Kress [31], considering the pre-processing time, the processing time and the post-processing time, as well as production costs and advantages and disadvantages of use in a time of scarcity such as the COVID-19 pandemic.

### 2.3 Mass-production and distribution

The Higia project website was created to recruit volunteers Makers to print the face shields on your 3D printers, to make available the open-source model of the Higia face shield, and to receive requests of face shields donations from hospitals all over Brazil using the application Google form (Google, USA). Additionally, an account was created on Instagram (Facebook, USA) to provide training videos for the volunteers and to disclose information regarding the face shield donation progress. A crowdfunding campaign was created to raise funds for financial support for material purchase for FDM and IM processing and logistics.

The mass production of face shields was launched in two phases. The first one was carried out using FDM process, and in the second phase relied on the IM process. The first phase accounted on a network of volunteers grouped into 3D printing production hubs all over the country remotely coordinated by the central hub in the city of
São Paulo due to the quarantine lockdown. A logistics system was created aiming at material delivery, to coordinate the distribution of the 3D-printed frames, assembling of face shields, and supplying to hospitals according to the demand. The second phase was carried out by a partner company, and deliveries in remote regions were made by sea and air transportation.

3. Results

The first version of the Higia frame has the shape of two arcs attached by their ends and united in a single piece with four anterior square pins for visor fitting, and two posterior round pins for the fixing of the frame to the head using a rubber band (Fig. 2). Several changes were implemented in this version during three prototyping cycles (Fig. 3). First, two strips were modeled to adjust the frame on the user's head (1); the angles formed by the union of the two bands were smoothed to facilitate cleaning (2), and the name “Higia” was imprinted (3) (Fig. 3A). However, the strips were fragile and broke during testing with users. In the second prototyping cycle (Fig. 3B), the shape of the anterior pin was changed into a hook to avoid detachment of the transparent sheet during face shield use (1); the distance between the pins was adjusted to ensure fixing and adjustment of the transparent sheet (2); The strips were remodeled for strength (3); The imprinted name “Higia” was removed to make cleaning easier and replaced by a triangle to indicate the position of use (4); the frame thickness was changed from 15 to 10 mm (5), and the frame type was changed from square to round (6). However, through the FDM process using PLA, the strips were not strong enough and were replaced by two elastic bands. In the last prototyping cycles, the distance between the two ends of the frame was increased from 101 to 128 mm, and the pin for the elastic band was changed for safety (Fig. 3C).

In the additive manufacturing FDM process, the frame printing time was about 90 minutes (Fig. 4A, B). For the face shield assembling, the transparent sheet was cut and perforated with a conventional sheet hole puncher according to a layout (Fig. 4C). Each hole was fitted into the anterior frame pin and an elastic band was used to attach the head protector (Fig. 4D). The assembled face shield Higia has a full-face length with outer edges reaching the tip of the ear, including chin and forehead protection. It is low-cost (U$ 0.75), light (frame 16 g, assembled 43 g), flexible and resistant, one size fits all, comfortable, disinfectable, and it allows repeated reuse several times (Fig. 4E, F). Higia's open-source model of was available on the internet with a guideline for production and use [32].

In the IM process, the injection time of each frame in polypropylene was 25 seconds (Fig. 5A, B). The stripes of the original Higia 3D printed model were reincorporated in the IM model resulting in one flexible strip of good mechanical resistance (Fig. 5C). A transparent plastic sheet of Polyethylene Terephthalate Glycol (PETG) with 0.5 mm of thickness was used as a visor (Fig. 5D). The Higia face shield manufactured under the IM process has the following characteristics: Easy to assemble and transport, low-cost (U$ 0.47), light (frame 29 g, assembled face shield 56 g), flexibility and resistance, one size fits all with adjustable band, comfortable and reusable (Fig. 5E, F).

The qualitative comparison of both processes, FDM and IM, for mass-production of the Higia frame is summarized in Figure 6.

In the first 11 days of the Higia project, almost 80% of the face shields orders were placed by the state of São Paulo, the initial epicenter of the pandemic in Brazil. In the second month, orders from other states started increasing, as the coronavirus had spread over south and southeast states also infecting Brazil's northern and northeastern states. In total, 61.6% of orders were placed by the state of São Paulo, and the remainder was
distributed among the other 26 Brazilian states. Apart from São Paulo, the northern and northeastern states, such as Amazonas, had the highest percentage of orders. The logistic system created is presented in Fig. 7. About 2,000 Makers volunteered, and 20 Brazilian 3D printing companies signed up for 3D printing and about 500 kg of filament donation. Through the crowdfunding campaign it was possible to pay for filament, transparent sheets, IM material, transportation, and other expenses.

With the collaboration of Makers, 35,000 Higia face shields were produced through the FDM process, and the IM process resulted in the production of another 80,000 face shields by partner industries (Fig. 8). The face shields were donated and distributed to public hospitals for emergency rooms, surgical units, oncology units, and intensive care units of all states in Brazil. These distributions reached even the indigenous population in remote regions of the state of Amazonas.

4. Discussion

The high demand for PPE during the COVID-19 pandemic left millions of healthcare workers unprotected, endangering the functioning of the healthcare system. Most of Brazil’s public healthcare institutions did not have enough PPE, and few of them had face shields, which were used only in high-risk areas. The Higia project was created on 20 March 2020 when the period of community transmission of the new coronavirus had started over the entire Brazilian territory, the number of confirmed cases of COVID-19 had reached 904 with 11 deaths. Ten days later, the Higia project was distributing their first volunteers-produced 3D-printed face shields to hospitals, while Brazil’s updated numbers were showing 4,309 confirmed cases with 139 deaths. After 13 days of production, more than 10,000 3D-printed face shields had already been delivered. Such data showed great potential for rapid device production using additive manufacturing in an emergency. Many 3D printer owners, small business owners, startups, and university students took their 3D printers home to have around 1,000 face shields printed daily in production hubs in different cities. Due to the application of a design for the face shield frame as simple as possible the 3D printing of the frame was carried by volunteers without difficulties. The greatest challenge was the materials acquisition for production, as since the stores and shops were closed and the volunteers were under a lockdown or social distancing measures, sometimes unable to leave their houses. The logistics for production and delivery of face shields mass production during the confinement period in a country with continental dimensions like Brazil was a big challenge. An important factor was the possibility of delivery of 3D-printed face shields for hospitals rapidly and continuously despite the lower number produced. This problem was solved with simple delivery logistics trying to access the volunteer closer to the requesting hospital. The IM face shields production allowed an increase in the number of manufactured frames by 100 times, each day. However, this high production volume was accumulated in a single location, and the logistics of delivery from a single spot became a challenge.

4.1 Design and usability

Many countries around the world have used the FDM process to produce cost-effective medical face shields [29, 33-38]. Some 3D-printed face shields are as good as commercial standard-models [28]. However, due to the process’ heterogeneity, some devices have been produced with no standardized procedure or medical approval. Face shields were adapted for oral and maxillofacial surgeons [33] and the radiology sector [37] with a design that makes cleaning a difficult activity. Face shields with very thin frames are more fragile, they can break during transportation or use, and are less comfortable and reliable. It is possible to define the practicality, and clinical
suitability of 3D-printed face shields related to weight, printing time, and if it required assembling tools to find an ideal dataset to be used for printing, scalability, and economic efficiency [38].

The Higia face shield designed in this study meets general requirements and specific ANVISA standards to reduce the potential for autoinoculation by preventing the user from touching their face [19]. The main features of the face shield are space for safe air ventilation and comfortable and low weight head fixation that does not limit the user's movements. Despite the recommendation that the face shield should avoid an open area between the first and second arc of the frame (Fig. 2), a consensus was established to reduce this distance and leave the area open, reducing the 3D printing time from 5 to 1.5 hours. This design ensures adequate space for the use of additional equipment such as surgical masks, respirators, eyewear, among others. In this study, the level of protection offered by the use of the face shield was not accessed, but it is known that this device protects to reduce transmissibility below a critical threshold [18]. The acetate and PETg used in the visors are transparent with high optical clarity, providing a good physical barrier to respiratory droplets. Acetate provides the best clarity and is more scratch-resistant against chemical splash protection, and PETg offers chemical splash protection at a lower cost. The Higia face shield is reusable, a replacement transparent sheet can be found in office supply stores. For disinfection, cleaning the face shield with soap and water or another type of disinfectant approved by the hospital infection control service is sufficient. Sterilization of the face shield using high temperatures or abrasive materials is not possible, due to the low melting point of the filament used in the FDM process.

**4.2 Qualitative comparison of FDM and IM processes to produce face shields**

The main advantage of additive manufacturing is the design freedom that may be applied at any point in the process. The FDM is the most commonly used 3D printing process with thermoplastics materials, with ease of handling, rapid processing, simplicity, and cost-efficiency [23]. The final cost of the FDM process is reduced due to the machine and material low cost, but the process shows some limitations [39], as filaments such as PLA and ABS vary in material composition, porosity, and environmental stability. Although in this study, no mechanical test was performed with the 3D printed face shields, it is known that mechanical properties such as tensile strength, Young's modulus, elongation at break, and impact strength are lower in an object manufactured under FDM process compared with the ones under the IM process [40]. However, the mechanical stress that a face shield receives during use is extremely low, and although the face shield produced by IM has better quality, both have a comparable functionality level.

Even though some authors claim that the FDM is a slow process and not suitable for mass production of face shields [29,35,38], the IM process, in contrast, requires skilled operators and relatively costly materials and equipment to be carried out. None of the additive manufacturing technologies is yet able to practically replace IM for medium- and high production volumes [41]. However, this study showed that low-volume production of a network on volunteers using the FDM process may offer an alternative for short lead times and a decreased overall production cost. While IM allows producing a large number of parts in a short period time, the distribution through a continental country like Brazil takes a long time, making it difficult to fulfill large orders quickly, regardless of production method. Despite not being as fast as IM processes, the FDM method allows the at-home, on-demand manufacture of face shields by a broad spectrum of users [38]. It is possible also to have multiple frames printed at the same time to decrease production time using stacked frames. In this study, it was not possible to calculate the effective cost of FDM process production, as different 3D printers and filaments were used. An effective analysis should be based on cost regarding the purchase of the manufacturing equipment, material, labor, and other costs.
This study showed the viability of using the FDM process in low cost 3D printers for rapid modeling and the production of small batches of face shields by volunteers with a simple process that can be organized for large-scale production. Due to the support provided by 3D printing, the delivery of face shields started first, whereas the IM mold was still being produced, which allowed for large-scale production. The FDM process allowed daily deliveries while the IM process allowed the production of large quantities in a short period of time and it may be the best option for the production of a large quantity for remote areas that do not have access to 3D printers. This research shows how the FDM process allows small scale decentralized production of consumer goods at a pandemic situation as a response from civil society, allowing assistance to hospitals in need [42]. The results highlight the role of the “maker” or “citizen supply chain” community across the world, with collaborators from industrial and academic institutions, in a network, in a short period, to donate face shields to healthcare professionals [36]. This mobilization happens mainly due to the commotion and the sense of unity that is ongoing during the pandemic. Since the STL file of the Higia face shield was made available on the internet, many people in other countries such as Israel, Portugal, Jordan, Poland, Germany, the USA, and China have also produced face shields. It comes to show the accessibility and possibilities of integration and collaboration that 3D printing can promote.

5. Conclusion

In this study, a qualitative comparison between FDM and IM manufacturing processes in a case of large-scale production and rapid distribution of face shield was performed. Considering the manufacturing resilience of the processes (quality, costs, and production time), in a situation such as the current COVID-19 pandemic with disturbances and uncertainties, both FDM and IM processes are suitable for mass production of face shields. Once a committed network of volunteers is formed in strategic regions, the FDM process allows for fast daily production of face shields. On the other hand, the IM process is proven to be the best option for large scale production and delivery to remote areas that have reduced access to 3D printers. The 115,000 produced face shields were donated and distributed to support the healthcare system during the COVID-19 pandemic in Brazil.

Declarations

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Conflicts of interest/Competing interests. Not applicable

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