RESEARCH PAPER

COVID-19 3DP Case Study Addendum

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BACKGROUND

On the 1st May 2020, the author team delivered a report to APICS entitled 'Impacts of Additive Manufacturing for the Surgical and Medical Device Supply Chain'. The aim of this research project was to review the challenges and opportunities for surgical and medical device development industries through the lens of supply chain organisations and management and explore strategies that correspond to the identified challenges and opportunities. The report highlighted new knowledge, discussed the implications for operational practice and provided recommendations on responding to key issues, in the short term and for further research follow up.

During the project's qualitative research phase, the global COVID-19 Coronavirus pandemic broke, officially classified as a pandemic by the World Health Organisation on March 11th, 2020. Whilst it was not within the scope of the wider report to investigate COVID-19 manufacturing responses during the outbreak, timing was pertinent to be able to include several example case studies that showcased how the 3D printing (3DP) industry mobilised to respond to the medical emergency, and at the same time, highlight the very challenges and opportunities identified as part of the wider study.

Such challenges included:

- Mobilising the medical technology 3DP supply chain to respond to a public health crisis.
- Integrating and connecting Australia's medical supply chain - including hospitals, surgeons, nursing staff, industry & regulatory bodies, printing manufacturers, material suppliers, post processing suppliers and product manufacturers.
- Understanding how firms adapted to respond to COVID-19 needs. What mechanisms were put in place to connect and enable collaboration of firms with universities, governments, and the health sector?
- Sustaining the local coordination benefits, as a result of COVID-19, to leverage further and longer-term cross sector collaboration.
- Identifying the Australian contact points or custodians of 3DP in medical and surgical device supply chains to champion and coordinate collaboration efforts.
- Linking regulatory, logistics and procurement requirements to the knowledge and capability base, and;
- Defining how organisations can collaborate more proactively.

The following case studies go some way in showcasing how addressing these challenges through 3DP could address mainstream and emergency health manufacturing requirements in countries like Australia.

ISINNOVA - HOSPITAL C-PAP MASK ADAPTER FOR SUB-INTENSIVE THERAPY

Issinova is a small consultancy start-up firm based in Brescia, Italy, that offers innovative business services to a wide range of clients including 3DP.

Dr. Renato Favero, a former head physician of the Gardone Valtrompia Hospital in Italy, approached Isinnova to address the challenge of a shortage of hospital C-PAP masks for sub-intensive therapy, which emerged as a concrete problem linked to the spread of COVID-19. Dr Favero's idea was to construct an emergency respiratory mask by reconfiguring an existing snorkelling mask already on the market.

Isinnova contacted Decathlon, as the creator, manufacturer and distributor of the original 'Easybreath' snorkelling mask and the firms agreed to collaborate by sharing CAD drawings of the mask.

The product was dismantled, studied and proposed changes were evaluated. The new component for the connection valve to the respirator designed, and a prototype 3D printed using common desktop fused filament fabrication technology. The prototype was tested on one of Issinova's physician colleagues at the Chiari Hospital, who connected the snorkelling mask to the ventilator using the 3D printed connector and it was proven to work. The hospital itself then tested the device on a patient in need. The testing again was successful.

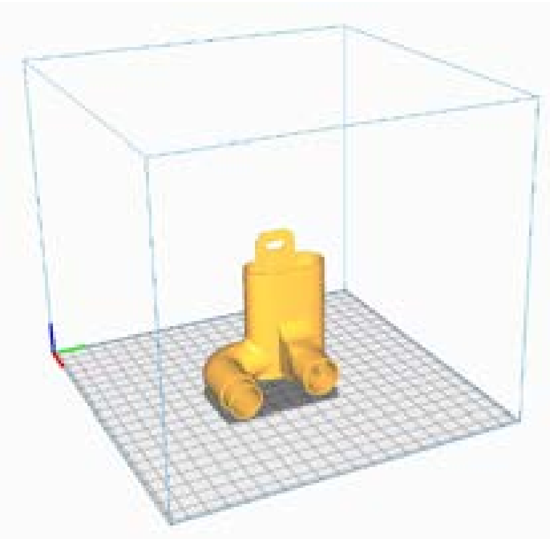
Neither the mask nor the valve fitting were certified by regulators (at the time) and use was subject to a situation of mandatory need. Utilisation by the patient was subject to acceptance of the use of a non-certified biomedical device, through a signed declaration.

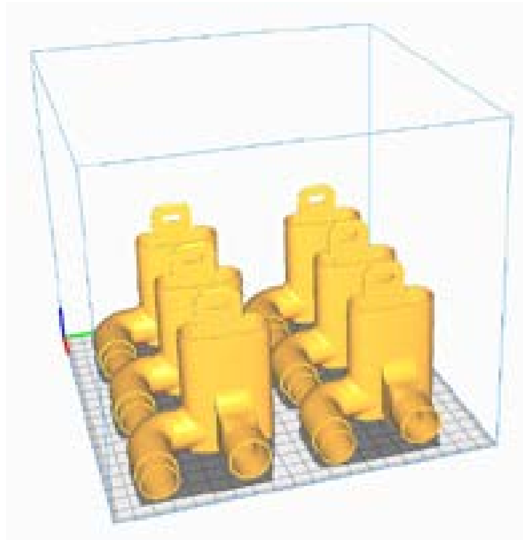
However, Isinnova decided to patent the connection valve (patent n, 102020000006334), to prevent any assumptions made on the price of the component. Today, the patent remains free for use so that all hospitals in need can access it, with all files free to download from the Isinnova website https://www.isinnova.it/easy-covid19-eng/.

Printing the valve was not expensive (approx. US$1) per piece, but Issinova only had six printers available which limited the supply of the production to such an extent it was unable to meet the sudden increase in demand. To help meet demand the firm teamed up with a 3DP manufacturing company, Lonati SPA to increase capacity in order to meet expected and continued increase in demand from a growing number of hospitals looking to use the innovation to treat patients. This collaboration has increased Isinnova's 3DP capacity and the firm can produce around 100 parts per day, thereby enabling further supply to surrounding hospitals and relevant areas of need.

When this product was first released online, some concerns were raised as to whether the original supplier of the respirator would mount a legal challenge. However, at the time of writing, no evidence exists that this is likely.

One of the transformational attributes of this project involved the rapid speed in which Issinova was able to mobilise their networks and capabilities. Issinova initially visited the hospital directly to inspect the valves themselves and went about





rapidly creating a prototype in collaboration with other designers and 3DP manufacturers. As the original manufacturer could not respond to meet the rapid demand of the hospital, Issinova reacted quickly – on the Friday, the firm was asked to assist, by Saturday a prototype was developed and by the Sunday on the same weekend, the hospital had tested the prototype and 100 were printed for use within the hospital.

As an indication, a single Charlotte Valve can be 3D printed in 3.5 hours on a standard <$1000 desktop fused filament fabrication 3D printer, using standard settings applied in the research of Novak and Loy (2020b). However, 6 can also be arranged on the same build plate to increase efficiency and machine throughput, requiring under 21 hours to print.

MATERIALISE – 3D PRINTED DOOR HANDLE

According to health experts, the coronavirus is capable of surviving on surfaces for extended periods of time, and door handles represent a high risk of contamination, requiring individuals to come into contact with them frequently.
In order to help global containment efforts, Belgian software and 3DP service provider Materialise opted to make its 3D printed hands-free door opener free for users to print around the world.

To present workable solutions to medical supply shortages, Materialise were in a position to create alternative products to fill a supply need, with a track record of 3DP medical products under strict guidelines and regulations.
Initiated by the CEO, Materialise collaborated with new and existing partners in the medical sector, whilst also drawing on its 30 years of experience developing medical products.

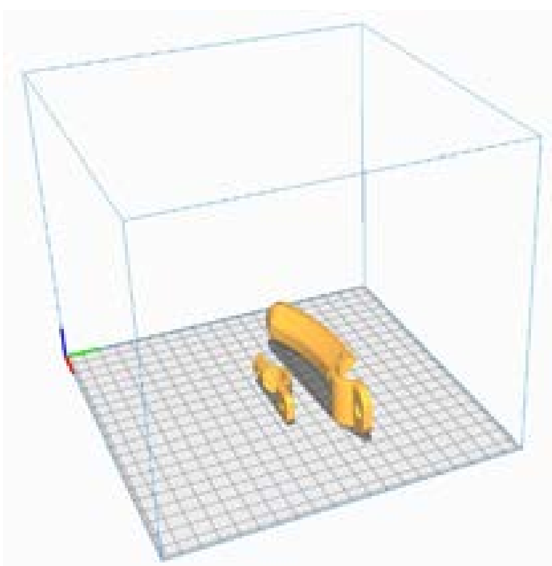
During the early phase of the COVID-19 outbreak, the CEO stopped the firm's entire engineering team one afternoon to pose an old-fashioned rapid prototyping challenge: He asked his engineers to formulate their best 3D printed door handle designs in the space of 24 hours. As the CEO highlighted, this meant following proper protocols by investing heavily in the initial design and development phase. The team analysed potential risks in order to anticipate and avoid any likely problems. This approach led to a series of analysed design parameters within which the team used in the initial door handle designs.

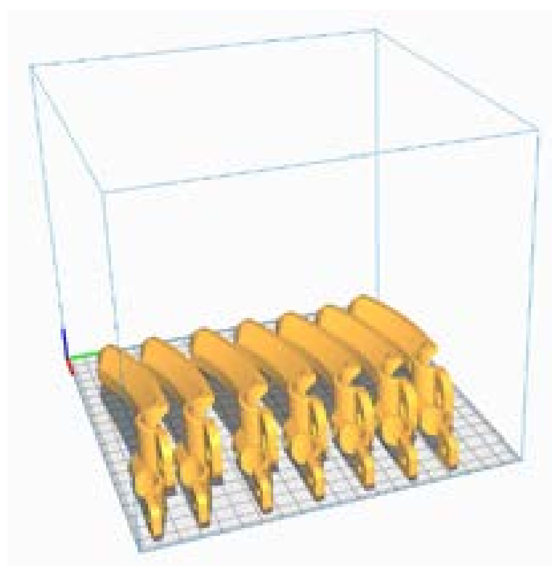
After selecting the best designs, the team were able to begin optimising the five chosen ones, the following day. Within another 24 hours, they had fully optimised each design. The selected door opener design made it possible to open and close doors using one's arm, eliminating the need for direct 'hand' contact with door handles, helping reduce the spread of the virus and removing the requirements for protective gloves.

The 3D printed door opener has been designed and manufactured by Materialise to attach to existing door handles without drilling holes or replacing the handle, thus allowing the door opener to be rapidly and temporarily available One of the features of the 3D printed door handle is a paddle-shaped extension, allowing people to open and close doors, as most doors can't remain open due to safety reasons.

After an initial design to attach to common cylindrical door handles, Materialise expanded the range of options to suit different handle styles. They also provided modified designs suitable for different 3DP technologies, including common fused filament fabrication, as well as commercial systems of selective laser sintering (SLS) and multi jet fusion (MJF). This meant that the handles could be manufactured in larger quantities using these commercial systems. All files are freely available to download and 3D print from https://www.materialise.com/en/hands-free-door-opener/technical-information.

Using desktop fused filament fabrication printing and standard settings used in Novak and Loy's research into COVID-19 3DP, a single door opener will take approximately 1.25 hours to produce both parts as pictured. However, 7 can be arranged on a build plate and 3D printed in just under 9 hours.





FORMLABS - NASAL SWABS FOR COVID-19 TESTING

Formlabs, a company based in Somerville in Massachusetts, USA, is a developer and manufacturer of resin-based 3D printers and related software.

One of the biggest global challenges during COVID-19 was the lack of available tests for coronavirus. There were nationwide shortages in the US of the nasopharyngeal (NP) swabs, needed to collect samples for COVID-19 testing. NP swabs are flexible sticks with a bristled end that are inserted into the nose to the back of the nasal cavity and swept around to collect material that sticks to or wicks up the bristles. The swab is then placed into a vial that contains a culture medium.

After identifying that nasal swabs for testing COVID-19 were in high demand and extremely limited in supply, a team from the USF Health's 3D Clinical Applications Division created an initial design, collaborating with Northwell Health and Formlabs to develop prototypes and secure materials for a 3D printed alternative.

3DP allowed for a new complex 3D geometry to be utilised at the tip of the swab, ideal for collecting sample material without requiring secondary manufacturing processes or additional materials.

Over the span of one week, these combined teams worked together to develop a nasal swab prototype and test it in the USF Health and Northwell Health labs. In two days, USF Health and Northwell Health developed prototypes using Formlabs' 3D printers and biocompatible, autoclavable resins. Once clinical validation was complete, 3D printers at USF Health and

Northwell Health produced the swabs and provided them to patients.
Formlabs mobilised its community of users to deploy nearly 1,000 printers to quickly mass-produce these swabs as well as other important personal protective equipment (PPE). A single print can produce 300 test swabs at a time, enabling Formlabs to produce 75,000-150,000 swabs per day. This development rapidly provided hospitals with access to large quantities of these essential COVID-19 test kit components.

The Formlabs team worked with three leading US hospitals and a medical professor on the swab design. The company shared the design files with its community as well as other health systems to scale the project nationwide. Formlabs has been working with the FDA for years on medical-grade software and materials and meets a wide range of regulatory, safety, and other standards, showing that this firm understands what is required to build products used in clinical settings.

MICRO-X – X-RAY MACHINE FOR COVID CHEST X-RAYS

Micro-X is an Australian (FDA approved) X-ray technology company producing medical and security imaging products. The firm has a flagship X-ray unit called the Carestream DRX Revolution Nano. Whilst it is lightweight, and versatile, the product team wanted to lower the product's weight whilst maintaining a high degree of product robustness. Micro-X selected the Markforged 3DP technology platform to make strong, lightweight, accurate parts to replace existing machined plastic and aluminium parts in production.

Whilst redesigning its flagship product, COVID-19 hit the globe. There was an urgent requirement for the delivery of the latest batch of orders within a four-week time frame to be deployed to Asia and Europe.

While the standard lead time for the delivery of a Nano machine is between 8-12 weeks from order date, Micro-X was able to transform and deliver its coronavirus orders within a time frame of approximately four weeks from order date using 3DP. Some of the design challenges for Micro-X with the Nano were ensuring the machine was lightweight, highly manoeuvrable, robust (chemical and strength) and ensured a long life. These challenges together with a sudden increase in demand required the need to collaborate with a 3DP manufacturer, hence a partnership was formed between Micro-X and Markforged.

Early-stage diagnosis of COVID-19 is by a blood test to confirm the infectious agent. A chest X-ray is used as an essential part of diagnosis of the development and progression of the severity of the illness. Like with pneumonia, a chest X-ray is used to detect fluid in the lungs, particularly with patients presenting with severe acute respiratory distress.
Micro-X managing director Peter Rowland said the mobile X-ray imaging units offered a flexibility of use most suited to the requirements of infection control procedures and also the nature of temporary hospital quarantine buildings.

"For most patients, COVID-19 begins and ends in their lungs because, like the flu, coronaviruses are respiratory diseases and chest X-rays remain a key tool in monitoring the progression of the pneumonia-like symptoms of severe coronavirus infection," said Peter Rowland.

"The number of countries that now continue to order the Nano illustrates a growing awareness of the product and its capabilities which has longer term benefits for increasing adoption."

Micro-X relocated from Victoria to South Australia in 2015 to establish a manufacturing hub at the Tonsley Innovation Precinct, a former Mitsubishi car assembly site in Adelaide's southern suburbs.

Assistance from the Australian Government Entrepreneurs and R&D Tax Incentive Program assisted in the transformation of the firm. Within a period of 3 months Micro-X has now begun exporting to 12 countries, and has increased its production team capacity by three-fold to respond to the COVID-19 pandemic.

SPEE3D – 3D PRINTED COPPER

Australian technology company SPEE3D conducted lab tests showing the effectiveness of their copper 3D printed coating against COVID-19.

The company traditionally makes manufacturing cells for cold spray deposition to rapidly create parts out of metal powders. It has developed new algorithms to coat existing metal parts – such as doorknobs and touch plates – with antimicrobial copper. Handles can be coated within five minutes using the technique.

When COVID-19 hit, SPEE3D founders Byron Kennedy and Steve Camilleri tried to work out how they could prevent the spread of the virus, and decided to investigate if antimicrobial copper could be the key.

According to Kennedy, copper has been known to kill viruses and bacteria for centuries, so they decided to research if it would kill this specific coronavirus.

Lab tests by NATA-accredited 360Biolabs examined the effectiveness of this coating, which SPEE3D has branded ACTIVAT3D, in "contact killing" the SARS-CoV-2 ("severe acute respiratory syndrome coronavirus 2," the virus that causes COVID-19.)

According to a statement from the Australian printer company, tests found 96 per cent effectiveness after two hours and 99.2 per cent after five hours at preventing the virus. In comparison, the virus can survive on stainless steel or plastic surfaces for up to three days.

"The lab results show ACTIVAT3D copper surfaces behave much better than traditional stainless, which may offer a promising solution to a global problem," said SPEE3D co-founder and CEO Byron Kennedy.

"The technology can be used globally addressing local requirements, be they in hospitals, schools, on ships or shopping centres."

Print files were shared with the company's partners and copper fixtures were installed in buildings at Charles Darwin University (CDU) in Darwin, Swinburne University in Melbourne, the University of Delaware in the USA and in Japan. Kennedy says they have received interest in ACTIVAT3D copper from German, Australian and US markets, and inquiries from countries including Chile and Belarus.

In addition to killing COVID-19, Kennedy says the science is fairly clear that antimicrobial copper kills other viruses and bacteria, including influenza A.
“That’s really where the long-term opportunity is — the prevention of not only the coronavirus but other bacteria and viruses that can be transmitted through touch,” he says.

SPEE3D has plans to coat door and railing surfaces with antimicrobial copper in environments including hospitals, aged care facilities, airports, prisons and other essential workplaces.

IORTHOTICS - QUEENSLAND BUSINESS PIVOTS FROM MANUFACTURING SHOE ORTHOTICS TO FACE SHIELD FRAMES WITH 3D PRINTERS

Established in 2009 in Mackay, Queensland, iOrthotics produce custom-made orthotic devices for patients and podiatrists. Their customisable orthotics are designed with patients in mind and to make life easier for both clinicians and patients. iOrthotics ensures that all orders are manufactured and sent out within three to five business days.

In addition to using the latest digital foot/cast scanning processes, computer-aided design (CAD), and computer-aided manufacturing (CAM), iOrthotics use 3DP to manufacture its orthotic devices.

During the past 18 months, iOrthotics' lab has investigated materials, software, hardware, and design processes to ensure their podiatry clients will receive a product that is superior to a traditional polypropylene product.

Most notably, iOrthotics has been working with the Research Fellows from the University of Queensland’s School of Mechanical and Mining Engineering (Advanced Materials) to test the stress and strain properties of different materials.
However, in March 2020, iOrthotics responded to the coronavirus pandemic. It completed an urgent manufacture of about 1000 face shield frames to be fitted to polycarbonate plastic sheeting to be worn by doctors and nurses in Queensland hospitals. It did this in response to a social media call-out for 3000 frames within three weeks.

The company, a subsidiary of the ASX-listed Healthia Limited, produced the frames over two nights with two 3D printers in four 12-hour production runs.
The printers, valued at about $600,000 each, produced each frame in less than three minutes. "We did them in two nights ... and yesterday the guys just spent the day assembling them, cleaning them up and getting them ready and packaged, and I think they were delivered this morning," Hartley (the CEO) says.

"What we do is very translatable into other areas of manufacturing. So I guess we're just pivoting a bit to say 'we can help in this phase and we want to do whatever we can'."

The first load of frames generated requests for a "few hundred" more shields from other hospitals, and from a large private health provider.

Following the COVID-19 responses, the company has also had a request to make special parts for a V8 supercar racing team. But it had nothing to do with gear boxes or advanced electronics in racing cars. Instead, the Triple Eight Race Engineering team asked iOrthotics to make components for a prototype ventilator it is developing.

"We can help solve a lot of these problems, rather than waiting for the factories in China to open up to send us parts. We can do this here in Australia," Hartley says.

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