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Innovation in the time of SARS-CoV-2: A collaborative journey between NHS clinicians, engineers, academics and industry

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Title:

Innovation in the time of SARS-CoV-2:

A collaborative journey between NHS clinicians, engineers, academics and industry.

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Short Title

Innovation between NHS clinicians, engineers, academics and industry.

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And to all those who contributed to this project by 3D printing for our frontline workers.

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Abstract:

During the pandemic healthcare faced great pressure on the availability of protective equipment. This paper describes the entire novel innovative process of design optimisation, production and deployment of face-visors to NHS frontline workers during SARS-CoV-2 pandemic. The described innovative journey spans collaboration between clinicians and academic colleagues for design to the implementation with industry partners of a face-visor for use in a healthcare setting. It identifies the enablers and barriers to development along with the strategies employed to produce a certified reusable, adjustable, high volume and locally produced face-visor. The article also explores aspects of value, scalability, spread and sustainability all of which are essential features of innovation.

Keywords

Innovation; dentistry; full-face visor; Engineering; 3D printing.

Introduction:

In the UK there have been 61,648 deaths and 1.34 million confirmed cases from SARS-Cov-2 up until 19th November 2020.¹ During this acute period numerous innovations have been developed in the NHS to meet the demands of the disease on the healthcare system. Given the critical timescale of COVID-19, the need for the rapid development of local personal protective equipment (PPE) solutions to address these shortages has become apparent.²

The development process of the full-length face-visor as a product, but also the collaborative development of it with engineers, academics and industry is itself an innovation because it fulfils an unmet clinical need through methods not commonly used in healthcare.^{3,4}

The innovation process within the NHS is very different to that in industry. Healthcare delivery is a highly complex system as demonstrated during this pandemic where processes and standards have constantly evolved in relation to safety and cross infection control.⁵

Development of Policy:

The first recorded eye glasses date back the 15th Century⁶; in modern history, the first patent awarded for eye protection was in 1880.⁷

In modern times, policy and legislation has been in place for a number of years as eye protection has been part of routine PPE involving aerosol generating procedures. Under the Health and Safety at Work Act 1974⁸, supported by the Management of Health and Safety at Work Regulations 1999⁹ and COSHH Regulations 2002¹⁰, employers have a legal responsibility to provide appropriate PPE for healthcare workers including eye and face protection against splashes and aerosol.¹¹

This can be achieved either by a surgical mask with an integrated visor, a full face-visor, polycarbonate safety spectacles or equivalent; regular corrective spectacles are not considered adequate eye protection.¹¹ During SARS-CoV-2 the need for a full-face shield or visor requirement has been unequivocal. Face visors need to meet specific standards (BSI EN 166:2001) prior to deployment.¹² These requirements were distilled by the British Standards Institute (BSI) during the COVID-19 response allowing a wider range of products to be used during this period.

Unmet Clinical Need:

The SARS-CoV family are transmissible by droplets, aerosol and splatter through saliva and bodily fluids. For healthcare clinicians who deal with the airway, there is material risk for inoculation through saliva due to high viral loads detected in saliva samples.¹³ Inoculation has been shown via mucous membranes of the respiratory tract with the infectivity through the ocular membranes an additional risk.^{14,15} The chance of infectivity increases due to the uncertainty introduced through asymptomatic carriers¹⁶; potentially giving clinicians a false sense of security of a patient not being infective and being treated with less robust protocols. There is evidence from previous regression analysis of SARS transmission, illustrating a statistically increased risk of inoculation of SARS-CoV in healthcare staff who did not wear suitable eye-protection.¹⁷

The acronym PPE has become part of the lexicon for all clinicians from the start of this pandemic. The UK government identified a shortage of certain items of PPE primarily due to massive global demand; as such reliance on overseas manufacturing for supply of this has been laid bare.¹⁸⁻²⁰

Existing visors used by UK healthcare workers including dentists, are usually short visors designed to retrofit onto glasses or onto a plastic frame more as eye protection only (Figure 1 A and B). Previously full-face visors have not gained much traction in frontline healthcare with visors failing to meet some desirable design properties:

1. Length of visor should cover the whole neck and forehead
2. Be height adjustable for various procedures and stature, and
3. For sustainability be designed in a way for easy disinfection and re-use.

The aim for this project was to identify and implement changes to improve the face-visor.

Innovation Process:

The innovative process for the development of this visor can be classed as a radical change in process, by changing the method of production, procurement and distribution of an existing product category.^{4,21} Being an innovation born out of constraint, the process shown is a simple (low cost), social (community driven), clean (efficient use of existing resources) and lean (elimination of supply chain waste) that has helped meet the clinical need at the frontline.²²

The evolution of the actual soft aspect of innovation (visor design) has progressed through six iterations of 3D printed and four injection moulded designs. The iterations are a consequence of multiple factors including:

1. Engineering feedback
2. Clinical feedback from frontline staff, and
3. BSI standards and policy implementations.

In the United Kingdom a 17-year lag is described between the development and research of an innovative idea and the translation into adoption of that idea.²³ Figure 2 outlines the innovative progression in relation to key national and international events for the COVID-19 response.

This innovative journey occurring in countries ahead of the UK's pandemic had been reviewed in relation to face-visors. One of the more prominent face-visor designs proliferating internationally was by Josef Prusa™ in March 2020.²⁴ Compared to the short face-visors, its improvements include visor length (below the chin) and crucially the modified Prusa™ design allowed higher volume, local 3D printing. There are however some limitations to this design specifically for dental use; the visor height is insufficient not covering the forehead to the trichion and the lack of height adjustability for variability of procedures.

Enablers and Barriers²⁵:

The enablers and their relationship within the process in developing this innovation (Figure 3) can be broadly categorised as:

1. Clinical healthcare staff
2. Charities and academic grants
3. Academic (non-healthcare) colleagues
4. Industry partners, and
5. Volunteers.

The barriers came from:

1. Lack of technical knowledge on product design
2. Understanding of BSI certification for CE marking
3. Agreement for infection control clearance for decontamination
4. National and local policy on PPE
5. Distribution logistics
6. Financial restraints and challenges, and
7. Sustainability.

The lack of economic potential promised by an innovative idea is the reason they are often not pursued. The economic value in clinical innovations can be determined by the quality and cost:

$$\text{Value} = \frac{\text{Quality (Outcomes, safety and experience)}}{\text{Cost (Over time and across the healthcare system)}}$$

The project ensured that the value proposition from the product would incorporate quality and ensure that the reusable nature allowed a more cost-effective option; however, a formal cost-analysis was not completed for this project due to the urgency and speed at which this development occurred. Funding was made more readily available during the pandemic through rapid funding calls allowing this project to progress with less financial concern. In addition, the call for expert input through industrial and academic partners was often provided at no cost. Additional financial support through in-kind contributions to the project, including cost-free tooling for injection moulding allowed allocation of funds to necessary areas such as British Standards Institute certification. This in-kind contribution would not allow for a conventional cost-analysis to be representative of real-world cost which would normally take into account other factors in addition to production costs such as employee costs, workspace and equipment maintenance.

Fundamentally the science and finance are not the problem; it's the skill mix and socio-political issues which are the real challenge.²⁵ Dentists, who are the originators of this innovation are not generally natural product designers but adopters of innovation.

Timeline:

Scaling up production to meet demand and reduce cost but maintaining or improving the quality was crucial. In this instance the 3D printed production of visor frames started four days after the first prototype being finalised on the 13 March 2020. The production delivery of mass-produced 3D printed visors took seven days from final concept approval. The injection moulded design took 21 days from approval to delivery. From the first 3D printed prototype it took just over one month to reach 100 visors; another two weeks to 1,000 and only a further one week until 10,000 units (Figure 2). This exponential increase in production was the result of multidisciplinary innovation, leading to both a product and a hybrid 'production and logistics' model that could satisfy the immediate need for the face-visors for frontline staff working in the highest risk environments such as Critical Care Units and Emergency Departments whilst eventually reaching sufficient volumes to equip a large multi-site NHS Trust.

The most common 3D printing method used was Fused Deposition Modelling (FDM); such printers create flat plastic shapes one on top of one another which build up into full 3D objects. A more advanced printing process, Stereolithographic (SLA), uses a laser to cure liquid resin in the same 2D shapes, which are again layered to build up an object; this type of printing was also utilised during production.

3D printers have become commonplace in schools, universities and even people's homes, as well as finding a niche in dentistry among several areas of healthcare.^{26,27} 3D printing carries several benefits over other manufacturing processes which were relevant to the needs of this project:

1. Low setup time and cost
2. Readily available materials
3. Virtually no material waste, and
4. Minimal operator attention.

The first part of this innovation relied heavily on 'crowdsourced' 3D printing capacity to iterate visor designs quickly and start production in volume very early in the project²⁸; enabling four days between the first prototype to first 3D printed delivery. Through various industrial and academic partners, a network of over 20 home and lab-based 3D printers were formed, with an additional industrial printing farm added to this capacity. To ensure the stringent functionality and quality standards required for the safe and effective delivery of the visors to frontline clinicians, this established a crowd-manufacturing approach embedded in this otherwise centralised design.¹² An online forum was set up to enable producers to share advice and make joint technical decisions as well as coordinate deliveries.

Several constraints must be taken into account when designing a 3D product. Firstly, FDM printers cannot deposit plastic in thin air or recreate intricate detail, limiting the shapes reproduced. Material choice is also limited to six commonly available plastics restricting the mechanical and chemical properties of parts. This was particularly important in this case, as the face-visors needed to be resistant to chemical disinfection. The design of the face-visor was based on relatively simple geometry replacing small and fragile hooks seen on similar 3D printed visors with a larger clamping mechanism across the entire front rim. Polylactic Acid (PLA) and Polyethylene Terephthalate Glycol (PET-G) were the materials of choice due to their slight flexibility and resistance to the strong sterilisation disinfectants.

Automation is key for large 3D print farms to maintain a high output. 3D printers traditionally require human input to off-load printed products prior to next batch printing; however, this is impractical for very large-scale production. Large print farms, such as those used by the industrial partners (batch.works Ltd) in this project used a number of techniques to accelerate the 3D printing process. Automation systems included robotic pistons that could remove parts when prints complete and cameras that compares the print to the 3D design to check for errors.²⁹ The printer set-up itself was optimised for speed, with large plastic extruders capable of depositing material up to 20 times faster than typical machines. The model design was also reworked to print quickly by examining the printhead's path and removing any geometry that created time consuming 'hops' around the 2D layers.

Whilst the 3D printing network produced batches at its peak of 1,000 visors per week, the team worked with another industrial partner (Halma PLC and Apollo Fire Detectors Ltd) to set up high-volume injection moulding tooling to produce batches of up to 10,000 visors per week. Injection moulding offered a much faster process, with a single visor produced in less than 30 seconds compared to the 20 minutes taken by the fastest 3D printers. However, this was subject to a three-week set-up time with sample batches taking up to a week to be despatched for verification; when compared to 3D printers which started printing as soon as digital design file was finalised resulting in a superior turn-around rate. A key element of success of this innovation was the adoption of technologies combining 3D printing to satisfy urgent need and then injection moulding to meet the ever-increasing demand longer term.

Another challenge in supporting a large, loosely connected network of manufacturers was the variation in specification of each machine. This led to constraints including smaller build volumes or lower print resolutions, whilst others offered distinct advantages which were leveraged to improve volume or quality; for example, dissolvable support structures in multi-material printers. Injection moulding required another design variant to accommodate restrictions on shapes that could be moulded. In total, six different versions of the visor were produced after receiving necessary clinical approval for production:

1. Reference design, suitable for the majority of desktop FDM 3D printers (Figure 4 A)
2. Low resolution design, with larger text and a more pronounced acetate clamping design suitable for low-resolution (but very high speed) print farms as described above
3. High clearance design for very fast chemical (resin) printers which experience a small amount of expansion during post processing (Figure 4 B)
4. Stacked design for printers able to print with easily removable support structures (Figure 4 C)
5. 2 colour design with high-contrast branding and instruction text for printers able to print in two different plastics (Figure 4 D), and
6. Injection moulding ready design with break-apart 'teeth' to replace the friction-based clamp, which could not be moulded (Figure 4 E).

The final stages of production included CE marking certification through the British Standards Institute (UK). The process marked the product as meeting the high safety, health and environmental requirements set out by the EU for all products sold in the European Economic Area for use during the COVID-19 pandemic^{11,12}; this objectively confirmed the radical change offered through this innovation met clinical and regulatory requirements.

Spread and Communication:

Communication and dissemination of information is crucial to development of any new innovation. Remote development has boomed with significant increases in the use of remote working programs such as Microsoft™ Teams and Slack™.^{30,31} Changes in working patterns have also been identified people are more likely to be flexible in their working day.³⁰ Challenges of remote working for novice users include a learning curve which can hinder productivity and speed of communication.³¹

This dramatic shift towards remote working was adopted by the stakeholders to collaborate on the project which would not have been possible without virtualisation; this primarily enabled dissemination of information, sharing and approval of designs.

In addition communication through social media allowed for the spread of knowledge to the existing online pool of information.³² The use of social media was not restrained to marketing purposes but for open innovation creation including 'ideation, R&D, and commercialization'.³² This paradigm shift in the use of social media allowed for the development of new ideas with important stages in visor development creatively linking healthcare and university stakeholders. More importantly the shift from the innovators being solely involved in the decision-making process is no longer an acceptable method of designing products. Instead it was recognised that collective intelligence from ideation to end-users were a necessity to rapidly develop and redesign the product allowing the final visor to reflect the unique clinical and technical specifications required.³²

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Sustainability:

Sustainability is essential in the innovative process due to the finite resources available. There is a rising risk of unsustainable behaviours localised in the acute fight against the virus; examples include the significant rise in single-use plastics in respirator masks, PPE and medical devices. 85% of all clinical waste is incinerated and not recycled; in the UK the waste heat produced from incineration is sometimes reclaimed for energy.³³

A life cycle analysis for any new sustainable idea is a process which assesses cost, impact and expected lifetime as important factors in decision making.³⁴ Specifically during the design process, functionality and demand are crucial components in decision making.³⁵ A negative impact of such rapid development is the loss of a life-cycle analysis in preference for meeting the unmet demand.

During the development of the visor, effort was instead placed simply on eco-efficiency and eco-design.³⁴ The 3D printed design allowed locality of 3D printers close to the required sites to achieve huge reductions in manufacturing and delivery times; printers with locally available staff to produce 3D visors round the clock was the driving factor to meet the initial unmet demand. The local mass 3D printing partner achieved high volume by reducing printing times through efficient design modifications; this coupled with recycled PET-G and the use of pedal bike delivery service allowed for an overall eco-friendlier approach to local manufacturing.^{36,37}

Reusability is an aspect of the Barts and QMUL Visor™ specification which has dramatically helped the on-going unmet clinical need; this has allowed for lower pressures on the production volumes longer term. There is a definite impact on production resources which can be reduced when reusable products are used in healthcare.³⁸ There is a growing trend amongst manufacturers towards producing reusable PPE products answering the calls by frontline users for exactly such products.^{39,40}

The financial impact of PPE during this pandemic has risen; the impact on frontline services can mean curtailment of care.^{41,42} The financial sustainability of single use items is not a solution to this pandemic; reusable items must be made a priority.

Discussion:

The collaborative effort of stakeholders allowed for the production of visors which to date have been distributed to primary and secondary care settings including those outside of healthcare with over 15,000 visors delivered from this one team alone. The final effort has resulted in a certified reusable, adjustable, high volume and locally produced visor (Figure 1 B and Figure 4 A-E).

This project has identified that innovation might be made easier and faster if computer aided 3D design (CAD) were to be taught as part of the standard Science, Engineering, Medical and Dental curriculum. The authors include team members who qualified in their respective degrees with and without dedicated CAD teaching as part of the curriculum. Initially, the project presented an enormous learning curve for the clinical and technical members of this team to learn basics of terminology, concepts and design skills. The integration of CAD trained engineers into the team, however, accelerated the product development process significantly, thus decreasing the time taken for innovation using user feedback to be delivered to frontline users. Modern dental practices now more than ever have 3D printing capacity with the technical competencies to operate printers; however, they do not carry the training reserved for mechanical engineers and product designers to design printable models from scratch. The innovation described in this article was made possible by

leveraging these skills held by mechanical and robotics engineers, but could have been vastly accelerated if basic CAD training had been part of training curriculums and available to the hospital where the innovation originated.

The innovative process of using a semi-automated 3D printing has shown that scalability and dynamic capacity can be achieved short periods of time. The authors feel there should be more automated and scalable production methods used throughout the medical industry with more manufacturing capacity devolved locally. This dynamic process will allow for much faster ramping up during periods of acute need and disruption to supply chains due to global, national or local events.

Parts of the world which do not have access to the facilities that were available to this team are likely to adapt their innovative processes according to the local resources available. It is therefore very likely that they would leap frog injection moulding and hard tooling and move directly to systems which are more flexible such as 3D printing; this leap frogging has been seen in the telecoms and communication industries.

In summary innovation in healthcare is not new, however the way the dental and medical profession can collaborate with academic and industry partners is not always realised. The production of this visor through wide collaboration was not truly the innovation but instead the act of collaboration for the production of the visor was. The professional ties built during this challenging period will likely flourish into new ventures of research and enterprise.

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Figure Captions

Figure 1:

Image showing face coverage with short visor (left) and longer visors (right). The short visor fails to extend to cover the whole forehead nor the neck. The side extension across to the ears is less.

Figure 2:

Timeline of 3D printed (yellow) and injection moulded (orange) visor production along with key developments in the pandemic including PPE related events (black). Green superimposed timeline shows the ramping up of visor production.

Figure 3:

Stakeholders involved this innovative visor project including the relationship with the production team.

Figure 4:

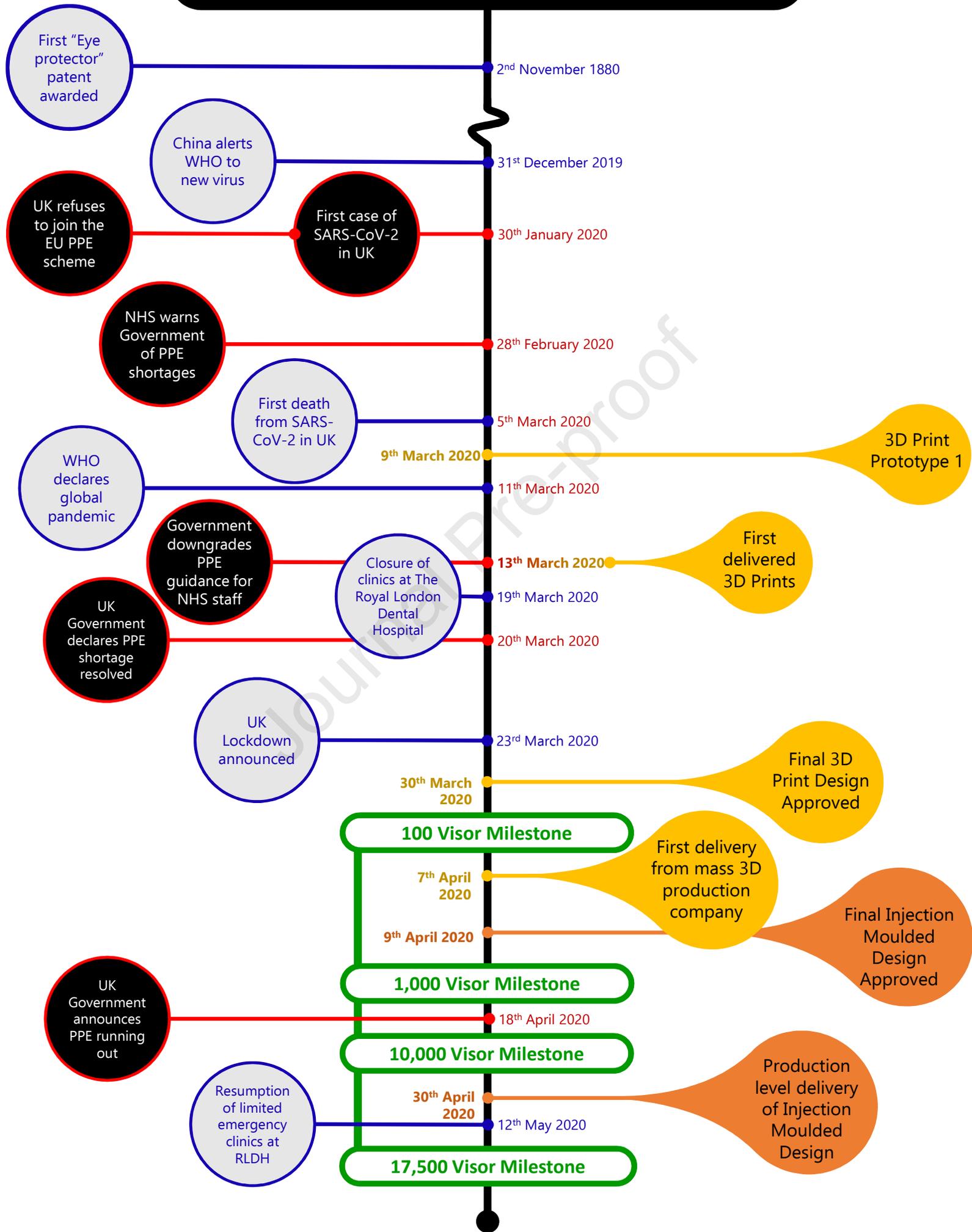
Visor design versions:

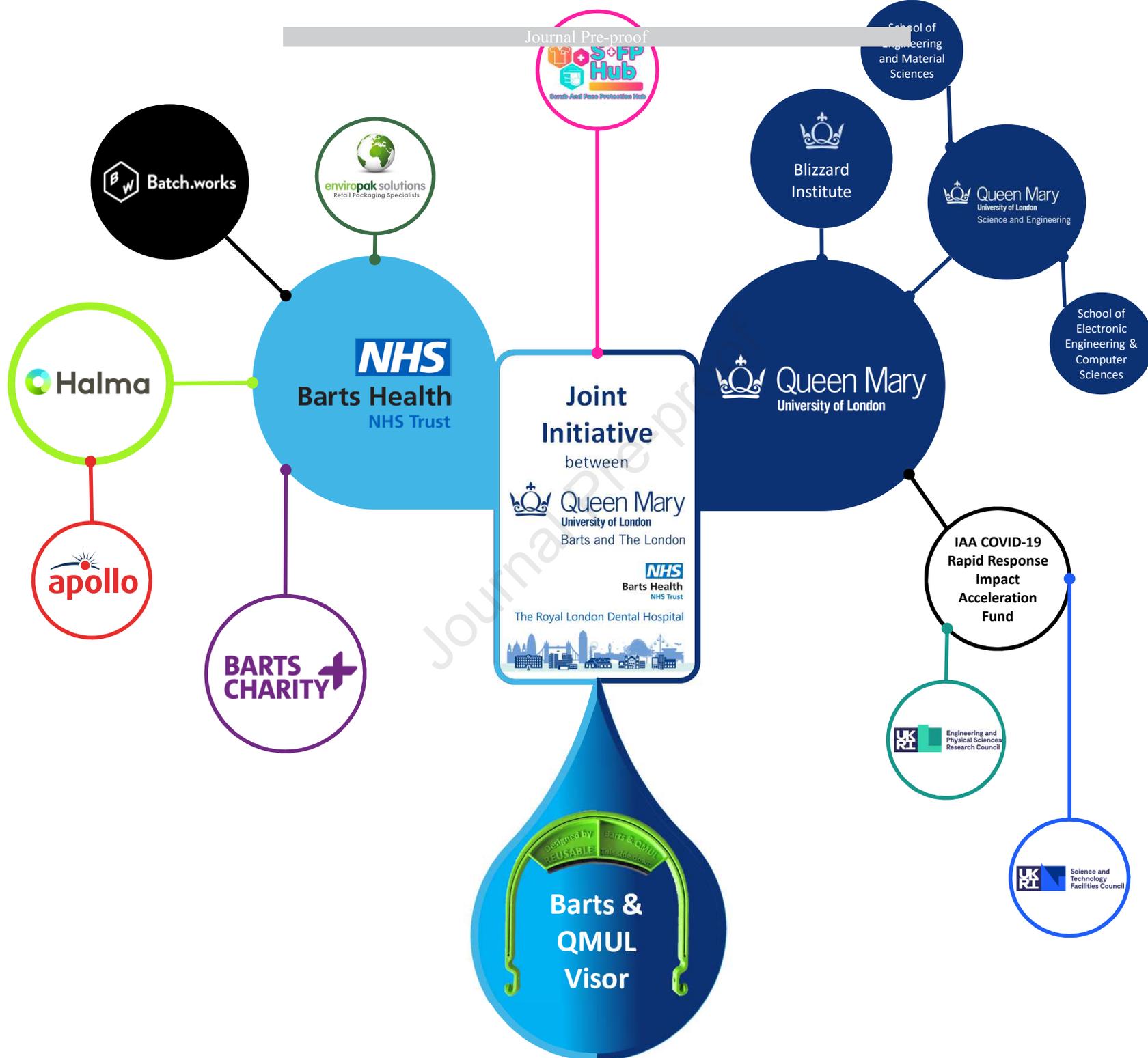
- A. Reference design
- B. High clearance design
- C. Stacked 3D design
- D. Colour design

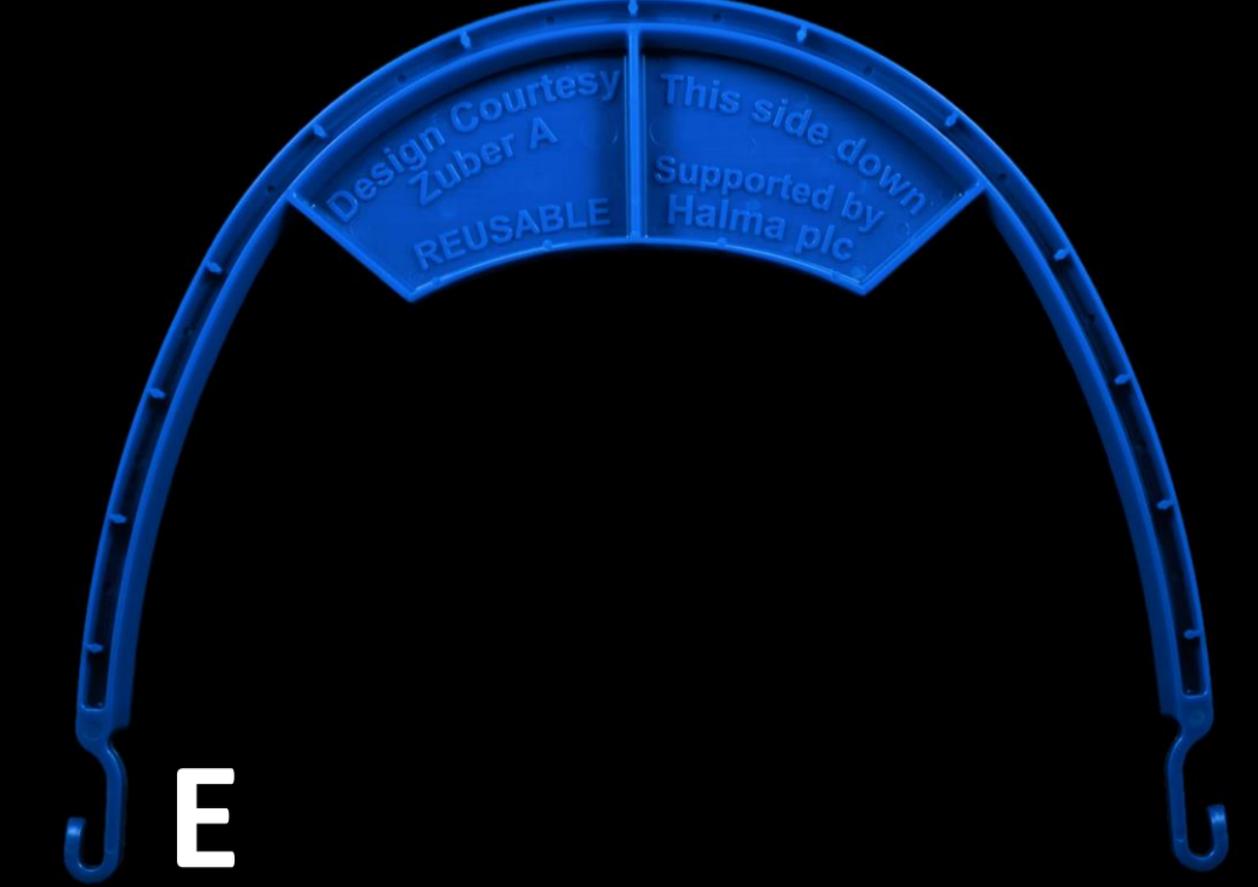
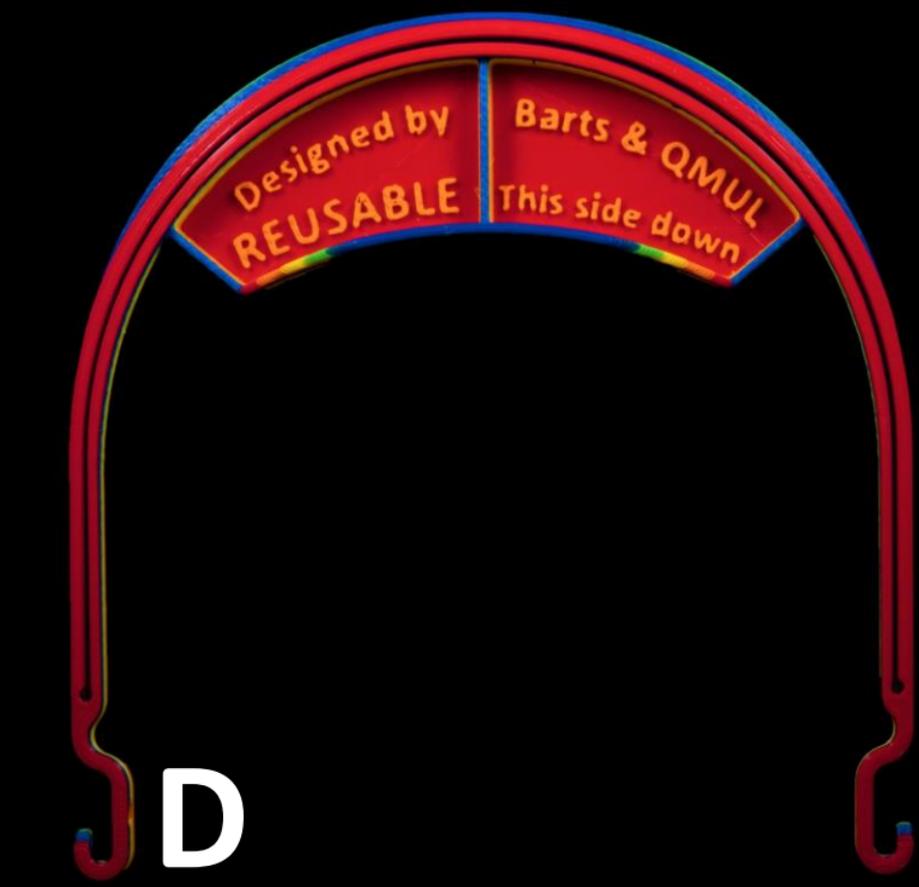
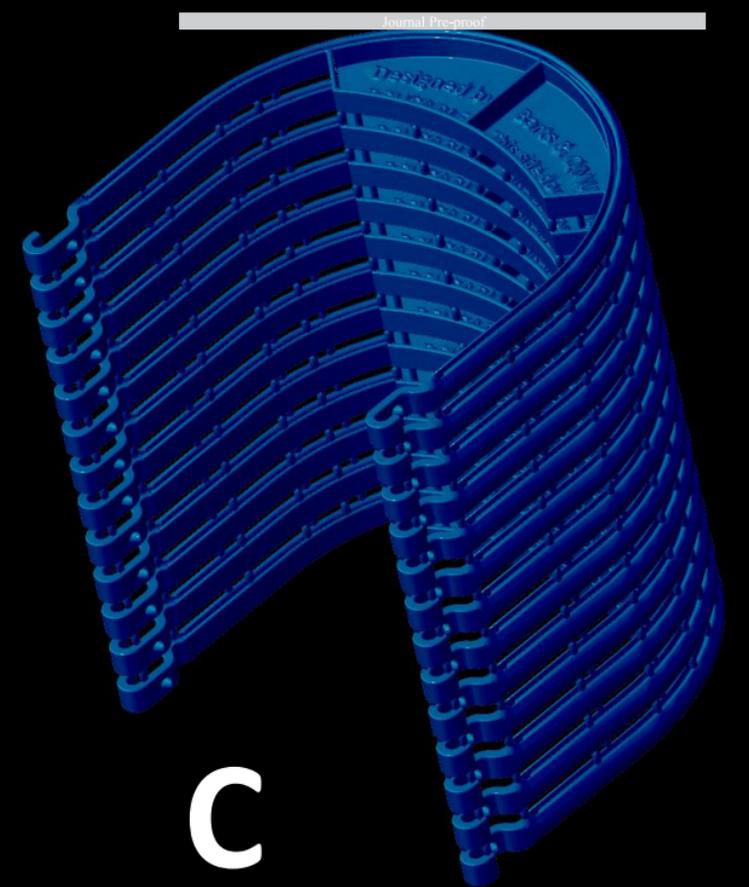
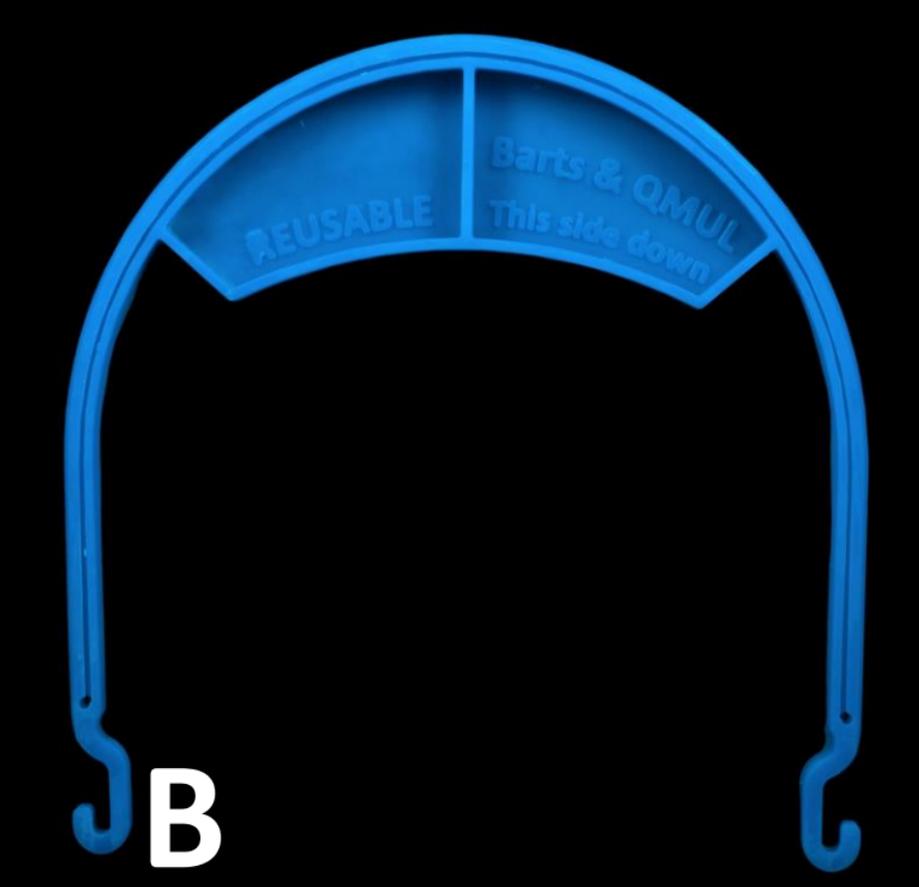
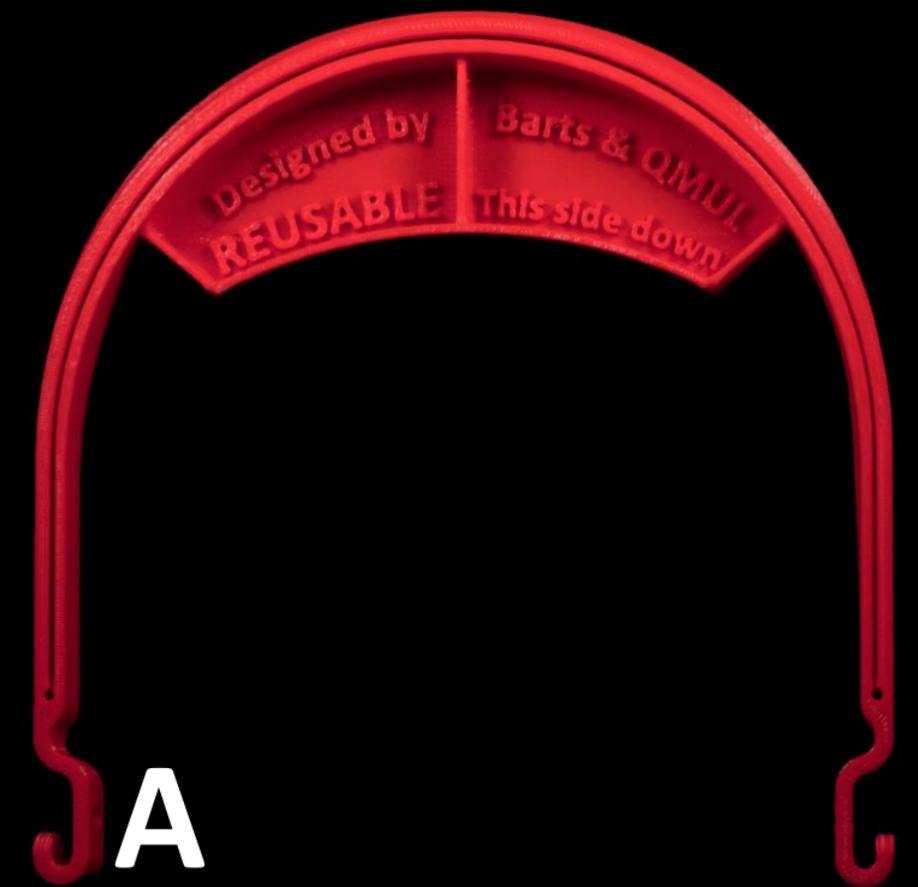
Injection moulding design



Development Timeline







Highlights

1. Innovation within dentistry and healthcare needs to be embraced
2. Collaboration with academic and industry partners results in successful outcomes
3. Academic syllabuses need new avenues of learning and collaboration

Journal Pre-proof