CoMFORT ventilation mask project - Lessons learned from the field

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CoMFORT ventilation mask project. Lessons learned from the field

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Abstract

This paper reports and discusses some key methods and findings of the inter-disciplinary design team undertaking a three year study into improving comfort for paediatric users of Non Invasive Ventilation (NIV) in the NHS. The project proposes a novel use of 3D scanning and printing technologies to offer a bespoke mask provision service.

Five "lessons" are proposed and contextualised with example scenarios from the project.

Key findings have shown the importance of

1. Visual communication methods
2. Involving diverse stakeholder groups
3. Getting hands on with enabling technologies
4. Designing and making test rigs
5. Going around, not stopping at obstacles

We conclude that the visual and tangible methods favoured by 3D designers can help to achieve project aims in interdisciplinary projects. They can improve project outcomes by encouraging engagement with collaborators and stakeholders, as well as building up tacit knowledge of the project context, the enabling technologies and the materials.

This paper also identifies opportunities for areas of related future research.

Keywords: ventilation, mask, 3D, scan, print

Introduction

The project looks at an innovative use of 3D scanning and additive manufacturing technologies to deliver bespoke mask-face interfaces to optimise mask fit to the needs of individual patients. The project also aimed to find out how best to structure a service for mask provision within the NHS.

The project was led by Sheffield Children's NHS Foundation Trust with the collaboration of Sheffield Teaching Hospitals NHS Foundation Trust, National Institute for Health Research (NIHR) Devices for Dignity MedTech Co-Operative and the Art and Design Research Centre at Sheffield Hallam University.

The team from Sheffield Hallam University has an industrial design consultancy background and during this project, observed that taking a "design based" approach has seemingly had a positive impact on project outcomes.

A design based approach can be thought of as having an emphasis on being visual and tactile, on iteratively making and testing, and additionally, being resourceful and adaptable to change.

Context

NIV is the delivery of breathing support via a facemask. It is used to treat people whose natural breathing is ineffective. Evidence shows that, when used long-term, it improves both quality of life and life expectancy.

Two particularly disadvantaged groups are very young infants and children with facial deformities or facial asymmetry. In these groups NIV may not be possible due to unavailability of an adequate mask. If the mask interface does not fit the face, it is possible that air leaks from the mask prevent the therapy from being delivered adequately. In this case, a common solution is to overtighten the mask which can lead to discomfort and facial marking. In extreme cases it can cause skin breakdown, pressure sores and even limit the growth of the face. Alternatively, the patient can be given a tracheostomy and ventilated invasively, but this represents a potential reduction in quality of life for the patient and can put additional strain on the NHS.

Findings

Lesson 1: Pictures are worth far more than 1000 words

As part of the engagement sessions, the team needed to communicate a series of complex, multifaceted clinical pathways (also called patient journeys) to stakeholders from diverse backgrounds, with the aim of gathering their feedback on the different routes. This included patients, their parents / carers, as well as healthcare professionals such as medical consultants, physiotherapists and nurses.

These pathways have an influence on, and are influenced by, a multitude of different stakeholders and external factors. The relationships between them can be intangible and it seemed like it would be difficult to rapidly communicate the dynamics of different scenarios to those unfamiliar with the concepts involved.

Method

The clinical pathways were illustrated in a cartoon-like style, split into scanning and printing scenarios. The patients were shown the scanning scenarios, and the remaining stakeholders saw both scanning and printing scenarios. A slight variation was created, with more technical information overlaid for the benefit of healthcare stakeholders who wanted these details.

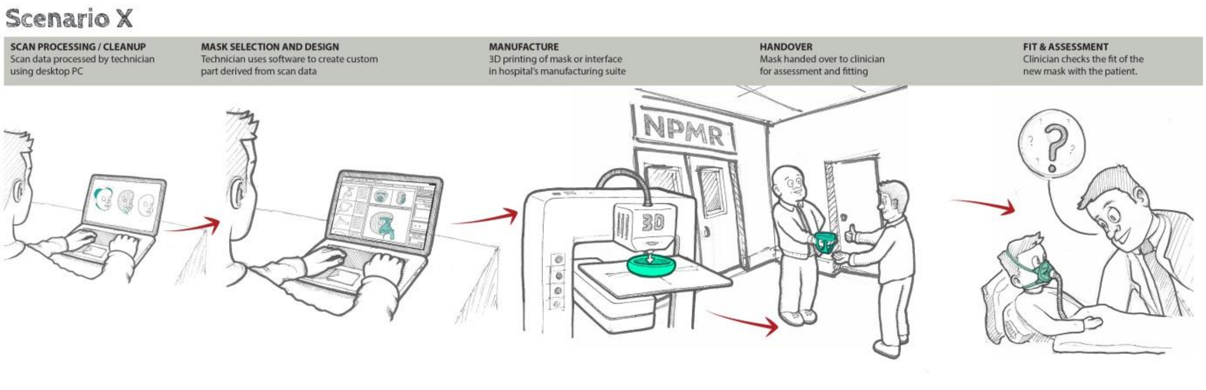

Figure 1: Example of mask design and printing scenario for healthcare stakeholders

Findings

The initial motive for creating the storyboard was as an internal resource for the benefit of the design team, who sought to make sense of the complex and varied demands of the proposed pathways in a way that made sense to them - visually. However, the storyboard went on to become an invaluable resource for successful engagement with stakeholders, in that it allowed for people to easily follow and digest complicated information in a non-technical way. This lowered barriers to understanding and, as it was fun and approachable, it contributed to creating the feeling of a safe space where people had the confidence to contribute their opinion.

Furthermore, it acted as a catalyst for discussion, prompting questions and making people consider things they hadn't thought about before, such as timing or ordering of events, staffing requirements, or the emotion of the patient at any given point.

It facilitated clearer communication between people, particularly if they were from different backgrounds, as they had something tangible they could point at and say "do you mean this? or that over there? And what about this, here?"

It also allowed for people to be more critical and objective, as discussion could be directed at the storyboard rather than at an individual.

Lesson 2: Involve diverse stakeholder groups

The project sought to engage with a range of stakeholders early in the project to uncover the issues with current mask provision, and later on get useful feedback on proposed concepts from patients, their families, and healthcare professionals.

Method

Repeated engagement sessions at regular intervals throughout the project were undertaken to get feedback from stakeholder groups. Sessions involved the creation of visual communication aids and also used tangible artefacts such as material swatches and current products to stimulate discussion. Clear ground rules were established at the beginning of the sessions, with the aim of creating a safe space encouraging people to share and to value each other's contributions.

The team created structured activities to guide discussion, such as a target with concentric rings of importance, onto which the stakeholders various requirements were placed.

Additionally, a graphic scribe recorded the discussion topics in the form of sketches.

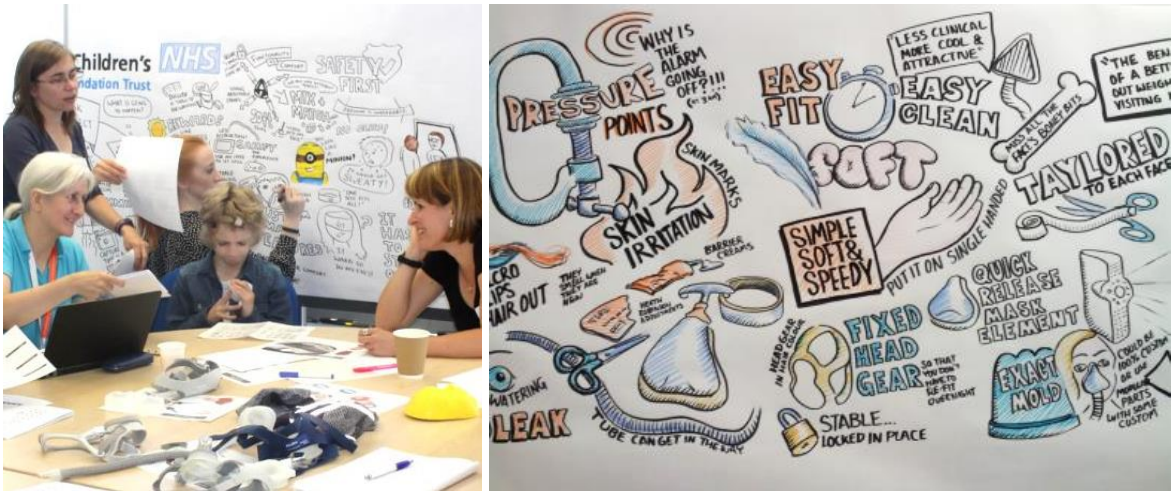

Figure 2: Image of various stakeholders from PPI session, graphic scribe output.

Findings

Structured activities helped to guide the discussion and provide a format where everyone could contribute to all aspects of the session, especially those who were shy or did not communicate verbally.

It was very useful to involve stakeholders from "patient/parent" and "healthcare professional" backgrounds in the same session. This helped to establish a greater sense of empathy between stakeholders, rather than one group making assumptions about the other, sometimes dubbed "staffroom mentality". Furthermore, it provided an opportunity for contradictions to arise, in the form of competing needs and requirements for mask provision between different stakeholders. This variety of opinions was sometimes surprising, sometimes conflicting, but always incredibly useful to inform the direction of the project. The graphic scribe recording helped people feel they were being listened to and made the sessions more fun, as well as being a useful resource to refer back to during following sessions.

The visual and tactile materials were very popular with the young patients who loved the soft and flexible materials in particular. This seemed to give them the feeling that these sessions were fun and as a result, more engaging. It also prompted questions and allowed for feedback from them on the suitability of the materials for this application.

People respected the ground rules aimed at creating a safe space where all opinions were valued.

Multiple sessions allowed for feedback on concept iterations - giving the team an opportunity to create prototypes based on initial mask needs, and then ask "is this what you meant?" therefore gaining more insight into what the stakeholders required.

The graphic scribe helped show people that what they were saying was being listened to, as well as serving as a visual reference for further discussions.

Lesson 3: Get hands on!

At the outset of the project, the team conducted research on suitable materials and additive processes with which to make the masks. Rigid materials are far more commonly used in additive manufacture than soft or flexible ones. As such, the focus was on determining the means of achieving the soft, cushioning components that are likely to be needed in the final mask design.

Method

Initial desk based research was conducted to create a shortlist for further investigation. Following this, physical samples of 3D printed silicone parts were ordered to see (and feel) what they were really like.

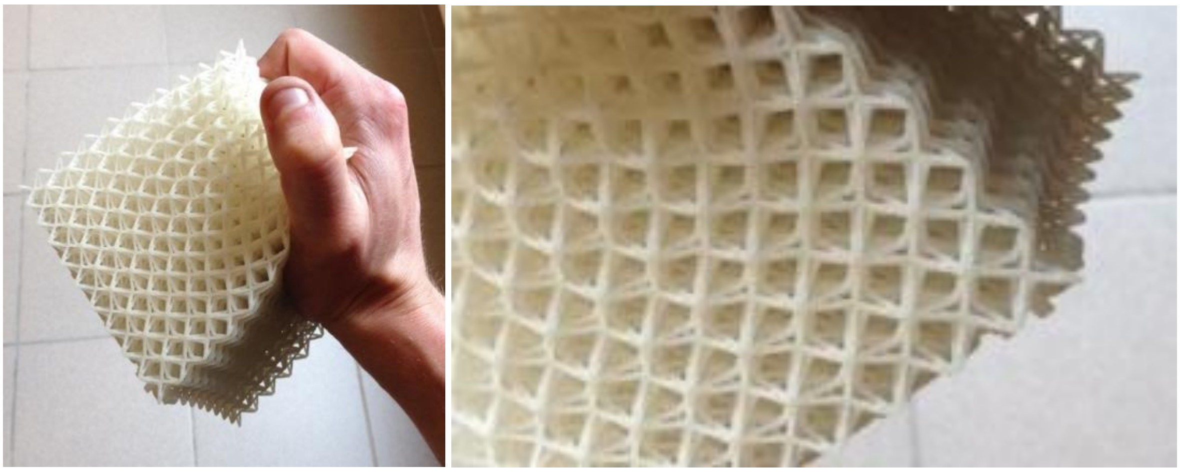

Figure 3: Image showing compliance under load of 3D printed sample.

Findings

Being able to see and touch 3D printed silicone samples led us to doubt if the relatively new (at the time) process was going be suitable for this small, delicate application - the thick layers and low resolution gave a poor surface quality and resulted in stepping on curved surfaces.

It was dimensionally inaccurate as it had warped slightly during curing, and the material wasn't quite as soft or stretchy as we would have liked.

Obtaining physical samples was key to building the tacit knowledge of the material required to make this important design decision.

Lesson 4: Make things to test the things you make

The team wanted to test the leak and pressure distribution of early mask prototypes, however an off the shelf solution for testing of prototype paediatric masks did not exist. Therefore, we chose to design and make a test rig to allow us to objectively test the masks we had designed. The team aimed to create a head phantom that was as realistic as possible in its shape and mechanical properties to ensure data was as relevant as possible.

Method

Head phantom design was informed by research into tissue depth and Shore hardness value across different regions of the face, and the final shape was derived from a composite of CT scan data from several real-life patients who use NIV to include realistic cranio-facial abnormalities.

Tests were conducted into different blends of silicone resin to replicate features such as soft cheeks and harder areas of cartilage.

The head form was created from 3D printed rigid plastic "bone" then covered in several layers of cast silicone "tissue" to replicate different shore harnesses in different areas of the face.

This head form was then mounted onto a rig that allowed for adjustment of headgear strapping tension to predetermined loadings, and combined with an array of sensors to measure how this load was distributed onto different areas of the face for different mask designs.

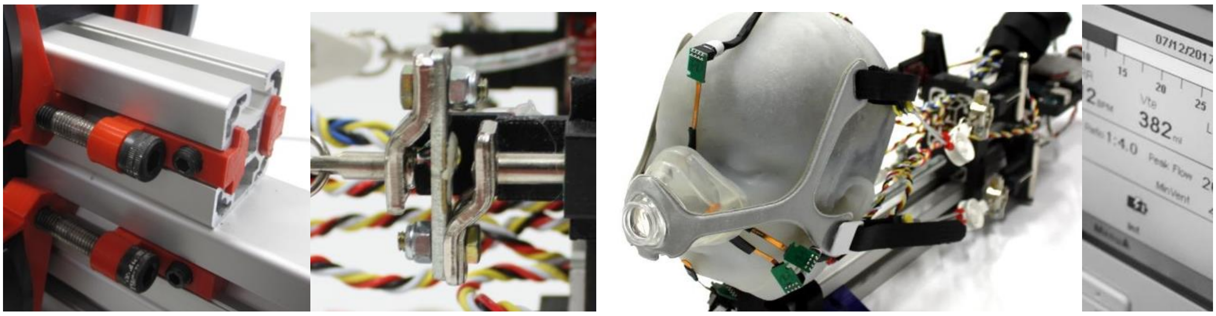

Figure 4: Images of testing rig L-R - adjuster screws, load cell, head form with mask, ventilator readout displaying leak.

Findings

Creating the custom test rig allowed the team to generate quantitative data to objectively compare current masks and new mask concepts. This informed which designs to take forward to later design stages.

Furthermore, designing and creating the head phantom helped the team build up their understanding of the physical structure of the face and potential facial abnormalities of mask users. This background knowledge helped inform the design of the mask by giving the non-medical design team more awareness of the physical structure of the face.

Building project specific rigs not only achieves the aims of providing test data, but inevitably also builds up additional knowledge around the core area of research.

Lesson 5: Don't stop at obstacles, go around them.

Owing to the limitations of silicone additive manufacture mentioned previously, the team needed to find a way of manufacturing a suitable cushioning component without 3D printing. The team had already carried out testing to verify that a degree of cushioning would be required for user comfort and to minimise air leakage - a fully rigid mask wouldn't provide this. Ideally, to best achieve the original project aims, this component would be 3D printed in silicone to allow it to be bespoke for each user without tooling investment. However, the 3DP silicone process was not at the quality required for user trials, and the regulatory conformity was not in place. Another way to create a part with the necessary physical properties was required.

Method

A variety of non-additive, alternative manufacturing concepts were proposed and discussed with potential suppliers. The clinical engineering team at Sheffield Teaching Hospitals provided expertise on medical device regulatory compliance. Physical prototypes were created to explore and communicate the various advantages and disadvantages of each process.

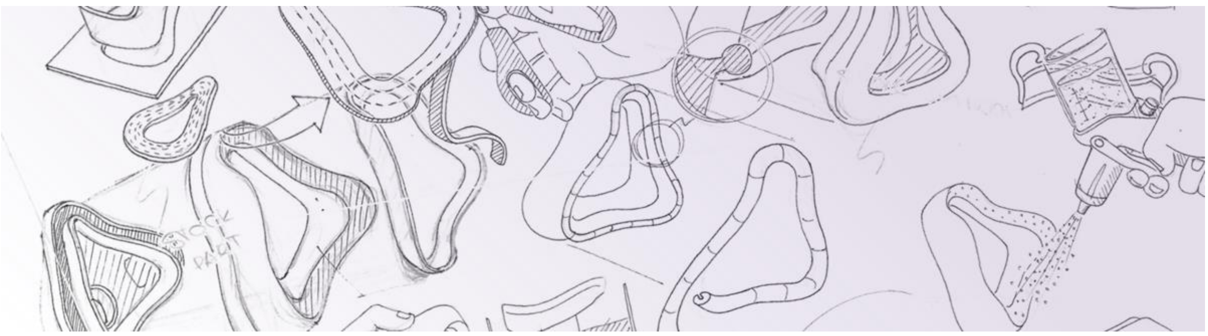

Figure 5: Sketch images of proposed post-print finishing techniques

Findings

After exploring various manufacturing options and discussing them with suppliers, the team decided on a hybrid approach to the mask production. The flexible component of the mask was formed by casting medical-grade silicone into a mould. This formed silicone component would be stretched over and deformed by a bespoke shaped, 3D printed, rigid frame to create the final bespoke mask. Each component was manufactured in a quality assured clean room by contracted companies operating a medical device quality management system (ISO 13485:2016). This combination provided the mechanical properties and regulatory compliance needed from the silicone part, and the bespoke, 3D printed part provided structure and a closely conforming fit to each individual patient's face.

We found that although this hybrid approach was a compromise on the original project aims, it allowed the remaining project aims to be met. We kept in mind that the 3D printing technology will improve in the future and although it uses different techniques, this project outcome can still successfully form the basis of a pathway for effective delivery of custom masks for ventilation therapy.

Conclusion

We conclude that the visual and tangible methods favoured by 3D designers in general, combined with the patient public involvement required for clinical research, can help to achieve project aims in inter-disciplinary medical device projects. Their use can improve project outcomes by encouraging engagement with collaborators and stakeholders and foster a building up of tacit knowledge around the project context as well as the associated enabling technologies and materials.

The resourcefulness of a designer is helpful in achieving project aims, even if outcomes are different than the scenario proposed at the project outset. This is particularly relevant where projects aim to make use of still emerging technologies, and where project timescales and the rate of technological progress are similar.

No individual piece of learning or observation has proved to have higher importance than another; it has been a combination of them together that has provided the most significant positive impact to the project.

Opportunities for future research

The project has identified opportunities for future research projects in the areas of:

- 3D printing of biocompatible, regulatory-compliant silicone for face mask cushioning
- Development of a medical device regulatory-compliant quality assurance process for 3D printed silicone
- 3D design software or tools that could enable mask design by healthcare professionals
- Development of new types of mask headgear
- Application of this local research to international healthcare settings

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