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Northumbria University NEWCASTLE

DIABETIC RETINOPATHY SLEEP MASK

Research through Design to explore and resolve the making of a fabric mask to house a hard pod digital OLED light therapy to arrest blindness in patients with Diabetic Retinopathy.

Type of output:
A healthcare garment/mask product

by
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SUMMARY

This research, carried out between 2015 and 2017, resulted in the making of a contour garment in the form of a mask to house a medical therapy for diabetic retinopathy.

The aim was to experiment with new materials to construct a mask that fitted around the complex anatomical areas of the head and face accommodating a wide-ranging individual variation in facial topography, so providing a comfortable 'garment' to wear in bed which allowed for undisturbed sleep.

This research was part of a wider project working with *Noctura*, who specialise in medical therapy to arrest Diabetic retinopathy (DR), the leading cause of vision-loss globally. The design addresses the issue of non-compliance from patients in wearing the mask due to lack of comfort during sleep that inhibits their ability to receive the therapy.

The approach uses both sensorial empathic design and research through design (RTD) as methods for understanding how digital healthcare can be worn with comfort around the face. Over 80 prototypes were tested with the established *Noctura* user group. The research calls upon the skills of the maker and their material insights and construction knowledge. It also explores the methods for collating user responses around compliance and comfort through sensorial and empathic design philosophies building on the work of Shusterman (2012), Pink (2013) and Margulies (1989).

Dissemination

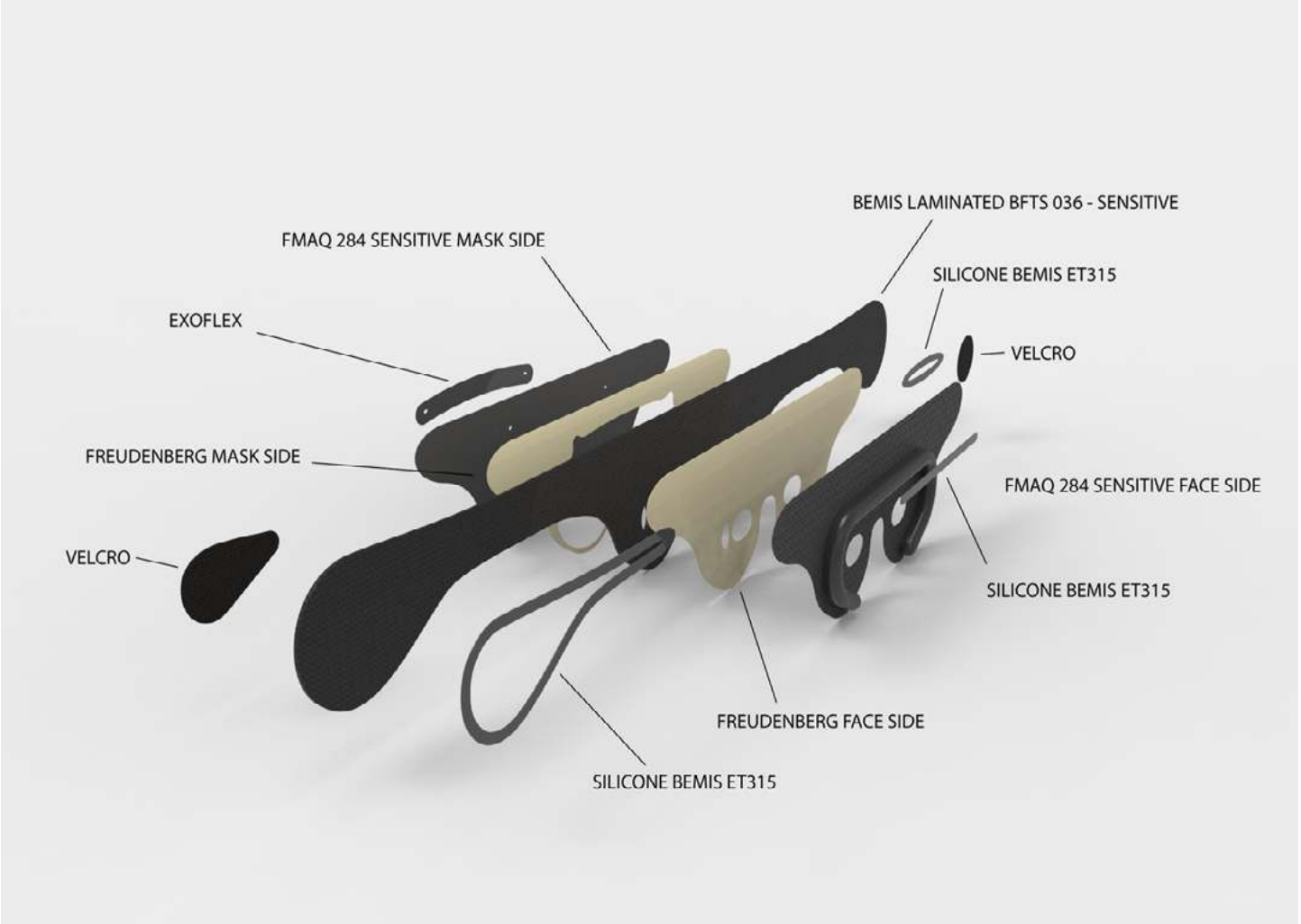
- 2019 presentation and associated paper
  Futurescan 4: Valuing Practice
  https://futurescan.figshare.com/articles/Imaginative_Empathy_and_use_of_Somatic_Perceptions_in_the_Designing_of_a_Therapeutic_mask_for_Diabetic_Retinopathy/9943265/1

- 2017 Presentation to UK Tech Forum Chair at Personal Safety Division of 3M on *Mask Construction and Designing products for and around the face*.

- 2017 Exhibited '*Craft Futures: Call for Makers*', Northumbria University.

This new design has yet to be launched or publicised. *Noctura* are currently seeking FDA approval and is in the process of developing manufacturing capacity in China.

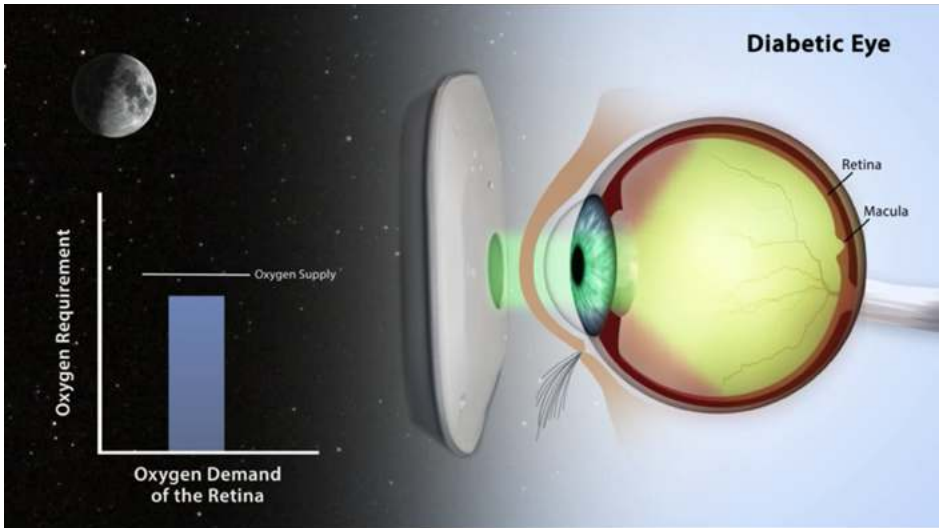
Right: Exploded mask
with fabrications
Photo credit: Josh South



CONTEXT

Diabetic retinopathy (DR) is a leading cause of vision loss globally. Of an estimated **285 million people** with diabetes mellitus worldwide, approximately one third have signs of DR and of these, a further one third have vision-threatening DR.

Noctura (https://noctura.com/), a subsidiary of *Polyphoton*, a bio-photonic research and development company, has developed a therapy to help reverse or stabilize the effects of DR.
They provide an innovative and unique non-invasive therapy based on a night mask where organic light-emitting diodes (OLEDs) illuminate the eye/retina during sleep combating the progression of DR.
The precisely-tuned wavelengths of light reduce the oxygen demand in the eye to daylight levels, and breaks the cycle of damage which leads to diabetic retinopathy. The OLEDs are specifically designed to stimulate the retina without disturbing the user's sleep.



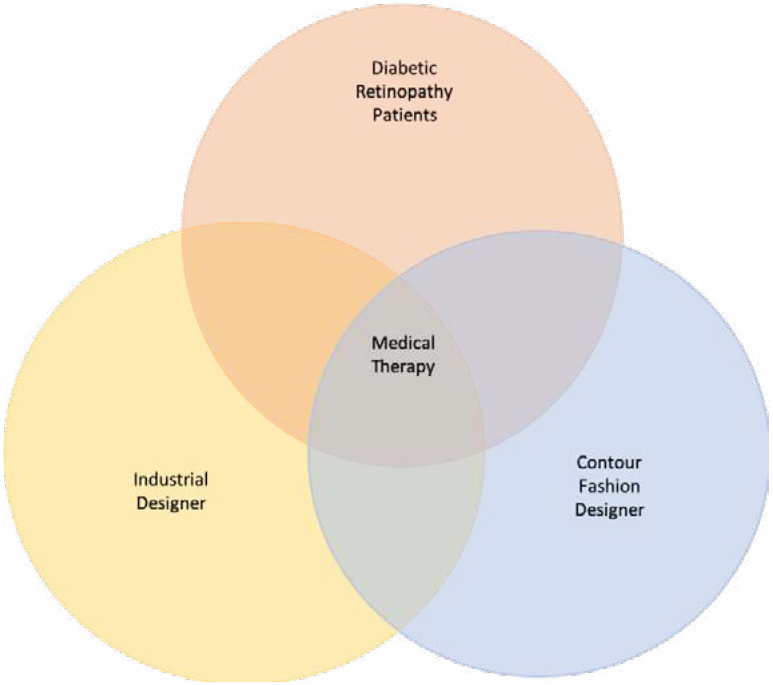
Above: Diabetic Eye
Photo credit: Noctura

The existing *Noctura* 400 Sleep therapy product is made up of the OLED array and a mask made up of 2 parts; a soft cushioned fabric mask and a 'pod' which contains OLEDs. The mask is heat pressed in foam and applied to a flat scuba 2mm strap.

The existing mask was made using foams and mouldings, with padding on the area where the pod therapy was at its hardest. The foams added pressure to the soft eyeball and caused discomfort. So although the therapy itself has been proved valuable in a number of trials, users had complained that the mask was hot and intruded into their eye sockets causing discomfort by putting pressure on their eyeballs. Consequently, they were not wearing the therapy for the recommended time and thus not receiving the OLED therapy.

Industrial designers at Centre for Design Research at Northumbria University had originally developed both the mask structure and the pod to house the OLED medical therapy in 2010. Since then, various designers had intervened, attempting to understand how to improve the fit and comfort of the mask. While Industrial Designers typically work with hard substrates and have knowledge of resistant materials to fine tolerances, Fashion Designers typically work with soft materials and bring an understanding the complexity of body shape and the challenges of designing intimate apparel.

Above: Original Mask structure
Photo credit: Noctura



Below: Situating the skills of the Contour Fashion Designer within triad of expertise involved in mask development.

RESEARCH CHALLENGE

To bring the skills and experience of a Fashion Designer/Researcher to bear on the challenge of creating a better fit mask, increase the adherence and compliance of users, and ultimately improve the medical outcomes of the product; extending the time in which suffers of DR have viable vision.

To investigate how *Noctura*'s fabric mask housing for light therapy could be made more comfortable and elicit greater compliance from patients in wearing the mask.

To understand the topography and contours of human faces to gain knowledge of the mechanics of how to articulate fabric around the head and keep a digital wearable in place.

To experiment with and demonstrate the possibilities in materials and processes that are new to clothing construction which may aid patient compliance surrounding fit, comfort and aesthetics.

To work with *Noctura* stakeholders and collect nuanced information through conversations and visual ethnographic inquiry into how the mask was worn by different individuals.

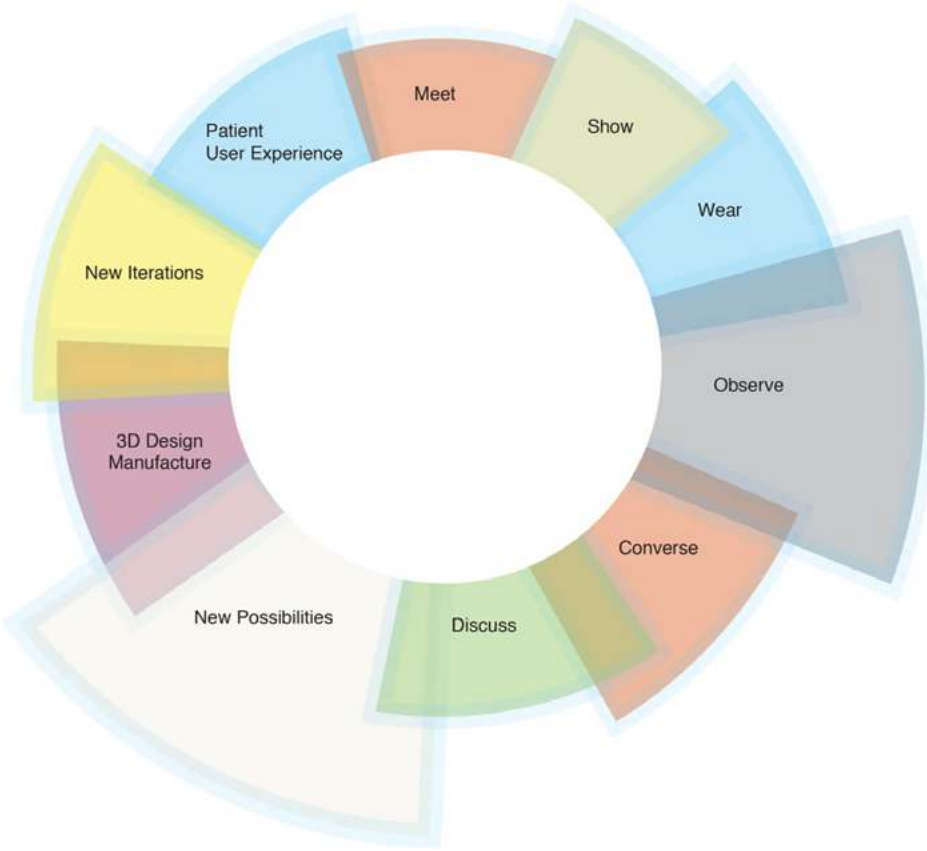
METHODS AND PROCESSES

Method

A research through design (RtD) method was adopted in this project involving a 2 year design process encompassing regular engagement with a *Noctura* user group and multiple iterations of prototyping and testing (see right).

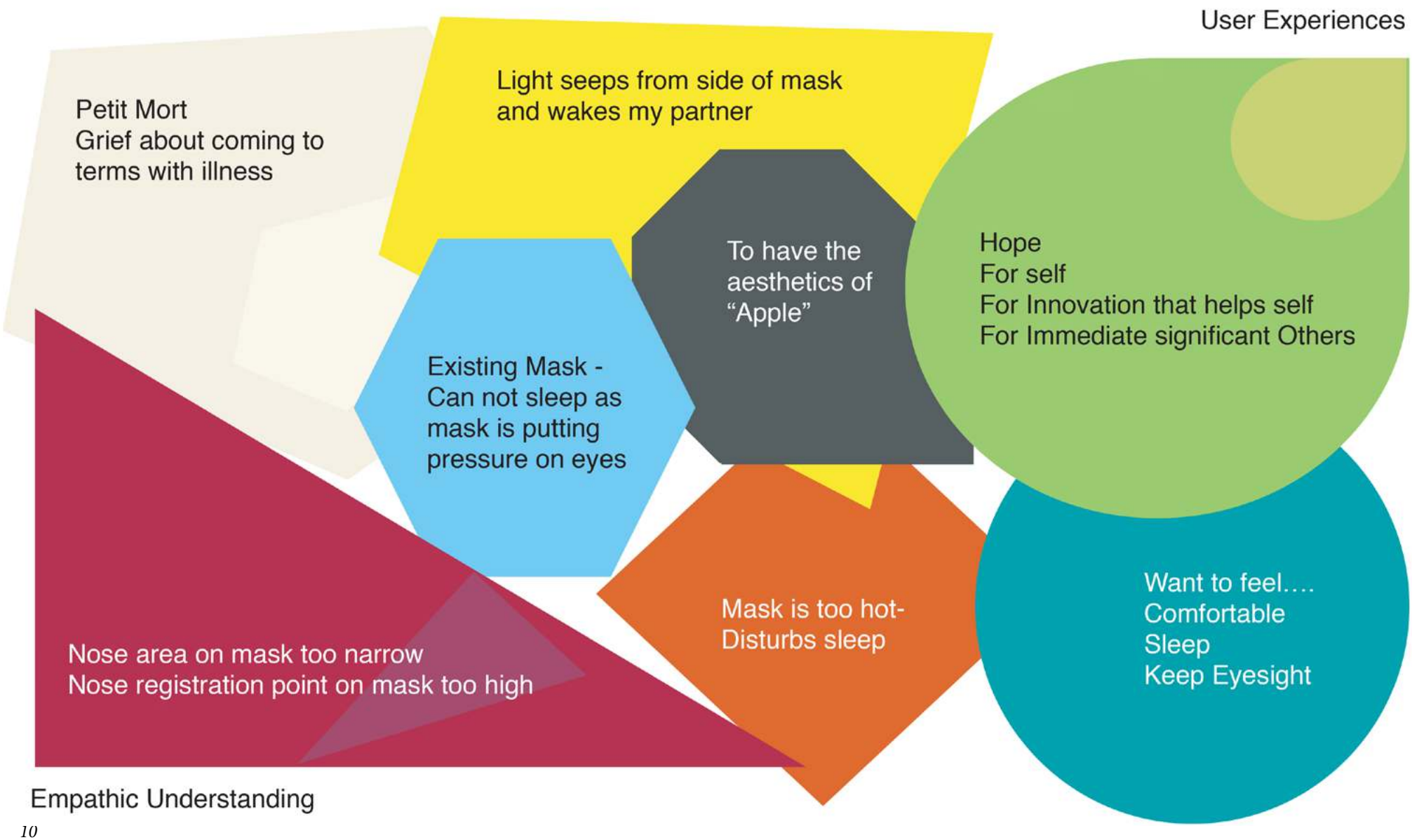
The aim of these activities was to observe the physicality of trying on the mask, taking note of the ways of being, and listening to the nuances of conversations around each iteration by the stakeholders. The author, as a both a participant and designer/observer then discussed the iterations to forge new possibilities. In addition, new manufacturing processes were discussed at each stage to foresee commercial application.

From these discussions refined designs were made for patients to wear and test. This approach sought to integrate the somatic presence and embodied knowledge (Shusterman 2012, Pink 2013, Margulies 1989) of the designer and the stakeholders in a process of co-creating new understandings and enable users to have an active participation in improving their own healthcare.



Right: Empathic sensorial iterative development process.

Below: User comments and experiences from using the mask design iterations.



Right: Multiple iterations of new mask design
Photo credit: Leon Maurice

Design development process

The author's expertise in contour design for bras, swimwear and activewear enabled her to address the initial problems of comfort in the existing mask very quickly. It was recognised that the pod needed to be lifted out away from the face to allow users to wake with the mask on and not feel pressure on their eyes and to be able to open their eyes easily.

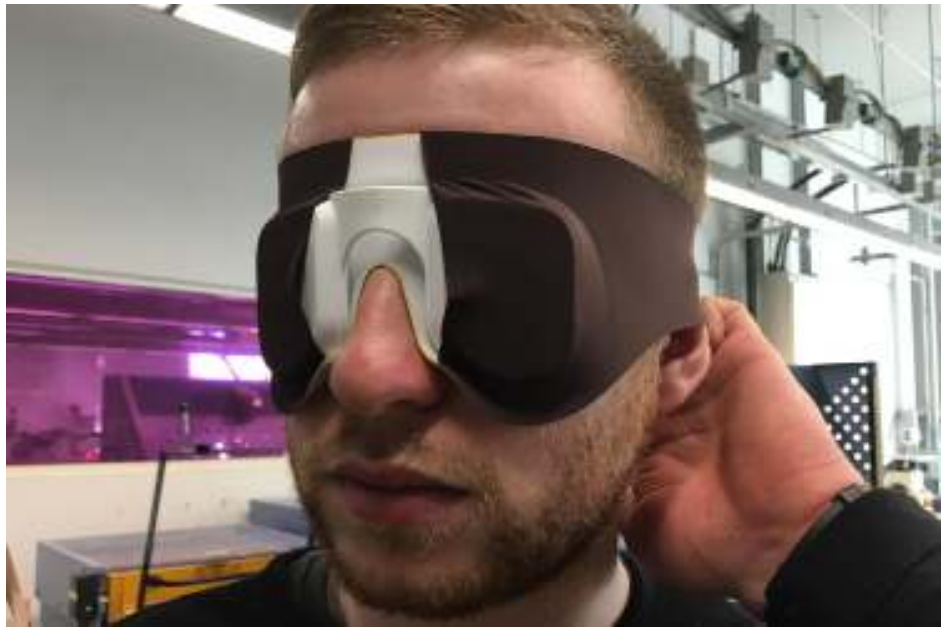
Eurojersey was chosen for the new mask. These fabrics have a particularly flat surface which allows for sonic seaming and bonding of surfaces to create structures.

Above: High Lycra content stretch jersey
Photo credit: Sensitive Fabrics Eurojersey

Below: Structure of flat knit making good surface to adhere bonding
Photo credit: Sensitive Fabrics Eurojersey

The first samples were successful in addressing users' immediate concerns and the team were happy with the samples where the nose bridge and temples were the 'bridge struts' to balance and lift the pod away from the face.

Significantly, two different weight *Eurojersey* stretch fabrications were bonded together to achieve the required effect. The heavier weight jersey enabled a flat surface that protected the eye like a timpani drum effect between the temples and supported by the nose bridge. The lighter weight jersey was used for the pod pocket because of its greater stretch and recovery which held the pod in place and allowed it to protrude outwards away from the face.



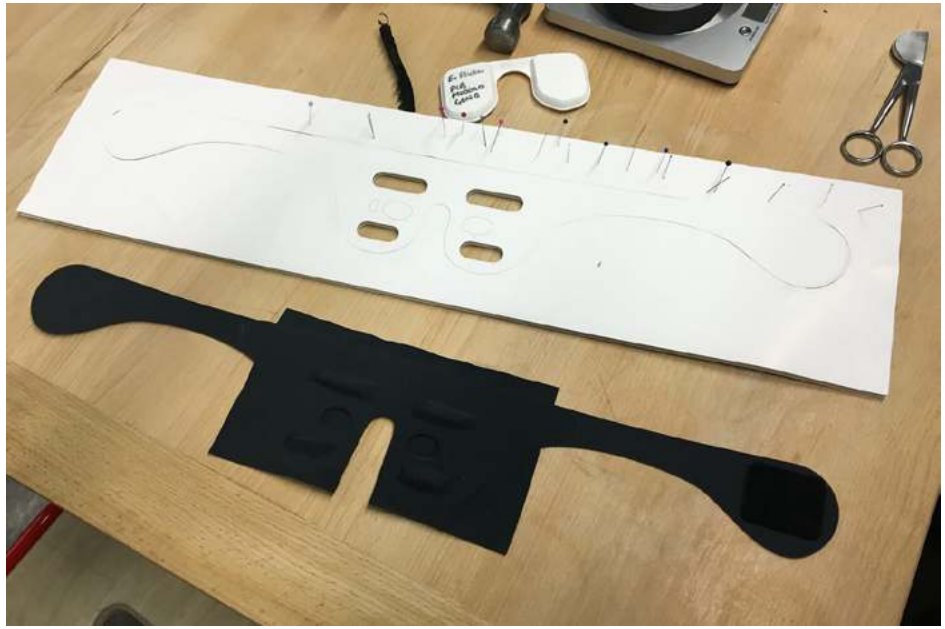
Above: First prototype demonstrating fabric qualities and principles of how different stretches in fabrics allow for enclosing objects such as the pod
Photo credit: Sarah Morehead

Below: Nose, eye and ear alignment with pod and mask fit
Photo credit: Sarah Morehead

There was a challenge in balancing individual user fit with creating an overarching product that met the needs of the majority. The balance needed to accommodate: different width nose bridges; different nose bridges in relation to ear positions; the alignment between nose bridge, ears and eye; eye socket depth; the rise in the cheek bones; and the hair texture or lack of hair.

As iterations were developed, the fidelity of prototypes became more sophisticated, both aesthetically and in their performance. From the foam mock-ups initially trialed on users, a first sample was made by forming a simple mould using foam board and acrylic to heat press the lighter weight jersey into the form followed by trapping foam inserts between the strap and light weight jersey. This low fidelity heat moulding of *Eurojersey* tested the principle without the need to make a costly tooling (see right).

Different iterations were trialed and a 'horseshoe' of foam section bonded into a moulded form and placed between the fabric layers proved most comfortable to users from different ethnicities and sizes. The 'horseshoe' shape also stopped light emitting from the sides of the mask and affecting partners' sleep.



Above: Foam lifts made with low fidelity mould
Photo credit: Sarah Morehead

Below left: Male 'horseshoe' mould to heat press the face side of mask
Photo credit: Sarah Morehead

Below right: Female 'horseshoe' mould to heat press the face side of mask
Photo credit: Sarah Morehead

Once the fit was resolved the next stage was to make the pod pocket easy to access but also secure.

The first method allowed access by adding the lighter 'stretchier' jersey onto the heavy jersey base strap.

The disadvantage was that once the lighter weight jersey had stretched several times, it did not recover (see above photo).

This was resolved by using *Exoflex* from Bemis, a resilient, decorative substrate which recovered after the opening was stretched. The teardrop holes at each end allowed for extra space for the user to open and insert the pod. The low profile hook and plush hidden behind the *Exoflex* ensured a secure closure (see below photo).

Above: Pod pocket, access and resilience
Photo credit: Sarah Morehead

Below: Use of *Exoflex* adding recovery and resilience to opening
Photo credit: Sarah Morehead

Right: Freudenberg
laminate pin dot sheet
introduced for layering bonded
mask sections with high stretch
and low stretch counterparts
Photo credit: Sarah Morehead

Left: Logo Placement
Photo credit: Josh South

Right: CAD rendering
of final mask design
Photo credit: Josh South

FINAL MASK DESIGN

For the final design, the original bonding material supplied by Bemis was substituted for a pin dot bonding laminate from Freudenberg to let the skin and the pod 'breathe'. The silicone laminate from Bemis was added to help users with long hair or no hair keep the mask in place during sleep.

The *Exoflex* Bemis laminate is decorative and practical and allows for a tight opening to insert the Pod that then retracts back into shape where a low-profile hook and plush keep the pod in place. This low-profile hook and plush also give a flat area at the back of the head which, when fastened, does not intrude on user felt experience. The large tab fastening gives a secure feeling to the head band area but also helps users feel the fastening area, as sometimes diabetic patients can lose feeling in their extremities.

The final mask was comfortable, gained users' trust as it was easy to insert and remove the pod from the front pocket, was smart, breathable, had an unobtrusive logo which gave a name to the product and had an aesthetic that pleased the users and their partners.

Right: A large tab aids those with sensation difficulties from diabetes to fasten mask with greater ease
Photo credit: Leon Maurice

Image: Final mask with pod
Photo credit: Leon Maurice

Right: CAD render showing Foam ‘horseshoe’ encased in Stretch Sensitive fabric with silicone bonded film placed on inside inhibits mask from sliding during sleep.
Photo credit: Josh South

DISSEMINATION

2020
The product is currently awaiting final FDA approval and manufacturers being secured.

2017
A trial of 20 users suffering from DR and had had problems with the initial mask design was undertaken by Polyphoton. The new mask design gained a broadly positive response, patient acceptability rate was very high (+90%). Positive comments were particularly noted in the area of material selection and finish, alongside the general look and feel.

2019
The method of collating and analysing feedback is discussed in the double blind peer-reviewed paper presented at the Association of Fashion & Textile Courses conference: Futurescan 4: Valuing Practice. Published in their online journal: Morehead, S. *Imaginative Empathy and use of Somatic Perceptions in the Designing of a Therapeutic mask for Diabetic Retinopathy*.

2017
Invited to speak on *Mask Construction and Designing products for and around the face* on 24th November 2017 by UK Tech Forum Chair at Personal Safety Division of 3M Aycliffe, Durham, UK.

2017
Exhibited at *Craft Futures - Call for Makers*. Northumbria University.

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REF2021 Research Excellence Framework