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Designing for patient empowerment: The application of multiple perspective problem framing in the development of Noctura 400 sleep mask

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Abstract

Medical technologies, especially self-administered interventions, have a critical role to play in addressing health service challenges: they can reduce the need for hospital-based surgical interventions and associated risk of infection, whilst also supporting patient empowerment (Cutler, 2007; García-Lizana & Sarria-Santamera, 2007). Additionally, during the Covid-19 pandemic, the burden on the NHS has been unprecedented (Willan et al., 2020), increasing the demand on limited resource leading to long waiting lists for hospital admissions (Smith et al., 2014).

This paper investigates a case study focussing on the design and ongoing development of the Noctura 400 sleep mask: a self-administered, non-invasive treatment for diabetic retinopathy (DR) and diabetic macular oedema (DMO) through the usage of a low level, controlled wavelength nocturnal light source. The mask, which has been developed by PolyPhotonix Ltd, can replace the need and eliminate the risk of regular surgical interventions involving laser treatment and injections into the patient's eye. Scatter Laser Photocoagulation is associated with possible complications such as vision loss, diminished visual field and reduction in colour vision and contrast (Huamonte et al., 1976), whilst eye injections can lead to complications such as peripheral retinal tear, postoperative rhegmatogenous retinal detachment, hard exudates in the centre of the macula, and neovascular glaucoma haemorrhage (Yamamoto et al., 2003).

This paper explores the application of a Multiple Perspective Problem Framing (MPPF) method, which was used to analyse the relationship of factors influencing patient behaviour alongside technological and medical parameters. This method involved a synthesis of medical research, technological innovation, human factors and functional considerations, sleep patterns and habits, product/service requirements, stakeholder networks, and change factors particularly relating to diabetes. By modelling the interrelationship of these parameters, a novel configuration of factors was identified. This unique configuration is described in the claims of a patent (granted internationally) and underpins the development of the Noctura 400 treatment.

A recent study of the Noctura 400 sleep mask, from Ashford and St Peter's NHS Hospital, saw 94% of patients achieve a beneficial outcome, with 66% enjoying stabilisation of their eyesight (preventing further degeneration) and 32% experiencing measurable improvement in their eyesight. The outcome of this study may lead to DR and DMO patients being supported to manage their own treatment whilst avoiding the burden and risks of surgical interventions. The study also validates the efficacy of a new self-administered treatment paradigm that frees health services of much of the clinical and financial burden of treating DR and DMO.

Keywords: *Medical Technology, Design Process, Multiple Perspective Problem Framing, Value Innovation, Diabetic Retinopathy*

Introduction

As a consequence of increased life expectancies, healthcare systems are struggling to meet increasing costs of treating the chronic conditions we develop as we age. The growing demand for nurses, doctors and clinical resources presents us with a difficult challenge in the coming decades. This paper demonstrates how a multiple perspective problem framing approach (English, 2010) was employed to balance factors related to patient needs, business viability, and technical feasibility to frame the key parameters for the development of a self-administered medical technology innovation that can benefit both patient empowerment and healthcare systems.

The PolyPhotonix Noctura 400 sleep mask provides a low level, controlled wavelength nocturnal light source, which offers a non-invasive treatment for diabetic retinopathy (DR) and diabetic macular oedema (DMO). This case study explores the role of design thinking in developing an innovative medical technology intervention that saves the patient multiple invasive procedures and significantly reduces the cost of DR and DMO treatment services.

The growing challenges for healthcare systems

Healthcare services are facing growing challenges related to the increasing number of patients who suffer from chronic diseases, with financial expenditure on clinician administered and hospital-based interventions increasing at an unsustainable rate. In the UK, the healthcare budget almost doubled from 3.5% in 1949–1950 to 6.5% in 1999–2000. More than 50% of this budget is allocated to hospital treatments (Emmerson et al., 2000). Other problems include lack of specialist clinicians (Torjesen, 2012), long waiting times, lack of resources, and lack of capacity, all of which impact the ability of health services to meet patients' needs (Silvester et al., 2004).

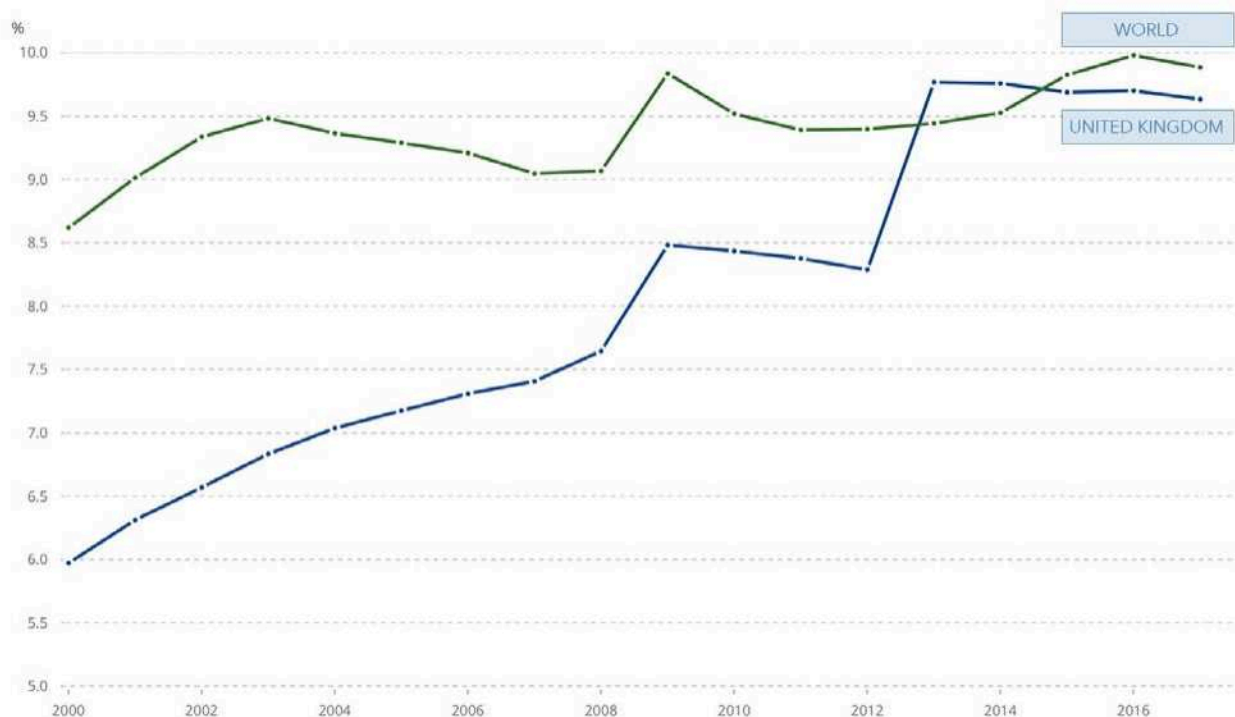


Figure 1. A comparison of global and UK healthcare expenditure as a percentage of GDP (The World Bank, 2020).

Global healthcare expenditure has risen from 8.6% in 2000 to 10% GDP in 2017, and in the UK this growth has been even more dramatic, rising from 6% in 2000 to 10% GDP in 2017 (The World Bank, 2020). This data shows that healthcare expenditure in the UK is one of the highest in the world and that the economic trajectory is unsustainable.

Healthcare challenges have increased further as a result of the COVID-19 pandemic. Hospital admissions have increased by 4.4%, and 30% of admitted cases have required critical care. COVID-19 has increased demands on healthcare services whilst also putting health workers at risk of infection and absence due to self-isolation. These factors have had a significant impact on the ability of hospitals to provide appointments for other diseases including life-saving chemotherapy (Willan et al., 2020).

Patient empowerment

Patient empowerment aims to move healthcare systems from an obedient relationship between clinician and patient to a concordant partnership relationship between both (Feste & Anderson, 1995; Awé, & Lin, 2003; Funnell, 2016; Segal, 1998). Patient empowerment provides a paradigm of medical treatment that widens the scope of traditional healthcare systems to include psychosocial aspects of patient experience such as emotional, social, and cognitive factors (Arnold et al., 1995). It can help patients to be pro-active in decisions related to their health and take a pro-active role in their own care. Currently, this concept of patient empowerment is an integral part of diabetes treatment and can educate patients about behaviour related to their nutrition, weight, and physical activities (Anderson & Funnell, 2010). The revolution in eHealth and web-based interventions contributes to extending the role of patient empowerment and self-efficacy (Samoocha et al., 2010).

Benefits for healthcare

Patient empowerment and self-administered treatments are based on self-determination theory, which is one of several theories that target improving adherence to the treatment regimen. Low adherence is one of the most significant challenges faced by healthcare systems, as it impacts negatively on the economy, the outcome of prescribed treatment, and patient appointments (Bosworth et al., 2006). Accordingly, empowering patients can have a positive impact on both patient adherence and healthcare services. These benefits can help to manage demands on the healthcare system by reducing the need for hospital appointments and dependence on clinicians. Additionally, extending the patient's contribution in the healthcare process can improve their self-care, especially in relation to chronic illnesses such as diabetes, hypertension, and depression. Patient participation can help to reduce unnecessary, invasive, and costly treatments (Colombo et al., 2012).

Challenges, risks and opportunities

Self-determination underpins changes in patient behaviour and improved adherence (Bosworth et al., 2006). However the application and effectiveness of social learning and behaviour change theories varies depending on the disease and its treatment, as found by Colombo et al. (2012) in relation to diabetes, Alegría et al. (2008) in relation to mental health, and Van der Vaart et al. (2013) in relation to rheumatology. The complex nature of factors related to patient behaviour may stand as a barrier to patient empowerment. Additionally, other studies have shown that the factors influencing patient adherence are not clearly defined (Anderson & Funnell, 2010).

Transformation towards patient empowerment can provide potential solutions to some of the critical challenges that face healthcare services, especially in the monitoring, treatment and management of chronic illness. Accordingly, the development of patient administered and patient empowered medical technology (Kramme et al., 2011), including wearable technologies (Teng et al., 2008) and wearable biosensors (Ajami & Teimouri, 2015), provides an opportunity to overcome these obstacles and increase patient empowerment.

This brings us to the crux of the problem that has to be solved in order to develop effective self-administered interventions that can truly lead to patient empowerment. For such treatments it is not enough simply to offer a technology that is known to have a clinical affect. Unlike hospital-based interventions that can be tightly managed within specialist facilities, there is enormous variability in the motivation, home life and habits of individual patients, and this variability invariably influences adherence to a self-administered treatment regimen. Because of this, it is necessary to consider a wider breadth of influencing factors when designing self-administered treatments than would be required for hospital-based interventions. Thus, if health services are to capitalise on the opportunity offered by greater patient empowerment, they must be able to address the network of stakeholders and complexity of issues that are inherent in self-administered treatments.

To illustrate this, we will explore the treatment of a particular chronic condition that affects millions of people worldwide.

Case study – Treatment of Diabetic Retinopathy (DR) and Diabetic Macular Oedema (DMO)

Globally, there are approximately 148 million people with diabetic retinopathy (DR), which is the leading cause of blindness in working age adults (Keenan et al., 2013). Worldwide, 415 million people

have diabetes, and it is estimated that another 193 million have undiagnosed diabetes (Chatterjee et al., 2017). In the UK, more than one in every 17 people is diabetic, and all diabetics are at risk of developing DR (Diabetes UK, 2015).

The development of diabetic retinopathy (DR) is linked to demand for oxygen by the eye. Consumption of oxygen by the retina increases by around 40% at night due to dark adaptation by rod photoreceptors. In the healthy eye, this increased demand for oxygen is fulfilled by increasing the blood flow through the retinal vasculature. The diabetic patient suffers from microvascular damage, which includes damage to the tiny blood vessels of the retina. This compromises retinal blood circulation and leads to retinal hypoxia. The increase in retinal hypoxia increases the vascular endothelial growth factor (VEGF). The newly created vessels are leaky (Bresnick, 1986) which may cause DR and DMO (Arden et al, 2005, Grierson, & Kirk, 2015). Current interventions employ two main treatments as outlined below.

Scatter Laser Photocoagulation (Pan Retinal)

Scatter laser photocoagulation is a physician-administered intervention that has been proven successful in treating DR and DMO (Fong et al., 2007). In this surgery, laser photocoagulation is directed at microaneurysms and applied in a grid system to diffuse leakage (Bresnick, 1986). Studies associated with randomised clinical trials have shown significant improvement in the treated eyes and reduction in visual deterioration compared with the untreated eye (Bresnick, 1986; Fong et al., 2007).

This intervention can reduce vision loss by 50% (Akduman & Olk, 1997). However, studies have identified side effects associated with laser treatment that include decline in visual function, reduction in colour vision, and reduction in contrast sensitivity.

Anti-VEGF Drugs

Another physician-administered intervention involves anti-VEGF eye injections that control the role of vascular endothelial growth factor (VEGF) which is the main cause of DR and DMO. Such injections can be given independently or in parallel with photocoagulation treatment (Stefanini et al, 2014).

Several drugs have been used to treat DR and DMO through anti-VEGF eye injection. Pegaptanib (Macugen) targets only one anti-VEGF isoform (VEGF-165), and has been shown to have a positive impact on treating DMO (Querques et al. 2009). However, current usage of this drug is limited, as other drugs such as Ranibizumab (Lucentis), Bevacizumab (Avastin) (Waisbourd, Goldstein, & Loewenstein, 2011) and Aflibercept (Bahrami, Hong, Gilles, & Chang, 2017) affect all isoforms of VEGF.

Because anti-VEGF injections only have a short-term effect they need to be repeated at regular intervals (Bahrami, Hong, Gilles, & Chang, 2017) and this increases the risk of retinal detachment. Additionally, in some rare cases, patients can develop inflammation in the intraocular cavities inside the eye, known as endophthalmitis. (Osaadon, Fagan, Lifshitz, & Levy, 2014).

Although both laser photocoagulation and anti-VEGF surgical injections provide effective treatment for DR and DMO, this comes at a cost. Fong et al., (2007) highlighted that scatter laser photocoagulation is aligned with complications such as vision loss, diminished visual field, and reduction in vision's colour and contrast. Other complications associated with laser photocoagulation include the risk of retinal bleeding, choroidal detachment, and exudative retinal detachment (Velez-Montoya et al., 2010).

Summary of existing DR/DMO treatment strategies

Eye damage caused by diabetes can lead to the risk of blindness (Meads & Hyde, 2003; Narayan et al., 2000), and, although anti-VEGF eye injections and laser photocoagulation can reduce such risks, these treatments maintain a significant economic burden on health services. The cost of a single anti-VEGF injection can vary from £550 to £800 (Hollingworth et al., 2017), and the majority of the direct medical cost is related to hospitalisation expenditure (Williams et al., 2002). To summarise; the cost for anti-VEGF drugs for DMO treatment in one eye is £6,536 per patient per year (based on £550 per injection, £267 per day-case appointment, and eight treatments per year) (NICE, 2018), and the annual cost of laser photocoagulation treatment is more than £7,800 (Royle et al., 2015).

Much of the substantial costs of both eye injections and laser photocoagulation are necessary to pay for administration by trained physicians in specialist facilities. Additional costs are also incurred by patients who are often obliged to make frequent long-distance journeys to their appointments. These costs could be reduced significantly through the development of a self-administered treatment that empowers patients whilst reducing the demand on both doctor's time and hospital facilities. However, whilst a physician-administered intervention can be precisely controlled by trained experts in a bespoke clinical environment with relatively few variables, a home-based self-administered treatment is invariably influenced by a far greater number of factors. To understand the relationship of these factors and how they might influence a possible self-administered treatment for DR/DMO, the researchers adopted a multiple perspective problem framing method (English, 2010).

Framing the problem space from multiple perspectives

Design thinking is a methodological approach that aims to solve problems and create new value by considering the interrelationship of three factors: 1) human desirability, 2) business viability, and 3) technological feasibility (Brown, 2008). Designing involves divergent and convergent thinking in both problem space and solution space (Dorst and Cross 2001). In problem space, designers discover a wide range of influencing factors which they then interpret to clearly define the bounds of their creative attention; we could call this problem definition (sometimes referred to professionally as stage zero). Designers need to be tolerant of the complexity and ambiguity of a design situation (Rittel and Webber, 1973). This tolerance is underpinned by an ability to navigate and interpret complexity. In the case study that follows, the researchers employed a multiple perspective problem framing approach (English, 2010) to map the complexity of the design terrain relating to DR and DMO, and to identify key cornerstones that were subsequently used to frame the development of a new kind of self-administered treatment.

Multiple Perspective Problem Framing Method

English (2008) provided an approach to overcome the limitations inherent in framing a problem or situation from a dominant perspective. Building on DeWaal's research (2006) and Galbraith's star model (1995), English (2010) presented a multi-perspective problem framing method that articulates the complexity of the problem space and reveals hidden opportunities for innovation and business value. To frame the opportunity for self-administered treatment of DR, the researchers employed a multiple perspective problem framing approach (English 2010), whereby data is collected through several distinct fields of enquiry. This data is then mapped onto a single canvas in order to construct an integrated 'Value Arena' (English 2010). The aim of the approach is to build a complex relationship of factors that can be interpreted in different ways, with relevance to the experience and expert choices of the development team. To facilitate this, MPPF involves a range of techniques that assist in interpreting a complex relationship of data, in order to frame potential opportunities by way of the concepts of 'Cornerstones of Innovation' and 'Design Universals'.

Fields of enquiry

In this case study, MPPF was used to explore factors relevant to DR and DMO with a view to framing the key characteristics of a potential self-administered treatment. To do this, six fields of enquiry (FoE) were identified:

1. **Current scientific medical research** into the impact of light in the treatment of diabetic retinopathy (Arden et al., 2010; Arden et al., 2011, Czanner et al., 2015; Kuchynyka et al., 2017) has shown that when the retina experiences an absence of light of wavelength approx. 460-550nm, the eye dark adapts. In this dark-adapted state, the eye demands an increased oxygen supply in order to build healthy vessels in the retina. Whilst, for most of us, this is not a problem, diabetic patients are unable to meet this demand and consequently build leaky retinal vessels caused by oxygen deficiency whilst the eye is in a dark-adapted state. However, this research also shows that exposure to a very low-level light source (approx. 460-550 nm) prevents dark adaptation and, consequently, there is no increased oxygen demand by the retina.
2. **Manufacturing innovation** in the manufacture of printed OLED lighting. With an active layer less than one micron thick, OLEDs provide a cool light source that can be manufactured to emit a specific wavelength. Through collaboration with the National Centre for Printed Electronics, the researchers gathered up-to-date information on the utility and limitations of printable technologies relating specifically to embedded sensors, power supply and OLED lighting.
3. **Human factors**. This field of enquiry involved the collection of anthropometric data relating to variations in head shape, the position of eyes in relation to the nose, width between eyes, and depth of eye sockets. Data on variations in the physical size and shape of human heads, along with informal primary research with project team members, contributed to an understanding of problem space that informed the researchers' ability to frame design attention. (It is also important to acknowledge the later development of prototypes in the design solution space that were testable in relation to different head shapes and sizes: however, such product development and testing was not part of the initial MPPF framing).
4. **Sleep patterns and habits**. Since dark adaptation of the retina takes place predominantly when we are asleep, it was necessary to gain an understanding of the factors that can influence our sleep patterns such as comfort, cleanliness, noise, darkness and temperature, as well as the kind of

pre-sleep habits that patients report. Sleep diaries were used to help identify factors that influence sleep patterns and habits. Additional secondary research was carried out into the circadian rhythms that regulate the body's sleep/wake cycle over a 24-hour period.

5. **Stakeholder networks.** The success of a self-administered intervention depends not only on the patient's use of the treatment product itself, but also on meeting the needs and requirements of a range of stakeholders, from the patient's doctor, family and friends, to the health service clinical approvals processes, and the industry's product safety, health and environmental protection requirements, such as CE marking. This field of enquiry helped to map out the requirements of different stakeholders to inform problem definition as a frame to scope out potential solution space.
6. **Change factors.** This field of enquiry explores the increasing prevalence of diabetes and the impact of the disease on both the patient and on health service economics that drives the demand for new solutions.

By mapping the data resulting from these distinct fields of enquiries, the researchers constructed a Value Arena describing the complex interrelationship of relevant influences as illustrated in figure 2. This visualisation of all of the collected data provides a single picture of the problem space that can be interpreted in different ways by rearranging the relationship of factors.

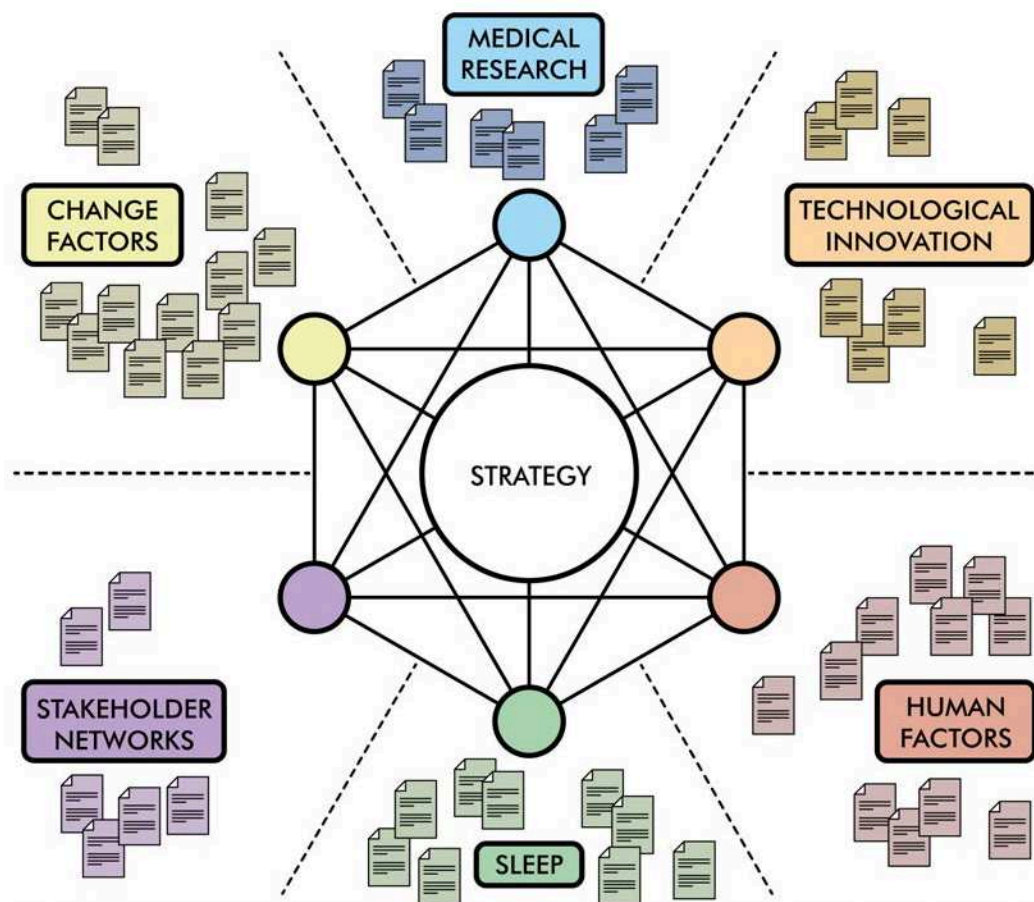


Figure 2 Relationship of fields of enquiry constituting a value arena

Framing using Cornerstones of Innovation and Design Universals

The researchers adopted two main MPPF methods to synthesise and interpret data in the Value Arena. Firstly, where relevant, some factors from different fields of enquiry were grouped in order to build a clearer picture of the form of the Value Arena. Secondly, the research and development team adopted a 'Centrifuge Method' whereby expert judgements are made about the level of importance of different factors. Contextual or more peripheral factors are moved to the edges of the Value Arena map, whilst key factors are clustered around the hub. This means that whilst none of the data from the fields of enquiry is lost, the complexity of the Value Arena is simplified. Through the use of these methods, the researchers

identified six 'Cornerstones of Innovation' (CoI) (English 2007a) used to frame the potential for creative product design:

- I. Patient-administered
- II. Professionally monitored
- III. Washable/cleanable
- IV. Dose-controlled light treatment device
- V. Consistently located over the diabetic eye
- VI. Normal, comfortable sleep

These cornerstones can also be written as a 'Design Universal' (English 2007b) that aims to completely and exclusively describe the bounds of the problem space. This is essentially a generic description of a design solution that could be realised in the form of many particular designs. Based on these Cornerstones of Innovation, a Design Universal described a *patient-administered, professionally monitored, washable, dose controlled light treatment device located consistently over the diabetic eye during normal, comfortable sleep*. By defining a problem in this way, many particular solutions are possible, all falling within the scope of a single Design Universal.

Scoping out the solution space

Using the above generic Design Universal to frame their attention, the researchers created and explored the scope of particular industrial designs for a DR/DMO treatment device (informed by FoE 1 medical research), comprising:

- A cool, substantially planar light source (informed by FoE 2 printed OLED technology innovation)
- A mount element or cartridge (The shape of cartridge informed by FoE 3 human factors) insertable into a
- A Holding element or mask (Mask shape Informed by FoE 3 human factors. Mask material informed by FoE 4)

Figure 3 illustrates development of the treatment cartridge and mask configuration, and investigates the variation of face shape and distance between the eyes in relation to the location of an OLED light source.

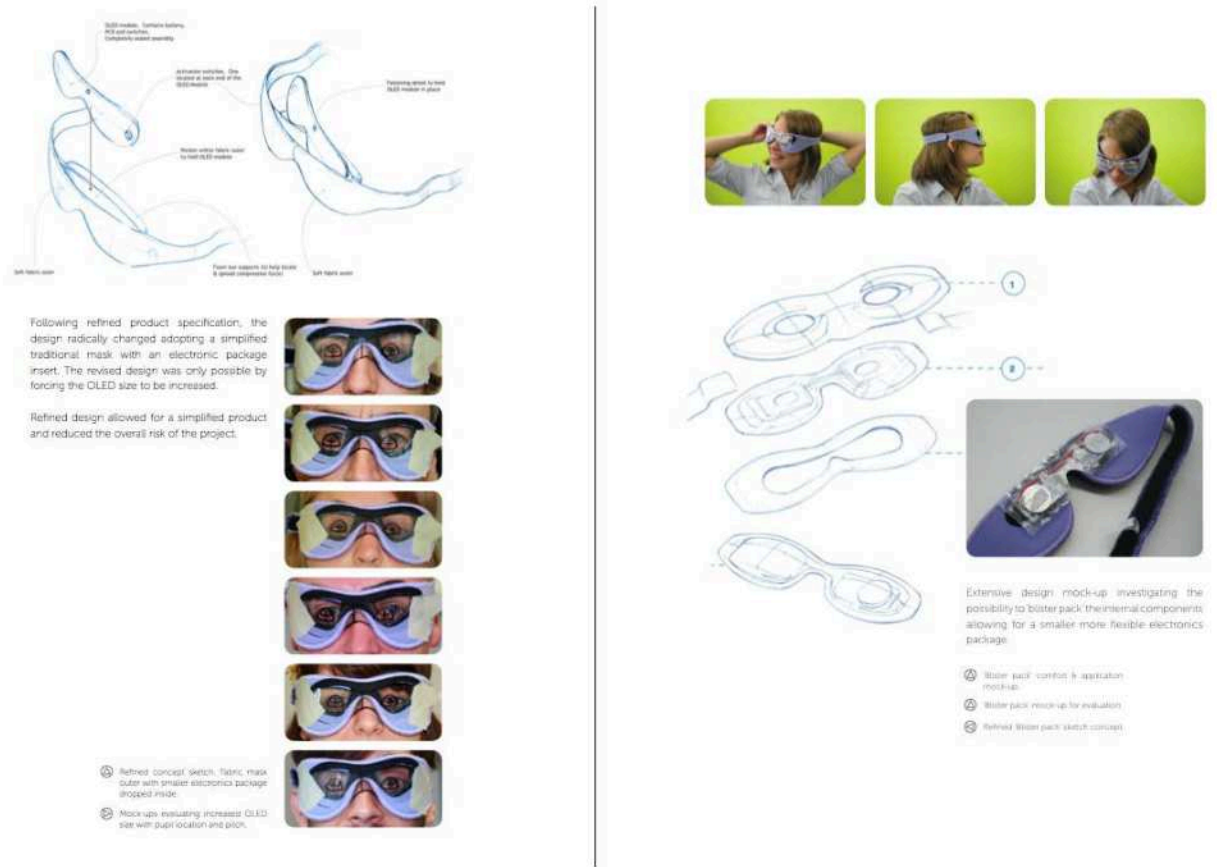


Figure 3 Development of treatment cartridge and holding element (mask).

IP and Development of Intellectual Property

Several patents have been granted for the device. However, evidence of the underpinning MPPF approach can be seen most clearly in the claims of the patent family first granted as EP2686066 (B1) (English et al., 2015). This patent has been granted in Europe, China, USA, Mexico, Japan, Australia, Canada, and South Korea. The patent grants PolyPhotonix a monopoly right over Noctura 400 and has led to international license deals in France, Brazil, Argentina, and Oman, and randomised control trials in Czech Republic, UK, and Hong Kong. As a result of this activity, PolyPhotonix Ltd. is developing an international network of clinicians and service providers and has been able to attract funds of over £27 million to fund business development globally.

The main claim of this patent reads:

*A cartridge for operable connection with a holding element to form a phototherapy apparatus, the cartridge comprising:
 a radiation source for emitting radiation towards one or more eye of a user;
 a mount element for positioning the radiation source in a predetermined position relative to the one or more eye;
 wherein the cartridge is substantially planar and flexible to fit to the face of the user;
 wherein the mount element comprises a locating portion configured for locating the cartridge at a predetermined position with respect to the face of the user, and
 wherein the cartridge is configured to be insertable and holdable in the holding device.*

The shape and configuration of the design is also registered through the EUIPO, European Community Design Registration (English et al. 2013).



Figure 4. Noctura 400 prototype (Credit: Ian Balmain Hewitt eon-designs.com- Source: PolyPhotonix)

Identification of development needs

Design process is characterised by its iterative, problem solving, reflective, and uncertain nature (Dorst & Cross, 2001; Brown, 2009). Accordingly, the cornerstones of innovation identified at the early stage of product development provide an explorative method to consider the factors that may affect a patient's usage of the device. The designer's engagement with these factors is further influenced by the outcome of the clinical trials and patient testing. As a result, field data can be used to refine and improve the particular product design specification in relation to the universal cornerstones.

When considered in relation to Sabaté's (2003) WHO report, that highlights the low level of compliance to chronic disease treatments, it is apparent that the development of successful self-administered treatments such as Noctura 400 should involve consideration of the factors that may affect the patient adherence to a recommend regimen. With this in mind, a further study that periodically monitored patients' experience of using the Noctura 400 prototype (figure 4) led the researchers to revisit the particular specification of the fabric mask to address three of the original cornerstones of innovation, namely; Col III -

Washable/cleanable, Col V - *Consistently located over the diabetic eye*, and, most importantly, Col VI - *Normal, comfortable sleep*. This led to the development of an improved fabric mask specification which is the subject of another paper (Morehead 2019) and is illustrated in figure 5.



Figure 5. Noctura 400 from PolyPhotonix. (Source: PolyPhotonix)

Noctura 400

PolyPhotonix Ltd. is an SME located in the North East of England, specialising in the application of Organic Light Emitting Diode (OLED) technology to improve health and wellbeing. The company's main product is the Noctura 400 sleep mask; a self-administered non-invasive treatment for Diabetic Retinopathy and Diabetic Macular Oedema.

The Noctura 400 (figure 5) offers a potential alternative to painful, invasive interventions (such as eye injections and laser treatment), and at £900 to £1250 per annum it is also a more cost-effective treatment when compared with other interventions (NICE, 2018).

The development of Noctura 400 began in 2010 as part of a Northern Way funding call 'Building a Sustainable Future for UK Printed Electronics', and led to a tri-party collaborative project between PolyPhotonix Ltd (Lead Organization), Northumbria University, and Iconet Ltd.

The researchers worked closely with PolyPhotonix, employing a multiple perspective problem framing method to identify the cornerstones of a new type of non-invasive treatment.

As a result of this method, a treatment pod was developed incorporating thin film OLEDs and positioned over each eye using a breathable fabric mask that can be worn comfortably during the hours of sleep. The resulting device allows patients to self-administer the treatment regimen. Patents for the device are granted in the EU, US, Japan, China, Mexico, Australia, Canada, and South Korea (English et al., 2015).

Evaluation

RENDER Study.

From June 2019 to July 2020, a real-world observational study (RENDER) was carried out at a single site, modifying previous studies to address concerns regarding patient adherence (Mayer-Bothling et al 2021). Unlike previous studies which gave patients masks to wear, but had little follow up or feedback on usage, the RENDER study investigated an improved intervention through periodic interaction with patients by phone and messages to provide encouragement and address any concerns or issues with mask use. The RENDER study also inadvertently intersected with the COVID pandemic and subsequent lockdowns, which significantly impacted the patient cohort, resulting in no visits to clinic. Nonetheless, with calls

continuing and delivery and collection of masks via the postal service, patients still saw good and consistent use of the mask usage going from 80.06 for the first mask to 76.61 % at study end. Patient experience was positive and clinical outcomes were similarly good.

- 29 patients invited to join the study – each selected because they were categorised as 'wait & see' in an ophthalmology clinic. Wait and see identifies they have a significant condition but no major treatment needs to be offered e.g. intravitreal injection.
- 25 patients continued to take part in the assessment. 24 complete the study period of 12 months (i.e. 48 eyes)
- Each patient received a sleep mask and was supported with telephone assistance
- Each patient was clinically assessed at baseline, 3, 6 and 12 months
- The clinical assessment included standard methodologies incorporating, OCTs, Vision testing, ophthalmic exam by clinician
- Each patient completed a sleep study and patient experience assessment
- Patients ranged in age from 38 – 92; with gender, faith, sexual orientation and ethnicity mix.
- Due to the COVID-19 pandemic extra support (telephone calls) and guidance offered to all patients within the study.

Out of 44 eyes studied with optical coherence tomography (OCT), 29 eyes remained stable (66%), 14 eyes improved (32%) and 1 eye became worse (2%). 98% of eyes treated in this study have had a positive outcome, either stabilisation of their condition and/or improvement.

Conclusion

This paper provides a case study of Noctura 400: a non-invasive, sleep mask developed by PolyPhotonix Ltd which offers self-administered treatment for DR and DMO caused by diabetes.

In this case study, a multiple perspective problem framing MPPF (English 2010) approach was used to collect and synthesise a broad range of contextual information and to model the potential relationships between these factors. This enabled the researchers to identify six 'cornerstones of innovation' (English 2007a) which, in combination, form a 'design universal' that represents a generic description of an innovative self-administered DR/DMO treatment device and inform the claims of an internationally granted patent. This universal outcome allowed the researchers to frame the development of a particular design outcome in the form of the Noctura 400 sleep mask. It is worth noting that this case study illustrates the development of two types of outcomes; a universal design and a particular design realisation.

From a healthcare perspective, self-administered health tech treatments can support patient empowerment through connected, cost effective, and user centred solutions. They can provide clinical and economic benefits for both patients, their families, and health services. However, to do this, design solutions and associated clinical trials must be able to address the complexity of the adherence issues that arise in patients' day-to-day lives as distinct from the scientific effectiveness of relevant technologies.

Noctura 400 is already being used by private patients in the UK, U.S.A, Belgium, France, Brazil, Oman and Portugal to preserve and/or improve their sight. In January 2022, PolyPhotonix announced it had entered into a \$10m agreement with US-based Preval InfoWorks as lead investigator of an FDA regulated clinical trial.

Further research

The Noctura 400 device has been used by over 700 patients, and feedback from clinical trials has informed further product and service refinement. Mapping MPPF to adherence literature studies has shown that a lack of effective consideration of adherence factors may critically influence the results of clinical trials, and that this may be a barrier to the adoption of valuable and clinically effective self-administered treatments. Consideration of complex adherence factors has been informed through primary and secondary research, and synthesized and interpreted through MPPF methods. The investigation described in this paper helps to inform a general patient adherence model that has been evaluated as part of a doctoral research programme.

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