From closed to open

*Democratising medical devices using additive manufacture
and open source development and distribution systems.*

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Victoria University of Wellington in fulfillment of the
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Abstract

Pupils can provide important neurological information that can aid in the diagnosis of a range of conditions, including aneurysms, impending strokes and tumors in the lung (Gale, et al). In a research context, there is increasing interest in studying the intrinsically photosensitive Retinal Ganglion cells (ipRGC), which respond to intense blue light thanks to a photo pigment called melanopsin. Studying these cells could lead to a better understanding of sleep disorders and a range of optic nerve diseases.

Although commercially available pupil testing devices do exist, all cost upwards of \$10,000, and suffer from either poor portability or limitations in the tests they can perform. Specifically, the ipRGC require a specific intensity of blue light to be activated and measured, which most devices cannot produce.

In recent years, the open source movement has enabled users from around the world to freely collaborate on the development and distribution of their own products. At first, only software could be produced using this approach, however the continued improvement of 3D printing technology has enabled the same model to be applied to physical products as well. From a medical perspective, this is particularly exciting.

The aim of this research was to produce an inexpensive, open source pupilometer that runs on widely available components, can be distributed online and manufactured using 3D printing technology. In doing so, this thesis asks the question; How can an open source development and distribution model be used in conjunction with online 3D printing services and widely available parts and components to produce an inexpensive and open source pupilometer?

To answer this, a range of practice based methodologies, including research for design and research through design were used to explore this new potential.

The resulting design proposal demonstrates how online file sharing platforms, in conjunction with distributed 3D printing services and online supply chains can be combined to develop new medical devices.

The ability to collect pupil data using an open source pupilometer may lead to expanded data collection and diagnostic capabilities from doctors in a number of clinical settings, while a cloud based data collection system taking the form of a smartphone app will create a large biometric database and cooperative online research community.

Situating the research

Clinical background

The function of the pupil is to regulate the amount of light that enters the eye, acting similarly to a camera aperture. The pupil light reflex (PLR) is a term used to describe the pupillary constriction that occurs in response to light (Binda, Pereverzeva, & Murray, 2013).

The PLR may have first been described scientifically by Charles Henry in 1896, when he observed the pupils of fish would contract at the approach of a candle (Henry, 1896), but the constriction of pupils to light has been observed throughout human history. The neurological basis of the PLR is clearly understood, with a minority of the optic nerve fibres projecting to the midbrain, and activating neurons which lead back to the iris sphincter muscle.

The optic nerve fibres arise from cells in the inner retina called retinal ganglion cells. In recent years, there has been growing interest in a small group of intrinsically photosensitive retinal ganglion cells (ipRGC) (Bailes & Lucas, 2010). These ipRGC receive input from retinal cells like other retinal ganglion cells, but they also have their own photo pigment called melanopsin, which allows them to respond to blue light in the absence of retinal photoreceptors (rods and cones) (Bailes & Lucas, 2010).

These ipRGC are interesting for numerous academic reasons, and they appear to serve the non-conscious visual functions such as circadian rhythm entrainment and pupil constriction. The optic nerve fibres which go to the midbrain and generate the PLR are largely these interesting ipRGC. Stimulating the melanopsin pigment using a blue light causes the ipRGC to remain active for several seconds, so the pupils may remain very small in the dark after a bright blue light has been turned off (the post-illumination pupil response, PIPR).

The PLR is an important signal in general practice, emergency medicine, neurology, ophthalmology, toxicology, anaesthesia and paramedical assessment. Most clinicians do not use any more advanced technology than a simple torch and ruler to measure pupils and test PLR. However,

increasing academic interest in the pupils led to the development of the pupilometer in the early 1960s (Larson & Singh, 2016). A pupilometer is a device used to measure pupil size under a variable light stimulation or in the dark, enabling clinicians to more-consistently stimulate and measure the PLR under standardised conditions.

In modern research where the ipRGC are of particular interest, the ability to produce intense blue light is an important functional requirement for the device, as it enables researchers to quantify the PIPR (Post Illumination Pupil Response) derived specifically from melanopsin signaling in ipRGCs. Despite this, current commercial pupil devices cannot produce the blue light required to generate the response, making them unsuitable for researchers studying ipRGC. Electrophysiology equipment can produce the blue light required to trigger the response, however this option is limited by high costs and poor portability.

In a primary care setting, pupilometers could enable clinicians to diagnose pupil asymmetry when assessing neurological problems (which may include brain aneurysms, impending strokes, lung tumours), as well as test the relative constriction to light in each eye when looking for problems with the optic nerve. With more development, pupilometers could be used in research on circadian rhythms, and there is emerging interest in pupil signals in neurodegeneration such as Alzheimer disease.

Although pupilometers have improved dramatically since their inception, costs have remained high. Currently, portable pupilometers cost approximately 5000 times more than a pen torch, the most common tool used to measure the pupil light reflex, despite it also being the least reliable (Lee, Mitra, Pui, & Fitzgerald, 2018). A cheap and versatile pupilometer may have application in a range of research settings, neurological and ophthalmology practice, and in many primary care settings such as ambulances, emergency departments and family practices (Gale et al, 2017).

The ability to collect pupil data using an open source pupilometer may lead to expanded data collection and diagnostic capabilities from doctors in a number of clinical settings, while a cloud based data collection system taking the form of a smartphone app will create a large biometric database and cooperative online research community.

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Figure 1. Fred Hollows treats a young Vietnamese boy, 1992.

“I believe the basic attribute of mankind is to look after each other.”

-Professor Fred Hollows

Medicines open source approach

The medical field has a strong culture of sharing important knowledge for the greater good of humanity. It is believed that this culture was established at some point in the 4th century BCE, when the Greek Physician Hippocrates and his students established a set of set of ethical standards for physicians that later became known as the Hippocratic Oath (Isaacs, 2011). Throughout history, the oath has been adapted and updated to better reflect the state of society at that particular point. On October 14, 2017, a newly revised version of the document was adopted by the World Medical Association (Parsa-Parsi, 2017). Included in the newly revised version is the line

“I WILL SHARE my medical knowledge for the benefit of the patient and the advancement of healthcare”

- The World Medical Association-WMA Declaration of Geneva, 2017

Perhaps the best modern example of a clinician that embodied these values was the Late Fred Hollows. Hollows was a New Zealand Ophthalmologist who studied medicine at the University of Otago in the 1950's. After finishing his studies, he moved to Australia in 1965, where he visited several indigenous communities. Hollows was shocked by the poor standards of eye health, particularly the incidence of infectious but easily treatable diseases such as Trachoma (“Vision fulfilled, Profiles, Otago Magazine, University of Otago, New Zealand,” n.d.).

In 1968, Hollows began lobbying for funds, and between 1976 and 1979 the National Trachoma and Eye Health Program was established, treating the eyes of 100 732 people; 62 116 of these were indigenous Australians (GHEBREMEDHIN 1998). The success of this program led to several more eye health programs in Eritrea, Nepal, and Vietnam, which have since restored the sight of thousands.

During the 1980s, Hollows worked with the World Health Organization in developing countries across Asia. Once again appalled at the lack of medical resources and the prevalence of avoidable blindness that he witnessed, Hollows developed a range of new techniques for performing basic cataract operations, better suited to low resource settings. To make the required equipment more accessible, he set up laboratories in Nepal and Eritrea to manufacture low cost plastic lenses, enabling local doctors to restore sight at a fraction of what it would cost in the developed world. Today, the same laboratories produce millions of lenses, with some of the proceeds reinvested in training local eye doctors and nurses (“Vision fulfilled, Profiles, Otago Magazine, University of Otago, New Zealand,” n.d.).

Fred Hollows died on 10 February 1993 at the age of 63 years after a brave battle with kidney, lung, and brain cancer. Doctor Hollows was renowned for his ‘boots on the ground’ approach to helping the most vulnerable members of society, and had a strong connection with the people in which he helped. In the last year of his life, Hollows began planning a foundation that could continue his legacy for years to come. Today, the Fred Hollows Foundation works in more than 25 countries and has restored sight to over two million people worldwide (“Fred’s Story, Vision and Legacy | The Fred Hollows Foundation NZ,” n.d.)

Figure 2. Diagram visualising the design process used in this thesis.

Methodology

Frayling (1993) breaks design research down into three main categories. Research into design, research through design and research for design. This thesis employed research for design and research through design as its overarching methodologies.

Research for design.

The first phase of this thesis involved research for design. Downton (2003) defines research for design as the research area that provides the information, implications and the data that can be applied to achieve an end result in a design project. Downton refers to this process as ‘research to enable design’.

The research for design phase of this thesis involved conducting a literature and design review (Hanington & Martin, 2012) to gain a contextual overview of additive manufacturing, distributed manufacturing, open source development and distribution models and relevant design precedents. Another aspect of the research for design phase came in the form of input from the wider design team working on the project. This included technical input from the engineers, and clinical input from Dr Gale.

Research through design

The second phase of this thesis involved research through design. Hanington & Martin (2012) define research through design as a practice-based research method, where designers generate new knowledge through the design process itself. Expansive design research is an aspect of research through design used to reveal previously unknown knowledge to the designer, similar to how a geographer maps a new area (Krogh, Markussen, & Bang, 2015). Expansive research through design was conducted with the aim of determining the optimal manufacturing process, material and online manufacturing service for producing the pupilometer.

Serial design research is an iterative approach to research through design where experiments are carried out chronologically. New knowledge is produced based on the insights gained from previous iterations, which in turn inform subsequent generations of the design (Krogh, Markussen, & Bang, 2015). In the context of this thesis, serial research through design was conducted using several methods, including sketching, CAD modelling, sketch modelling and 3D printing to iteratively produce pupilometer prototypes, where the findings from each new iteration informed the configuration of its successor (Krogh, Markussen, & Bang, 2015).

Parallel prototyping

A long standing criticism of the iterative design process is that designers can become fixated on a single design, which can lead to ‘hill climbing’ to a less optimal design resolution (Hanington & Martin, 2012). One method that can be used to prevent this from happening is parallel prototyping. Parallel prototyping is the act of producing a range of prototypes simultaneously, and then selecting the best based on user feedback or an expert evaluation. In the context of this thesis, parallel prototyping was conducted after the initial iterative design stage to explore a range of different ergonomic forms and configurations to ensure that the device was comfortable for the user to pick up and hold in their hands, while at the same time ensuring the device met all of its functional requirements.

The final stage of the design process involved optimising the device based on the findings from the ergonomic and form studies carried out during the parallel prototyping stage. The goal of this stage was to make the device as inexpensive as possible, while at the same time incorporating a high level of usability and aesthetic refinement into a design configuration that can be easily 3D printed and assembled.

Aims & objectives

Table 1. The aims, objectives, methods and design tools used within this thesis.

Aims	Objectives	Methods	Design criteria
Design an open source pupilometer that can be hosted online and manufactured using 3D printing technology	Conduct a literature and design review to gain a contextual understanding of 3D printing, digital manufacturing services and open source development and distribution models	Research for Design (Downton 2003)	Literature and design review (Hanington & Martin, 2012 pg. 112)
	Determine the most effective printing processes, materials and printing services for manufacturing the pupilometer		Cost-benefit analysis (Cervone 2010)
	Produce an initial 3D printed pupilometer Prototype	Expansive, serial and accumulative research through design (Krogh, Markussen & Bang, 2015)	Rapid prototyping (Hanington & Martin, 2012 pg. 146-147).
	Conduct a form study by analysing existing products, sketching and producing a range of low fidelity foam prototypes		Design workbook (Gaver, 2011) Parallel prototyping (Hanington & Martin, 2012)
	Transition the device from a functional prototype to a resolved product		Rapid prototyping (Hanington & Martin, 2012 pg. 146-147).

Literature review

Introduction

The purpose of this literature review is to understand the issues surrounding the development and distribution of an open source pupilometer (and in a wider context, medical devices in general) using distributed 3D printing services and widely available components that can be sourced online.

This research will investigate 3D printing as a method of manufacture and identify any potential contexts where 3D printing may be more functionally suited or cost effective than traditional methods of manufacture. This research will also investigate the feasibility of distributing the design files of the pupilometer digitally via an online file hosting platform, where users from around the world can

download the files, manufacture the pupilometer using distributed manufacturing services and assemble the device themselves.

Finally, this research will investigate the advantages and disadvantages of developing open source products in comparison to products developed using traditional proprietary models. To achieve this, several open source case studies will be examined to identify the advantages and disadvantages of implementing an open source development and distribution model in comparison to traditional proprietary development models.

This research aims to identify the most effective ways in which an open source development model can be used in conjunction with distributed 3D printing services to design and manufacture a robust, inexpensive and accessible pupilometer that can be digitally distributed to clinicians around the world via the Internet.

3D printing

3D (3 Dimensional) printing is an additive manufacturing process in which objects are built from a digital model known as a CAD (computer-aided design) file (Berman, 2012). 3D printing differs from other manufacturing processes because it bonds materials together on a layer by layer basis. This is in contrast to traditional manufacturing techniques, which usually build structures by cutting, molding, or otherwise manipulating raw materials (Michalski MH & Ross JS, 2014).

The first 3D printer was conceived by Charles Hull, a plastics engineer who started work on fabricating plastic devices from photopolymers in the early 1980s. Tired of the lengthy fabrication processes available at the time (up to two months), combined with the high probability of design imperfections which would then require several further iterations to resolve, Hull started thinking of ways to improve the prototyping process. In 1984 he developed the SLA (Stereolithography) 3D printing process, which he then patented in 1986 (U.S. patent No. 5,174,931, 1986). With Hull's work, in addition to the development and subsequent patenting of FDM (Fused Deposition Modeling) by Scott Crump at Stratasys in 1990 (U.S. patent No. 5,121,329, 1990), 3D printing was poised to revolutionize the manufacturing industry. Initially, the 3D printing process was used primarily to prototype designs before they entered mass production. However,

continued technological improvements combined with lower associated costs have prompted an explosion of growth around the 3D printing industry in the 21st century. Today, 3D printers are used in a diverse range of applications, and are capable of producing complex structures using a variety of materials, including metal, sandstone, ceramics, and even chocolate (Michalski MH & Ross JS, 2014).

There are several advantages to 3D printing when compared to other manufacturing methods. Firstly, 3D printing produces less waste than subtractive manufacturing methods. Like the name suggests, the additive manufacturing process builds objects by depositing material on a layer by layer basis, rather than cutting away excess material. This means the additive manufacturing process uses only the required amount of material necessary to produce the desired object (Prince, 2014). The additive process also allows parts to be built with geometric complexities that could not be formed using other manufacturing processes (Prakash, Nancharaih, & Rao, 2018).

Secondly, there are no initial tooling requirements associated with additive manufacturing. Processes such as injection molding often require initial moulds to be produced before production can begin. Injection moulds can cost hundreds of thousands of dollars, and still require the product to be mass manufactured to make it economically viable.

In comparison, additive manufactured products require only a digital CAD file containing the dimensional data of the design. This data is split into layers by a computer, which can then be interpreted and constructed by the printer (Prakash, Nancharaih, & Rao, 2018). The lack of tooling requirements associated with the additive process means that small or even one off production runs of highly customisable objects can be produced at affordable costs (Berman, 2012).

Despite these advantages, 3D printing still suffers from a range of limitations. For example, some additive manufacturing processes require support material to be produced around the object being manufactured. The support material acts like a scaffolding, providing a platform for the nozzle to build steep overhangs and complex internal structures, and can be difficult to remove during post processing. In some instances, support material can even distort the surface texture of the final object.

Another disadvantage is mass production costs. To 3D print an object, the cost per object is still high in comparison to items produced using mass manufacturing methods such as injection moulding. However, if only a small number of objects are required, 3D printing is the cheaper option. Using

a comparative analysis, Franchetti & Kress (2017) concluded that injection moulding is a cost-effective choice for higher batches of parts, while additive manufacturing is more cost effective for small or customised production runs. Based on their analysis, 200 units is the break-even point when deciding between the AM and injection moulding processes (Franchetti & Kress, 2017). This makes 3D printing more economically viable when producing low numbers of an object.

For 3D printing to be competitive with traditional mass manufacturing methods such as injection moulding, niche applications that provide an advantage in either cost, quality or time must be identified. For example, using 3D printing as a prototyping tool is a faster and more cost effective process than injection moulding, due to the lack of tooling requirements, the speed of the 3D printing process and the ability to produce highly customisable one off objects.

By leveraging 3D printing technology in such a way also enables seamless work flow integration from the iterative prototyping stage of the design process through to the final production run. As such forms a fundamental and useful basis for this project.

Table 2. Services offered by Online 3D printing platforms.

Service	Description
Design supply	Designs files created by the platform are offered (for free or for a fee) to customers.
Design hosting	Platform hosts third-party designs that are sold (marketplace) or offered free of charge (repository)
Design customisation	Designs (own or third-party) can be customised (e.g. shape, size, layout) by users.
Co-design service	Assistance offered to consumers when designing a 3D object, generally by transforming two-dimensional sketches or pictures into a 3D object.
Design crowdsourcing	Users can crowd source a design by posting a detailed project that is then developed further by the crowd.
Printing	3D models are printed into objects and are shipped to customers or delivered in store.
Crowd sourced printing	Intermediary service between users wanting to print 3D objects and users (or companies) owning 3D printers and willing to print out 3D objects for a fee.

Note. From *Co-creation and user innovation: The role of online 3D printing platforms*, by Rayna, Striukova, & Darlington. Copyright 2015 Creative Commons Attribution 4.0 International Public License.

Distributed manufacture

In the industrial age, proprietary development models and mass production were relied on heavily to make products economically viable (Smith & Mortati, 2017). In the 21st century the emergence of the Internet and 3D printing technologies have enabled users to begin designing and manufacturing their own products independently. New online manufacturing pathways that include both distributed networks of printers as well as online 3D printing services are enabling users to design, develop and then produce one off or small production runs of their own products at affordable costs. In doing so, users can bypass the traditional mass manufacturing model that requires enormous amounts of equity to produce tooling molds, and relies heavily on an ‘economies of scale’ approach to be profitable.

The first well known digital manufacturing platform Ponoko, was established in 2007 and based in Wellington city, New Zealand. Ponoko offered 3D printing and laser cutting services that could be accessed through a browser based user interface (Rayna, Striukova, & Darlington, 2015). Since then, several dozen services following the same

model have been established around the world. The widespread establishment of these services has been fueled by a growing number of groups wanting to produce their own products, as well as users looking for low cost alternatives to existing products. Table 1 catalogs several different services provided by a range of online 3D printing platforms, ranging from co-design services, file hosting and design manufacture.

To maximise efficiency and convenience, several services are often integrated into a single digital platform. For example, Shapeways is an online 3D printing service that offers a combination of design hosting, design customisation and 3D printing services (“Shapeways - Create Your Product. Build Your Business,” n.d.). Shapeways manufacturing facilities are located in the United States and the Netherlands, however their website allows users to upload their original designs from anywhere in the world (“Shapeways - Create Your Product. Build Your Business,” n.d.). From here, users can adjust the size and scale of their design, troubleshoot printability issues and select which material they would like to print with. In 2011, Shapeways shipped nearly 750,000 parts worldwide, in materials ranging from plastics, stainless steel, silver and ceramics (Petrick & Simpson, 2013).

Figure 3. Diagrams showing the differences between a distributed manufacturing network and a centralised, online 3D printing service.

Another prominent online 3D printing platform is 3D hubs. Up until February 2018, 3D hubs was a global network of manufacturing hubs, with services connected in over 140 countries (“3D Hubs: Local Manufacturing | 3D Printing & CNC Machining,” n.d.). 3D hubs business model was an example of a distributed manufacturing network, described by Kühnle et al (2015) as “A manufacturing network, whose functionality and performance is independent of the physical distance between the involved systems, units and elements”. 3D hubs provided a crowdsourced 3D printing service, supplying the digital infrastructure that facilitated transactions between 3D printer owners (Hubs) and customers that wanted to print their own designs (Rayna, Striukova, & Darlington, 2015).

There are several advantages to the distributed manufacturing model; one being lower logistics costs. After decades of decline, logistic costs are increasing due to rising energy, fuel, transport and personnel expenses (Matt, Rauch, & Dallasega, 2015). Distributed manufacture mitigates these issues by manufacturing products closer to their final destination. This in turn reduces the distance a product is required to travel, resulting in lower overall costs and a reduced carbon footprint (Petrick & Simpson, 2013). Time from production to sale is also reduced, whilst providing local communities with the means to manufacture and repair their own products, which may one day lead to a more circular economy (Attaran, 2017).

Although the peer to peer approach appeared to be at the core of 3D hubs business model, the service was discontinued in February 2018 and replaced with a cloud based manufacturing service. In a blog post, 3D hubs founder Bram de Zwart explained that “Our offering is fully focused on professional

engineers and designers as they have the strongest need for on-demand parts, but we’ve learned that part of this group is hesitant to use our original peer-to-peer open marketplace as there’s no guarantee on the quality and timeliness of parts” (“3D Hubs,” 2018). 3D hubs new system now relies on a select few manufacturing partners that are required to adhere to a set of strict quality standards, allowing the company to support customers in even the most regulated industries. 3D hubs change in business model suggests that 3D printing technology is not yet sophisticated enough to support a consistent and reliable peer to peer system. Although the distributed manufacturing model holds great potential, machines capable of producing high quality parts currently cost several hundred thousand dollars and can only be purchased by large manufacturing companies.

These companies tend to manufacture parts in one or two centralised locations and then ship the orders to customers around the world. In contrast, the vast majority of printers available to individuals looking to set up small distributed manufacturing hubs are only capable of producing low resolution parts, making it hard to compete with the quality and consistency of larger additive manufacturers. Despite its current limitations, distributed manufacture holds great potential in terms of affordable low volume production. As industry competition continues to increase and the technology itself continues to improve, Attaran (2017) predicts the price of 3D printers will continue to decrease. This rise in quality/decrease in price will enable individuals to obtain 3D printers capable of producing industrial quality parts, resulting in the inevitable formation of more reliable and robust distributed manufacturing networks.

Open source products

Facilitated by distributed additive manufacturing services and the increasing communicative power of the Internet, networks of individuals now have the ability to design, manufacture and distribute their own open source products (Smith & Mortati, 2017). The term open-source refers to a development model that exploits the distributed intelligence of participants in Internet communities (Kogut & Metiu, 2001). The open source development model originated with software development, where people would share pieces of code with each other across the Internet, and collectively collaborate to develop software further (Kogut & Metiu, 2001). This development model is known as OSS (Open source software). The open source development of software has been so successful that it now serves as a blueprint for the development of OSH (Open source hardware) (Pearce, 2017).

According to the Open source hardware association (2016) “Open source hardware is hardware whose design is made publicly available so that anyone can study, modify, distribute, make, and sell the design or hardware based on that design.” In recent years, developing OSH has gained significant traction as an alternative to purchasing traditional equipment in a range of different contexts. One reason for this is cost. The implementation of an open development and distribution model can lead to technically superior equipment at only a fraction of the cost of equipment developed privately (Pearce, 2017). This is because once the initial development of the product is complete, the digital CAD (Computer Aided Design) files of the device can be uploaded to the Internet and made freely available to other

users using online file hosting services such as Github (“The world’s leading software development platform · GitHub,” 2019). From here, the design files of the device can be downloaded for free and manufactured using online 3D printing services, distributed manufacturing networks or using a personal 3D printer. This scaled replication saves 90–99% on conventional costs, making equipment cheaper and more accessible (Pearce, 2014).

A good example of open source hardware is the Arduino microcontroller (“Arduino - Home,” n.d.). Arduino is a small, inexpensive microcomputer with an easy-to-use development environment that makes it an ideal starting point when developing more complex electronic products. It has a large online network of supporters, as well as community generated open software libraries available to simplify many tasks (Niezen, Eslambolchilar, & Thimbleby, 2016). The low costs, strong support networks and wide availability of the Arduino microcontroller have all contributed to its success, prompting the development of other open source microcontrollers, most notably the Raspberry Pi (“Teach, Learn, and Make with Raspberry Pi – Raspberry Pi,” n.d.). Because the Arduino and the Raspberry Pi micro processors both run on open source software, implementation can result in improved device longevity, as users can continue to update the software of the device even after the initial development phase has been completed. Designing products to be compatible with open source hardware such as the Arduino and Raspberry Pi instead of developing custom electronics can save considerable time and money during the development stage of a product, while also improving product life expectancy.

Smartphones & the Internet of things

The Internet of things describes the increasing interconnectivity between electronic products or ‘things’ that are able to interact and communicate with each other wirelessly to simplify tasks or achieve a common goal (Iera, Floerkemeier, Mitsugi, & Morabito, 2010). The touch point (literally) of the Internet of things is the smartphone, a device that can be used to control the other products via a wifi or bluetooth connection.

There are a number of advantages to designing open source products to be compatible with smartphones. In doing so, less built in components need to be included in the product itself. Instead, products can be designed to leverage the built in hardware of the smartphone via a bluetooth or wifi connection. For example, if an open source product requires a screen and a user interface, instead of integrating a screen into the hardware of the device and coding a user interface, it may be a better option to design the device to leverage the screen and user interface of the users smartphone. This option is advantageous from both a hardware and software perspective.

In terms of hardware, most smartphones have much higher quality screens than what is available on the commercial open source marketplace.

This, combined with the familiarity and widespread adoption of smartphones today make the device inherently more user friendly. In terms of software, this option is advantageous because the user interface can be packaged as an app that can be downloaded directly onto the phone via the app store. In doing so, the need for any complex installation process is mitigated, while also enabling the user to operate the device remotely from their smartphone. This strategy reduces the amount of required components, saves money on development costs, while simultaneously delivering a more integrated and user friendly product.

Offering a companion app to be used in conjunction with a physical product also presents several opportunities to generate revenue from the device. One way this can be done is by giving away the CAD files of the device for free so users can source and assemble their own device at no cost, but charging a small fee to download the app. Variations of this model include charging a subscription service to be able to run the app, providing additional app functionality for a small fee, as well as running adverts from within the app (Pearce, 2017).

If users do not possess the time nor the technical abilities to source and assemble the device themselves, the reverse of the above can be achieved by offering users the option of purchasing a pre-assembled device for an additional fee.

Case studies

Open source products are typically developed as an alternative to an existing product that is hard to obtain due to high costs or limited resources, and are becoming increasingly popular in a range of different contexts. The following case studies leverage 3D printing technology, widely available components and/or smartphone integration to deliver an inexpensive and accessible alternative to an existing product.

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Figure 4. oDocs visoscope. Retrieved November 5, 2018, from <https://web.archive.org/web/20190713104307/http://www.odocs-tech.com/visoscope/#>

Case study 1: oDocs eyecare

oDocs (“Smartphone Ophthalmoscope & Smartphone retinal camera,” 2016) is a New Zealand based social enterprise established in 2014 by Dr. Hong Sheng Chiong and Dr. Benjamin O’Keeffe. oDocs main focus is the design and distribution of a range of cell phone attachments that transform any smartphone into an ophthalmologic tool capable of capturing high resolution images of the human retina (“Smartphone Ophthalmoscope & Smartphone retinal camera,” 2016). One of oDocs products is the visoscope. The visoscope is a 3D printed Ophthalmoscope that can be purchased from the oDocs website. Alternatively, clinicians can download the design files of the device for free and 3D print their own visoscope using online 3D printing services such as Shapeways (“3D Printing Service | Shapeways,” 2019). By designing the visoscope to be compatible with most smartphones, oDocs mitigated the need for the device to include any complex electronics of its own. Instead, oDocs

created a free smartphone application called oDocs capture (“visoScope Smartphone Ophthalmoscope & Smartphone Retinal Camera,” 2019). The application acts as the interface of the device, allowing users to access the phones camera and capture images of the patient’s retina. Image data can then be examined from the phone, exported to a computer or sent to a colleague for further analysis. oDocs open source approach enables clinicians working in disadvantaged areas to acquire crucial diagnostic equipment at a fraction of the cost of premium equipment. For example, the iExaminer by Welch Allyn costs approximately \$1000.00 USD (Hong, 2015), while the oDocs visoscope costs approximately \$325.00 USD to purchase pre assembled from the oDocs website (“visoScope Smartphone Ophthalmoscope & Smartphone Retinal Camera,” 2019). Alternatively, the visoscope can be 3D printed for approximately \$100.00 USD using online 3D printing services such as shapeways if the clinician is willing to source and assemble the device themselves.

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Figure 5. 3D printed Glia stethoscope. Retrieved June 15th, 2019, from <https://web.archive.org/web/20190713104550/https://newatlas.com/glia-model-3d-printed-stethoscope/53811/>

Case study 2: The Glia Project.

Another example of a project focused on producing open source medical equipment is the Glia Project. Glia is a social enterprise that focuses on the development of inexpensive, open source medical devices that can be manufactured in low-resource settings using 3D printing technology. According to the Glia project website (“Glia,” 2019)

“If low-resource communities can access the equipment they need via an open source model, they are empowered to troubleshoot problems, customize designs to meet their needs and share their findings with others. The ability to share successes in an open-access environment allows medical and technical communities to work together and avoid duplication of work and long feedback cycles. This model allows off-patent devices to exist as high-quality low-cost generic models, which also exerts downward pressure on prices for high-quality premium brands.”

Glia’s most popular device is the Glia stethoscope. Modern stethoscopes can be an expensive part of the physician’s required equipment, costing approximately several hundred US dollars. The Glia stethoscope is a low cost, 3D printed alternative to premium stethoscopes that costs under three US dollars to produce (Pavlosky et al, 2018). The CAD files for the stethoscope are available through file hosting services such as Github (“The world’s leading software development platform, GitHub,” 2019) and can be downloaded by anyone for free. The components can then be 3D printed using an FDM (Fused deposition Modeling) printer and assembled by the user. The device does require additional components such as ear buds and silicone tubing, however both are cheap and can be sourced easily online. When tested, the Glia stethoscope was found to perform at the same level as expensive premium devices and has been deemed a class I medical device according to Health Canada, and the Food and Drug Administration (FDA; Pavlosky et al, 2018). Currently, the stethoscope is in clinical use in the London Health Sciences Centre in Canada as well as hospitals on the Gaza strip (Pavlosky et al, 2018).

This content is unavailable. Please consult the figure list for further details.

Figure 6. E-nable raptor prosthetic hand. Retrieved June 14th, 2019, from https://web.archive.org/web/20190713104807/https://3dprint.nih.gov/sites/default/files/models/additional_images/large_IMG_4824.JPG

Case study 3: E-nable

E-nable (“Enabling The Future,” 2019) is an online, open source community that provides amputees with low cost 3D printed alternatives to traditional prosthetics, which are often expensive and time consuming to produce. Enable began in 2013 when a South African carpenter reached out to Ivan Owen after watching a video he posted online of a mechanical puppet hand he had built for a costume (“Building an Online Community: Jennifer Owen,” 2017). After receiving several more requests for prosthetic digits, Ivan posted his designs in an online forum, and asked others to help improve the design. Today the E-nable community is made up of teachers, students, engineers, scientists, doctors, designers and artists who collaborate to develop and manufacture a range of open source prosthetics hands. The community also includes a distributed network of 3D printer owners who 3D print prosthetics for amputees in their area, meaning users without access to a 3D printer can still receive a custom prosthetic. To ensure E-nable prosthetics are as accessible as possible, all designs are licensed under a Creative Commons share-alike license. This allows all intellectual property to be shared freely, modified and adapted as users see fit (“Creative Commons — Attribution-ShareAlike 3.0 Unported — CC BY-SA 3.0,” n.d.) The design files for each prosthetic can be downloaded for free

from the E-nable website (“Enabling The Future,” 2019) and printed using any consumer grade FDM 3D printer (Ferreira et al, 2018), while the rest of the required components can be purchased through e-commerce services such as Amazon (“Amazon.com,” n.d.) and Alibaba (“Alibaba.com,” 2019). One of E-nables most popular designs is the raptor reloaded prosthetic hand. Designed collaboratively by members of the E-nable online community, the prosthetic works by mimicking the joints and tendons of the human hand, and allows users to articulate the fingers by flexing their wrist and palm in different directions. Unlike traditional prosthetics which aim to disguise the missing limb by mimicking the color and shape of the human form, E-nable has embraced the 3D printed aesthetic. This encourages users (especially children) to have pride in their new limb, rather than trying to hide it. E-nable prosthetics are particularly applicable to child amputees; especially those living in low resource settings. This is because the design files can be scaled to fit the child using special CAD software and 3D printed at low cost. As the child grows, the CAD files can be resized and reprinted in a matter of hours, at almost no cost. This is in comparison to traditional prosthetic manufacturing methods which can take weeks and cost thousands of dollars to produce a single custom prosthetic. So far E-nable has provided over 2000 3D printed prosthetic limbs to individuals in over 45 countries (Ferreira et al, 2018).

This content is unavailable. Please consult the figure list for further details.

Figure 7. Defense Distributed's 3D printed Liberator handgun. Retrieved July 1st, 2019, from <https://web.archive.org/save/https://www.dezeen.com/2018/07/24/downloadable-files-3d-printed-guns-publicly-accessible-cody-wilson-defense-distributed/>

Case study 4: The Liberator

Defense Distributed is a nonprofit organization based in the United States, committed to promoting Second Amendment rights by “facilitating global access to information related to the 3D printing of arms” and publishing this information online for free (Harvard Law Review, 2017). The organisation rose to prominence in 2013, when digital CAD files for the world’s first fully 3d printed, single shot handgun called the liberator were posted on the organisation’s website, where they could be downloaded for free.

Although ethically questionable, the liberator is a great example of an open source, 3D printed product that relies on a distributed manufacturing model. In just two days, the digital CAD files for the gun had been downloaded over 100,000 times by users from around the world (Harvard Law Review, 2017). The sheer amount of downloads the liberator received in such a short space of time prompted the American State department to take action, ordering

Defence Distributed to take the CAD files down, citing national security concerns (Harvard Law Review, 2017). Despite the forced removal of the files from Defense Distributed’s website, the digital nature of CAD files meant that the blueprints for the liberator have remained available online to this day, reuploaded by users and made freely available through third party websites and torrenting services. If these sites are taken down, new ones emerge soon after, making it almost impossible to regulate the distribution of the files. The success of the liberator has also prompted several online communities of 21st century gunsmiths to begin developing, printing, testing and distributing their own 3D printed gun designs, many of which now eclipse the liberator in both performance and durability.

Despite politically charged debate that surrounds the topic of 3D printed guns, the liberator serves as an excellent example of an open source product designed to be distributed via the Internet and manufactured using 3D printing technology.

Conclusion

Online 3D printing services, widely available components and global distribution networks have enabled small scale development, production and distribution models to become a viable alternative to the traditional mass manufacture model. The ability to produce CAD (computer aided design) files that can be replicated and shared via the internet, combined with online 3D printing services have enabled much of the development, manufacturing and distribution processes to be digitised, saving time, money and improving efficiency. These new digital pathways present new, novel opportunities for the development and distribution of a range of open source products. In a medical context, this is particularly exciting. The literature suggests that by leveraging Online 3D printing services in

conjunction with widely available, inexpensive components, medical devices can be designed, manufactured and distributed at a fraction of the cost of premium equipment. These findings support Doctor Gales proposition of an open source pupilometer that can be sourced and assembled by clinicians around the world. It is hoped that the data collected using the Openpupil device can then be shared via a cloud-based data collection system in the form of a smartphone mobile app. This will enable researchers to collaborate and share their findings with their colleagues, and forms the basis for a global Online research community where the data generated represents the real value of the project, rather than the device itself.

Based on the findings from the literature and design review, this thesis will focus on answering the question:

How can an open source development and distribution model be used in conjunction with online 3D printing services and widely available parts and components to produce an inexpensive and open source pupilometer?

Development of an open source pupillometer for testing melanopsin responses

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Background	Hardware	Software
<p>The intrinsically-photosensitive melanopsin-expressing retinal ganglion cells are of interest for several reasons. Quantifying melanopsin function with the post-illumination pupil response (PIPR) is of potential use in clinical research.</p> <p>Moreover, a cheap and versatile pupillometer may have application in a range of research settings, neurological and ophthalmology practice, and in many primary care settings such as antenatal, emergency departments and family practice.</p> <p>Standard video pupillometry uses infrared (IR) video of the pupil, lights to stimulate pupil constriction, and software to measure pupil size from the video. The PPR additionally requires stimulating blue light of high luminance (> 100 mcd/m²). Portable pupillometers cost thousands of dollars and do not have capability to test PPR, while PPR is usually tested with non-portable electrophysiology equipment costing many tens of thousands of dollars.</p>	<p>Figure 1 Exploded view of device</p> <p>Goggle (housing) This functions to exclude ambient light, position the camera at the correct distance in front of the eye, and diffuse incident light to illuminate the whole field. It must be comfortable, ergonomic (fitting most orbits), and hygienic (easy to clean).</p> <p>We have tested a range of designs and 3D printing materials. Further prototyping continues with flexible, cleanable materials that can diffuse light. Our intention is to provide all designs for free at 3D printing service and marketplace shapeways.com, allowing interested users to create the parts easily in the ideal materials at cost (approximately USD \$10.00).</p> <p>www.shapeways.com/shops/openpupil</p> <p>Background illumination Two super-bright 5 mm IR (840 nm) light emitting diodes (LEDs, cost USD \$0.75 each) were housed in the goggle, providing background IR illumination of the pupil.</p> <p>Optics This biconvex lens functions to bring the camera into focus at a short working distance. These 25 mm plastic lenses of 22 D power are widely available for USD \$10.00.</p> <p>Stimulation This ring of 16 NeoPixel individually controllable red, green and blue LEDs is widely available for USD \$10.00.</p> <p>Each NeoPixel in the ring can control red, green and blue light individually with 255 levels of brightness. The maximal luminance of blue light is adequate to generate a robust PPR. The ring arrangement allows for sectoral testing of the visual field.</p> <p>Figure 2 Commercial images of 16 NeoPixel ring showing size, function</p> <p>Power source This battery pack is rechargeable with a simple USB cable and provides two power sources of 5 V, one 1 A supply for the stimulation LEDs and one 2 A supply for the Raspberry Pi and downstream devices. Batteries of this type are available with 10,000 mAh storage for USD \$39.95.</p> <p>Micro-processor This Raspberry Pi 2 model B+ board is available for USD ~\$35.00. It contains a 900 MHz quad-core central processing unit (CPU) with 1 GB random access memory (RAM), multiple ports and interfaces. We intend to use the Raspberry Pi 3 with wireless interface and Bluetooth in upcoming prototypes.</p> <p>Although other more powerful micro-computers are available, this is the cheapest board with the necessary specifications for image processing, data transfer and video display simultaneously. Software was written for the operation of the hardware and analysis of the collected video images using C++ programming on the Raspbian open source operating system.</p> <p>Total hardware costs - some assembly required The plans to replicate this device are available open source for free access and collaborative refinement. The components cost a total of approximately USD \$140.00 plus a minor degree of circuit board connection and assembly with soldering and BluTack and a container. We hope that this hardware gains increasing use in research projects internationally.</p> <p>Figure 3 Images of the stimulation LEDs in use</p>	<p>Frame-by-frame image processing software was written using C++ language to run on the Raspbian operating system. The red channel was isolated, and histograms showed a peak of darkest pixels representing the pupil (Figure 4). Trial of numerous dynamic and static and adjusted threshold settings led to a static threshold at the luminance of the 6000th darkest pupil (after 10 s dark adaptation) to estimate the pupil signal. This led to a binary image for all subsequent video frames, from which pupil area (pixels), and vertical and horizontal and mean pupil diameter were calculated.</p> <p>Figure 4 showing the sequential processing of one frame by one iteration of the program.</p> <p>Unprocessed RGB Red channel Histogram, threshold shown Binary image Pupil diameter</p> <p>Experimentation with increasing contrast was found to reduce signal-to-noise ratio, median blur reduced single pixel noise but slowed performance excessively, and the Canny edge-finding and Hough circle-finding algorithms resulted in errors and increased noise from reflections on the cornea (Figure 5).</p> <p>Figure 5 shows discarded processing techniques</p> <p>The program illustrated in figure 4 was used to record from volunteers in the laboratory, and a robust PPR could be demonstrated (Figure 6). Processing time (using the RPi 2B+) board allows for real time measurement and display of pupil size at around 20 Hz, although raw video at a faster frame rate could be also be streamed for measurement in retrospect.</p> <p>Figure 6 shows the pupil area above and pupil diameter below in response to 9 s darkness, then a bright red flash of 1 s, then 9 s darkness, then a bright blue flash of 1 s followed by darkness for 18 s. The PPR to blue light is shown.</p> <p>Conclusions</p> <p>The proliferation of cheap components, powerful and versatile microprocessors, and 3D printers enables the development of new clinical and research tools at low cost.</p> <p>Future directions</p> <ul style="list-style-type: none"> Evaluation and refinement of the goggle design to improve ergonomics and hygiene Calibration of pupil size measures for accuracy and stimulation LED photometry for safety Validation studies comparing to existing pupillometry devices Development of phone application to enhance the portability and usability of the device Development of cloud based data storage and analysis <p>References</p> <p>Funding was received from Capital Vision Research Trust</p> <p>Kapeteni Polutea, L. et al. Post-illumination pupil response in subjects without ocular disease. <i>IOVS</i> 2015;56(12):3564</p> <p>Kapeteni Polutea, L. et al. The post-illumination pupil response is reduced in glaucoma patients. <i>IOVS</i> 2017;58(2):258</p> <p>van Trigt, M. et al. Development of a smartphone-based pupillometer. <i>J Ophth Soc India</i> 2015;13:445</p> <p>Kapeteni Polutea, L. et al. Characterizing pupil response. <i>Optometry</i> 2016;116:156</p> <p>A full list of references, our production files and current program codes, available at: https://github.com/kaiwhata/openpupil</p> <p>Contacts</p> <p>To inquire or contribute, or to obtain one of these devices for your own research, please contact us.</p> <p>Jesse Gale jesse.gale@gmail.com +64 21 272 979 Surge & Anaesthesia University of Otago PO Box 1540 Wellington 6142 New Zealand</p>

Figure 8. Poster showing work completed on the pupillometer during the first summer research scholarship. Retrieved from: <https://web.archive.org/web/20190713164133/https://github.com/kaiwhata/OpenPupil>

Previous research

Research stage no. 1

Before the start of this thesis, the pupillometer had already undergone two separate stages of development. The first stage was carried out in 2017, after Dr Jesse Gale approached the Victoria University of Wellington's Faculty of Engineering department with a research project proposal.

The project was to develop a device capable of stimulating the melanopsin pigment in the eye using an intense blue light and then recording the PIPR (Post Illumination Pupil Response). To fulfill the open source requirements of the project, the device needed to be constructed using only widely available technology. The proposal was approved, and a summer research scholarship was setup within the engineering school.

The first goal of the project was to produce the required hardware for the device. Using a raspberry Pi, an infrared camera, a NeoPixel ring and a handful of other widely available components, a functional prototype was successfully produced.

The second goal was to develop the software necessary to successfully test the melanopsin function of the eye. To achieve this, frame by frame image processing software was written using the c++ programming language that could successfully quantify the image data recorded by the infrared cameras.

Overall, the project achieved both of its goals by producing a functional 'proof of concept' prototype that could stimulate the melanopsin response and record the PIPR. However, a number of recommended improvements were outlined at the end of the project. These included: Refining the eyecup design and component housings to improve comfort and hygiene, as well as refining the software to improve the accuracy of the device. mprove the accuracy of the device.

Figure 9. Poster showing work completed on the pupillometer during the second summer research scholarship.

Research stage no. 2

The second phase of the project was carried out in conjunction with the Victoria University Faculty of Engineering department, as well as the Victoria University Faculty of Design through another summer scholarship.

The design goals of this project were to transition the device from a monocular to binocular format so that both eyes could be tested independently or simultaneously, while also ensuring the device was easy to assemble, and could be consistently manufactured using a standard FDM (fused Deposition Modeling) 3D printer. The engineering goals for this project included adapting the device's software so that it could successfully record both pupils independently or simultaneously, as well as optimising the hardware to cope with dual camera video feeds.

Although a number of issues hindering the functionality and usability of the device remained at the end of this stage, the overall concept of an open source. 3D printed pupillometer had been validated.

Figure 10. Iterative prototypes produced during the second summer research scholarship.

Figure 11. Head mounted pupilometer prototype produced during the second summer research scholarship.

Safety testing and validation

At the end of the summer scholarship, a functional, 3D printed pupilometer prototype had been produced. However, the prototype was still clunky, had a variety of usability issues (ranging from handling to assembly) and suffered from a range of software bugs that hindered the functionality of the device.

Because the device is designed to interact with human eyes, safety testing of the LEDs was necessary to ensure the device was safe for use on patients in a clinical research setting. Specifically, the device was required to pass the safety standard titled Maximum permissible exposures for ocular safety (ANSI 2000), with emphasis on ophthalmic devices (Delori, Webb, & Sliney, 2007). The testing was carried out by the Measurement Standards Laboratory of New Zealand (MSL), and involved

measuring the outputs of the LEDs used within the device to ensure they were safe for use on humans.

The testing found that the LEDs do not produce a stable light output until they have been on for roughly an hour. The testing also found the LEDs emit a very high frequency flickering light when the brightness is reduced. Overall MSL found applying the standard to diffuse annular light sources such as the ones produced by the LEDs within the device was difficult. Soon after this point, the prototype stopped functioning completely, preventing any further testing from being conducted.

However the testing was sufficiently comprehensive to confirm that the device was safe in principle and on that basis it was decided that MSL would continue testing the device at a later date, once a more robust device in terms of both hardware and software had been produced.

Design phase 1.

Part optimisation

The continued improvement of 3D printing technology combined with faster and more integrated IT (information technology) in the last two decades has prompted the establishment of several online additive manufacturing services around the world.

As the online 3D printing market has become more and more competitive, an increasing number of 3D printing technologies, capable of manufacturing objects from a wide range of materials have become accessible to a global audience. Not only this, but a range of online services (depicted in table 1, page 24) provide users with access to a wide variety of online CAD (computer aided design) files which can be downloaded for free, adapted and reprinted based on the users requirements.

These continued innovations have resulted in a diverse online 3D printing market, where CAD files can be sourced for almost any application imaginable and manufactured via online printing services with only a few clicks of a mouse. Although incredibly powerful, this newfound freedom can make the task of selecting the right printing processes, materials and manufacturing services a daunting task.

To simplify this process, the International Organization for Standardization (IOS)/American Society for Testing and Materials (ASTM) ASTM52910 – 2018 classify standard, AM processes into seven categories, displayed in table 10 (page 156 & 157).

Based on the information displayed in table 2, (Selective Laser Sintering), FDM (fused deposition modelling), SLA (Stereolithography) and material jetting printing were all identified as potential candidates for printing the pupilometer.

Expansive research through design

To test which of the processes identified in table 2 would be most suitable to manufacture the pupilometer, expansive research through design was conducted. This process involved testing the ability of several online 3D printing services to manufacture a range of test objects, each adapted from the existing pupilometer design.

Each object file contained geometry that is traditionally difficult to 3D print, and tested the printing services' ability to manufacture each of the designs using the printing processes and materials identified in table 2.

Figure 12 (a). Digital representation of the eyecup.

Figure 12 (b). Digital representation of the Raspberry Pi

Figure 12 (c). Digital representation of the Eyepiece

Figure 12 (d). Digital representation of the Diffuser

The eye cups are an important component of the design, as they come in contact with the users face. Because of this, the eye cups must be strong and durable, yet also soft and malleable in order to accommodate a wide variety of facial structures. Because the skin surrounding the eyes is a sensitive area, the printing material must have a smooth surface finish to minimise discomfort. The eyepieces also need to maintain a light seal around the users eyes, as any ambient light that enters the eyepiece may affect the pupilometers measurements.

The raspberry pi is a popular open source motherboard, and is a key component of the pupilometer. A common problem with many 3D printing processes is that they are prone to producing warped parts when printing flat geometries with a large surface area. The raspberry pi housing will test the 3D printers ability to print thin, flat geometry accurately without any warping.

The eyepiece housing is a critical part of the pupilometer as it contains several internal housings, each of which accomodate its own component. These components include the Lenses, the neopixel rings, the infrared LEDs as well as the LED diffusers. The internal housings need to be printed at a high resolution for the components to fit correctly. To achieve this, the eyepiece housing must be printed as accurately as possible, as even small distortions in the geometry may prevent the components from achieving a tight fit.

The diffusers clip over the Neo pixel rings, and diffuse the LED's so as to provide an even spread of light, improving the quality of the results. To achieve aequedute levels of diffusion, the diffusers need to be printed using a clear opaque plastic, so as to effectively spread the light from the LED's.

Table 3. Table comparing the range of 3D printing services, processes, and materials used to manufacture the eyecups.

Printing process	Material	Manufacturing service	Cost (NZD)	Advantages	Disadvantages
Fused deposition modelling (FDM)	Polylactic acid (PLA)	Treatstock	\$17.09	Cheap and localised manufacturing option	<p>The FDM printing process builds objects by stacking layers of material on top of each along the z axis. This limits the levels of flexibility that can be achieved</p> <p>Low resolution, layered surface quality</p>
Selective laser sintering (SLS)	Thermo-plastic poly-urethane (TPU)	i.materialise	\$55.16	<p>The eye cup was printed using a strong and durable TPU material that had an attractive, grainy surface finish</p>	<p>Porous, Grainy surface texture</p> <p>Although the material is somewhat flexible, it is still quite hard. This can cause discomfort when pressed against the users face</p>
Stereolithography (SLA)	Resin	3D hubs	\$88.77	<p>The eyecup was printed using a Soft, flexible resin material that was very malleable and provided good levels of comfort</p>	<p>Most expensive printing process</p> <p>Limited to an opaque white color</p> <p>The eyecup became discolored over time</p>

Figure 13 (a). Eyecup printed via Treatstock using the FDM printing process

Figure 13 (b). Eyecup printed via Shapeways using the SLS printing process

Figure 13 (c). Eyecup printed via 3Dhubs using the SLA printing process

Figure 14. Standardised rubber eyecup

Outsourcing components

Because none of the 3D printing processes tested were suitable for producing eyecups, a set of binocular eyecups were used instead. This is an example of outsourcing components. Binocular eyecups are advantageous over the 3D printed eyecups tested for several reasons. Firstly, they are made from injection molded rubber, meaning they are soft, flexible and very durable. They are a standardised size, meaning even if the specific pair pictured are discontinued, there are several others to pick from. Finally, they are cheaper. The eyecups pictured were purchased for \$17.84 NZD. Although similar in price to the eyecups printed through Treatstock, the outsourced eyecups outperform them by a substantial margin.

Table 4. Table comparing the range of 3D printing services, processes, and materials used to manufacture the Raspberry Pi housing

Printing process	Material	Manufacturing service	Cost (NZD)	Advantages	Disadvantages
Fused deposition modelling (FDM)	Polylactic acid (PLA)	Treatstock	\$14.40	Cheapest printing option tested The print was strong and durable	The Treatstock FDM print was warped in multiple directions, seriously affecting the parts functionality and making it very difficult to insert the Pi
Fused deposition modelling (FDM)	Polylactic acid (PLA)	3D Hubs	\$27.77	The pi housing was printed at a satisfactory resolution No signs of warping The Raspberry Pi fit into the housing with little resistance	The 3D hubs FDM print was visibly lower resolution than the SLS printing options Minor surface defects
Selective laser sintering (SLS)	Nylon (PA12)	Shapeways	\$45.41	The Pi housing was printed at a high resolution The print was very durable and showed no signs of warping The Raspberry Pi fit into the housing with little resistance	The Shapeways SLS print had a slightly porous surface texture. This could potentially be difficult to clean When scratched, the textured surface finish wore away, leaving a shiny surface underneath
Selective laser sintering (SLS)	Nylon (PA12)	3D Hubs	\$119.00	The Pi housing was printed at an extremely high resolution and showed no signs of warping The Raspberry Pi fit perfectly into the housing with little resistance	The 3D Hubs SLS print was over double the cost of the Shapeways SLS print By far the most expensive printing option tested

Figure 15 (a). Raspberry Pi housing printed via Treatstock using the FDM printing process

Figure 15 (b). Raspberry Pi housing printed via 3Dhubs using the FDM printing process

Figure 15(c). Raspberry Pi housing printed via 3D3Dhubs using the SLS printing process

Figure 15 (d). Raspberry Pi housing printed via Shapeways using the SLS printing process

Table 5. Table comparing the range of 3D printing services, processes, and materials ability to manufacture the eyepiece.

Printing process	Material	Manufacturing service	Cost (NZD)	Advantages	Disadvantages
Fused deposition modelling (FDM)	Polylactic acid (PLA)	Treatstock	\$14.40	<p>Cheapest printing option tested</p> <p>The print was strong and durable</p>	<p>The Treatstock FDM print was of a low resolution, and contained several small defects</p> <p>The internal geometry was not printed accurately, resulting in several components not fitting into their housing, making the part Non-functional</p>
Fused deposition modelling (FDM)	Polylactic acid (PLA)	3D Hubs	\$27.77	<p>Cheap manufacturing option</p> <p>The eyepiece was printed at a satisfactory resolution</p> <p>The internal geometry was printed relatively accurately</p>	<p>The 3D hubs FDM print had some small surface defects, however they did not affect the functionality of the part</p>
Selective laser sintering (SLS)	Nylon (PA12)	Shapeways	\$45.41	<p>The eyepiece was printed at a high resolution</p> <p>The internal geometry was printed accurately</p>	<p>The Shapeways SLS print had a textured surface finish that was slightly porous. This could potentially be difficult to clean</p> <p>When scratched, the textured surface finish wore away, leaving a shiny surface underneath</p>
Selective laser sintering (SLS)	Nylon (PA12)	3D Hubs	\$88.90	<p>The eyepiece was printed at an extremely high resolution and showed no signs of warping</p> <p>The internal geometry was printed accurately</p>	<p>The 3D Hubs SLS print was almost double the cost of the Shapeways SLS print</p> <p>By far the most expensive printing option tested</p>

Figure 16 (a). Eyepiece printed via 3Dhubs using the FDM printing process

Figure 16 (b). Eyepiece printed via 3Dhubs using the FDM printing process

Figure 16 (c). Eyepiece printed via 3D Hubs using the SLS printing process

Figure 16 (d). Eyepiece printed via Shapeways using the SLS printing process

Table 6. Table comparing the range of 3D printing services, processes, and materials used to manufacture the diffuser

Printing process	Material	Printing service	Cost (NZD)	Advantages	Disadvantages
Fused deposition modelling (FDM)	Polylactic acid (PLA)	Treatstock	\$2.15	None	The manufacturer cancelled the order due to lack of opaque material, despite it being available on their website
Fused Deposition Modelling (FDM)	Polyethylene Terephthalate Glycol (PETG)	3D Hubs	\$12.00	None	The manufacturer cancelled the order due to lack of opaque material, despite it being available on their website
Material jetting	Resin based plastic (Photo-polymer)	Shapeways	\$7.50	High resolution print The photopolymer is opaque, and provides adequate levels of diffusion	According to the literature, photo polymer plastics degrade over time However no degradation was observed in the diffusers

Figure 17. Diffuser printed via Shapeways using the SLA printing process

Results & analysis

Based on the experiments conducted in design phase 1, the SLS (selective laser sintering) process printed using nylon (PA12) was decided upon as the optimal manufacturing method for the eyepieces and the pi housing. Although the SLS prints from 3D hubs provided a smoother surface finish and slightly higher levels of detail, they were approximately twice as expensive as the shapeways prints, making them unsuitable for use in an open source medical device. The shapeways prints provided a high quality, textured surface finish with satisfactory levels of detail at a much more affordable price, making it the optimal choice for manufacturing the pupilometer.

In terms of the eye cups, no ideal solution was found. Although the SLS print from i.materialise was of a superb quality, its grainy surface texture and limited flexibility proved to be uncomfortable when pressed against the users face. The same can be said about the FDM (fused deposition modelling) print from treatstock, as the low resolution print quality and extremely limited levels of flex also made it uncomfortable to push against the users face. The

Stereolithography print from 3D hubs was very soft and malleable, however that material is only offered in an opaque color, meaning it will not create an effective light seal around the eye. Not only this, but the print has shown signs of degradation over time, making it unsuitable for real world application.

The diffusers proved hard to obtain, as three orders were placed in a range of clear/opaque materials, but only one arrived. Both Treatstock and 3D hubs cancelled their orders due to lack of material, despite each respective material being displayed as available on each site. This eliminates each service from selection, as having materials available at all times is imperative for the manufacture of open source medical devices.

The diffuser that did arrive was a material jetted photopolymer from shapeways. The print was of high resolution and displayed a good level of opaqueness, making it a satisfactory choice for the diffusers. The diffusers are made from a photopolymer which can degrade when exposed to sunlight, however no signs of diffusion were observed thus far

Figure 18. Non 3D printed Components housed within the pupilometer.

Design phase 2.

Accommodating the technical package

The first step in producing the pupilometer was to develop housings for each of the devices internal components. To achieve this, serial research through design was conducted using an FDM (Fused Deposition Modelling) 3D printer to iteratively prototype each housing to a satisfactory level of refinement. From here, the parts were manufactured using Shapeways' SLS nylon 3D printing service to ensure each of the components fit correctly.

The initial components within the device included:

4x IR (infrared) LED's

2x Infrared Webcams

2x NeoPixel rings

2xGoogle cardboard lenses

1x Raspberry Pi 3

SLS tolerance tests

To better understand Shapeways' SLS (selective laser sintering) nylon material, a set of slot fit test objects were designed and manufactured via Shapeways' online 3D printing service. Starting at a tolerance of 0.04mm and ascending incrementally by a scale of 0.02mm up to 1.0mm, these objects tested the consistency of Shapeways' SLS nylon material and determined which tolerance would provide the optimal push fit between two SLS nylon parts.

Based on these tests, it was determined that a 0.04mm tolerance provided the optimal push fit tolerance for parts printed using SLS nylon.

Figure 19. The 0.04mm tolerance test provided the best slot fit.

LED housing

To accommodate the infrared LEDs, a 2.5mm ring with 10 holes extruded through its walls was designed and printed using Shapeways SLS nylon material. The smallest of these holes had a diameter of 5mm, (the diameter of the LED) with each hole getting incrementally larger by 0.02mm; the biggest hole being 5.2mm.

When tested, the 5.02mm hole provided a firm push fit that kept the LEDs secure, yet did not require a massive amount of pressure to install/remove the LED.

Figure 20 (a).

Figure 20 (b). Infrared LED housed within the 5.02mm housing.

Lens housing

To accommodate the lens, a push fit housing was designed using the circumference of the lens as a reference point. Tolerance optimisation was then conducted by producing a range of housing prototypes using an FDM 3D printer until a satisfactory push fit was achieved. The housing was then printed via Shapeways to ensure the tolerance also applied to SLS nylon.

Figure 21 (a). Prototypes created during the tolerance optimisation process of the lens housing.

Figure 21 (b).

Figure 21 (c).

NeoPixel Ring housing

To accommodate the NeoPixel Rings, an initial push fit housing was designed using the circumference of the ring as a reference point. Tolerance optimisation was then conducted by producing a range of housing prototypes using an FDM 3D printer until a satisfactory push fit was achieved. The housing was then printed via Shapeways to ensure the tolerance also applied to SLS nylon.

Figure 22 (a). Prototypes created during the tolerance optimisation process of the Neopixel Ring housing.

Figure 22 (b).

Figure 22 (c).

Infrared camera housing

To accommodate the infrared cameras, a push fit housing was designed using the outline of the cameras as a reference point. Tolerance optimisation was then conducted by producing a range of housing prototypes using an FDM 3D printer until a satisfactory push fit was achieved. The housing was then printed via Shapeways to ensure the tolerance also applied to SLS nylon.

Figure 23 (a). Prototypes created during the tolerance optimisation process of the camera housing.

Figure 23(b).

Figure 23 (c).

Raspberry Pi housing

To accommodate the Raspberry Pi, a push fit housing was designed using the outline of the Pi as a reference point. Tolerance optimisation was then conducted by producing a range of housing prototypes using an FDM 3D printer until a satisfactory push fit was achieved.

Unlike the other components however, the push fit approach did not house the Pi securely. In response, several different housing configurations were developed and tested. Eventually, a housing configuration that relied on four small clips to securely hold the Pi in place was produced. The housing was then printed via Shapeways to ensure the tolerance also applied to SLS nylon.

Figure 24(a). Prototypes created during the tolerance optimisation process of the Raspberry Pi.

Figure 24 (b).

Figure 24 (c).

Initial prototype configuration

Once all of the component housings had been successfully developed, they needed to be synthesised into an initial prototype.

The primary goal of this prototype was to provide the engineers something with which they could test and trouble shoot their software.

The development of this prototype also enabled each component to be optimised in terms of how much material it used, so that the prototype would be cheaper to print using Shapeways SLS nylon material.

Because this prototype contains the dimensional data necessary to house each of the internal components of the device, it also acted as the structural skeleton for the rest of the design process.

Figure 25 (a). Exploded view of the initial prototype configuration.

Figure 25 (b). Assembled Initial prototype.

Design phase 3

Ergonomic analysis

The goal of the third design phase was to take a step back from the more technically oriented research through design conducted in the previous design phases to address the ergonomic and usability aspects of the device.

To achieve this, existing optical devices designed to interact with the users eyes in some way were collated and analysed to identify any design features that may be applicable to the design of the Openpupil device.

Following this, a range of sketches were produced to help solidify the ideas generated throughout this process and develop them further.

Finally, parallel prototyping was conducted using a range of low fidelity gold foam models. Parallel prototyping is the act of producing a range of prototypes simultaneously, and then selecting the best based on user feedback (Hanington & Martin, 2012). This process prevents 'hill climbing' to a less optimal design resolution, which can occur when conducting linear iterative design research.

By producing a range of different prototypes simultaneously and testing them with users, valuable ergonomic and usability feedback was gathered and applied to the overall design of the pupilometer.

Precedent analysis 1.

Virtual reality headset

A virtual reality (VR) headset is a head mounted device that sits over the users face and projects moving images into the users eyes. Virtual reality headsets are required to sit comfortably over the users eyes and face for long periods of time, and because of this the ergonomics of the device must be carefully considered.

Google cardboard
 - Low fidelity, cheap material
 - Simple form language: circles, (eye) triangle (nose) rectangle (face)

- Disposable technology

- Flat pack

○ ○ - facial indicators
 △

Flange for comfort

Oculus rift
 - Traditional headset design
 Rounded, boxy aesthetic
 Black on black

Ergonomic considerations

Black on black
 - Sleek & shiny
 - curves
 - no straight edges (fluid)

Valve Index VR Plastic, rubber glass?

Comfort a design priority
 - Fabric
 - unexpected comfort

Google daydream

- Move a piece of clothing then a VR headset?

Headset sketches

Based on the VR precedent analysis, a number of 2D form finding sketches were produced. Sketching is an effective method of rapidly generating ideas, and was used to explore possible forms that could be applied to a head mounted design configuration.

Figure 26. Ideation sketches based on VR headset precedents.

Ergonomic tests

To test the viability of the headset configuration, a low fidelity cardboard VR prototype was produced, and two different head straps were tested. Both of the head straps performed well, providing a comfortable fit for both users.

Figure 27. Low fidelity headset prototype & assorted straps.

Ergonomic Reflections

During the initial summer research scholarship, the device was conceived as a head mounted device. However, ergonomic testing conducted throughout the thesis stage of the project indicated a number of issues relating to the head strap configuration.

Firstly, the size and weight of the battery made it unsuitable to be housed within the device over the users face. Instead, it would need to be mounted on the back of the head strap, resulting in exposed cables running from the battery to the Pi. The strap also made the device cumbersome to carry and time consuming to fit to the patient, particularly in the field. Taking into consideration the fact that the pupil tests only lasted several seconds, it became evident that the head mounted configuration added no real benefit to the testing process.

Another problem encountered during the design process was component obsolescence. It became evident that the electronic components would need to be continuously updated as new and more efficient configurations become available. To accommodate this, the design needed to be versatile and adaptable.

As a result, the device was ultimately conceived as a utility 'box' configuration. By providing additional space around the electronic components, internal additions/modifications to the device can easily be accommodated. This format also enables other users to 'hack' the device to their own specifications, increasing the versatility of the device in the field where portability, handling and durability in as yet unknown contexts need to be accommodated.

Once it was established the device would be hand-held, a parallel prototyping process was conducted. Parallel prototyping is the act of producing a range of prototypes simultaneously, and then selecting the best based on user feedback. To achieve this, a range of foam and card prototypes were produced, addressing how the device would be held, as well as how the components would be configured. Prototypes were then tested with users, where valuable ergonomic and usability feedback was gathered and applied to the design of the device.

From here, an FDM 3D printer was used to iteratively develop each individual component to a satisfactory level of refinement. This process also enabled the assembly of the device to be tested and troubleshoot with each new iteration, until the components fit together seamlessly. The final device was then 3D printed via Shapeways using an SLS nylon material.

Precedent analysis 2.

Binoculars

When considering possible design configurations for the device, the question of whether or not the device was required to be mounted on the users head was asked. Through consultation with the wider team of Engineers and clinicians working on the project, it was decided that there was no reason the device could not be conceived as a hand held device, where the user holds the device to their eyes similar to how somebody would hold a pair of binoculars. This revelation lead to the next precedent.

Nikon Travelite Ex

all lines converge at one point

twist?

Tapered cylinders

simple, clean lines

- compact

Boxey aesthetic

rugged, durable outdoor aesthetic

Embossed Pattern grip

twist?

Detachable handle

Nikon Stabileyes

Steiner 7x50 commander

winged eyecups

compass? modular design?

rubber or plastic?

Embossed Pattern for grip

twist?

Tough, durable survival aesthetic

machined Aluminium
- Aesthetic
- grip

simple yet elegant form language

- Luxury
Designed in collaboration with Italian car mfr Zagato

Leica ultravid 8x32
- choice of color red stands out

cylinders

Binocular sketches

Based on the binocular precedent analysis, a number of form finding sketches were produced. These sketches started to explore 3-dimensional forms, and attempted to address how the user would comfortably grip a hand held pupilometer.

Figure 28. Ideation sketches based on binocular precedents.

Ergonomic tests

Based on the binocular precedents and subsequent sketches, a range of gold foam models were produced. These models focused on identifying the most comfortable forms to hold when positioned in front of the users eyes.

Figure 29. Gold-foam ergonomic experiments based on binocular precedent analysis.

Precedent 3.

Camera

The camera is another hand held device that is used to capture and store still images of the external environment. For a clear image to be captured, the camera must be held steady, and the shot lined up by staring through the cameras view finder.

To ensure both of these things occur, the camera must be easy to grip and comfortable to hold, while the view finder must also be comfortable when pressed up to the users face. For both of these things to occur, the ergonomics of the camera must be well thought out.

Camera Sketches

Based on both the Binocular and camera precedents, as well as the previous ergonomic research conducted in this chapter, a range of more resolved, higher detailed sketches were produced. These sketches focused on how to ensure the device would be comfortable to hold, while also being comfortable to hold up to the face. Components and other functional requirements of the device also began to be considered at this stage.

Figure 30. Ideation sketches based on camera precedents.

Ergonomic tests

Based on all previous ergonomic research conducted, a range of foam models were produced based on how a camera is typically held, as well as the forms cameras usually take. The battery was also introduced into the testing at this point, to get an idea of how much the device would weigh and whether or not this would affect how it was held.

Figure 31. Gold-foam ergonomic experiments based on camera precedents.

Component considerations

At this point, the components contained within the device began to play a larger role in how the device might be configured. Low resolution card models were produced to try and gauge how much room would be required to house the battery within the device, while old 3D printed prototypes and other spare parts were taped together in a range of configurations, in an attempt to try and find the optimal component configuration .

To get a better idea of how to effectively house all of the components, a range of utility container precedents were examined.

Figure 32 (a). Low fidelity card prototype used to contain a raspberry PI and a battery.

Figure 32 (b). Exploratory prototyping conducted by taping together a range of components to test different configurations.

Figure 33. Box-like utility prototypes made from foam.

Figure 34. Refined sketches based on the utility cannister prototypes and the ergonomic research conducted thus far.

Figure 35. Box-like utility prototype made from card.

Results & analysis

The findings from the ergonomic analysis phase of this thesis indicate that when the components are taken into consideration, a 'box like' configuration is the most suitable for a hand held, open source pupilometer.

By designing the device to be slightly larger than what is required, adaptations to the device can easily be made, encouraging other users to 'hack' the device to their own specifications. This simultaneously increases the versatility of the device, enabling it to be taken outside of the clinical context, into the field.

Findings from the ergonomic analysis also indicate that for box-like designs to be successful, the design details need to be carefully considered to ensure the device does not become cumbersome to operate and uncomfortable to hold.

Figure 36. Digital render of the Openpupil device.

Design phase 4.

Design synthesis & contextualising the final design

The goal of design phase 4 was to reflect on the knowledge gained from the previous three design phases, and then synthesise this knowledge to produce a final design output.

Using both the technical and ergonomic insights gained from design phases 1, 2 & 3 an FDM 3D printer was used to iteratively develop each individual component to a satisfactory level of refinement. This process also enabled the assembly process of the device to be troubleshoot and developed with each new iteration, until the components fit together seamlessly to form the final device.

Once this was achieved, the design files of the device were manufactured via the Shapeways online 3D printing service using the SLS nylon material identified in design phase 1.

Figure 37. Prototypes created during the development of the final eyepiece design. .

Figure 38. Prototypes created during the development of the final LED cap design.

Figure 39. Prototypes created during the development of the final camera housing design

Figure 40. Prototypes created during the development of the final battery housing design.

Figure 41. Development of the ergonomic finger indent on the side of the device.

Figure 42. Prototypes created during the development of the final body design.

Figure 43. Partially disassembled final prototype.

Figure 44. Partially disassembled final prototype

Figure 45. Closeup image of the carry strap connected to the final prototype

Figure 46. Closeup image of the ergonomic finger indent positioned on the side of the device.

Figure 47. Final prototype in use.

Figure 48. Exploded view of the Openpupil device displaying the layout of the internal components, and how the device is configured.

Cost analysis

Table 7 displays the cost of each 3D printed component that makes up the Openpupil device, while table 8 displays that total costs associated with the non 3D printed parts required to assemble the device.

In total, the device costs approximately \$676.25 NZD to source all of the required parts of the device.

This is substantially cheaper than what it would cost to purchase a commercially available pupilometer, most of which range from between \$10,000 to \$100,000.

Table 7. Table depicting the cost to purchase the non 3Dprintable parts and component of the Openpupil device.

Component	Cost of part (NZD)	Total cost (NZD)
Carry strap	\$14.87	\$204.23
Google cardboard lens (x2)	\$2.00	
Infrared camera (x2)	\$74.00	
Infrared LEDs (x2)	\$4.00	
NeoPixel ring (x2)	\$28.27	
Raspberry Pi	63.25	
Rubber eyecups	17.84	

Table 8. Table depicting the cost to print the Openpupil device using Shapewats SLS nylon .

Component	Cost of part (NZD)	Total cost (NZD)
Battery housing	\$69.73	\$472.42
Body	\$166.66	
Eyepieces	\$107.11	
Camera housing	\$40.30	
LED caps	\$44.71	
NeoPixel diffusers (x2)	\$22.35	
IR LED Diffusers (x2)	\$22.35

Figure 49. Closeup image of the surface texture of the eyepiece.

SLS surface finish

Shapeways offers both a natural and polished surface finish to SLS printed parts. To investigate the differences in quality of each finish, two additional eyepieces were ordered, one receiving the polished surface finish, and one left natural.

Figure 50(a). Design detail of the Polished SLS printed eyepiece.

Figure 50 (b). Design detail of the natural SLS printed eyepiece.

Material analysis

Based on the test prints, the Polished finish is of a much higher quality than the natural finish. The surface texture of the polished part was glossy, and did not mark as easily in comparison to the more porous, matte surface of the natural finish.

In terms of cost, the Polished part cost \$171.85 NZD, in comparison to the natural part, which cost \$107.11 NZD, meaning the polished part was considerably more expensive.

When tested, each component functioned exactly the same, meaning the only advantages to the polished surface finish are of a cosmetic nature. Another constraint associated with the polishing process is that parts bigger than a certain size cannot be polished.

Based on the above, the polished surface finish is not suitable for use on open source products due to high costs, size constraints and lack of functional benefits, however may find application when offered as a 'premium' option for smaller objects.

Contextualising the final design

Clinical context

One of the most immediate applications for the Openpupil device is for use within a clinical research setting, such as the office of an Ophthalmologist. Currently, the device is capable of studying a group of intrinsically photosensitive retinal ganglion cells (ipRGC) located in the inner retina of the eye. These ipRGC are interesting for numerous academic reasons, as they appear to serve the non-conscious visual functions such as circadian rhythm entrainment and pupil constriction (Gale, et al).

With more technical development, application of the device could be expanded to a range of diagnostic applications, such as measuring pupil asymmetry when assessing neurological problems (which may include brain aneurysms, impending strokes, lung tumours), as well as testing the relative constriction to light in each eye when looking for problems with the optic nerve (Gale, et al). There is also emerging interest in using pupil signals to study neurodegeneration such as Alzheimer disease.

Figure 51. Dr Jesse Gale carrying the Openpupil device.

Figure 52 (a). The Openpupil device being handed to a patient.

Figure 52(c). A patient undergoing a pupil measurement test, while Doctor Gale examines the results from his computer.

Figure 52 (b). A patient preparing to use the Openpupil device.

Figure 52 (d). Openpupil device placed amongst other Ophthalmologic tools.

Emergency/ First responders context

The ability to record objective pupil data using a portable pupillometer would enable paramedics and other emergency medical staff to diagnose and monitor the condition of injured patients rapidly and more accurately than current methods. Because the device has bluetooth/wifi capabilities, the data collected from the patient can then be sent to existing monitoring equipment; for example, within ambulances. This enables enhanced data collection capabilities, and seamless integration of the device into existing diagnostic/monitoring processes.

Figure 53. Wellington free ambulance paramedic wearing the Openpupil device.

Figure 54 (a). TheOpenpupil device stored within an ambulance, ready for use.

Figure 54 (c). A paramedic fitting a patient with the openpupil device to test the pupil light reflex.

Figure 54 (b). A patient being fitted with the openpupil device to test his pupil light reflex.

Figure 54 (d). A paramedic monitors the pupil data of the patient

Contact sport context

Although the Openpupil device is currently not capable of diagnosing concussion, use on the sports field was identified as a possible application for the device with further development.

Currently, concussion tests are performed on the sideline, usually by a coach or physiotherapist after a player receives a significant blow to the head. The test involves holding a finger up in front of the players eyes, and moving it from left to right whilst simultaneously monitoring the players ability to track the finger with his pupils. This test is very subjective, and can lead to players being sent back onto the field of play with an undiagnosed concussion.

A compact, versatile device capable of performing pupil tracking tests would mitigate this problem by enabling objective concussion tests to be performed by anybody, resulting in less instances of misdiagnoses.

Figure 55. Physiotherapist carrying the Openpupil device around his shoulder during a rugby match.

Figure 56 (a). The Openpupil device stored in the teams gear bag awaiting use.

Figure 56 (c). Player suspected of suffering a concussion undergoes a pupil screening test.

Figure 56 (b). Player suspected of suffering a concussion prepares to undergo a pupil screening test.

Figure 56 (d). Physiotherapist monitors the players test results from his mobile phone.

Navigating the regulatory environment

To assess the commercial viability, as well as the legality of the Openpupil device, a screening report was conducted by Vic link, Victoria University of Wellington’s commercialisation office. The goal of the report was to firstly evaluate the market potential of the device, and secondly map the most effective way to get the device to market. The screening report also identified any legal issues surrounding the open source nature of the device.

Therapeutic products act.

Putting the OpenPupil device on the market in New Zealand is very easy under the current legislative system, however the New Zealand government is currently developing a new therapeutic products regulatory regime that will provide regulation of all therapeutic products used in New Zealand. This includes medical devices and cell and tissue therapies which are currently not fully regulated in New Zealand (“Therapeutic products regulatory regime,” 2019). The new regime will look to align with international standards, and will assure the safety of products used in health care delivery in

New Zealand, while simultaneously securing New Zealand producers a positive position in the global marketplace (“Therapeutic products regulatory regime,” 2019).

What is a Therapeutic product?

According to the most recent draft of the therapeutic products bill, a product is therapeutic if it is intended for use in, on, or in relation to humans for a therapeutic purpose. The bill defines a therapeutic purpose as:

- Preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury
- Influencing, inhibiting, or modifying a human physiological process
- Testing the susceptibility of humans to a disease or ailment

According to this definition, the Openpupil device would be classed as a therapeutic product under the proposed therapeutic products act.

Taking the device to market.

If the decision was made to take the device to market following the traditional regulatory pipeline, gaining certification under the EMA (European Medicines Agency) makes the most sense as the CE mark is respected by most country’s regulators. Doing so in any country following the EU model is not a cheap exercise however, as consultants are required to navigate the confusing Pre-Market Assessment process and regulators have both one-off fees during application and recurring fees once market access is granted. Gaining FDA (Food and Drug Administration) approval to enter the United States market is even harder, as proof of efficacy (Proof of a therapeutic effect, usually through clinical trials) is required. Releasing the device’s files without going through the regulatory process and indicating it is ready for use in a clinical environment may lead to legal issues that result in the device being taken off the market.

However, the intention of the Openpupil project is not to take a traditional route to market. Instead, the goal is to establish an online research community made up of clinicians from around the world, each conducting their own research using the device, and in turn building a more robust dataset around the intrinsically photosensitive retinal ganglion cells (ipRGC).

To achieve this, making the device accessible to as many clinicians as possible through an open-source design and distribution Model is fundamental to the intent to democratise the associated clinical science for the greater good.

One way to sidestep the expensive and time consuming regulatory process is to release all IP (intellectual property) required to source and assemble the Openpupil device, but stipulating (through a license agreement as a preference) that the device is not a registered therapeutic product, and is only suitable for research purposes. This sits in a legislative grey area, the key phrasing in NZ’s new act being “likely (because of the way in which it is presented or for any other reason) to be used for [a therapeutic] purpose”.

The points which make it unlikely for a regulator to intervene include: the device being treated as a work-in-progress academic project that seeks input from global contributors, releasing all relevant files being a necessary element of this. Another reason being the intangible nature of the ‘product’ – this is not something regulators would encounter often and are unlikely to possess the legal apparatus necessary to control the information surrounding the device. As long as ethics approval can be gained by a researcher, there are much fewer hurdles to jump through to get a device such as this into use as a research tool, however regulators do require some form of notification that research on/using an unapproved product is occurring.

Discussion

Research question

This thesis asked the question: How can an open source development and distribution model be used in conjunction with online 3D printing services and widely available parts and components to produce an inexpensive and open source pupilometer? To answer this question, a research through design (Krogh, Markussen & Bang, 2015) methodology was applied.

3D printing

3D printing’s ability to produce parts from digital CAD (Computer Aided Design) files makes singular [AJ1] or small batch production runs economically viable. This is ideal for the production of open source products, as parts can be manufactured to order, rather than relying on the traditional mass manufacture model, which relies on economies of scale to make a product economically viable. Of the 3D printing processes tested during the expansive design phase of this thesis, the SLS (selective laser sintering) printing process was identified as the most suitable for manufacturing the Openpupil device. The SLS printing process produces durable, chemical resistant and high-resolution parts from a nylon powder called nylon PA12, making it ideal for products designed for a medical context.

The research also indicated that flexible 3D printing materials are not yet of a high enough quality to produce soft and flexible, yet robust parts. This was reflected in the expansive eyecup research, where each of the printing processes tested were either too rigid, too rough, or not durable enough. In response, rubber binocular eyecups were outsourced as an alternative. The binocular eyecups were a suitable alternative as they were cheap, widely available online and came in a standardised size.

Distributed manufacture

Online 3D printing services such as Shapeways are currently the most effective manufacturing option for producing open source medical products. These platforms allow users to upload and customise CAD files through a web interface, which are then printed and dispatched from a centralised manufacturing facility. Because parts are manufactured in a centralised location, production quality can be monitored and assessed before dispatch, resulting in a higher quality, more consistent service.

In comparison, distributed manufacturing services simply connect 3D printer owners to individuals requiring 3D printing services using an online user interface. This model does not allow for any centralised quality control, resulting in orders being frequently late and of unsatisfactory quality. This is reflected by 3Dhubs recent transition from a distributed manufacturing network to a centralised 3D printing service (“3D Hubs,” 2018). Despite this, the literature suggests that if 3D printing technology continues to improve at its current rate, distributed manufacturing networks may be able to consistently supply high quality parts in the near future (Attaran, 2017).

The research conducted throughout this thesis supports the literature, with parts ordered through distributed manufacturing network Treatstock coming back warped and low resolution, while all parts ordered through centralised online 3D printing services Shapeways, 3D Hubs and i.materialise coming back at a consistently high quality.

Of the centralised online 3D printing services, Shapeways was found to be the most suited for manufacturing the Openpupil device. Although the SLS prints sourced from 3D Hubs were of a higher surface quality, they were over double the price of the SLS prints sourced from Shapeways. Overall the Shapeways prints provided a good balance between cost and quality. This is ideal for manufacturing open source products, as low production costs are one of the main advantages to developing open source products.

Open source design

Because it is expected that the components used within the device will become obsolete and need to be updated over time, Openpupil was designed to be as adaptable as possible. For example, the device is powered by a standard 12500mah power bank, however a wide variety of 12500mah power banks exist in a range of shapes and sizes, and are updated frequently. Openpupil’s utility ‘box’ design leaves enough room within the device for a range of power banks to fit. This enables users to select a power bank most suited to the context they intend to use the device within. For example, if the device is being taken into the field (for example to a rugby game), users can install a higher capacity battery so that the device lasts longer. However if it is being used in a clinical context, a smaller power bank could be used, and the device recharged inbetween patients.

Future research

To improve the adaptability of Openpupil further, the device needs to be rebuilt using a parametric CAD system such as Solidworks (“3D CAD Design Software,” 2019) or the free Rhinoceros plugin grasshopper (“Grasshopper - algorithmic modeling for Rhino,” 2019). This will enable the CAD files of the device to be easily updated to accommodate new components as they become available, while also lowering the costs associated with keeping the device up to date. The adoption of parametric software will also enable a wide range of users to modify or ‘hack’ the device for use in a range of contexts.

To achieve this, several technical aspects of the device need to be developed further. Firstly, the electronics need to be optimised by an electronics engineer to ensure the device functions as effectively as possible. This process is also critical to the software development, as the software engineers need a stable hardware platform to effectively troubleshoot their software and develop it further. Once a stable and robust prototype that has passed the ANSI 2000 safety standard has been achieved,

a validation study can be conducted, testing the devices ability to accurately stimulate melanopsin pigments in the eyes using an intense blue light and then measure the PIPR (Post Illumination Pupil Response). Results can then be compared to existing commercial pupil measuring devices to gauge the Openpupils level of accuracy.

Another aspect of the project that needs to be addressed is the user experience. Because users are required to assemble the device themselves, clear and concise assembly instructions will need to be designed and trialled. Furthermore, a smartphone app that acts as a user interface for clinicians to perform pupil tests, as well as interpret the data collected through the testing process will need to be developed.

Implications

This thesis demonstrates the implications of using 3D printing in conjunction with an open source development and distribution model to develop a high-quality, yet inexpensive pupilometer. Perhaps a more interesting implication of this research is the idea of using the open source distribution model as a means of establishing a global, online research community, where clinicians can conduct their own research using the device, share their findings with colleagues and other researchers and in turn build a better understanding of the pupil. There is potential for enhanced diagnostic decisions (in a range of clinical settings from ambulances to neurology clinics) and cloud-based data collection (creating a large biometric database). For this to occur, it is imperative the device is made as accessible and user friendly to as many clinicians as possible.

In terms of manufacturing and design, this research may have significant implications as a case study for individuals and organisations seeking to design and distribute their own open source products by providing a framework that can be followed and built upon through the development of similar devices; thereby supporting the growth of new open source communities.

Safety

From a regulatory perspective, at minimum the device is required to pass the safety standard titled Maximum permissible exposures for ocular safety (ANSI 2000), with emphasis on ophthalmic devices (Delori, Webb, & Sliney, 2007) to ensure the LEDs within the device are safe. These tests were being conducted by the Measurement Standards Laboratory of New Zealand (MSL) prior to the start of this thesis. While initial tests gave confidence the device was not hazardous, further testing had to be postponed due to the instability of the prototype, which eventually stopped working midway through the testing process. To ensure these tests can be conducted effectively, a more robust, stable prototype in terms of both hardware and software is required.

Conclusion

The research conducted throughout this thesis indicates that open source development and distribution models, online 3D printing services and inexpensive, widely available components can be used in conjunction to substantially lower the costs associated with developing, manufacturing and distributing medical devices. By leveraging Shapeways online 3D printing services, in conjunction with a range of widely available parts and components, the Openpupil device was produced for approximately \$650.00 NZD. With more development, this cost could be reduced even further, however it is still substantially cheaper than other pupil measuring devices currently available, all of which cost between \$10,000 and \$100,000. These findings are consistent with the literature, which suggests that for 3D printing to compete with traditional mass manufacturing processes such as injection moulding, niche applications that provide an advantage in terms of cost, quality and/or accessibility need to be identified. In the case of this thesis, the niche identified is an open source pupilometer that leverages online 3D printing services, readily available components and worldwide distribution networks to deliver an inexpensive alternative to expensive commercial devices, and aims to demonstrate how open source technology can democratize interesting new clinical science (Bradford, n.d.).

7.

Appendix

Table 9. Additive manufacturing processes defined by the International Organisation for Standardisation (ISO)

Classification	Description	Technology	Materials	Advantages	Disadvantages
Binder jetting	Additive manufacturing technique where a liquid bonding agent is selectively deposited to join powder materials on a layer by layer basis	Binder Jetting	Metals, sand (Silica), sandstone, glass	Can produce full color parts at relatively low costs compared to other processes. Can produce large parts and complex metal geometries.	Limited mechanical properties due to High porosity. Parts can be Brittle and more complex geometry is prone to cracking.
Material extrusion	Additive manufacturing technique where molten thermoplastics are extruded through a nozzle and deposited onto a build tray. Build material is then deposited layer by layer until the object is complete	Fused deposition modelling (FDM)	Polymers (PLA, ABS, TPU, PETG)	Lowest costing and most widely available printing method, resulting in shorter lead times. Relatively durable.	Low dimensional accuracy. Layered, low resolution surface finish.
		Fused Filament Fabrication (FFF)	Polymer composites (wood, fibreglass, copper)	Wide range of thermoplastics and composite materials available.	Support material is required to build certain geometries. This can be difficult to remove in post processing and limit the geometrical complexity of the part.
Material jetting	Additive manufacturing technique that utilises a similar process to standard inkjet printing, but instead of depositing ink onto paper, the nozzle deposits a liquid photopolymer onto the build tray. This process is then repeated on a layer by layer basis until the object is complete	Polyjet	Resin based plastic (Liquid photopolymer)	Can produce full color parts with a high resolution surface finish. Ability to combine soft and hard materials within a single object.	Expensive printing process Photopolymers degrade overtime, Unsuitable for functional parts
Material jetting	Additive manufacturing technique that utilises a similar process to standard inkjet printing, but instead of depositing ink onto paper, the nozzle deposits a liquid photopolymer onto the build tray. This process is then repeated on a layer by layer basis until the object is complete	Polyjet	Resin based plastic (Liquid photopolymer)	Can produce full color parts with a high resolution surface finish. Ability to combine soft and hard materials within a single object.	Expensive printing process Photopolymers degrade overtime, Unsuitable for functional parts

Classification	Description	Technology	Materials	Advantages	Disadvantages
Powder bed fusion	Additive manufacturing technique that uses lasers to selectively fuse or melt particles from a bed of plastic powder on a layer by layer basis, until the object is complete	Selective Laser Sintering (SLS) Multi Jet Fusion (MJF)	Metals, Nylon polymers, Nylon composites	Does not require support material, so designs with complex geometries can be easily produced. SLS produces strong, durable objects at relatively affordable prices.	Grainy surface may require post processing depending on the required finish. Large flat geometries are prone to warping
Sheet Lamination	Additive manufacturing process in which sheets of material are bonded together to form the finished object.	Laminated Object Manufacture (LOM)	Paper, plastic, sheet metal	Poor surface finish Process makes it difficult to produce hollow geometries	High manufacturing speeds Components don't need support structures
Vat photo polymerisation	Additive manufacturing process that uses a beam of UV light to harden or 'cure' liquid resin on a layer by layer basis. After each layer of the object is cured, the build platform is lowered into the liquid resin and then raised to the appropriate height where the next layer is then cured. This process continues until the object is complete	Stereolithography (SLA)	Resin based plastic (Liquid photopolymer)	Produces high resolution parts at a high detail	Expensive printing process Photopolymers degrade over time when exposed to sunlight. Unsuitable for functional parts

Note: Printing classifications for additive manufacture from the International Organization for Standardization (ISO)/American Society for Testing and Materials (ASTM) ASTM52910. Description and printing technology columns compiled from Prince, 2014 and Prakash, Nancharaih, & Rao, 2018. Advantages and disadvantages columns compiled from <https://www.3dhubs.com/3d-printing/processes/>. Copyright (2019) by 3D hubs.

Anthropometry

When designing products for human use, the body dimensions of the target population are a critical factor that need to be carefully considered. Attributes such as gender, ethnicity and age all have a strong influence on the anthropomorphic measurements of a population. If not taken into account, designers can unintentionally exclude large groups of potential users (de Vries & Parkinson, 2014).

For example, face masks designed for an American population could potentially prevent 35% of Chinese users from using the mask due to an incorrect fit (Yang, Shen, & Wu, 2007). Because the pupilometer is expected to be downloaded, assembled and used by clinicians across the globe, the device is required to fit comfortably across a range of different facial types.

In 2001 the National Institute for Occupational Safety and Health (NIOSH) created an anthropometric database representing the heads and faces of United States civilian respirator users. The sampling plan called for roughly equal numbers of male and female subjects in four racial/ethnic groups (White, African American, Hispanic, and Other) divided into three age groups (18-29, 30- 44, and over 45) (Zhuang & Bradtmiller, 2005).

In total 4026 subjects were measured for 21 dimensions. Figure 9. displays the relevant anthropometric measurements identified as crucial in terms of ensuring a comfortable and functional fit for the pupilometer.

Table 10. Table comparing the range of 3D printing services, processes, and materials used to manufacture the diffuser

Measurement	Male (mean)	Female (mean)	Average (mean)
Interpupillary distance	64.5 mm	61.9 mm	63.2 mm
Bizygomatic Breadth	143.5 mm	135.1 mm	139.3 mm
Nasal Root Breadth	16.6 mm	16.3 mm	16.45 mm
Maximum Frontal Breadth	112.3 mm	108.6 mm	11 mm

Note. From Facial anthropometric differences among gender, ethnicity, and age groups, by (Zhuang, Landsittel, Benson, Roberge, & Shaffer, 2010)

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