Skynet Retinal Prosthesis

Project Proposal

Product Design and Development

Mahri K[redacted]

Background

Glaucoma is diagnosed by measuring intraocular pressure in connection to the loss of retinal ganglion cells, which leads to optic nerve degeneration. The equilibrium between the ciliary body's secretion of aqueous humor and its drainage through two distinct channels, the trabecular meshwork and the uveoscleral outflow pathway, determines intraocular pressure. Glaucoma is divided into two categories: open-angle glaucoma and angle-closure glaucoma. Due to the lack of symptoms, open-angle glaucoma is a chronic illness that progresses slowly, resulting in late diagnosis. Increased resistance to aqueous outflow through the trabecular meshwork occurs in open-angle patients, obstructing drainage channels. Angle-closure glaucoma, on the other hand, can arise abruptly but is unpleasant, which is why vision loss is less common with this type. Angle-closure is distinguished by the fact that the site of aqueous outflow in the eye is obstructed by apposition (bulging) of the iris, resulting in an anatomically closed angle (defined as an occluded angle of at least). This prevents the fluid from flowing freely through the eye, resulting in increased pressure [3].

Glaucoma can be asymptomatic until it is severe, making it difficult to cure and increasing the risks of people with advanced Glaucoma. Glaucoma is commonly divided into five stages, each with its own set of symptoms.

Stage I: Any alteration to your drainage system that leads to an increase in intraocular pressure.

Stage II: Usually when an individual notices a change in the system by eye pain or blurry vision.

Stage III: Eye pressure increases significantly, beginning of advanced stage glaucoma.

Stage IV: Damage to the optic nerve that must be corrected

Stage V: Last stage where vision loss occurs

Though depending on the stages, Open-angle Glaucoma usually displays symptoms of patchy blind spots in the eye and tunnel vision with advanced stages. In contrast, angle closure glaucoma displays severe headaches, eye pain, blurred vision, halos around lights [5].

Glaucoma affects more than 70 million people in the world with an approximate 10% being blind. This statistic makes glaucoma one of the leading causes of irreversible blindness in the world. Roughly 15% of people with glaucoma become blind in at least one eye within 20 years even with treatment [4].

Glaucoma itself is not life threatening.

Glaucoma tends to be a genetic disease relating to genes with high eye pressure and optic nerve damage. Though medical conditions like diabetes, heart disease, high blood pressure and sickle cell anemia have also shown risk factors. Serious eye injuries or eye surgeries can also lead to this disease.

Needs statement

A way to treat vision loss in Stage V Glaucoma patients that is performed by an Ophthalmologist with a recovery less than 2 days.

Value proposition statement

Our retinal prosthesis helps stage V glaucoma patients who want to treat vision loss by minimizing abnormal intraocular pressure, damage to healthy eye structure, and uncertainty of user response and increase recovery rate and vision performance unlike Keratoprosthetics.

Value map (including Customer Profile)

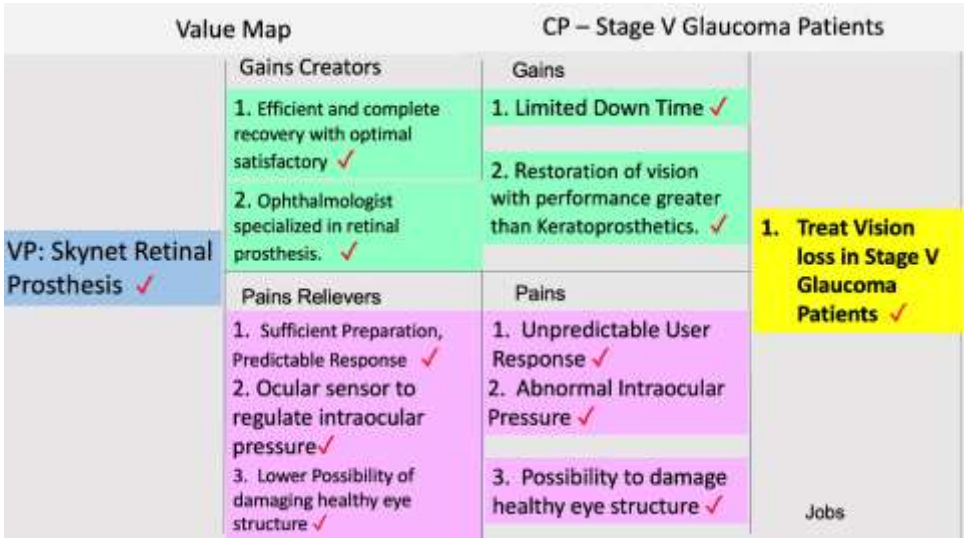

Figure 1. Value map and customer profile details.

Product design

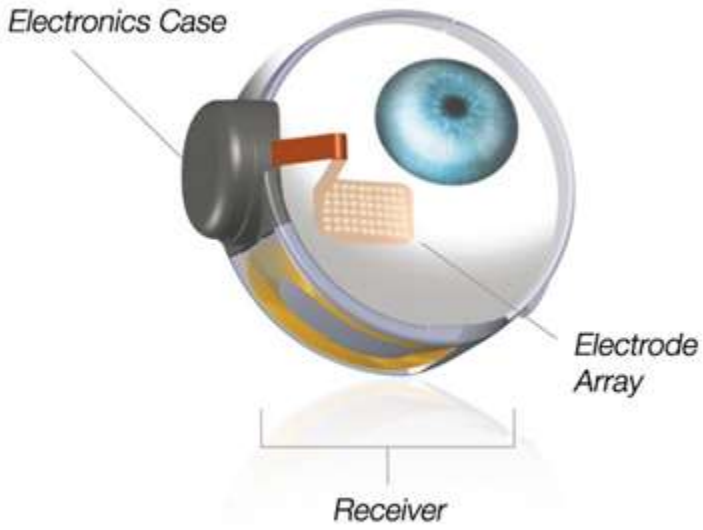

Figure 2. Representation of Skynet Retinal Prosthesis.

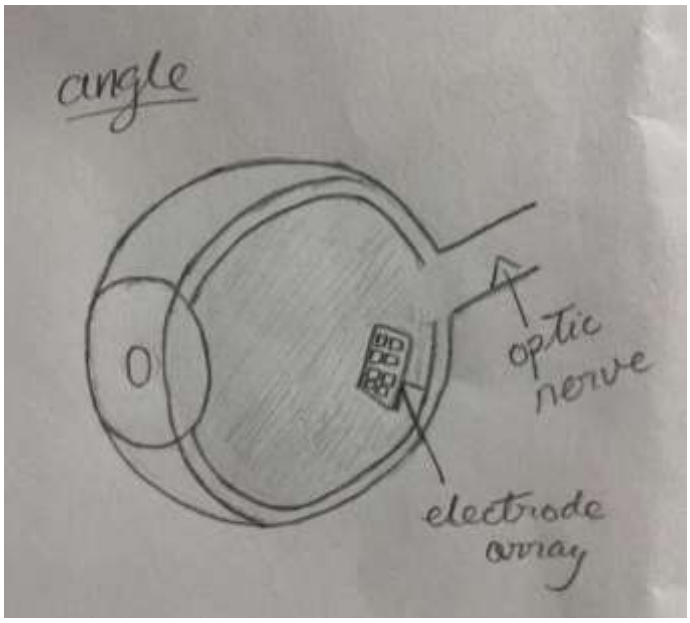

Figure 3. Drawing of Skynet Retinal Prosthesis.

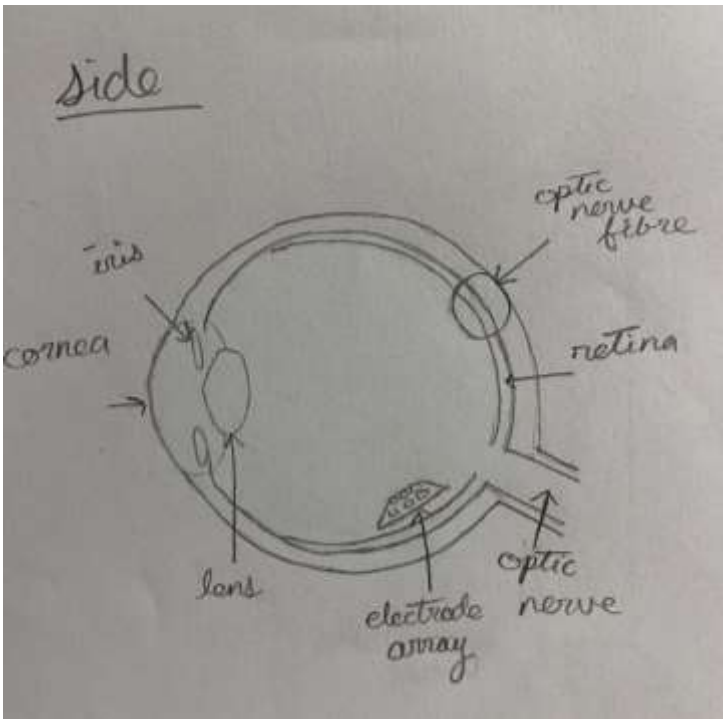

Figure 4. Drawing of Skynet Retinal Prosthesis.

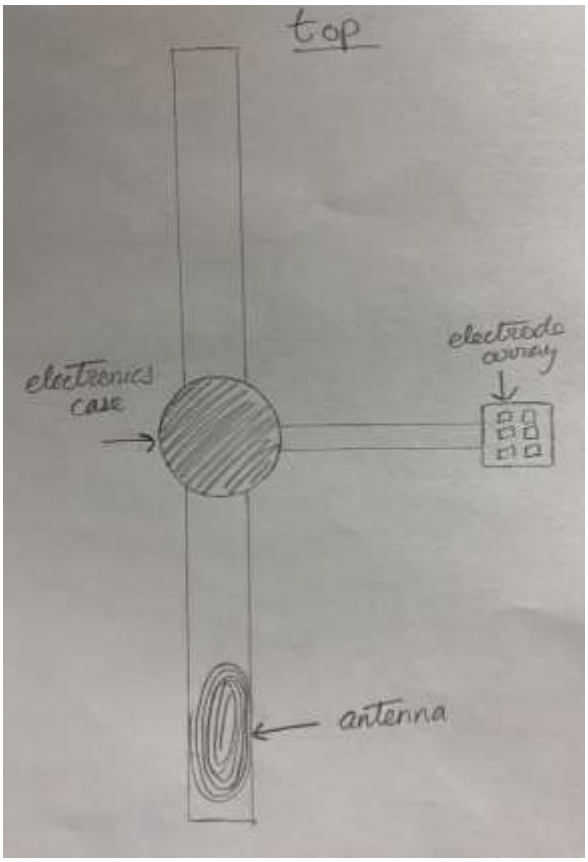

Figure 5. Drawing of Skynet Retinal Prosthesis.

FDA classification

Most implanted neural prosthetic devices for novel applications will be in FDA Device Class III. In the US, the highest classification, Class III, includes risky implantable systems, such as deep brain stimulators for Parkinson's disease, dystonias and epilepsy, and novel devices that have yet to be classified.
All Class III products must follow the rules and steps leading to eventual submission of a Premarket Approval Application (PMA) or a modified Humanitarian Device Exemption for products whose applications address rare conditions, as described below. The first stage of regulatory interaction for such products is typically the submission of an Investigational Device Exemption (IDE) to use devices experimentally in humans in order to collect data on safety, efficacy and performance.
Novel neural prostheses aimed at relatively small markets such as quadriplegia are often eligible for FDA's Humanitarian Use Designation (HUD) (not more than 8,000 population)
Qualification as an HUD allows the company to replace the PMA submission with a submission for Humanitarian Device Exemption (HDE) in which data from a much smaller clinical trial can be used to demonstrate safety and "probable efficacy."
In the EU, it is likely that most implantable neural prostheses will be classified in Class III for products that are "in direct contact with heart or central circulatory/nervous system."

Memorandum of invention

Invention Title:

Skynet Retinal Prosthesis

Names of persons connected with the work- inventors:

Dawson Almeida

Where recorded:

Digital records can be found on Mr. Almeida's laptop.

Date the invention was first conceived:

The invention process of the new device started in March of 2021.

Has the invention been produced?

Skynet Retinal Prosthesis was not produced yet.

A similar device was invented by Second Sight Medical Products and the device was called Argus II Retinal Prosthesis.

Has the invention been shown in a public setting?

Skynet Retinal Prosthesis was not shown to the public setting.

On the other hand, similar device called Argus II Retinal Prosthesis was shown to the public and has gone through trials because it has the FDA's Humanitarian Device Exemption (HDE)

classification. According to online sources, the production of the device was discontinued in 2020 and possible reasons might be the serious side effects that the device was reported to cause [1].

Brief Description of the Invention:

What is it?

Retinal prostheses, a type of bionic eye, are implantable electronic devices designed to substitute the lost vision in patients with blindness. This invention was created to target the stage V glaucoma patient due to the coupling design of the system which functions to replace the damaged retinal ganglion cells.

What is the fundamental purpose?

The main purpose is to treat vision loss in stage V Glaucoma patients and the procedure will include surgery and training period.

What is the fundamental principle (physics, chemistry, biology, etc.)?

The principle underlying our retinal prosthesis device revolves around implants that will be placed inside the empty eye socket as well as microarray implants attached to the major eye membranes.

The fundamental principle lies in being able to mimic the signals produced by the retinal ganglion cells that will be able to interact with other essential structures within the eye to produce image.

The main principle in placing the implants within an eye socket and attaching implants onto the eye membranes is to ensure flawless signal transduction and minimal damage while performing at top capacity.

What is the problem to be solved and how does the invention solve the problem?

Patients suffering from stage V glaucoma experience blindness in one or both eyes which results from retinal ganglion cell damage by increased retinal intraocular pressure.

The invention will be able to mimic the function of human eyes by being coupled to multiple eye structures while causing minimal damage and no damage to residual tissues.

Summary of Novelty and Usefulness:

a) How was the problem solved in the past?

Before Argus II Retinal Prosthesis, there were not many solutions or treatments to blindness. Eye transplants were one solution but due to low availability rates and surgery challenges, eye transplants is not the best option at times. Argus II Retinal Prosthesis was stopped in 2020 and currently FDA has not approved any retinal prosthesis devices that help obtain some type of vision.

b) What is the disadvantage to overcome?

Spatial resolution of prosthetic systems is one of the biggest disadvantages which is related to several factors including electrode density, size, number and pitch, electrode contact, and visual encoding.

Many previously recorded health-related complications and side effects of Argus II decreased the longevity of the device which led to many patients stopping wearing the device and production of the device. Biocompatibility, longevity, and stability of the new device will need to be optimized before letting patients use the device as part of their daily routine.

The system does have to be trained and one of the disadvantages of the system that did not go through the clinical trials is the unpredictability of responses of blind users with Stage V Glaucoma. Clinical trials as well as optimization using animal models will be performed beforehand.

c) Advantage(s) the invention has over other ways of solving the problem?

The biggest advantage for blind people is to obtain some type of vision. The vision that will be substituted by the device will not be perfect, but some researchers showed that the patients were able to distinguish objects and see enough to be able to walk without a white cane when using artificial systems mimicking the function of eyes [2].

Our system and surgery procedures will result in efficient and complete recovery with optimal satisfactory response and patients will have limited down time after going through the surgery.

d) Attach drawing or photos of the invention.

Refer to Figures 2-5.

Value-added features:

Due to the fact that there are no vision providing devices in the market currently that were FDA approved, our device will be able to provide the following features:

- Sense of vision
- Independence from white cane and ability to move freely
- Complete recovery and limited down time after surgery

Potential product use risks and risk mitigation approaches

Skynet Retinal Prosthesis is a device that has similar functions to Argus II Retinal Prosthesis System by Second Sight Medical Products.

To use the device, the patient needs to go through the surgery and the training session. The surgery will consist of implanting the device into one empty eye socket of a patient and coupling the device to the major eye structures. The training session will include training the device and adapting the system to the patient's brain activity.

The structure of the eye is very complex and still very little of it has been understood or discovered. Eye has a neuroactivity conductive layer on the very inside of the structure which is called retina and retina has two nuclear layers as well. On the outside of the retinal nuclear layers, retinal ganglion cells can be found. Retinal ganglion cells have two ends where one end connects to the inner retinal nuclear layer and the other end connects to the optic nerve fiber. Retina ganglion cells are the target cells in our procedure because those are the cells that are responsible for the blindness of patients with stage V glaucoma. Retinal ganglion cells become damaged in stage V glaucoma due to the high inner optical pressure which results in damaging the retinal ganglion cells' optical nerve heads. It is not fully known if other cells or other eye structures are damaged in bind patients with stage V glaucoma or if stage V glaucoma cause blindness in one or both eyes. This device is intended to be implanted into one eye socket.

The main product risks emerge when considering the abnormal intraocular changes within the patient's eye and the necessary retinal coupling . The mitigation of both of these risks will be explained within the following paragraphs.

The device will include being able to pair with the major structures within the eye to be able to conduct the signals to optic nerve. More specifically biocompatible and tiny microarray electric implants will be placed on the major eye structures such as inner limiting membrane, retinal nuclear layers, retinal pigment epithelium, choroid and sclera. This will ensure the coupling with the major eye structures to deliver the signals needed to be delivered to the brain for image formation and processing. Overall, a maximum of four implants can be utilized to couple with the major eye structures which are retinal, subretinal, suprachoroidal, and intrascleral layers. The implantation of these microarrays will ensure that the electrical stimulation is distributed within major eye structures and that the necessary retina coupling is built and the damage from electrical overstimulation is omitted.

The device will include the eye like implant with the main function of producing signals that will results in image formation in the eye which will be delivered by the microarray attachments in the eye's major membranes. The device will also include the main ocular implant that will include a sensor to measure the intraocular pressure. This sensor will results in informing the patient of the abnormal pressure changes and accommodating its size so as not to damage any residual healthy eye structures.

Team members and contributions

Mahri K[redacted]	•Potential product risks; Risk mitigation approach; Memorandum of Invention; References; Presentation; Report
Is[redacted]	•Product design schematics; Report; Presentation
M[redacted]	•FDA classification; Report
D[redacted]	•Background; Needs statement; Value map; Value proposition statement; Presentation; References; Report
H[redacted]	•Memorandum of concept draft

References

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