ICES
Institute for Complex Engineered Systems
College of Engineering

EXTERNAL UNIT FOR RETINAL PROSTHESIS

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Executive Summary

Degenerative retinal diseases (RP) and age-related macular degeneration (AMD) affect the normal function of photoreceptor cells in the retina, causing patients with severe afflictions to develop extensive vision loss.
Our team worked with Professor Shawn Kelly, Ph.D. from Carnegie Mellon University to develop a retinal prosthesis for partients with severe RP and AMD. Our prosthesis will consist of 2 overall units, the implant and the external device. The implant will be placed on the eye through a small incision in the conjunctiva, and implanted on the back of the retina.

Clinical Need

Retinitis pigmentosa (RP) affects more than 1 million people worldwide, while age-related macular degeneration (AMD) affects 8 million people in America.
A new treatment option for those with advanced forms of RP and AMD can be retinal implants. There is only one retinal prosthesis approved in the US, the Argus II by Second Sight Medical Products.
There exists a need, in the US market, for a more cost-effective retinal prosthesis that can offer better vision capability, form and human factors than the current alternative.

Market

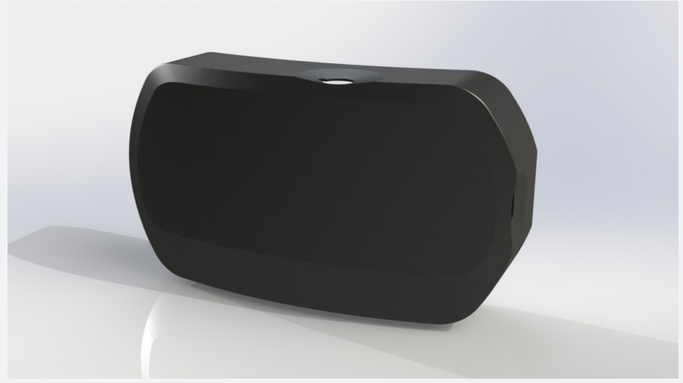
We expect the target market for the retinal prosthesis among those with macular degeneration to be limited to those under 70 years of age, with a sufficiently advanced form of the disease. This would limit the AMD market to under 30,000 people, about half of whom are likely to be viable candidates for the procedure. This number will increase (by 75% by 2030 and 150% by 2050) as baby boomers age.

Additionally, there are 8,000-12,000 Americans with sufficiently advanced retinitis pigmentosa to make them candidates for a prosthesis.

Design Overview

Final design consists of two wearable external units, a remote control, and a charger: The first,a pair of glasses with an induction coil and a micro-camera mounted on it to send video and power wirelessly to the prosthesis.

The second, is a waist-mounted housing that will contain the unit’s batteries, telemetry circuit and microprocessor.



The device will be charged by a special power adapter: the top half of the charger functions like a button, alerting the user of remaining charge when pressed. On the wire connecting the glasses to the circuitry, there is a remote which will control basic functions of the prosthesis: zoom, focus, pattern recognition software, etc.

Novelty of Concept

Our retinal prosthesis is innovative in its use of frequency shift key and load shift key to transmit video feed to the implant using the same induction coil used for power. It also promises to deliver 256 pixels of vision to patients, rather than the 64 pixels currently offered by competing products.The external unit is designed to consider the needs of the patients who would use device. The glasses are a simple form so as to not stand out, waist-mounted housing is rounded for comfort, has surface details to indicate which side is top and bottom, charging port, and on/off switch. The top of the portable charger, will also read the battery status.

Product Cost

Our prosthesis is currently estimated to cost between $50,000 and $100,000. As of 2013, Medicare and Medicaid have confirmed that they will reimburse patients who receive the Argus II retinal implant “for both a new technology add-on payment (inpatient setting of care) and a transitional pass through payment (outpatient setting of care). Based on the similarities, we expect our prosthesis to be eventually covered by Medicare and Medicaid as well.

Regulatory Pathway

We believe that a 510(k) filing for a class III device will be sufficient to receive approval to market it in the United States. Due to similarities in function and underlying technology, we believe our device will be determined “substantially equivalent” to the Argus II, the competitor, from a regulatory perspective.

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