2015

An economic analysis of the wireless intraocular pressure transducer (WIT)

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http://hdl.handle.net/2144/16137

Boston University
BOSTON UNIVERSITY
SCHOOL OF MEDICINE

Thesis

AN ECONOMIC ANALYSIS OF THE WIRELESS INTRAOCULAR PRESSURE TRANSUDUCER (WIT)

by

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B.Sc., McGill University, 2013

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ACKNOWLEDGMENTS

First of all, I would like to express my deepest appreciation to Dr.Melki for his idea and guidance throughout the project. Aside from his ingenuity and attention to details, observing Dr.Melki’s interaction with patients has been an eye opening experience. My stay at Boston Eye Group was by far the most enriching and interesting learning experience I have ever had.

I would also like to thank Dr.Fadlallah and Dr.Seaton in their contributions towards this thesis. The project cannot be done without their insightful advice.

Lastly I would like to offer my gratitude for my colleagues at Boston Eye Group, their thorough guidance and sparks of originality helped me to get through my most struggling moments.
Glaucoma is a condition that affects millions of Americans and is the second most prominent cause of blindness worldwide. In addition, the disease inflicts a significant financial burden on the U.S. Medicare system. Among many risk factors for blindness, intraocular pressure (IOP) is the only one that can be effectively altered by physicians. While a rigorous monitoring of IOP will improve the care of patients through early diagnosis and prompt treatment, the frequent visits patients must make to the clinic will aggravate their financial burden.

The wireless intraocular pressure transducer (WIT) shows potential in effectively reducing cost inflicted by glaucoma, while maintaining the quality of patient care. The WIT shows the promise of reducing clinical visits for IOP measurements and preventing the progression of glaucoma. Direct and indirect savings, as well as cost of implantation will be analyzed through the construction of a flexible model using currently available data. The model yields favorable outcomes in the cost-reduction effectiveness of the WIT, but suggests a clear indication that further information is needed in order to make an accurate and complete assessment.
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LIST OF ABBREVIATIONS

ACG .......................................................... Angle-Closure Glaucoma

ASIC .......................................................... Application-Specific Integrated Circuit

DTC .......................................................... Diurnal Tension Curve

GAT .......................................................... Goldman Applanation Tonometer

IOL .......................................................... Intraocular Lense

IOP .......................................................... Intraocular Pressure

OAG .......................................................... Open-Angle Glaucoma

OTS .......................................................... Ocular Telemetry Sensor

SD .......................................................... Standard Deviation

WIT .......................................................... Wireless IOP Transducer
INTRODUCTION

From Light to Image

The eye is the mediator between the light sources in the environment and the perceptions by our brain. Vision starts by the light entering from the cornea, the transparent, avascular, dome shaped outer layer of the eye. It is held in place by the tough fibrous sclera, covered by the conjunctiva. The cornea is also the primary refractive apparatus of the eye, responsible for 65-75% of the eye’s focusing power. The cornea is composed of 5 layers: the epithelium, bowman’s layer, stroma, Descemet’s membrane,
and the endothelium. Any damage deeper than the epithelium layer will likely leave a corneal scar, leading to vision deterioration [2].

The light then travels through the anterior chamber filled with the aqueous humor to the pupil. The pupil size is controlled by the iris, a pigmented muscle that alters the amount of light that enters the eye [3].

The anterior chamber angle is located at the junction between the cornea and the iris. The ciliary bodies residing behind the iris are responsible for producing the aqueous humor. The pressure inside the eye is maintained by a continuous outward transport of such humor through the trabecular meshwork [4]. If the pupil is dilated, the iris will retract towards the lens. In some patients with inherently narrow angles, such retraction would cause pupillary blockage, resulting in acute angle-closure glaucoma. More details on the aqueous drainage will be discussed in the following sections [5].

After passing through the pupil, the light is further refracted by the lens, a crystalline focusing device that gradually loses its clarity and flexibility as one ages [3]. The cells of the lens do not contain blood vessels, and obtain their nutritional supply mainly from the surrounding aqueous humor.

The light will then be focused on the retina layer in the back of the eye. The retina is structured into three layers of cells: photoreceptors, intermediate neurons and ganglion cells. Together, these cells transform the captured photons into coded electrical impulses [6].
These electrical signals will finally be sent to the brain via the optic nerve, for higher level processing. In adults, the optic nerve displays limited regenerative capacity. As such, damage done to the optic nerve by glaucoma and the associated vision loss becomes nearly impossible to reverse.

**What is Glaucoma**

While glaucoma is historically defined by an elevated intraocular pressure (IOP), most modern physicians agree that glaucoma is a group of conditions that is characterized by a progressive optic neuropathy that may or may not accompany an elevation of IOP [7]. If untreated, glaucoma will gradually deplete the optic nerve of its nerve fibers, ultimately leading to blindness [8]. Depending on the type of glaucoma, symptoms may include eye pain, elevated IOP and loss in peripheral vision. However, glaucoma often times causes permanent damage to the optic nerve without noticeable symptoms, making the prevention of glaucoma of the utmost importance [9].

**Type of Glaucoma**

Contrary to the common belief that glaucoma is a single disease, there are many types of glaucoma that each manifest differently. The three most common types are the open-angle glaucoma (OAG), angle-closure glaucoma (ACG), and low-tension glaucoma, with the OAG accounting for more than 90% of all cases [7].
Risk Factors

It is statistically shown that African Americans are 3 times more likely to get glaucoma compared to Caucasians [10]. Aside from race, studies also indicate that older age, male gender, lean body mass, history of cataract, family predisposition of glaucoma and high IOP are major risk factors for POA [11]. Among these factors, only the elevated IOP can be therapeutically targeted and treated [10].

Aqueous Flow

![Aqueous Flow Diagram](image)

Figure 2: Conventional and Uveo-Scleral Pathway of Aqueous Outflow. Figure downloaded from Glaucoma – Basic and Clinical Aspects, Chapter 3 [12].

In addition to the maintenance of IOP, the aqueous flow takes on a similar responsibility as blood in vasculated structures. The aqueous humor provides nutrient, removes waste material, and transports neurotransmitters for the avascular structure of cornea and lens [13].

Up to 90% of aqueous humor is produced by the process of active secretion via the ciliary bodies; this is then supplemented by the process of diffusion and ultrafiltration.
More specifically, the ciliary processes occupying the anterior section of ciliary bodies are responsible for the production of aqueous humor. Their secretion is controlled by both sympathetic and parasympathetic nervous systems [13][14].

The aqueous humor leaves the anterior chamber via two pathways located at the chamber angle, being the trabecular meshwork and the uveo-scleral meshwork. The main outflow of aqueous is through the trabecular meshwork, which occupies the area of scleral sulcus and forms a circular channel named Schlemm’s canal. The aqueous then enters the veins beneath the conjunctiva and then back to the bloodstream. The uveo-scleral pathway acts as an overflow pathway, and is located in the ciliary bodies [13][14].

A turbulence in the production-excretion equilibrium, especially in the conventional trabecular meshwork pathway, may lead to a disturbance in the IOP of the eye. This may ultimately become a risk factor for the pathogenesis of glaucoma [13]
Glaucoma Pathology

Figure 3: Stages of Glaucoma. From left to right, the pictures depict the cupping of optic nerve head through the early, intermediate and late stage of glaucoma. Figure downloaded from Glaucoma: mode of action and properties of current treatments [8].

It is demonstrated that the vision loss caused by glaucoma may be in great part attributed to the death of retinal ganglion cells [12]. Clinically manifesting as the “cupping” phenomenon of the optic nerve head, high IOP induces an axonal compression, blocking the axoplasmic flow and other intracellular pathways. This stress induces an apoptosis phenomenon of the retinal ganglion cells, and as a result, progressive vision loss starting from the peripheral visual field [15][16].

Prevalence and Cost

According to Quigley et al., there are 60.5 million people world-wide (representing 2.65% of people over the age of 40) and 3.3 million people in the United...
States with glaucoma in 2010. This number is likely to increase to 79.6 million by 2020, with 74% of cases being open-angle glaucoma. Among these, 4.5 million people with OAG and 3.9 million with ACG are afflicted with bilateral blindness in 2010, contributing to about 15% of global blindness. This number will increase to 5.9 million and 5.3 million by 2020 for OAG and ACG, respectively [17]. In 2014, more than 2.8 million Americans are currently affected by glaucoma. This number is projected to increase by about 50% to 4 million in 2032 [18]. Currently, about 120,000 Americans are blind due to glaucoma, which makes it the second most prevalent cause of blindness [7][10].

In 2006, it is reported that the care of glaucoma patients inflicts a financial burden of 2.86 billion dollars on the United States medical system. This number does not include patients who were diagnosed of the disease but were not treated. It is also likely that the number is higher due to an increased patient population since 2006 [19].

Based on publically available data, care specialist survey and hospital record investigations, Lee et al. conducted a study aiming to clarify the economic burden of glaucoma on the United States [20]. After stratifying the patients’ disease stage according to International Classification of Diseases, the patients in each stage were followed for 5 years and their glaucoma care expense monitored.
As the stages increase, the average number of medications prescribed and surgical procedures performed was also observed to increase. For stages 0 through 4, direct medical expenses include ophthalmologist visits, Humphrey Visual Field testing, glaucoma surgeries, medications, and other services such as gonioscopies, optic disc photographs, nerve fiber thickness analysis and IOP measurements. Stage 0 patients require an average of $623 per patient per year. As the disease progresses, the associated medical expenses increase as well, with stage 4 patients requiring about $2,464 per patient per year [20]. Stage 5 patients require additional expenses including low vision care specialist visits ($232 per year), non-HVF testings ($30 per year) and physical rehabilitation center services ($249 per year) [20]. From the produced graph, it is...
estimated that the cost for office visit has stayed the same at approximately $250 per year throughout the glaucoma stages. Another study by Rein et al. reported that the annual cost for managing glaucoma, disregarding the medications, is $276, which is consistent with the study by Lee et al [19].

A second study by Quigley et al. analyzed the cost of glaucoma care provided to Medicare beneficiaries. A 5% random sample was selected from the Medicare beneficiaries and analyzed for expenditure associated with glaucoma. Within the sample of 1.38 million people, 163,972 patients have submitted at least one claim under the title of glaucoma. Cumulatively, these patients were accounted for 302,019 office visits for glaucoma examination or evaluations. Together, these visits represents 17 million dollars of Medicare expenditure [21].

The economic burden of glaucoma is should also consider the indirect costs inflicted by the disease. These include an increase in productivity losses, depression, accidents and other comorbidities [19].

**Current Glaucoma Treatment**

Often times, glaucoma does not manifest any symptoms until a late stage. As such, its diagnosis often relies on periodical examination of the optic disc, retinal nerve fibers, and visual field. Of all the risk factors, current technology only allows us to treat possible elevated IOP. Nevertheless, evidences suggest that lowering the IOP provides a protective environment that may delay or prevent the progression of glaucoma at both early and late stage [16][22].
In order to lower the IOP, several techniques ranging from medication to surgery are currently being employed. Commonly used medications including prostaglandin analogues, prostanides, and α2 adrenergic agonists which primarily aim to reduce IOP by increasing aqueous outflow. β blockers are also being used to reduce aqueous secretion. Surgical treatments for OAG mainly involve laser trabeculoplasty which induces biological changes in the trabecular meshwork, resulting in increased aqueous flow. For ACG, peripheral iridotomy is primarily used to relieve the pupillary block and resume aqueous flow [16][22].

**IOP and Current Measuring Techniques**

While flowing against its resistance, the aqueous humor generates an average IOP of 15mmHg, with a range of 10mmHg to 21mmHg. Such pressure is needed to inflate the eye and maintain its daily functionalities. [13]

Among other methods of measurements, the most prominent tonometry techniques include the Tonopen, non-contact tonometer, and the Goldman applanation tonometer (GAT) [23]. The non-contact tonometer measures the IOP by recording the deformation of the reflection on the corneal surface after a puff of air. The applanation tonometry measures the IOP based on the amount of force required to flatten a fixed area of cornea with the help of topical anesthetics [24]. According to a comparative study between the above mentioned methods, the GAT is still considered as the current gold standard. The study indicated a moderate agreement between the GAT and the other methods within the normal IOP ranges. However, both the Tonopen and non-contact
method have a tendency of overestimating IOP at high pressure range and underestimating IOP at low pressure range[23].

**Fluctuation in IOP**

While monitoring the IOP has been an established way to track the progression of glaucoma, the fluctuation in IOP has been attracting more and more attention as a potential risk factor for glaucoma. It is also observed that some patients with normal mean IOP measurements consistently lost peripheral visual field. Hence, a proposed hypothesis is that increased variability in IOP by itself may represent a risk factor for glaucoma in addition to the elevated IOP [25]. Monitoring late stage glaucoma patients suggested that variability in the patients who eventually became blind is 2.9mmHg higher than those who did not go blind. Nevertheless, the exact effect of IOP fluctuation is still under investigation, as other studies provided mixed results. The Early Manifest Glaucoma Trial, the Ocular Hypertension Study and the European Glaucoma Prevention Study found no relation between IOP variation and progression. Nevertheless the Advanced Glaucoma Intervention Study and the Collaborative Initial Glaucoma Treatment Study did find an association [26].

In the studies arguing for the significance of IOP fluctuation, the authors found that an IOP fluctuation with a standard deviation (SD) of 2mmHg or more is associated with 30% of visual field deterioration in OAG, and 28.6% in ACG, compared to the respective 9.7% and 10% in patients with a SD below 2mmHg. It is also found that even after surgical interventions, the patients with a higher IOP fluctuation experience higher
level of visual field deterioration [27]. On the other hand, a comparative number of studies argued that fluctuation in IOP does not cause significant change in glaucoma progression. A major contributing factor to the discrepancies is a lack of standardized measuring methods. From the instruments being used to the patient’s past medical history, numerous factors alters the measured IOP and thus the conclusion of the studies.

**Continuous Measurements**

The current standard GAT has the inherent limitation of offering a static, single and momentary measurement of IOP. Based on Jonas et al.’s review on 3025 diurnal IOP curves, it is demonstrated that such measurement done within the normal office hours has less than 25% of chance to represent the peak IOP for the patient [27]. As such, the demand for a reliable and continuous method of measuring IOP becomes imperative.

An improvement on the single GAT measurement is the diurnal tension curve (DTC), where a patient’s IOP is measured multiple times throughout usual clinical hours via GAT [28]. Nevertheless, such a method fails to provide information regarding patient’s IOP fluctuation during the night, while it is demonstrated by Liu et al. that the peak IOP in the majority of people occurs in the nocturnal period [29]. Other additional drawbacks such as poor reflection of physiological IOP in a patient’s normal daily life, prolonged time requirement, and significant cost limits the use of DTC on a routine basis [28].

Recently, the approval of ocular telemetry sensor (OTS) sheds light on possible continuous measurement of IOP. The OTS is a silicon contact lens with an embedded
electromechanical system that measures the IOP based on the change in corneal curvature. The signal is then read by an external antenna mounted around the patient’s eye. The limitations of this device include induced discomfort, occasional device failure, decreased visual acuity and the impossibility of continuous and long term usage. The precise impact of night time change in corneal thickness and ocular movement on the precision of the device is also under investigation [30][31].

**The Wireless IOP Transducer (WIT)**

The WIT is a circular implantable device that allows wireless and continuous IOP measurements. The transducer itself is a digital and miniature device that combines the functionality of pressure-sensor, temperature-sensor, identification encoder and analog-to-digital converter and telemetry into an application-specific integrated circuit (ASIC). The ASIC chip is connected to a circular, gold microantenna while being encapsulated by biocompatible, platinum-cured silicone rubber. The WIT distinguishes itself from the OTS by its capability of measuring the true pressure inside the eye, instead of inferring it from the corneal curvature [32].
The implantable system is powered by the reader device via inductive coupling to an external magnetic field generator when it is held at a close proximity, and thus does not require batteries. The external reader unit is powered by batteries. The same reader device is responsible for receiving the digital data transmitted by the ASIC chip via telemetric link and is capable of storing at least 3,000 IOP readings [33].
In 2011, Todani et al. tested the biocompatibility and safety of the WIT by implanting the device either in the ciliary sulcus or vitreous cavity of rabbit eyes. While transient mild anterior chamber inflammation is observed in both the experimental and the sham group immediately after the implantation, no fibrinous reaction, membrane formation or chronic uveitis is observed. Histology examination revealed no evidence of gross intraocular inflammation, membrane formation or transducer encapsulation. The study thus established a high degree of biocompatibility between the rabbit eye and the WIT up to 25 months. Nevertheless, the presence of possible irritant such as gold and silicone present a possible risk of leakage if the integrity of the device is damaged [32].
A series of 12 IOP measurements were taken from sedated rabbits with the WIT and compared to the readings from direct manometric measurements. These measurements demonstrated excellent reproducibility and small SD. It is also observed that the values taken by the WIT had significantly less variability than by pneumotonometer or the Tono-Pen by having a SD of 0.81mmHg in comparison to 2.70mmHg and 3.35mmHg respectively. Nevertheless, a downward drift in the IOP measurement was noted over time in two of the rabbits, requiring the device to be recalibrated [32]. A follow up study involving an 8-week monitoring of IOP fluctuation in rabbit was conducted in attempt to eliminate IOP disturbances from animal restraints, sedatives and anesthesia during the surgery. It is observed that the WIT measurements had a lower SD (1.8mmHg) than both the GAT (2.3-3.7mmHg) and Tono-Pen (4.3mmHg) [34].

Figure 7. The Implantation Process of WIT. Figure downloaded from An Implantable Intraocular Pressure Transducer: Initial Safety Outcomes [33].
In 2014, Melki et al. conducted the first implantation of WIT in a human eye and gathered the preliminary safety data of the WIT in human. A female patient in her 60s with a history of primary OAG and cataract received the WIT implant concurrent with her cataract extraction and intraocular lens (IOL) implantation. After an uncomplicated cataract extraction and IOL placement, the WIT was inserted into the sulcus space after one attempt. The patient was monitored postoperatively for 18 months. Despite the longer recovery period possibly due to additional manipulations, no complications were observed despite an initial mild corneal edema and iritis that resolved. IOP values were taken by GAT and the WIT throughout the postoperative monitoring. The Brown-Forsythe test of equality of variances were conducted and indicated an absence of significant group variance. Risks of implantation include anterior iris displacement, peripheral anterior synechiae, angle narrowing and intraocular fibrosis around the device. Nevertheless, the device seems to be biocompatible in the human eye while providing the expected reliable IOP measurements, thus providing an initial favorable indication of WIT [33].

In addition to providing the possibility of reliably monitoring the IOP on a 24h basis, the WIT also has the potential of reducing patients’ office visits. The device may have the additional usage of improving the patients’ accessibility to continuous IOP monitoring in medically underserved areas. The WIT’s ease of usage also eliminates the necessary human aids involved in other IOP monitoring methods [32][33][34].
GOAL OF THE THESIS

This thesis has the aim of studying a promising device used for wireless continuous IOP measurement using the WIT. The study has the specific aims of: 1) understanding the current epidemiological data regarding glaucoma; 2) reviewing the financial cost inflicted by glaucoma; 3) analyzing the potential financial saving capability of the WIT; and 4) constructing an analytical model that would allow further analysis on the impact of the WIT.
METHODS

The Wireless IOP Transducer

A review of existing literature is performed and sheds insight on the epidemiology, pathology and economic burden of glaucoma. Details regarding the WIT’s properties and experimental outcomes are also drawn from published studies. Specific measurements of cost and visit numbers are obtained from the most recent available Medicare data, being Quigley et al.’s study on Medicare patients from 2002 to 2009 [19]. Other published results used in the analysis include Lee et al.’s paper on the cost of glaucoma patients based on disease stage [18].

Eligible Patients

Based on Quigley et al.'s study, 5% of the Medicare population will be selected, and the number of glaucoma patients calculated. As the device can only be applied to glaucoma patients with previous or concurrent cataracts, estimation on the number of patients eligible for the WIT will be performed. The estimation is done by multiplying the prevalence of cataract in the US population (17.11%) to the number of glaucoma patients identified by the Medicare study (163,972 patients) [19][35]. This estimation is done under the assumption that the presence of cataract and glaucoma are independent of each other, which is supported by existing evidence[36].
Glaucoma Cost Per Patient

The recommended visits to the doctor's office for glaucoma patients generally fall in the range of 2-4 visits annually [37]. While the number of visits for the most severe patients can be as high as 12 visits per year, these patients are rare and will not be included in the general model of analysis. As such, patients will be hypothetically divided into 3 categories: mild glaucoma/glaucoma suspect, intermediate glaucoma, and severe glaucoma. The assumed number of visits annually would be twice, three times, and four times for these patients respectively, as recommended by the American Optometric Association [37]. Depending on their clinical conditions and visit frequencies, each of the above mentioned categories will have a distinct assembly of visit types. Such assumption has to be made because to the best of our knowledge, there is no existing study that precisely depicts the distribution of visit types for each of glaucoma severity groups. With the implantation of WIT, all three categories of patients can potentially have their conditions monitored by only attending a single comprehensive annual exam.

Direct Savings

Based on its penetrance, a quantitative analysis will be performed on the direct saving of the WIT through visits reduction. In this above model, penetrance is defined as patients who are eligible for WIT implantation, who received the implant, and on whom the implant effectively reduced clinical visits. For each increment of 20% penetrance, direct saving per year, remaining payment per year, and saving percentage will be calculated. This analysis will be done for the mild, intermediate, and severe glaucoma.
patients separately, as they each have a different estimated visit frequencies. This also allows flexibility in the analysis model, as one can mix and match the three tables with separate penetrance to better simulate the actual patient distribution when it becomes available.

**Indirect Savings**

Due to the benefits of continuous monitoring, it is reasonable to hypothesize that the WIT can be used to prevent the glaucoma patients to progress. Indirect savings from preventing the worsening of the disease will also be analyzed quantitatively. This will be done by calculating the medical expenditure saved by preventing various percentage of patient from worsening to the next disease stage. Since there is no existing clinical trial studying the effect of WIT on glaucoma progress prevention, its effect will be analyzed for every 20% of progression prevented. Other types of savings that are unable to measure precisely will also be discussed on a qualitative basis.

**Cost of Device and Implantation**

The manufacturing and operational cost of the WIT will be obtained from its manufacturer and factored into the analysis as a cost of the device. The cost for implantation will be discussed for both potential methods. A short cost benefit analysis will also be performed on the impact of patients’ age when receiving the implant.
RESULTS

Current Visit Types and Cost

Table 1: Office Visits. Data from Quigley et al. are compiled and the frequency of visit, percentage of total visits, mean cost per visit and total cost are computed for each of the major visit types.

<table>
<thead>
<tr>
<th>Visit Code</th>
<th>Visit Type</th>
<th>Frequency</th>
<th>% of Total Visits</th>
<th>Cost/Visit</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>92004</td>
<td>New patient, comprehensive</td>
<td>7,240</td>
<td>2.40%</td>
<td>$84.83</td>
<td>$614,141</td>
</tr>
<tr>
<td>92012</td>
<td>Established, Intermediate</td>
<td>104,702</td>
<td>34.67%</td>
<td>$50.31</td>
<td>$5,267,407</td>
</tr>
<tr>
<td>92014</td>
<td>Established, Comprehensive</td>
<td>85,429</td>
<td>28.29%</td>
<td>$70.84</td>
<td>$6,052,191</td>
</tr>
<tr>
<td>99212</td>
<td>Established, Office Eval</td>
<td>23,493</td>
<td>7.78%</td>
<td>$26.26</td>
<td>$616,809</td>
</tr>
<tr>
<td>99213</td>
<td>Established, Office Eval</td>
<td>59,276</td>
<td>19.63%</td>
<td>$42.87</td>
<td>$2,541,155</td>
</tr>
<tr>
<td>99214</td>
<td>Established, Office Eval</td>
<td>17,849</td>
<td>5.91%</td>
<td>$63.69</td>
<td>$1,141,579</td>
</tr>
<tr>
<td>992141-45</td>
<td>Outpatient Consult - No longer in effect</td>
<td>4,030</td>
<td>1.33%</td>
<td>$123.99</td>
<td>$499,689</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>302,019</td>
<td>100.00%</td>
<td></td>
<td>$16,732,971</td>
</tr>
</tbody>
</table>

According to the data from Quigley et al.’s study on 5% Medicare population (1.38 million beneficiaries), 163,972 patients made at least one claim under the glaucoma categories[21]. These patients incurred a total of 302,019 visits billed under different visit codes, ranging from the brief IOP checkup (99212) to the more comprehensive examinations (92014). The most prominent visits types listed in Table 1 incurred a total annual cost of $16,732,971. If additional less prevalent visit types, such as “New patient, Intermediate”, are included, the total annual office visit cost would increase to
$17,341,588 [21]. Note however, this cost only includes the office visits. Among office visits, diagnostic tests, and surgical/laser procedures, office visits represent 46.3% of total spending[21]. Additional costs such as medications are not included in the study.

Among the listed visit types, the most common three types are 92012, 92014, and 99213. These visit types contribute to 37.1% of total costs. It is worth noting that visit types 99241-45 are no longer being used and thus should not be taken into further analysis.

As these data come from a patient pool of 5% of Medicare population, we can extrapolate the data to find the total number of visits and associated cost in all Medicare beneficiaries, providing that the original study is accurate. In the entire Medicare population, with an estimated total of 27.6 million patients, 3.2 million patients will make at least one claim under glaucoma, and will incur a total clinical visit cost of $346,831,766 annually.

**Eligible Patients**

A premise for the implantation of the device is that the patient must have already had or will have cataract surgery in the eye of implantation. Assuming that risk of having glaucoma and risk of developing cataract have no influence on each other [36], the prevalence of cataract in the national population should be the same as it is in the glaucoma population. According to the National Eye Institute, the overall prevalence of cataract in the US is 17.11%, and the older a patient becomes, the more likely he or she will develop cataract [35]. As such, potential eligible patients for the WIT in the 5%
Medicare population would be 17.11% of 163,972 patients, which represents 28,056 patients. Following the same assumption, approximately 561,120 patients would be eligible for WIT implantation in the entire Medicare population. However for the purpose of this analysis, the 28,056 eligible patients in 5% of Medicare beneficiaries will be used as population.

**Patients’ Visits**

To the best of our knowledge, both the visit frequencies and visit codes used vary greatly with each patient, thus making it nearly impossible to precisely apply the information in Table 1. While there are no existing data on the exact distribution of visit types according to glaucoma severity, estimation can be done according to the visit frequencies and mostly used visit codes.

Without the WIT, patients diagnosed with mild, intermediate or severe glaucoma are recommended to visit their physician two, three or four times respectively. We can then hypothesize that all the visits are billed under the most frequently used codes.
Table 2: Visit Code Frequency and Distribution According to Patients’ Conditions, for patients without WIT.

<table>
<thead>
<tr>
<th>Patient Status</th>
<th>Visit Codes</th>
<th>Annual Cost per Patient</th>
<th>Annual Saving after WIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild/Suspect</td>
<td>1x 92014 ($70.84) 1x 99213 ($42.87)</td>
<td>$113.71</td>
<td>$42.87</td>
</tr>
<tr>
<td>Intermediate</td>
<td>1x 92014 ($70.84) 1x 99213 ($42.87) 1x 99212 ($26.26)</td>
<td>$139.97</td>
<td>$69.13</td>
</tr>
<tr>
<td>Severe</td>
<td>1x 92014 ($70.84) 1x 92012 ($50.31) 1x 99213 ($42.87) 1x 99212 ($26.26)</td>
<td>$190.28</td>
<td>$119.44</td>
</tr>
</tbody>
</table>

According to current practitioners, each patient receive a comprehensive exam billed either under codes 92014 or 99214. In our analysis, the cost for 92014 ($70.84) will be utilized as it used at a much higher frequency than 99214. While mild patients receive another office evaluation annually, the intermediate patients require a more rigorous IOP monitoring, reflected by the addition brief 99212 ($26.26) visit. Severe patients are usually recommended to visit their physician 4 times yearly, and their visit types vary greatly. For our analysis, we assumed all severe patients get at least one comprehensive, two intermediate, and one brief visits per year. This tallies down to 113.71$, 139.97$ and 190.28$ annual office visit cost for mild, intermediate, and severe patients respectively.

After the implantation of WIT, patients would only need to visit their physician once every year if their conditions are stable and no additional interventions are required. In this case, patients would need to be billed under the comprehensive 92014 ($70.84) code, as this one visit is likely to include additional tests such as visual field and optic
nerve imaging. As such, all patients’ annual office visit costs would be reduced to 70.84$. The annual savings through visit reduction would be 42.87$, 69.13$ and 119.44$ for each of the mild, intermediate and severe glaucoma patients, respectively.

**Annual Glaucoma Costs**

As there is no existing data on the severity distribution of glaucoma patients, a model will be constructed to permit maximal flexibility. This model can be used to estimate the annual glaucoma cost if the severity distribution is determined by future studies. The model will calculate three distinct sets of glaucoma cost and direct savings induced by WIT, by assuming that 100% of 28,056 eligible patients belong to each of the three severity categories.

**Table 3:** Annual Glaucoma Care Cost for Patients Eligible for WIT. This is assuming either 100% mild glaucoma, 100% intermediate glaucoma or 100% severe glaucoma.

<table>
<thead>
<tr>
<th>Glaucoma Severity</th>
<th>Calculation</th>
<th>Total Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild/Suspect</td>
<td>28,056 patients x $113.71/year/patient</td>
<td>$3,190,247.76/year</td>
</tr>
<tr>
<td>Intermediate</td>
<td>28,056 patients x $139.97/year/patient</td>
<td>$3,926,998.32/year</td>
</tr>
<tr>
<td>Severe</td>
<td>28,056 patients x $190.28/year/patient</td>
<td>$5,338,495.68/year</td>
</tr>
</tbody>
</table>

**Annual Glaucoma Costs**

The direct saving by WIT from visit number reduction will then be analyzed with regard to possible penetrance in the eligible population. Three distinct tables will be created, for mild glaucoma, intermediate glaucoma, and severe glaucoma respectively. The effect of WIT’s penetrance will also be analyzed for each 20% increment in penetrance.
Table 4: Direct Saving – Mild/Suspect.

<table>
<thead>
<tr>
<th>WIT % penetrance</th>
<th>Number of Users</th>
<th>Direct Saving in $/year</th>
<th>Remaining Payments/year</th>
<th>Saving %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00%</td>
<td>0</td>
<td>$0.00</td>
<td>$3,190,247.76</td>
<td>0.00%</td>
</tr>
<tr>
<td>20.00%</td>
<td>5,611</td>
<td>$240,543.57</td>
<td>$2,949,704.19</td>
<td>7.54%</td>
</tr>
<tr>
<td>40.00%</td>
<td>11,222</td>
<td>$481,087.14</td>
<td>$2,709,160.62</td>
<td>15.08%</td>
</tr>
<tr>
<td>60.00%</td>
<td>16,834</td>
<td>$721,673.58</td>
<td>$2,468,574.18</td>
<td>22.62%</td>
</tr>
<tr>
<td>80.00%</td>
<td>22,445</td>
<td>$962,217.15</td>
<td>$2,228,030.61</td>
<td>30.16%</td>
</tr>
<tr>
<td>100.00%</td>
<td>28,056</td>
<td>$1,202,760.72</td>
<td>$1,987,487.04</td>
<td>37.70%</td>
</tr>
</tbody>
</table>

Table 5: Direct Saving – Intermediate.

<table>
<thead>
<tr>
<th>WIT % penetrance</th>
<th>Number of Users</th>
<th>Direct Saving in $/year</th>
<th>Remaining Payments/year</th>
<th>Saving %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00%</td>
<td>0</td>
<td>$0.00</td>
<td>$3,926,998.32</td>
<td>0.00%</td>
</tr>
<tr>
<td>20.00%</td>
<td>5,611</td>
<td>$387,888.43</td>
<td>$3,539,109.89</td>
<td>9.88%</td>
</tr>
<tr>
<td>40.00%</td>
<td>11,222</td>
<td>$775,776.86</td>
<td>$3,151,221.46</td>
<td>19.75%</td>
</tr>
<tr>
<td>60.00%</td>
<td>16,834</td>
<td>$1,163,734.42</td>
<td>$2,763,263.90</td>
<td>29.63%</td>
</tr>
<tr>
<td>80.00%</td>
<td>22,445</td>
<td>$1,551,622.85</td>
<td>$2,375,375.47</td>
<td>39.51%</td>
</tr>
<tr>
<td>100.00%</td>
<td>28,056</td>
<td>$1,939,511.28</td>
<td>$1,987,487.04</td>
<td>49.39%</td>
</tr>
</tbody>
</table>

Table 6: Direct Saving – Severe.

<table>
<thead>
<tr>
<th>WIT % penetrance</th>
<th>Number of Users</th>
<th>Direct Saving in $/year</th>
<th>Remaining Payments/year</th>
<th>Saving %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00%</td>
<td>0</td>
<td>$0.00</td>
<td>$5,338,495.68</td>
<td>0.00%</td>
</tr>
<tr>
<td>20.00%</td>
<td>5,611</td>
<td>$670,177.84</td>
<td>$4,668,317.84</td>
<td>12.55%</td>
</tr>
<tr>
<td>40.00%</td>
<td>11,222</td>
<td>$1,340,355.68</td>
<td>$3,998,140.00</td>
<td>25.11%</td>
</tr>
<tr>
<td>60.00%</td>
<td>16,834</td>
<td>$2,010,652.96</td>
<td>$3,327,842.72</td>
<td>37.66%</td>
</tr>
<tr>
<td>80.00%</td>
<td>22,445</td>
<td>$2,680,830.80</td>
<td>$2,657,664.88</td>
<td>50.22%</td>
</tr>
<tr>
<td>100.00%</td>
<td>28,056</td>
<td>$3,351,008.64</td>
<td>$1,987,487.04</td>
<td>62.77%</td>
</tr>
</tbody>
</table>
**Indirect Savings**

Aside from savings achieved from visit reduction, it is reasonable to belief that WIT will also contribute to indirect savings such as increased medication compliance and better monitoring of glaucoma progression. These factors all lead to a probable outcome of preventing glaucoma patients to progress in disease stage. However, as the WIT is not yet approved in the United States, its effect on glaucoma stage stabilization will only be analyzed on a theoretical basis.

Data from Lee et al.’s study have been extracted to build the analysis model. Increase in overall glaucoma cost, including office visits, medication, tests, and surgeries, have been calculated for the eligible WIT recipients.

**Table 7:** Increase in Glaucoma Care Cost Due to Disease Progression. Please refer to Figure 4 for a more visual representation.

<table>
<thead>
<tr>
<th>From Stage…to Stage…</th>
<th>Increased cost/patient/year</th>
<th>Total increase in cost for 28,056 eligible WIT patients/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 1</td>
<td>$700.00</td>
<td>$19,639,200</td>
</tr>
<tr>
<td>1 to 2</td>
<td>$194.00</td>
<td>$5,442,864</td>
</tr>
<tr>
<td>2 to 3</td>
<td>$135.00</td>
<td>$3,787,560</td>
</tr>
<tr>
<td>3 to 4</td>
<td>$508.00</td>
<td>$14,252,448</td>
</tr>
<tr>
<td>4 to 5</td>
<td>$65.00</td>
<td>$1,823,640</td>
</tr>
</tbody>
</table>

Since the glaucoma stage stabilization potential of WIT has not been experimentally determined yet, we will construct a flexible model. This model takes into account the savings in different glaucoma stages and the potential percentage of prevention, ranging from 0% to 100%. The increase in cost as glaucoma progresses will equal the amount of money saved by preventing this stage progression.
Table 8: Reduction in Glaucoma Care Cost by Preventing Disease Progression in 28,056 Eligible WIT Patients.

<table>
<thead>
<tr>
<th>Percentage of Progression Prevented</th>
<th>Cost Saved Annually by Preventing the Progression from…</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stage 0 to 1</td>
</tr>
<tr>
<td>0%</td>
<td>$0</td>
</tr>
<tr>
<td>20%</td>
<td>$3,927,840</td>
</tr>
<tr>
<td>40%</td>
<td>$7,855,680</td>
</tr>
<tr>
<td>60%</td>
<td>$11,783,520</td>
</tr>
<tr>
<td>80%</td>
<td>$15,711,360</td>
</tr>
<tr>
<td>100%</td>
<td>$19,639,200</td>
</tr>
</tbody>
</table>

Once the percentage of progression prevention is specified by future studies, this table can be used to simulate the reduction in glaucoma care cost, as it takes into account the possibility that the WIT will have different effects on different stages of glaucoma.

Cost of Device and Implantation

Even though the WIT promises both direct and indirect savings in glaucoma care expenditures, the implant does come at a price. According to the manufacturers of the device in Germany, the WIT will likely cost about $2,500 while introducing it to the public. After the market stabilizes, the device’s price will likely be settled around $1,500 each.

There are two methods of implantation available for the device. The first one is the same as what Melki et al. used in the first clinical trial of the WIT. The device will be
placed into the ciliary sulcus space concurrently with the extraction of cataract. While the implantation procedure is unlikely to significantly prolong the cataract surgery’s duration, this does incur additional $500 surgeon’s fee for each implantation. This value is an estimation from procedures with similar length and difficulty. Since the procedure is done concurrently with cataract surgery at the same place, no additional facility fee will be incurred. As such, patients undergoing this method for both eyes would have to pay $3000 for the WIT and another $1000 for the surgeons’ fee, tallying to a total of $4000 for both eyes.

The second method of implantation is intended for the patients who already have had cataract surgery prior of being diagnosed with glaucoma. For such patients, a standalone procedure will be needed. According to the manufacturers, this implantation is a 15 minute long ambulatory procedure similar to cataract surgery. Local surgery centers confirmed that such procedures usually incur a facility fee of around $1500 for Medicare patients. In addition to the cost of WIT and surgeon’s fee, a standalone procedure for both eyes will be around $5500 for both eyes.

The choice between the two methods relies on whether the patients previously had a cataract surgery. The nationwide prevalence of cataract surgery in Medicare beneficiaries is 6.18%. As such, assuming the patients in this study have the same probability of getting cataract surgery as the national average, 6.18% of the participating patients will adopt the standalone method.
**Hypothetical Simulation**

In order to demonstrate the methodology of the model, we can create a hypothetical situation and fit it into this model. Suppose that among the 28,056 eligible WIT patients from the 5% of Medicare populations, 25% have mild glaucoma, 50% have intermediate glaucoma, and 25% have severe glaucoma. This means that there will be 7,014 patients with mild glaucoma, 14,028 patients with intermediate glaucoma, and 7,014 patients with severe glaucoma. Based on table 3, the cost for clinical visits for these patients will be $4,095,685.

Considering the WIT’s increased benefit on the severe patients, we can suppose that the WIT’s penetrance in mild, intermediate and severe patients are 20%, 40% and 60% respectively. This would mean that 1,403 mild patient, 5,611 intermediate patients, and 4,208 severe patients will receive the WIT implant, a total of 11,222 patients.

Using data from table 4, 5, and 6, we can calculate the glaucoma care cost saved through direct visit reduction. The annual cost reduction for mild, intermediate and severe glaucoma patients would be $60,135.89, $387,888.43, and $503,663.24 respectively. This tallies down to an annual saving of $950,687.56 for 5% of the Medicare population, representing a 23.21% decrease in annual costs related to office visits.

The progression prevention effect of WIT is likely to have a higher level of protection on the earlier stages of glaucoma, as the symptoms are usually mild and the disease often progresses unnoticed. In the later stages of glaucoma, the disease will usually have been identified and monitored by the physicians. In this case, it is the
availability of medications, surgeries and medical professionals that become the main determining factors of progression prevention.

Following this logic, a reasonable hypothesis of overall cost reduction due to progression prevention would be the following scenario: the WIT prevents 60% of stage 0 to stage 1 progression, 40% of stage 1 to 2, 20% of 2 to 3, and 0% of 3 to 5. Using table 7, the total annual cost saved from the 11,222 patients who received the implant would be $5,887,061$, which represents 32.75% of the cost inflicted if these patients were to progress to stage 5.

The cost of device manufacturing and implantation should also be considered and factored into the analysis. Out of the 11,222 patients who received the implant, 694 patients (6.18%) will receive it through the stand-alone procedure. The total cost for device and implantation will be $45,929,000. This would in turn mean that the cost of device and implantation will be recovered by the annual saving if the device is allowed to work for around 7 years. Under the current scenario, the usage of WIT after 7 years would incur a net saving for the care of glaucoma patients.

With the addition of more precise data in the future, this estimation would be made better, and serve as a more accurate indicator of the WIT’s efficiency in both direct and indirect cost reduction.
DISCUSSION

Glaucoma is a serious disease currently affecting the quality of life of millions of Americans, and inflicts a heavy financial burden on the US healthcare system. The monitoring of glaucoma progression, as well as its prevention, heavily depends on reliable, continuous and long-term monitoring and management of the IOP [38]. While the Goldman applanation tonometry is the current gold standard in term of precision, its complicated usage and low availability at home settings make it unrealistic to be used as a continued monitoring device. Usage of other portable devices such as Tono-pen often implies compromising the precision of the measurements [32]. In addition, these measurements provide only snapshots of the continuously changing IOP, which is unlikely to represent the IOP that the patient is exposed to most of the time.

The WIT will allow physicians to better monitor the progression of glaucoma through a continuous, long distance, accurate and facilitated method of IOP measurement. It is also possible to set a threshold limit of 21mmHg whereby if the patient’s pressure exceeds this value, the device automatically relays this finding to the responsible physician. This would in turn allow earlier diagnosis or treatments, yielding improved therapeutic outcomes. In addition to its clinical benefits, the WIT is likely to lighten the financial burden inflicted by the disease by reducing office visits and preventing glaucoma progression.

Our analysis has attempted to estimate the reduction in glaucoma care cost after the introduction of WIT. However, since the device is yet to be approved in the US, many
of the fundamental data for our analysis are still to be researched, making it impossible to achieve a specific calculation on the cost reduction by WIT. As a result, we have constructed a model that is able to take into account multiple factors and demonstrated its usage via a hypothetical situation. Nevertheless, we are forced to make assumptions and educated estimations in several steps of our model construction, decreasing its accuracy of prediction. In order for the model to be applied to the United States, further studies must be done to acquire the missing information. The missing information includes: the distribution of glaucoma patients’ severity, the exact distribution of visit numbers and types according to glaucoma severity, the glaucoma progression prevention potential of WIT, as well as the exact cost of implantation of the WIT. The data source that this study mainly depends on also dates from 2009. The epidemiology and economics have likely changed since then, making the data in our model an imperfect estimation of current situation. Once this information is acquired and renewed, the model can be reconstructed using the recent factual data, making it a truly flexible predictor for the WIT’s financial outlook. The usage of the model can even be expanded to assess the economic impact of other novel medical devices given the necessary information.

Nevertheless, the WIT does show promise in alleviating the heavy financial burden of glaucoma. As seen in our hypothetical calculation, the WIT may achieve a 23.21% reduction in clinic visit costs, as well as a 32.75% reduction in cost associated with glaucoma severity progression. Note that the extremely severe patients who often require up to 12 visits annually are not included in the analysis. However, it is precisely these patients who will benefit the most from the device, as it is observed that the more
severe the glaucoma is, the more visits we can save with the introduction of WIT. As such, it is likely that the actual saving is higher than what is predicted by the model.

In addition to the quantifiable savings such as reduced clinical visits and disease progression, the WIT also grants additional savings including increased medication compliance, reduced loss of productivity, reduced comorbidity and reduced travel for care. These factors will be especially pronounced if the WIT is introduced to rural and medically underserved areas, as people may have to travel for long distances just to get their IOP checked by the physicians.

The simulation also shows that it takes a few years to recover the cost of manufacturing and implanting the device. As such, physicians should take into consideration the patient’s age and life expectancy before recommending the implantation. However, determining the precise age that makes the device most cost effective requires the use of the above mentioned missing information.
CONCLUSION

In conclusion, the WIT demonstrated promising outcomes both in term of improving the care of glaucoma patients and alleviating the economic burden imposed on the healthcare system. Future studies are needed to complete the information required to construct a model that can precisely predict the economic outcome of the device in the U.S. Medicare population. Additional clinical studies are also needed in order to screen for possible complications and to monitor the device’s performance after implantation.
REFERENCES


CURRICULUM VITAE

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Education

Boston University M.Sc in MedicaScience 2013-present
McGill University B.Sc Major in Anatomy & Cell Biology 2010-2013
Marianopolis College Health Science Program 2008-2010
Ecole Secondaire Saint-Luc

- Secondaire 2-5 2004-2008
- Classe d’Accueil 2003-2004

Work Experience

Intern, Ophthalmic Technician, Boston Laser 2014-present

- Interviewing patients to obtain relevant medical history
- Conducting diagnostic tests to gather information for the physicians
- Assisting in LASIK/LASEK surgeries and other minor procedures
- Working on individual research project under the supervision of Dr. Samir Melki, M.D., Ph.D

Alumni Multidisciplinary Tutor, Marianopolis College 2011-2013

- Ensuring the success of students having difficulty in Biology, Organic Chemistry and General Chemistry

Service to Community

Volunteer, Boston Medical Center Rehabilitation Department 2014-present

- Assisted the physiotherapists

Medic, Emergency Medical Service (EMS) of City of Cote-Saint-Luc 2011-2012

- Responded to 911 calls in sector
- Assisted the paramedics with patient care and transport
- Ensured public wellbeing during festivals and community events

Medic, Marianopolis First Aid Team 2008-2010
- Offered first aid services to students and staffs

**Volunteer, Richardson Hospital** 2007-2010
- Assisted the patients with their meals physiotherapy exercises

**Research Experiences**

**Research Assistant, Colonoscopy Complication Screening** 2012-2013
- Led by Dr. Sewitch of the McGill University Health Center Research Institute, interviewing patients to screen for post operational complications.

**Research Assistant, Quality of Life Survey** 2011-2012
- Led by Dr. Barkun of the Royal Victoria Hospital, assessing the wellbeing of post-surgical cancer patients in order to determine the need of exercising surgery for similar causes.

**Extracurricular Activities**

**VP Finance, Friends of Médecins Sans Frontières (MSF) at McGill** 2012-2013
- Managing the funding flow of the club, assisting with event organizations
- Raising public awareness of developing world health
- Organizing speaker events featuring MSF expatriate workers sharing their experience

**Musician, Marianopolis Classical Music Club** 2010-2013
- Participating in charity concerts in various hospitals and rehabilitation centers

**Founder, Executive, Marianopolis Classical Music Club** 2009-2010
- Cooperated with external organizations to launch concert
- Coordinated resources and meetings
- Scheduled auditions and concert programs

**Award and Honours**

**Silver Medal Award from the Royal Conservatory of Music** 2008
- Champion of the province for the grade

**The Hypatie math contest held by Waterloo University** 2008
- Awarded the Etalon d’Argent

**The Fermat math contest held by Waterloo University** 2008
- Classed top 10%, which allowed me to participate in the Hypatie contest