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April 6th, 2021

Dr. Craig Scratchley & Dr. Shervin Jannesar School of Engineering Science Simon Fraser University 8888 University Dr. Burnaby, BC V5A 1S6

Re: ENSC405W proposal document for livEn's Retina Imager and Laser Beamer, RILab.

Dear Dr. Craig Scratchley & Dr. Shervin Jannesar,

In the attached document, please find our project proposal for the RILab as prepared by livEn's Puru Chaudhury, Jiung Choi, Eduard Durech, Vincent Le, Kyle Smolko, and Daria Zhevachevska.

The RILab's purpose is to safely and efficiently semi-automate laser eye therapy dealing with abnormal and diseased tissue in the eye. Treatments include Pan Retinal Photocoagulation, PhotoDynamic Therapy, Proliferative Diabetic Retinopathy, and more. The nature of laser eye therapy allows the RILab to be applicable through many of these treatments.

The design of the RILab will feature a fundus camera, an optical scanning mirror, and a medical-grade laser where we will be viewing the image of the retina through our proprietary GUI with further proprietary software to semi-automate the process.

The proposed project will have a plethora of benefits including a streamlined procedure leading to successful therapies and healthy eyes. Risks of the project will be discussed and analyzed to avoid, mitigate, and contain. This document will also analyze the target market and competition of the RILab and, lastly, we will outline the project's timeline with appropriate milestones, costs, and funding.

If you have any questions regarding the attached proposal, please contact our Chief Communications Officer, Vincent Le, at 778-881-6800 or at <u>byle@sfu.ca</u>.

Sincerely,

Eduard Durech Chief Executive Officer livEn

Enclosed: Project Proposal for the Retina Imager and Laser Beamer (RILab)



Proposal

Retina Imager and Laser Beamer RILab Company 5

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livEn Partners:

Daria Zhevachevska Puru Chaudhary Eduard Durech Kyle Smolko Vincent Le Jiung Choi

Contact: Vincent Le - bvle@sfu.ca

Submitted for approval to:

Craig Scratchley & Shervin Jannesar Chris Hynes & Michael Hegedus School of Engineering Science Simon Fraser University

> Issue Date: April 6th, 2021



Executive Summary

The Overview

Our company, livEn, is a biomedical engineering company bridging the ophthalmology field and engineering field together to design state of the art laser eye therapy systems.

The Problem

- Lack of useful training options for laser eye therapies.[1]
- Shortage of ophthalmologists.[2]
- Manual processes require cognitive safety checks by the ophthalmologist which may leave a margin for user error.
- Growing number of patients necessitating laser eye therapies.[3]

The Solution

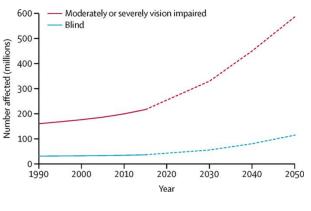
• The Retina Imager and Laser Beamer (RILab) is a semi-automated all-in-one system to safely, easily, and efficiently perform laser eye therapies.

The Market

- Ophthalmologists
- Medical Residency Students

The Benefits

- An efficient device that can speed up laser eye therapies and decrease hands-on tasks for ophthalmologists.
- A useful training option for medical residency students.
- Software that checks and confirms the appropriate safety checks and protocols.



Expected growth of vision impairment and blindness [3]

The Development to Success

- Iterative Design: Identify & modify, design, construct, and evaluate
- Partnership with Dr. Zaid Mammo at the Vancouver General Hospital.
- Proof-of-Concept completed by April 23rd.
- Beta-Phase completed by the end of August.

The Funding

• Biomedical Optics Research Group, Stakeholder - Dr. Marinko V. Sarunic



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1 livEn

We were formed by a group of two biomedical engineers and four computer engineers who are looking to make an impact on the world and improve the well-being of humans. Our name is derived off the root words "**live**" and "**en**gineering", combining to form **livEn**. We are a group of individuals who are interested in bridging together our engineering sector with the medical sector for healthy lives. We are currently focused on the ophthalmology field which contributes to our company name and logo. The cross-shaped logo seen in Figure 1.1 represents the medical sector whereas the array of circles represents the dotted laser pattern seen through many laser eye surgeries. The capital E in "En" represents our roots as engineering students while the lowercase I in "liv" serves as an aesthetic to distinguish our company name.



Figure 1.1: Our branding and logo



Eduard Durech CEO *Image processing, machine learning, control algorithm* edurech@sfu.ca

Eduard is a 4th-year Biomedical Engineering student with two and a half years of academic research experience in image/data processing and machine learning. He is interested in medical applications of machine learning and data science. Eduard will be developing the image processing and machine learning pipelines for detection and segmentation of diseased and avoidant tissue as well as the tracking algorithm.



Dasha Zhevachevska CDO *UI/UX, clinical restraints* <u>dzhevach@sfu.ca</u>

Dasha is a 5th-year Biomedical Engineering student with an interest in medical imaging. She has done volunteering and worked at Biomedical Optics Research Group with a focus in optical imaging; in addition, her previous experience includes quality assurance of medical imaging software at Change Healthcare. Dasha will be implementing the RILab's graphical user interface and its system control algorithm.





Vincent Le CCO *Documentation, Administration, UI/UX Evaluation* <u>bvle@sfu.ca</u>

Vincent is a 5th-year Computer Engineering student with a passion for technology and business in the world. His experience in Information Technology at the BC Cancer Research Centre, Simon Fraser University, and the University of British Columbia gives him the necessary interpersonal skills. His responsibilities are administration, research, documentation, and user interface testing.



Puru Chaudhary CTPO *Hardware Integration, Electronics & CAD design* <u>pchaudha@sfu.ca</u>

Puru is a 5th-year Computer Engineering student who has experience as a firmware engineer at Netint Technologies and as a software developer for SFU FAS. He is interested in machine learning and cryptography. Puru will be responsible for hardware and software integration along with product design for the RILab.



Jiung Choi CRO *Optical design* jiungc@sfu.ca

Jiung is a 5th-year Computer Engineering student with an interest in VLSI design. He has worked at Gatekeeper Systems as a QA analyst in the company's software, IP camera, and DVR; in addition, he has project experience creating a full-stack web application. Jiung will be in charge of the RILab's optical design.



Kyle Smolko CFO *Hardware Integration, Firmware Development* <u>ksmolko@sfu.ca</u>

Kyle is a 4th-year Computer Engineering student with an interest in embedded and real-time systems. His previous work experience includes co-ops working as a Firmware Developer for Blackberry Ltd., and a Systems Engineer for Intel of Canada Ltd. Kyle will be responsible for implementing the control firmware for the RILab.



2 Introduction

2.1 Background

Laser eye therapy is a popular treatment option to correct refractive eye errors and other abnormal developments that can lead to difficulties with sight and, in extreme cases, blindness.[4] These therapies include, but are not limited to, Pan Retinal Photocoagulation (PRP) and PhotoDynamic Therapy (PDT). PRP is most known for reducing the risk of vision loss by 50% to those affected with proliferative diabetic retinopathy (PDR).[5] PDT is an older treatment dating back to the 2000s where doctors would use a laser to activate an applied photosensitizing agent which would collect in abnormal blood vessels in the eye.[6] Figure 2.1.1 shows an example of PRP therapy after a session of laser therapy for correction.

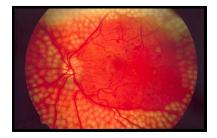


Figure 2.1.1: Fundus image with PRP therapy (white dots created by laser burns) [7]

These therapies are currently done manually by ophthalmologists and we, along with Professor Dr. Marinko Sarunic and Dr. Zaid Mammo, have identified that a semi-automated system would be needed and advantageous. The current procedure involves ophthalmologists using either slit lamps, as seen in Figure 2.1.2, or headlamps along with a laser attached coaxially,[7] The current procedure protocols are lengthy and require each exposure to be manually positioned and timed, with tens of such exposures being completed per procedure. The field is also experiencing a shortage of these specialists as per [2] and our goal is to streamline and ameliorate their workload to cover for this shortage.







2.2 Document Scope

This document begins by covering the project scope of the RILab in Section 2. Section 3 will describe the target market of the RILab and its competition. Sections 4 and 5 will highlight the risks and benefits that our system provides to our users. Following, this proposal will detail the major processes and milestones throughout the next couple of months straight to the end of our capstone term in Section 6. Lastly, we will discuss the costs and funding needed and provided for the project in Section 7.

2.3 Scope

Introducing RILab

This project and device will make laser eye therapy procedures easier to perform as time will be freed for ophthalmologists to focus on more hands-on procedures where they are most needed. The system proposed in this document will also further enable more users, specifically medical residency students.[1]

This product includes hardware components that will support the clinician with a guaranteed increase of safety and efficiency as compared to current systems. We are integrating a fundus camera, a high-powered laser, and an optical scanning mirror controlled by our software. The control system does not consider elements such as a mounted contact lens to keep the patient's eyes open, and head/chin rests to keep the motion of their head still. Figure 2.3.1 features the system as a whole.

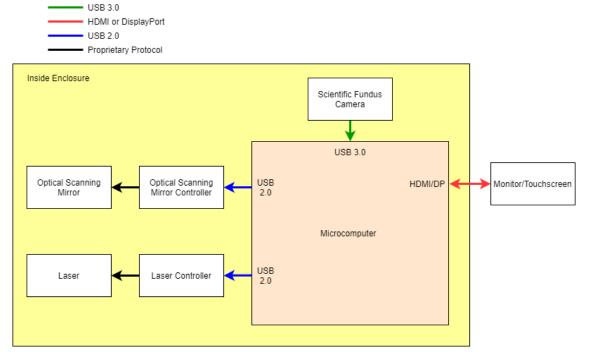


Figure 2.3.1: High-Level System Block Diagram



Automating the Procedure

The RILab is also an algorithmic design project used to determine where it is safe and not safe to fire a laser onto a human retina. We are developing novel processing techniques to detect diseased and avoidant tissue and auto-populate the therapy patterns while tracking the eye for movement. Imaging is done via the fundus retinal camera while processing is done on a standalone board. The auto-segmented regions may be further refined and confirmed by a clinician to ensure safety. The appropriate regions in the patient's retina can then be targeted by the laser using coordinates derived from our algorithm. These coordinates guide the laser beam via the optical scanning mirror. With the highest priority on safety, the algorithm will also decide when it is safe to fire the laser and allow the clinician to monitor and override the procedure at any time. During the procedure, the laser titrates its power from low to high depending on the degree of burn needed. Figure 2.3.2 is a short block diagram that summarizes the process.



Figure 2.3.2: Block Diagram of the RILab's Procedure

Inside RILab

Our software is controlled with a microcomputer while the rest of the equipment is set up in a coaxial position to an eye as seen in Figure 2.3.3. The system is stationed on a stable optical breadboard to ensure safety.

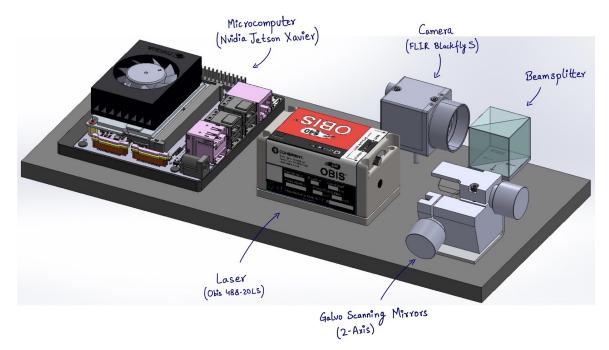


Figure 2.3.3: The inner system of the RILab



3 Market Analysis

3.1 Target Canadian Market

5.5 million Canadians live with vision threatening eye conditions and this number is predicted to only grow higher following the trend of an aging Canadian population as per the BC Medical Journal.[9] This large number is indicative of the growth and need of this market. This growing trend goes along with the trend of an aging Canadian ophthalmologist population as per Figure 3.1.1.[10]

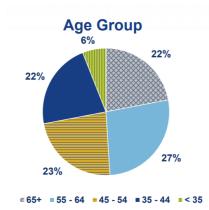


Figure 3.1.1: Ophthalmologists age trend [10]

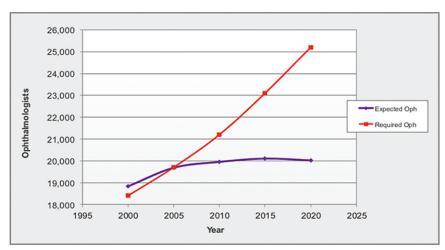
This denotes a growing market where the number of ophthalmologists just does not match the need as can be seen in Figure 3.1.2 with data obtained by the Canadian Medical Association.[10]

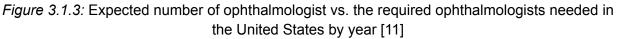
Province/Territory	Physicians	Phys/100k pop'n
Newfoundland/Labrador	15	2.9
Prince Edward Island	5	3.2
Nova Scotia	41	4.2
New Brunswick	25	3.2
Quebec	377	4.5
Ontario	427	3.0
Manitoba	30	2.2
Saskatchewan	22	1.9
Alberta	111	2.6
British Columbia	192	3.8
Territories	1	0.8
CANADA	1246	3.3

Figure 3.1.2: Total number & number/100000 population by province, 2019 [10]



The number of ophthalmologists is far too few, with more than a 20% deficit in required Opthamologists for 2020 in the United States as shown in Figure 3.1.3.[11] Canada is seeing the same shortage, with a significant 45% of ophthalmologists feeling that they are overworked as shown in Figure 3.1.4.[10] This encroaching Achilles' heel in our health system motivates our mission to ameliorate the current procedures of an ophthalmologist's workload and also opens a large market of opthamologists to systems which can streamline and speed up their procedures.





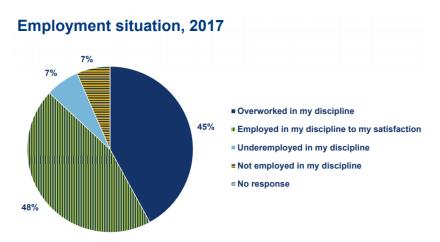
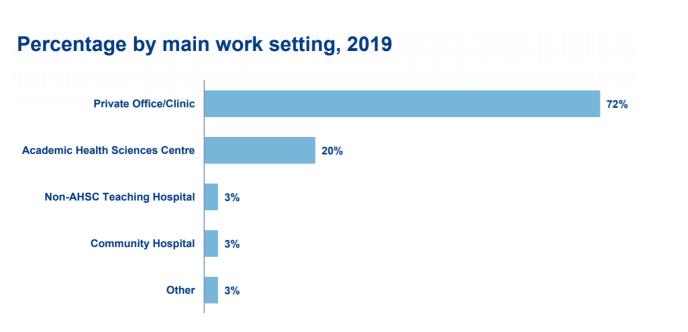


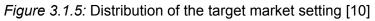
Figure 3.1.4: Ophthalmologist satisfaction with their work hours and workload [10]

Our target market are these ophthalmologists and their setting of occupation. Data from The Canadian Medical Association [10] shows that our primary target will be private offices and clinics, as per Figure 3.1.5. This is epitomized by our partnership with Dr. Zaid Mammo as his practice is based on his own office and clinic at the Vancouver General Hospital.[1]



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3.2 Market Forecasts

The ophthalmic laser market will continue to grow in the coming years.[12] In 2016, the market was sitting at 970.2 million USD. At a compound annual growth rate of 5.1%, a project increase of up to 1,245.4 million USD is expected to be reached by this year, 2021. This market share is mostly accounted for by North America with Asia-Pacific rising up in the next few years in terms of compound annual growth rate. This rise in growth can be attributed to a high prevalence of chronic disorders, increasing regulatory approval for the prevention of vision impairment, the introduction of initiatives for the prevention of blindness, treatment projects for various ophthalmic disorders, and the rising aging population.

3.3 Competition

The companies below feature our main competition. Two registered products, the PAttern-SCAnning Laser and the NAVIgated LASer stand out as direct competitors highlighted in SpringerLink's published article, New Laser Technologies for Diabetic Retinopathy.[13]



Zeiss is the largest company that pioneers in scientific optics and optoelectronics. Their work includes research in ophthalmic devices, their production, and consumerism in setup and function. They are an international company headquartered in Germany with representation in over 50 countries. 812 million EUR are put into their research and they had a fiscal year revenue of 6.297 million EUR in 2019/2020.[14]







Topcon has filed a patent for semi-automated ophthalmic photocoagulation methods and apparatuses.[15] Their research has led them to create the PASCAL, which would be a direct competitor to the RILab. Topcon is a global leader in manufacturing ophthalmic lasers with a research base in Stanford University.[16]

OD-OS is a company that co-invented the NAVILAS.[17] The NAVILAS is a registered trademark for OD-OS and they continue to use it as a base to advance in ophthalmic therapy innovations. They are a German-American based team with solid investors as well as a recognized ISO 13485 certified medical device company.



ellex.

Lumenis' business is one that expands through the vast range of medical technology. They have been known to revolutionize currently medical treatments which is what our company is currently aiming to do. They have been a leader in ophthalmic laser technologies and renowned for keeping an industry gold standard.[18]

Ellex is an international company with headquarters across four countries that distributes globally to hundreds of countries. Since 1985, they have made it their mission to address the treatment needs of the visually impaired through their OEM approved ophthalmic laser technologies. Ellex claims to be growing and meeting the needs of today's ophthalmologists.[19]



4 Risks

Laser eye therapies come with the innate risks that all ophthalmologists must highlight with their patients. As such, our product, stakeholders, and users must be aware and review these risks as well. These risks highlighted by [20] can include:

- Mild loss of central vision
- Reduced night vision
- Decreased ability to focus
- Mild loss of peripheral vision

Rare complications include [20]:

- Vitreous hemorrhage
- Traction retinal detachment
- Accidental laser burn of the fovea

Additional side effects as detailed by [21] include:

- Pain from laser burns
- Development or worsening of macular edema
- Loss of colour vision
- Reduction in contrast sensitivity
- Choroidal complications

These risks are very real but do have a low likelihood to be severe. Minor side-effects will have a higher likelihood but the path of not choosing laser eye therapies will increase the risk of major detrimental eye effects more.

Our product must also consider its own risks to increasing these effects and injuries detailed in table 4.1.

Inaccurate segmentation of retina blood vessels	
Likelihood of Risk	Low
Impact of Risk	High
Avoidance of Risk	Thorough testing with retinal images.
Mitigation of Risk	Research and gather more data to train a more accurate model. Adjust model parameters when training.
Containment of Risk	Manual checks by the clinician. Manual segmentation by the clinician.
Imprecise retina region tracking	



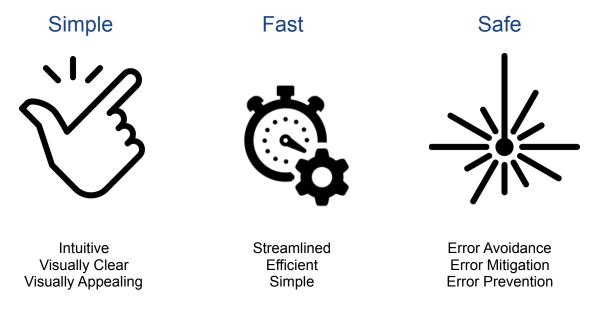
Low		
High		
Research upgrades on components.		
Research and gather more data to train a more accurate model. Adjust model parameters when training.		
Remember to manually place a mounted contact lens to directly align the camera with the pupil if necessary.		
Imprecise and inaccurate laser control and eye damage		
Low		
High		
Rigorous testing of laser timing and power thresholds to minimize likelihood of this ever occurring.		
Include confirmation pop-ups to review settings. Test processes at a lower power before the actual procedure is done.		
Timed laser cut-off to minimize. Emergency stop button.		

Table 4.1: Risks Identification and Risk Management



5 Benefits

The benefits of the RILab are three-fold:



Ease of use will be guaranteed such that an ophthalmologist can intuitively learn and move through their laser eye therapy procedures. Usability is important and our system will feature aesthetic designs that are pleasing to look at. This benefit further extends the capability of residency medical students to perform the laser eye therapies.

Efficiency is guaranteed to speed up the laser eye therapy procedure for ophthalmologists. This will provide them more time to handle other tasks, take appropriate breaks, and reduce stress. Our streamlined process will epitomize simplicity as compared to current processes.

Safety will be a guarantee. Our system benefits from automated safety checks and manual confirmations. Risk avoidance, mitigation, and containment are considered throughout all phases of the system to minimize and prevent any risks and errors. The repeatability and consistency of automation also mitigates human-error.

These three points will lead to better and more successful laser eye therapies. Risks of eye damage will be lessened, leading to further improvement in patient satisfaction and restoring a core ability for them to experience this world - through sight.



6 Development Plan

6.1 Timeline

Our development plan is listed in GANTT charts below in Figures 6.1.1 and 6.1.2. This schedule is made to hit all of our milestones as marked by the blue diamonds. This project projects an eight month plan that moves from brainstorming to the proof-of-concept in 4 months, and the details of the beta phase product in the last four months.

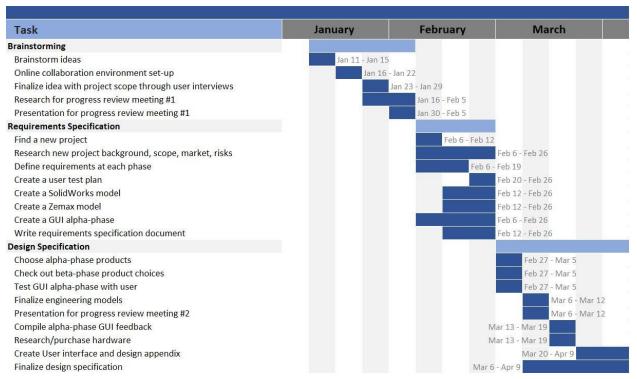


Figure 6.1.1: GANTT Chart of the RILab's Development from brainstorming to the design specification



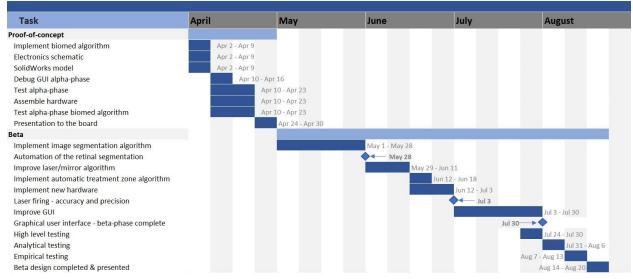


Figure 6.1.2: GANTT Chart of the RILab's Development from the proof-of-concept to the beta

6.2 Milestones

6.2.1 Automation of the retinal segmentation – skeletonization, treatment & non-treatment zones

This milestone is important to the efficiency of the RILab. This automation will speed up the time used by a clinician and ensure safety with the non-treatment zones. Manual confirmation is still needed to go forward with the procedure.

6.2.2 Laser/Mirror Algorithm – accuracy and precision

This milestone is important to the safety of the RILab. Our medical grade laser will be controllable within nanometer precision in order to perform laser eye therapies in the correct location. Laser power will also need to be titrated in order to properly perform the procedures.

6.2.3 Graphical user interface – beta-phase complete

The beta-phase graphical user interface will include all functions needed for a typical laser eye therapy. These additional features include laser power titration, laser wavelength/colour, laser firing intervals, laser patterning, and a laser testing process.



7 Finances

7.1 Cost Analysis

Table 7.1.1 highlights the cost estimate of the RILab. As most parts are purchased from the US, prices are all in US dollars.

Part	Cost Per Unit (USD)	Quantity	Total Cost (USD)
Blackfly S USB3 Model: BFS-U3-16S2C-CS: 1.6 MP, 226 FPS, Sony IMX287, Color	\$335	1	\$335
Tamron 1/2.7" 3MP CS-Mount 2.7-13mm f/1.4 Vari-Focal Lens	\$54.94	1	\$54.94
Volk 20D Lens	\$359	1	\$359
OBIS 488nm LS 20mW Laser System	\$5,985	1	\$5,985
QS7XY-AG - Dual-Axis, Ø7 mm Beam Galvo System	\$3,880	1	\$3,880
NVidia Jetson Xavier NX	\$399	1	\$399
AC254-060-B Lens	\$94.42	4	\$377.68
AC508-075-A Lens	\$128.77	1	\$128.77
DMLP550R Beamsplitter	\$254.30	1	\$254.30
3D Printed Casing	\$200	1	\$200

Table 7.1.1: Estimated costs of the RILab

Total Estimated Cost = \$11,973.69 USD

At the time of writing, this comes out to ~\$15,072.42 Canadian dollars.

7.2 Funding

7.2.1 BORG, Stakeholder: Dr. Marinko V. Sarunic

Our primary source of funding will be through Dr. Marinko V. Sarunic of the Biomedical Optics Research Group. Our sponsored project and its parts will ultimately fall back to the research



group when we have accomplished our final project appearance design and beta-phase prototype which will be further detailed in ENSC440. Project costs, parts, and justifications are submitted to Dr. Marinko V. Sarunic for approval.[22]

The next few sections discuss our other contingent options for funding.

7.2.2 \$50 Engineering Science Parts Budget

This simple and small fund is provided to cover the costs of ordered parts. This fund can include 3D printing jobs.[23]

7.2.3 Engineering Science Student Endowment Fund (ESSEF)

The ESSEF is also known as the Engineering Science Undergraduate Student Project Award.[24] This award is considered by a panel of judges. The funding adjudication council will consider student project proposals through an eligible award recipient via an application form as well as a short presentation and meeting with the entire group. Additional funding may be of interest if the parts required by our project is of interest to the Engineering Science Parts Library and, as such, will be owned by the Engineering Science Student Society. The RILab will be submitted for consideration in Class C, "Projects that originate from an Engineering Science class or a special projects laboratory."[25]

7.2.4 Wighton Engineering Development Fund

The Wighton Engineering Development Fund is a competition-based and fixed budget fund as organized in SFU by Dr. Andrew H. Rawicz. A written proposal similar to this proposal will be required for submission to deem if our project will satisfy the Wighton's requirement of practicality. That proposal will be submitted to Dr. Andrew H. Rawicz and other faculty and staff members for evaluation.[26]



8 Conclusion

Simpler, Faster, and Safer Laser Eye Therapies

Our mission statement is to improve ophthalmic laser solutions, increasing the quality of work and safety for clinicians and patients. Manual procedures are well developed but our company has identified a need to improve on these procedures to ensure their safety and efficiency, as well extend their usability to medical residency students. These in turn help in accomplishing our mission statement.

The Canadian market for ophthalmologists and clinicians are much needed as they are experiencing overexertion in their line of work and an aging clinician population. Training solutions are also desired as expressed by our user interviews with our contact ophthalmologist, Dr. Zaid Mammo. We will ensure that the RILab will be made to alleviate these issues, as simplicity and ease of use are one of the main goals.

Our research and development will accumulate into proprietary software and algorithms used to control our proprietary optical system. This project will ultimately show that laser eye therapies can be successfully performed and further be developed to compete with the PASCAL and the NAVILAS.

Our talented team of engineers have accumulated 4 years of biomedical optics and image processing research experience, 10 years of hardware and embedded systems experience, and 20 years of software development experience. Our team also includes experts in the field such as Professor Dr. Marinko Sarunic of the Biomedical Optics Research Group and Dr. Zaid Mammo of Vancouver General Hospital. We are all dedicated to our mission statement and our solid financial benefactors.

Our development plan will take into account all the highlighted risks in our document and we will have a working beta prototype by the end of August to present. This will be the first step in creating a working prototype of a system leading to fully-automated laser eye therapies. Such a system enables a future where laser eye therapies are as easy as walking in for a routine eye check and vision-robbing diseases can become a thing of the past. This remains our goal while keeping to our core tenants of simplicity, efficiency, and safety.



9 References

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Appendix A: Glossary

Term	Definition	
Choroid	The spongy layer of blood vessels that lines the back wall of the eye.	
Clinician	A clinician is a doctor having direct responsibilities and contact with a patient. In our document, this includes ophthalmologists, their assistants, and medical resident students.	
Fovea	A depression in the central macula that contains no blood vessels	
Fundus	The bottom, the base, or the inner lining of a hollow organ. In terms of our document, fundus will be referring to the inner lining of the eye opposite to the lense, also known as the retina.	
Macular Edema	Build-up of fluid in the macula, an area in the center of the retina. This condition causes swelling and thickening which distorts vision.	
Medical Residency	Postgraduate students who are training in the field of medicine.	
Microcomputer	A small computer ran by a single-chip microprocessor as its central processing unit. It has memory and minimum input/output circuitry on a single printed circuit board.	
No Treatment Area	A region on the image that is selected by the algorithm or selected by the clinician where the macula and the vessels are located. No laser is allowed to shine there.	
Ophthalmologist	A specialist doctor in the field, study, and treatment of disorders and diseases in the eye.	
Optical Scanning Mirror	A small rectangular mirror that is able to scan a laser in two axes.	
Optical Table	A vibration control platform that absorbs shock and vibrations to minimize any movements that may misalign any lasers or optical components.	
PDR	Proliferative Diabetic Retinopathy is an effect as a result of diabetes. The conditions of diabetes results in abnormal blood vessels forming in the eye which can lead to a loss of vision.	
PDT	PhotoDynamic Therapy is a two-stage treatment that combines light energy with a drug (photosensitizer) designed to destroy abnormal cells and vessels after light activation.	



Phantom Eye	A phantom eye is a term used to generalize the test subject for optics. A phantom eye has a wide range from a piece of tissue to a piece of paper, and a drawing of an eye to a porcine eye to a rat's eye.
PRP	Pan Retinal Photocoagulation is a laser eye therapy that can decrease the size of abnormal blood vessels which can lead to blindness.
Retinal Camera	A specialized camera that is able to photograph the retina of an eye.
Treatment Area	A region on the image that is selected by the algorithm or selected by the clinician where the laser treatment shall be applied.

Table A.1: Glossary covering the important terms in this Design Specification Document