March 27, 2022

Dr. Mike Hegedus
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia, V5A 1S6

Subject: ENSC 405W Final Project Proposal for Zeta

Dear Dr. Hegedus,

Halcyon has prepared this proposal document for Project Zeta for ENSC 405W. Our Capstone mission is to establish a radically new bracing methodology to enable adolescents who are afflicted with Adolescent Idiopathic Scoliosis to become fully functioning and contributing members of society by optimizing their brace treatment for an improved and accelerated recovery.

We strive to establish a new additive manufacturing methodology utilized by orthotists by creating a sensing system to measure pressure and force between the torso and brace, and then perform a digital topology optimization process for brace design in the treatment of AIS.

This document has several pieces of information that it presents. Particularly, our product on a high level, market competition, cost/risk considerations, and also details the planning we have done to ensure the completion of this project by the expected deadlines.

Our team consists of Systems and Computer Engineering students, namely Roy Ataya, Aidan Cook, Hamza Kamal, Kirill Melnikov, Paige Rattenberry, and Aki Zhou. Among others, we will also be collaborating with our industry contact, Carl Ganzert, a Certified Orthotist and the Acting Director of the Hodgson Orthopedic Group's Research Division.

We can be contacted through our Chief Communication Officer, Aidan Cook at aidanc@sfu.ca.

Sincerely,

Aidan Cook
Chief Communication Officer
Halcyon (Company 8)

Halcyon

Final Project Proposal

Zeta

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Executive Summary

Adolescent Idiopathic Scoliosis is a condition characterized by 3D spinal deformities in children. This condition has significant negative impacts on both patients and the medical system, responsible for physical, psychological, and surgical trauma.

The individuals attempting to treat this disorder are orthotists, professionals responsible for the creation and fitting of braces and orthotics. These orthotists create torso braces that carefully apply pressure to the patient’s spine as they grow, and if done right, can halt and greatly reduce the need for surgical intervention later in the patient's life. Due to a lack of standardization and available data, orthotists are forced to rely on their past experience and anecdotal evidence to make decisions. If these professionals could be given the tools to collect pressure data from patient braces, they could enforce standardization, and optimize brace designs. Furthermore the need for X-rays, which is the current standard for measuring AIS progress, can also be reduced. We hope to rectify this with Zeta, our pressure mat system.

Zeta is a combined hardware and software product. It allows orthotists to quickly attach pressure mats to the interior of a brace, collecting pressure data that’s being applied to a patient at high resolution. The design is simple, easy to use, and inexpensive.

Zeta consists of three pressure mats, a central housing, and the software package. The mats plug into the central housing where a microcontroller reads data from the mats and uploads it via USB connection to the computer running our software. This data is segmented and organized for easy consumption and use in various tools, such as nTopology a generative design software.

The market for this product is niche but untapped. There are roughly 10,000 medical professionals who fall under the orthotists umbrella across the US and Canada. Due to the lack of competitors in the space and the history of the profession, we are confident in Zeta being a viable tool for this market.

Our goals are to complete a working proof-of-concept by April 12th, and to build a full prototype by August. Total prototype unit cost is expected to be no more than $379.

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Glossary

Term	Definition
AIS	Adolescent Idiopathic Scoliosis
CAD	Computer Aided Design
DMM	Digital Multimeter
FM	Firmware
FSR	Force Sensitive Resistor
GUI	Graphical User Interface
HW	Hardware
R&D	Research and Development
SR&ED	Scientific research and experimental development
SW	Software

1 Introduction

1.1 Impact of Scoliosis on Adolescent Lives

AIS is a 3D spinal deformity, characterized by a vertebral/trunk rotation and lateral spinal curvature, that accelerates during growth periods and can progress to necessitate surgical intervention [1]. Therefore, early and optimal treatment is crucial because most optimal curvature correction results can only be achieved while a child is still growing. AIS has significant physical, psychological, surgical, and financial impacts on both patients and the medical system. Severe AIS cases have an increased risk for morbidity problems and mortality, musculoskeletal back pain, deformity, psychosocial distress, and pulmonary disorders [2].

1.2 Problem Background & Current Brace Treatment Limitations

Screening, diagnosis, treatment, and follow-up of AIS present several challenges because patterns of scoliotic spine evolution have not been well defined [1]. Curve magnitude, skeletal maturity, and curve morphology are important factors in brace treatment efficiency [3]. However, clinically relevant AIS spinal curvature classification and monitoring of brace correction is based on 2D back and lateral spinal X-ray images, which cannot describe the 3D deformity completely. Current methods for curve magnitude and angle measurements have limited reliability and have led to variations and suboptimal brace design, treatment, therapeutic management, and surgical results [4].

According to our industry contact, Carl Ganzert, a certified orthotist and the acting director of the Hodgson Orthopedic Group's Research Division, a major reason for this is that orthotists are currently limited to relying strictly on their experience and anecdotal evidence to develop torso braces which aim to push the spine into the correct position. Additionally, there are no accurate methods of quantitatively measuring the fit and effectiveness of braces outside of full spinal X-ray imaging, which can only be performed about once a year due to their harmful long-term severe radiation consequences. Furthermore, X-rays are not conducted by orthotists, so there is high variability in the images produced, and consequently, the degree of reliability is a concern. As a further complication, there is no consensus on the required magnitude of corrective pressure for ideal therapeutic results, and no commercially available pressure sensor systems tailored to remedying scoliosis, especially for long-term use [5].

Evidently, without concrete data, orthotists are prevented from providing patients with the most optimal recovery scoliosis brace treatment they require from the start, and therefore suffering children cannot get the most optimal treatment that they deserve.

1.3 Project Mission and System Overview

We strive to establish a new brace design methodology utilized by orthotists by creating a sensing system to measure pressure between the torso and brace. Thereafter, digital topology optimization for brace design would be used in the treatment of AIS.

With our system, pressure measurements could be collected frequently, allowing orthotists to make quantitative, data-driven decisions based on success trends in spinal curvature correction, enabling the efficient creation of optimal braces for treatment, and eliminating the need for manual customization of the standard brace by orthotists.

Force-sensing resistors will be connected to a microcontroller to obtain the pressure readings, which will be sent to a computer to be processed and displayed on a graphical user interface, to enable non-technical users to easily use this technology. The pressure data will then be converted to a point map that will be overlaid onto a CAD brace model and fed into nTopology software. nTopology is expected to generate a mesh of an optimized and perforated 3D brace, that is comfortable, breathable, and lightweight, offering a significant improvement over the clinical standard 3mm thick, rigid plastic hard shell brace, without compromising biomechanical correction. [6]

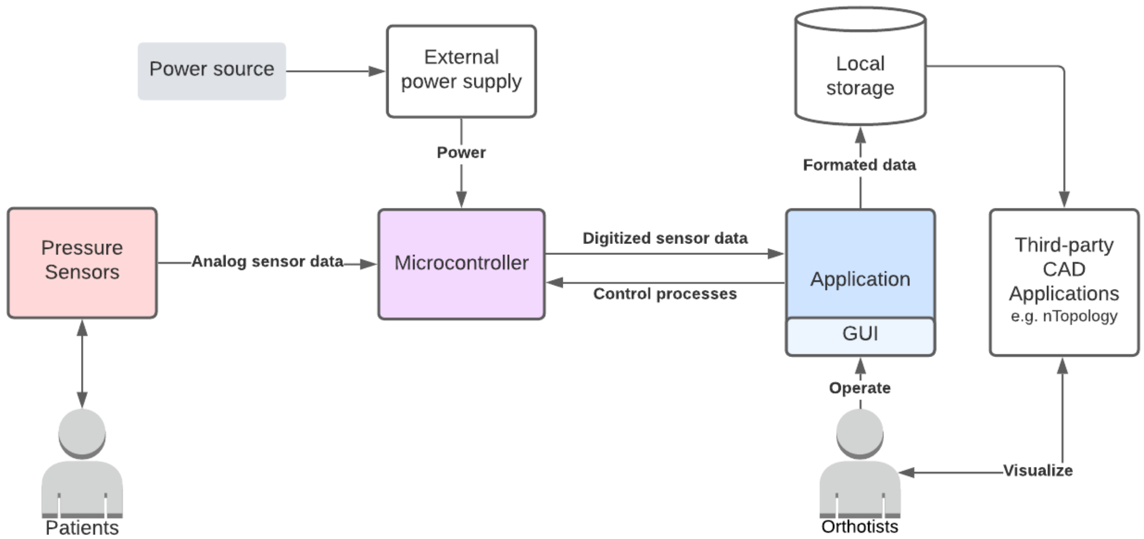


Figure 1 - Overall System Design

2 Scope

At this point, our project scope has been characterized by two hard deadlines, which was chosen based on how capstone is a two-part project. The first would be signaled by the end of 405W, and the next would be off the completion of 440. We have created tasks and key milestones based on these deadlines to help us accomplish our goals.

2.1 Proof of Concept

For 405W, the project stage would be limited to a proof-of-concept. Overall, our goal is to prove that the full integration of the system is possible. The hardware, firmware, and software must work in conjunction to enable a full data flow, from input of pressure data, to outputting a text file usable for nTopology optimization.

In addition to the integration effort, we must show that this system is capable of being worn under a brace by patients. For our proof-of-concept, the logistics were simplified to ease the integration. Particularly, the mats used to hold the pressure sensors are very minimalistic in design. Also, the CAD models used for optimization are not actual braces. Instead, we incorporated simple geometric shapes to prove that data is actually being used for optimization. For example, a flat surface, such as a square, would be one of the first models we would use to test our design.

As we verify more and more use cases, we would become more rigorous in the test CAD models we chose, incorporating curvatures into the shape. However, these would still be relatively simple geometric shapes, and would not be able to fully replicate the complexity of a brace. Nonetheless, using geometric shapes should be enough to show that the system is operational, as we would prove that it works on a multitude of differing surfaces.

2.2 Prototype

If the goal of our proof-of-concept is to show the workflow of the concept as a whole, the project at the end of 440 should deal with all details that come with the system and scale up the design. Particularly, it would address safety concerns, comfort for patients, and also the complexity that comes from mapping onto actual brace CAD models. A full scale prototype is the objective.

Safety Concerns:

For this system to be usable within a medical setting requires us to create safety measures to reduce the risk of injuries. In particular, this would include silicon wrapping, use of proper connectors to ensure no wires or pins are exposed. We would also encase the microprocessor and pressure sensors in proper plastic material to prevent exposure of sensitive and fragile parts of the hardware.

Comfort:

In our system, mats have to be placed between a brace and a patient's torso. Although a mat would only be applied in a limited time period, typically a few minutes during a clinical checkup, we still want to ensure that it is something comfortable to put on. As mentioned, the pressure sensors would be wrapped in plastic sheeting to ensure they are durable. This is uncomfortable, so we must include a foam matting that will wrap around the mat. This will be a large focus for us when testing the product.

Complexity:

The complexity is directly characterized by two aspects: the CAD model, and the number of sensors used. As the proof-of-concept is tested against simple geometric shapes, our prototype must be functional with a full-scale brace. The goal for the prototype is to enable capture of data across the whole brace. A mat should be able to be placed within any particular region on a brace, where a region is a uniform mapping of positions where mats are attached.

3 Risks/Benefits

Any product offers its risks and benefits to society. Our product is aimed at the medical field, specifically for children and thus our risks have to be rigorously evaluated. However, because our system is low impact and low wear time, these risks will be mitigated.

3.1 Societal Risks

Our societal risks are minimal and mostly revolve around the patient and any harm that may befall them while using the device. The device could be uncomfortable or could cause injury if worn incorrectly. The device requires supervision to be used, and therefore could be broken if used by a patient without an orthotist or professional present. There is also the risk to the environment. The system does not have a high degree of repairability because the electronics are small and the mat must be low profile, making it difficult to replace components within a mat. Therefore, if the product is not robust enough to handle regular use, it would cause unnecessary waste. These risks are actively being mitigated, through careful design and construction choices and robust testing.

3.1 Business Risks

In terms of business risks, cost and funding considerations are the biggest issues. Because of our initial market size, kickstarting this project is difficult. We picked a high need market, but ensuring that our customers are willing to buy and engage with our product is a difficult endeavor. Because of the small market size, we rely heavily on customer engagement through constant marketing to attract investors.

If we fail to finance our product sufficiently, we will not be able to scale our production causing our cost of goods to be high and thus lowering our profit margin and growth. Ensuring we capture the market quickly is paramount to ensure we are not beat out by large medical device companies mimicking our product.

A large hardware component means that we are constantly in need of pressure sensors to build our system, which makes us directly dependent on suppliers. If sensor replacement is necessary, due to issues when shipping our product, buying pressure sensors in bulk is crucial. If we can't get the necessary materials to build our product, our supply chain will suffer.

In addition, because our device is within the medical field, clinical trials are required. This process is expensive, and is necessary for commercialization. Until this is accomplished, we are limited on our product applications, and in turn, our investment opportunities. This is because investors often want to see revenue generation as proof of product validity.

3.2 Benefits: Future Potential

In spite of these risks, Mr. Ganzert proposed that as increased data is obtained through mapping of pressure scenarios, the brace optimization process would set the foundation for the generation of a machine learning based predictive analysis model.

We believe that the model could algorithmically look for success trends in previous patients with similar spinal curvatures and pressure measurements. This would in turn improve the accuracy, sensitivity, and specificity of predicting AIS curve severity, curve progression, brace design and effectiveness, leading to faster, more responsive and precise AIS correction progress. This would also thereby eliminate the need for anecdotal, manual customization of the standard brace by orthotists.

Furthermore, the topology optimized mesh brace model generated by nTopology software could be further refined by cutting 3 separate panels into the back of the 3D brace through additive manufacturing. This would thereby allow for ultrasound visualizations that would be collected in the clinic more frequently than X-rays can be, as ultrasound does not emit the damaging and long-term harmful radiation consequences that x-rays do, which have been established as a risk factor of scoliosis management; bracing or otherwise. The pressure/force and ultrasound data could then be algorithmically analyzed together to refine optimization and treatment.

Finally, this sustained effort caters to better treatment outcomes which at their core are focused on surgical prevention. Decreased scoliosis surgeries reduce burden on the medical system which is particularly strained due to the secondary and tertiary effects of Covid-19.

Unfortunately, we are limited by time constraints, and these ideal outcomes are not practical to achieve within the Capstone time frame. Therefore, we have narrowed down our project to creating the described pressure sensing system, achieving reliable and accurate results from the sensors, designing an interactive and intuitive GUI for orthotists to obtain and save the pressure measurements easily, performing the necessary data processing steps, and establishing a workflow in nTopology to generate the 3D optimized brace mesh. We hope that accomplishing these goals will make it possible for our ideal future potential optimizations to be achieved.

3.3 Benefits: Scaling Up

The potential for this technology is massive. This project's goal is to bridge the gap between available software and off-shelf pressure sensors. A visual mapping of pressure values would allow orthotists to find trends in data, providing feedback on a brace's comfort and wearability. The goal of our capstone is to enable this technology. The way this can be scaled up goes beyond bracing technology. Pressure sensing can be used in a variety of medical applications, such as diabetes and bedsores. With our system, we not only provide a gateway to enable data capture, but a workflow to synthesize data into actionable insights.

4 Market / Competition / Research Rationale

4.1 Current Solutions and Research

Research endeavors have been mostly aimed at developing real-time sensor monitoring systems for brace wear compliance in AIS patients using measurements such as force and temperature [7, 8, 9, 10]. These products are not commercially available, nor are they used within a clinical setting on a common basis. Our project differs in a few key areas. Firstly, we are creating a product that will be commercially available for orthotists to use clinically. Secondly the research endeavors all had sensors fixed onto the brace while we are able to move the sensors to any point on the torso. Thirdly we are utilizing the data from the pressure sensors a step further through a software process to create an optimized and sustainable brace design.

There exist similar products, such as socks meant to measure foot pressure of diabetes patients, but no products aimed specifically at scoliosis or brace pressure measurements.

4.2 Market Outline

The market we seek to sell to is the medical space. In particular, we seek to sell directly to every orthotists, prosthetist, and orthopedician since these 3 professions often overlap in their treatment of AIS. Within Canada and the US there are about 24,000 orthopedicians [11][12] and about 10,000 orthotists and prosthetists [13][14]. Thus, our total market size for

Canada and the US is about 34,000 medical professionals. This would be the maximum theoretical market size that is possible to target.

If we look at the market size, assuming everything that is theoretically targetable, this would amount to the total number of orthotists and prosthetists in North America. This is about 10,000 medical professionals. According to research, around 30% of Americans are early adopters so we think we can reach around 30% of all orthotists and prosthetists in North America within 2 years of launch [15]. This amounts to about 3000 people.

The total market cap can seem small, but it should be mentioned that this is something currently marketed to a very small population for a very specific need. This technology is new, and hasn't been commercialized. There has not been much exploration done on data trend analysis through pressure data, which is why we believe we can capitalize on this.

The beauty of this system is that the scope that it can be applied to is very large. Right now, we're building this so that orthotists can have a technology to ease their workload by making it less reliant on personal judgment, but instead on sound data. We would be marketing to them as they are our early adopters.

Once we've captured this market, we can expand and apply our product into more general use cases. The CAD model can be easily replaced from a brace, to another object, such as wearable medical device, or some type of clothing for athletes. The main idea is optimizing an object to be something comfortable for humans to wear. This is an important topic for any wearable technology, no matter the industry. This is why we believe that starting with a very specific, high need market, is important, as only once it has been proven that it can work can we expand into larger horizons.

5 Cost Analysis

The largest costs for a single prototype unit would be the microcontroller and the sensors, and these items are still very reasonably priced. Note that all costs are scaled to the price that would be needed to create one unit of the product. Cost considerations show the pricing for both a single mat versus a tri-mat system. A tri-mat system would be the expected configuration for a user.

Main Component	**Component Parts**	**Cost (CAD)**

Mat - non electronics	Semi rigid 0.3 mm PVC sheet	$0.10
	Cotton fabric	$0.04
	Thin neoprene foam sheet	$0.03
	Double sided nano tape	$0.90
	6 pin cable harness	$2.00
Mat - electronics	Interlink UX 402 FSR	$4.00 per, $20 - $100 total
	30 AWG copper wire	$0.05
	10K resistor	$0.27 per, $1.35 - $6.75 total
	Solder	<$0.01
Total Mat Cost (high end)		**$109.87**
Microcontroller - electronics	Elegoo ATmega2560	$30.00
	6ft USB 2.0 A To B cable	$14.00
Microcontroller - housing	¼ ” Hard plastic shell	$4.63
Total Cost with Three Mats		**$378.24**

Table 1 - Product costs

5.1 Cost Considerations

As shown above, the cost to create a single mat comes out to around 100$. The bulk of the cost depends on the quality of the pressure sensors you buy. Thus, this is the portion of our bill of parts we can modify to lower costs if need be. We believe that for our market, the sensor we have chosen is a good choice since it has a large range of sensing while still being cost effective enough that a single mat costs about $100.

5.2 Funding

We initially plan to fund our project primarily through bootstrapping. Our plan is to sell around 3000 units, within 3 years of operation through the help of our industry contact and his large network. After exhausting his network, we seek to initiate sales through discussions with clinics and hospitals. Finally we seek to exhibit our product at medical trade shows to reach an even larger audience.

Once we establish our device within the orthotics market, we will expand our product offering to other medical spaces where pressure data is valuable such as in preventing bedsores. To accomplish these goals, we will require government funding at an early stage through sources such as InnovateBC's R&D grant [16]. Later we will seek private investment to fuel our growth strategy. Finally we will apply for SR&ED credits [17] to lower our actual R&D costs each year.

Another potential funding source can be through providing a subscription based service where users can access the prediction models trained on data collected via the software of our system. However, seeking funding this way accompanies ethical dilemmas, therefore we consider this as a possible but not a definite source of funding.

6 Timeline

In Figures 2-4 below, we've outlined our project schedule and timeline.

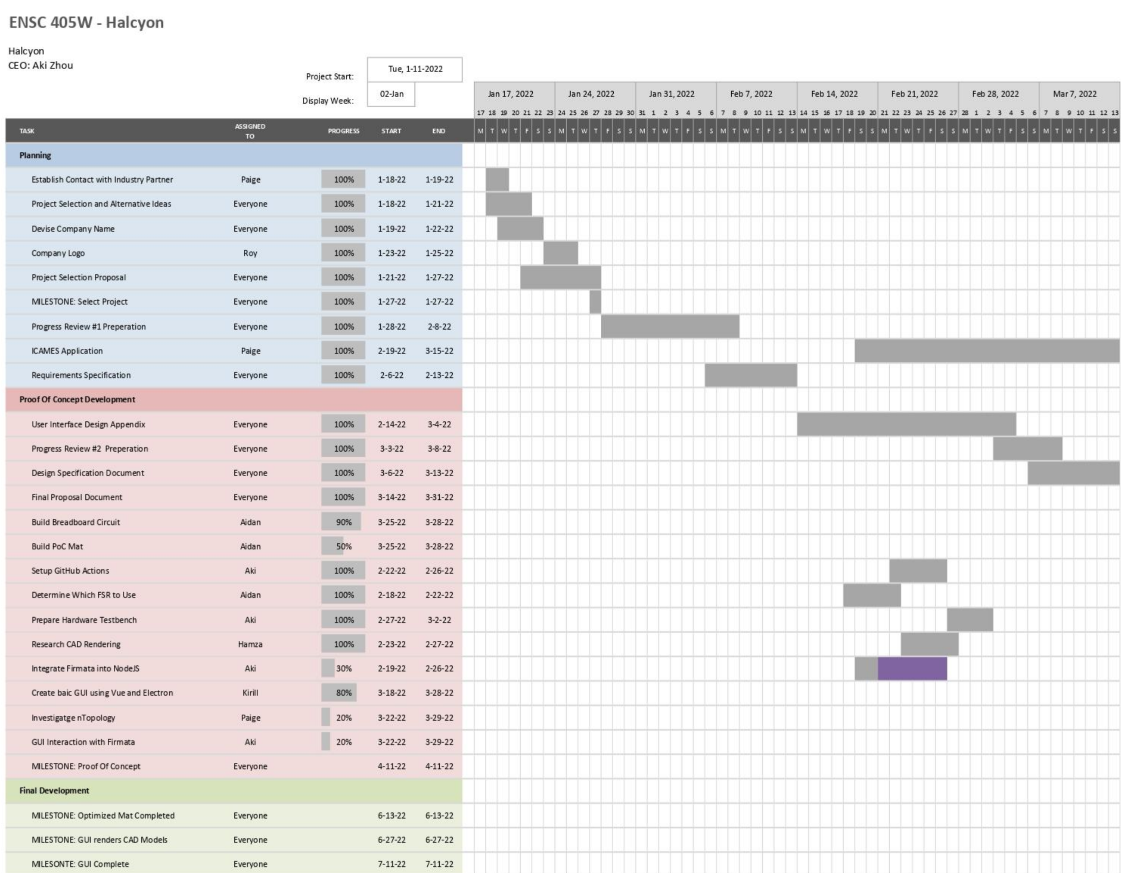


Figure 2 - Gantt chart Jan 11 - Mar 13, 2022

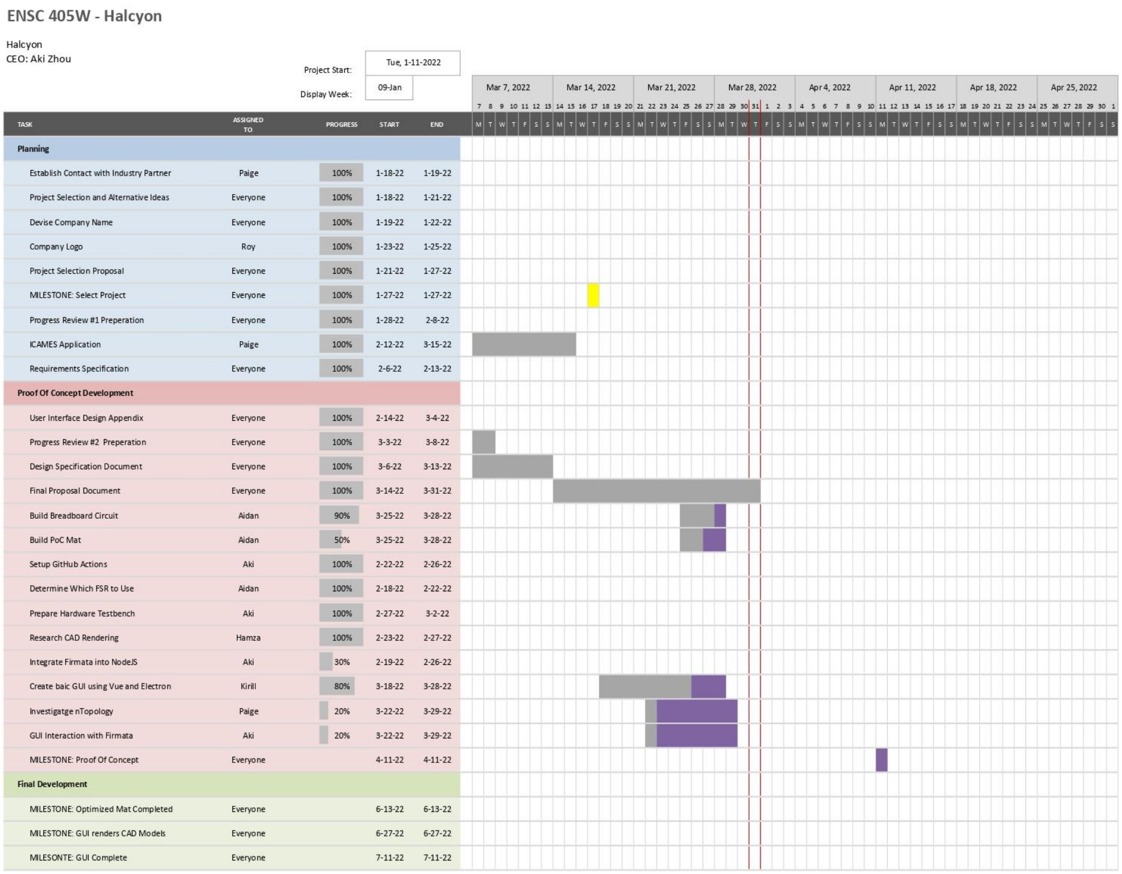


Figure 3 - Gantt chart Mar 13 - Apr 25, 2022

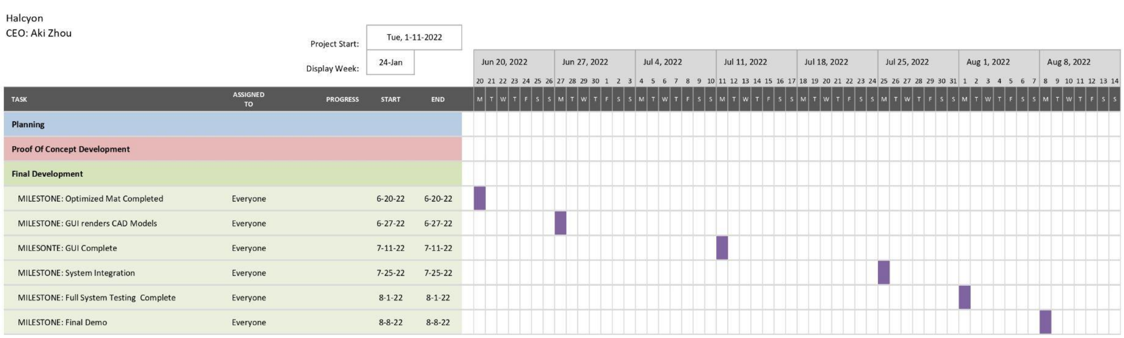


Figure 4 - Gantt chart Apr 25 - Aug 8, 2022

7 Company Overview

We are Halcyon, a start-up medical device company. Halcyon was founded in 2022 by 6 like minded engineering students at Simon Fraser University, each with a passion for creating

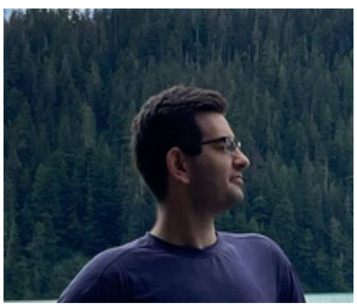
Halcyon

innovative technology. Our first prototype of Zeta, is an affordable pressure sensing device expected to be completed in August 2022. Joint and equal team effort was put into the production of this project.

7.1 The Team

Aki Zhou - CEO/Tech Lead

I am a 5th year computer engineering student minoring in computing science. My interest is in data acquisition and machine learning based prediction. I am currently working as a data engineer/machine learning engineer at enechain, the largest energy market place operator in Japan. I am also a 3d printing hobbyist, who enjoys tinkering around with sensors, microcontrollers and all sorts of CAD models. I hope my knowledge and experience can contribute to the success of our project.



Roy Ataya - CFO

I am a 5th year systems engineering student. My interests are wide ranging but primarily center on robotics and cybernetics. I also hold a B.Sc in Molecular Biology and Biochemistry and a Certificate of Genomics and am well versed in general science. I hope my background in software development from my previous work experiences and my previous degrees will aid in the design of a successful product.

Aidan Cook - CCO

I am a 5th year engineering student with a passion for hardware design, system optimization, and software. I have experience working as a full-stack developer through my co-ops at Traction on Demand, where I worked face to face with clients on multiple complex projects. Through this I learned what it takes for a project to be successful both from a business and technical perspective. I hope to use this experience to drive this project forward successfully.

Hamza Kamal - CIO

I am a 5th year Computer Engineering student minoring in Computer Science. I have experience working in firmware development through a co-op at Sierra Wireless and at Intel. The courses I have enjoyed most at SFU are databases I and II and Operating Systems. I have an interest in Linux development.

Kirill Melnikov - CTO

I am a 5th year computer engineering student, minoring in business. I have experience working in frontend development work, with a co-op at Avigilon in C#, and at LifeBooster working in Vue.js. Within my degree, my favorite courses were software specific, particularly CMPT 300 for its multithreaded operations, and CMPT 275.

Paige Rattenberry - CRO

I am a 5th year Computer Engineering student with a passion for applying Artificial Intelligence and Machine Learning to Biomedical and Neuroscience applications. I was a Product Analyst Co-op at Samsung, Software Engineering and Explore Intern at Microsoft, and a Computer Vision Co-op at Stryker, a Medical Technologies company. I also have experience as a Volunteer Research Assistant at BrainNet, Rostrum Medical, and the SFU FAISAL Lab.

8 Conclusion

Overall, our goal is to improve the lives of children and adolescents suffering from scoliosis, by empowering orthotists to make data driven decisions to optimize treatment, produce more comfortable braces, and accelerate recovery for those afflicted with AIS.

Our system will be comfortable, safe, and non-invasive. It will be robust enough to handle pressure measurements along brace curvatures and not break under regular use. It will provide accurate pressure data to the user, while being easy to set up, and intuitive to use. Data will be formatted for use in nTopology, or other generative design tools, to optimize brace design effectiveness.

As Mr. Ganzert has stressed, successful completion of our project caters to the opportunity for orthotists to move beyond anecdotal practices and standard fabrication techniques which are relatively waste intensive due to current manufacturing realities which require the use of either plaster of paris or foam carvings that are discarded once braces are produced. Furthermore, the improved comfort and breathability would make the prescribed full time bracing protocols more sustainable for patients due to a reduction of hardship when it comes to brace wearing.

Therefore, our project will lead to enhanced environmental, medical, and social sustainability while improving patient outcomes. Through reducing the need for X-rays and using environmentally friendly material for our optimized brace, we will provide a safer and more environmentally friendly solution for treatment of children suffering from AIS, a devastating, life-threatening condition if not treated promptly and optimally.

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