Final Design Report: Flap Mask

Prepared for:

Ms. Cristina Mix
Shirley Ryan AbilityLab
Chicago, Illinois 60611

Date:

March 14, 2022

Submitted by:

Gabriela Oyarzún Batlle, Maya Hanck, Lily Lee, Rohan Wedam
Section 3, Team 1

Sponsored by:

Professors Leslie Fischer and Emma DeCosta
Design Thinking and Communication Program
McCormick School of Engineering and Applied Science
Northwestern University
Evanston, Illinois 60208

Table of Contents

List of Figures iii
List of Tables iv

Executive Summary 1

Introduction and Problem Statement 2

Design Concept and Rationale 6

Further Development 14

Conclusion 16

References 17

APPENDICES 19

APPENDIX A: PROJECT DEFINITION 20
APPENDIX B: CLIENT INTERVIEW SUMMARY 24
APPENDIX C: USER OBSERVATION SUMMARY..... 26
APPENDIX D: FEEDBACK SUMMARY 29
APPENDIX E: SILICONE INSERT SHAPE TESTING RESULTS..... 36
APPENDIX F: BACKGROUND RESEARCH SUMMARY 37
APPENDIX G: BILL OF MATERIALS 43

List of Figures

Figure 1: Spinal cord areas……..2
Figure 2: Mouth stick example……3
Figure 3: Mouth stick in use example…….....……..…..3
Figure 4: Sip and puff wheelchair example.……3
Figure 5: Final design sketch with dimensions……6
Figure 6: Final design sketch of outer and inner silicone inserts and flaps with dimensions…….……..7
Figure 7: Final exploded view design sketch……..8
Figure 8: Final prototype…….……9
Figure 9: Teammate illustrating placing mask on user……...…….……9
Figure 10: Teammate ensuring straw is in the right location….…….…….……..10
Figure 11: Flaps self-sealing back to original position after device use……...….10
Figure 12: Flaps sealing around mouth stick…….....……..…..11
Figure 13: Mask in use while mouth stick in use…….....……..……11

List of Tables

Table 1: Summary of LUX Testing Results……...12
Table 2: Mr. Jennings's Daily Schedule…….32
Table 3: Mockup Ratings……...33
Table 4: User Observation and Testing……..34
Table 5: Summary of LUX Testing Results……...36
Table 6: Mask Type/FFE Percentage for Commonly Used Facial Masks…….41
Table 7: FDA Characteristic Requirements and their FDA Recognized Consensus Standards Citations for Surgical Facial Masks……..42
Table 8: Bill of Materials……...43
Table 9: Materials Used for Construction……..44

Executive Summary

Introduction

The COVID-19 pandemic has mandated the use of face masks in public spaces for all individuals, especially in healthcare settings like Shirley Ryan AbilityLab (SRAL) which will continue to require masks in the future. Face masks pose problems for many individuals, especially those with disabilities such as spinal cord injuries (SCI). Many individuals with SCI have quadriplegia, and are limited physically. Due to this limitation, many individuals use orally-controlled assistive devices such as mouth sticks and sip and puff powered wheelchairs daily.

Problem Statement

Face masks completely restrict the use of orally-controlled devices because the mouth is fully covered with proper mask usage. The challenge is how can users be granted protection and coverage from COVID-19 while not compromising the use and accessibility of their assistive devices.

Users

The user is Kenneth Jennings, a man in his 50s with a high-level SCI and quadriplegia. A high school sports incident that resulted in this high-level SCI left him unable to move his body from the neck down. Mr. Jennings uses a sip and puff powered wheelchair for independent mobility as well as a mouth stick to complete daily tasks.

Design Concept

The design is a N95 mask with an elliptical-shaped double-layered rubber insert with 8 triangular flaps on the outer layer and 16 of the same flaps on the inner layer. This allows the mask to self-seal when devices are not in use and conform its shape to the devices while they are in use. This design does not sacrifice protection from COVID-19.

Design Rationale

The material, insert shape, flap shape, number of flaps, and number of layers were chosen based on the combination of factors that led to the lowest amount of light shining through the mask during light testing when a sip and puff like straw was inserted into the flaps.

Future Research

Future testing could be done to calculate particle filtration in the proposed design. Future development and research could be done to explore ways to detach the silicone insert and create a reusable insert for disposable N95 masks.

Introduction

The COVID-19 pandemic has made face masks an essential part of an individual's personal defense against the contraction and spread of the coronavirus. With masking mandates nationwide in public spaces, many individuals with disabilities have had issues with finding masks that provide them with adequate protection while not compromising their mobility, access to assistive devices, or mental stability. Individuals with spinal cord injuries (SCI) have been faced with this problem. This problem will persist as healthcare facilities will continue to mandate facial masking for the foreseeable future.

Spinal Cord Injury

Spinal cord injuries are often caused by trauma and affect the sensation and motor control of bodily regions that are located below the injury. Thus, an injury which is more superior (closer to the head) is more severe. The traumatic nature of spinal cord injuries means they can either partially or fully heal, leading to either a recovery of function or result in permanent damage and loss of function respectively. Physical disabilities such as quadriplegia and paraplegia are the result of spinal cord injuries [11].

Figure 1 displays the impact of injury to different spinal locations.

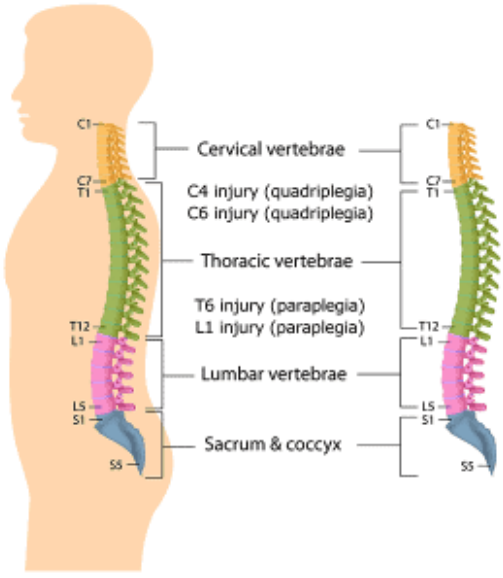

Figure 1: Spinal cord areas
Source: "Spinal Cord Injuries" <https://hohmanrehab.com/spinal-cord-injuries/>

Assistive Devices

Many individuals with SCI opt to use a mouth stick device, which is for physical interaction with the environment. The device is a mouth-controlled stick that an individual can use to type, use electronics, and other activities. Many also utilize a sip and puff device to control a motorized wheelchair through breath pressures.

Figure 2: Mouth stick example
Source: “Straight Wand Mouth Stick”
<https://www.healthproductsforyou.com/p-straight-wand-mouth-stick.html>

Figure 3: Mouth stick in use example
Source: “Mouth Sticks for Quadriplegics”
<https://mouse4all.com/en/articles/mouth-sticks-for-quadriplegics/>

Figure 4: Sip and puff wheelchair example
Source:
<https://jasonwebb.io/2013/02/overview-of-the-sip-n-puff-interface-for-educators-of-students-with-diverse-needs/>

Causes of Mask Difficulty

Since face masks cover both the mouth and nose completely, individuals with SCI who use mouth sticks and sip and puff devices need to have unhindered access to their mouths. Furthermore, Berlowitz et. al. found that individuals with SCI may have difficulty breathing, because of loss of function of muscles which support respiration (abdominal and intercostal muscles) [3]. This can make breathing with a facial mask difficult and cumbersome.

Additionally, due to the decreased lung capacity many individuals with SCI have, these individuals may not be able to effectively clear their lungs, risking potentially severe COVID-19 symptoms. A study in 2021 done by Hoogenes et.al. in the *Journal of Neurotrauma* revealed that while known symptoms of COVID-19 were presented in numbers that mirrored that of the general public, the mortality rate for patients with SCI was much higher at a rate between 10% and 19% [1].

Such considerations complicate the ability to use a mask to sufficiently cover the lower face, especially the mouth. This coverage inherently limits the ability to both use assistive devices and breath with already weakened respiratory muscles.

Problem Statement

The COVID-19 pandemic has created the need for individuals to wear face masks in public spaces, especially in medical spaces such as the Shirley Ryan AbilityLab. Individuals with disabilities however can have trouble with this masking requirement due to limited mobility, sensory overload, or interferences with assistive devices. Specifically, mouth stick users and sip and puff users are unable to wear face masks while maintaining their ability to control these assistive devices properly.

The user, Kenneth Jennings, uses a mouth stick and sip and puff daily. He is a middle-aged man with quadriplegia due to a high school sports injury. In general, users are individuals with a disability who require easy access to assistive devices. The users need a face mask that provides adequate protection from COVID-19, provides accessibility to their assistive devices, is easy to use, is comfortable, is breathable, does not modify the user's assistive devices, and employs a push mechanism.

Without a proper face mask, an individual's protection from COVID-19 is compromised and their risk of contracting the virus is heightened. Masking is important to reduce the chances of contracting COVID-19 and falling severely ill. In addition, it is important for all individuals to wear a face mask to protect others and slow the spread of the virus.

The design engineering team has worked through identifying the problem, generating and iterating on various design concepts, testing said concepts and mockups, and creating a final design that meets the users needs. The report will first go on to discuss the final design concept, how it is used, design features, and lastly design benefits and shortcomings. In addition, the rationale supporting the final design will be exhibited. Then, possible future development of the final design will be discussed such as future performance and user testing, new features, alternative materials, maintenance issues, and fault analysis considerations. Lastly, the report will conclude with a summary of the design requirements and how they were met.

Design Concept

Design Overview

The Flap Mask is a face mask that allows the user, a man in his 50s with SCI and quadriplegia, to easily use their mouth stick and sip and puff assistive devices while maintaining protection and coverage. The Flap Mask is a N95 face mask with an elliptical silicone insert with permeable flaps, enabling the user to push and pull his assistive devices in and out of the mask. The design takes into account several requirements: provides better protection against COVID-19, provides accessibility to assistive devices, is comfortable, is breathable, and does not modify the user's assistive devices. The following sections describe the features of the mask as well as the rationale behind them. Additional information on design requirements can be found in Appendix A Table 1.

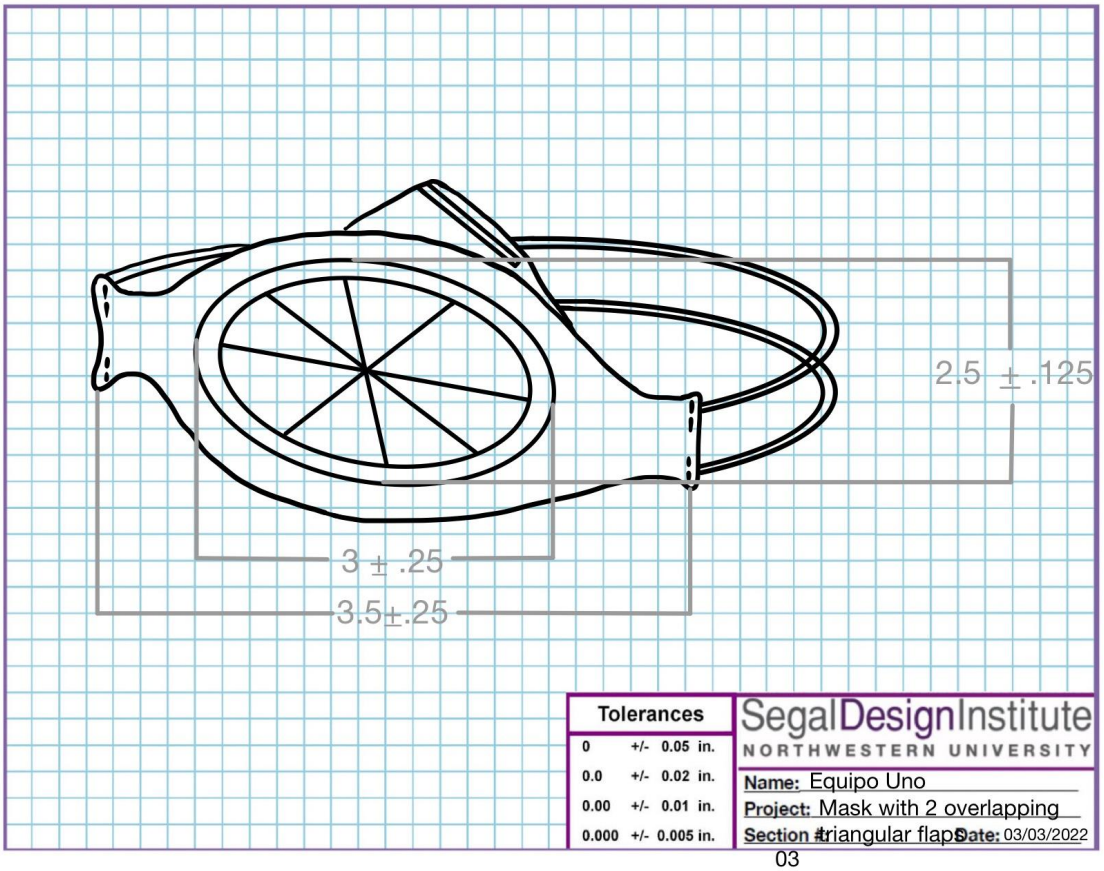

Figure 5: Final design sketch with dimensions.

Design Features

Our design looks like a typical N95 mask and works like a N95 mask, but with some slight modifications for ease of use and accessibility with various assistive devices. The design includes an elliptical cutout covered by a double layered rubber opening with triangular flaps.

The design will use a food grade, FDA-approved silicone and neoprene material as it is safe, durable, comfortable against facial skin, and provides a tight seal. The purpose of this feature is to enable the user to push and pull his mouth stick and sip and puff devices into and out of the mask easily, providing easy accessibility.

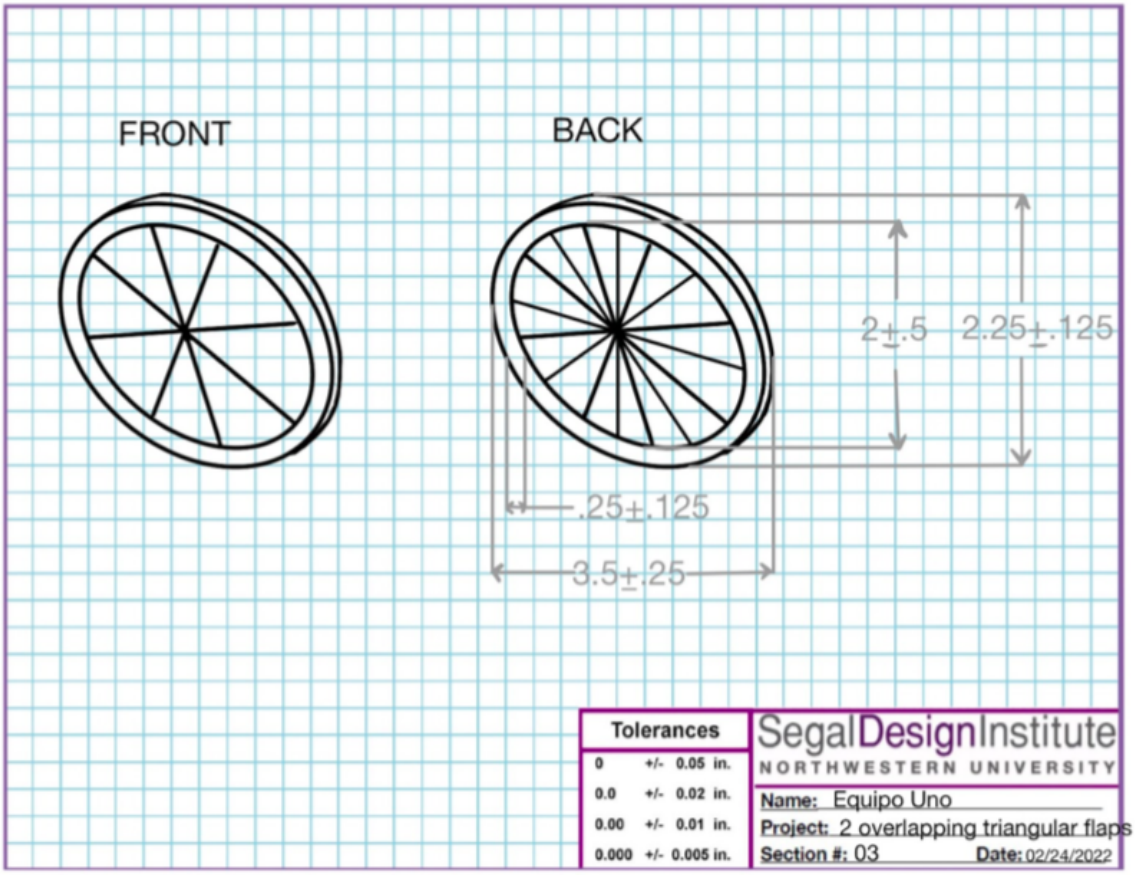

Figure 6: Final design sketch of outer and inner silicone inserts and flaps.

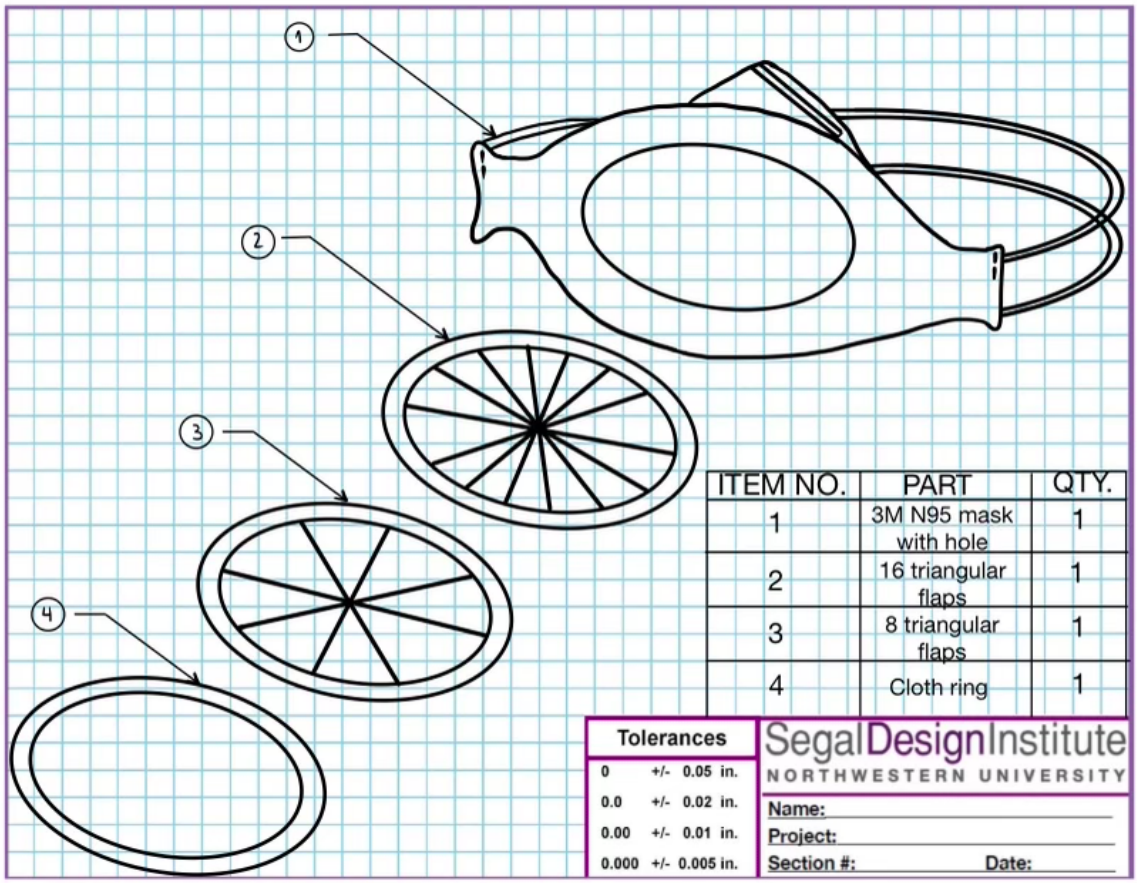

Figure 7: Final exploded design sketch.

Another key feature of the Flap Mask is the number of flaps the opening has and their placement. Light testing revealed that two offset overlapping layers of 8 and 16 triangular flaps, respectively, 24 in total, let the least amount of light through the openings, and therefore the most coverage and protection from COVID-19. Therefore, to provide the best coverage and protection for the user, the design employs this idea of using overlapping layers of flaps. The outermost layer has 8 flaps. Below this layer is an additional layer of 16 triangular flaps. This provides an extra layer of coverage and a better seal around circular objects (Appendix E).

The final key feature of this design is the use of the existing N95 mask itself. The existing flat front structure of this mask provides a stiffness that supports a push-through/pull-out mechanism and takes pressure off of the jaw of the user to open and close a mask opening. This provides an added element of comfort to the design. The existing mask also has ear loops as well as a nose wire for a snug yet comfortable facial fit.

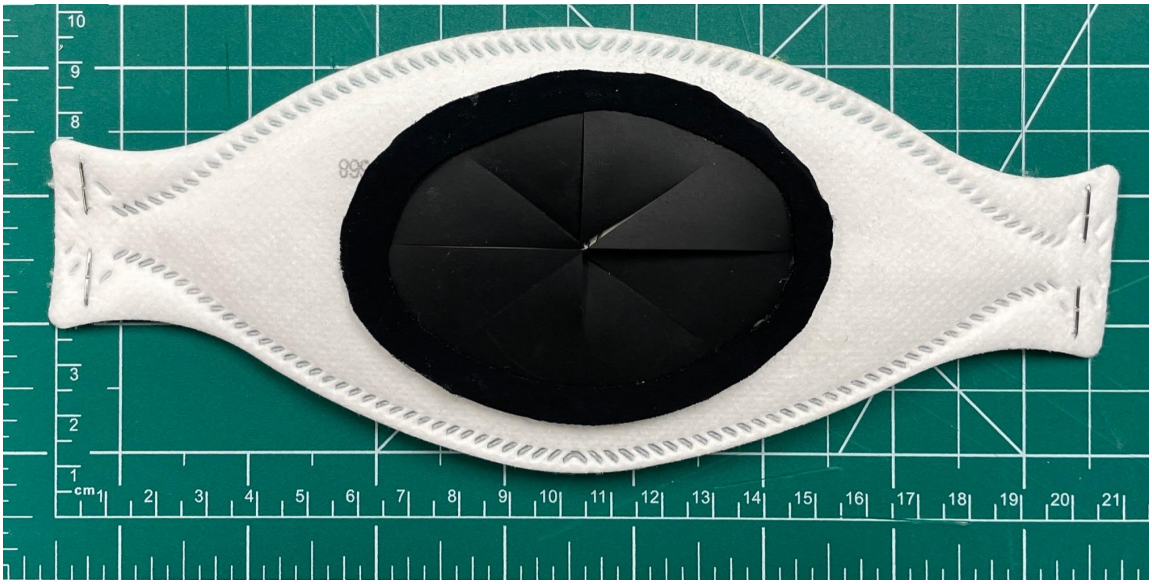

Figure 8: Final prototype

User Scenario

Before entering SRAL for the workday, Mr. Jennings has an individual place the modified N95 mask on their face, making sure that the nose wire is sufficiently bent, and that the ear loops are in a comfortable position.

Figure 9: Teammate illustrating placing mask on user

The assisting individual will then help the user ensure that the sip and puff straw is in the right location, and they will push it through the middle of the mask and into their mouths.

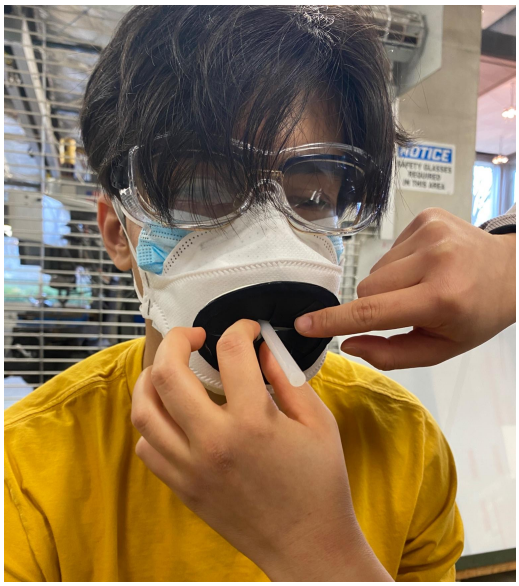

Figure 10: Teammate ensuring straw is in the right location

Now they are able to enter SRAL and make it right on time to their meeting. When positioned at the conference table, the user pulls their head back to remove the sip and puff straw. The mask flaps close up, creating a tight seal that provides protection from COVID-19.

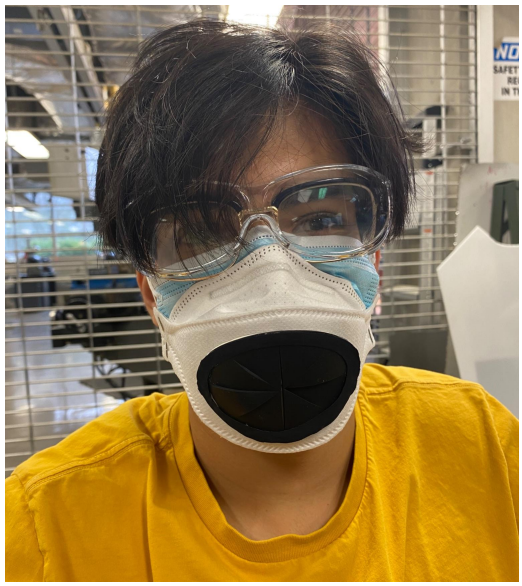

Figure 11: Flaps self-sealing back to original position after device use

During the meeting, the user needs to type something out on their tablet, so they locate their mouth stick and push it through the mask and into their mouth.

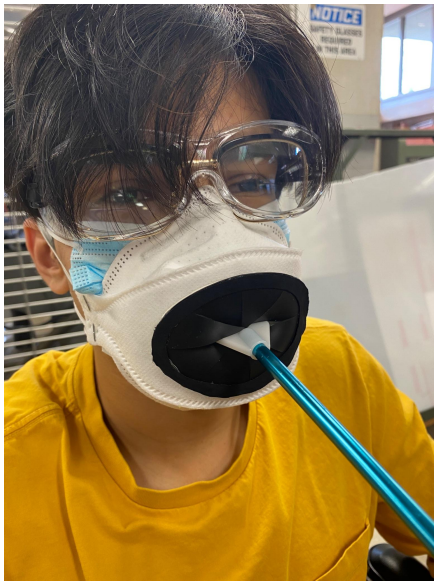

Figure 12: Flaps sealing around mouth stick

Figure 13: Mask in use while mouth stick in use

The double layer of flaps create a seal around the mouth stick itself, not compromising the protection of the mask. When finished with taking notes, the user places their mouth stick on its stand and it pulls out of their mouth and mask. The mask reseals.

Design Benefits

This design was created specially for sip and puff and mouthstick users. The users will be able to use their masks when necessary, and still use their devices comfortably. With that being said, the benefits of this design for the users is that this mask allows flexibility and

accessibility of mouth devices while keeping the user safe and comfortable. The benefits and rationale behind specific features is discussed in the *Design Features* section.

Design Rationale

The rationale behind the silicone insert shape, number of layers, flap shape, and flap number were determined through light testing. A summary of the testing results of the can be seen below in Table 1. The final design was chosen based on the combination of shapes, layers, and flaps that resulted in the lowest amount of light (LUX) detected. For more information, please refer to Appendix E.

The N95 with the flaps allow for a generous air chamber that allows for both breathability and comfort. The strong structure of the flat-front N95 mask enables the use of a push-in/pull-out mechanism which is important for not fatiguing the jaw of the user. Furthermore, it allows for constant easy access throughout the day of both the sip and puff and mouth stick. These devices require fine motor control from the mouth making mouth access a requirement.

Table 1: Summary of LUX Testing Results

(Baseline Light: 24 LUX; Baseline Dark 0.2 LUX)

Shape		**Number of Flaps**	**Amount of Light (lux)**
Overall Shape	**Flap Shape**		
Rectangle	Triangle	8	15
Rectangle	Jagged Rectangle	12	4.4
Rectangle	Rectangle	24	3
Circle	Triangle	4	2.7
Circle	Triangle	8	1.2
Circle	Triangle	16	1.3
Circle	Triangle	32	2.8
Rectangle	Jagged Rectangle	12	3.1
Rectangle	Rectangle	10	2

Rectangle	Jagged Rectangle	5	2.2
Rectangle	Triangle	8	1.6
Rectangle	Triangle	14	1.9
Circle	Triangle (double flap overlap)	8, double layer	0.2 - 0.5
Circle	Triangle (double flap overlap)	16, double layer	0.2
Ellipse	Triangle (double flap overlap)	Outer layer - 8 Inner layer - 16	0.2

The rationale behind the silicone and neoprene rubber materials was determined through testing with a rubber sample pack obtained from McMaster-Carr. First, each rubber sample in the pack was researched for its FDA-compliance and toxicity. Due to the insert being in direct line of inhalation and exhalation, it was important that the rubber be safe to breathe. After narrowing down the samples based on this criteria, the options were narrowed down further based on flexibility. In the end, both neoprene and silicone were the clear choices due to their food-grade safety, FDA-approved status, flexibility, and comfort. Furthermore, the precedence for neoprene has been established as it has been previously been researched as a material in COVID-19 masks. Specifically, the flexibility of the material has been found to be preferred for maintaining shape and it has been found to be more sanitary and less likely to be contaminated [8].

The rationale behind sewing the silicone inserts to the N95 mask was determined through testing with various types of adhesives, like SuperGlue and hot glue, as well as sewing. Due to the toxicity of SuperGlue fumes and the non-durable and impermanent nature of hot glue, these options were discarded. Hot glue, an adhesive made from molten silicone, is not toxic but is not suitable for heavy duty. Sewing offered a permanent solution that would not create toxic fumes for the user, therefore maintaining the safe use of the design.

The use of spandex around the edge of the flap was determined after finding it adhered with hot glue compared to cotton and felt. This was tested by attempting to detach a small piece of hot glue from a sample of each cloth. Furthermore, spandex did not collect dust from the air and surfaces compared to cotton and felt, which makes it more hygienic.

Further Development

Performance and User Testing

For this design to be completely finished, more user testing and observation needs to be done, especially for comfort and performance. For the former this includes, testing the mask while the user is using his sip and puff device and mouthstick, separately, testing the mask while the user changes from using mouthstick to sip and puff device, and asking for feedback on comfort to the user.. In regards to the latter, this involves wear and tear testing to gauge how many times we can impel and withdraw a sip and puff device and mouthstick before a point of deteriorating structural integrity.

Prototype Development

Regarding further prototype development, it is suggested to devise a way to make the rubber flaps detachable from the mask. This would improve the reusability of the rubber flaps, ease of sanitation, and ease of replication by the user (or whomever may assist the user). The idea of removability is that there could be a way for the user to construct their own modified mask with fresh masks at home, so old masks can be disposed of.

Safety

There is a key safety consideration to keep in mind. When testing prototypes, make sure to sanitize the parts that are going to be in close contact with the mouth. Ideally, the rubber flaps should be sanitized after each use of the mask, to keep its main objective.

Furthermore, a few maintenance issues could be encountered after long term use which could increase durability if addressed. First, the stitches holding the rubber piece to the mask could unstitch after a certain amount of uses. In addition, the slit between the triangular flaps on the silicone part of the mask could extend past the intended cut to the edge of the rubber piece. Finally, the rubber could deteriorate towards the tips of the flaps after long term wear and impact.

There are a few key factors when considering new features or materials. These additions should enhance the protective, comfort, or durability components of the mask. More specifically, attempt to limit the size of the rubber flap in order to leave as much of the original mask, and thus filter, intact. Also, try to find materials or methods of making the flaps less permeable to air when not in use and seal around assistive devices when in use.

Design Shortcomings

With regards to safety, the mask should be sanitized between uses with a sanitizing wipe, liquid, spray, or UV light.

Conclusion

In conclusion, our design meets the key needs of patients with quadriplegia and users of orally operated assistive devices (sip and puffs and mouth sticks) who require use of a mask. The design utilizes a combination of:

- A higher particle blockage facemask: N95.
- Food-grade, FDA-approved silicone material as it is safe, durable, comfortable against facial skin, and provides a tight seal.

Mouth stick and sip and puff users need a facemask that is easy to use but also provides adequate protection from COVID-19. Unfortunately, the current solutions in the market do not have both of these characteristics. Our mask meets this twofold need by allowing a method of permeation through the mask while not compromising the users health to the same degree as the current solutions.

Patients that use mouth sticks and sip and puffs desire safety, comfort and a straightforward product that does not alter the current function or method of use of assistive devices. Wearing this mask is the same as any other and allows the same mouth stick and sip and puff use.

References

References

[1] B. Hoogenes, M. Querée, A. Townson, R. Willms, and J. J. Eng, “Covid-19 and Spinal Cord Injury: Clinical presentation, clinical course, and clinical outcomes: A rapid systematic review,” Journal of Neurotrauma, vol. 38, no. 9, pp. 1242–1250, 2021.

[2] “Cervical spinal cord injury: Symptoms and prognosis,” What Is a Cervical Spinal Cord Injury? | Shepherd Center, 2022. [Online]. Available: https://www.shepherd.org/patient-programs/spinal-cord-injury/levels-and-types/Cervical-Spinal-Cord-Injury. [Accessed: 12-Jan-2022].

[3] D. J. Berlowitz, B. Wadsworth, and J. Ross, “Respiratory problems and management in people with Spinal Cord Injury,” *Breathe*, vol. 12, no. 4, pp. 328–340, 2016.

[4] D. M. Hinton, “Surgical Masks EUA LOA.pdf.” U.S. Food and Drug Administration, 05-Aug-2020.

[5] D. Wang, Y. You, X. Zhou, Z. Zong, H. Huang, H. Zhang, X. Yong, Y. Cheng, L. Yang, Q. Guo, Y. Long, Y. Liu, J. Huang, and L. Du, “Selection of homemade mask materials for preventing transmission of COVID-19: A laboratory study,” *PLOS ONE*, vol. 15, no. 10, 2020.

[6] E. Sickbert-Bennett, J. Samet, P. Clapp, H. Chen, J. Berntsen, K. Zeman, H. Tong, D. Weber and W. Bennett, "Filtration Efficiency of Hospital Face Mask Alternatives Available for Use During the COVID-19 Pandemic", JAMA Internal Medicine, vol. 180, no. 12, p. 1607, 2020.

[7] S. C, “Spinal Cord Injuries,” *Hohman Rehab Physical Therapy*, 06-Nov-2020. [Online]. Available: https://hohmanrehab.com/spinal-cord-injuries/. [Accessed: 12-Jan-2022].

[8] S. Faucher, D. J. Lundberg, X. A. Liang, X. Jin, R. Phillips, D. Parviz, J. Buongiorno, and M. S. Strano, “A virucidal face mask based on the reverse‐flow reactor concept for thermal inactivation of sars‐cov ‐2,” *AIChE Journal*, 2021.

[9] “Spinal Cord Injury,” *Mayo Clinic*, 02-Oct-2021. [Online]. Available: https://www.mayoclinic.org/diseases-conditions/spinal-cord-injury/symptoms-causes/syc-20377890. [Accessed: 13-Jan-2022].

[10] T. Solano, R. Mittal, and K. Shoele, “One size fits all?: A simulation framework for face-mask fit on population-based faces,” *PLOS ONE*, vol. 16, no. 6, 2021.

[11] “Types and levels of spinal cord injuries,” Levels and Types of Spinal Cord Injury | Shepherd Center, 2022. [Online]. Available: https://www.shepherd.org/patient-programs/spinal-cord-injury/levels-and-types. [Accessed: 13-Jan-2022].

APPENDICES

APPENDIX A: PROJECT DEFINITION

Project Name: Face Mask for Mouth Stick User
Client: Christina Mix
Client Organization: Shirley Ryan AbilityLab
Team Members: Maya Hanck, Lily Lee, Rohan Wedam, Gabriela Oyarzún Batlle
Date: 25 January 2022
Version: 3.0

Mission Statement

Design an independent, easy-to-use mouth covering device for people with high level spinal cord injuries who use sip and puff straw and mouth stick devices that will filter air particles for COVID-19 protection while retaining mouth access.

Project Deliverables

- Final physical prototype
- Final report printed and bound
- Final presentation and poster during Design Expo

Constraints

- Final prototype, presentation, and poster due by *March 12, 2022*
- Final report due by *March 14, 2022*
- Project budget of $100
- The mouth stick nor sip and puff may not be modified
- Adherence to aesthetics of user for final prototype aesthetic
- High durability for all-terrain use
- Surgical grade minimum for final mask prototype - cloth masks are not permitted at SRAL
- No metal material contact with skin during mask usage

Users and Stakeholders

- Kenneth Jennings, user and stakeholder, will use the device on a daily basis in combination with mouth stick and sip and puff devices to maintain COVID-19 protection
- Caregivers, user adjacent, may help users use the device at home, in the community, or in the workplace

- Christina Mix, client partner and stakeholder, will interact with Kenneth when he is in their shared workplace
- Patients, user adjacent, will interact with Kenneth when he is in their shared space

User Profile

Kenneth Jennings is a man in his 50s with quadriplegia and paralysis. He uses a sip and puff wheelchair device as well as a mouth stick device. He uses this mouth stick device to use a large touchscreen Android cellular device to send emails, search the Internet, and do his work. Current facial masks available make it difficult for him to use both of his assistive devices while maintaining adequate coverage and protection from COVID-19.

Illustrative User Scenario

The user in the illustrative scenario below is based on Kenneth Jennings, who is a man in his early fifties who has quadriplegia resulting from a sports injury in his upper spinal cord. Due to this injury, he has no control of his limbs, but retains full mobility of his neck and head.

Kenneth wakes up each morning at 6:30 and proceeds to check what he has on his schedule for the day. He has several assistants in his household who help him with everyday tasks he is unable to do independently. An assistant helps him get out of bed and get dressed for the day. Around 9:00 in the morning an assistant helps him with his personal hygiene routine and with eating breakfast, which he is also unable to do independently. When Kenneth is at work at the Shirley Ryan AbilityLab or coaching football, he is required to wear a mask due to the COVID-19 pandemic. He does not have independent use of his arms, so he is unable to loop surgical masks over his ears and pull it over his nose. He must have an external individual, perhaps an assistant, to place the mask on his face when it is needed. He also must have someone unzip the zipper flap on his mask so he can independently grab his mouth stick and interact with his Android device to attend meetings and do work.

Project Requirements

Table 2. Project Requirements

Requirements	**As-Built Specifications**
COVID-19 Protection The final product must be able to provide more protection from COVID-19 than the current solution. Rationale: The COVID-19 pandemic requires individuals to wear masks for protection and transmission reduction in public spaces, especially the SRAL. Measurable: Surface area measurement of filter without the rubber insert vs. surface area measurement of filter with rubber insert.	The surface area measurement of the filter with the rubber insert is 12.62 square inches. The surface area measurement of the filter without the rubber insert is 19.49 square inches. ~65% of filter maintained
Assistive Device Accessibility The final product must be able to allow use of a sip and puff and mouth stick. Rationale: These assistive devices allow for movement and interaction with the environment and such functions are necessary for all actions in life. Measurable: Must have a horizontal diameter of at least 2.5 inches to allow for mouth stick insertion at the widest point (Appendix D).	The horizontal diameter of the rubber insert is 3 inches.
Breathability The final product must allow the user to breathe normally. Rationale: The user needs to breathe to sustain normal life and activity Measurable: Surface area measurement of filter removed for rubber insert and resulting filter surface area.	The surface area measurement of the filter with the rubber insert is 12.62 square inches. The surface area measurement of the filter without the rubber insert is 19.49 square inches.

	~65% of filter maintained
Comfortability The final product must be comfortable for the user to wear daily. Rationale: The user will be wearing this design for long periods of time on a daily basis. Measurable: The durometer of the rubber material must not exceed 60A. S. Williams, "What is Durometer? – elastomer and plastic hardness," *Industrial Specialties Mfg.* [Online]. Available: https://www.industrialspec.com/about-us/blog/detail/what-is-durometer-elastomer-and-plastic-hardness. [Accessed: 08-Feb-2022]. "Silicone hardness & shore durometer: Articles," *Jehbco Silicones*, 01-Apr-2021. [Online]. Available: https://jehbco.com.au/silicone-hardness-shore-durometer/. [Accessed: 08-Feb-2022].	The durometer of the rubber material is 50A.
No Modification of Assistive Devices The final product must not modify the user's assistive devices in any way. Rationale: The user required that his devices not be modified for personal comfort. Measurable: The user can use their devices as normal. (Appendix D Table 3)	The user can use their devices how they normally would without a mask on.

APPENDIX B: CLIENT INTERVIEW SUMMARY

Interview with Christina Mix - Project Partner

Introduction

The intention of this interview was to ask initial questions which could not be answered through secondary research but were essential to contextualizing our ideation process and finding client preferences in design. These questions were centered around the mask type, specific user dimensions, wheelchair setup, and modification of current assistive devices. Gaining answers and insight into these questions broadens our options while setting a baseline and limitations for future design solutions. In addition, the team wanted to find out what parts of the current accommodations work efficiently and thus should be retained if possible. This information can also help direct features of the team's design toward those the user currently likes. Questions that arose during this interview surrounding characteristics of devices and materials which were discussed allowed for a direction of further secondary research.

Methodology

This interview was conducted over Zoom. Due to the COVID-19 pandemic and the rise of the omicron variant, the team was unable to conduct an in-person interview. The interview time ran about one hour in length on Saturday January 8, 2022 from 2:00pm - 3:00pm CT. The only materials the team brought were their laptops and pencil and paper to take notes.

During the interview, the team asked questions that fell into the following categories: current and previous solutions as well as their faults and strengths, project constraints, project expectations, context for assisting device usage (mouth stick and sip and puff), and current mobility. The team took notes on the interviewee's responses to these questions and kept record of them in a Google Document.

Results

First, the team learned that surgical masks are required in the SRAL to enter public spaces, so it is required for the user to wear one. The team learned that the user currently wears a zippered mask with an attached face shield that covers the eye region. Unfortunately, this mask and shield combination make it difficult for the user to use their mouth stick and sip and puff device as they normally would without the mask and shield. This also revealed that the zippered face mask does not provide adequate coverage or protection when the assistive devices are in use. The user mentioned that an additional individual is needed to assist in taking on and off the mask as well as opening the zipper for the user.

The only limitations that were mentioned in the interview by the interviewee were that the product design should ideally blend in with the current aesthetics that the user adheres to, be durable for all terrain the user encounters daily, and be at least at the surgical grade level to meet SRAL and hospital masking requirements.

The team found out that the user lives very independently due to his assistive devices. The mouth stick is used for a variety of tasks, including but not limited to transportation use, phone use, elevator use, and moving items. The user also has many technological devices in his home to provide accessibility to things like doors. The mouth stick is used for their phone usage and the sip and puff device is used to move the wheelchair in whichever direction the user pleases. In his home, the user uses both the mouth stick and sip and puff devices, but does not wear a mask or face shield.

In terms of mobility, the team learned that the user is able to shrug their shoulders, has full range of motion at the neck, and is capable of bending forward to grab their mouthstick with their mouth; however, the user has no arm or hand functionality.

As far as the user themself, the team learned that they are very active in SRAL as well as high school football, they are writing a book, enjoy peer mentoring, and appreciate their independence.

Discussion

The project partner, Christina Mix, was incredibly helpful in providing the team with insights regarding the user's current masking situation. Her description and visual of the current face mask and shield combination setup was very beneficial to the team's understanding of the problem, and helped with the beginnings of ideation. The background information she gave the team about the user allowed the team to understand how important independence is to the user, and that in turn made the team place value on having their design allow the user to use the mask in an independent manner. Learning what had not previously been useful for the user and what they think would be useful for themself steered the team's ideation in the right direction and contributed to their brainstorming session the following week. Overall, the interview with Christina solidified the questions that the team needed to ask the user, created new ideas, gave adequate background, and was very constructive.

APPENDIX C: USER OBSERVATION SUMMARY

Introduction

The purpose of this observation was to view our user perform various daily activities using his mouth stick and sip and puff controls, as well as to ask questions to the user in order to gain a deeper understanding of the issues he currently faces. These questions helped to guide our design by showing what functionality the user must retain with our design and how the assistive devices of the user interface with the mask. Moreover, we also intended to find out more user preferences and what are positive and negative aspects of the current sip and puff and mouth stick.

Methodology

For our observation, we met on Zoom with our user Kenneth Jennings and project partner Christina Mix. We took turns asking Mr. Jennings to show us how he performs different day-to-day activities, such as switching from using the mouth stick to the sip and puff device, how he answers calls and texts, etc. He also responded to some questions that we could not get answers to from the interview with our project partner, like his preferences for the mask, and walked us through his daily routine.

Results

Sip and Puff Uses

Now we have a clear image of how he uses his mouth stick and sip and puff and for what and in which specific situations, including:

- Typing text messages and emails.
- Answer calls.
- Turn light switches on and off.
- Press elevator buttons.
- Using his phone.
- Generally move.

The sip and puff straw controls his wheelchair but his mouthstick acts like a biological appendage in that it is how Mr. Jennings interacts with his environment without arm or hand function. Since smartphones have a touchscreen that can be used with a stylus on the end of a mouth stick, Mr. Jennings has been using his Android smartphone in place of a computer for the past few years.

Daily Schedule of Mr. Jennings

He also told us about his daily routine and usual lifestyle:

1. 6:30 – Wake up
2. Check Schedule for the day
3. Schedule rides for the next day
4. 9:00 – Hygiene and Breakfast
5. Lay on side for 1 hr
6. Meetings
7. Football Coaching (Prior to COVID)
8. 5:00 – Ending workday
9. Lay on side for 1 hr
10. End of Day

His activities and career include being a poet, motivational speaker, advocate, and football coach. Furthermore, he is in the process of writing his own book. Additionally, he works for Shirley Ryan AbilityLab, the GridIron Alliance (his foundation), and Neurolink which his meetings tend to be for.

Adding to what we have previously mentioned, we also obtained information about what is not working with the current mask he is wearing: the zipper is always open, the zipper gets cold during the winter, the face shield that goes on top of it gets foggy, and the mask can get a little hot.

We also obtained permission to modify the mouth stick or sip and puff if needed.

Discussion

During the observation, Mr. Jennings proposed his own idea for a face mask. He suggested that we create a face mask with rubber flaps in the center that would allow him to push his mouth stick and sip and puff straw through.

He also mentioned some flaws in his current face mask situation. He described the discomfort of having the cold zipper against his lips when it is cold outside. This is explained by the fact that the zipper is metal, which makes it a good conductor of heat, and will thus easily transfer heat to the colder environment. In addition, the zipper was also always kept open, which constantly exposed Mr. Jennings's mouth. This is not ideal as it means the mask does not provide COVID protection. Furthermore, regarding the mouth stick and sip and puff, Mr. Jennings noted how he likes what he uses to be durable and sturdy. For instance, he notes how he uses a stiff gooseneck for his sip and puff and how many mouth stick mouthpieces tend to break too easily. These characteristics are necessary for the devices which Mr. Jennings uses, because he is constantly active and works on rough terrain when he coaches football.

Overall, through this observation, we were able to gain clarity on Mr. Jennings' current situation and understand his pain points. By being able to speak directly to our user, we were also able to gain a better sense of his vision for this project moving forward.

APPENDIX D: FEEDBACK SUMMARY

Introduction

The team's primary discovery research consisted of a remote user interview and in-person user testing. The remote user observation was to gain an understanding of how the user uses their assistive devices, their current chair setup, and their current masking solution. The team also desired to understand user preferences, requirements, and context for the design. These were details which could not have been discovered through secondary research. The objective of the in-person user testing was to test initial mockups of possible designs and receive feedback across a wide variety of categories.

The main research subject for both the user observation and testing was Kenneth Jennings. For initial testing before user testing, teammates tested the mockups on each other using a mouth stick provided in class to test opening dimensions in the mask modification mockups.

Verbal consent was obtained from Mr. Jennings and Ms. Mix during both the online user observation and the in-person user testing to take screenshots, screen recordings, pictures, and videos.

Methodology: Online User Observation

The user observation was conducted over Zoom on January 14, 2022. Due to the state of the COVID-19 pandemic and Shirley Ryan AbilityLab Visitor Rules, the team was unable to access the facility. Therefore, this user observation was conducted over Zoom. The interview began at 3:00 PM and ended at 4:00 PM CT. The team used their personal computers to connect to the interview and utilized Google Docs to take notes on their observations, as well as the screenshot/screen record features to take photos and videos of the interaction. The user was Kenneth Jennings, a middle-aged man with quadriplegia.

During the interview the team observed Mr. Jennings as he did a variety of activities. They observed the project partner, Cristina Mix, place Mr. Jennings's zippered mask upon his face and unzip the closure. The team then observed Mr. Jennings as he used his sip and puff to control his power chair. Furthermore, Mr. Jennings was observed removing his mouthstick from its stand and using his mouth stick to operate his touchscreen tablet device. After observing him using his current setup, Mr. Jennings was asked about different preferences and how and what his mouthstick is used for.

Methodology: In-Person User Testing

The user testing was conducted in person on February 5, 2022. The meeting was conducted in a conference room on the second floor of the Ford Motor Company Engineering Design Center. Due to the state of the COVID-19 pandemic and Shirley Ryan AbilityLab Visitor Rules, the team was unable to access the facility; however, the user and project partner were able to visit Northwestern's campus for an in-person interaction. The project partner, Cristina Mix, arrived by personal transport while the user, Mr. Jennings, arrived by Uber, a rideshare app which offers assisted transportation for individuals with wheelchairs. A teammate met both Ms. Mix and Mr. Jennings outside the building and escorted them to the conference room. The user testing began at 2:00 PM and ended at 3:15 PM CT. The team used their personal computers to access Google Docs to take notes on their observations and the feedback provided by both Ms. Mix and Mr. Jennings. The team also utilized their personal cell phones to take photos and videos of Mr. Jennings using the mockup designs. For sanitation purposes, the team used sanitizing wipes that were in the conference room to sanitize their designs before presenting them to the user.

During the interview the team asked Mr. Jennings to test out their designs through wearing the mockups and trying to use his sip and puff as well as mouth stick. The team tested the mockups centered on mask modifications first. With each new mockup, the mask was sanitized with sanitizing wipes before Ms. Mix placed the mask on Mr. Jennings's face and adjusted it for proper comfort and fit. Mr. Jennings was then asked to try and use his sip and puff and mouth stick as he normally would. After these tasks, Mr. Jennings was asked to rate each mockup directly after testing on comfort, ease of use, aesthetics, accessibility, and preferences on a scale of 1 (lowest) to 10 (highest). The team took notes on the feedback they received on this category of mockup designs.

After the mask modification designs were presented, the team moved on to designs requiring a mouth stick/sip and puff modification. Since the mockup was at a low-fi stage, the team did not ask Mr. Jennings to wear the mockup, but simply asked for his feedback on the idea.

At the end of the user testing, the team took measurements of Mr. Jennings's mouth stick with a measuring tape and caliper (measurements: diameter, length) for future iterations of their mockups.

Results: Online User Observation

Figure 1. Kenneth Jennings (pictured) with sip and puff (left, in use), zippered mask, and mouth stick (right).

Figure 2. Kenneth Jennings (pictured) with sip and puff (left), zippered mask, mouth stick (right), and desk setup attached to power chair.

The team learned about Mr Jennings's daily activities and during which activities he uses his mouth stick, sip and puff, and zippered mask. He revealed a timeline of his daily schedule which can be seen below in Table 2. The team also learned about the setup Mr. Jennings used. This setup included his sip and puff control, which was attached to the power chair on the right side. The team learned that the sip and puff is powered by how intensely the user sips on the straw. His mouth stick is positioned on his left side and there is a holder there for storage and placement when he is not using the device. The chair also has a desk/table setup where Mr. Jennings keeps many of his belongings, the most important being his Android device.

Table 2: Mr. Jennings's Daily Schedule

Time	**Activity**
6:30 AM	Wake Up
7 AM	Check Schedule
8 AM	Schedule car rides for following day
9 AM	Hygiene and Breakfast
10 AM	Lay on side for 1 hour
11 AM	Meetings/SRAL work/GridIron Alliance Foundation work/Work for Neurolink
3 PM	Football Coaching
5 PM	Lay on side for 1 hour

Results: In-Person User Testing

Figure 3. Kenneth Jennings (pictured) in his power chair with assistive device setup. The user is pictured using a mockup mask modification design and can be seen using his mouth stick wearing the design. These two frames are captured from a video of Kenneth Jennings using the mask modification mockup to insert and pick up his mouth stick.

In regards to the mockups that fell under the mask modification category, the team was given a variety of feedback from both Mr. Jennings and Ms. Mix on the mockups that were presented and tested. Mr. Jennings was asked to rate his responses on a scale of 1 (lowest) to 10 (highest) on access, preferences, use and control, as well as aesthetics of each mockup. The results can be seen in the table below.

Table 3: Mockup Ratings

Design	Access	Preferences	Use and Control	Aesthetics	General Thoughts
Black Mask with silpat-lined mouth slit	8	7 - would like the mask to be adjustable around the ears	8	8	1. Prefers a push through mechanism in contrast to the design's jaw-powered mechanism 2.Would like a stiffer material to be used in opening
N95 mask with blue foam pie-sliced push through opening	8	6.5	8	8	1.N95 mask is tighter - would be something to get used to as breathing is a bit more difficult 2.Likes the foam material because it closes back up after use 3.Would prefer a rubber material

Results: General

Table 4: User Observation and Testing

Meeting/Design	**Key Takeaway**	**Implications**	**Potential Next Steps**
User Observation	Metal zipper on current mask causes discomfort in cold weather	This fact revealed that the user would like the design to remedy this issue.	Look into what could replace the zipper to ensure a seal on the mask while providing comfort during all types of weather, especially cold.
User Testing - Mask Modification Designs	1. User preference for a push-through mechanism instead of a jaw-open/close mechanism. 2. User preference for a rubber material for opening	1. Material needed for a push-through mechanism must be stiffer than foam but softer than hard plastic. 2. Research is needed into types of rubber materials.	Create an iteration with a push-through mechanism. Research and test different rubber and rubber-like materials for opening.
User Testing - Assistive Device Modification Designs	Design mockup was presented to the user. The user revealed that the design must not modify his current mouth stick nor his sip and puff devices.	This was a previously unknown limitation. The team will now adhere to this feedback.	Focus on designs that do not modify the user's assistive devices.

Discussion

Upon user observation and testing, the team was able to gain a more refined understanding as to how to proceed with the mask design for the user, Kenneth Jennings.

Some of the issues Mr. Jennings faced with his current zipper mask situation was the temperature of his zipper getting cold whenever he went outside which led to discomfort on his face, as well as the large opening in the middle of the zipper mask that exposed him to airborne particles. In order to mitigate these issues, the team created mockups using less conducive materials such as plastic and soft rubber in order to prevent the mask from getting cold against the user's lips. The team also experimented with adding a second flap to the back of the mask in order to provide an extra layer of protection and seal from airborne particles.

Because the opening of the zipper mask was initially too large, the team created mockups using various types of openings. Two of the mask opening types that were used in user testing included two flaps overlapping slightly with one flap on top and the other on the bottom, as well as an opening where the center was cut out in an asterisk-like shape to allow the straw and mouth stick to push through.

After testing these various masks with the user, Kenneth Jennings, the team was able to learn that both of these opening types are effective in providing access to the mouth stick and straw, but could be improved in terms of the material used to create the opening and a more precise size. Mr. Jennings suggested that the opening of the mask be created using a hard rubber that would conform to the shape around the mouth stick and straw as well as close up easily when not in use.

Another key takeaway from the user testing was the fact that the second flap on the back of the mask was ineffective in providing an extra layer of protection for our user. The flap prevented access to the mouth for devices and in effect acted as a standard mask and thus presented the same accessibility issue. Moving forward, the team will no longer be creating a second flap on the back of the mask but will experiment with various material types to determine which material provides the best protection from airborne particles.

Guidance Questions

1. How do we test what materials will work best when we do not have access to a variety of silicone rubber products?
2. Uncertainty surrounding a hi-fi final prototype with limited material access
3. Will there be more testing sessions with Mr. Jennings?
4. How can we make sure that our solution is sanitary?
5. Which type of surgical mask should we modify?

APPENDIX E: SILICONE INSERT SHAPE TESTING RESULTS

Testing
Light: 24 LUX Baseline
Dark: 0.2 LUX Baseline

Table 5: Summary of LUX Testing Results

Shape		**Number of Flaps**	**Amount of Light (LUX)**
Overall Shape	**Flap Shape**		
Rectangle	Triangle	8	15
Rectangle	Jagged Rectangle	12	4.4
Rectangle	Rectangle	24	3
Circle	Triangle	4	2.7
Circle	Triangle	8	1.2
Circle	Triangle	16	1.3
Circle	Triangle	32	2.8
Rectangle	Jagged Rectangle	12	3.1
Rectangle	Rectangle	10	2
Rectangle	Jagged Rectangle	5	2.2
Rectangle	Triangle	8	1.6
Rectangle	Triangle	14	1.9
Circle	Triangle (double flap overlap)	8, double layer	0.2 - 0.5
Circle	Triangle (double flap overlap)	16, double layer	0.2
Ellipse	Triangle (double flap overlap)	Outer layer - 8 Inner layer - 16	0.2

APPENDIX F: BACKGROUND RESEARCH SUMMARY

Introduction

At the onset of the project, our team conducted background secondary research on the condition of our user and the context provided by our client, a peer mentor and program manager at the Shirley Ryan AbilityLab (SRAL). Our project involves designing a face mask for a sip and puff and mouth stick user; this means creating masks that maintain face coverage while not limiting the usability of assistive devices. Due to the COVID-19 pandemic, people are required to wear facial masks for public safety. Our research included: (1) basic information about high level spinal cord injuries; (2) causes of difficulty in mask usage; (3) current products used for masking; (4) various mask characteristics; (5) government requirements; and (6) the mask solution used at SRAL.

Physiology of high level Spinal Cord Injury

Spinal cord injuries are often caused by trauma and effect sensation and motor control of regions below the injury. Thus, an injury which is more superior (closer to the head) is more severe. The traumatic nature of spinal cord injuries means they can either heal in part or full (incomplete spinal cord injury) leading to recovery of function or result in permanent damage and loss of function (complete spinal cord injury). Physical disabilities such as quadriplegia and paraplegia are the result of complete spinal cord injuries [10].

In our project, the user is said to use a mouth stick, which is for physical interaction with the environment and a sip and puff, which is for operating his wheelchair. This indicates that the user has quadriplegia, which means he has no mobility below the head and neck and likely has in injury .

The figure below (see Figure 1) displays the impact of injury to different spinal locations.

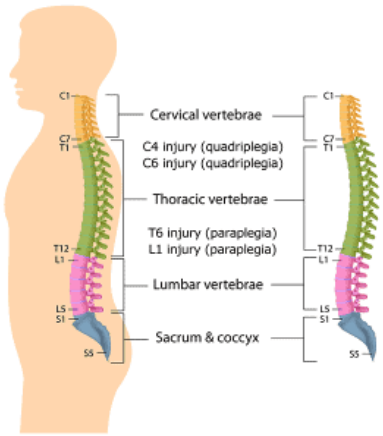

Figure 1: Spinal cord areas

Source: “Spinal Cord Injuries” <https://hohmanrehab.com/spinal-cord-injuries/>

Causes of difficulty in mask usage

Individuals with quadriplegia who need to use a sip and puff and mouth stick operate such devices with their mouth. Furthermore, Berlowitz et. al. found that these individuals may have difficulty breathing, because of loss of function of muscles which support respiration (abdominal and intercostal muscles) [2].

Such considerations complicate the ability to use a mask to sufficiently cover the lower face, especially the mouth. This coverage inherently limits the ability to both use assistive devices and breath with already weakened respiratory muscles.

Characteristics of Current Masking Products

There are several masking products currently available in the market that offer some protection against airborne particles while retaining access to the mouth. These include a manufactured mask with a mouth zipper, a manufactured mask with a straw hole, and a KN95 mask.

Manufactured mask with mouth zipper

A manufactured mask with a mouth zipper (see Figure 2) is a cloth mask with a zipper embedded in the center of the mask. The user has access to their mouth without having to remove the mask entirely, thus making it easier to eat and drink. It can also alternatively be used to insert a mouth stick or a sip and puff straw in the user’s mouth without having to lift up the mask. The zipper function, however, increases the user’s exposure to

airborne particles due to the open gap formed between the zippers. It also requires the user to have the ability to unzip the mask themselves.

Figure 2: Manufactured mask with mouth zipper
Source: “Zipper face masks”
<https://www.lyfestylenyc.shop/products/lyfestyle-zipper-face-masks>

Manufactured mask with straw hole

A manufactured mask with a straw hole (see Figure 3) is typically used to insert a straw through a mask for drinking purposes. The mask itself is commonly made out of cloth material and the hole on the mask is covered with a cloth flap when not in use. This hole can be sized differently based on the size of the straw in order to create a tight seal around the straw. Thus, it can be effective in creating a seal around a mouth stick or a sip and puff straw that provides adequate particle blockage. This type of mask also requires the user’s ability to lift up the cloth flap to access the hole and insert the straw.

Figure 3: Manufactured mask with straw hole.
Source: “Continental Luxury Face Covering with Drink Straw Hole use at The Bar, Pool, Parties Black”
<https://www.amazon.com/dp/B08DDGP26K/ref=cm_sw_em_r_mt_dp_BF41ZQ6KRGZ46K5HXADQ?_encoding=UTF8&psc=1>

KN95 Masks

The KN95 mask (see Figure 4) is one of the most efficient face masks in providing particle blockage. It is designed to have a very close fit to the face and therefore protect the user from airborne particles. The KN95 mask is labeled as a single-use, thus, if the mask gets damaged, wet, or if breathing become difficult, it must be removed and disposed.

Figure 4: KN95 mask
Source: " White Powecom® KN95 Respirator Face Mask(...)"
<https://bonafidemasks.com/Powecom-kn-95/>

Government Health and Safety Requirements

Mask Ventilation

The breathability of a facial mask is critical to its use. Breathability entails the proper inflow and outflow of air so that the user sustains proper breathing. A standard associated with ventilation is Fitted Filtration Efficiency (FFE). According to Sickbert-Bennett et al., FFE is a measurement of the concentration of particles that are within the mask, and this concentration is represented as "a percentage of the particle concentration in a sodium chloride particle-enriched chamber atmosphere [FFE% = 100 x (1 - behind the mask particle concentration/ambient particle concentration)] measured during a series of repeated movements of the torso, head, and facial muscles" [6]. Their study found that the higher the FFE%, the better the mask was at filtering out particles. Some of the masks tested and their corresponding FFEs are in Table 6 below.

Table 6: Mask Type/FFE Percentage for Commonly Used Facial Masks

Mask Type	FFE Percentage (%)
Fitted N95	98.5
Surgical Mask with Ties	71.5
Surgical Mask without Ties	38.1

Source: E. E. Sickbert-Bennett, J. M. Samet, P. W. Clapp, H. Chen, J. Berntsen, K. L. Zeman, H. Tong, D. J. Weber, and W. D. Bennett, "Filtration efficiency of hospital face mask alternatives available for use during the COVID-19 pandemic," *JAMA Internal Medicine*, vol. 180, no. 12, p. 1607, 2020.

Mask Fit

Mask fit is a dimension that is important to facial mask design. Solano et al. found that one size masks typically do not fit all people due to different face sizes, shapes, facial contours, and facial structures present in the human population. Due to these facial differences, mask leakage can occur with these one sized facial masks [9].

Mask Material

The material a facial mask is constructed out of is crucial for particle blockage. Wang et al. found that the material used in mask manufacturing directly correlates with the particle size that the mask can block out. In their study, they found that surgical mask material has a higher bacterial filtration efficiency than homemade cloth mask material [5].

FDA Requirements

There are several performance criteria that surgical facial masks need to meet legally if they are to be given authorized use to stop the spread of COVID-19 [3]. As Table 2 indicates, there are five main characteristic requirements, matched with their FDA Recognized Consensus Standards citation. These characteristics important for our project's future ideation, design, and final product as all of these steps need to comply with these requirements.

Table 7: FDA Characteristic Requirements and their FDA Recognized Consensus Standards Citations for Surgical Facial Masks

FDA Characteristic Requirement	**FDA Recognized Consensus Standards Citation**
Fluid resistance requirements (liquid barrier performance)	ASTM F1862: *Standard Test Method for Resistance of FMedical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*
Flammability performance consistent with the definition of either a Class 1 or Class 2 textile	16 CFR Part 1610
Particulate filtration efficiency requirements	ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks*
Air flow resistance (i.e., breathability) requirements with an acceptance criterion of <6 mm H_2O/cm_2 for differential pressure (delta P) testing	ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks* for those masks composed of 4 or more layers
Materials of manufacture are either (1) non-cytotoxic, non-irritating and non-sensitizing or (2) conform to biocompatibility standards	ISO 10993-1: *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* ISO 10993-5: *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* ISO 10993-10: *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.*

Source: D. M. Hinton, “Surgical Masks EUA LOA.pdf.” U.S. Food and Drug Administration, 05-Aug-2020.

Face mask at SRAL

In the project description, our client detailed that a mask with a mouth opening is used at SRAL. This face mask allows access to the user’s mouth stick, but compromises the facial coverage the mask is intended to provide. A face shield is used in conjunction with the face mask, but compromises accessibility for use of mouth stick and sip and puff control.

APPENDIX G: BILL OF MATERIALS

Table 8: Bill of Materials

Name of the material	Quantity	Vendor	Price
N95 disposable masks	50 pcs	Amazon Link here	$18.99
Rubber Silicone Sheet 6” x 6” x 0.04”	1	McMaster-Carr	$18.48
Rubber Neoprene Sheet 6” x 6” x 0.0625	1	McMaster-Carr	$10.90

APPENDIX H: INSTRUCTIONS FOR CONSTRUCTING THE PROTOTYPE

Instructions for Constructing the Flap Mask

The following table lists all materials one will need to build the Flap Mask.

Table 9: Materials Used for Construction

Material	Specifications	Quantity
N95 Mask	8.125” x 3.3”	1
Silicone Mat	6” x 6” x 0.04”	1
White Food Grade Neoprene Rubber Sheet	6” x 6” x 0.0625”	1
Fabric	4” x 3”	1

Note: See Bill of Materials in report for detail on cost and part numbers.

The following tools are required to construct this device:

- Sewing Machine
- Fabric Scissors
- Paper Printer
- Utility Knife
- Painter’s Tape
- Ruler

Preparing the materials

1. Print out prepared stencils (Appendix X) which are two 3.5 inches wide and 2.5 inches tall ellipses. One has 8 flaps and the other is 16 flaps.
2. Cut one pair of 8 flaps and 16 flaps ellipses from the stencil. Cut along the outer border. (Figure 1)

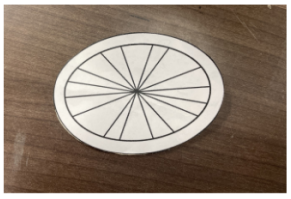

Figure 1: Cut out stencil

Cutting the rubber inserts

3. The first insert will be an ellipse with 8 triangular flaps.
    a. Secure the stencil of the 8 flap ellipse to a sheet of food grade neoprene rubber using 4 small pieces of painter tape, one for each covertex and vertex. (Figure 2)
    b. Using the stencil, trace the outline of an ellipse on the rubber sheet. (Figure 3)
    c. Cut along the traced ellipse outline.
    d. Then to create the flaps, cut along the 3 intersecting lines in the center of the stencil, through the stencil. The use of a ruler along stencil lines can help with straight cuts. (Figure 4)
    e. Remove the tape and stencil. The ellipse should now have 8 flaps.
    f. Do not discard this 8 flap ellipse stencil as it will be used in step 3.
    g. A good practice is to make sure the cuts do not go all the way to the edge of the ellipse and strictly follow the stencil
    h. Put the resulting ellipse with 8 triangular rubber flaps aside. It will be used in Step 4.
4. The second insert will be an ellipse with 16 triangular flaps.
    a. Repeat Steps a-e from 3 on a silicon mat, but using the stencil with 6 intersecting lines to create an ellipse with 16 flaps.
    b. The ellipse should now have 16 triangles.

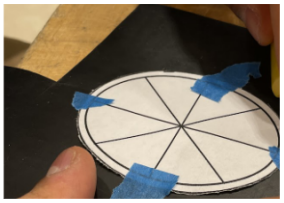

Figure 2: Tape on stencil

Figure 3: Trace stencil

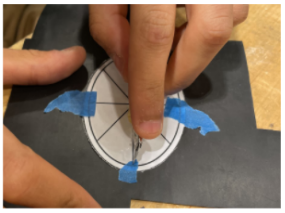

Figure 4: Cut out rubber

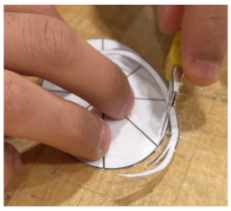

Figure 5: Remove outer border

Cutting the Mask

5. Measure out a 3 inch wide by 2-inch tall cross in the center of the flat front of the N95 Mask to mark the center of the mask
6. Cut along the inner ellipse outline of the stencil from Step 3 (Figure 5)
7. Center the stencil on the cross drawn on the mask.
8. Outline the elliptical shape of the stencil on the front of the mask using a pen/pencil. (Figure 6)

Figure 6: Trace on mask

Figure 7: Ellipses Hole

9. Cut the resulting elliptical shape out with scissors. Cut a small slit in the center of the outlined ellipse for scissor access. Discard the cutout elliptical shape of mask material. (Figure 7)
10. Put the resulting N95 Mask with an elliptical hole aside.

Figure 8: Stacked ellipses

Assembling the Mask

11. Place the 8 flap ellipse over the 16 flap ellipse to where the horizontal slits are aligned with each other.
12. Using a sewing machine, lightly sew along the border of the stacked ellipses to sew the two ellipses together. It only needs to be sewed on the left and right side of the ellipse. This will prevent the ellipses from moving around when being sewed on the mask. (Figure 8)
13. Open up the N95 Mask
14. Place the stacked ellipses on the front of the mask, making sure that the stacked ellipses are centered on the mask and aligned with the border of the ellipses hole on the mask
15. While holding the stacked ellipses in place on the mask, feed the mask facing downwards (inside of the mask facing upwards) through the presser foot of the sewing machine until it goes to the border of the ellipses. (Figure 9)
16. Sewing along the entire border of the ellipses using a sewing machine in order to attach the ellipses to the mask. When sewing, make sure that the tension of the sewing machine is set to its highest setting. (Figure 10)

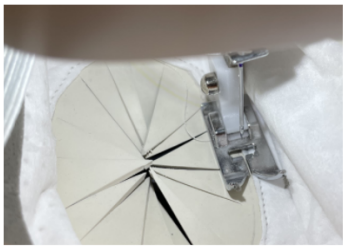

Figure 9: Sewing machine set up

Figure 10: Sew along border

Creating a fabric border

17. Trace and cut out a piece of fabric in the shape of the border. This can be done using the stencil outline. (Figure 11)
18. Hot glue the fabric on the border of the ellipses on the mask to cover the stitches. (Figure 12)

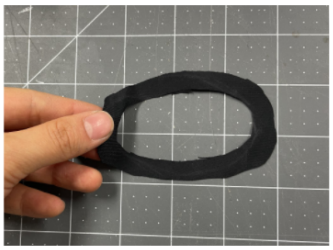

Figure 11: Fabric Ring

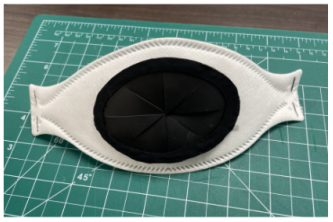

Figure 12: Final Product