Ultraportable Surgical Enclosure: Human Centered Design for High Usability in Unpredictable Environments

by
Annie Tianci Zhang

Submitted to the
Department of Mechanical Engineering
in Partial Fulfillment of the Requirements for the Degree of

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ABSTRACT

Access to safe and sterile surgical infrastructure dramatically reduces the risk of infection for both patients and medical providers. However, this access is limited for many, especially those in austere environments and developing countries. SurgiBox is a product that aims to solve this problem by providing a sterile surgical micro-environment in a cost-effective manner. SurgiBox is a transparent, inflatable plastic enclosure which isolates the surgical site, creating a localized, sterile region in which surgical procedures may take place. The two primary markets — humanitarian and defense applications — have overlapping needs and similar design constraints. For both markets SurgiBox needs to be highly portable and useful in unpredictable environments with ad-hoc medical infrastructure. Using SurgiBox should be a predictable, reliable, and easy to understand experience even in the most unpredictable environments. The redesign of SurgiBox components through a Human Centered Design approach has enhanced its usability, effectiveness, and efficiency for both patients and medical providers.

Thesis Supervisor: Daniel Frey
Title: Professor of Mechanical Engineering, MIT D-Lab Faculty Research Director

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ACKNOWLEDGEMENTS

SurgiBox is the first and longest design research project I have had the opportunity to partake in. I'm deeply thankful for the opportunity to have worked alongside such a creative team of people with such noble goals. I would like to acknowledge and express my gratitude to the people who have guided me along the way and helped me grow as a better engineer and designer through my work with Surigbox:

Thank you to Sally Miller for being an excellent mentor to my freshman year self, and for introducing me to the SurgiBox project and team.

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1. BACKGROUND

1.1. Surgical Site Infections

For many surgery patients, the highest risk is not during the operation, but in the process of recovery after the surgical procedure. One of the most easily mitigated postoperative risks is the risk of infection. Surgical site infections (SSI) account for between 14-17% of hospital acquired infections and remain a substantial cause for death. [1] In order to mitigate the risk of infection, stringent operating procedures and techniques are in place to reduce the number of microbes to as few as possible in order to prevent infecting the surgical site. [2]

One of these techniques for reducing the number of microbes around the surgical site is the use of a sterile field. The sterile field is a region in which all tools, protective equipment, and personnel are sanitized as thoroughly as possible before entering. The sterility of this field depends on the quality of the equipment used, as well as the quality of the behavioral practices employed by personnel interfacing with the sterile field and the patient within it. Fortunately, over many decades of iteration a set of rigorous standards of practice has been established to ensure behavioral practices are consistently and successfully effective in mitigating infection risk. The nine standards from The Association of Surgical Technologists is summarized below:

1. To provide for a safe and uneventful surgical procedure, the Certified Surgical Technologist (CST) should have all the necessary instruments, supplies, and equipment needed to prepare the sterile field for the surgical procedure.
2. The operating room (OR) furniture and equipment should be grouped and positioned prior to opening the sterile items.
3. Sterile technique must be strictly adhered to by the surgical team members when opening sterile instrument sets, packages, and peel packs.
4. Traffic in and out of the OR should be monitored and controlled when the surgical team begins to open sterile items.
5. Sterile supplies should be opened and set-up as close to the time of surgery as possible and for one surgery only.
6. The CST should apply the principles of economy of motion when establishing a routine for setting up the back table and Mayo stand. While setups will vary according to surgical specialty, procedure, and facility policy, there are principles that can be applied to all back table and Mayo stand setups.
7. The electrosurgery active electrode handpiece should be controlled when not in use to prevent inadvertent activation to avoid burns to the patient and sterile surgical team members, and ignition or puncture of the drapes
8. The surgery department should review the policies and procedures regarding the sterile field, including principles of asepsis on an annual basis.
9. CSTs should complete continuing education to remain current in their knowledge of the sterile field and principles of asepsis.[3]

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[1] A.M. SPAGNOLO et al., “Operating Theatre Quality and Prevention of Surgical Site Infections,” *Journal of Preventive Medicine and Hygiene* 54, no. 3 (September 2013): 131–37.

[2] Karie Tennant and Cynthia L. Rivers, “Sterile Technique,” in StatPearls (Treasure Island (FL): StatPearls Publishing, 2020), http://www.ncbi.nlm.nih.gov/books/NBK459175/.

[3] “Guidelines for Best Practices for Establishing the Sterile Field in the Operating Room,” n.d.

Guidelines 2 through 6 are ostensibly about managing tools, equipment, and supplies. However a further reading into the notes under each guideline shows that these guidelines are also about airflow and airborne particles. Surgeons can practice near-perfect sterile techniques, but this is futile if the operating room or sterile field itself is unable to maintain sterility. Thus, the quality of the sterile field itself turns out to be just as important as the behavioral practices that the surgical team follows.

Our understanding of SSIs is not new. Even the airborne particles, invisible to the naked eye, have been studied and understood for decades. One of the pivotal studies in this field was conducted in 1972 by British surgeon John Charney. He constructed the first clean-air enclosure system with unidirectional flow and over the course of hundreds of surgical procedures mapped a correlation between how often air was changed in the room and how likely infection was to occur. When the rate of air change was increased from 130 air changes per hour to 300 air changes per hour, the rate of infection fell by 50 percent.[4]

This airborne particle problem requires quality infrastructure to scrub the air of microbes. In quality operating rooms, there are HVAC systems that control air currents and airborne particles in the room, as well as creating a slight positive pressure to encourage airborne particles to flow out of the room. However, this kind of infrastructure needed to support the creation and maintenance of a sterile field is not available everywhere that it is needed. For instance, rural areas or developing countries simply may not have the necessary equipment to create the conditions for a sterile field. Furthermore, in the wake of natural or man-made disasters, the scarcity of resources and the sharp uptick in need for surgical intervention can overwhelm any remaining surgical infrastructures.

1.2. Surgery in Austere Environments

Access to surgical care and adequate medical infrastructure is severely limited for many in developing countries. An estimated 5 billion people--mostly in lower and middle income countries (LMICs)--do not have access to safe, timely surgery or anesthesia.[5] This inequality in surgical care is shown most clearly by the fact that the poorest one-third of the world's population receives only 3.5 percent of all surgical procedures. [6] Around the world, surgeons and their teams are trained to follow guidelines to help maintain sterility before, during, and after each procedure. Despite fairly standardized surgical workflows around the world, the supporting infrastructure is not the same quality around the world, therefore the rate of SSI is disproportionately high in developing countries.

While this inequality in access to surgical care is undoubtedly tied to global wealth inequality, man-made and natural disasters also exacerbate the problem by depleting or destroying resources in times with high need for surgical intervention. In times of natural disaster, the

[4] John Charnley, "SECTION II GENERAL ORTHOPAEDICS Postoperative Infection after Total Hip Replacement with Special Reference to Air Contamination in the Operating Room," A Publication of The Association of Bone and Joint Surgeons® | CORR® 87 (September 1972): 167–187.
[5] "WHO | Emergency and Essential Surgical Care," WHO (World Health Organization), accessed April 18, 2020, http://www.who.int/surgery/en/.
[6] Thomas G Weiser et al., "An Estimation of the Global Volume of Surgery: A Modelling Strategy Based on Available Data," The Lancet 372, no. 9633 (July 12, 2008): 139–44, https://doi.org/10.1016/S0140-6736(08)60878-8.

demand for operative trauma care increases dramatically, with orthopedic surgery being the most prevalent type of surgery provided after natural disasters such as earthquakes.[7] Natural disasters often disrupt power distribution and supply lines, which can further diminish the capabilities of strained hospitals. Regarding man-made disasters: If standard peacetime health services are already overwhelmed or inaccessible, during times of armed conflict the system is overburdened with injured patients in need of surgical care. In both cases of disaster response, SurgiBox would allow for surgical intervention to be performed in remote locations. In the most urgent cases, SurgiBox could even allow for emergency procedures to be safely performed in the field.

The problem is ultimately an infrastructure and access problem, but the solution need not be an infrastructure solution. SurgiBox, an ultra-portable surgical enclosure, aims to help close this gap in surgical care by shrinking the surgical infrastructure to a containment-zone around the sterile field itself. A traditional operating room is not necessary if the same guidelines of sterile surfaces and clean airflow can be contained within a smaller boundary. SurgiBox gives surgeons a localized sterile field that can be used in austere and ad-hoc environments in order to decrease the risk of SSIs in patients who have no choice, no time, or no access to quality surgical infrastructure.

1.3. SurgiBox Development

The first iteration of SurgiBox was designed in 2010 by Dr. Debbie Teodorescu. The innovation was in taking the room out of the operating room: Dr. Teodorescu identified the opportunity to create a sterile environment that was isolated around the surgical site, rather than needing to create an entirely sterile operating room. The first SurgiBox took the form of a rigid, box-like frame supporting a transparent plastic enclosure. The enclosure wrapped around the entire patient's torso and HEPA-filtered air was cycled through the interior of the enclosure to provide a sterile environment. Because there was a physical barrier between patient and surgeon, not only were contaminants kept outside of the sterile field, the plastic enclosure also kept bodily fluids inside the sterile field. In this regard, SurgiBox is even better than traditional operating rooms in protecting the surgeons as well.

[7] Kanchan K.c et al., “A Study of Surgical Cases During Earthquake Disaster in A Medical College,” Journal of Nepal Medical Association 57, no. 215 (February 28, 2019), https://doi.org/10.31729/jnma.4063.

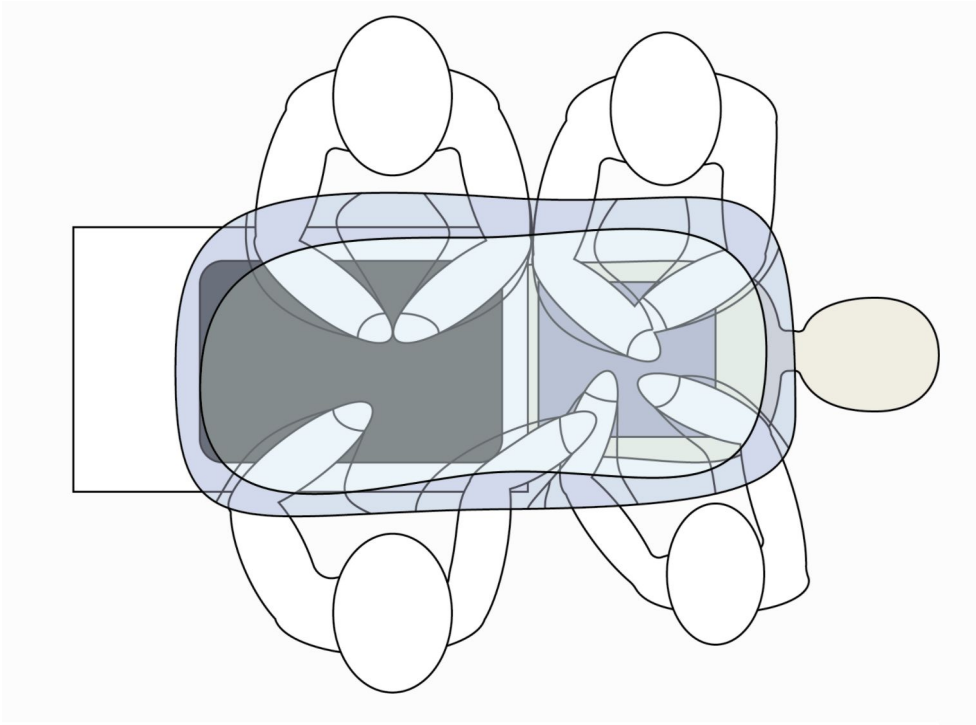

Fig 1-1: Schematic of SurgiBox concept: a transparent enclosure positioned on the patient's torso, with sleeves for surgeons to access the surgical site. [8]

At a high-level, the SurgiBox product architecture consists of an enclosure, a frame, and an air filter box. The function of each component is detailed below:

> **Plastic Enclosure:** The enclosure is made of a transparent plastic. The size and shape of the enclosure must allow for an adult torso to fit inside or underneath, as well as for 2-4 members of a surgical team to reach inside and perform the surgery. The enclosure needs to be able to prevent airborne particles from entering while at the same time allowing surgeons to have their hands inside the enclosure to perform the operation.
> **Air Filter Box:** A HEPA filter, blower fan, and microcontroller are housed together in a box. The blower fan creates a pressure differential as well as airflow, pulling filtered air into the enclosure. This box should prevent the ingress of particles of fluids when in operation.
> **Support Frame:** A rigid frame that supports the shape of the plastic enclosure during operation.

The core concept of an enclosure around the surgical site, that uses filtered air to maintain a sterile field has not changed. However since the original design, SurgiBox has undergone several major design iterations:

> **Generation 1 and 2:** The original surigbox design. A rigid, boxy frame supports a transparent plastic enclosure. Like a glove box, there are sleeve ports for the surgeon to access the patient. The enclosure encapsulates the patient's entire torso.

[8] "Our Solution," SurgiBox, accessed April 23, 2020, https://www.SurgiBox.org/solution.

Generation 3: The frame is changed to a PVC-pipe construction, which can more readily be disassembled into smaller pieces. This drives the product architecture closer toward the goal of being ultra-portable.

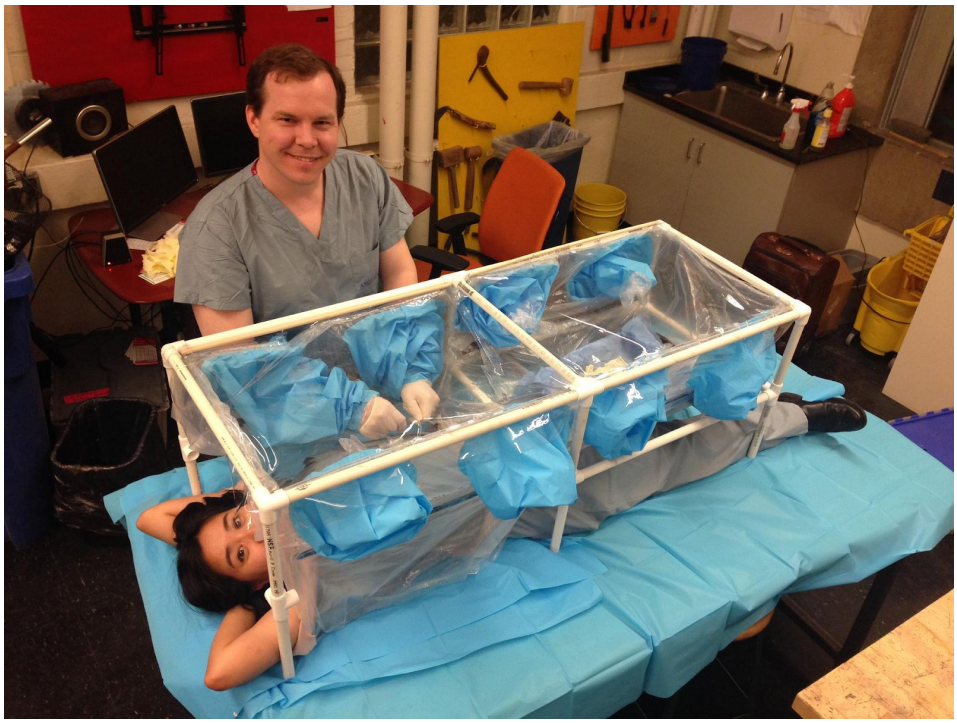 [9]

Fig 1-2: Generation 2 SurgiBox Prototype

Generation 4: A major architecture change: the enclosure becomes an inflatable design. The enclosure is completely made of soft plastic and can hold its shape if positive air pressure is maintained. The frame is relegated to a backup role, to hold the enclosure up in the case of sudden deflation.
Generation 5: The enclosure material is changed to TPU plastic. TPU provides better optical clarity, while maintaining material properties that are best for a soft plastic, inflatable structure. TPU film is easy to join via heat sealing, but thick enough that it is not easily punctured.
Generation 6: The addition of ports for allowing surgical tools and tubing to be passed in and out of the enclosure. This change makes the support frame more relevant once again.

[9] "SurgiBox | Medical Education - Harvard Medical School," accessed April 23, 2020, https://meded.hms.harvard.edu/SurgiBox.

Fig 1-3: Generation 6 SurgiBox Prototype. Note the black line on the left is where the port is. The port is sealed by two thin strips of flexible magnetic sheet, which gives it a black color.

I joined the SurgiBox team during the development of the Generation 6 prototype. At that time, SurgiBox was well past the proof-of-concept stage, and was preparing to refine designs for manufacturability and usability. My contribution to the project was exploring how some of the key components could be redesigned to be more "user-friendly" through a Human Centered Design perspective.

1.4. Human Centered Design

There is no single definition of HCD, but the closest thing to a comprehensive definition is one set forth by the International Organization for Standardization (ISO): "Human-centred design is an approach to interactive systems development that aims to make systems usable and useful by focusing on the users, their needs and requirements, and by applying human factors/ergonomics, and usability knowledge and techniques. This approach enhances effectiveness and efficiency, improves human well-being, user satisfaction, accessibility and sustainability; and counteracts possible adverse effects of use on human health, safety and performance." [10] In the context of medical device design, HCD is particularly useful because in making the product or device easier to understand and use, the design can have the consequence of reducing training and support costs. Additionally, reducing discomfort and stress during use helps to free up cognitive bandwidth for the user (in this case the surgical team) to focus on the actual surgery itself.

To understand the benefits of a HCD approach, we can look at a case study of hand hygiene in an intensive care unit (ICU). A study by a senior physician found that despite the same rigorous training on how and when to scrub down hands between handling patients and touching other

[10] 14:00-17:00, "ISO 9241-210:2019," ISO, accessed April 19, 2020, https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/07/75/77520.html.

surfaces, many nurses develop their own behavioral patterns of hand washing. The nurses in the study had each formed different mental models (conceptualized boundaries and relationships) of what constitutes sterile zones in the ICU, and thus they followed the hand-washing training with varying degrees of success. A HCD approach to solving the problem identified that a lack of cues demarcating the sterile zones was the root cause of non-compliance with the training. The solution was to implement hand sanitizer stations with blinking lights (visual cues) where nurses would enter or leave patient zones. This cue helped successfully raise the compliance rate of hand washing without having to provide additional training or signage and instructions. [11]

Early stage research and development efforts make a product work. However, the role of HCD is to make the product work well for humans. This framework for design combines a knowledge of engineering design along with a sensitivity for human emotions, perceptions, and limits in order to bridge the gap between highly optimized solutions and the diverse and often unpredictable ways that people employ those solutions.

[11] H. Sax and L. Clack, "Mental Models: A Basic Concept for Human Factors Design in Infection Prevention," Journal of Hospital Infection 89, no. 4 (April 2015): 335–39, https://doi.org/10.1016/j.jhin.2014.12.008.

2. MOTIVATION

This paper focuses on the design and development of 3 components within the whole SB system: air intake unit, the connection between the air-intake unit and the enclosure, and the support frame. These 3 components were developed using a HCD approach. The HCD framework makes heavy use of human factors and ergonomics knowledge, which results in designed products that are safer and easier to use. Specifically in the context of medical care products, products that prioritize usability typically reduce user reliance on manuals and training. The HCD design process also tends to produce products with safer connections between device components and accessories (e.g., power cords, leads, tubing, cartridges). Finally, with better usability, there is generally a better understanding of the device's status or operating state.This increased clarity of understanding leads to reduced risk of user error.

These improvements in reliance on training, understanding of device operating state, and reliable product assembly are critical for the markets and users that SurgiBox hopes to serve.
For doctors in developing countries, training can be inconsistent across different regions, language, and cultural contexts. This presents a risk for misunderstanding how to use the product. Therefore, SurgiBox should be as easy to use as possible, reducing the amount of training needed. Given the ad-hoc and austere environments that SurgiBox will be used in, another key design requirement is portability. The system that should be able to fit into a backpack when disassembled, and thus some set-up and assembly is required before SurgiBox can be used. This presents several opportunities to improve how SB is designed so that it can be assembled quickly, and correctly. After SurgiBox is assembled, it must continue to be easy to use and understand. Free time and free hands are scarce during a surgical procedure, therefore there should be minimal cognitive energy and user input required to monitor and maintain the operating status of SB. Failures--leaks, deflation--should be obvious, and the controls to adjust and maintain the air-pressure needed to inflate the enclosure should be responsive and simple to use. Through a HCD approach, the improved usability of the product will allow medical providers to spend less time on figuring out how to use the product, therefore freeing up more cognitive energy to focus on actually treating the patient.

3. PRECEDENTS AND PRIOR PROTOTYPES

Fig 3-1: Generation 6 SurgiBox prototype shown in inflated state (left) and deflated state (right).

When I joined the SurgiBox team, the Generation 5 prototype was in development. This prototype had solved most of the major technical feasibility challenges of reducing airborne particle count, creating a good seal between enclosure and skin at the incision site, as well as ensuring unidirectional laminar air flow inside the enclosure. A lot of work had been invested in previous iterations to achieve an efficient yet effective enclosure design. However, many of the supporting components had unresolved usability problems. I focused my efforts on bringing the rest of the system to the same level of usability as the enclosure. The following sections will describe the state of three main areas of the Generation 6 prototype: the architecture of the air-intake box, the box-enclosure connection, and the support frame.

3.1. Air Filter Box

In its simplest form, the air filter box is a container with a fan that draws air in through a filter on one end, then blows the filtered air out of the other end. However, by Generation 6 the design of the air filter box had grown to include a few more components that make it easier to control the airflow:

A. HEPA filter to reduce airborne particle count
B. Blower fan to create airflow into the enclosure and a pressure differential
C. Microcontroller carrier board to control the speed of the fan
D. Cable to connect the fan and carrier board to the external battery
E. Nozzle for clean air to pass into the enclosure

Fig 3-2: Air filter box and internal components. Full assembly (left) and blower and microcontroller carrier board (right).

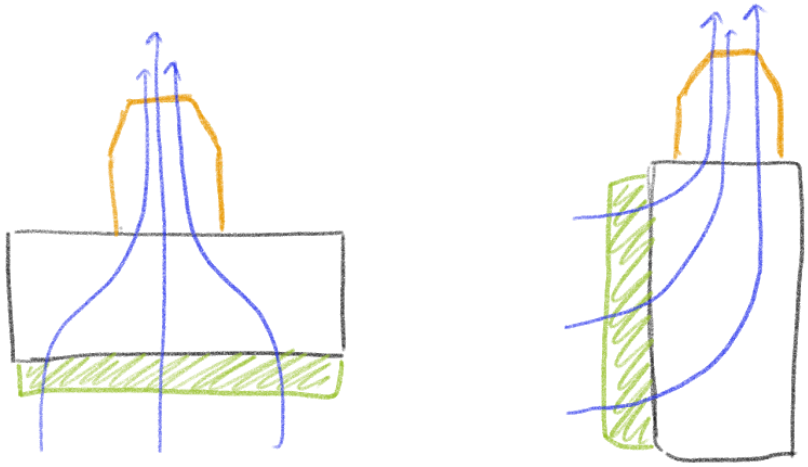

Fig 3-3: Two air filter box architectures: T-shaped (left) and L shaped (right). The filter is shown in green, nozzle shown in orange, and the airflow direction shown in blue.

As seen in the figures above, there is a curious geometry to the air filter box architecture. When all the components are stacked together, the resulting “T” shape makes it awkward to pack. However, the obvious alternative of putting the filter to the side of the fan does not allow the entire surface area of the filter to be used effectively. This begs the obvious question: “Can we find a more spatially efficient arrangement of the parts?”

3.2. Enclosure-Box Connection

The nozzle piece on the air filter box is a pipe diameter reducer that not only helps to direct the air flow into the enclosure, but the tapered end also allows for easier insertion into the opening of the enclosure. However, there is no mechanism to hold the soft TPU of the enclosure to the rigid

plastic of the nozzle. This slip-fit is not only a source of air leakage, but it is also very susceptible to accidental jostling that might cause the enclosure to separate from the air filter box.

Fig 3-4: "Slip fit" enclosure-box connection. Note the duct tape on the blower. The duct tape was used to secure the enclosure box connection on some prototypes that had loose connections.

3.3. Support Frame

The support frame consists of a particle board base and four pieces of aluminum tubing. Using small connectors, the segments of aluminum tubing are connected in a pentagonal shape. The particle board base forms the fifth side of the pentagonal shape and it is also stable enough to support the rest of the frame. As seen in the figures below, the aluminum members are slightly bowed because they are pre-loaded with a bending moment when fully assembled. This preload keeps the planar structure taut, but it also makes it difficult to assemble. In addition, the base must go underneath the patient's torso, which can prove difficult if the patient is unable to be lifted.

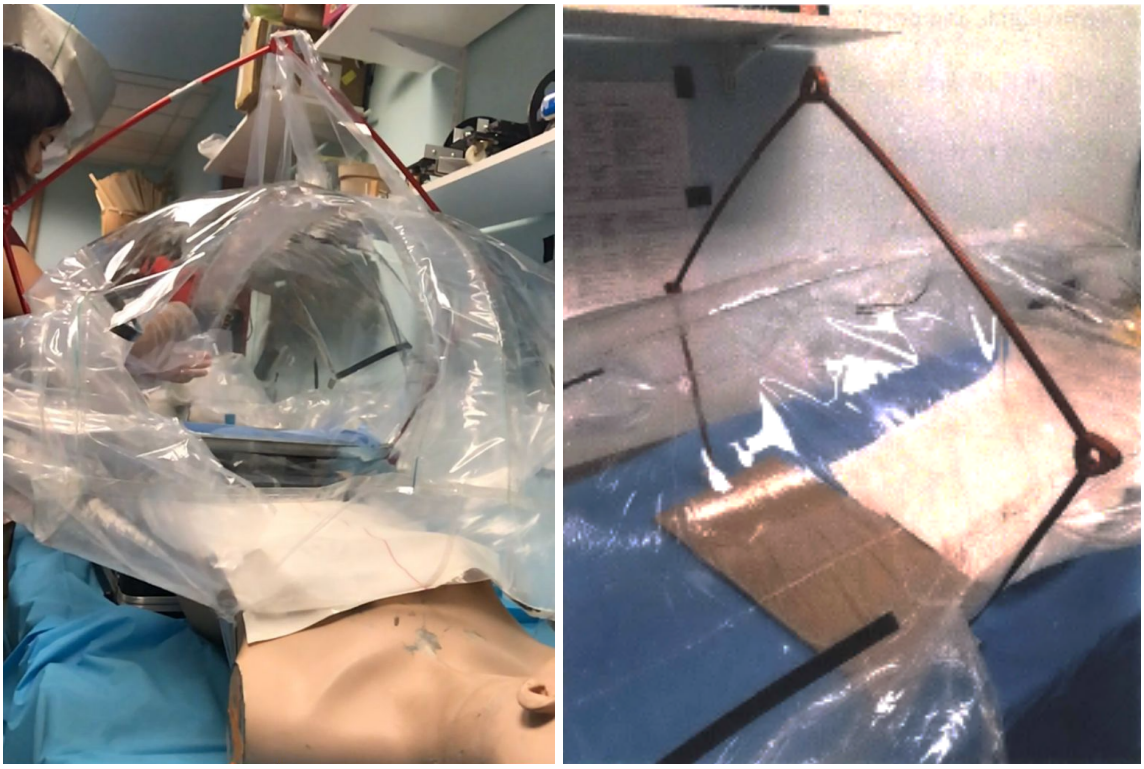

Fig 3-5: Pentagonal support frame. The enclosure is tethered to the top of the frame using some plastic ties attached to the surface of the enclosure. As seen in the photos, the red-anodized aluminum frame members are slightly bowed under the pre-load required for assembly.

4. HCD OBSERVATIONS

Although the Generation 6 prototype satisfied the engineering specifications, it was difficult to understand how to correctly use SurgiBox. This gap between intended use and the user's mental models for how to use Suribox is captured largely through the HCD method of qualitative research of user studies, interviews, and observations. HCD allows a designer to understand where things technically work, but don't work very well for humans. The observations are summarized below:

4.1. Air Filter Box

The box size is a little too large to comfortably grab and move with one hand. The shape of the air filter box also makes it difficult to pack along with the rest of the SurgiBox system. There is no indication of the correct orientation for the air filter box when in use, or where to put it when it is in us. When the enclosure is fully inflated, the box will tilt upwards precariously as the height of the enclosure-box connection changes.

4.2. Enclosure-Box Connection

The connection between the air-filter box and the TPU enclosure is tenuous at best. If it is tight enough to form a good seal, then it is difficult to slip the plastic over the nozzle. If it is loose enough to easily slip on, then it is not a robust connection. Users have resorted to using a piece of tape to more tightly secure the nozzle to the TPU enclosure.

4.3. Support Frame

The support frame is difficult to assemble. It takes time to find all the pieces and make sure that they are assembled correctly. The base is sturdy, but can be difficult to place under the patient if the patient is already lying down.

5. PROTOTYPE ITERATIONS

5.1. Air Filter Box

The biggest challenge with the air intake box was understanding how to shrink the size to make it more portable. Given an engineering spec of at least 35 cubic feet per min of volumetric air flow, the size of the filter and the size of the fan become a" chicken and egg" type of problem. A smaller filter has more resistance to airflow, so a larger and more powerful fan would be required to achieve the air flow spec. A larger filter has less resistance to airflow, so a small fan would suffice. Among all the combinations of fan size and filter size, there is a solution set of viable fan-filter combinations that can achieve the air flow spec. The way to find the best combination would be to select a fan-filter combination from this viable solution set that also has small and compatible dimensions. In order to find the right combination of filter and fan, I designed a testing rig.

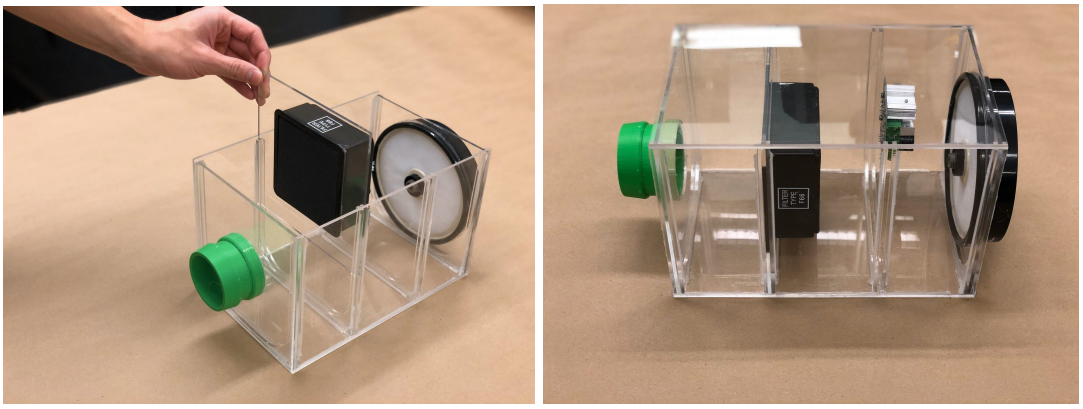

Fig 5-1: Testing rig with interchangeable plates.

Each component was mounted on plates which could be shuffled in any order within the box. These plates slid into channels inside the box to ensure a tight seal between each chamber of the box. This allowed us to try different fan and filter combinations. It also allowed us to try components in different configurations to understand if there was an appreciable difference between having the filter upstream or downstream of the fan. The results show that there is no appreciable difference between having the filter upstream or downstream of the fan. While this testing rig was a great way to control other variables and test components against each other, the interior shape of the testing rig is not optimal for air flow. Thus this testing rig was only useful for direct comparisons of different components, rather than testing the architecture of the filter box itself.

In addition to this reconfigurable testing rig, I also conducted tests to understand if there was a minimum threshold for filter surface area. Using a digital gas pressure sensor, the time to inflate the enclosure was recorded at varying levels of filter surface area. The conclusion was that surface area is inversely proportional to the time it takes to inflate the enclosure. This helps to determine that even though the fan and filter selection inform each other, the size limitation comes from the filter. Therefore we need to first choose a filter that works, then choose the fan that best matches the filter.

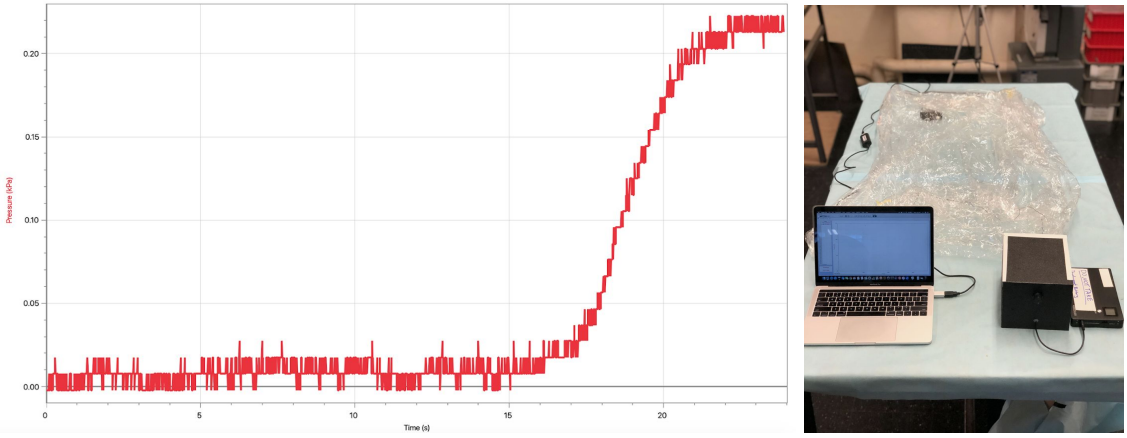

Fig 5-2: Sample data of the filter surface area experiment, the graph shows pressure as a function of time.. The time to inflation is measured from when the slope first begins to increase, to when the slope decreases back to zero.

Fig 5-3: Experimental setup for filter surface area experiment. Setup was a gas pressure sensor inside the enclosure, with a data read-out on a laptop.

In order to maximize surface area available without compromising the portability of the air filter box, we explored the concept of a foldable filter. This filter can be compressed and packed into a small shape for storage and transport, but then can be expanded during operation. Ultimately this idea did not prove to be fruitful because of impracticability for manufacturing such a filter.

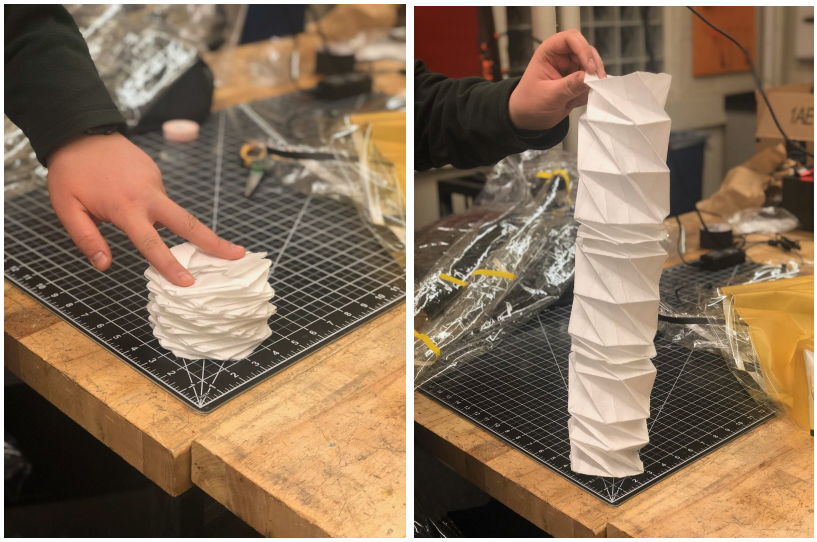

Fig 5-4: Small scale prototype of foldable filter

5.2. Enclosure-Box Connection

The enclosure-box connection is a simple mechanism that should not be over-engineered. The critical issue is that the connection needs to be an interface between a soft plastic and a hard plastic. Any rigid connection would pose a risk of tearing the soft plastic when loaded in tension. Some of the ideas currently being pursued are the use of a velcro cinch, or a TPU and adhesive

cinch. Both of these are compliant enough that they would not rip the TPU, rather they would move with the TPU while still maintaining a good seal.

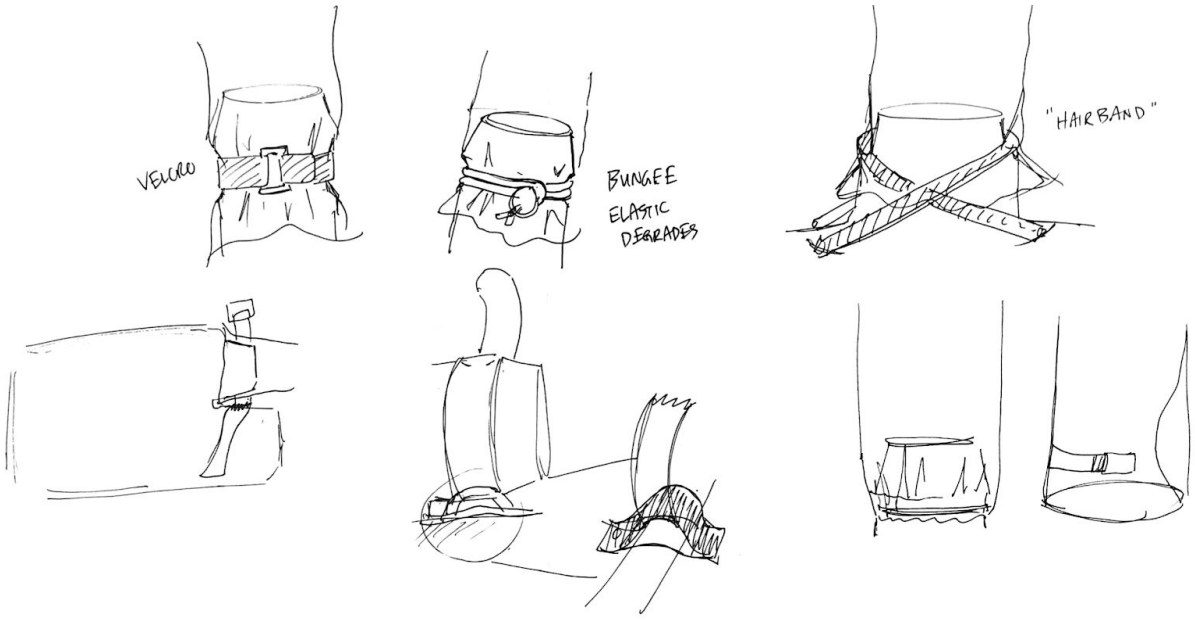

Fig 5-5: Ideation sketches of potential enclosure-box connection mechanisms

5.3. Support Frame

In order to be successful as a support frame, the frame needs to be easily assembled, stiff enough to hold the weight of the plastic enclosure, and small enough when disassembled to be easily packed away. The frame should not obstruct the vision or the movements of the surgical team.

The first frame prototype was using 2D-materials to create a 3D structure through folding. I prototyped with cardboard, with the intention that this design could be easily translated into sheet plastic. By folding the flat cardboard into a U-channel shape, the cardboard stiffness was greatly improved and thus could support enough weight. However, folding from a flat sheet into the 3D structure took too many steps. Instructions were needed to detail the many steps required to achieve the right shape, and if the user was not practiced in setting up the frame, it could take upwards of 5 minutes to complete.

Fig 5-6: Folded cardboard support frame

In search of a more intuitive set-up that could be assembled more quickly and with fewer errors, I returned to the idea of the tent-pole design. This was the inspiration behind the Generation 6 pentagonal frame. Taking the same idea of aluminum tubing with elastic cord running inside, I designed an A-frame tent-pole system. The elastic allows the aluminum parts to stay in the correct orientation and order, then easily snap together so there is no effort wasted on finding the right parts to assemble together. The shape of the A-frame is held together by two plastic components. The total part count of this frame is just 5 parts: 3 aluminum-elastic rods and 2 plastic connectors.

Fig 5-7: Assembled A-frame support frame

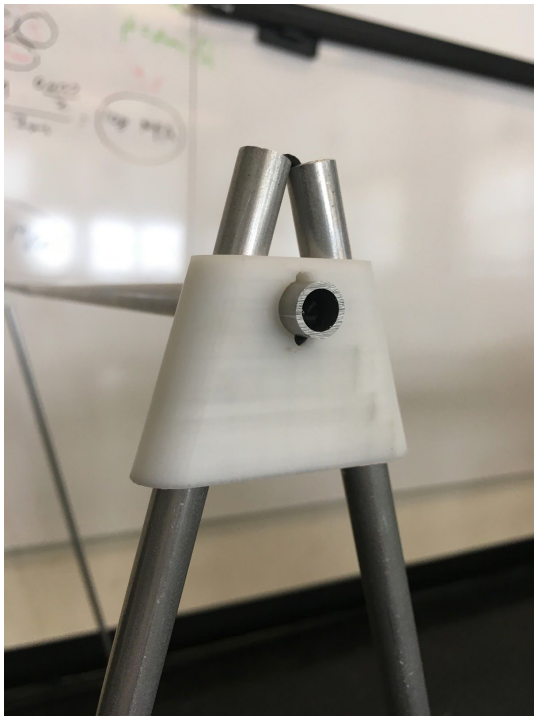

Fig 5-8: A-frame support frame in packed configuration
Fig 5-9: Detail of plastic components on support frame

In addition to the improved assembly, another strength of this design is that there is no need for a base. The A-frame is a 3-D structure rather than a planar structure, so it is able to stand on its own without a weighted base. This is an advantage for set-up, but it also introduces a new risk of having the frame move too much if it was bumped or jostled during the surgical procedure. To mitigate this risk, I added rubber “feet” to the ends of the side pieces. Not only did it help prevent the frame from sliding around, it also indicated how the frame should be set up. The rubber feet do not fit into the plastic connector, so even without instructions a user could quickly deduce that those ends of the frame do not interface with the connector. This design could be assembled in less than 2 minutes. This prototype was a clear improvement on the pentagonal frame prototype, yet I still thought that the design could be simplified even more for ease of use.

The most recent prototype has only a single part and can be “assembled” in less than a minute. Instead of using elastic cord for tension, I returned to the idea of using the material itself in a pre-loaded state to provide the structural shape. I explored this idea by cutting out a strip of spring steel from a pop-up laundry hamper. The saddle-shaped spring steel can easily be folded through a twisting motion into a small loop, approximately the size of a dinner plate. It readily springs into the shape of the frame when unfolded. In its expanded state, linearly applied force cannot permanently change its shape, it returns to the saddle shape that is imposed on the spring steel by two tethers. The result is a strong, minimal structure with only one part. Despite its strength, the spring steel still allows the frame to be moderately compliant, which helps it be robust against any movement of the enclosure or any jostling. There are also no sharp parts on the loop of spring steel, so puncture risk is also decreased.

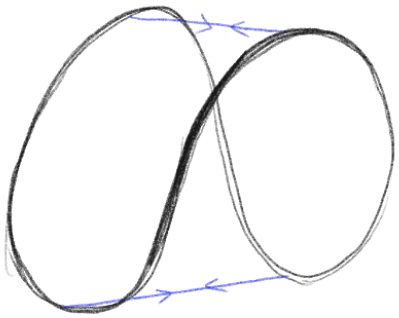

Fig 5-10: Position of tethers for saddle shaped spring steel frame. The tethers will always be located opposite of each other, in orthogonal directions.

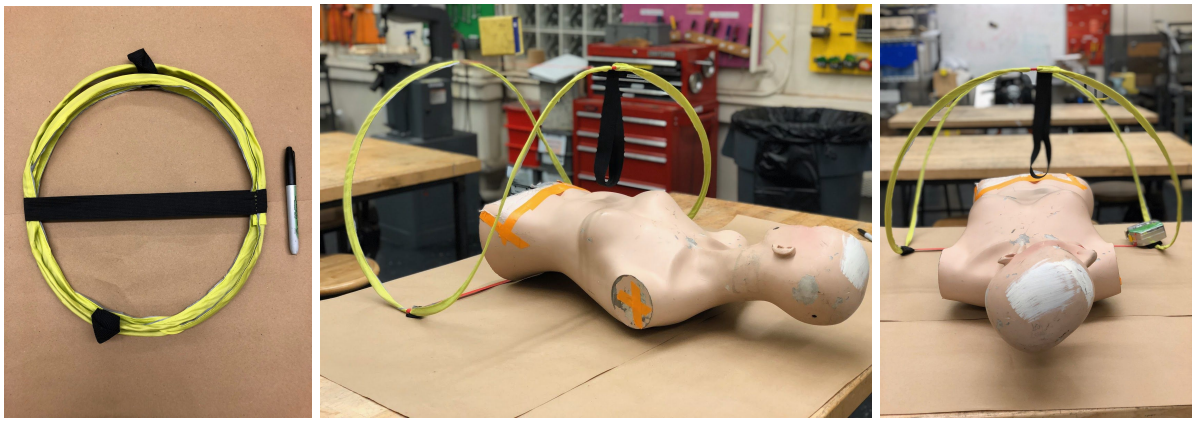

Fig 5-11: Frame prototype using laundry hamper wire

A more refined version was created to better fit the dimensions of the enclosure. In order to more securely attach the frame to the enclosure, “pockets” on the enclosure were added for the spring steel loop to fit into. This allows the enclosure itself to provide the tension at the bottom of the loop. It also allows for the enclosure to stay attached to the frame and the patient simultaneously. Although it is a separate piece, this makes the frame more integrated into the enclosure without making the frame obstructive.

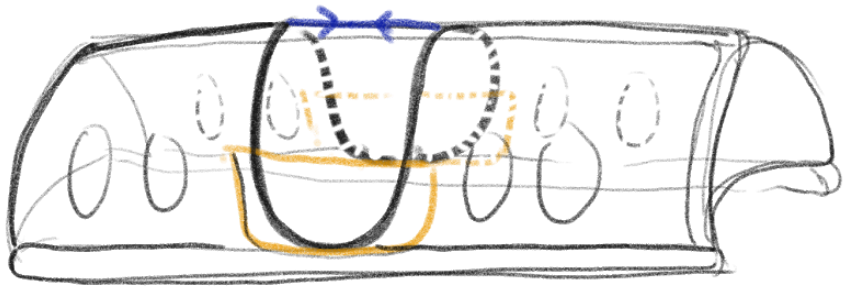

Fig 5-12: Position of pockets for spring steel frame. Pockets are shown in orange. Single tether at the top is shown in blue.

Fig 5-13: Spring steel frame in TPU enclosure, axial view.

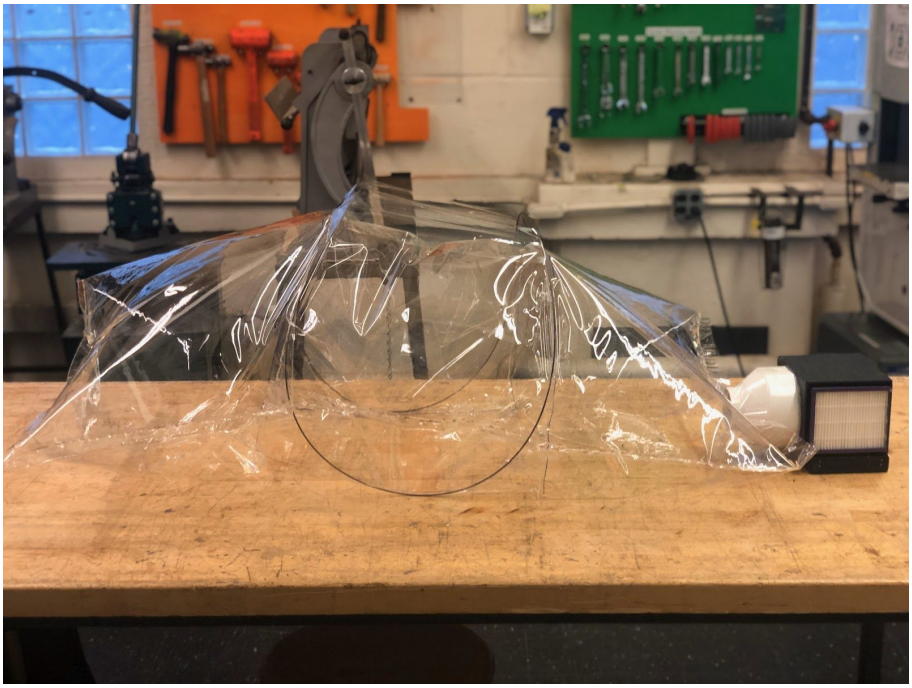

Fig 5-14: Spring steel frame in TPU enclosure, side view. Pockets are hard to discern because they are made of the same transparent material as the enclosure.

6. FUTURE WORK

SurgiBox is currently undergoing development for the Generation 7 prototype. The Generation 5 and 6 prototypes were tested through Operation Bushmaster (a military run mass casualty and humanitarian mission simulation over two weeks). These first iterations of human factors testing gave us the HCD observations that motivated my design work. Now these new designs discussed above have not yet been tested with similar groups of users. The first step would be to run a user study with several different surgeons to understand how the intended user used these new designs. This would allow us to understand the limitations of these new designs, as well as the strengths. If the designs above prove to be effective and usable, the next step is to examine where these prototypes can be tweaked to improve manufacturability and cost.

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