REDESIGNING THE INCENTIVE SPIROMETER

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By

Isabelle Talicuran

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

ADVISOR
Dr. Masahiro Morikawa, MD, MPH UVA Family Medicine

Abstract

Postoperative pulmonary complications (PPC) refer to conditions that adversely impact the pulmonary system and are a significant concern for patients who have undergone major surgery. Additionally, the COVID-19 pandemic further emphasized the importance of preventing PPC. The incentive spirometer is a plastic, non-electric medical device typically prescribed to patients recovering from a major surgery. The incentive spirometer exercises and expands patients' lungs to prevent the development of PPC. Despite how crucial this device is in recovery, there is low patient adherence to using the device. This low adherence was attributed to the boring design and mechanics of the conventional incentive spirometer; therefore, a primary goal of this project was to redesign and gamify the incentive spirometer to create a more engaging and fun experience for patients, hopefully improving patient adherence. To do so, a Ferris wheel component would be incorporated into the device, with the goal of picking up plastic balls and depositing them into buckets. Laser cutting, vacuum forming, and 3D printing were used to prototype the redesigned device. Although the team did not finish a complete prototype, a Drop Test and Inhalation Test were conducted to observe the integrity and functionality of the components that were printed. The Drop Test demonstrated the superiority of ASA filaments over PLA for prototyping, and the Inhalation Test exposed errors and areas of improvement for the gas flow indicator. This project will be passed on to a future group. Future work will involve completing the prototype, and going into the clinic to gather data regarding patients' experience with the redesigned device. The work completed the past two semesters laid a solid foundation for exploring whether the redesigned incentive spirometer affects patient adherence.

Introduction

Postoperative Pulmonary Complications Background

Of the more than 230 million major surgical procedures performed each year worldwide, up to 40% of patients experience postoperative pulmonary complications (PPC) (Jin et al., 2015). Though some complications are well-understood, PPC are under-reported. PPC refers to a group of conditions damaging to the respiratory tract such as hypoxia, bronchospasm, alveolar collapse, and pulmonary infection (Patel et al., 2016). These conditions range in severity and require additional drugs and therapies, longer hospital stays, and even death. PPC disrupts patients' recovery progress and negatively impacts other aspects of life. Thus, due to the short-term and long-term effects of PPC, it is crucial to prevent the development of PPC in the first place.

Furthermore, the COVID-19 pandemic made PPC more relevant than it has ever been before. In an observational study conducted by COVIDSurg Collaborative, researchers reported the clinical outcomes of COVID-19 patients who underwent surgery. Out of 1128 patients, 577 patients experienced at least one PPC; a little over half of the patients with perioperative SARS-CoV-2 infection experienced complications and a high mortality rate. Furthermore, COVIDSurg Collaborative even states that the "postoperative outcomes in…patients are substantially worse than pre-pandemic baseline rates of pulmonary complications and mortality" (Nepogodiev, D., 2020, p. 36). Thus, the COVID-19 pandemic has exacerbated the urgency of PPC, especially in light of decreasing and limited hospital capacity.

Incentive Spirometer Background

Given the urgency of the pandemic, it is imperative to utilize any strategies or devices to prevent PPC from developing. One device used to do so is the incentive spirometer (IS), which is a plastic, handheld medical device typically prescribed to lower the risk of developing PPC. Figure 1 depicts the conventional design of an incentive spirometer. The primary role of the incentive spirometer is to exercise the lungs and expand alveoli in the lungs that may have collapsed due to general anesthesia. In addition to restoring the lungs to proper condition, the incentive spirometer also decreases the occurrences of PPC that may occur during recovery (K. Westwood et al. 2007). The conventional incentive spirometer typically has five main components: flexible tubing, a mouthpiece attached to the tube, a gas flow indicator to gauge the appropriate rate of airflow, a piston, and an outer casing to create an airtight chamber for the piston to move. To use the device, patients place their mouth on the mouthpiece and inhale until they reach their full lung capacity. As patients inhale, the piston rises and falls to its original position once inhalation stops. The gas flow indicator shows whether the patient inhales at an optimal rate to best exercise lungs.

Figure 1: Existing Incentive Spirometer

Project Hypothesis & Aims

Despite how crucial this device is in recovery, the technical advisor for this project, Dr. Masahiro Morikawa, MD, MPH, the clinical director of UVA Family Medicine, noticed that patient adherence to using this device is consistently poor. Furthermore, in a study conducted by Eltorai et al. (2018) regarding incentive spirometry adherence, respiratory therapists and nurses agreed that patient adherence needs to improve (p. 534). Dr. Morikawa attributed this poor patient adherence to the boring design of conventional incentive spirometers and therefore proposed that redesigning the incentive spirometer to make using it more fun and engaging would improve patient adherence.

Thus, the hypothesis that this project tests out is that, by gamifying the incentive spirometer, patients will feel more motivated and engaged using the device, thus improving patient adherence to using the device. The team aimed to gamify the device by incorporating a Ferris wheel component into the incentive spirometer; as the patient inhales, the Ferris wheel spins, occasionally picking up plastic balls at the bottom of the device to deposit into buckets inside the device. The aims of the project are twofold:

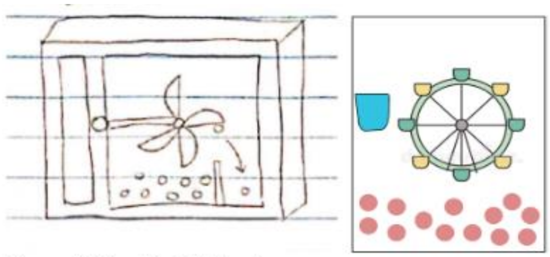

Figure 2: Gamified IS Design

Specific Aim 1: Develop a prototype with gamified element

- Using CAD design the gamified element, which is a Ferris wheel that's able to pick up balls whenever the patient is able to inhale at a correct rate.
- The gamified part of the incentive spirometer will most likely be made from 3D printed parts, or laser cut and vacuum form pieces.
- The gamified part will be a redesigned incentive spirometer

Specific Aim 2: Run test with prototype

- Test out the prototype making sure the mechanics of the gamified part works without loss of original function (measure volume of breathing)
- Dispense the gamified incentive spirometer to Dr. Morikawa's patients at UVA hospital in order to collect data such as the number of times used, ease of use, and etc.
- Conduct a survey to evaluate patient feedback on the gamified incentive spirometer in comparison to the original incentive spirometer to see what the patient prefers

Preliminary Work

Past members Danna Du and Shirley Zhang completed preliminary work surveying a small sample group to gauge interest in a gamified incentive spirometer. Their findings demonstrated 100% interest in a gamified incentive spirometer over the current conventional spirometer. Furthermore, the sample group believed that a gamified spirometer would perform just as effectively and be enjoyable for a typical patient. These results, therefore, demonstrated general interest and promise in the gamification of the incentive spirometer.

Prior Art

Previous efforts have been made to redesign and gamify the incentive spirometer. The first example of the prior art is a gamified incentive spirometer that fires a Nerf gun as the patient inhales (*Gamified Incentive Spirometer Fired Nerf Gun for Pediatric Patients*, n.d.). The problem with this incentive spirometer is that there are multiple components, resulting in unnecessary complexity and a lack of overall portability for the device. Furthermore, the inherent use of a Nerf gun presents a mild hazard for the user and those around the user.

The Game-based Incentive Spirometer is a patented incentive spirometer that also aims to gamify the patient experience. This device is more of an electronic redesign of the IS in that when the patient inhales, it is able to keep track of air flow rate and air volume through sensors in the device. The sensors produce an electrical signal that is then converted into a computer-generated game of either a bird or superhero flying. The flying is controlled by the breathing of the patient depending if it is the correct rate of flow and volume, which the patient has to keep either the bird or the superhero above and below an optimal range.

Another strategy to gamify incentive spirometers has been to print pictures on the outer casing such as cartoons of animals. These devices are currently sold on the market; nevertheless, their overall design and mechanics are the same as those of a conventional incentive spirometer (*CareFusion AirLife Pediatric Volumetric Incentive Spirometer With One-Way Valve*, n.d.). As such, these spirometers do not greatly affect the level of patient engagement and adherence to using the device.

The proposed design is unique compared to the aforementioned prior art because it strikes a balance between simplicity and complexity. It is simple so that the general objective of the device's "game" is intuitive, but there is still a level of difficulty that challenges and engages the patient. Furthermore, unlike the electronic and Nerf gun incentive spirometer, there are no additional, unnecessary components, ensuring portability and lightweightness. This is especially beneficial for older patients and those who have difficulty using technology, as the device and its mechanics are easily understood. Thus, research of prior art indicates that the proposed Ferris wheel design is novel.

Materials and Methods

Design

The overall design of the gamified incentive spirometer was based on the carnival water ring toss game and a Ferris wheel. As said before, the Ferris wheel-like structure will rotate while the user inhales. There will be small plastic balls resting at the bottom of the IS, as the Ferris wheel rotates it will pick up the balls and dispense them in a collection bucket. This will be done over sustained periods of time while using the device. The main objective is to transfer all the balls into the collection bucket.

We decided to design the incentive spirometer using Computer-Aided Design (CAD) in AutoDesk Fusion 360. As seen in Figure 3, we redesigned the incentive spirometer from the ground up but kept some similarities to the original IS. Certain minor aspects of the original were changed including removing the quantitative measurements, removing the "smiley face" indicator, adding a gas flow indicator, and adding a Ferris wheel with hollow balls in the main compartment. The removal of the quantitative measurements was a suggestion by Dr. Morikawa, stating that he would want the patient to just use the device in general rather than worrying about lung volume measurements. In addition, removing the “smiley face” indicator was due to the fact that the rotation of the Ferris wheel and dispensing of the balls will replace it as an “indicator” that the patient is using the IS correctly.

Outer Casing

To begin the design process, the outer casing of the IS had to be made in Fusion. A two-piece design was decided on when making the case to ensure easy assembly once put together. In Figure 3, the outer casing is the transparent outline, a handle was incorporated into the case on the left-hand side. The parts were divided into the front and back parts of the case. The connection would be ensured by either glue or screws in place. The casing will house the Ferris wheel, balls, and the gears connecting to a gas flow indicator (GFI).

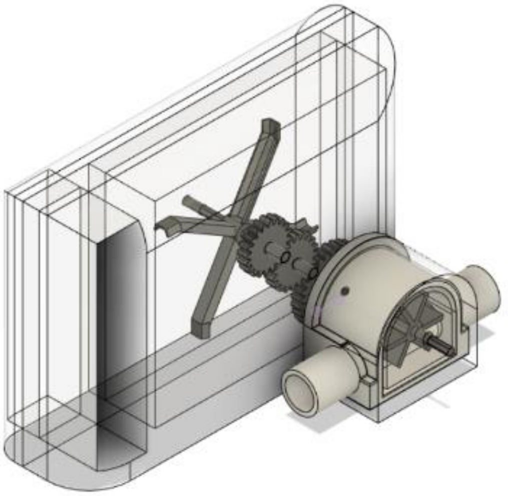

Figure 3: CAD Assembly of Gamified Incentive Spirometer

Figure 4: CAD of Ferris Wheel

Ferris Wheel Design

The Ferris wheel design consists of a centerpiece that holds the scoops needed to transfer the balls. The centerpiece consists of a hexagonal hole in the middle which connects to another hexagonal rod suspending it in the case. There are also connection ports in the shape of the base of the scoops for easy insertion and integration by welding or gluing the parts together. The scoops are shaped in a way that can be made from thin plastic and folded into the desired shape almost like origami. The channels on the scoops allow for them to hold the balls without falling out while the wheel rotates. There are four scoops as seen in Figure 4.

Connecting Gears

In order for the wheel to move, there are connecting gears on axles going down from the Ferris wheel to the gas flow indicator, which drives the whole spirometer. The gear connecting directly to the GFI is bigger than the rest with an increased number of gears to ensure that the Ferris wheel is able to spin even with minimal rotation from the GFI. The increased rotation of the smaller gear and in turn the Ferris wheel is caused by the way gear ratios function. The smaller gears will spin a number of times more than the larger gear when doing a full rotation. Each of these gears will be attached via a hexagon hole in the middle that interlocks with hexagonal rods (Figure 5) with axles that will be able to rotate; the hexagonal locking system is to ensure that the gears are held in place while rotating.

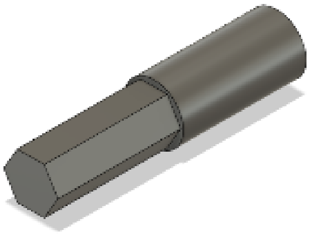

Figure 5: CAD of Hexagonal Rods with Circular Axle

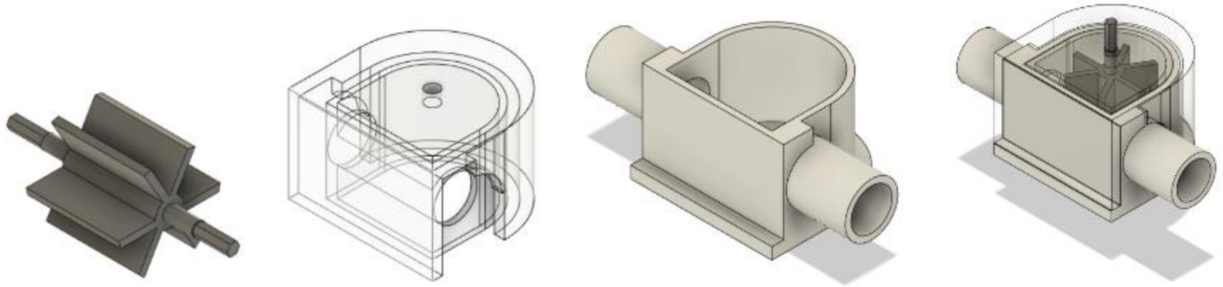

Figure 6: CAD Parts of Gas Flow Indicator and Full Assembly

Gas Flow Indicator

The gears and Ferris wheel will be rotated by a gas flow indicator, which is the main source of pushing all the moving parts of the IS. The patient will breathe through a tube connected to one open end of the GFI. Air will flow through the casing and push on a fan inside the GFI, rotating it. The fan has axles on the ends going through the GFI casing to allow for rotation and also hexagon connection points extending beyond the axles. The hexagon connection points will insert into the hexagon holes of the gears inside the IS case, interlocking the GFI and gears. The spinning of the fan will turn the gears which in turn will rotate the Ferris wheel, allowing the scoops to pick up the plastic balls. We went with the design of using a gas flow indicator as the driving force for the whole device because it allowed the user's inhalation to be converted into a rotational motion of the Ferris wheel.

Methods

There were three main methods for prototyping the gamified incentive spirometer: 3D printing, laser cutting, and vacuum forming. These methods were all done in UVA's Architecture School Fabrication Lab (FabLab). For 3D printing, the team converted the CAD files into STL files so that they would be readable for 3D printers. The team initially used the Lulzbot TAZ 6 Aerostruder, but that came with some roadblocks. The printer has a lack of availability being shared among architecture students. The printers would also be out of service frequently contributing more to its scarcity. Even if the team was able to secure a printer the parts that were printed were either inaccurate or unusable due to the printer messing up. The team would later switch to a new printer called the Stratasys printers that were also found in the Architecture School. However, unlike the initial printers, there was a built-in queue available in the Stratasys printers making them more accessible. These printers were also higher in accuracy leading to better quality parts that fit well together. 3D prints of the gas flow indicator were created using both the Lulzbot and Stratasys printers (Fig. 7).

Figure 7: 3D Printed Parts of the Gas Flow Indicator from the Stratsys Printer using ASA Filament

For laser cutting the team used a brand of laser cutters called Universal Laser Systems. These laser cutters were used to cut out the shovel designs meant for the Ferris wheel. First, the CAD files were again converted into STL files for the laser cutters to read them. Then each individual line was manually designated for either a vector cut, vector etch, or raster. When a line is designated as a vector cut the laser cutter will cut through the material all the way, but when selected as a vector etch it won't cut through. A raster cut is typically used for detailing or when wanting to incorporate a design. Next, the laser cutter's settings for power and speed are adjusted based on the material being used. Finally, the machine was ready to go and the actual cutting time was a quick process. The difficulty resides when adjusting the setting of the laser cutting having to adjust as the team goes along.

Finally, vacuum forming was planned to be used to mold the outer casing of the gamified incentive spirometer. Vacuum forming works by heating a sheet of plastic until it is pliable then it is stretched over a mold using vacuum pressure. The team planned to 3D print the mold of the outer case in order to vacuum form. When vacuum forming two halves will be created from the mold and will be combined together using a snapping mechanism. This will allow for the gamified incentive spirometer to be taken apart easily if needed to be clean or adjustments are needed to be made.

Materials

The materials used were polyethylene plastic, polylactic acid plastic (PLA), acrylonitrile styrene acrylate (ASA), and polyethylene terephthalate glycol (PETG). The team made sure that the materials chosen were nontoxic and safe for the patient to come into contact with them ("ASA Filament 1.75mm for 3D Printer | ECO," n.d.)(Powers, 2020). Polyethylene plastic which is from binder dividers was used to create the shovels for the Ferris wheel. This material was chosen for its lightweight and the plastic was thin enough for the laser cutter to cut through cleanly. PLA was the filament used in the Lulzbot TAZ 6 Aerostruder to print out the gas flow indicator and gears. ASA was the filament used in the new Stratasys printers to also print out the gas flow indicator and gears.The team favored the ASA filament over the PLA filament because it is lighter weight and is more impact resistant which is a plus in the event the patient accidentally drops it ("Comparing PLA, PETG & ASA - Feat. PRUSAMENT," 2020). Finally, PETG is a thermoplastic vacuum-formed retainer that will be used to create the outer casing of the gamified incentive spirometer (Ahn, Ha, Lim, & Choi, 2015). This material can be easily pliable, which is a favorable characteristic to have when vacuum forming. Another advantage this material has is that it is resistant under high loads, which is useful in the event the gamified incentive spirometer is dropped it is able to withstand the impact (Bratu et al., 2019).

Drop Test

A Drop Test was conducted to observe the durability of the 3D filaments used to print, PLA and ASA. The test was also used to compare the filaments to determine and justify which one is more fit to prototype with going forward. To conduct the drop test, two gas flow indicators, one printed with PLA and the second printed with ASA, were dropped from varying heights on two different types of floors. The experimental parameters were specified as such to simulate different scenarios in which the incentive spirometer could be used. Thus, the carpet floor represents settings such as the living room or bedroom in a house, and the hard floor represents the type of flooring typically found in hospitals. Furthermore, the 20 in. height corresponds to use sitting on the ground, 35 in. to use sitting on a chair, and 55 in. to use the incentive spirometer standing up.

Each time a gas flow indicator was dropped, the part was inspected to check for any signs of physical damage such as dents or chipping. The part was deemed to "pass" if no signs of damage were observed; otherwise, any dents or scratches, no matter how minor, were noted.

Inhalation Test

In order to test the functionality of the gas flow indicator, an inhalation test was conducted. First, a qualitative assessment of proper airflow rate when breathing through a standard incentive spirometer was tested. The assessment was done by using the standard IS (Fig. 1) and qualitatively assessing the flow air rate when the green ring in Figure 1 was floating in the "smiley face" indicator; the "smiley face" indicator represents the optimal inhalation rate for the patient. Then, using the same approximate air flow rate, we inhaled through the gas flow indicator and qualitatively inspected the rotation of the fan in the gas flow indicator (Fig. 6). We performed this using an optimal breath and an increased breathing rate on each of the PLA and ASA gas flow indicators.

Results

Drop Test Results

Table 1 illustrates the results of the Drop Test. From the test, both gas flow indicators passed on the carpet; no physical damage to the part was observed at all heights. However, on the hard floor, the gas flow indicator made of PLA dented at 35 in. and 55 in. and chipped at 55 in. The ASA gas flow indicator was also dented on the hard floor but only at 55 in. The results from the Drop Test show that the PLA filaments dented and broke off more than the ASA filaments; ASA was found to be more durable than PLA.

Drop Test Results				
Height	PLA - Carpet	ASA - Carpet	PLA - Hard Floor	ASA - Hard Floor
20 in.	Pass	Pass	Pass	Pass
35 in.	Pass	Pass	Slight dent on the corner	Pass
55 in.	Pass	Pass	Slight dent on other corner, Some material off	Slight dent the corner

Table 1: Results of the Drop Test to test the integrity of the 3D filaments

Inhalation Test Results

Table 2 shows the results of the Inhalation Test. The PLA fan had no visible rotation whatsoever even with an increased breathing rate. Also, the ASA fan had no rotation at a normal breathing rate, but with an increased breathing rate it was able to rotate steadily.

Inhalation Test Results		
	PLA Fan	ASA Fan
Normal Breath	No rotation	No rotation
Increased Breath	No rotation	Steady rotation

Table 2: Results of the Inhalation Test to ensure functionality of Gas Flow Indicator

Discussion & Conclusion

Drop Test

Since the prototype is not completely finished, the tests conducted studied the durability and functionality of the parts that were able to be printed. The results of the Drop Test demonstrated that the gas flow indicator made of ASA was more durable than the PLA gas flow indicator. This finding is consistent with the literature comparing ASA and PLA filaments. For instance, Theisen et al. (2020) evaluated the efficacy of 3D-printed parts and sensors in gathering meteorological data using ASA filaments. The authors justified their use of ASA by highlighting the fact that ASA has a higher impact resistance than PLA filament (Theisen, Ungar, Sheridan, & Illston, 2020). Furthermore, Valencia et al. conducted a study to design and implement 3D printed radiation shields using two material approaches, PLA and ASA. The group found that, since ASA is known to be harder and offers more resistance to degradation, it is the preferred material for their shield design (Botero-Valencia, Mejia-Herrera, & Pearce, 2022). The Drop Test proved that ASA is the more viable material to prototype over PLA.

Inhalation Test

Since the gas flow indicator was the main part of the gamified IS that would be driving all the moving parts, it was important to see its functionality. The PLA fan having no observed rotation even with an increased breathing rate may be due to the fact that the Lulzbot printer using the PLA filament was less accurate during the printing process. This can cause extra friction within the axle of the fan, making it harder to rotate. The ASA fan also had no rotation when using a normal breathing rate, most likely because there is still friction between the axle of the ASA fan and the casing of the gas flow indicator. However, when using an increased breathing rate, the ASA fan did have some rotation. This may be caused by the smoother edges along the axle because the Stratasys printer using the ASA filament has a more accurate printing process. Another reason why both fans did not rotate at a normal breathing rate, may be due to the fact that there was not an air seal around the axle of the fans and around the casing of the gas flow indicator. We were unable to seal the casing of the GFI because we still needed it to be opened during the prototyping process.

Limitations

The limitations that the team encountered were mainly the use of the initial printers, which were the Lulzbot TAZ 6 Aerostruder. There were only 6 printers and were on a first come first served basis shared among all of the Architecture School. This had led to a lack of accessibility to these printers causing the team to lose valuable time for prototyping. These printers were low in accuracy causing the parts printed to fit poorly.

Another limitation is that with the new Stratasys printers that the team used the printing times were much longer. This is because the print quality is much higher with the Stratasys printers causing the printer to take more time to focus on the details. In addition, the printer also used supports to hold the printed parts in the right position and this needed to be removed via a solution bath that will gradually dissolve the support. The parts had to be in that bath for at least 12 hours at a time, but there were some cases in which the supports didn’t dissolve all the way, needing more time in the bath. This caused the overall printing time to take about one or two days at a time to print out the parts. All this made the reiteration part of rapid prototyping much longer than the team had anticipated.

Limitations in the inhalation test included the fact that the entire gas flow indicator was not airsealed. The area around the axle of the fan was still open allowing air to leak out. The GFI casing was also not sealed because we were still in the middle of prototyping, so we needed to easily open the casing. The leaks in air can cause an insufficient amount of air flow to push the 3D printed fan within the GFI since air would not flow in one direction, but rather in multiple through the leaks. One way we aim to solve this problem in the future is to seal the entire GFI once we are able to do so. Also to add airtight bushings around the axle of the fans and in the axle holes of the GFI. These airtight bushings will allow for reduced friction and keep an air seal around the axles while still allowing for rotation of the fan. Furthermore, another limitation to the inhalation test was that the airflow rate of breathing was assessed only qualitatively. This can lead to inconsistencies in breathing rate when testing the GFI. Ultimately to improve this, we can use a quantitative measurement of air flow rate, such as using a laboratory air pump that can mimic the rate of breathing that is optimal in a standard IS. This type of pump can display a quantitative measurement so there can be a consistent flow rate when testing the GFI.

Future Work

This project will be passed down to a future group, again overseen by Dr. Morikawa. The immediate next steps involve completing a fully assembled prototype that functions to some extent. After the needed modifications to the gas flow indicator are made, the IRB process will be continued, and IRB approval can be obtained. From there, patients from Dr. Morikawa's clinic will be surveyed to study and observe their overall experience and level of engagement with the redesigned incentive spirometer. Before distributing our prototype to patients, however, the team must first ensure that the prototype functions correctly and is safe for use. Through the patient surveys, the team will collect data on factors regarding patients' overall experience with the IS, including frequency of IS usage and how engaging and intuitive using the IS was on a scale of 1-10. Additionally, the survey can gather feedback and suggestions from patients regarding the overall design and mechanics of the device, which can guide the design of future iterations of the incentive spirometer.

Furthermore, the team can distribute the redesigned incentive spirometer for a given amount of time, and subsequently distribute a conventional incentive spirometer for the same duration. The team could then observe patient adherence for both spirometers, either through self-reporting by the patient or by some other means. Testing the prototype against the conventional spirometer will allow the team to gather more conclusive evidence as to whether redesigning the incentive spirometer significantly improves patient adherence.

Conclusions

Medical device development tends to prioritize general safety and efficacy, often neglecting to take into account the diversity of patients and their experiences with a device. This is especially urgent in the medical device industry, where devices are often determining factors between life and death. As such, this project focuses on improving patient adherence to using the incentive spirometer by redesigning and gamifying the device to create a more engaging experience for the patient. If the redesigned incentive spirometer improves patient adherence, fewer patients will experience PPC and be at risk of conditions such as chronic lung disease and even death. On a larger scale, this project can help pave the way for a more human factor-centered approach to medical device design, prioritizing the needs and interests of patients. There exist guidelines emphasizing this approach, but they are not necessarily heeded during medical device development. For example, Jakob Nielsen's 10 usability heuristics outline general rules of thumb in identifying possible usability errors of a design (Nielsen, 2020). Universal design principles also ensure that a product is designed as inclusive as possible, allowing it to be used by as many people as possible, without any sort of adaptation to the original design (Abts & Butler, 2017). It is crucial that medical device design considers both technical and human factors, and this project does so by designing a functional incentive spirometer while also considering the experiences, opinions, and adherence of patients.

The past two semesters were spent prototyping a redesigned incentive spirometer with a Ferris wheel incorporated into it to eventually improve low patient adherence to using the device. The team used various techniques to prototype but relied primarily on 3D printing first with PLA filaments and eventually with ASA filaments. While all components were designed with CAD, only the gas flow indicators, gears, and hex rods were successfully printed out. Despite having only half the prototype completed, tests were run to assess components' durability and functionality. These tests validated the ASA material and highlighted aspects that could be improved in future iterations. Though resulting in an incomplete prototype, the work completed this year laid the groundwork needed for future teams to assess whether a redesigned incentive spirometer significantly impacts patients' adherence.

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