Tracheostomy Tube Security Device

Client: Dr. Timothy McCulloch

Advisor: Professor Paul Thompson

Leader: Katie Pollock

Communicator: Rebecca Clayman

BWIG: Kim Safarik

BSAC: Paul Fossum

Table of Contents

Abstract

The purpose of our project was to create a tracheostomy strap which improved safety and comfort for patients who have undergone surgery. Currently, our client uses a twill tie strap to secure the tracheotomy tube which is held in place with square knots. This method is notable for safety but at the same time it is quite uncomfortable for the patient. Our client has requested a strap that has secure connections which will not cause ulcers on a patient's neck. The device must be safe, comfortable, and inexpensive. This design will reduce complications seen in current straps as well as improve upon patient safety and satisfaction. After analysis of several alternatives, we selected, fabricated, and tested our final prototype.

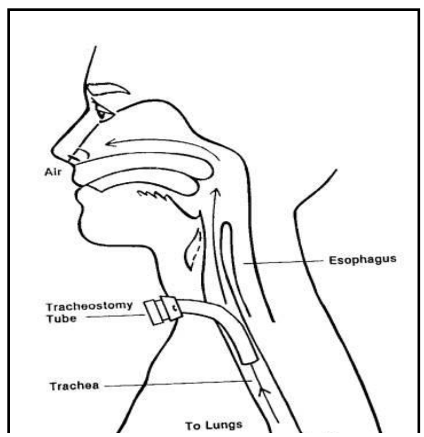
Introduction

A tracheotomy is a surgical procedure in which a cannula (a very thin tube) is placed into the tracheal lumen. A tracheotomy tube is then placed inside the cannula creating a semi-permanent or permanent hole. The tube is stitched in place with sutures, and is further secured by a tracheostomy strap. Currently, our client uses a twill tie because he believes it is the most secure method of connection. However, the twill tie often causes ulcers due to its narrow size and lack of deformation when attached. Many of our client's colleagues use a wider strap that is secured with Velcro connections which our client believes to be unsafe. Patient comfort and safety can be increased by creating a wider strap with secure connections. We propose a strap with locking connections that has a pressure monitoring system.

Background

What is a tracheostomy?

A tracheotomy is a surgical procedure in which a cannula is placed into the tracheal lumen. A tracheotomy tube is then placed inside the cannula creating a semi-permanent or permanent hole. This creates a tracheostomy hole, which allows the patient to breathe via the tracheotomy tube. Tracheotomies are a common and necessary procedure. They are performed when a patient's airway is obstructed, most commonly by a foreign object or tumor. Tracheotomies can also be performed in cases of lung



http://www.kevinmd.com/blog/hello/51/959

Figure 1 Diagram of the anatomy surrounding a tracheotomy tube.

disease or severe airway inflammation. The tracheotomy procedure bypasses the obstruction and creates an airway through which the patient can breathe.

After a tracheotomy is performed, the surgeon sutures the tube onto the front of the neck and then secures it further with a tracheotomy strap or collar. The strap ties into one side of the tracheotomy tube and around the back of the neck into the other side of the tube. Currently, our client Dr. McCulloch uses a long simple piece of cloth called a twill tie to secure the tracheotomy tube. He prefers this method not only because he can control the tension of the strap, but he doesn't have to worry about the size of the patient's neck during the operation.

Tracheotomy vs. Tracheostomy

A tracheotomy is a procedure through which a tube is placed within the tracheal lumen to bypass an airway obstruction and a tracheostomy is a hole through which the tube is placed. The terms tracheostomy and tracheotomy are used interchangeably in a hospital setting.

Problem Statement

In patients who have had a tracheotomy performed, a major post surgery problem is discomfort from the tracheotomy collar. The collar must be secured tightly to keep the tracheotomy tube in place so the patient can breathe. However, if the current strap is kept at the tension required to secure the tracheotomy tube, it can cause ulcers on the patient's skin. Our goal is to design a tracheotomy strap that is comfortable, easy to clean and equipped with monitoring devices that ensure proper pressure is exerted on the neck. We propose a wider strap with breathable fabric that is equipped with an alert system. This device will ensure the safety of the patient and reduce their discomfort.

Problem Overview

Our goal is to design a tracheostomy strap that is comfortable, easy to clean and equipped with monitoring devices to ensure that proper pressure is exerted on the neck. This will involve the fabrication of a wider, more comfortable strap around the back of the neck. The material should be able to expand and contract with neck size fluctuation. Neck size fluctuation is a direct result of changing fluid levels in the body. We will also be fabricating a pressure control and monitoring system using an alarm circuit in conjunction with deformable pressure balloons which will increase the comfort and adjustability of the pressure on the back of the neck. The strap must also be easy to maintain and be used for 5-7 days without being taken off of the patient.

Problem Motivation

The most common post surgery problem is discomfort from the tracheostomy strap. The strap must be secured tightly enough to secure the tube in place; however, if it is secured too tightly, skin ulcers may develop underneath the strap due to capillary relapse. If the strap exerts more than 30mmHg of pressure on the neck, it causes the capillaries in the neck to close. This limits circulation and begins the ulceration process. However, accidental decannulation can result if the strap is not tied tightly enough. In this instance, the tracheotomy tube to slowly work its way out of the tracheostomy hole which leads to suffocation and potentially death. Our product should limit complications in patients and avert accidental decannulation.

Design Constraints

The product must be disposable or able to be sterilized if it is to be reused. It must be usable for 5-7 days without being removed. It must have non-absorbent fabric that does not bunch. The strap must fit average adult neck sizes 12-20 inches, as current straps are sized to fit necks measuring 12-20 inches. The strap should be aesthetically pleasing and well finished so that no sharp or rough edges come in contact with the patient's skin. The design should be less than $20 so that it may be used realistically in a hospital setting and disposed of.

Current Devices

Currently, Dr. McCulloch uses a simple white cotton strap called a twill tie to secure the tracheotomy tube (Figure 2). He ties the strap in a knot on either side of the tracheotomy tube, so that the strap cannot be loosened and cause an accidental decannulation. The problem with this strap design is that although it is very secure, it can cut off circulation in the patient's neck and create ulcers.

http://www.medicdirect.co.uk/images/tracheostomy_large.jpg

Figure 2 Tracheostomy strap currently used by Dr. McCulloch

Most of Dr. McCulloch's colleagues use the collar shown in Figure 3. This collar is convenient because it can be adjusted to any neck size due to its two pieces connected by Velcro. This allows nurses to undo the strap and evaluate the patient's neck to determine if they are developing ulcers. However, this adjustability sacrifices the integrity of the tube's position. If the strap is not adjusted to precisely the same location when it is reattached, the tracheotomy tube will not be secured as tightly as it should, and it can slowly work its way out of the hole resulting in accidental decannulation. Our goal was to design a strap which safely holds and locks the tube in a given position, with adjustability for patient neck size and nurse access so that a patient's neck may be monitored for ulcers.

Figure 3 Top collar is model currently used by Dr. McCulloch's colleagues.

Competition

Currently, there are no other straps on the market that have an alarm circuit or pressure monitoring capabilities. There are numerous variations of the straps seen in Figure 3 above and Figure 4 below, made by a few different companies including Portex, Marpac, Posey, and others. Most employ either a cotton or foam padded strap with adjustable Velcro connections. They vary in price from $72.95 for a box of 25 to over $100 for boxes of special sized pediatric collars. These models are all disposable. (Nextag)

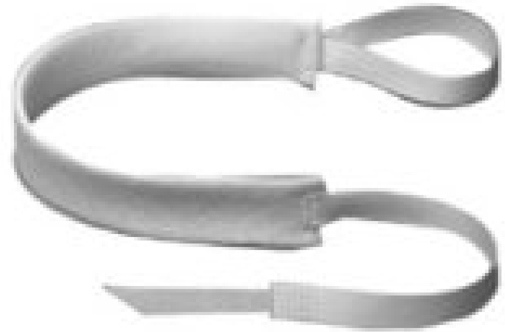
Alternate Designs

Our design will have three main components: the front connections that attach the strap to the tracheotomy tube, the back pressure system that is somewhat self adjusting, and the material out of which the strap will be made.

Strap Connections

The strap connections are an important design element because they provide the first level of protection against decannulation. If the straps are attached and remain stationary, then so must the tube.

<u>Velcro</u>



http://www.southwestmedical.com/images/products/images/RTK101-201.jpg

Figure 4 Velcro strap currently used by many doctors

Currently, many straps like the one shown in Figure 4 are produced which employ Velcro as their means of attachment to the tracheotomy tube. Velcro is easily adjustable, but is difficult to reposition accurately. For this reason, we did not select Velcro as our strap attachment method.

<u>Redesigned hat snaps</u>

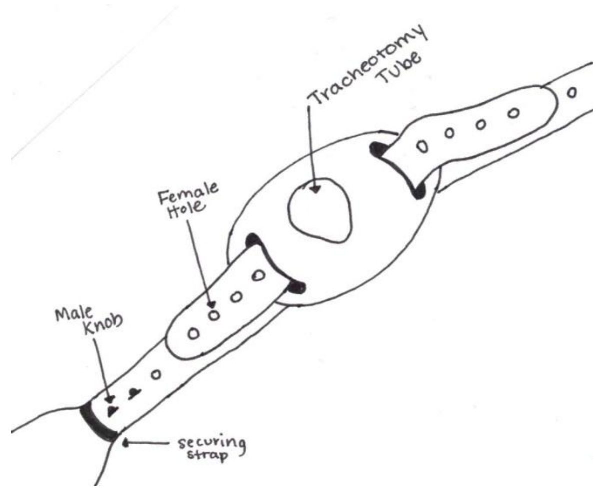


Figure 5 Redesigned hat snaps connection

In this design, the stationary part of the strap on the back of the neck would have two male knobs on the furthest edge of each side of the strap. These would be connected to a long series of female holes which can wrap through the slits in the tracheotomy tube and double back to connect to the male knobs. This method would be convenient because it would allow for a wide range of neck sizes. This method is also locking. The whole position can be marked down and duplicated if the nurse needs to monitor the patient's neck or detach the strap for any reason.

<u>Belt Design</u>

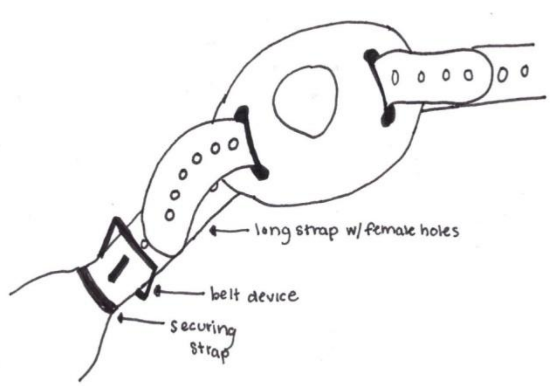


Figure 6 Belt connection

This design is very similar to the hat snap design. Instead of male knob connections at the edge of the permanent strap, there would be a pin and cradle that lock into the long string of holes and secure them in place. This method would also be easily monitored for position; the hole being used could be marked. This would allow nurses easy access to the back of the neck as well. This design may be a little more bulky than the hat snap design.

Cable tie design

In this method, a cable tie (Figure with the box permanently located at the edge of the permanent strap would be threaded through the slits on either side of the tracheotomy tube. This method would be locking, but could only be adjusted in one direction. Although it would be easy to make this design tighter, nurses would not be able to loosen the straps to access the neck. This is also problematic because if the cable ties are tightened or removed, there is no way to reliably return to the original tightness at which the ties were fixed

http://jwbasecamp.com/Articles/Canister%20Stands/Images/Cable_Tie.jpg

Figure 7 Cable tie for strap connection

At midsemester, we originally selected the redesigned hat snaps as the best method to attach our strap to the tracheotomy tube. Upon reevaluation of comfort for the patient and price considerations, we changed our design from the hat snap straps to the belt connection straps.

Strap connections	**Cost (20)**	**Size (10)**	**Comfort (20)**	**Safety (20)**	**Ease of Construction (20)**	**Aesthetics (10)**	**Total**
Velcro	19	9	13	5	20	7	73
Hat snaps	15	7	13	18	15	8	**76**
Self locking pressure strap (like cable tie)	15	9	13	14	15	8	74
Belt design	18	8	15	18	15	8	**82**

Table 1 Strap connections design matrix

Monitoring System

The next crucial element associated with our design of tracheotomy security strap is a self adjusting back pressure system. The current concerns associated with tracheostomy tube security and patient skin deterioration will be taken care of with the back pressure design. As mentioned in the previous section, our final design will consist of strap connections that provide a great deal of security but have limited adjustability. Therefore, the back of our strap will self adjust to a set pressure, importantly allowing maintenance of patient comfort as well as constant pressure on the tracheostomy tube.

The basic scheme of this design can be seen in Figure 8. As shown, on the anterior of our strap there are a certain number of pouches or capsules which contain a fluid, through which pressure is controlled to remain at a set value. Air, foam, gel or water could potentially fill the pouches. As shown in the materials matrix in the appendix, water would best meet the expected design requirements. Water was also the material of choice in this design due to its wide availability and usage in environments such as a hospital or clinic. The various other materials listed were less suitable for our design. For instance, gel was ruled out of probable design materials due to its lack of availability, price, and difficulty of implementation.

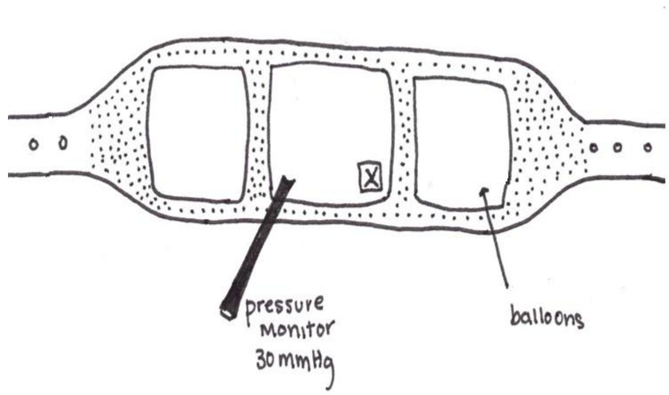


Figure 8 Basic strap design

Balloon fluid	Cost (20)	Size (10)	Comfort (20)	Safety (20)	Ease of Construction (20)	Aesthetics (10)	Total
Air	20	10	13	15	13	8	79
Gel	7	10	18	17	10	10	72
Water	18	10	15	15	14	8	**80**
Foam	8	10	17	18	16	9	78

Table 2 Balloon fluid design matrix

An additional aspect of our strap design is an automated pressure release valve. One of the main characteristics of this design is to have a valve in place on the strap which can release pressure if it exceeds 30 mmHg: capillary relapse pressure. This should decrease the occurrence of ulcers. The water filled capsules in the strap will have a pressure monitor and indicator which will allow for pressure adjustment. This concept would be achieved by integrating a system of one way valves into the strap. This would permit the free flow of water, automatically equilibrating the pressure a patient would feel on his or her neck. In Figure 9 the monitoring balloon can be seen in greater detail. The valve design matrix shows that a plastic valve was chosen over any fabricated valve at midsemester. This decision was due mainly to expense issues as well as ease of integration.

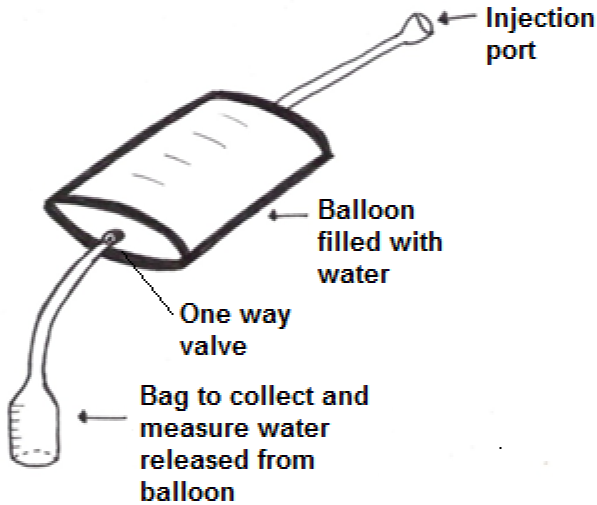


Figure 9 Pressure design

We started research on ordering a plastic valve for this design, and could not find any which released at the low pressure of 30mmHg. We then discussed having an alarm circuit that would be triggered by the movement of the strap. This design would operate with a battery, an LED light, and two wire leads that would be complete the circuit when the strap moves and they come in contact with aluminum foil affixed to the strap. Ultimately, this alarm circuit was chosen to pursue in the final design.

Pressure monitoring system	Cost (20)	Size (10)	Comfort (20)	Safety (20)	Ease of Construction (20)	Aesthetics (10)	Total
1-way valve with refilling - hardware	15	5	13	19	17	8	77
1-way valve with refilling-plastic	15	7	17	19	17	9	**84**
Alarm circuit	20	8	15	15	20	8	**86**

Table 3 Monitoring system design matrix

Materials

When looking at the material for the collar itself, we discussed four options: cotton, a malleable plastic, fleece, and a mesh material. Each of these materials has pros and cons in terms of price, usage, comfort, and cleanablility. The materials design matrix in the appendix shows the main aspects we took into account when selecting the best material for our final design. The plastic would be the easiest to keep clean and could be more easily re-used, but would likely be uncomfortable for the patient. Cotton would be relatively comfortable and inexpensive, but would soak up a lot of moisture from the patient's neck such as sweat and blood. Likewise, the fleece would also be quite comfortable, but is more expensive and tends to soak up moisture. The mesh appears to be the best option. Not only is it relatively comfortable and inexpensive, it does not soak up much moisture and allows for airflow.

Strap Material	Cost (20)	Size (10)	Comfort (20)	Safety (20)	Ease of Construction (20)	Aesthetics (10)	Total
Plastics	16	10	5	20	10	7	68
Cotton	17	10	13	20	18	5	83
Mesh	12	10	15	20	18	9	**84**
Fleece	14	10	15	20	14	9	82

Table 4 Strap material design matrix

Final Design

The final design is based on each of the components discussed above. It features belt connections for the straps, an alarm circuit that monitors if the strap has changed position, a non-absorbent mesh material, and comfort balloons made out of condoms in the back which deform under pressure. Figure 9 below shows the extended strap without the alarm circuit. We believe this combination of components will best satisfy what our client is looking for in an

Figure 9 Extended strap without alarm circuit.

exceptionally secure, comfortable tracheostomy collar. The strap fits necks sized 12-21 inches. The alarm circuit is affixed to the patient after the strap has been secured (Figure 10). It slips over the front portion of the strap. The wires have a piece of fabric connecting them that is taped to the neck so that they remain stationary relative to the patient. The wires are positioned above a piece of plastic on a larger piece of aluminum that is affixed to the strap. When the strap changes position due to neck size fluctuation, the wires move off of the plastic and on to the aluminum, completing the circuit and turning on the LED light to alert a nurse on duty that the strap has changed position.

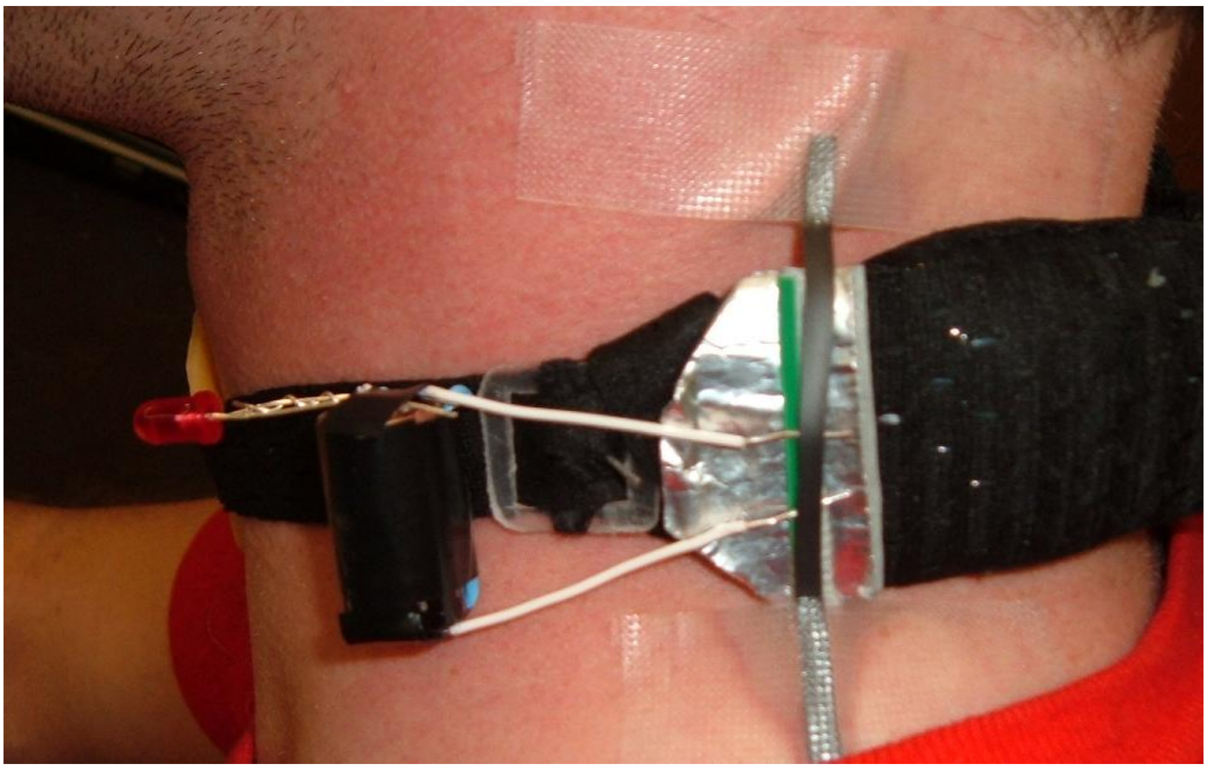


Figure 10 Alarm circuit

Materials and Methods

The cloth portion of the strap was fabricated using a sewing machine. The plastic cradles in the belt connections were cut out of a plastic box lid using an exacto knife. The pins in the belt connections were fabricated from bending paper clips around the cradles. The cradles were affixed to the strap with thread. The comfort balloons in the back of the strap were made out of condoms which were filled with 20 ml of water. They were secured with a knot on the top covered in heat shrink tubing to ensure the knot remained stationary. There are three of these balloons located in the back of the strap.

The removable/reusable portion of the alarm circuit was fabricated by placing a battery and LED light in series with two wire extensions. These connections were secured with electrical tape. The portion of the circuit that is permanently affixed to the strap was fabricated out of a piece of aluminum foil with a piece of plastic affixed using permanent double sided tape. A full cost analysis of our materials used follows:

Materials	**Total price ($)**	**Price of material we used ($)**
Mesh Fabric	1.50	0.25
Thread	2.29	0.03
Condoms (3)	4.99	4.99
Heat Shrink tubing	4.00	0.50
Medical 6 V battery	5.49	5.49
Red LED light	1.49	0.75
Wire	3.99	0.08
Electrical Tape	3.99	0.07
Aluminum Foil	1.69	0.08
Sheet plastic	0.99	0.10
Double sided tape	3.49	0.10
Duct tape	6.99	0.10
Total	**40.90**	**12.54**

We are satisfied with our result because our goal was to produce a strap for under $20. This product would be inexpensive enough to utilize in a hospital setting. The circuit price totals $6.39 and will be reusable. This will in effect reduce the overall price of the strap when the circuit is reused.

Testing and Results

Absorbency Testing

To evaluate the absorbency of the fabric that we utilized in our design, we soaked a 2.25 x 0.5 in. (7.72 x 1.27 cm) section of our mesh fabric, the twill tie Dr. McCulloch uses, and the blue foam strap his colleagues in separate vials filled with 10 mL of water. After allowing them to soak for 1 minute, we removed the strap sections and measured the volume of the remaining water in the vials. The mesh material used in our strap was the least absorbent while the blue foam strap used by Dr. McCulloch's colleagues was the most absorbent. This is a good result because the less absorbent our material is, the less sweat and other secretions it will absorb, which will be more comfortable for a patient wearing it. A summary of our findings are shown in table 5 below.

Material	Starting volume (mL)	Remaining volume (mL)	Volume absorbed (mL)	Area (cm^2)	Absorbency (mL/cm^2)
Mesh	10	9.8	0.2	9.80	0.020
Twill tie	10	9	1	9.80	0.102
Blue foam	10	7.8	2.2	9.80	0.224

Table 5 Absorbency testing results

Subject Testing

To determine qualitatively how comfortable our strap was, we polled 11 subjects on their levels of overall comfort (on a scale from one to 10), how abrasive the strap was (1 = worst, 3 = best), their impression of the safety of the strap connections (1 = worst, 3 = best), and their impression of the overall function of the strap (1 = worst, 3 = best). The results were averaged over all of the subjects. Based on the averages, our strap was ranked highest in overall comfort, safety, and overall function. Our strap tied for the least abrasive with the blue foam strap. The average results are summarized below in Table 6, and a graphical depiction of the overall comfort results is shown in Figure 11 below. Full testing results are contained in Appendix C.

Comfort			Abrasiveness/ Roughness			Safety			Overall Function		
Twill tie	Blue foam	Mesh	Twill tie	Blue foam	Mesh	Twill tie	Blue foam	Mesh	Twill tie	Blue foam	Mesh
3.4	6.0	7.6	1.5	1.9	2.6	1.9	1.4	2.6	1.2	1.8	3.0

Table 6 Subject testing averages

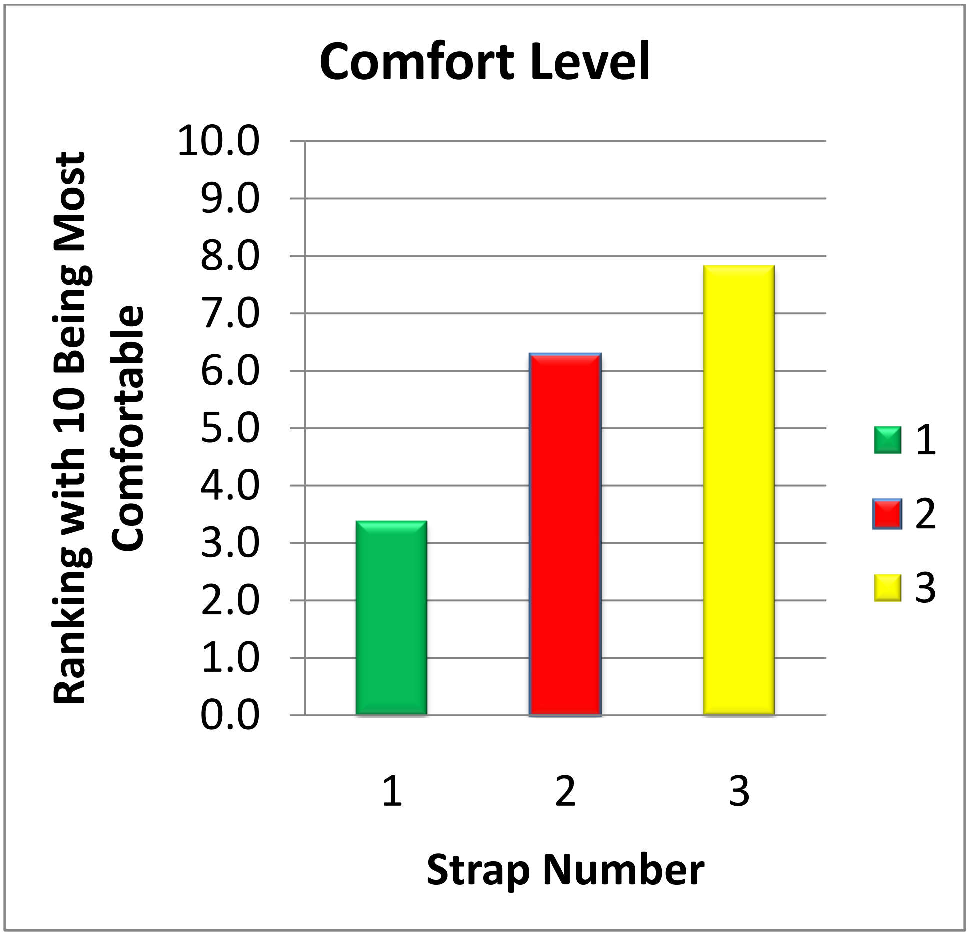


Figure 11 Graphical overall comfort subject test, 1= white twill tie, 2 = blue foam strap, 3 = mesh strap

Conclusions and Future Work

The next steps to take for our design would be to obtain further input from our client and his colleagues at the UW-Madison hospital. After receiving additional feedback from the medical personnel at the hospital, we would add additional features or tweak the current features of our product. Some possible tweaks that we already have in mind are a sound alarm system to replace the LED light alarm system, making our strap applicable and usable for all neck sizes, and to determine a way to ideally make the strap self-adjusting.

We realize that the LED light alarm system that our strap currently uses would not be completely practical in a hospital setting since it requires staff to be in the room with the patient to see the light go on. By using a sound alarm instead, the medical personnel would be notified in a much more reliable way. Furthermore, if the circuit were connected to the same machine that the vitals were connected to, the nurse would be able to know if there is a problem with the strap pressure from the nurses' station down the hall. This would be much more beneficial for the patient and healthcare personnel caring for the patient.

While our strap can be used for an average adult neck with circumference from 12 to 21 inches, it is not applicable to small children or infants who have a neck circumference of less than 12 inches, or for bariatric patients who often have a neck circumference of greater than 21 inches. In the future, we could attempt to fix this problem by having one strap that could be used for all neck circumferences, or by having three different straps to fit three major neck circumference sizes (child, adult, bariatric).

As stated before, if we could determine a way to make our strap self-adjustable to fix the pressure/tension on the neck when the strap becomes too tight or too loose, this would be ideal. In our original plan for this project we had planned on using pouches connected to valves and an overflow container that would release water from the pouch when the tension was too great. However, not only did this solution inadequately address the problem of the strap becoming too loose, it also turned out to be impossible to fabricate since valves working with such a low pressure did not exist.

After looking into each of the above ideas, we would fabricate a second or third prototype that would eventually be tested clinically and used in a hospital setting on tracheostomy patients. Our strap and its subsequent improvements will better the lives of patients in the real world. We have produced a safer and more secure device than what is currently on the market.

Appendix A- References

Unknown. 2009. Nextag Comparison Shopping. [Online] http://www.nextag.com/tracheostomy-collar/products-html

Robert Vaux. 2009. How to make an alarm circuit. [Online] http://www.ehow.com/how_4611520_alarm-circuit.html

Unknown. 2009. Walgreens. [Online] www.walgreens.com

Unknown. 2009. Radioshack. [Online] www.radioshack.com

Cynthia Bissell. 2009. Aaron's Tracheostomy Page. [Online] www.tracheostomy.com

Ess, S. M. 1998, Ventilator tube retaining device for endotracheal tube or tracheostomy. U.S. Patent 5782236

Appendix B- Product Design Specifications- February 8, 2009

Function: In patients who have had a tracheotomy performed, a major post surgery problem is discomfort from the tracheotomy collar. The collar must be secured tightly to keep the tracheotomy tube in place so the patient can breathe. However, if the collar is kept at the proper tension, it can cause ulcers on the patient's skin. Our goal is to design a tracheotomy strap that is comfortable, easy to clean and equipped with monitoring devices to ensure that proper pressure is exerted on the neck.

Client requirements:

- Wider, more comfortable strap around the back of the neck.
- Adjustment monitoring system for placement of straps
- Balloons filled with air or gel to increase comfort and adjustability of pressure on the back of the neck.
- Easy to maintain.
- Last for 5-7 days.

Design requirements:

1. Physical and Operational Characteristics
a. *Performance requirements*: One time use, for 5-7 days. Cleanliness must be easy to maintain while device is stable.

b. *Safety*: Must keep tracheotomy tube secured within the trachea.

c. *Accuracy and Reliability*: Pressure must be determined within 1mmHg, to maintain tracheotomy strap pressure. Position of securing straps on front should be monitored within 1mm.

d. *Life in Service*: Disposable, life span of 5-7 days.

e. *Shelf Life*: There are no degradable components to our design. Theoretically the device should have an indefinite shelf life when properly sealed.

f. *Operating Environment*: The device should be impervious to blood, sweat and other human secretions. The device should also allow air flow to the back of the patient's neck.

g. *Ergonomics*: 30mmHg pressure applied around the patient's neck.

h. *Size*: Adult necks are generally categorized into two sizes: 12-16 inches and 16-20 inches.

i. *Weight*: n/a

j. *Materials*: hypoallergenic materials, no skin irritants.

k. *Aesthetics, Appearance, and Finish*: Aesthetically pleasing; no rough edges as it will be in direct contact with human skin.

2. Production Characteristics

a. *Quantity*: 1-2 deliverables, eventual mass production.

b. *Target Product Cost*: below $20

3. Miscellaneous

a. Standards and Specifications: FDA approval required

b. *Customer*: Optimal comfort; the strap shouldn't bunch and should aerate the back of the neck.

c. *Patient-related concerns*: The device will need to be sterilized so it needs to be easy to clean daily. After 5-7 days the device can be disposed.

d. *Competition*: The tracheostomy collar is currently used to secure the tracheotomy tube after surgery. It is manufactured by Marpac. The current model has many disadvantages that we hope to improve upon with our design.

Appendix C- Complete Results of Subject Testing

	Comfort			Abrasiveness/ Roughness			Safety			Overall Function		
	Strap 1	Strap 2	Strap 3	Strap 1	Strap 2	Strap 3	Strap 1	Strap 2	Strap 3	Strap 1	Strap 2	Strap 3
Subject 1	1	6	10	1	2	3	2.5	1	2.5	1	2	3
Subject 2	7	9	8	1	3	2	2	1	3	1	3	2
Subject 3	3	5	8	1	3	2	1	2	3	1	2	3
Subject 4	3	7	6	1	3	2	1	2	3	1	2	3
Subject 5	3	7	8	1	3	2	1	2	3	1	2	3
Subject 6	3	5	8	1	3	2	1	2	3	1	2	3
Subject 7	1	7	9	1	3	2	1	2	3	1	2	3
Subject 8	3	5	9	1	2	3	3	1	2	2	1	3
Subject 9	4	6	5	2	2	2	1	2	3	1	2	3
Subject 10	4	5	7	2	1	3	2	1	3	1	2	3
Subject 11	5	7	8	2	1	3	3	1	2	1	2	3
Average	3.4	6.3	7.8	1.3	2.4	2.4	1.7	1.5	2.8	1.1	2.0	2.9

Strap 1 = white twill tie

Strap 2 = blue foam

Strap 3 = black mesh