Tracheostomy Tube Security Device

Client: Dr. Timothy McCulloch

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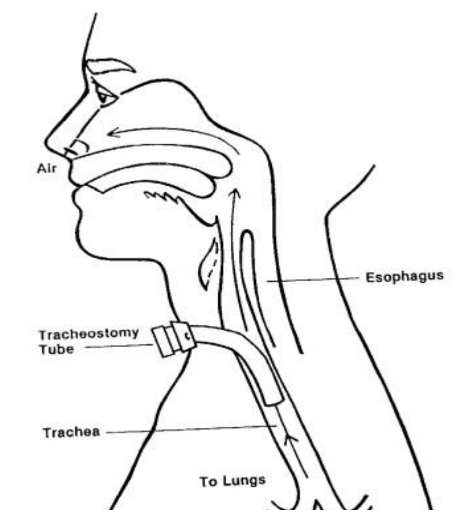
Background:

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 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.

Background:

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. This creates a tracheostomy hole, which allows the patient to breathe through the tracheotomy tube. The terms tracheostomy and tracheotomy are used interchangeably in a hospital setting although technically a tracheotomy is a procedure and a tracheostomy is a hole through which the tube is placed.



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

Figure 1 Diagram of the anatomy surrounding a 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 disease or severe airway inflammation. The tracheotomy procedure bypasses the obstruction and creates an airway for the patient to breathe.

After a tracheotomy is performed, the surgeon secures the tube with sutures onto the front of the neck and then secures them 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 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 during the operation.

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

Figure 2 Tracheotomy strap currently used by Dr. McCulloch.

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, causing the tracheotomy tube to slowly work its way out of the tracheostomy hole which leads to suffocation and potentially death.

Client Requirements:

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 fluctuation. Neck fluctuation is a direct result of excess fluid in the body. We will also be fabricating a pressure monitoring system using balloons filled with a comfortable substance that 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.

Design:

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 remain stationary, then so must the tube.

Currently, Dr. McCulloch uses a simple white cotton strap to secure the tracheotomy tube. 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 cuts off circulation in the patient’s neck and creates ulcers.

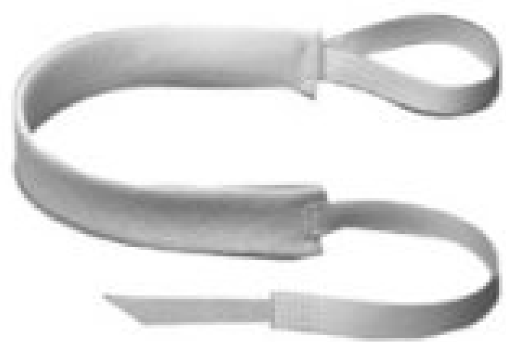
Most of Dr. McCulloch's colleagues use the collar shown in Figure 3. This collar is convenient because it can be adjusted to any neck size due to its two pieces connected by velcro. This allows nurses to undo the strap and evaluate the patient's neck to determine if they are developing ulcers. However, 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.

Velcro

Currently, many straps 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.



Redesigned hat snaps

In this design, the stationary part of the strap on the back of the neck will have two male knobs on the furthest edge of each side of the strap. These will 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 will be convenient because it will allow for a wide range of neck sizes. This method is also locking. The hole position can be marked down and duplicated if the nurse needs to monitor the patients neck or detach the strap for any reason.

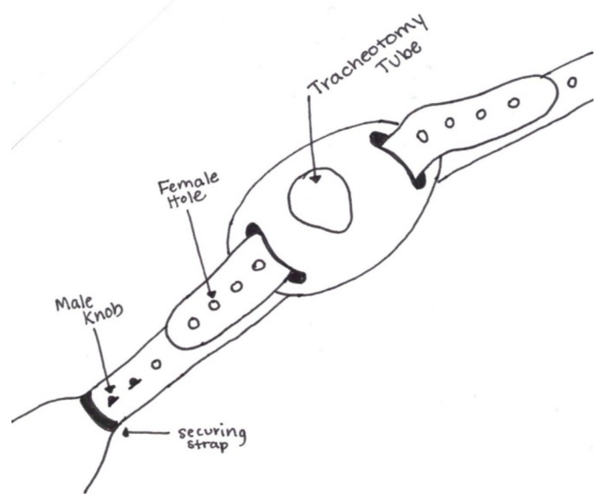


Figure 4 Redesigned hat snaps connection

Belt Design

This design is very similar to the hat snap design. Instead of male knob connections at the edge of the permanent strap, there will 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.

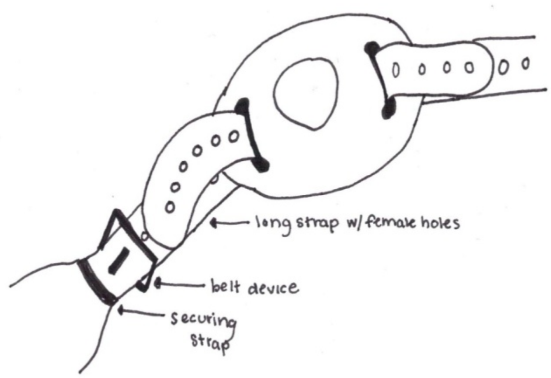


Figure 5 Belt connection

Cable tie design

In this method, a cable tie 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

Ultimately, we selected the redesigned hat snaps as the best method to attach our strap to the tracheotomy tube.

Back Pressure System

The next crucial element associated with our designed 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 uphold a great deal of security but have limited adjustment ability. Therefore, the back of our strap will self adjust to a set pressure, importantly allowing a patient to constantly maintain comfort as well as maintain pressure on the tracheostomy tube.

The basic scheme of this design can be viewed in Figure 7. As shown, on the anterior of our strap there are a certain number of

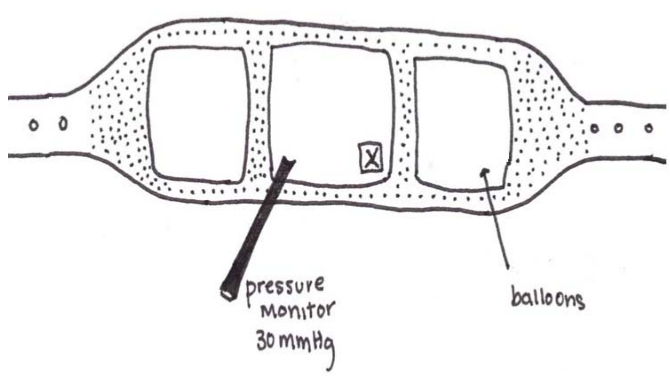


Figure 6 Basic strap design

pouches or capsules which contain a specific material, through which pressure is manipulated to remain at a set value. Air, foam gel or water are the four materials that could potentially fill the pouches. As shown in the materials matrix in the appendix, water will load the pouches to best meet the expected design requirements. Water was also the material of choice in this design due to its ease of accessibility and usage in environments such as a hospital or clinic. The various other materials listed did not fit with key aspects of our design. For instance, gel was ruled out of probable design materials due to its availability and difficulty of implementation.

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 to not exceed 30 mmHg: capillary relapse pressure. This should decrease the occurrence of ulcers. The water filled capsules in the strap will have an allocated pressure monitor and indicator which will allow for tolerable pressure. This concept is achieved by integrating a system of one way valves into the strap. This permits the free flow of water, automatically equilibrating the pressure a patient would feel on his or her neck. In Figure 8 the monitoring balloon can be seen in greater detail. The valve design matrix shows that a plastic valve was chosen over any fabricated valve. This decision was due mainly to expense issues as well as ease of integration.

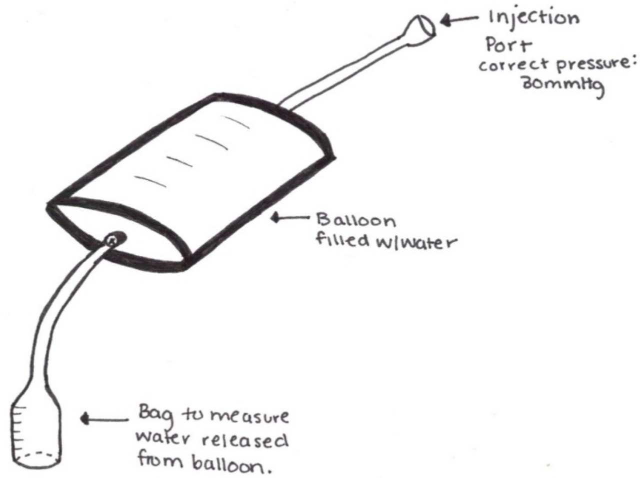


Figure 7 Pressure design

Materials:

When looking at the material for the collar itself, we developed four options: cotton, a malleable plastic, fleece, and a backpack strap-like mesh. Each of these materials has pros and cons in terms of price, usage, comfort, and cleanliness capabilities. The materials design matrix in the appendix shows the main aspects we took into account when deciding anticipation best material work within 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 patients 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.

Final Design

The final design our group will move forward with for the semester is based on each of the components discussed above. Our final design features the redesigned hat snaps, water filled pouches for pressure, a plastic one way pressure valve to keep the correct pressure in the pouches, and backpack mesh material for the collar itself. We believe this combination of components will best satisfy what our client is looking for in an exceptionally secure, more comfortable tracheostomy collar.

Future Work

We still have a lot of work ahead of this semester, and we will continue to keep our client informed and on the “same page” as us. Before we can actively begin any type of fabrication, we must research the exact materials that we need and place orders for them. After we have all of our materials we will fabricate our design prototype and begin testing it. Some of the preliminary tests that we have already discussed include: testing our prototype in environments with high and low temperatures and pressures, testing its durability by puncturing the water pouches, testing how the strap handles different types of moisture, and comparing how different sizes of the collar do in similar experiments. After we have done sufficient testing to satisfy both our client and each of the group members, we will redesign and fabricate our final prototype. After completion of the final prototype, we will present it to our client, advisors, and fellow students.

Appendix

Front	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-with liner	18	7	15	18	15	8	**81**
Self locking/pressure (like cable tie)	15	9	13	14	15	8	74
Belt thing	15	8	15	18	15	8	79

Back	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

Pressure Design	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**

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
Backpack mesh	12	10	15	20	18	9	**84**
Fleece	14	10	15	20	14	9	82