DIABOLO

Redesign of a tracheostoma valve using user feedback

Bachelor assignment Industrial Design

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umcg

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Summary

In the Netherlands every year about 200 people have their larynx removed as a cure for laryngeal cancer. Because the vocal folds are removed, they are unable to speak which is the reason for the UMCG to develop a voice prosthesis: the UFO. Being placed on the tracheostoma, this product allows its users to speak again without the use of hands.

The Diabolo is a concept in the redesign of the UFO. This new product is less complex, has fewer parts and is easier to use. However, prototypes showed some little problems with the membrane which have to be solved prior to in vivo testing. Instead, the prototypes were tested on an artificial lung. Tests showed that the operational characteristics of the first Diabolo are rather good (opening pressure: 4,15 kPa; closing flow: -2,31 L / s; breathing resistance: min. 0,5 kPa · s^2/L^2).

Finally, recommendations are made which include an adjustment to the Diabolo's membrane. With this new membrane, the Diabolo is expected to function well and in vivo tests can be executed.

Samenvatting

Elk jaar wordt in Nederland bij ongeveer 200 mensen het strottenhoofd verwijderd ten gevolge van strottenhoofdkanker. Omdat zij geen stembanden meer hebben kunnen zij niet meer praten en daarom wordt in het UMCG een stemprothese ontwikkeld: de UFO. Met dit product, dat op de tracheostoma wordt geplaatst, kunnen gebruikers weer praten zonder hiervoor hun handen te hoeven gebruiken.

De Diabolo is een concept voor het herontwerp van de UFO. Dit nieuwe product is veel minder complex, bestaat uit minder onderdelen en is makkelijker in het gebruik. Er zijn echter nog wat kleine problemen met het membraan die verholpen moeten worden alvorens het product met patiënten te kunnen testen. Daarom zijn de gemaakte prototypes eerst met een kunstlong getest. Hieruit bleek dat de operationele eigenschappen van de eerste versie van de Diabolo al redelijk goed zijn (open druk: 4,15 kPa; sluit stroomsnelheid: -2,31 L / s; ademhalingsweerstand: min. 0,5 kPa · s^2/L^2).

Tot slot is een aantal aanbevelingen gegeven met onder andere een voorstel voor een concrete aanpassing van het membraan van de Diabolo. De verwachting is dat met dit nieuwe membraan het product goed zal werken en met gebruikers kan worden getest.

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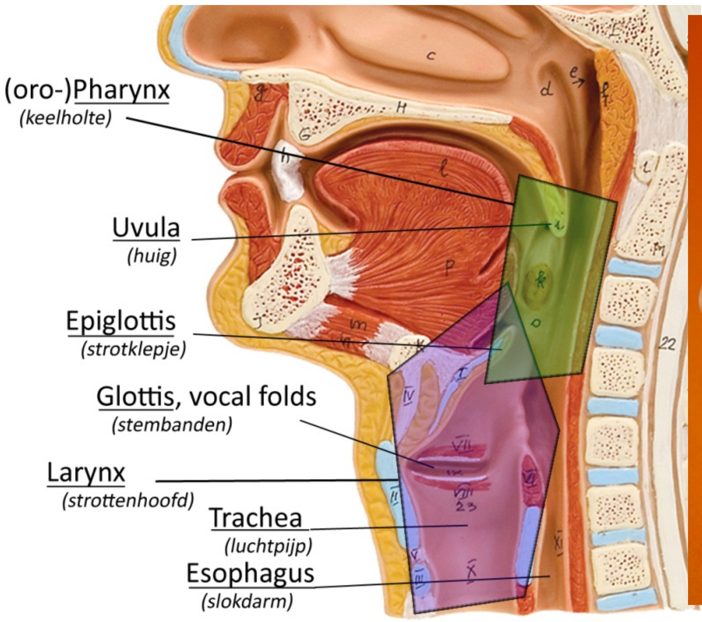
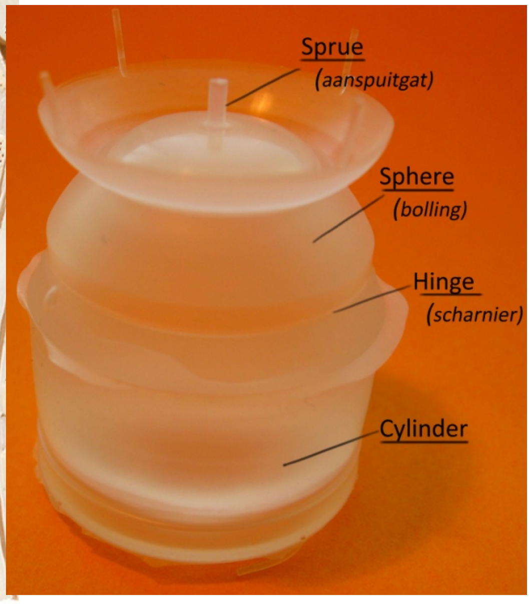
Glossary

This glossary might help in understanding some of the words used in this report.

Alveoli	Enable gas-exchange in the lungs. (Dutch: “longblaasjes”).
Bistability	Something having two stable states is bi-stable.
Buckling	A sphere going from its convex state into its concave state or vice versa.
HME-filter	Heat and Moist Exchange filter, placed on the tracheostoma to replace some of the functions of the nose.
Laryngectomee	Someone who had a total laryngectomy; the total removal (*ectomy*) of the larynx. A laryngectomee has a tracheostoma.
Mucus	Slippery secretion of the human body. (Dutch: “slijm”)
Phlegm	Mucus from the lungs.
Pseudoglottis	Fold of the esophagus which vibrates to create a burping sound. *Pseudo* means “false” or “fake”, so “fake vocal fold” (Dutch: “nep stemband”)
TE-prosthesis	Shunt placed between trachea and esophagus to allow for speech.
Tracheostoma	Opening just above the breastbone which connects to the trachea.
TSV	TracheoStoma Valve.
UFO	A concept for a new inhalation tracheostoma valve.
UMCG	University Medical Center of Groningen.





1 Introduction

Every year, around 700 people in the Netherlands are diagnosed with laryngeal cancer. Depending on the stage at which it is discovered, surgery is required. This results in having multiple handicaps, the foremost one being the disability to speak. After reconstructive surgery, the patient has to close the tracheostoma by covering it with his thumb or fingers. This is unpleasant, because the patients have to point at their handicap every time they wish to speak. Besides that, it is unhygienic and for certain activities very unpractical. Hands-free tracheostoma valves allow the patient to speak without using their hands. However, existing hands-free tracheostoma valves are inefficient and not very user friendly.

This report handles about the redesign of an existing prototype, the UFO. This valve is based activated with a strong inhalation and is completely made of silicon rubber. It consists of a patch to connect the prototype to the tracheostoma and three more parts; the cap, capseat and a HME-filter. With feedback from users, new concepts have been generated in an attempt to improve the UFO.

This report starts with the background information on the subject of tracheostoma valves (chapter 2). In chapter 3 the feedback from users is gathered to create a schedule of requirements in the next chapter. Following chapters handle about the concept generation (chapter 5) and its results (chapter 6) which concludes in a detailed design in chapter 7. Prototypes have been made for the chosen concept (chapter 8) and are tested on an artificial lung (chapter 9). The final chapter gives recommendations towards future versions of the concept and further research.

2 Orientation

This chapter gives background information about laryngectomees and the UFO-project to understand the design assignment.

2.1 Larynx

The larynx has multiple functions and consists of many complex structures. This chapter gives a short introduction on the anatomy of the human larynx.

2.1.1 Functions of the larynx

The larynx connects the lower airways and the upper airways. Furthermore it separates the respiratory and digestive tract. The larynx has two functions. The first is protection of the lungs. The true vocal folds, false vocal folds and epiglottis close the trachea during swallowing and heavy lifting. Coughing for clearance of the airways is also a form of protection of the lungs. The epiglottis is partly responsible for this action. It closes the trachea, after which the air is released violently. The second function is voice production. The larynx enables voice production together with the vocal tract (articulators).

2.1.2 Anatomy

The *larynx* (Figure 2-1) is composed of an external skeleton of cartilage plates that prevents collapse of the structure. The plates are fastened together by membranes and muscle fibers. The front set of plates, called thyroid cartilage, have a central ridge and elevation commonly known as the Adam's apple. The plates tend to be replaced by bone cells beginning from about 20 years of age onward. The *epiglottis*, at the upper part of the larynx, is a flap-like projection into the throat. As food is swallowed, the whole larynx structure rises to the epiglottis so that the passageway to the respiratory tract is blocked. After the food passes into the *esophagus* (food tube), the larynx relaxes and resumes its natural position. The centre portion of the larynx is reduced to slit-like openings in two sites. Both sites represent large folds in the mucous membrane lining the larynx. The first pair is known as the *false vocal cords*, while the second is the *true vocal cords* (*glottis*). Muscles attached directly and indirectly to the vocal cords permit the opening and closing of the folds. Speech is normally produced when air expelled from the lungs moves up the trachea and strikes the underside of the vocal cords, setting up vibrations as it passes through them; raw sound emerges from the larynx and passes to the upper cavities, which act as resonating chambers, and then passes through the mouth for articulation by the tongue, teeth, hard and soft palates, and lips.

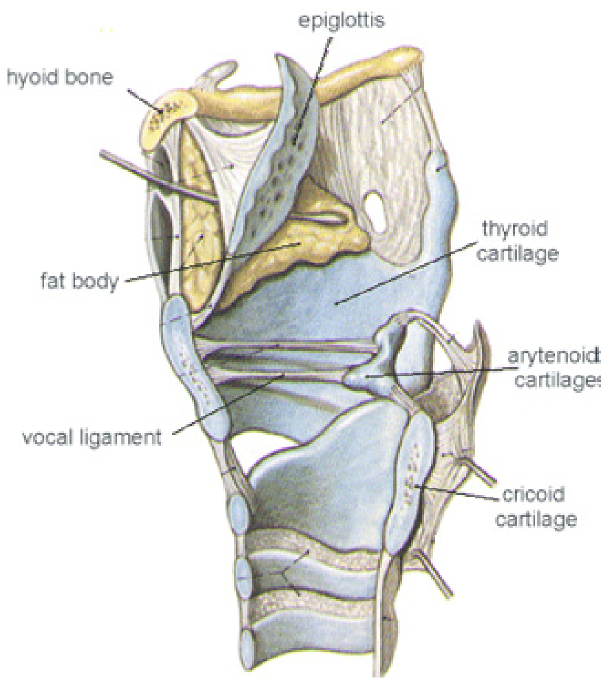


Figure 2-1: cross-section of the Larynx

2.2 Laryngeal cancer

Every year, around 700 people are diagnosed with laryngeal cancer in the Netherlands (StatLine CBS ,2010; iKC Net, 2010) (Figure 2-2). Worldwide this number is 151.219 (Ferlay et al., 2010). Cancer can develop in any part of the larynx, but the cure rate depends on the location of the tumor. Most laryngeal cancers originate in the glottis. Supraglottic cancers are less common, and subglottic tumors are least frequent.

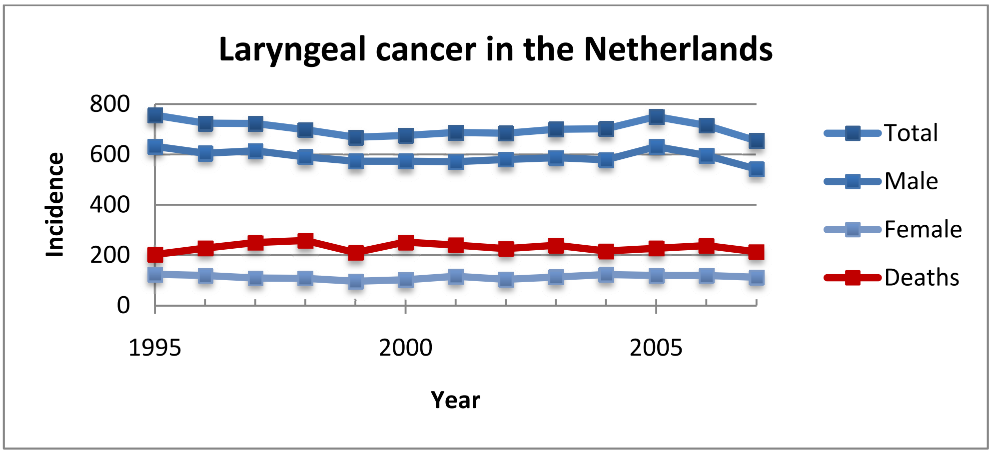


Figure 2-2: graph generated with data from StatLine and iKC Net

2.2.1 Risk factors

Smoking is the most important risk factor for laryngeal cancer. Death from laryngeal cancer is 20 times more likely for the heaviest smokers than for non-smokers (Ridge et al., 2008). Heavy chronic consumption of alcohol, particularly alcoholic spirits, also plays a significant role. When combined, these two factors appear to have a synergistic effect. Some other quoted risk includes low socioeconomic status, male sex, and age greater than 55 years. But these factors are most likely related to prolonged use of tobacco and alcohol consumption.

2.2.2 Treatment and surgery

Specific treatment depends on the location, type, and stage of the tumor. Treatment may involve surgery, radiotherapy, and chemotherapy. Laryngectomy is the removal of the larynx and separation of the airway from the mouth, nose, and esophagus. During this surgery, the trachea is connected to the skin just above the breastbone. This means the laryngectomee breathes through an opening in the neck, which is called a *tracheostoma* (Figure 2-3). Obviously, this procedure means the laryngectomee can't breathe through the nose and mouth anymore. The esophagus is connected to the pharynx, where the larynx was attached previously (see Figure 2.4).

According to the Dutch Patients Association for Laryngectomees (Patiëntenvereniging NSvG, 2008) 200 to 250 laryngeal cancer patients per year get a tracheostoma. In 60% of the cases this treatment is effective and the patients are cured from cancer. An estimated 2000 to 3000 people in the Netherlands have a tracheostoma.
Most laryngectomees are older than 60, women are usually about 5 years younger.

Figure 2-3: Laryngectomee with a tracheostoma

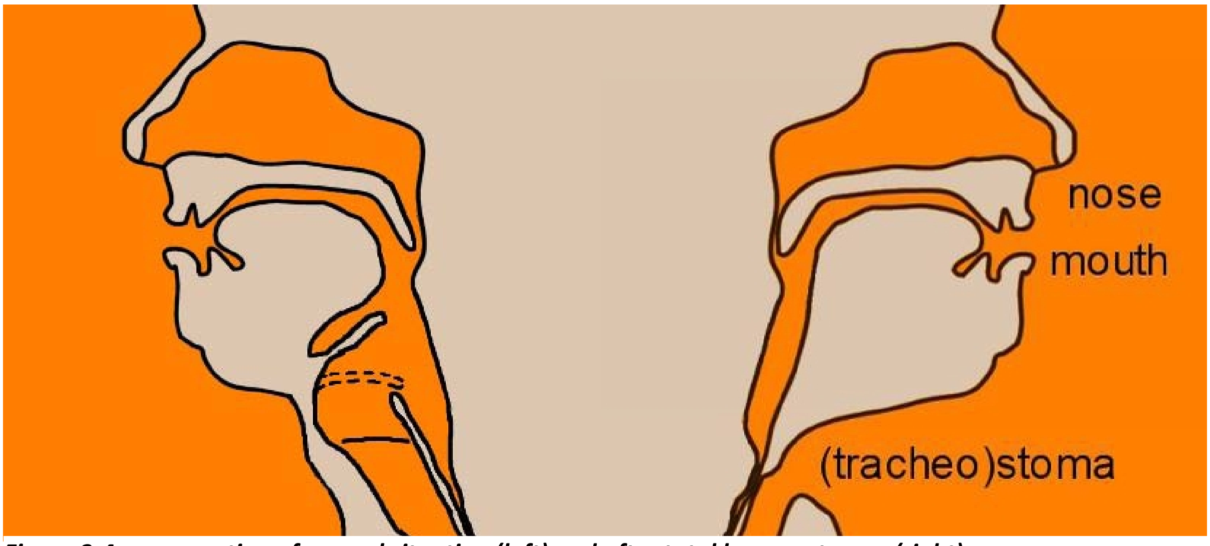


Figure 2-4: cross-section of normal situation (left) and after total laryngectomee (right)

2.2.3 Consequences of surgery

By the removal of the larynx, most of its functions are lost:

- Voice
  People with a larynx are able to talk because of their vocal folds. Air passes these small muscles, which makes them vibrate. The frequency of this vibration can be changed by putting more tension on these muscles, narrowing the opening of the trachea. A laryngectomee doesn't have vocal folds and therefore is unable to speak or adjust the pitch of his voice. It's impossible to talk, sing, whisper, hum, cry, shout, whistle, etc. The pressure of the lungs determines the volume of the sound. The vibrating air flows through the mouth and is shaped into vowels by the resonance of cavities in the mouth and nose. The position and movement of the tongue, lips, teeth and jaws shape these vowels into words, making it possible to speak.

  Someone's voice is strongly connected to one's personality, so the loss of one's voice can be an emotionally very traumatic event, both for laryngectomee as his surroundings.

- Air conditioning
  A tracheostoma is a direct connection from the lungs to the outside air, so the lungs are unprotected from dusty or cold places. In the lungs, mucus is produced to capture dirt which normally is swallowed or removed by coughing, but having a tracheostoma the mucus has to be removed by coughing and by hand.

  Normal inhaling through the nose filters, warms and humidifies the air so the inhaled air in the lungs is about 32°C with 95% humidity. A HME-filter (Heat and Moisture Exchange) is designed to help laryngectomees regain some of these lost respiratory functions. When placed over the tracheostoma, a HME captures warm and moist air in the filter as it is exhaled from the body. The cool, dry air breathed in then passes through the filter where it is warmed and moisturized as it enters the body.

- Smelling & tasting
  Air can't be inhaled through the nose, so no smell can be detected by the olfactory system. This also reduces the experience of taste in a great amount. Being unable to smell (anosmia) can be dangerous, for example to detect fire, when gas is leaking or food is rotten. Sensing a smell can arouse strong emotions, for the olfactory memory is strongly connected to the emotional part of the brain. People suffering from anosmia complain about missing the smell of their loved ones or things like freshly mowed grass. According to Deems et al. (1991), 35% of people having anosmia are depressed.

Some techniques exist for the rehabilitation of olfactory after a total laryngectomy (Hilgers, 2004), the most elegant one being the polite yawn method (see Figure 2-5).

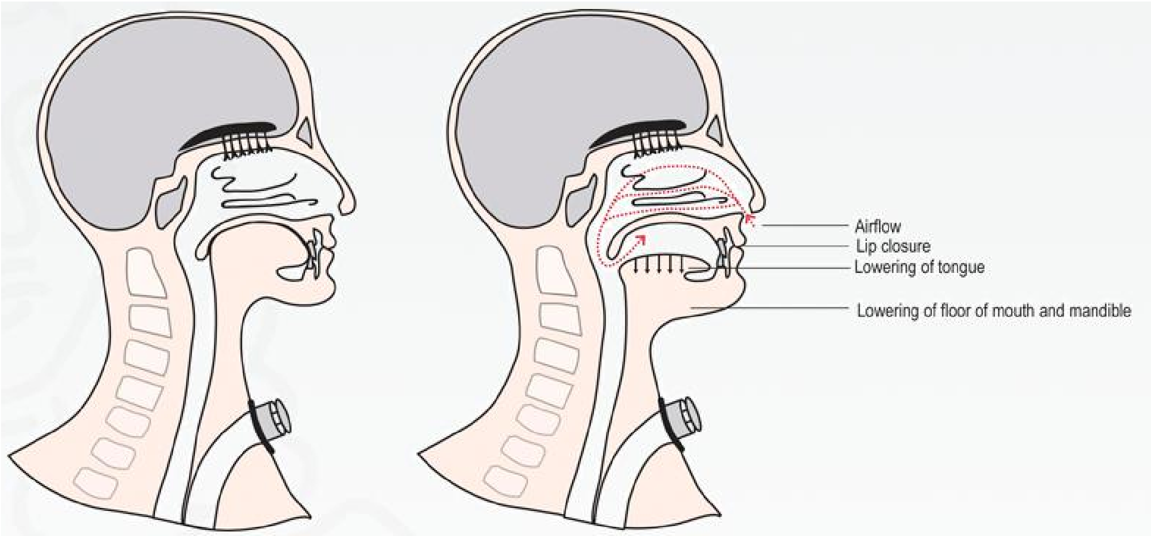


Figure 2-5: the polite yawn method (source: www.hoofdhals.nki.nl/olfaction)

- Breathing resistance
  The upper airways have some resistance which slows down the flow of air, requiring a high vacuum pressure to inhale. This breathing resistance is needed to facilitate deep inhaling, making the pulmonary alveoli use their full capacity. To do this, the chest is fully expanded to get air deep into the alveoli. During exercise this breathing resistance is lowered by opening the mouth so in a short time large amounts of air can be inhaled. Laryngectomees almost haven't got any breathing resistance because the air doesn't flow through vocal folds, pharynx and mouth or nose.
- Building up pressure
  By closing the epiglottis and tightening the big muscles around the lungs, a big lung pressure can be created which is needed for coughing, heavy exertion, defecation and giving birth. Laryngectomees have to close their tracheostoma manually to be able to build up pressure, so activities like weightlifting are impossible.
- Shielding the lungs
  The epiglottis normally shuts the lungs when food is swallowed, making it almost impossible to get food and fluids in the lungs. Although all mammals have a larynx, the position of the human's larynx is very low which allows them to have complex communication with a larger variety of sounds. However, this is also the reason that people sometimes choke to death when it doesn't function well (Watcher, 2009). With a tracheostoma the esophagus and trachea are totally disconnected so choking because of eating cannot occur. Nevertheless, swimming or taking a shower has become a very dangerous activity.

The loss or decrease of most of these functions clearly decreases the quality of life after a total laryngectomy. Although the main goal of the assignment is to let laryngectomees talk, it's desired that the product can diminish the loss of these functions.

2.3 Solutions

Speaking without a larynx is difficult but fortunately there are some solutions.

2.3.1 Self reliant

Although it requires much practice, having a tracheostoma it's still possible to speak without the use of additional products. To do this, two techniques are used. With *injection speech* air is swallowed and released from the stomach, making a fold of the esophagus (*pseudoglottis*) vibrate, creating a sound; burping. This burping sound can be used for speech. Not every person is able to learn this technique. Additionally it has the disadvantage over normal speech that the stomach has a small volume so only short sentences can be said.

Another technique is *buccal speech*, where an even smaller amount of air is pressurized between cheek and upper jaw and released into the mouth. This sounds like the voice of Donald Duck. This technique is even harder to learn and is rarely used.

2.3.2 Electrolarynx

A different solution of creating a voice is the use of an electrical vibration source. This is put against the side of the neck making the air inside the pharynx vibrate to produce words. The produced voice has a distinct monotonous mechanical sound and only little power. Another disadvantage of this product is the fact that the produced sound is not controlled by the flow of air from the lungs. This makes it harder to have small pauses in between words and sentences. Some products exist to operate this device by using the chin instead of hands (Figure 2-6).

Figure 2-6: (left) a handsfree electrolarynx (right) Southpark's Ned uses an electrolarynx

The supervisor of this project, Ward van der Houwen, is also working on the design of a promising new type of electrolarynx. This device is placed in the mouth like a chewing gum, and when the user opens his mouth, the device detects a change of light and starts vibrating.

2.3.3 Tokyo Artificial Larynx

Some products are available to redirect the air from the tracheostoma into the mouth. This allows the user to control his speech using his lungs. An example of this type of products is the Tokyo Artificial Larynx (Figure 2-7). This device is put over the tracheostoma to direct exhaled air into the mouth. At the connection with the tracheostoma, a rubber band starts vibrating, creating a sound. The vibrating air flows through a tube into the mouth were it can be formed into intelligible speech. By adjusting the flow of air, both volume and frequency can be adjusted. Although the quality of the speech is rather good, the biggest limitation of this device is the high visibility and therefore it's rarely used. In 1975, Nelson et al. recommended the device to people who are unable to vibrate the pseudoglottis.

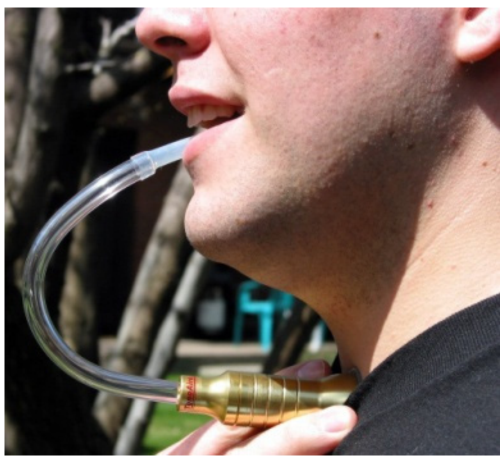


Figure 2-7: The Tokyo Artificial Larynx. Exhaled air makes a rubber band in the metal part of the device vibrate, allowing the user to speak.

2.3.4 Tracheostoma occlusion

Nowadays, most laryngectomees get a Trachea Esophagus (TE)-prosthesis which facilitates the ability to push air from the lungs into the pharynx and into the mouth (Figure 2-8). The valve ensures food and fluids not to leak into the lungs. When the tracheostoma is closed and the laryngectomee exhales, air is pushed through this TE-prosthesis and makes the pseudoglottis vibrate. Using this valve makes it possible to speak using the lungs for pressure and air flow and the mouth for forming words. The voice still has a burping sound but is a lot more comfortable.

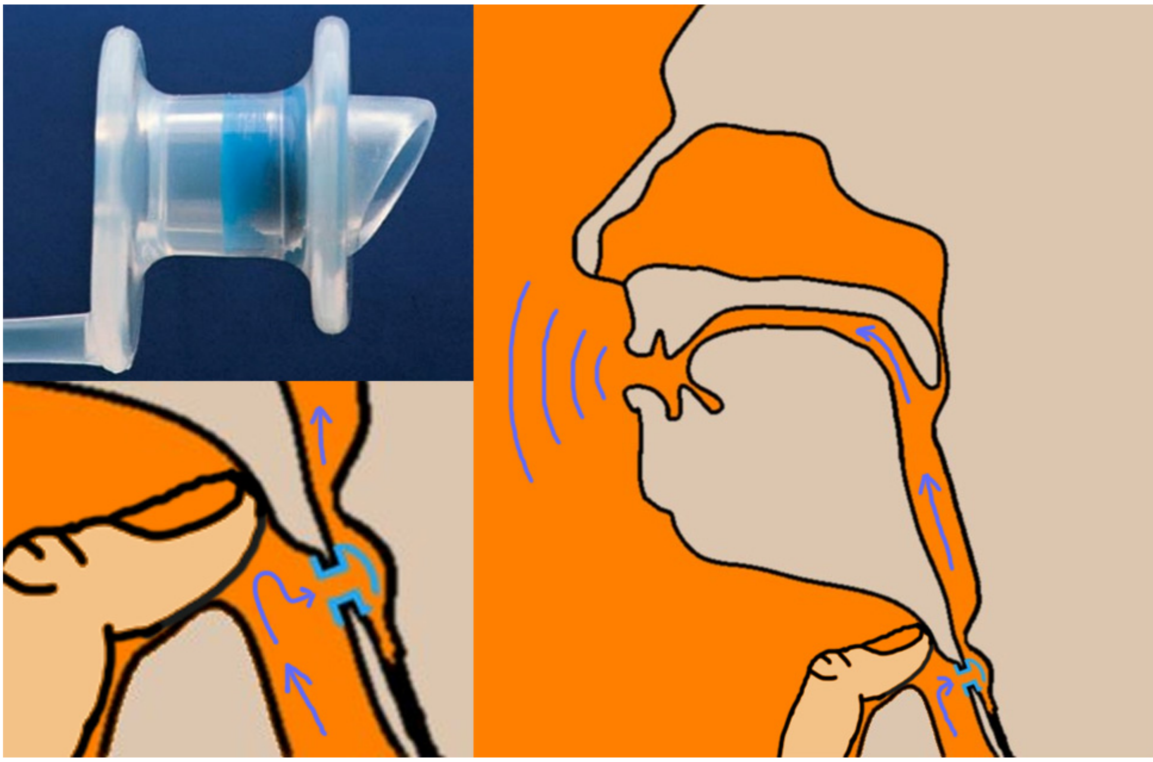


Figure 2-8: TE-prosthesis. With occlusion of the tracheostoma, exhaled air is redirected through this valve. The pseudoglottis gives a vibration to the air and allows the user to speak.

Promising research is done on the possibility of TE-prostheses with integrated artificial vocal folds (Tack et al. 2007). With this new type of TE-prosthesis, the quality of the voice no longer depends on the vibration of the pseudoglottis, making it possible to produce a more natural voice.

Normally, laryngectomees would close the tracheostoma with some fingers or a thumb. This being rather unhygienic and the fact that inhaled air is no longer filtered, heated and moisturized by the nose, creates a high production of phlegm. To overcome this problem, a HME-filter is placed on the tracheostoma. Most HME-filters are placed in a cassette which can be closed by a finger to allow for speech. Examples of these HME-filters are the Provox HME Cassette (Atos) and the Blom-Singer HME System (InHealth) (Figure 2-9).

Figure 2-9: (left) Provox HME cassette. (right) The Blom-Singer HME System, open and closed

2.3.5 Hands free products

Closing the tracheostoma by hand is unwanted because this requires one free hand, is considered unhygienic and makes the handicap rather visible. For these reasons some handsfree TracheoStoma Valves (TSVs) are produced and commercially available. In the open position both inhalation and exhalation is possible. The closed position still allows inhalation, but disables exhalation, allowing the user to speak.

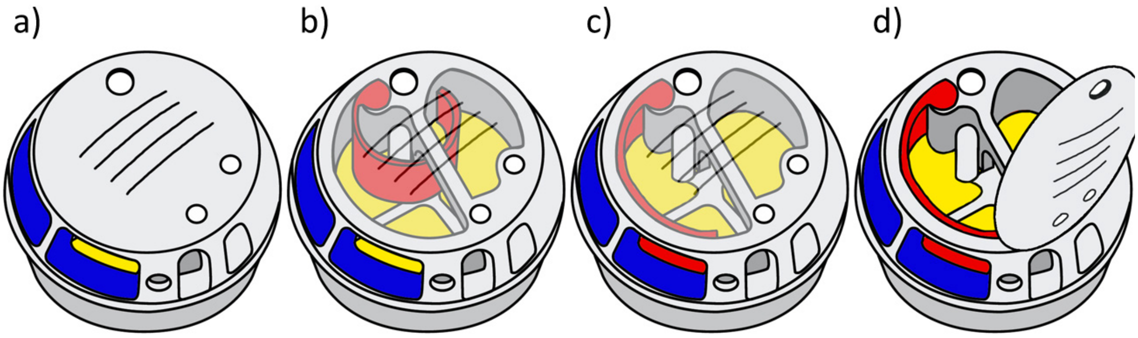


Figure 2-10: a) The Provox Freehands HME filter in its normal position. Air flows through the HME-filter (yellow) and the breathing holes. b) With normal breathing, the membrane (red) doesn't move. c) On strong exhalation, the flexible membrane is pushed away to block the breathing holes to allow for speech. d) With even stronger exhalation (coughing), the cough-relief valve opens

There are only a few hands free TSVs available, the Provox FreeHands HME from Atos (from here just "Provox") being the most popular. All these TSVs use exhalation to close the valve to allow speech. Figure 2-10 shows how this works in the Provox. The flexible membrane is kept in its normal position by a small magnet. The required pressure to close the TSV can be adjusted by twisting a part of the TSV to change the position of this magnet.

Despite the clear advantages of this product, it's even better to use inhalation to close the breathing holes. In 3.1 Testing an Inhalation TSV this is explained.

2.4 UFO

In the University Medical Centre of Groningen (UMCG) a new TSV is being developed which uses inhalation to activate the valve. A concept for this TSV is called the UFO (Figure 2-11). The redesign of the UFO is the main subject of the rest of the chapters in this report.

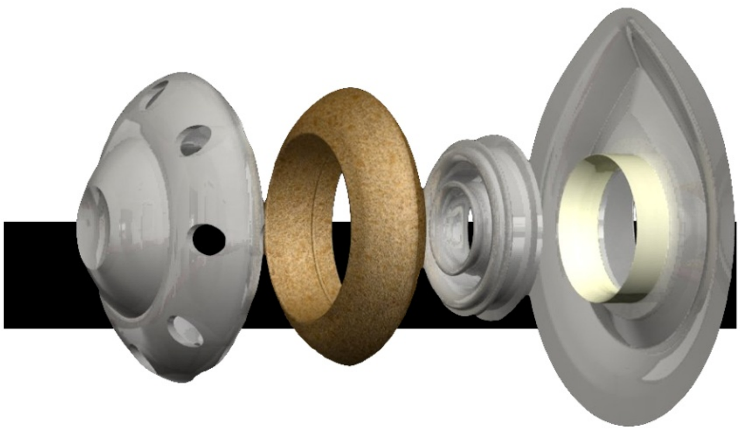


Figure 2-11: an exploded view of the UFO. From left to right: cap, HME-filter, capseat and droppatch.

2.4.1 Working principle

As with the other TSVs, in open position the user can breathe normally, but in closed position exhaled air is blocked to allow the user to speak (Figure 2-12). This means in opened position a breathing hole is fully opened while in closed position breathing holes act as valves. To shift between the two positions, the UFO has a flexible sphere which has two stable positions: convex (opened) and concave (closed). Because both positions are stable, the user doesn't need to reactivate the product again before each sentence.

With strong inhalation, the sphere is sucked inwards to put it in its concave, closed position. This is called buckling. It closes the large inner breathing hole of the TSV. However, around this breathing hole a circular pattern of valves is created by a membrane to allow inhaled air to enter. Because exhaled air is blocked for the inner breathing hole and for the valves, it has to exit the body via the TE-prosthesis and the mouth so speech is possible (see Figure 2-8).

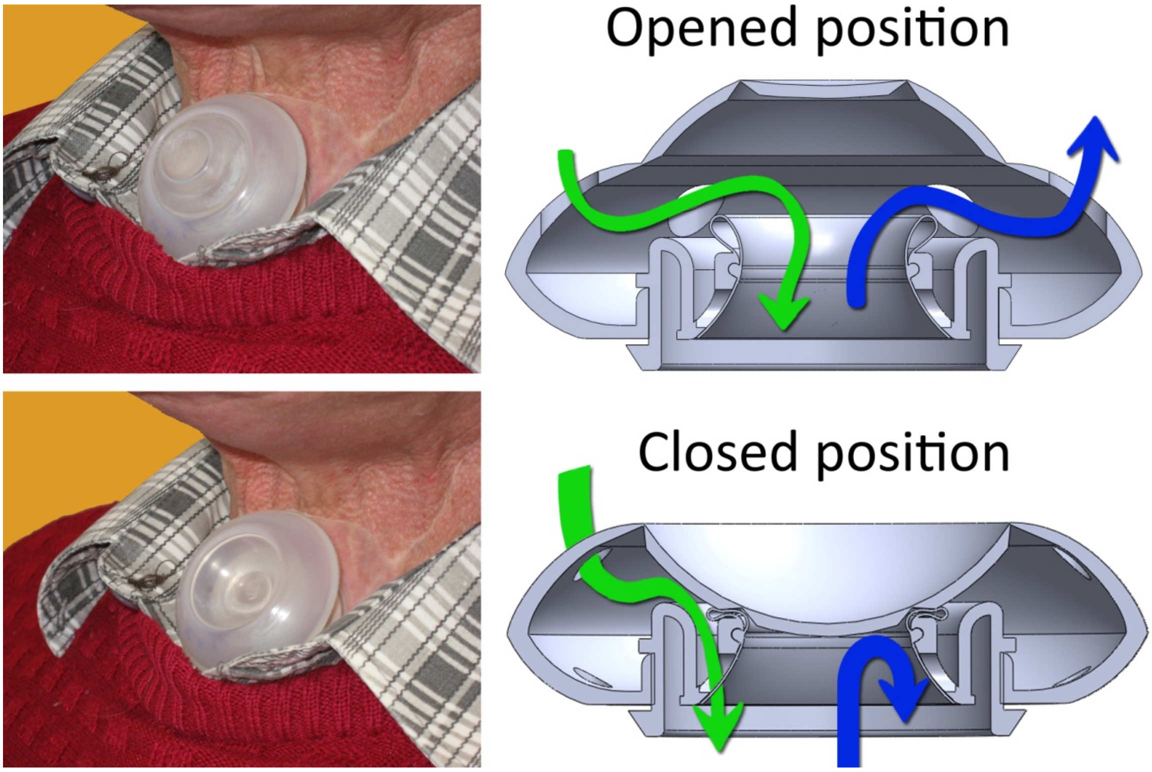


Figure 2-12: the UFO in opened and closed position. The green and blue arrows represent respectively inhalation and exhalation. In closed position exhalation is blocked to enable speech.

2.4.2 Droppatch

The *droppatch* can be seen as a separate part of the UFO. This concave patch is placed around the tracheostoma and has the shape of a drop to fit on the shape of the skin around the tracheostoma. The patch is connected to the skin with special adhesive which is rather strong but can easily be peeled off. However, currently much research is being done on improving the adhesive since for most users the patches don't stay on long enough. Additionally, research is done on other methods to connect a TSV to the tracheostoma.

The fixation of TSVs to the tracheostoma is still one of the biggest issues, but this problem is not assessed in this assignment because this is done by other students and researchers.

For the current versions of the prototype a standard connector ring is placed inside the moulds of the droppatch to assure other TSVs can also be placed on the same patch. This standard connector has a flat horizontal basis which is captured inside the silicon of the droppatch, and a ring with a small inner edge to connect a TSV to it (Figure 2-13).

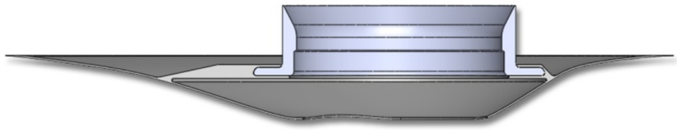


Figure 2-13: a cross-section of the droppatch

2.4.3 Capseat

The capseat (Figure 2-14) is the first part of the UFO to be placed on the droppatch and is tightly attached to the droppatch's inner edge. The capseat has a circular membrane which produces the valve to allow inhalation in closed position. Besides that, it has a breathing hole in the middle and a folded membrane to create an airtight closure with the cap. The membrane of the capseat is very thin and therefore rather hard to produce because it often tears. The membrane of the capseat is molded inside-out and everted afterwards to create the small fold and the valves.

The capseat's functions are to connect the cap to the droppatch, to create an airtight connection with the cap in closed position and to allow the user to inhale in closed position.

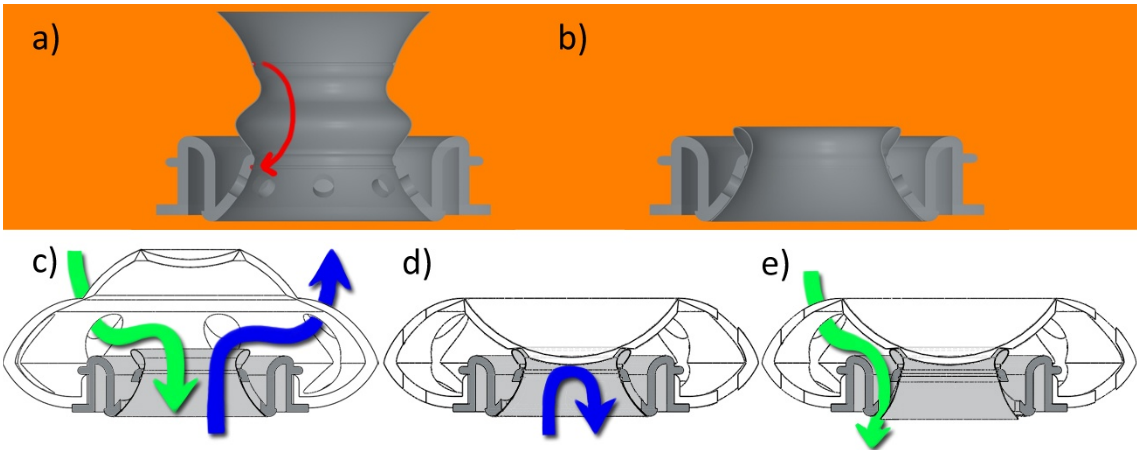


Figure 2-14: a) the capseat in molded position, the membrane is everted. b) Ready for use. c) In combination with the cap in opened position normal breathing is possible. d) But in closed position the cap pushes against the capseat's folded membrane to create an airtight closure and block exhalation. E) The membrane creates valves on the side to allow inhalation during speech.

2.4.4 Cap

The cap is the second part of the UFO to be placed on the droppatch and is tightly attached to the outer edge of the capseat. The cap is the most visible part and accounts for the name because of its UFO-shape. It has a circular pattern of breathing holes and a sphere. Strong inhalation makes the sphere buckle into its closed state and vice versa (see Figure 2-12).

2.4.5 HME filter

The ring-shaped HME filter is placed in the cap underneath the breathing holes. The function of the HME-filter is explained in 2.2.3 Consequences of surgery.

2.5 Design assignment

This paper reports about the assignment to redesign the UFO. A flexible TSV is designed which uses inhalation as activator. Additionally the functionalities of flexible materials like bistability is used in the new design. The focus of the assignment is to integrate user feedback in the design to improve usability, ergonomics and aesthetics.

Additionally, the aim is to make overall improvements to the UFO. This means the following aims are set (some have overlap with aims for usability):

- reduce the complexity of all parts, assembly and functioning
- reduce the number of parts
- reduce the breathing resistance in closed position
- reduce the size
- add adjustability of closing flow, opening pressure and breathing resistance
- add a cough valve

3 User feedback

As the development of an inhalation tracheostoma valve is a big project, a lot of research is already done by others. In this chapter the findings of researchers, students and an artist are summarized into recommendations to use for the redesign of the UFO.

3.1 Testing an Inhalation TSV

Geertsema et al. (2002) has done extensive research on the different commercially available TSVs. For this research he also designed a TSV based on inhalation. His research concludes in the following recommendations:

Use inhalation as activator
To keep an exhalation TSV closed, pressure has to be put on the valve. After each sentence this pressure drops which opens the valve again. The inhalation TSV makes it possible to inhale at the end of a sentence to continue speaking. Additionally it takes up to 22% of the total lung volume to close the valve with an exhalation TSV. Therefore, speaking with an exhalation TSV isn't very efficient and can be exhausting.

Minimize leaking air
In closed position exhaled air leaks from the inhalation valve. This reduces the amount of air available for talking and therefore should be minimized. With a tight closure and a small transition between open and closed position, no leakage should occur.

Coughing
Most TSVs have a cough relief system which allows the user to cough. Unfortunately this doesn't always work because it closes the exhalation valve, resulting in embarrassing situations when the TSV is shot from the tracheostoma. With the inhalation TSV coughing is always possible because it just opens the valve. However, the breathing resistance of the inhalation TSV in opened position should be low enough to make it possible for the exhaled air to flow away without shooting the TSV from the tracheostoma. Otherwise an extra cough valve should be added to the inhalation TSV which opens completely at very high pressures.

Adjustability
Some patients use more pressure to talk than others and need a higher opening pressure. Others have weaker lungs and need a smaller closing flow. During exercise both values should be higher. Most exhalation TSVs can be adjusted to the user's needs but until so far the UFO doesn't have this option.

Low inhalation resistance
In closed position the breathing resistance of the inhalation TSV is too high for comfortable breathing. Although some resistance is required to be able to fully expand the chest and effectively breath, with too much resistance breathing becomes hard.

Fixation
In closed position, pressure is put on the TSV to force air to go through the TE-prosthesis. This pressure makes the fixation of the TSV on the tracheostoma weak. Although this is a major problem, it's not a part of this design assignment and will therefore not be assessed.

3.2 In Vivo Tests UFO

One of the previous students in this project, Willemijne Schrijver (2010), has done extensive research on the experience of users of the UFO in comparison to the Provox. In this research a questionnaire was held on a group of 22 laryngectomees. Her summarized results are quoted in the textbox below.

“63,6% of the patients are of the opinion that closing the stoma with a finger or thumb is not annoying, because they are used to it. However, 85,7% thinks hands-free speech makes life more easy, since they can speak when both hands are occupied.

All patients would use an automatic speech valve, if it would work optimally and usage is not difficult. 33,3% of the patients think usage of the UFO is more difficult than closing the stoma with the hand. The rest thinks it is easier or that there is no difference.

If the Atos and UFO are compared according to usage, 57% thinks the UFO is more easy to use.

When questions are asked about the flaws of the UFO, 81% is of the opinion that inhalation in closed position is too difficult, 47,4% thinks the valve opens too easy at loud speech and 54,5% thinks the whistling noise when the valve opens is annoying.” (p.21-22)

Additionally, the patients said the dimensions of the UFO are too big. Furthermore, 50% of the patients mentioned that patches do not stay attached for longer than a couple of hours. One patient said the UFO made it possible to whisper again.

With her report more recommendations to the redesign of the UFO have been made:
- A hands free TSV is desirable
- Inhalation is considered to be better than exhalation as activator
- The breathing resistance for inhalation in closed position should be lowered
- For some people, loud speech is impossible, so the opening pressure should be adjustable
- The UFO shouldn’t make any noise (i.e. no whistling or plopping sounds)
- The dimensions of the UFO are too big and should be decreased
- The patches don’t stay on long enough.

3.3 UFO research

More students have worked on the design of the UFO and all have made their recommendations to the next students. Here a small summary is given of relevant recommendations of previous students.

Flexible material
Wearing a TSV should be comfortable, also when the neck is moved. Flexible material should be used to facilitate this. The functionalities of the material (like bistability) should be used to reduce complexity and to have a small number of parts.

Optimize buckling effect
When an increasing pressure is put on the UFO in closed position, the UFO first starts to leak before opening completely. The length of this phase should be reduced to minimize leakage to facilitate longer sentences. This can be done by optimization of the buckling effect.

HME-filter
It’s obvious that an HME-filter should be used to prevent respiratory complications. This filter should be positioned as close as possible to the tracheostoma so phlegm will be absorbed by the filter instead of blocking the valve. As the filter can be occluded with phlegm, it should be possible to replace the filter in a convenient way, preferably without soiling the hands.

Adjustable breathing resistance
No TSV exists with an adjustable breathing resistance. This feature could be very interesting for sportive users as it equals opening the mouth. This could be a unique selling point.

Simpler capseat
Preparing the capseat for assembly is rather difficult, so less complex parts are desired. One part of the mould is a small core which forms the inside of the thin membrane. Removing this core often results in a tear in the membrane which makes the capseat unusable. Producing the capseat should be made easier.

3.4 ENT-Nurses

After surgery, laryngectomees are helped by Ear, Nose and Throat (ENT)-nurses to learn to cope with the tracheostoma. ENT-nurses teach them to talk again and make recommendations to the use of additional products like HME-filters and TSVs. Speech therapists are the main stakeholders in informing patients. They say the Provox is the only known brand for hands free speech, but the hands free TSVs work for only 10% of the patients. A former student, Agnes Uijttewaal (2008), has done a large inquiry on the findings of experienced ENT-nurses of all hospitals in the Netherlands and summarized their conclusions towards the problems to be solved in the redesign of the UFO:

<u>Airtight connection</u>
The connection of the TSV to tracheostoma should stay on with movement of the neck. The currently used patches don't stay on long enough and peal of when pressure is put on the TSV.

<u>Mucus</u>
Laryngectomees cough a lot and secrete much mucus. This shouldn't block the TSV so the use of a cough release system is desired. Most laryngectomees remove every product when they have to cough, so this cough release system has to work very well to convince the users to use it. Easy cleaning is also desired. The best option should be to find a way to reduce the mucus production.

<u>Pseudoglottis</u>
Laryngectomees are able to speak because a fold of the esophagus starts vibrating when air passes. Because this is similar to the normal vocal folds (glottis), this fold is called the pseudoglottis. Some laryngectomees don't have this fold and their esophagus has to be tightened or relaxed (with an injection) to enable vibration. Without vibration they can only whisper.

3.5 Feedback from a laryngectomee

After watching the procedure of changing the TE-prosthesis in two laryngectomees, one of the laryngectomees was interviewed. The conversation soon diverged from the planned interview but the most relevant questions were answered and it was very helpful in the further design process. The planned interview and the answers can be found in **APPENDIX A – INTERVIEW PATIENT** (in Dutch).

3.6 Artist's recommendations

In former days, glasses had the stigma of being dumb. The thick glasses and inconvenient models made the user look silly. Nowadays millions of trendy models are available and it's very acceptable to wear them. This trend of increasing acceptability of a handicap is also visible in the product of hearing aids. The first hearing aid products were big and unpleasant to wear, making one's handicap rather visible. Following models were increasingly smaller and skin colored to hide the handicap, but nowadays colorful, funky hearing aids are available and popular (see Figure 3-1).

It's not unlikely that this trend will also occur with products for the tracheostoma. The first signs of this trend are visible in the work of Marianne Hoedemaekers (see Figure 3-2). She is the only artist in the Netherlands who makes jewelry to wear on the tracheostoma. With this jewelry the products for the tracheostoma are hidden which makes the user feel more comfortable in public.

In an interview which can be found in **APPENDIX B – INTERVIEW TRACHEOSTOMA ARTIST** (in Dutch) she said the following:

- Not all people feel ashamed of their tracheostoma, but the sight of the tracheostoma can be confronting for other people. So, all laryngectomees like to hide their tracheostoma
- For some people the jewelry is liberating, making them feel comfortable in public for the first time after the operation. It gives them more courage.
- A tracheostoma filter should be as flat as possible to make it easy to cover. The currently available hands free filters are rather high, making them unsuitable for jewelry.

Figure 3-1: pictures of different types of hearing aids. The one on the left is the most ancient; more to the right are currently available models.

Figure 3-2: Jewelry from Marianne Hoedemaekers for laryngectomees

3.7 Physical requirements

A lot of research has been done on the respiratory system, both for people with and without a larynx. A broad literature study has been done (see **APPENDIX C – PRESSURE AND FLOW REQUIREMENTS**) of which the conclusions are stated in this paragraph.

The inhalation TSV should close at a flow of 1,2 L / s, it should open at a pressure of 6,0 kPa and have a breathing resistance of 400 Pa · s^2 / L^2 maximum. It's desired to have multiple versions of the TSV with closing flow in the range of 0,5 to 2,5 L / s, opening pressure in the range of 2,0 to 8,0 kPa and an adjustable breathing resistance of 50 to 500 Pa · s^2 / L^2. The used references to find these values are stated in the appendix.

4 Schedule of Requirements

A product is designed which makes it possible for laryngectomees to talk. The requirements of this product are categorized in six subjects. Additionally a list of desired properties is mentioned.

4.1 Speech

- The product lets the user decide when to be silent and when to talk
- The product doesn't make unwanted additional sounds
- The produced speech has a sufficient volume and can be changed voluntarily
- The product makes it possible to have short inhalation breaks in long sentences without having to reactivate the product
- The product enables comfortable inhalation during speech with a breathing resistance of maximum 400 $Pa \cdot s^2 / L^2$
- The product is closed voluntarily using forceful inhalation flow of -1,2 L / s
- The product is opened voluntarily using forceful exhalation of 6,0 kPa
- The product doesn't leak air during speech

4.2 Breathing

- The product facilitates easy breathing: a breathing resistance in the range of 100 – 400 $Pa \cdot s^2 / L^2$
- The product filters out particles bigger than 10 µm
- The product heats and moisturizes the inhaled air to 32°C and 95 humidity, as normally in the end of the tracheostoma
- The product doesn't increase the production of mucus and allows for easy removal of it
- The product allows the user to cough without having to remove the product

4.3 Safety

- The product can be removed at any time
- The product never hinders breathing
- The product doesn't make it possible for food or fluids to leak into the lungs
- The product doesn't irritate to the skin or damages it
- The product shields the tracheostoma for hygienic reasons

4.4 Use

- The product is made from flexible material and uses the functionalities of this material
- The product can be operated without the use of hands
- The product stays on the tracheostoma when the neck is moved
- The product is usable for at least 80% of all laryngectomees with a TE-prosthesis
- The product has an intuitive design and is understandable with less sight or locomotion
- The product is small (height and diameter both max 30 mm) and has a discreet visual appearance
- The product is comfortable to wear and to use
- The product motivates the user to practice his voice
- The product is easy to clean or it's disposable
- The product is easy to attach and detach from the tracheostoma

4.5 Economy

- The product aims at the world market and is suitable for mass production (500 000 p/y)
- The product is cheap but profitable
- The product is made from easy accessible materials which aren't harmful for the environment
- The product is easy to produce, having simple mould parts and easy to release from its mould

4.6 Desired

- The product had an adjustable closing flow of -0,5 to -2,5 L / s
- The product has an adjustable opening pressure of 2,0 to 8,0 kPa
- The product has an adjustable breathing resistance of 100 to 400 Pa · s^2 / L^2
- The product improves the frequency range of the user's voice
- The product improves the volume range of the user's voice
- The product makes it possible to whisper, whistle and / or hum
- The product improves olfactory and taste
- The product is self-cleaning
- The product is bio-degradable
- The product has a beautiful appearance

5 Idea generation

The goal of this assignment is to make it possible for laryngectomees to talk again. As shown in previous chapters the UFO has been designed to solve this problem. The first part of this chapter elaborates on other possibilities for speech, the second on the design choices for the redesign of the UFO.

5.1 Sketches

Many sketches have been made to explore the possibilities for voice restoration. In **APPENDIX D – SKETCHES**, a selection is given to show the process towards the concepts presented in chapter 6.

5.2 Future concepts

5.2.1 Basic communication

Some laryngectomees use an electrolarynx to speak. This vibration source is considered to be inconvenient as one hand has to operate the electrolarynx. Currently, promising research is being done on a small vibration source which will be placed in the mouth and activated when the mouth is opened. A simpler version of this product could be an internal jaw harp (Figure 5-1), struck by the uvula.

Figure 5-1: Photo of Jaw Harp

When basic communication is the most important function to restore, some options are already available for laryngectomees. In addition to the obvious solutions like writing on a piece of paper, typing on a computer screen or reading lips, one could learn sign language or a click language like some African tribes still do.

In addition to the inability to speak, laryngectomees miss other functions as explained in 2.2.3 Consequences of surgery. An existing product is the larkel (see Figure 5-2) which makes it possible for laryngectomees to swim. Breathing through this larkel also allows the user to inhale through the nose so smelling is enabled.

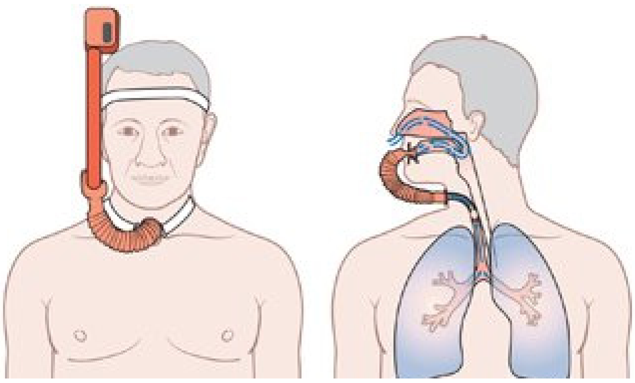


Figure 5-2: drawing showing how a larkel is worn for swimming after a laryngectomy.

These options are far from convenient and can hardly be called a solution, so it's interesting to look at future possibilities of new technology. Nowadays researchers are able to place a chip in one's brain to control the position of a cursor on a screen (Hochberg et al., 2006). It's likely that in the future this technology will be developed further and someone can send words to a computer. This computer can pronounce the words making it possible to speak again.

5.2.2 Biofeedback

A technology which is applicable for voice restoration a lot sooner is biofeedback. During the surgical operation of the laryngectomy it might be possible to attach a connector to remaining muscle tissue of parts of the larynx. Now the activation of the muscle can be recorded and processed by a CPU to activate or adjust some mechanical parts. With this technique, a TSV could be operated just by tightening a muscle. Putting even more tension on the muscle could increase the frequency of the voice. The next step is to create artificial vocal folds which mimic the natural vocal folds or even the complete larynx.

In most cases, the larynx is removed because of throat cancer. The laryngectomy is the final option to take after severe radiation treatment and chemo therapy. The radiation damages the nerves and muscle tissue, possibly hindering future use for e.g. artificial vocal folds. As long as no medicine is found for cancer, this will remain a problem. However, other healthy muscles which have become useless could be trained to do the same action. For example the muscle nasalis pars alaris which widens the nose. As a designer these subjects are very complex to understand and should be assessed by others with more medical knowledge.

5.3 Design choices

The choice was made to focus on hands free solutions for the closure of the tracheostoma, using flexible material and the existing adhesion plaster. With this in mind some choices have to be made in the design of the inhalation TSV.

5.3.1 Two or three parts

It’s desired to make the inhalation TSV consist of as less parts as possible to make the production very easy and therefore the costs very low. At the moment the UFO consists of 4 parts, the droppatch, the capseat, the cap and the HME-filter. For safety reasons the TSV has to be removable at any moment. It’s very inconvenient if the droppatch has to be removed with this action, because it can be painful to remove the sticker. Instead, the droppatch and the other parts of the TSV should be separate parts to overcome this problem or the parts have a hinged connection to the droppatch. This could also function as a cough relief system. The HME-filter has to be replaced at least once a day (Atos Medical, 2009), while the other parts can last for weeks. It would be a waste of material to dispose the complete TSV together with the HME-filter. For that reason the HME-filter is a separate part too. This results in a minimum amount of 2 parts.

5.3.2 HME placement

Some TSV users have commented that the HME-filter can become rather cold on windy or cold days. The HME-filter should be shielded from the cold by keeping it as close to the body as possible. In the UFO, the HME-filter is ring-shaped and wrapped around the capseat. In this way it requires much dexterity to replace the HME-filter properly. As many laryngectomees are old and sometimes have less sight and locomotion, this is unwanted. The HME filter therefore should be placed directly on the droppatch to be as close to the body as possible.

Another disadvantage of a ring shaped HME-filter is that its outside surface is large in comparison to a compact cylinder shaped one. With a larger surface the moist can evaporate easier, resulting in a colder HME-filter. Consequently, the HME-filter should have a compact cylinder shape.

When coughing, phlegm might obstruct the TSV making it impossible to breathe normally. The HME-filter can absorb some of the mucus, but can also be obstructed by it. Many laryngectomees remove their tracheostoma product when they need to cough, but this is unwanted. Some TSV’s have a cough relief system which opens only at high pressures. An inhalation TSV doesn’t need a cough relief valve as doesn’t block exhaled air like normal TSV’s do.

5.3.3 Complexity capseat

For the functioning of the capseat a membrane is everted to cover the breathing holes and act as a valve. In prototypes this process requires a great amount of patience and dexterity which makes it doubtful if the same could be done by a machine for mass-production. Additionally, the very thin membrane is molded around a core which then has to be removed. In prototypes this process often fails, because the membrane tears, making the prototype useless. Although the functioning of the capseat is rather ingenious, the capseat is discarded, leaving only a droppatch, cap and a HME-filter. The functions of the capseat are transferred to either the cap or the droppatch.

5.3.4 Closure of TSV

Bistability is used to close the TSV. As closing the cap is supposed to be easier than opening, the TSV should be molded in closed position. This has some consequences. It's complicated to design the mould for a TSV with an airtight closure on itself. Since the flexible material should press with some force on the hole it has to close, it's impossible to mould it in this position. If the cap closes on a different part, the droppatch, this problem is solved. Unfortunately, the standard droppatch has a small edge on the inside of the cylinder on which a TSV should be clamped. This edge is needed to prevent the TSV from being shot away when high pressures are put on the TSV. With the edge on the inside, the TSV has to be connected on the same side, thus covering the droppatch completely. This makes it impossible to make an airtight closure of the TSV on a standard droppatch without using a capseat as shown in Figure 5-3.

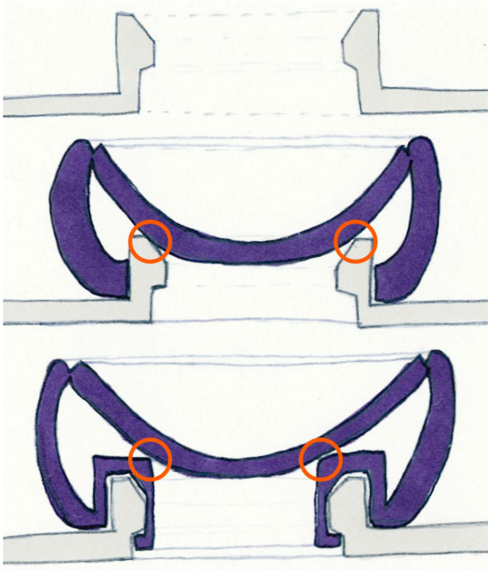


Figure 5-3: Cross-section sketch of TSVs on standard patches. Orange circles show it's impossible to create an airtight closure when the product is molded in closed position.

There are two solutions to solve this problem. The first solution is not to use an airtight closure. The closure of the cap only has to block exhaled air, so if the cap doesn't close completely but is being pressed lightly against a membrane, a valve is created and the problem is solved. The second solution is not to use a standard droppatch. An adjusted droppatch could have exactly the required properties like an edge on the outside of the ring. Adjusted droppatches are already being made for the UFO project, so it shouldn't be a problem to adjust them further. An adjusted droppatch is also convenient for the placement of the HME-filter.

6 Concepts

With the schedule of requirements concepts of an improved inhalation TSV are generated.

6.1 Concept 1

See Figure 6-1. The sphere pushes on the inward membrane of the droppatch. In closed position this creates a valve which only allows inhalation to enable the user to speak. In opened position the membrane doesn't move and normal breathing is possible. With a strong inhalation the sphere buckles into its closed position.

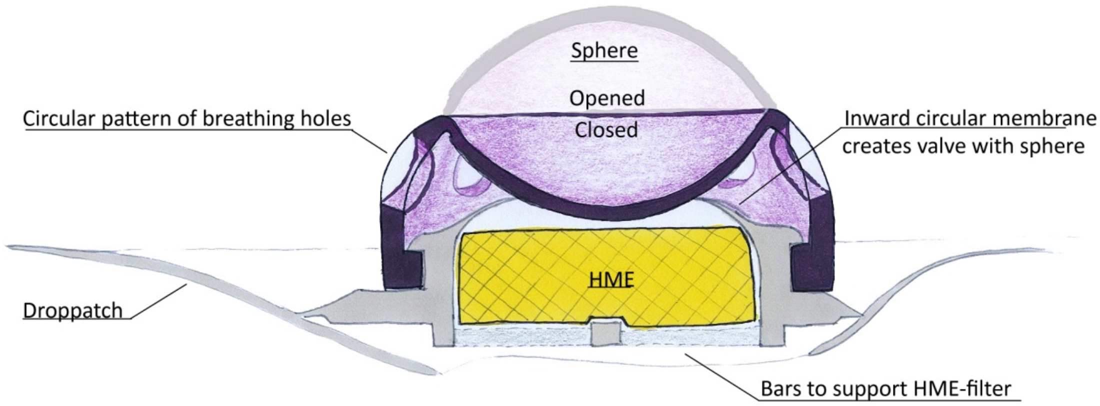


Figure 6-1: cross-section sketch of concept 1 with droppatch (grey), TSV (purple) and HME-filter (yellow)

The benefits of this concept compared to the UFO are the smaller size, easy production and the ability to simple design. A limitation of this concept is the uncertainty of the membrane functioning as a valve.

6.2 Concept 2

See Figure 6-2. In closed position the sphere pushes the membrane against the inside of the cylinder to create a valve with the breathing holes. Because exhalation is blocked, this enables the user speak and it allows inhalation. In opened position the membrane flaps away and normal breathing is possible. With a strong inhalation the sphere buckles into its closed position.

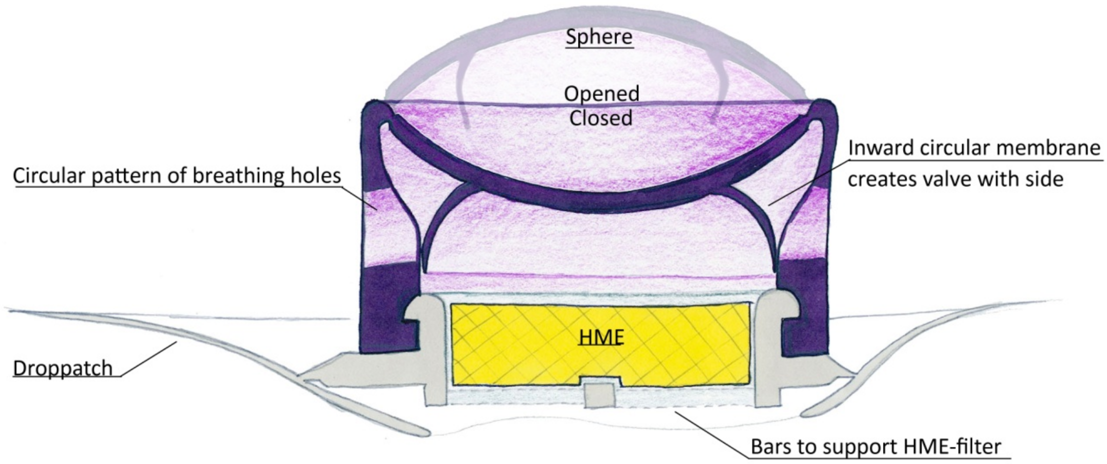


Figure 6-2: cross-section sketch of concept 2 with droppatch (grey), TSV (purple) and HME-filter (yellow)

The benefits of this concept in comparison to the UFO are the simple design, low breathing resistance in opened position and small adjustments to the droppatch. The limitations of this concept are the height of the TSV and the difficulty of production.

6.3 Concept 3

See Figure 6-3. The top of the ring of the droppatch has a small ridge which fits neatly in the groove of the cap's sphere, making an airtight connection. In closed position this blocks exhaled air completely, enabling speech, but in the middle of the sphere a valve is placed to allow inhalation. With a strong exhalation the sphere buckles, opening the TSV to allow the user to breathe through a circular pattern of holes in the sphere.

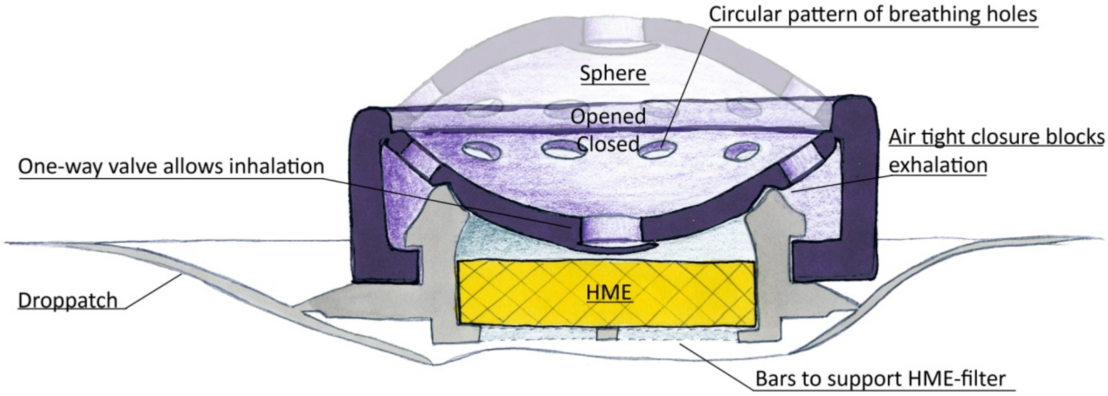


Figure 6-3: cross-section sketch of concept 3 with droppatch (grey), TSV (purple) and HME-filter (yellow)

The benefits of this concept in comparison to the UFO are the relative small size, its adjustability and relative easy production. The limitations of this concept are the opening of the valve and the change of air leakage in closed position. The opening of the valve should be big enough to have a small breathing resistance in closed position, but small enough to allow buckling.

6.4 Concept 4

See Figure 6-4. The TSV uses 4 spheres to cover its breathing holes with a membrane. In closed position these membranes create valves, allowing the user to speak, but also to inhale within sentences. With a strong exhalation the spheres buckle to make the membranes flap away from the breathing holes. This position allows normal breathing.

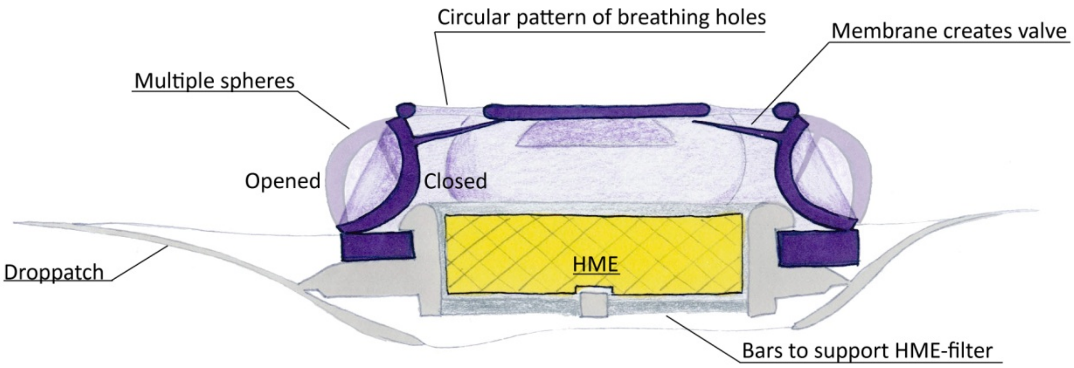


Figure 6-4: cross-section sketch of concept 4 with droppatch (grey), TSV (purple) and HME-filter (yellow)

The benefits of this concept in comparison to the UFO are the smaller size, the small breathing resistance in both opened and closed position and the simple design. The limitations of this concept are that it has 4 spheres instead of 1 which can be hard to control, and that it could be difficult the produce.

6.5 Concept choice

With only little time left for the project of the inhalation TSV a concept should be chosen which is likely to work and doesn't need many iterations in testing. The chosen concept is investigated further and a functional prototype is made.

Concept 1 seems to have the most benefits in comparison to the UFO. It's very likely that this concept will work and since it has the smallest design, it's probably the most esthetical one. To make a functional prototype for this concept will be hard since both cap and droppatch need to be redesigned and made in the workshop.

Concept 2 seems to be the most production-ready. The concept can be placed on the existing capseat to be connected to the droppatch so only one part has to be processed further. This concept has the biggest size and has the least possibilities for further minimization, since the height is at least two times the height of the sphere. Nonetheless, the design for this concept is for more simple than the UFO.

Concept 3 is the least likely to function well. It will be very hard to find the right relation between the opening pressure of the valve and the closing flow of the sphere. A solution has been sought for a valve which would be completely closed in the sphere's opened position and act as a valve in its closed position, but all solution made the design rather complex, moving the problem from the capseat into this valve. After many iterations this concept could work very well, creating one of the most simple TSV yet. Unfortunately there's only one iteration to go.

Concept 4 is the most different from the UFO. This is seldom a negative thing, and this concept has much potential as it opens the way into new designs. Prototyping this concept will be a hard thing to do since all some parts will be very small and complex. Additionally, it's hard to predict how the four spheres will act when one buckles. It's interesting to test this in a prototype.

Initially, concept number 1 and 2 were chosen to process further and detailed SolidWorks drawing were made to make a functional prototype for both of them. However, as chapter 8 shows, only one functional prototype was build: concept 2.

7 Detail design

This chapter handles about the detailed design for the chosen concept, concept 2 (Figure 7-1).

7.1 Design

For the user there's no difference in operating the UFO or the concept: strong inhalation closes it to allow for speech and strong exhalation opens it again. However, the use of the concept differs from the UFO. Placing the new concept is easier because it has less part, the HME-filter can easily be replaced without having to dispose the product and the placement of the HME-filter is better. Additionally, the production of the concept is made easier.

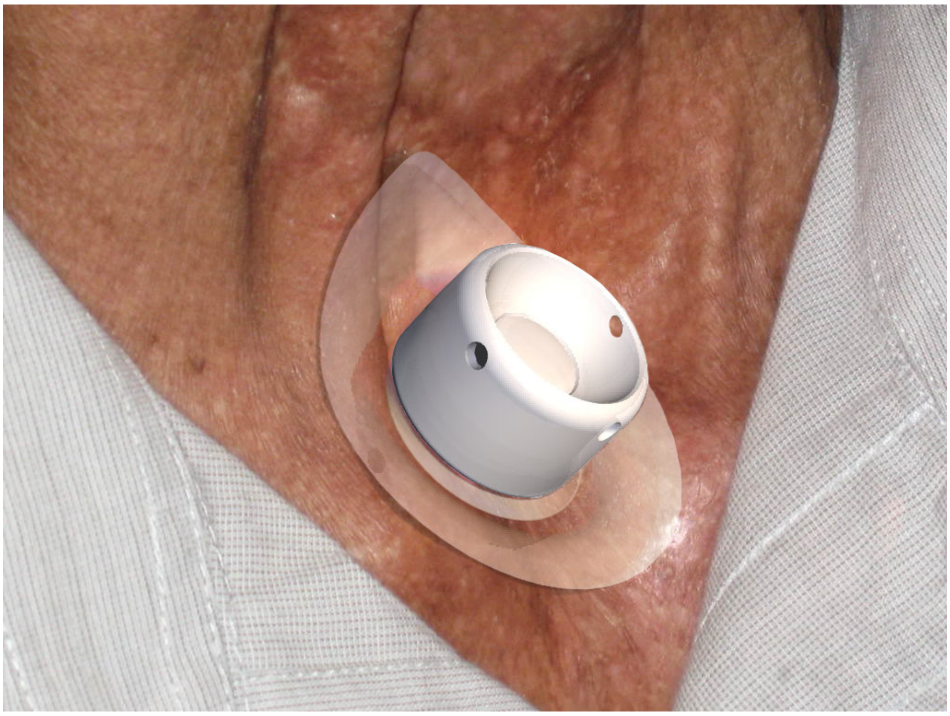


Figure 7-1: a graphic representation of a user wearing the new concept

7.1.1 Diabolo

The concept is named Diabolo for its diabolo-shaped part of its membrane and sphere (Figure 7-2). Despite recommendations of Marianne Hoedemaekers, with 21 mm the Diabolo isn't very flat. However, with its cross-section surface of 6,89 cm^2, it's 4% smaller than the UFO (7,16 cm^2) (Figure 7-3).

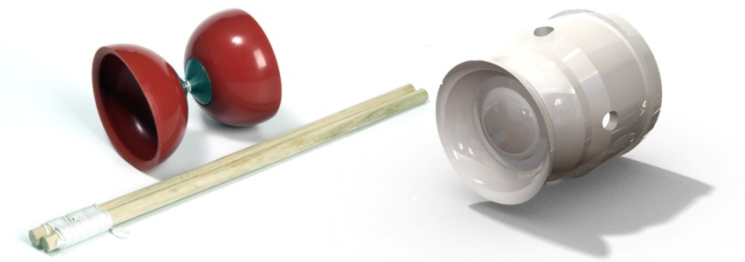


Figure 7-2: a diabolo and the new TSV

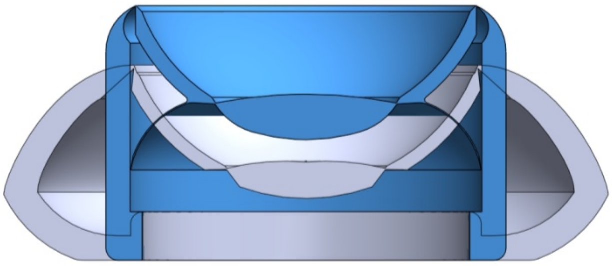


Figure 7-3: comparison of cross-sections of the UFO and the Diabolo (highlighted in blue)

7.1.2 Structure

The Diabolo is placed on an adjusted droppatch which is placed around the tracheostoma. This adjusted droppatch has an outer edge to attach the Diabolo and it has a HME filter. An exploded view of this structure is given in Figure 7-4. In future versions the Diabolo will be connected to the droppatch with a hinge and acts as a cough relief system.

The HME filter is placed in the droppatch and has a plastic casing with a small edge to prevent it from entering the user's trachea. The user can use this edge to easily remove the HME-filter to replace it with a new one. Because the HME-filter is placed directly on the tracheostoma, it absorbs phlegm which then can't enter the TSV. Besides that, it's kept closer to the body and has a smaller outside surface so it stays warm on colder days.

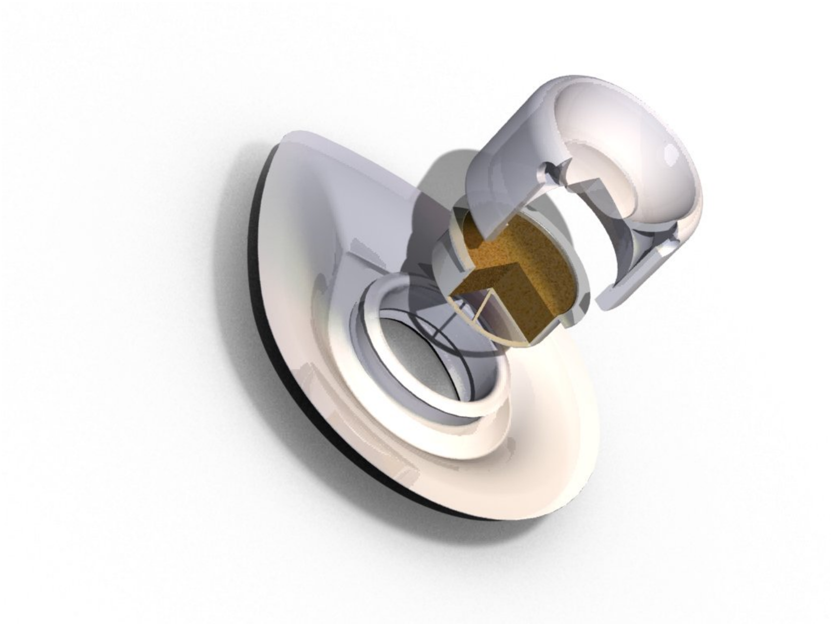


Figure 7-4: SolidWorks representation of the Diabolo on a droppatch with HME-filter.

7.2 Buckling behavior

As much research is already done on the best properties of the UFO, conclusions of previous students are used to get the best result.

7.2.1 Sphere

The opening pressure of the inhalation TSV fully depends on the thickness of the cap's sphere. Charissa Roossien found that a thickness of 1,24 mm has the best results for the opening pressure. Additionally the recommendation was made to use the same shape for the sphere as it took a lot of time to find the right properties. This means the same height, hinges and thickness are used.

The closing flow of the inhalation TSV depends both on the thickness (and shape) of the sphere and on the size of the breathing holes. The amount of required pressure to generate the flow of -1,2 L /s is lower than the opening pressure of 6,0 kPa. To reach this, the sphere is molded in its closed position so in its opened position there is already some pretension to close it easier. This is also done in the UFO. In future versions even better solutions can be sought to minimize the size without taking away the good characteristics of the current design.

7.2.2 Breathing holes

The breathing resistance of the UFO is too high. To find out what causes this high breathing resistance a calculation has been made on the expected resistance of the breathing holes (see **Appendix E – Minimum size of Breathing Hole**). The goal was to calculate the minimum diameter of a tube with a breathing resistance of 400 Pa · s^2 / L^2. With a length of 5 mm, the diameter could be a small as 4,7 mm.

Tests showed that the prototype has the best characteristics with 4 breathing holes of 4,5 mm. According to the calculation in the appendix, the resistance of one of these holes, at a flow of 0,5 L / s, would be about 194 Pa · s^2 / L^2. Multiple holes reduce the resistance even further as it's similar to parallel electrical resistances. Therefore, the resistance of four of these holes should be about 50 Pa · s^2 / L^2. However, Charissa's tests showed that the breathing resistance of the UFO is a lot higher, as shown in the next graph (see Figure 7-5) which is a comparison with the Provox.

It's clear that the resistance of the breathing holes is only a fraction of the total resistance, and the high breathing resistance is mostly due to the capseat's valve and the HME-filter. The influence of the valve is also visible in the graph as the breathing resistance decreases with an increase of the flow. This is because the membrane of the capseat's valve is pushed away further with a bigger flow, resulting in a wider opening of the valve and less resistance.

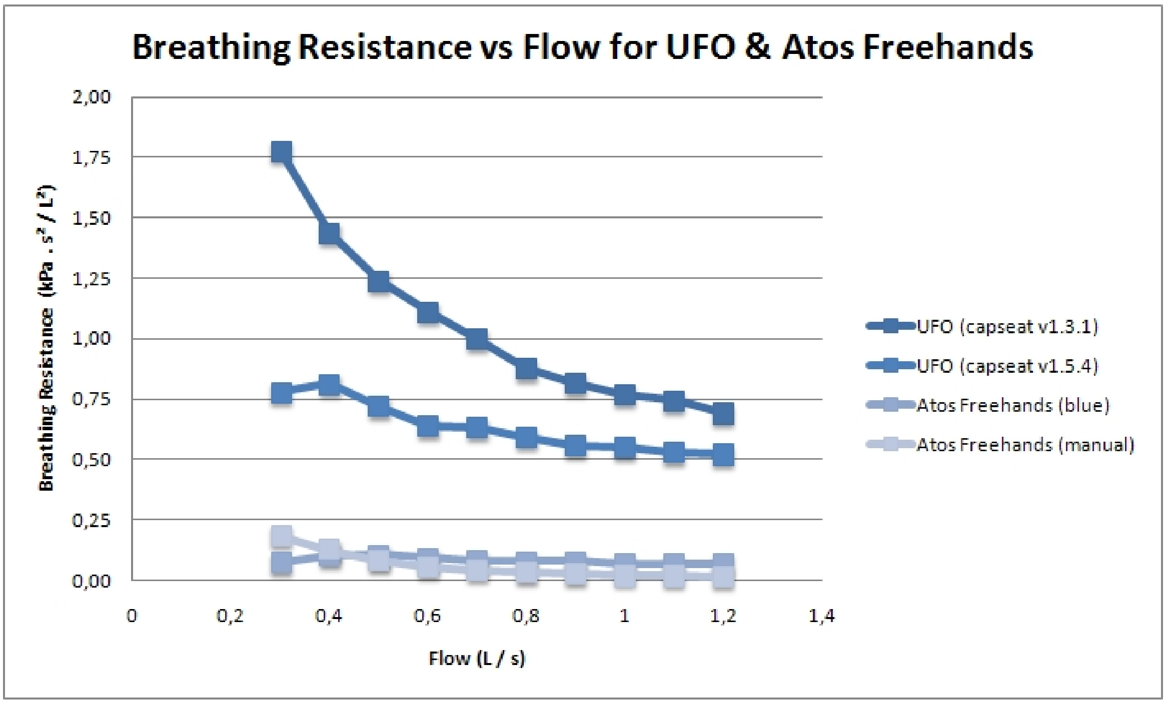


Figure 7-5: comparison of breathing resistance of UFO and Provox

7.3 User

The user will probably not always use Diabolo, but mostly for situations in which he needs both hands, during conversations or for example when giving a presentation. Therefore it's convenient that the Diabolo can be removed while droppatch and HME-filter remain. The user might carry the Diabolo in his pocket until he needs it.

Every user has different lungs with different abilities. For the Diabolo this means multiple versions will be produced with different opening pressures and closing flows. Alternatively, the Diabolo can be delivered with rubber bands of different strengths which can be put around the Diabolo to increase both opening pressure and closing flow. A perforator could be used to add more breathing holes to decrease the breathing resistance and increase the closing flow.

8 Prototyping

The chosen concept is described in detail in previous chapter. The next step is to prepare and adjust the concept for prototyping. In this chapter the adjustments are described, but first a better view on the goal of the prototypes is stated.

8.1 Goal

The goal of all prototypes in this project is to test if it functions well. This means a laryngectomee would be able to use the product. Before testing the prototypes on people, first an artificial lung is used to test the prototype's properties. Relevant properties are in this case the closing flow, opening pressure and the breathing resistance. These three values should fit in the requirements set in Physical requirements (p.20). Additionally, there shouldn't be any danger in using the prototype like inhaling small parts, chance of suffocation or damage to the skin.

8.2 Adjustments to the concepts

Prototypes are made to test the functioning of the concept. Tests are done in vitro, using an artificial lung, the B.A.R.T. (pictures can be found in **APPENDIX I – IN VITRO TESTING**). Because patients aren't involved in testing, there's no need to make the adjusted patches which is a very time consuming process. Instead, a connector is used to attach the prototypes to the standard patch which is glued to the end of the artificial lung. If the prototypes can be connected to this, no adjustments are needed to test them on real patients.

As stated before, the disadvantage of the standard patch is its inner edge while the Diabolo needs an outer edge for connection. The Provox HME filter can't be used for this. The small outer edge of the HME filter can be used to connect the prototype. However, this edge is too small to create a strong connection with the flexible material used for the prototypes. Therefore a broken capseat is used with the inside cut out.

8.2.1 Moulds

The prototypes are molded with a special silicon rubber (Principality LSR Bellows Z001), and the moulds have been designed. The moulds are made from PMMA using a CNC milling machine. Because programming the CNC machinery can be very time consuming, the design is adjusted to minimize the use of CNC. The PMMA is available in different sizes, round 30, 40 and 80 mm, so the moulds are adjusted to this. Additionally the moulds are adjusted to fit the protocol for molding the material (see **APPENDIX G – MOLDING PROTOCOL**).

For the mould of the Diabolo it's not possible to use a core to create the membrane because it isn't possible to position this core, nor is it possible to remove it without damaging the prototype (see Figure 8-1). Hence, a different approach is needed to create the prototype. The base of the prototype (the cylinder) is molded inside out, turning it back afterwards.

The behavior of the material being flipped inside out has been studied for the case of a small tube (Figure 8-2). This tube has a small edge (1 mm) on the outside. When the tube is flipped inside-out, this part of the tube tends to widen to a trumpet-shape, because now the edge is on the inside. Measurements have been made to calculate the needed curve to compensate for this trumpet shape to create a straight edge when flipped inside-out.

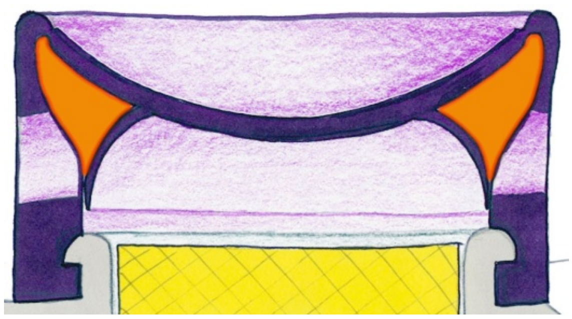


Figure 8-1: (orange) impossible core

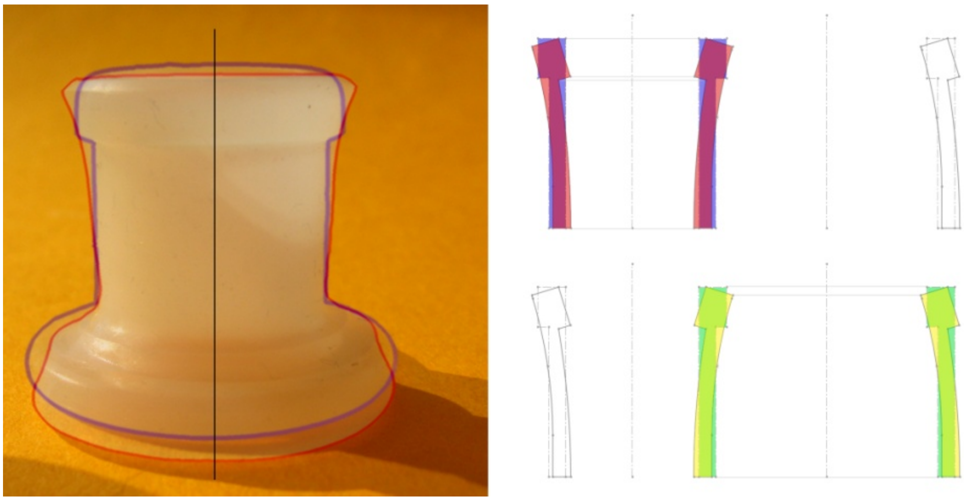


Figure 8-2: tube normal (blue line) and flipped inside-out (red line) to study the differences. The aim is to create the green cross-section, so to realize this it should be molded like the yellow cross-section.

8.3 Building the moulds

Initially the plan was to build the moulds for 2 prototypes and an adjusted capseat in the workshop of the University of Twente (UT) with some help of the people from the workshop. A detailed plan was prepared to build the 3 parts and can be found in **APPENDIX F – WORKSHOP PLAN** (in Dutch). However, they were very clear in explaining it wouldn't be possible to build the moulds there because of the required small cutters. CNC expert Theo Pünt said he wouldn't be able to build just one of the moulds within a month and gave the advice to search for an external company to make it. Another workshop from the UT, *TCO*, does have small cutters, but didn't have the time to make it.

8.3.1 GME

As a possible solution, companies for Rapid Prototyping were contacted. However, *Materialise* in Leuven, Belgium explained that the accuracy for 3D printing is ±0,2 mm whereas ±0,05 mm is needed to be able to create a membrane of about 0,1 mm. With Rapid Prototyping being discarded, external CNC milling companies were contacted (*Ten Heggeler*, *Amitek*, *CNC-speedform*, *AFMI, VSO*, *B&S machine fabriek Hengelo*, *Hemabo* and *GME*). Of all these companies only Hemabo and GME said to be able to produce the moulds within 3 weeks. GME was chosen for this assignment because of its location which enables personal contact. It adjusted two edges to reduce the difficulty and the chances of mistakes (Figure 8-3). With this adjustment, the trumpet-shape isn't fully compensated any more, yet no problems occur to place it on the capseat.

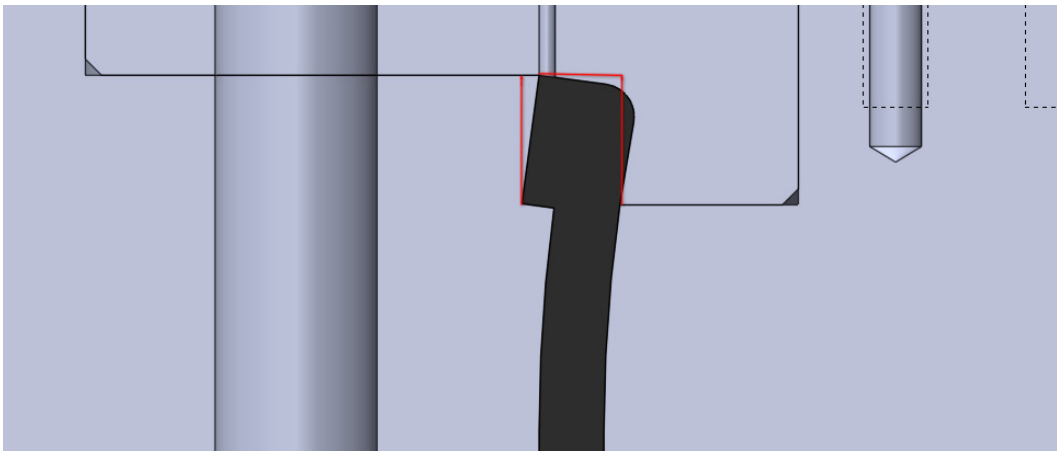


Figure 8-3: GME adjusted some parts which were difficult to produce. The red lines represent the way GME made the moulds

8.4 Molding

With the moulds from GME, several copies of the prototype were made using the protocol for the silicon rubber (**APPENDIX G – MOLDING PROTOCOL**). In this appendix pictures can be found of the molding process.

8.4.1 Paper

Removing the prototype from its mould caused some problem because the thin membrane tore, leaving some useless prototypes (Figure 8-4). After some investigation, it became clear that the sphere of mould part 1 was made a little bit too high. This made the membrane thinner than it should be, making it easier to tear. Additionally, it made the membrane more flexible while some rigidity is needed. To solve this problem some pieces of paper were placed between the mould parts to create more space (0,25 mm) and thus a thicker membrane (Figure 8-5).

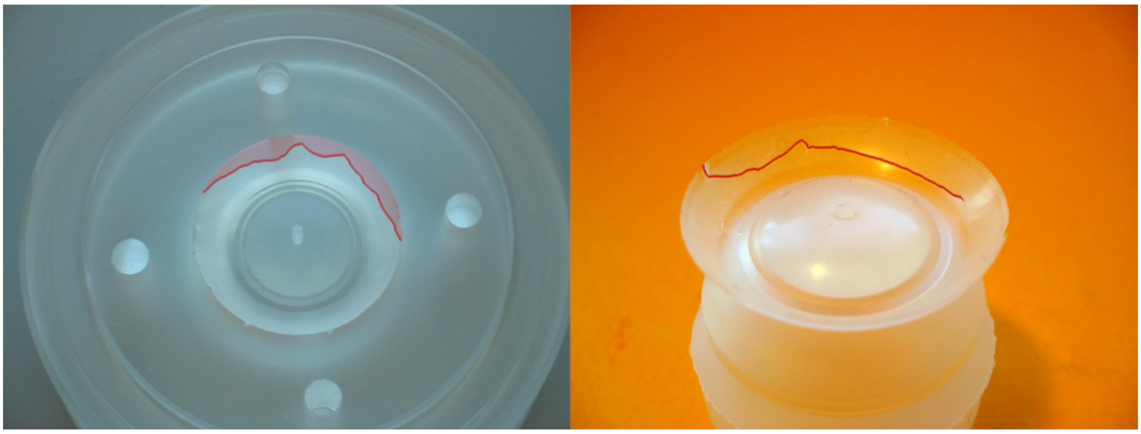


Figure 8-4: when the prototypes were removed from their mould, some were torn

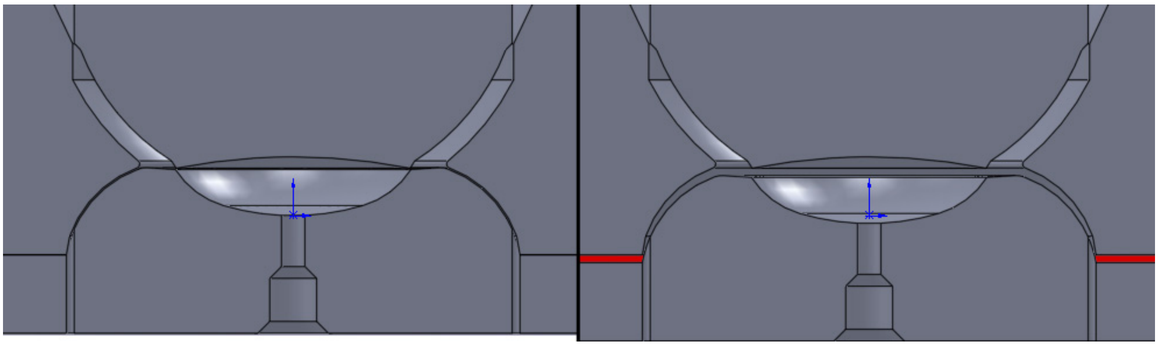


Figure 8-5: (left) the normal situation, (right) the red lines represent pieces of paper which were added between parts 1 and 2 to create more space for a thicker membrane

8.4.2 Tube added

Another problem with molding is air bubbles. A probable cause is the short and thin filling hole. When the mould is placed in the pressure cylinder, the content of the filling hole is pressed into the mould. If the filling hole was bigger, this would be silicon and air bubbles would enter the mould. To solve this problem, a small flexible tube was placed over the filling hole while molding (see Figure 8-6). When the mould was totally filled, more silicon was added while the injection nozzle was retracted to fill the tube too. After adding this feature, no prototype had a problem with air bubbles.

In **APPENDIX H – PROTOTYPE LIST** a list of all prototypes is given with photos, problems and comments on the adjustments.

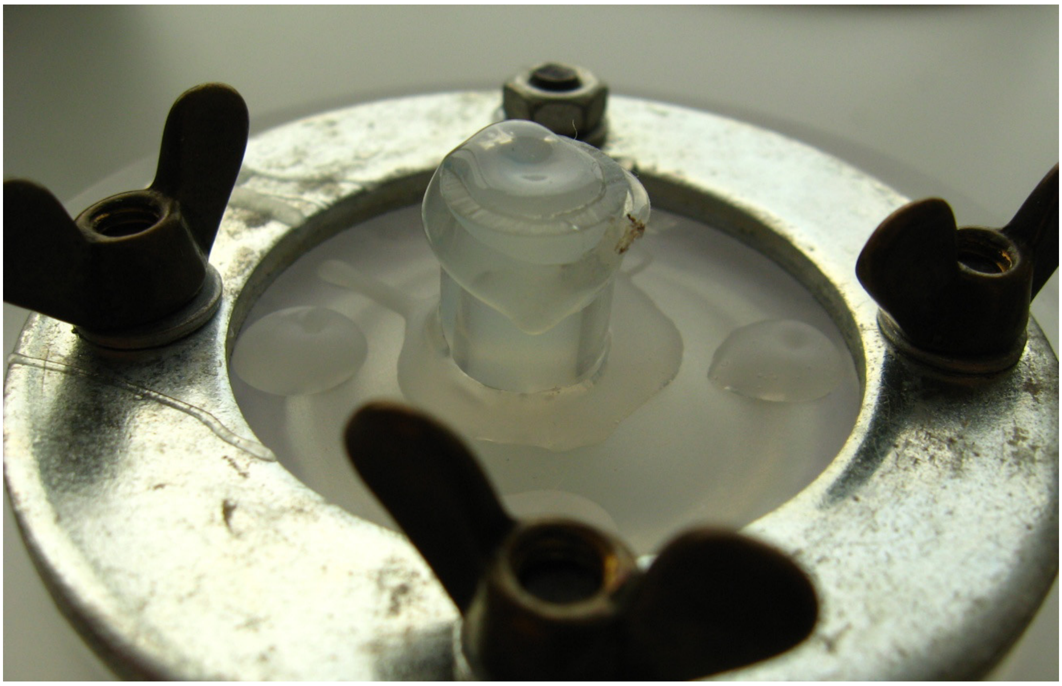


Figure 8-6: a small flexible tube was added to successfully solve the problems with air bubbles

8.5 Functional prototypes

With the small adjustments, usable prototypes were created and with the manual artificial lung (see Figure 8-7), the behavior of the prototype was tested on inhalation and exhalation. To connect the prototype a capseat was used with the inside cut out, which fitted perfectly. In opened position both inhalation and exhalation were fine and didn't cause any problems. With a strong inhalation the prototype was closed properly. In the closed position inhalation was still possible and didn't cause any problem. With strong inhalation some weird sounds were made because the membrane started vibrating. Exhalation was hindered but only to a certain level: when the pressure was increased a little bit, the membrane folded backwards to allow air to pass through the 4 breathing holes. With a strong inhalation the membrane folds back into the right position. To open the prototype a sudden strong exhalation was needed.

Although the Diabolo almost functions well, in the closed position the membrane often folds back, being useless. This results in much air leakage on exhalation and sometimes a total blockage of inhalation. As this can be dangerous, the prototype won't be tested in vivo but only in vitro.

Figure 8-7: manual artificial lung. Prototypes can be connected on the right side. Moving the black handle on the left mimics breathing.

If the membrane doesn't fold back, the Diabolo functions well so some adjustments have been made to the prototypes in an attempt to keep the membrane in position. In fact there are two separated problems to be solved:

1) In closed position, the membrane folds back on exhalation, resulting in leaking breathing holes.
2) While closing the prototype, the membrane gets caught by the inside of the cylinder resulting in a back folded membrane in closed position. However, this doesn't occur when the prototype is closed with a very strong inhalation.

8.5.1 Ribs

Ribs were added to some prototypes with some liquid silicon to keep the membrane in place (Figure 8-8). The ribs add rigidity to the membrane to hinder it from folding back. This was tested with 3 prototypes. This worked rather well to solve problem 1, but, after some artificial breaths, the membrane did fold back in the places between the ribs. More rigidity is needed to fully keep the membrane in place. However, flexibility is needed to enable easy inhalation during speech.

Figure 8-8: ribs were added to some prototypes

The ribs don't solve problem 2. The membrane still gets caught, and mostly on the places where a rib was added. From one prototype with added ribs, a small ring was cut from the membrane to make it a little less wide. When enough membrane was removed to effectively reduce the chance of the membrane getting caught, the membrane wasn't able to block the breathing holes any more.

8.5.2 Knobs

Another attempt was made with the addition of knobs (Figure 8-9). These small bumps were placed on the sphere, below the membrane. These knobs would have the same function as the ribs, but they push whereas the ribs pull. Problem 1 wasn't solved by this because the knobs were too far away to push the membrane. Problem 2 wasn't solved because, while buckling, the membrane was caught between knob and the inside of the prototype. So, instead of pushing the membrane over the breathing holes, it was pulled away from it.

Figure 8-9: knobs were added

8.5.3 Breathing holes on sphere

In one prototype the breathing holes were placed on the sphere instead of on the side of the cylinder in an attempt to used the back folded membrane. This was wrong because in closed position both inhalation and exhalation were possible, and only if the membrane folds back, exhalation is blocked. In opened position inhalation is possible but exhalation is completely blocked.

With breathing holes on the sphere a very simple inhalation TSV can be designed which looks similar to concept 1 (p.26). A circular membrane is attached to the inside of the cylinder to create a large breathing hole in the middle. The membrane doesn't need to be very thin and therefore is less likely to fold back. It might be difficult to produce the moulds for this design (Figure 8-10).

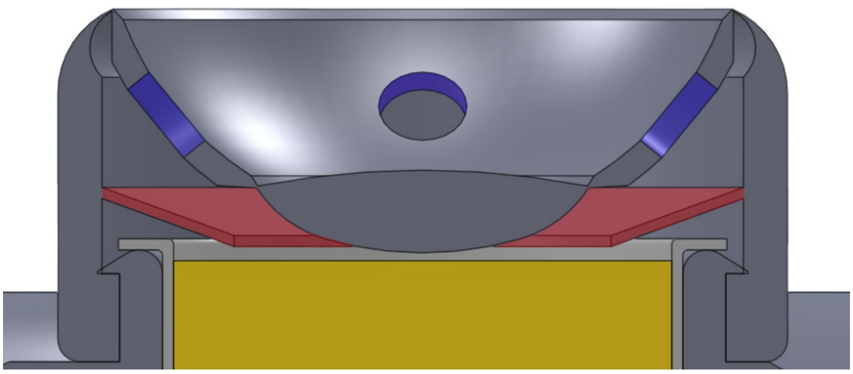


Figure 8-10: an adjusted version of the Diabolo with in red the new membrane.

8.5.4 Ropes

Figure 8-11: ropes were added

Thin elastic tubes were attached to the membrane and the base of the cylinder (Figure 8-11). These 'ropes' cross each other to pull the membrane away from the side. In opened position, the ropes are stretched a little so they pull back the membrane, but also the whole sphere. In closed position, the ropes are released because the membrane is closer. This solution keeps the membrane from folding back, but it also hinders the functioning of it. The membrane doesn't close well enough to block exhalation. It will be very hard to find the right elasticity and to put exactly the right tension on the ropes.

8.6 Conclusion

The first prototypes for the concept work rather well but have some complications with the membrane. Some options have been tried in an attempt to solve the problems but weren't sufficient. To solve the problems, the membrane should be adjusted. In addition to the redesign proposed in 8.5.3, here another redesign is given to solve the found problems.

While buckling, the membrane gets caught in the side of the cylinder (Figure 8-12). To solve this, the membrane should be made a little smaller. However, this is no solution since the membrane is needed to close the breathing holes. Instead, the membrane should unfold itself like an umbrella when the sphere is being closed (Figure 8-13).

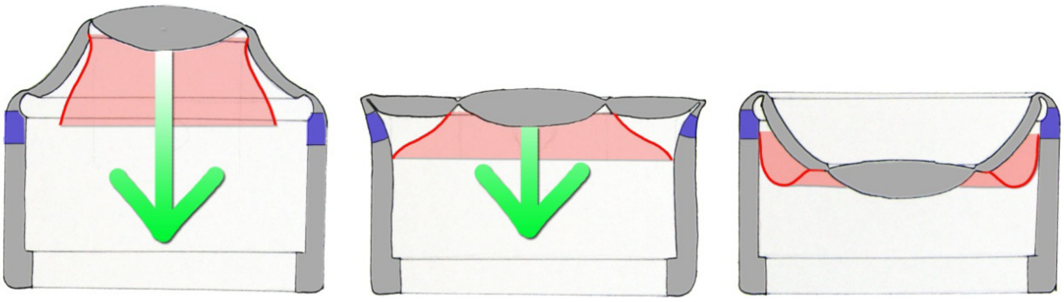


Figure 8-12: with the current membrane, the membrane is attached to the sphere in a tangential way. While closing, the membrane soon touches the inside of the cylinder, making the membrane fold back.

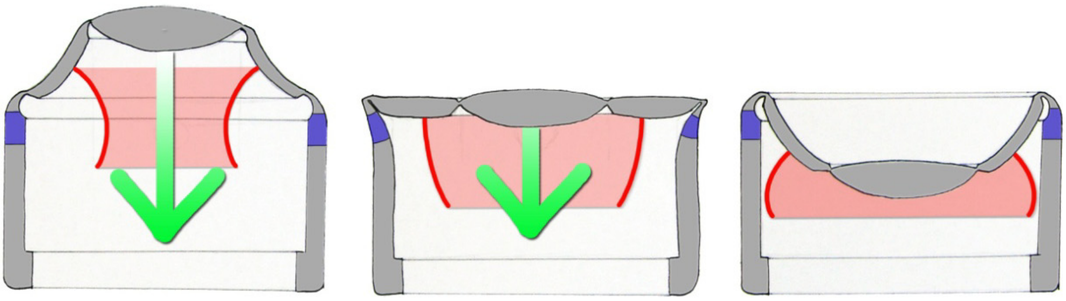


Figure 8-13: with a membrane attached normal to the sphere, the membrane unfolds like an umbrella when it's closing. The membrane stays away from the cylinder during buckling.

The membrane should be attached more away from the middle and normal to the sphere's surface instead of tangent. With these adjustments, the membrane will fold inward in opened position due to its normal position to the sphere. When it buckles, it flaps open like an umbrella to cover the breathing holes. Because of this movement, the membrane won't get caught by the inner edge of the cylinder and thus won't fold. By increasing the membrane's thickness, it will be harder to fold the membrane back so exhalation will be blocked in closed position.

9 Testing

The best prototypes were selected to be tested on the artificial lung. **APPENDIX I – IN VITRO TESTING** *shows detailed descriptions of these experiments but here the results of all experiments are discussed too. Initially, also a use test was planned with at least three laryngectomees (see* **APPENDIX J – IN VIVO TESTING***), but since the use of the prototype can be dangerous when inhalation is blocked, this test was skipped.*

9.1 Closing flow

The closing flow of the prototype was measured to be -2,31 ± 0,10 L / s which is more than the aimed -1,2 L / s. To lower the closing flow, the prototype should have fewer breathing holes (with which the breathing resistance increases) or the shape of the sphere should be adjusted (with which also the opening pressure is affected). Alternatively, the membrane should help in closing the product. At strong inhalation, the membrane should be sucked inward to act as a parachute and pull the sphere with it. In the current prototypes, the membrane is tightly pushed against the inside of the sphere in opened position so air won't come in between. With some minor adjustments, the membrane is folded inwards in opened position and can act as a parachute.

9.2 Opening pressure

The opening pressure of the prototype was measured to be 4,15 ± 0,16 kPa which is a little lower than the expected 4,5 kPa. As said in 3.7 Physical requirements, the opening pressure should be 6,0 kPa. The shape of the sphere should be adjusted to reach this value. This can be done by making the sphere thicker, higher or by making it less wide. The membrane adds some resistance because it pushes against the inside of the cylinder.

9.3 Breathing resistance

The breathing resistance of the prototype is presented in the graph of Figure 9-1; a more detailed version of the graph is presented in the appendix. It's interesting to see how much the membrane influences the breathing resistance. The orange line represents the breathing resistance of a prototype without its membrane, which is very constant and a lot lower than the breathing resistance of prototypes with a membrane. The aim of 500 Pa · s^2 / L^2 was only reached for very high flows. To decrease the breathing resistance, the size or number of breathing holes could be increased. This clearly conflicts with the adjustments for the closing flow, so a better solution is to decrease the resistance of the membrane. This could be done by decreasing the membrane's outer diameter to reduce its pressure on the inside of the cylinder.

9.3.1 Comparison with theory

In this measurement the resistance of the four breathing holes was measured. Previously this has been calculated to be about 50 Pa · s^2 / L^2 for four holes at a flow of 0,5 L / s. The measurements show the incorrectness of this calculated value, as in practice the breathing resistance is 4 times higher with 204 Pa · s^2 / L^2.

At closer investigating, the diameter of the breathing holes seems to be a little smaller (3,5 mm), probably caused by folding the prototype inside out. With a thickness of 2,3 mm the resistance is calculated to be

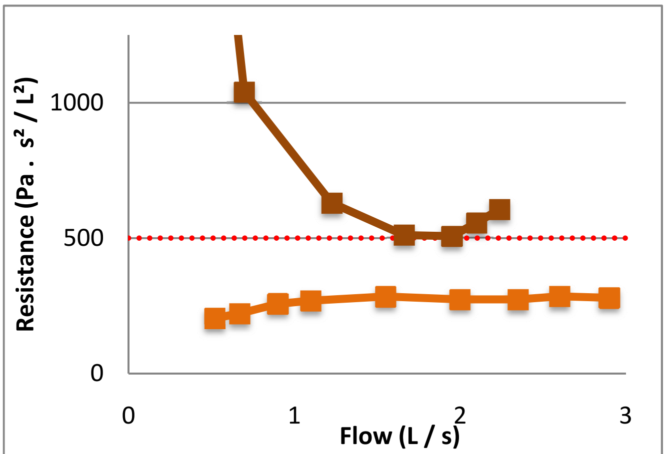


Figure 9-1: breathing resistance vs flow for4 prototypes with a membrane (brown) and 1 without (orange)

795 Pa · s^2 / L^2, or 200 Pa · s^2 / L^2 for four holes. This means the only unknown parameter of the formula (the inner roughness ε) was is chosen very well. The only conclusion that can be taken from this calculation is that the diameter of the breathing holes has an enormous influence on the breathing resistance.

9.4 Conclusion

The size and number of breathing holes influence both closing flow and breathing resistance. As a compromise, it should remain the same but the membrane should be changed instead. With the adjustments proposed in Figure 8-13, both closing flow and breathing resistance could be lowered. The closing flow is lowered because the membrane has more chance to 'catch the wind' and act as a parachute and the breathing resistance is lowered because the membrane would have less contact with the inside of the cylinder.

It's likely that the new 'Umbrella'-membrane will add some rigidity to the sphere. This increases both the opening pressure and the closing flow. Tests have to show what the net effect will be for the closing flow.

10 Conclusions

This chapter describes the conclusions of the redesign of the UFO.

10.1 Conclusion

According to test persons, the UFO was too big, the breathing resistance was too high and the UFO opened to easy when speaking loudly. Additionally, the UFO had too many parts and was too complex. Concepts have been designed to improve all these aspects of the UFO.

The new inhalation TSV, the Diabolo, was chosen to be developed. Prototypes for this concept showed a problem with the membrane which tends to fold back. With minor adjustments to the moulds this problem could be solved to result in a working product. Tests on the artificial lung showed that small adjustments need to be done on the membrane to make the use of the Diabolo more comfortable. So, with an improved membrane the flaws of the first prototype for the Diabolo are very likely to be solved.

10.1.1 Schedule of Requirements

When verifying the Diabolo with the Schedule of Requirements (p.21), every subject has exactly one interesting entry.

- Speech: *the product DOES make unwanted additional sounds*
  The membrane starts vibrating against the inside of the cylinder at high flow velocities. To remove these sounds, the membrane's resonant frequencies should be adjusted, possibly by adding some ribs. Additionally, a flow through the breathing holes sometimes gives a high whistling sound. This could be reduced by smoothing the sides of the breathing holes.
- Breathing: *the product DOESN'T allow the user to cough without removing it*
  Although the Diabolo would open when the user coughs, there is still a chance that the product might be shot away. A cough relief valve could be added to the product by connecting the Diabolo to the droppatch with a hinge and hook. This hook is released at a certain high pressure, making the product flap open.
- Safety: *the product COULD hinder breathing*
  As shown in previous chapters, the membrane sometimes folds back. In some special occasions, this blocked inhaled air completely. This was the reason why the in vivo tests were skipped.
- Use: *the product is NOT usable for 80% of all laryngectomees with a TE-prosthesis*
  With a closing flow of -2,31 L / s, only the users without any lung problems are able to use the product. As many laryngectomees have weak lungs due to Asthma or COPD, only a fraction of all laryngectomees would be able to use the product (assuming the problem with the membrane was solved).
- Economy: *the product is made from materials which ARE harmful for the environment*
  Personally an important one, although the medical world might asses this requirement only when all others are already met. There is no need to dispose the combination of inhalation TSV and HME-filter when the HME-filter can easily be replaced and the TSV can be cleaned without problems. Currently prototypes are made from special silicon, but for mass production a biodegradable material could be used.
- Desired: *the product DOES make it possible to whisper, whistle and hum*
  Although untested, all three actions are possible with an inhalation TSV and therefore are expected to be possible with the Diabolo.

10.2 Discussion

The presented concepts are rather similar to the current design of the UFO since they all use the functionality of a buckling sphere. This might appear uncreative, but after many other options were explored with pieces of rubber and in sketches, a buckling sphere obviously was the best element to use for an inhalation TSV.

Prototypes are made to make problems visible. Regularly, these problems occur on unexpected things which were thought to be obvious, resulting in useless prototypes. Therefore, it's incredible how many aspects of the Diabolo are good and didn't cause problems. The mould parts fit perfectly; molding it only caused minor problems which were easily solved; the product was released from its mould without problems; the product was flipped inside out the way it was planned; the product connects very well on the capseat; there were no problems with the buckling of the sphere and no problems occurred while testing the prototypes on the artificial lung. The real problems were caused by the membrane which wasn't unexpected. For a first prototype of a concept it's clear this has been a success.

Some adjustments have been made to the prototypes but didn't totally solve the problems with the membrane. Maybe more options should have been assessed. The weakest link in the process of improving the inhalation TSV is the amount of time to produce new mould parts. If this wouldn't be a problem many more adjustments would have been applied and a working prototype would have been made.

It's obvious that still many improvements can be made to make the use of the inhalation TSV more comfortable for the user. Although much user feedback was available, not everything was used in the design of the concepts. The biggest miss is the problem with phlegm. Many sources tell about the problems laryngectomees have with coughing, but nonetheless this problem hasn't been assessed. The only improvement towards this problem is the relocation of the HME-filter. Future research should focus on solving this problem as well as solving the problems with tracheostoma fixation.

Still much can be learned from the currently available Provox. This device has a cough relief system, has only very little breathing resistance, is smaller than the Diabolo, and both the closing pressure and the pressure to open the cough-valve can be adjusted. Still for some laryngectomees, the Diabolo would be more comfortable to use. Speaking is more natural, no air is lost to start speaking, pauses can be held between sentences and whispering is possible. Additionally, the Diabolo can be a lot cheaper than the Provox (a starter kit costs almost € 400,- (MedicalMega, 2010)).

In comparison to the UFO, the Diabolo is a lot less complex, has fewer parts and is easier to produce. Still a thin membrane was put in the design of the Diabolo despite the clear disadvantages of producing it. The relocated HME-filter has some clear advantages of the HME-filter in the UFO. Although just one version of the Diabolo has been made, it's already clear that it could be a better TSV than the UFO. Despite the improved aspects, one thing remains unchanged, which makes it a good thing that both TSVs are still in progress and not on the world market: the name…

10.3 Recommendations

10.3.1 Adjustments to Diabolo

The Diabolo needs some adjustments to become a working product. It's probable to function with the adjustments made in Figure 8-13 (p.38). In **Appendix K – Umbrella**, drawings for the mould of this design are added. Only part 1 and 2 have to be made because the other parts of the Diabolo can be used for the same mould. Additionally, an adjusted droppatch should be made with an outer edge on which the Diabolo can be attached.

Previously the idea was presented to use rubber bands of different strengths to make the opening pressure and closing flow of the Diabolo adjustable. This could be a very interesting feature and should be tested. A groove should be added to the outside of the cylinder of the Diabolo (this means 2 grooves in mould part 5) to keep the rubber band in place (Figure 10-1). If this doesn't generate a fairly constant increase of the opening pressure and closing flow, this option shouldn't be taken too serious.

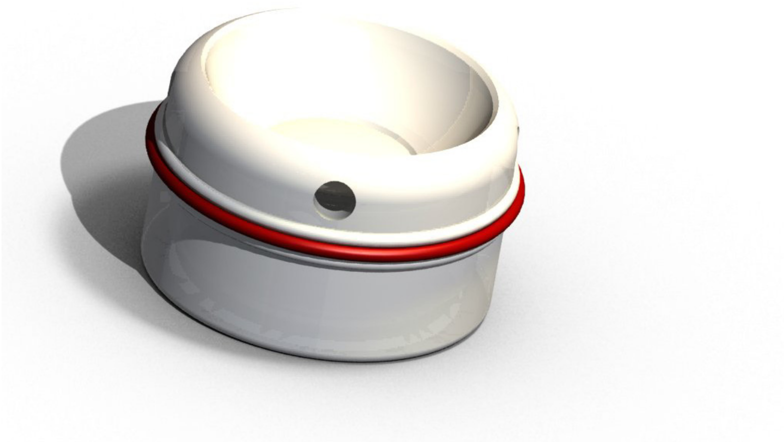


Figure 10-1: add a rubber band to increase opening pressure and closing flow. This effect should be tested.

10.3.2 Further research

When the required changes have been made to the Diabolo to make it work, some other aspects should be explored.

Coughing. Mucus production is one of the most important problems to solve. Laryngectomees cough a lot, so if a user has to remove the product every time he has to cough, most comfort is lost. A cough valve as the Provox has could be sufficient, but preferably a new system is designed in which the TSV not only opens but also captures mucus without getting blocked.

Appearance. Marianne Hoedemaekers has much experience making jewelry for laryngectomees and her advice should be used to improve the visual appearance of the Diabolo. It could be interesting to add a feature to make it easy to attach jewelry or other products to the Diabolo. To facilitate this, the Diabolo should be made flatter to allow the user to wear the products close to the body.

Sphere. Currently a well functioning sphere is created. It has cost many students much time to come to this setting. However, in the future the sphere should be improved even further to decrease its size without losing its functionality.

Concept 1. The main reason not to choose concept 1 was the difficulty of producing the moulds for prototypes. However, a complete workshop plan has been made with detailed drawings. The concept is likely to function and could be even better than the Diabolo. It would be a small effort to let GME build the moulds for concept 1 too.

10.3.3 Project

The design of a new inhalation TSV has been very technical and theoretic; it appears to be very distant from the users. For obvious reasons it's very important to involve users in the design process, but it's hard to do so because the focus mostly lays on values for the different parameters of the users. Now it seems like the goal is to design one TSV to be perfect for every laryngectomee, while it's probably better to design several TSVs for different users. It would be wise to make a visit to a laryngectomee obligatory for future students.

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Diabolo

Appendices

Redesign of a tracheostoma valve using user feedback

Contents

A Interview with patient

Vragen aan KNO arts

Wat doet een KNO arts?

Wat doet u met uw patiënten?
Waarover heeft u het met uw patiënten?
Wat voor klachten hebben uw patiënten?

Hoe is het om een tracheostoma te hebben?

Wat wordt gemist door het tracheostoma?
Hoe vinden uw patiënten dat?
Wordt de tracheostoma bedekt? (schaamte?)

Hoe is het om met een tracheostoma te spreken?

Leert u uw patiënten te spreken met het tracheostoma?
Lukt het iedereen om met handmatige afsluiting te spreken?
Welke producten biedt u aan?
Hoe bevallen deze producten?
Waarom lukt het niet iedereen om handsfree te spreken?

Antwoorden van Rebecca Baldal & co.

De meeste patiënten komen voor een lekkende button (TE-prothese). Dat merken ze als ze bijvoorbeeld koffie drinken, dit lekt dan door de button heen, in de longen. De buttons zijn gemaakt om ongeveer 6 maanden te blijven zitten, maar er is een grote groep die steeds al na ongeveer 6 weken terug komt omdat het begint te lekken.

Eigenlijk bedekt iedereen zijn stoma, meestal met een klein sjaaltje. Dit is niet alleen uit esthetisch oogpunt, maar ook omdat veel mensen last hebben van hoesten wat dan kan worden opgevangen door dit doekje.

Tiny Sanger is logopedist en is in het UMCG de enige die patiënten weer leert ruiken. Eigenlijk lukt het iedereen om weer te spreken met een TE-prothese en bijna iedereen doet dit met de hand.

Vragen aan patiënt

1) Hoe is het om een tracheostoma te hebben?

Waarom heeft u een tracheostoma?
Wat mist u door uw tracheostoma?
Hoe is het om die dingen te missen?
Bedekt u uw tracheostoma? Hoe? Waarom?

2) Hoe is het om met een tracheostoma te spreken?

Is het moeilijk om te spreken met een tracheostoma? Waarom?
Duurde het lang om weer te leren praten?
Wat vindt u van uw eigen stem?

3) Hoe bevallen bestaande producten?

Heeft u producten geprobeerd om mee te spreken? (bijv. Provox)
Hoe bevallen deze producten?
Wat vindt u vervelend aan bestaande producten?

4) Kunt u spreken zonder handen?

Wilt u kunnen spreken zonder uw handen te moeten gebruiken?
Weet u van het bestaan van handsfree spraakkleppen? (bijv. Provox)
Waarom / wanneer gebruikt u die wel / niet?
Hoe bevalt het om met een handsfree spraakklep te spreken?
Wat vindt u vervelend aan de gebruikte handsfree spraakkleppen?

5) Wat verwacht u van een nieuwe spraakklep?

Welke problemen heeft u met bestaande producten?
Wat hoopt u verbeterd te zien in een nieuwe spraakklep? Waarom?
Hoe ziet een ideale stemprothese er volgens u uit?

6) Overige vragen (gewoon interessant maar misschien minder relevant)

Hoe gaat gapen?
Kunt u ruiken? Hoe? Is dit moeilijk te leren?
Wat voor producten gebruikt u nog meer?

Antwoorden van patiënt (mr van der Heide)

Mr van der Heide had een afspraak met de KNO arts voor het wisselen van de button (TE-prothese). In het begin had hij kort de Groningen button gehad maar dit gaf te veel weerstand. Nu had hij de Provox button maar die was na 5 maanden begonnen met lekken. De binnenkan van de tracheostoma is niet zo gevoelig en het doet daarom ook niet echt pijn om de button te vervangen. Het vervangen is heel even vervelend omdat er veel druk nodig is om de TE-prothese door het gat te duwen. Verwijderen van de oude button is relatief gemakkelijk.

Hij was nog maar redelijk kort z'n stembanden kwijt, maar kon daarna al naar 10 dagen weer spreken. Op de afdeling werd hij daarom wel Snelle Jelle genoemd. Hij vindt dat het leven met een tracheostoma best wel meevalt, hij kan goed verstaanbaar praten en ruiken lukt ook steeds beter.

In de tracheostoma had hij een canule die hij met de hand afsluit. Daar overheen draagt hij een donker sjaaltje. Dit doet hij omdat het met hoesten anders nog wel eens fout gaat. Behalve de canule gebruikt hij eigenlijk geen producten voor de tracheostoma. Tijdens het douchen houdt hij gewoon zijn hoofd er een beetje voor en zelfs als het buiten koud is heeft hij nog geen behoefte aan een HME-filter. Hij heeft het douche opzetstuk en een filter beide 1 keer gebruikt, maar later nooit weer gebruikt. De pleister die hij gebruikte raakte snel los door opgehoest slijm dat tussen de pleister en de huid kwam.

Omdat hij veel aan het knutselen is en deze dingen dan ook op de markt verkoopt lijkt het hem erg handig om zonder handen te kunnen spreken. Hij had echter nog nooit zo'n product uitgeprobeerd. Hij klonk erg verrast over het bestaan van zulke producten en was daarom ook erg geïnteresseerd in het ontwerp van de UFO.

De UFO leek hem groter te zijn dan nodig maar dat zou voor hem geen probleem zijn zolang hij er gewoon goed mee kon ademen en kon spreken. Wat volgens hem wel een groot probleem zou zijn is hoesten. Hij verwachtte het ding steeds weg te moeten halen als hij zou moeten hoesten. Nu deed hij dan ook met zijn canule, maar met een spreekklep leek hem dit moeilijker. Hier zou volgens hem een oplossing voor moeten worden gevonden.

Als hij moet gapen, doet hij nog steeds zijn mond ver open en ademt hij diep in. Hij kon weer een beetje ruiken door met zijn tong op en neer te bewegen en zo een luchtstroom door zijn neus naar binnen te zuigen. Koffie ruikt hij niet zo goed, maar de hond wel. Het spreken gaat hem goed af en het is voor hem geen probleem om een telefoongesprek te voeren.

B Interview Tracheostoma Artist

03-05-2010 – Interview met Marianne Hoedemaekers - Kunstenares en maker van sieraden voor op het tracheostoma. www.mijnsieraad.com, jacobspt@planet.nl

1) Denkt u dat gelaryngectomeerden zich schamen voor hun tracheostoma? Waaraan merkt u dit?

Dat is heel verschillend. Sommigen verbergen het stoma het liefst en hebben er grote moeite mee. Anderen doen of het de gewoonste zaak van de wereld is en dragen niets voor het filter. Dat is weer confronterend voor anderen. Het ligt dus nogal gevoelig. (zie o.a. antwoord bij vraag 3)

2) Wat zeggen uw klanten over de uitstraling van bestaande producten (zoals die van Provox)?

Omdat ik voor nogal wat verschillende soorten filters sieraden ontwerp en maak, zien ze dus ook andere filters bij mij. Daar hebben ze wel belangstelling voor, omdat ze natuurlijk graag een filter dragen wat het minste opvalt. Het ligt niet alleen aan de hals en de opening welk filter ze krijgen, maar ook aan het ziekenhuis heb ik de indruk. Hoe minder het filter opvalt, hoe liever ze het hebben. Ze waren bijvoorbeeld heel blij toen er eindelijk vleeskleurige filters kwamen. Ook de bevestiging is erg belangrijk. Het scheelt nogal of de filter met een kleurloze pleister vast zit, of met een wit of blauw klittenbandje. In plaats van de klittenbandjes kunnen ze ook een kettinkje dragen, wat al heel wat modieuzer staat.

3) Wat doen uw sieraden met uw klanten? Heeft het een grote invloed op hun gevoel?

De sieraden zijn erg belangrijk voor mijn klanten. Ze zijn dan ook dolgelukkig als ze met een sieraad naar huis kunnen. Even een voorbeeld: Een mevrouw was al 7 jaar niet meer naar het strand geweest, omdat ze niet in badpak durfde te lopen met om haar hals een sjaaltje. Met mijn sieraad heeft ze dat weer gedaan en ze was er dolgelukkig mee. Ook een man wilde om die reden een sieraad. Na een tijd kreeg ik een mail met de vraag hoe het zilver het beste schoon gemaakt kon worden, want hij droeg het sieraad altijd.

4) In "de 2e stem" stond een verhaal over iemand die een sieraad met een F van Feyenoord en Ferrari wilde. Ik moet daarbij meteen denken aan tatoos die ook altijd een diepere betekenis hebben, bijvoorbeeld om iets te verwerken. In hoeverre klopt die vergelijking?

Die jongen wilde graag zo'n sieraad om de laten zien dat hij fan van Feyenoord was en hij was helemaal weg van een Ferrari. Ik heb daarom een sieraad ontworpen waarbij hij de plaatjes kon verwisselen, zodat hij bij de voetbalwedstrijden de "F" aan kon doen en op andere tijden het symbool van de Ferrari. Bovendien was een sieraad met twee verwisselbare plaatjes goedkoper dan twee sieraden. En de prijs is voor de meeste mensen ook erg belangrijk en soms ook wel een struikelblok.

5) Is het mogelijk een sieraad te maken die elke gelaryngectomeerde mooi zou vinden?
Ik ontwerp en maak meestal voor elk soort filter enkele sieraden zodat de klant in ieder geval een sieraad kan passen en uitproberen bij mij. Als het sieraad bevalt, kunnen ze het kopen, anders kijken we, in overleg, welk ontwerp ze dan zouden willen. Als het technisch haalbaar is, dan wordt het gemaakt. Zo heb ik eens een antieke opengewerkte broche zo in het sieraad verwerkt, dat het ook weer als broche te gebruiken is.

6) Mijn nieuwe te ontwerpen tracheostoma klep zal qua grootte en plaatsing vergelijkbaar zijn met de Provox Filter Handsfree (zoals u ook op uw site heeft staan). Heeft u tips voor de uitstraling van mijn nieuwe tracheostoma klep?
De tips die ik je mee zou willen geven zijn de volgende:

Probeer de filter zo te ontwerpen dat hij zo laag mogelijk blijft. De handsfree filter die nu op de markt is, is erg hoog en daardoor minder geschikt om een sieraad op of overheen te dragen. Het geheel steekt dan erg ver naar voren en valt daardoor ook weer meer op. En hoe minder een filter opvalt, hoe fijner de mensen het vinden.

Zorg als het enigszins mogelijk is, dat je alles uitprobeert met mensen die misschien voor zo'n filter in aanmerking komen. Ik heb er bij mijn studie enorm veel plezier van gehad dat ik alles uit kon proberen. Daardoor kwamen snel de mogelijkheden en onmogelijkheden aan het licht. Het levert ook tijdwinst op, omdat je sneller de fouten eruit haalt.

C Pressure and flow requirements

In this summary pressure and flow values are mentioned for closing and opening the UFO. The values are based on literature and Willemijne Schrijver's research. Negative values represent inhalation, positive ones represent exhalation. A complete list of all used references is added on the last page.

Some words and numbers have a different color. Texts in **orange** are highly significant for the requirements of the UFO. Texts in **blue** have been cited by others bad weren't found in the article or the article couldn't be accessed. Numbers in **red** are found in articles but are considered very unlikely.

Some additional information about the data in the tables:

[1] LG = Laryngectomee, N = Normal subjects

[2] Grolman (2007) shows that endotracheal pressure is independent of tracheostomal occlusion method (i.e. manual, using an TSV)

[3] Liu's (2004) research is about electro speech. The measured values of flow during comfortable speech are therefore irrelevant and are not added to the list.

[4] Geertsema (1998, 1999, 2002) only did in vitro testing but in his articles he doesn't mention how it's possible that he knows exactly in what range the values should be.

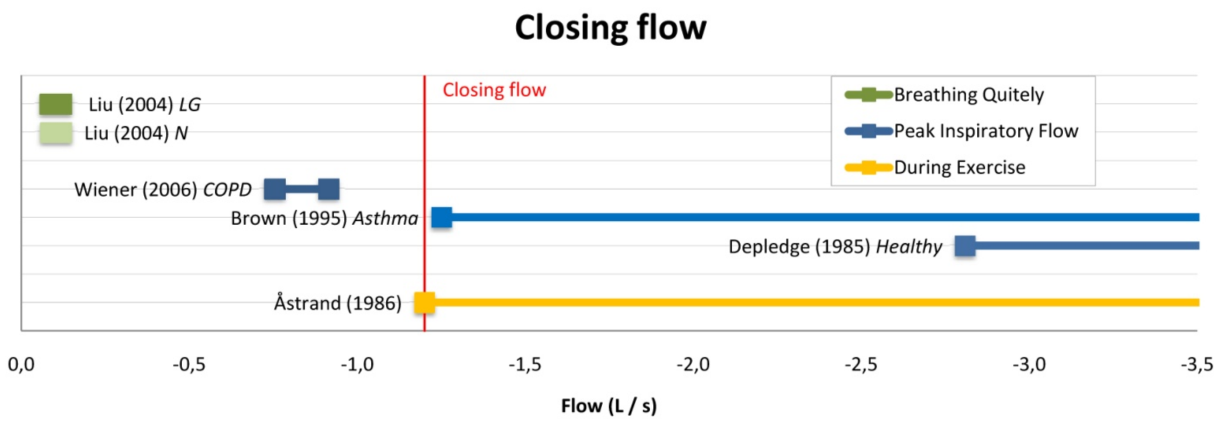
[5] Comroe (1970) is cited multiple times for its value of breathing resistance, however, this source remains unfound.

[6] Willemijne Schrijver (2010) has done extensive research on the use of the UFO. However, she did this for her master's thesis so her results are unpublished. Her measurement of maximum exhalation seems to be false because with 0,120 L / s the exhalation flow is far too low. Additionally the measured endotracheal pressure is irrelevant because no TSV was used.

Closing flow

Because the user can always inhale through the UFO, inhalation flow can always be created and adjusted. The parameter responsible for closing is therefore the inhalation flow V_{in}.

Aim for closing → inhalation flow, V_{in} < -1,2 L / s



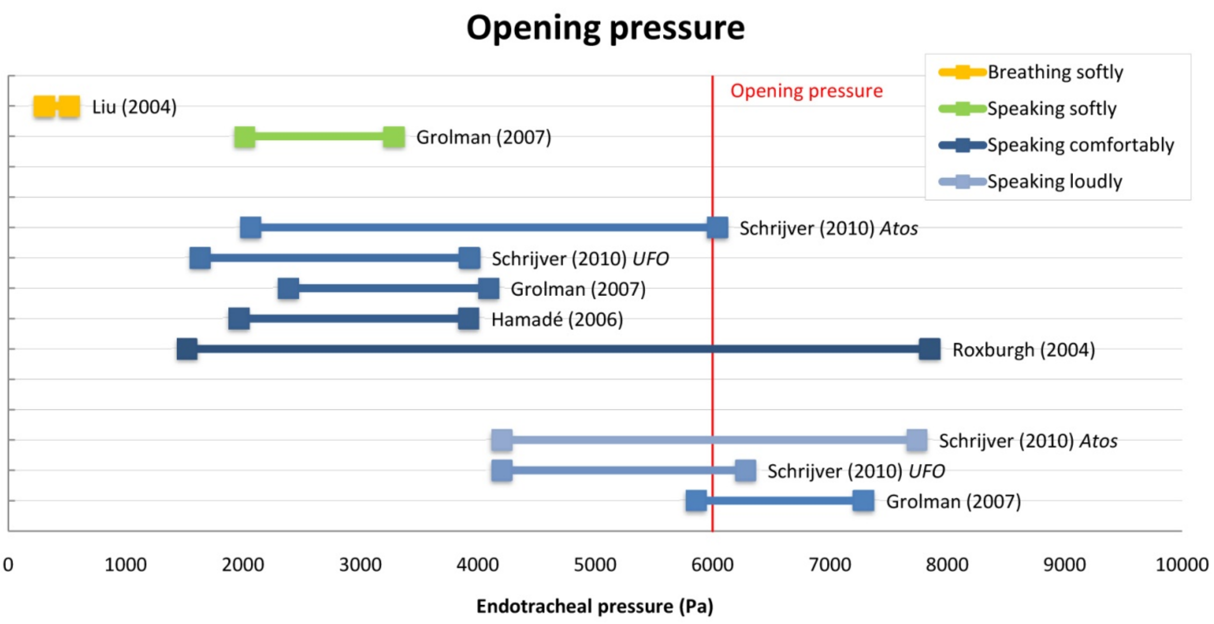
- The UFO shouldn't close while breathing normally (-0,12 < V < -0,09 L / s, Liu (2003))
- With a forceful inhalation which is below physical maximum, the UFO closes, allowing the user to speak. However the Peak Inspiratory Flow varies with different lung diseases like Asthma (-3,8 < V < -1,3 L / s, Brown (1995)) and COPD (-0,92 < V < -0,75 L / s, Wiener (2006)). This makes it very clear that multiple UFO's should be made for the different user groups.
- During exercise the inhalation flow is raised to higher levels (-1,2 < V_{in} < -6,0 L / s, Åstrand (1986)), but the UFO shouldn't close unwanted. This contradicts previous point.

Future aim for closing → multiple series, $-0,5 \le (V_{close} - k \cdot 0,25) \le -2,5$ L / s

	LG / N [1]	Endotracheal Pressure (kPa)	Flow (L / s)	
Breathing quietly				
Liu (2004) [3]	12 LG	-0,20 kPa	-0,103 L / s	
	8 N	-0,21 kPa	-0,102 L / s	
Normal breathing				
Geertsema (2002) [4]		-0,5 kPa	-1,5 L / s	(from graph, p4)
During exercise				
Younes (1984)	10 N	-5,0 – -2,0 kPa		(peak inspiratory P from mouth)
Åstrand (1986)	N		-6,0 – -1,2 L / s	(calculated from L / min)
"To close valve"				
Geertsema (1998) [4]	in vitro!	-7 – -1 kPa	-2,7 – -1,2 L / s	
Geertsema (1999) [4]	in vitro!	-7,2 – -0,8 kPa	-3,8 – -1,7 L / s	
Geertsema (2002) [4]	in vitro!	-7,1 – -1,2 kPa	-3,8 – -1,2 L / s	
Peak inspiration Flow				
Wiener (2006)	8 N		-0,92 – -0,75 L / s	(COPD patients)
Brown (1995)	99 N		-3,8 – -1,3 L / s	(Acute asthma patients)
Depledge (1985)	36 N		-7,4 – -2,8 L / s	
Maximum				
Younes (1984)	7 N		-10 – -6,0 L / s	(from graph, p7)

Opening pressure

Because the user can't exhale through the UFO when it's closed, endotracheal pressure can be created and adjusted. The parameter responsible for opening is therefore the exhalation pressure P_{out}.



Aim for opening → exhalation pressure, P_{out} > 6,0 kPa

- In closed position the user should be able to talk comfortably (1,5 < P_{out} < 4,1 kPa, Hamadé (2006), Grolman (2007), Willemijne (2010)), so the UFO shouldn't open in this pressure range.
- When the user is speaking louder, the endotracheal pressure is higher (4,2 < P_{out} < 7,7 kPa, Grolman (2007), Willemijne (2010)) but the UFO still shouldn't open.
- The UFO is opened with a strong pressure which is below physical maximum, allowing the user to stop speaking.

Future aim for opening → multiple series, 2,0 ≤ (P_{open} + k ·1,0) ≤ 8,0 L / s

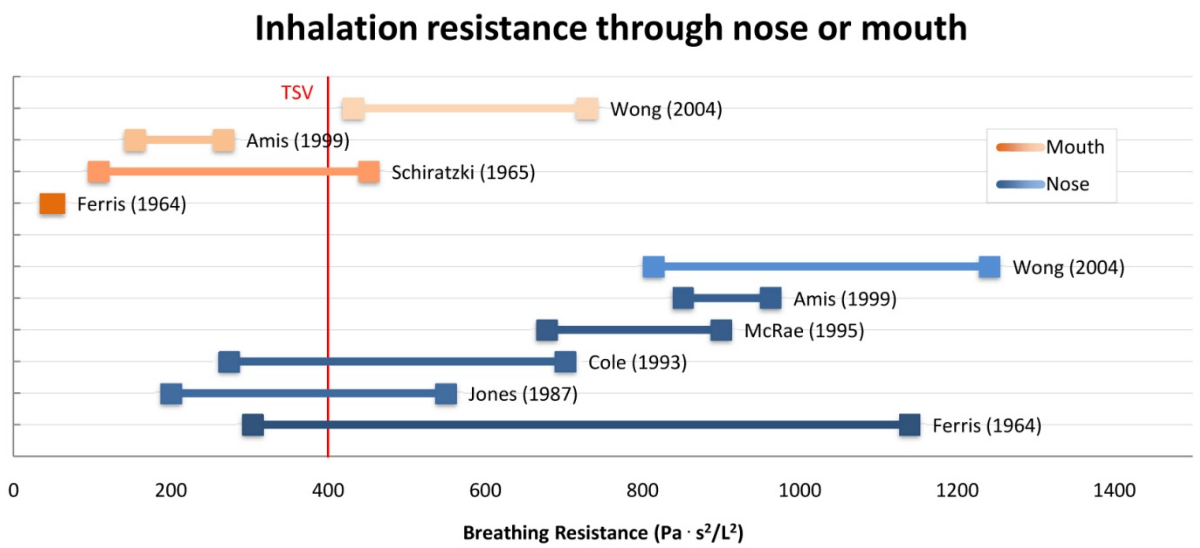
	LG / N [1]	Endotracheal Pressure (kPa)	Flow (L / s)	
Maximum				
Schrijver (2010) [6]	16 LG	5,93 kPa	0,110 L / s	
NESDA (2010)	N		9,45 L / s	(data from an email conversation)
During exercise				
Younes (1984)	7 N	0,34 – 2,12 kPa		(peak expiratory P from mouth)
Åstrand (1986)	N		1,2 – 6,0 L / s	(calculated from L / min)
Speaking loudly				
Schrijver (2010) [6]	15 LG	4,89 kPa	0,120 L / s	(/aa/ with UFO)
	13 LG	5,72 kPa	0,130 L / s	(/aa/ with Atos)
	14 LG	5,24 kPa	0,120 L / s	(sentence with UFO)
	12 LG	5,97 kPa	0,140 L / s	(sentence with Atos)
Grolman (2007) [2]	6 LG	6,57 kPa	0,267 L / s	(manual occlusion)
	7 LG	6,47 kPa	0,245 L / s	(with TSV)

Speaking comfortably					
	Schrijver (2010) [6]	15 LG	**2,78 kPa**	0,100 L / s	(soft sentence with UFO)
		14 LG	**4,05 kPa**	0,120 L / s	(soft sentence with Atos)
	Grolman (2007) [2]	6 LG	**3,24 kPa**	0,133 L / s	(manual occlusion)
		7 LG	**3,15 kPa**	0,150 L / s	(with TSV)
				0,200 L / s	("healthy LG's")
	Roxburgh (2004)	10 LG	**1,52 – 7,85 kPa**		(Blom-Singer TSV)
	Hamadé (2006)	4 LG	**1,96 – 3,92 kPa**		(manual occlusion)
Breathing quietly					
	Liu (2004) [3]	12 LG	0,41 kPa	0,232 L / s	
		8 N	0,30 kPa	0,194 L / s	

Breathing resistance

In some way the UFO can be seen as an artificial nose. This means the breathing resistance (or Airway Resistance Coefficient, ARC) of the UFO should be similar to the nose. Because of a high Reynolds number, turbulent flow will occur and breathing resistance will be measured in Pa · s^2 / L^2.

Aim for breathing resistance → ARC = 400 Pa · s^2 / L^2



- Some breathing resistance is needed to make the pulmonary alveoli use their full capacity. The breathing resistance is increased by wearing a HME-filter or a TSV with integrated HME-filter.
- In the normal situation, during exercise, someone would start breathing through mouth (46 < ARC < 452 Pa · s^2 / L^2, Ferris (1964), Schiratzki (1965), Amis (1999)) which is about 3 times easier than breathing through the nose (200 < ARC < 1140 Pa · s^2 / L^2, Ferris (1964), Jones (1987), Cole (1993), McRae (1995), Amis (1999)).
- COPD patients have very weak lungs and therefore wouldn't be able to breathe if the breathing resistance is too high. This means multiple UFO should be made for the different user groups. Additionally, it's desired to have an adjustable breathing resistance for during exercise.

Future aim for breathing resistance → adjustable ARC, 50 < ARC < 500 Pa · s^2 / L^2

		LG / N [1]	Breathing Resistance	
	Comroe (1970) [5]	N	**120 – 470 Pa · s^2 / L^2**	***(source not found)***
Breathing through mouth				
	Amis (1999)	7N	ARC_{in} is 155 – 268 Pa · s^2 / L^2	(calculated with V = 0,4 L / s)
	Verkerke (2002)	9N	ARC_{in} is 46 ± 52 Pa · s^2 / L^2 ARC_{out} is 50 ± 56 Pa · s^2 / L^2	(according to Ferris et al (1964)) ***(source not found)***
		4-6N	ARC_{in} is 108 – 452 Pa · s^2 / L^2 ARC_{out} is 100 – 216 Pa · s^2 / L^2	(according to Schiratzki (1965))
	Wong (2004)	47 N	ARC is **431 – 730** Pa · s^2 / L^2	(during normal breathing)
Breathing through nose				
	Cole (1993)	4N	ARC_{in} is 274 – 702 Pa · s^2 / L^2 ARC_{out} is 446 – 986 Pa · s^2 / L^2	(nasal cavity + pharynx + larynx), (calculated with V = 0,5 L / s)
	Jones (1987)	59N	ARC_{in} is 200 – 550 Pa · s / L	(90% interval)
	Verkerke (2002)	9N	ARC_{in} is 304 ± 1140 Pa · s^2 / L^2 ARC_{out} is 266 ± 298 Pa · s^2 / L^2	(according to Ferris et al (1964)) ***(source not found)***
		16N	ARC_{in} is 678 – 900 Pa · s^2 / L^2 ARC_{out} is 662 – 832 Pa · s^2 / L^2	(according to McRae et al (1995))
	Wong (2004)	47 N	ARC is **814 – 1242** kPa · s^2 / L^2	
Vowel production				
	Hoit (1992)	70 N (f)	ARC_{vowel} is 3,7 – 5,7 kPa · s / L	(during vowel production in 70 women)
	Miani (1998)	LG	Max ARC_{TSV} is 3,9 kPa · s / L	(for vowel production)
Extra information				
	Åstrand (1986)	N	Nose has 2 – 3 x more resistance	
	Olafsson (1969)	N	ARC doesn't increase during exercise	
	Zuur (2006)	N – LG	HME is very effective	

Coughing

Homnick (2007) shows that effective coughing requires at least 3,9 kPa to remove mucus. One subject of Lavietes (1998) showed that the endotracheal pressure of coughing can be as high as 21,3 kPa. In currently available TSV's with a cough release valve, the pressure to open this valve can be adjusted between 1,2 and 7,0 kPa (Geertsema, 2000). In the future, when the UFO will have a cough release valve, the pressure to open this valve P_{cough} should be higher than P_{open} and adjustable.

Future aim for coughing → adjustable opening pressure, 1,2 < P_{cough} < 7,0 kPa

		LG / N [1]	Endotracheal Pressure (kPa)	Flow (L / s)	
Coughing					
	Homnick (2007)		**3,9 – 9,8 kPa**	4,5 – 12 L / s	
	Lavietes (1998)	5 N	**5,7 – 21,3 kPa**		
	Geertsema (2002) [4]	in vitro!	1,2 – 7,0 kPa		(adjustable coughing valve opens at this pressure)

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D Sketches

For the redesign of the UFO many sketches have been made. Here a selection is given to give a view of the design process.

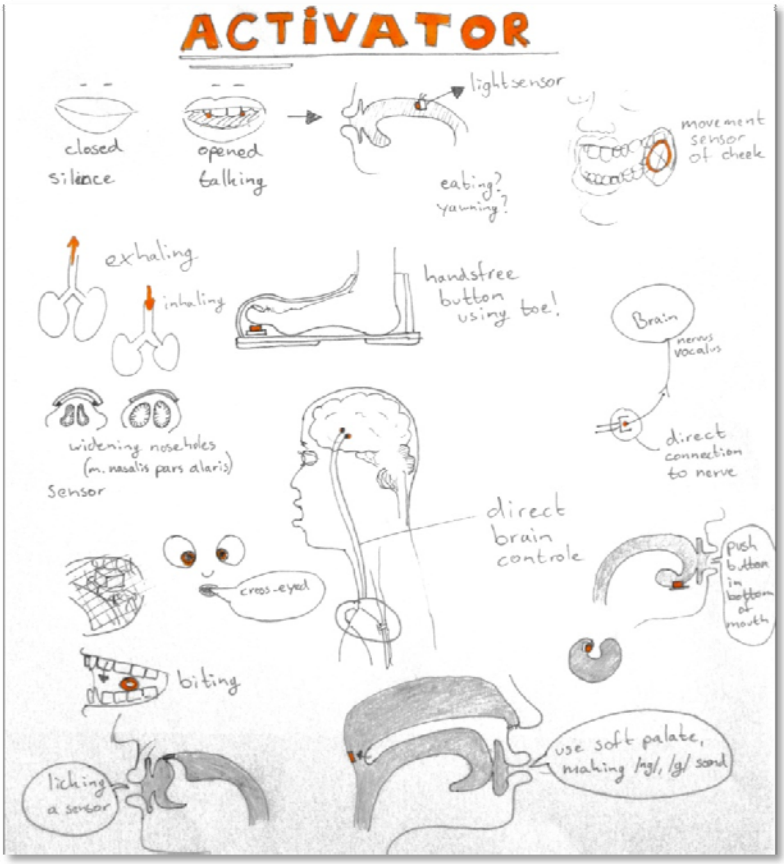


Figure D-1: how to activate the TSV

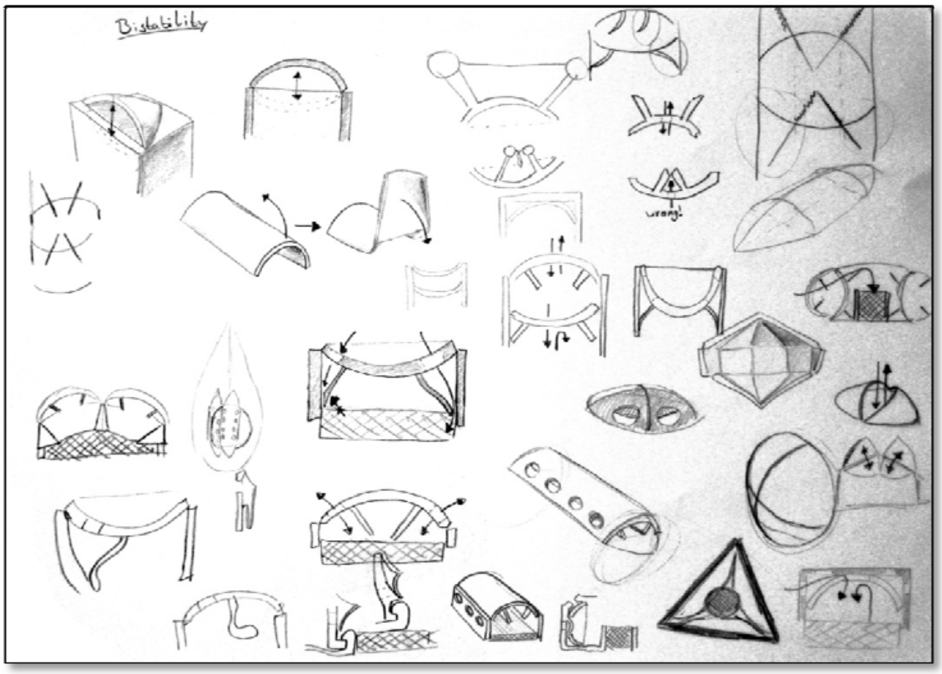


Figure D-2: how to use bistability

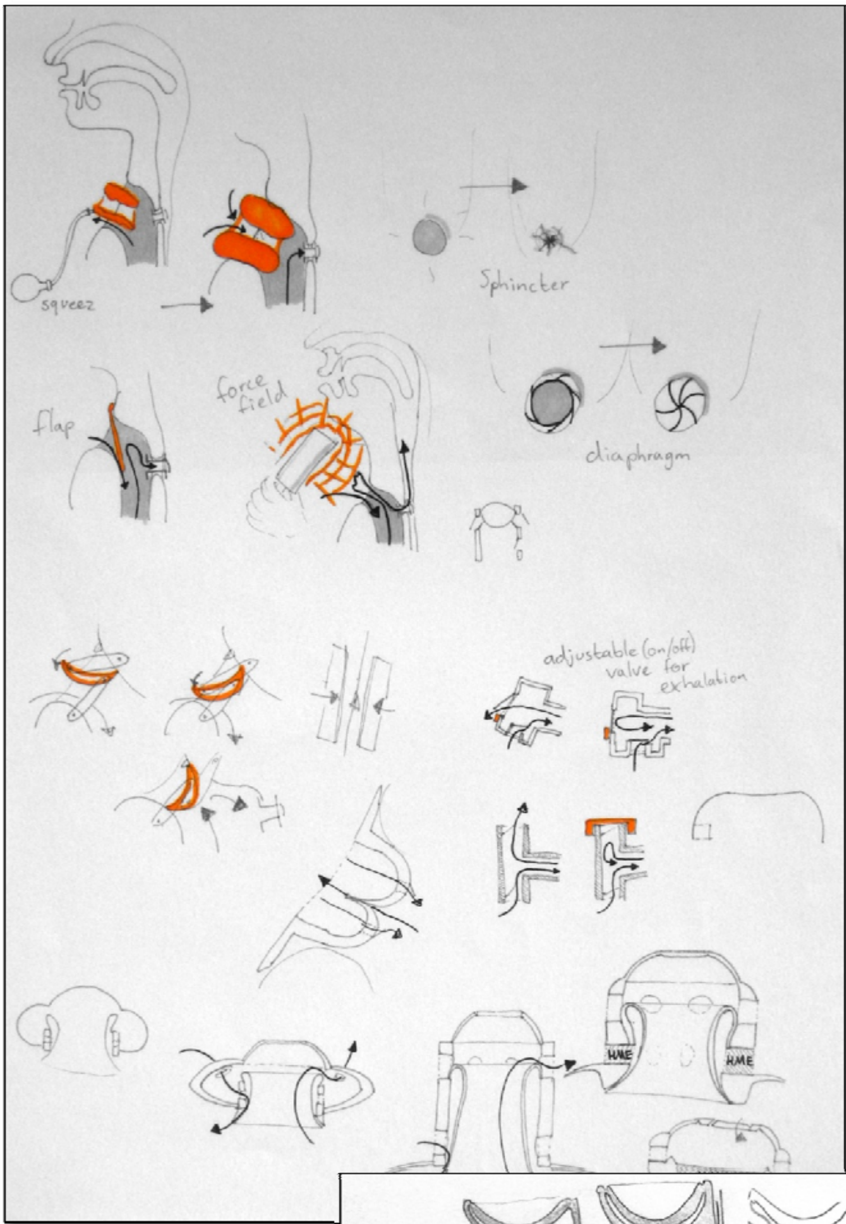


Figure D-3: how to close the tracheostoma

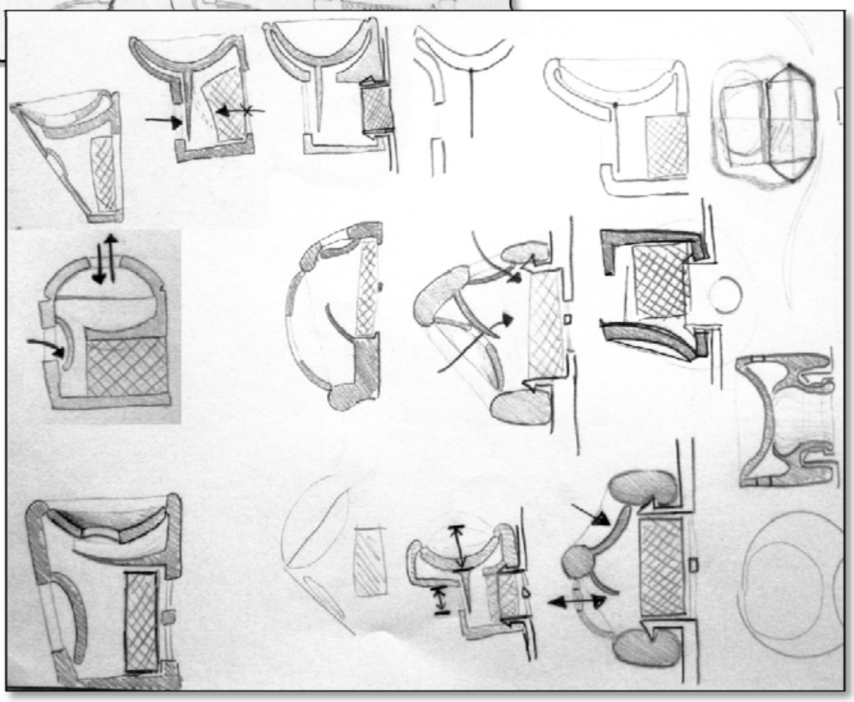


Figure D-4: how to use a membrane attached to a buckling sphere

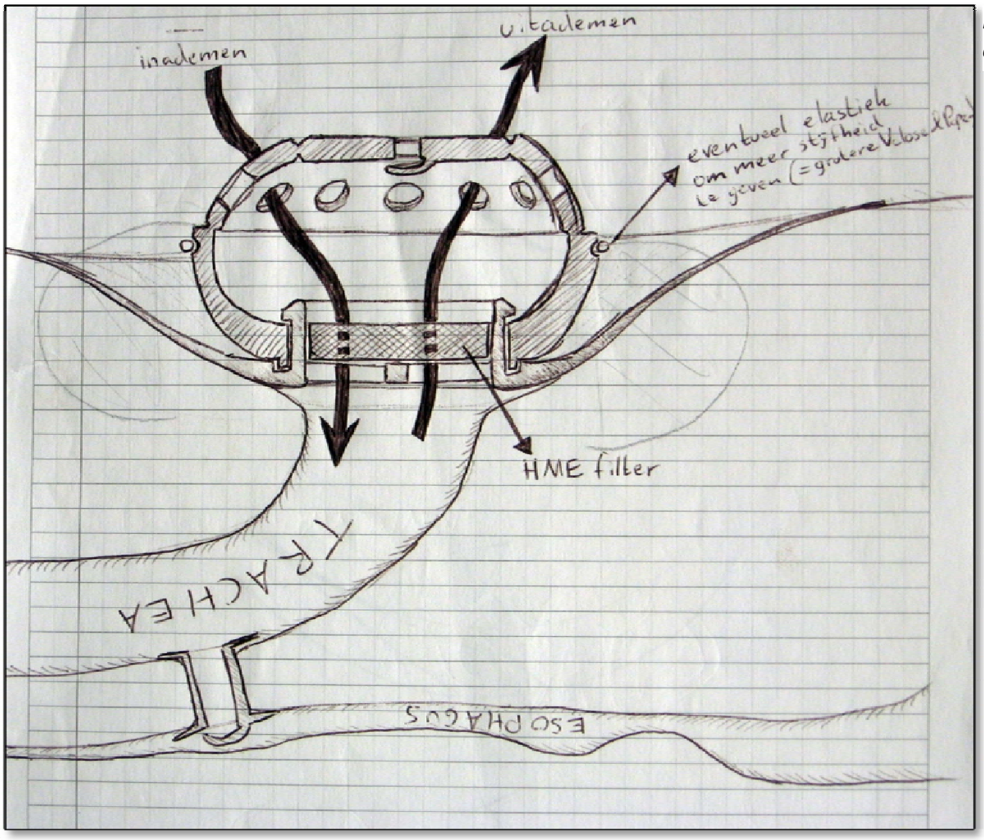


Figure D-5: new concept

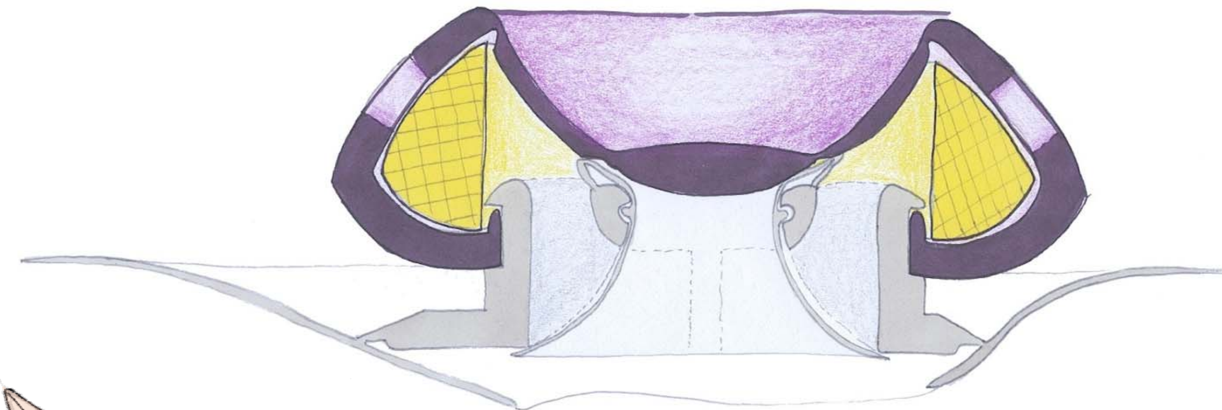


Figure D-6: UFO on Lotus

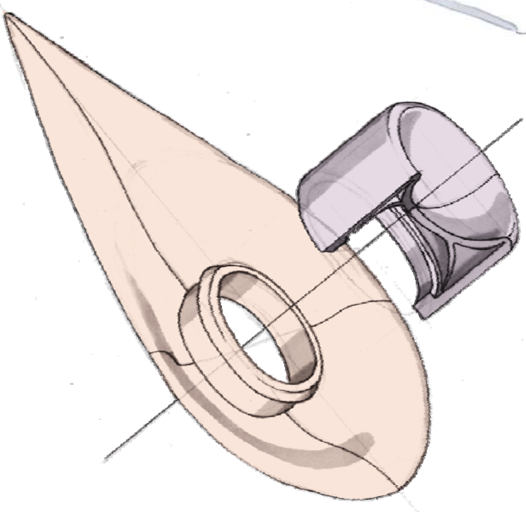


Figure D-7: Diabolo on droppatch

E Minimum Size of Breathing Hole

Theoretically, the diameter of the TSV can be calculated. It's important that the inhalation breathing resistance of the TSV during speech doesn't exceed 400 Pa · s^2 / L^2 at a flow of around 0,5 L / s. This report can be used for the design of the TSV and to verify the measured breathing resistance of the prototype.

Reynolds number

The Reynolds number is a dimensionless number that gives information about a dynamic flow. In this case, the Reynolds number is used to show that the flow through the breathing holes is turbulent and the dimension of the breathing resistance should indeed be Pa · s^2 / L^2 (and not Pa · s / L).

$$Re = \frac{V \cdot L \cdot \rho}{\mu}$$

Re Reynolds number [-]

Laminar flow occurs at low Reynolds numbers

Turbulent flow occurs at high Reynolds numbers (for pipe flow when Re > 4000)

V Mean flow velocity [m / s]

Normal breathing Q = 0,5 L / s =0,0005 m^3 / s

$$V = \frac{Q}{A} = \frac{Q}{\pi\left(\frac{d}{2}\right)^2} = \frac{4Q}{\pi d^2}$$

L Characteristic linear dimension [m]

For pipe flow this is the diameter of the pipe or d.

ρ Density [kg / m^3]

density of air (20°C) = 1,20 kg / m^3

μ Dynamic viscosity [Pa . s] (http://www.lmnoeng.com/Flow/GasViscosity.htm)

viscosity of air (20°C) = 1,84. 10^{-5} kg/m-s

So the Reynolds number of the flow in a tube (at 20°C) is:

$$Re = \frac{V \cdot L \cdot \rho}{\mu} = \frac{4Q \cdot d \cdot \rho}{\pi d^2 \cdot \mu} = \frac{4 \cdot 0{,}0005 \cdot d \cdot 1{,}20}{\pi d^2 \cdot 1{,}84 \cdot 10^{-5}} = \frac{41{,}5}{d}$$

This means a tube with $d < 0{,}0104\ m$ or $A < 84{,}6\ mm^2$ will have turbulent flow.

Breathing Resistance

Because the flow is turbulent, the breathing resistance is:

$$\mathcal{R} = \frac{\Delta P}{V^2} < 400\ Pa \cdot \frac{s^2}{L^2} = 400 \cdot 10^6\ Pa \cdot \frac{s^2}{m^6}$$

Darcy friction factor

To be able to calculate the pressure drop, the Darcy friction coefficient λ has to be calculated. This can be done with the Reynolds number Re and the inner roughness ϵ (about $0{,}9 \cdot 10^{-3}\ m$).

$$\frac{1}{\sqrt{\lambda}} = -2log\left(\frac{2{,}51}{Re\ \cdot \sqrt{\lambda}} + \frac{\epsilon}{3{,}72 \cdot d}\right)$$

Pressure drop

The Darcy friction factor depends on diameter d and is used to calculate the pressure drop.

$$h_f = \lambda(d) \cdot \frac{L}{d} \cdot \frac{V^2}{2 \cdot g}$$

$$\Delta P = h_f \cdot \rho \cdot g = \lambda(d) \cdot \frac{l}{d} \cdot \frac{\rho V^2}{2}$$

h_f is the head loss (m)

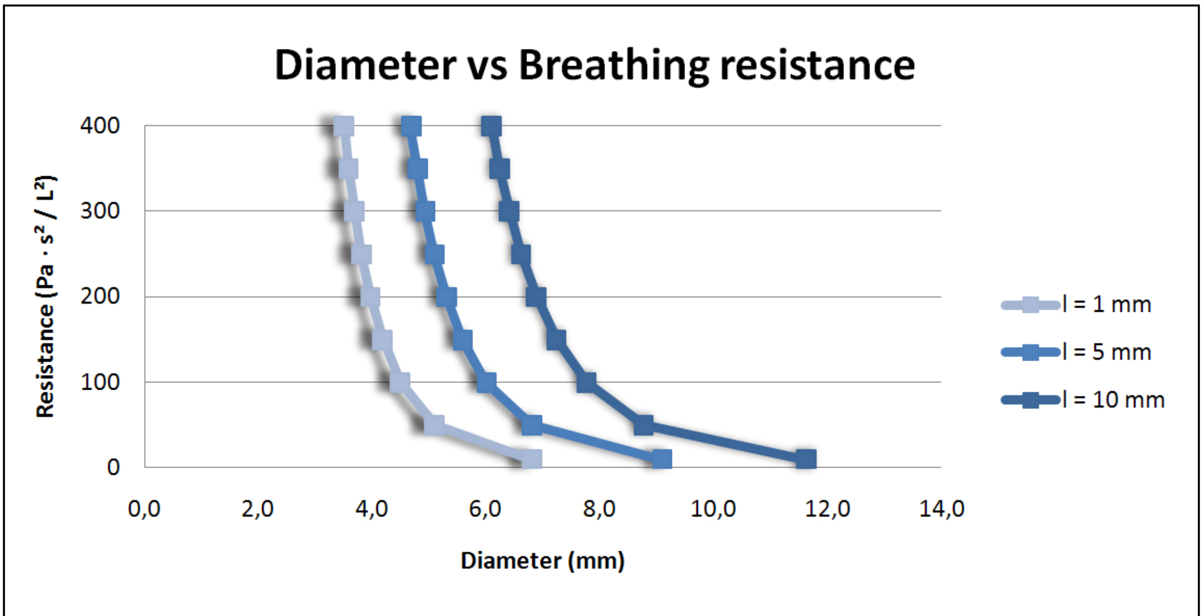
ΔP is the pressure drop (Pa)

l is the length of the pipe (0,01 m)

So now a relation between resistance and diameter can be created:

$$\mathcal{R}(d) = \frac{\Delta P}{Q^2} = \frac{\lambda(d) \cdot \frac{l}{d} \cdot \frac{\rho V^2}{2}}{Q^2} = \lambda(d) \cdot \frac{l \cdot \rho}{d \cdot 2A^2} = \lambda(d) \cdot \frac{8 \cdot l \cdot \rho}{\pi^2 d^5} < 400 \cdot 10^6\ Pa \cdot \frac{s^2}{m^6}$$

With excel, answers can be found to the equation which results in the following graph:



So, the minimum size of a hole with a breathing resistance of 400 Pa · s^2 / L^2 at a flow of 0,5 L / s and a tube length of 5 mm is 4,7 mm.

F Workshop plan

Bachelor eindopdracht – Bob Giesberts – 3 juni 2010

Voor mijn bacheloropdracht heb ik voor het herontwerp van een tracheostoma klep twee concepten uitgewerkt waarvoor ik nu 2 prototypes ga maken. Beide prototypes worden met een bepaald soort siliconen gegoten met mallen die ik in de werkplaats in Enschede zal maken uit PMMA stafmateriaal (uit de werkplaats van Groningen). Alle onderdelen kunnen op de draaibank gemaakt worden, maar omdat (op één na) alle delen lastige rondingen hebben is dit niet conventioneel te doen maar zal dit met de CNC draaibank moeten worden gedaan.

Het liefst zou ik alles zelf maken in de werkplaats, maar aangezien ik nog nooit met de CNC draaibank heb gewerkt lijkt me dit geen goed idee. Ik hoop dat er tijd en ruimte is om mij op weg te helpen zodat ik zo veel mogelijk zelfstandig op kan lossen.

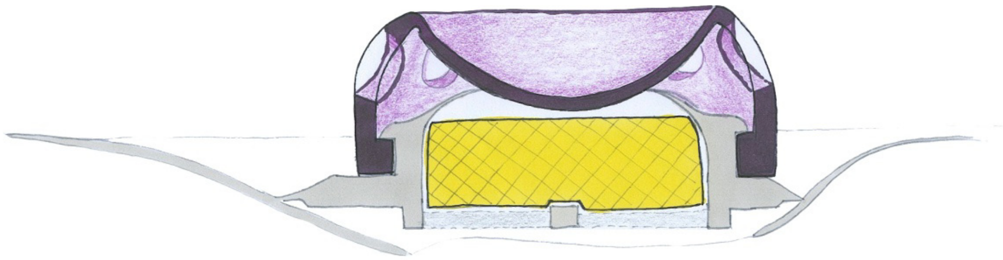
Edit: aangezien alleen concept 2 is uitgevoerd is alleen van dit onderdeel de technische tekeningen toegevoegd.

Statistieken:

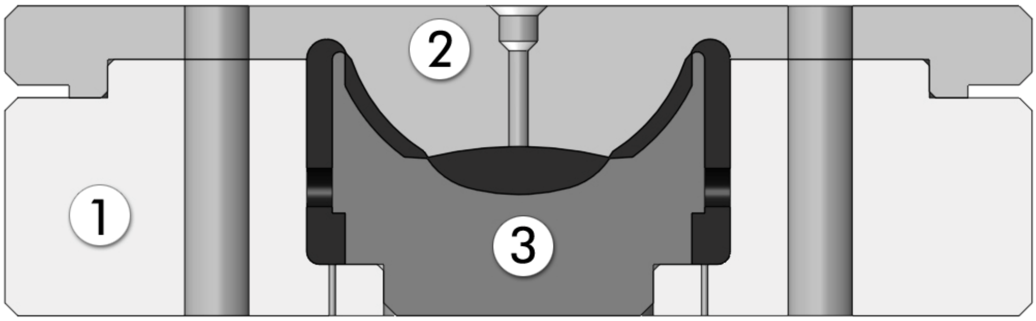
- 5 Dagen de tijd
- 2 Concepten
- 3 Onderdelen
- 11 Maldelen
  - 1 volledig conventioneel
  - 12 CNC bewerkingen
  - 10 µm nauwkeurigheid
- 148 mm PMMA rond 80
- 15 mm PMMA rond 40
- 60 mm PMMA rond 30

Concept 1

Voor dit concept moeten 2 x 3 onderdelen worden gemaakt. 1 onderdeel kan met de hand worden gemaakt op de draaibank, de overige onderdelen zullen (gedeeltelijk) met de CNC draaibank gemaakt worden. In de schets is met paars de *Cap* aangegeven, met grijs de *Capseat*. In de doorsneden is met zwart het product aangegeven. De nummers geven de volgorde aan waarin de delen na het gieten zullen worden verwijderd. Na het gieten worden de ademgaten in het prototype geponst.



Cap



Deel 1

Rond 80 PMMA (20 → 22 mm)

1. Volledig conventioneel maken op draaibank
2. Ontluchtingsgaten (4 x 0,5 mm) boren

Deel 2

Rond 80 PMMA (11,81 → 15 mm)

1. Vertrapt deel maken op draaibank + Aanspuiting (3 mm) boren
2. Rondingen maken met CNC draaibank

Deel 3

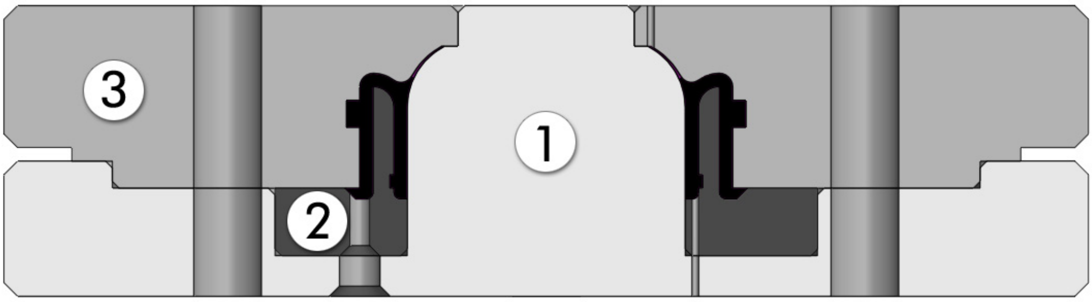
Rond 30 PMMA (20,58 → 24 mm)

1. In draaibank juiste diameter geven (29 mm)
2. Vertrapping aan onderkant maken in draaibank (is de inklemming voor CNC)
3. Rondingen maken met de CNC draaibank

Assembly

Vastschroefgaten boren (5 mm)

Capseat



Deel 1

Rond 80 PMMA (21,50 → 23 mm)

1. In draaibank vertrapping maken
2. Ronding met CNC draaibank maken

Deel 2

Rond 40 PMMA (12,50 → 15 mm)

1. Juiste diameter geven op draaibank (40 mm)
2. Hoek afsteken op draaibank + groot gat (20,5 mm)
3. Uitstekend deel rond maken met CNC draaibank (eventueel conventioneel)
4. Inkeping in uitstekende deel in draaibank

Deel 3

Rond 80 PMMA (13,50 → 15 mm)

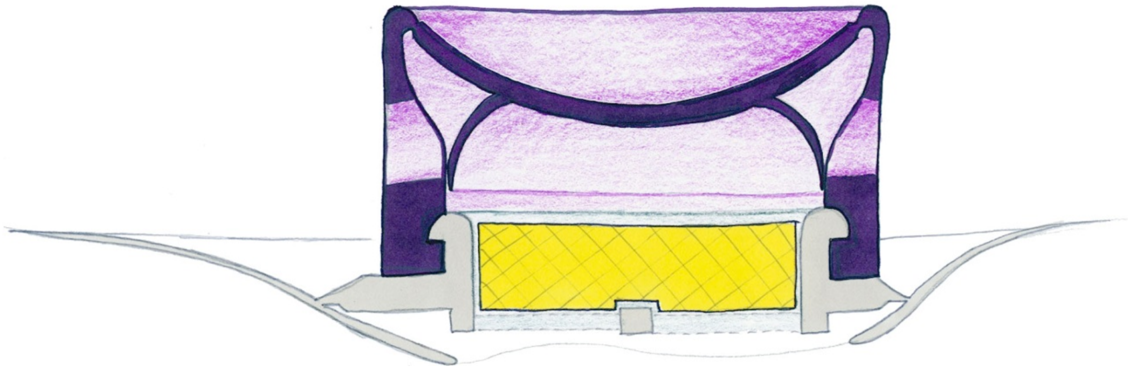
1. Vertrapt gat maken op draaibank
2. Inkeping in zijkant van gat op de draaibank
3. Golvend deel met CNC draaibank maken
4. Ontluchtingsgaten (4 x 0,5 mm) boren

Assemblage

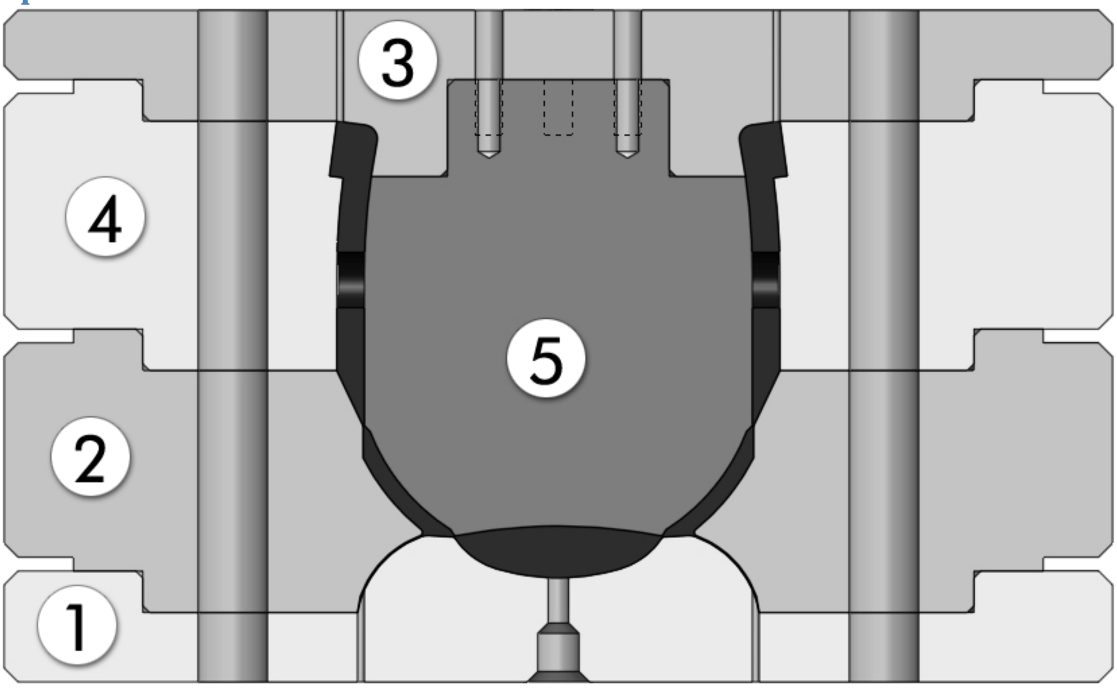
1. Aanspuitgat (3 mm) + ontluchtingsgaten (0,5 mm) boren
2. Vastschroefgaten boren (5 mm)

Concept 2

Concept 2 wordt binnenste buiten gegoten en zal om worden gevouwen bij de knik die gemaakt wordt door maldeel 2 en 5. Om de vervorming van het binnenstebuiten klappen te compenseren is de mal iets naar binnen gevormd. Omgeklapt zal dit er voor zorgen dat de zijkanten recht gaan staan. Maldeel 5 wordt aan deel 3 vastgeschroefd om het in de juiste positie te houden. Het vlies, in de tekening onderaan weergegeven is 0,10 mm dik. Na het gieten worden de ademgaten in het prototype geponst. Voor dit prototype is het niet nodig een Capseat (het grijze deel in de schets) te maken, dus alleen de *Cap*.



Cap



Deel 1

Rond 80 PMMA (10,55 → 14 mm)

1. Vertrapt deel maken op draaibank + Aanspuiting (3 mm) boren
2. Ronding maken met de CNC draaibank
3. Ontluchtingsgaten (4 x 0,5 mm) boren

Deel 2

Rond 80 PMMA (20,47 → 22 mm)

1. Vertrapt deel maken op draaibank + afsteken op juiste lengte
2. Omdraaien en vertrapt deel maken op andere kant in draaibank
3. Groot gat maken op draaibank
4. Rondingen maken met de CNC draaibank
5. Omdraaien en rondingen maken op de andere kant met de CNC draaibank

Deel 3

Rond 80 PMMA (12 → 14 mm)

1. Vertrapt deel maken op draaibank
2. Schuin deel met de CNC draaibank maken (eventueel conventioneel)
3. Ontluchtingsgaten (4 x 0,5 mm) + assembly gaten (4 x 2mm) boren

Deel 4

Rond 80 PMMA (21 → 23 mm)

1. Vertrapt deel maken op draaibank + afsteken op juiste lengte
2. Omdraaien en vertrapt deel maken op andere kant in draaibank
3. Groot gat maken op draaibank
4. Rondingen maken met de CNC draaibank

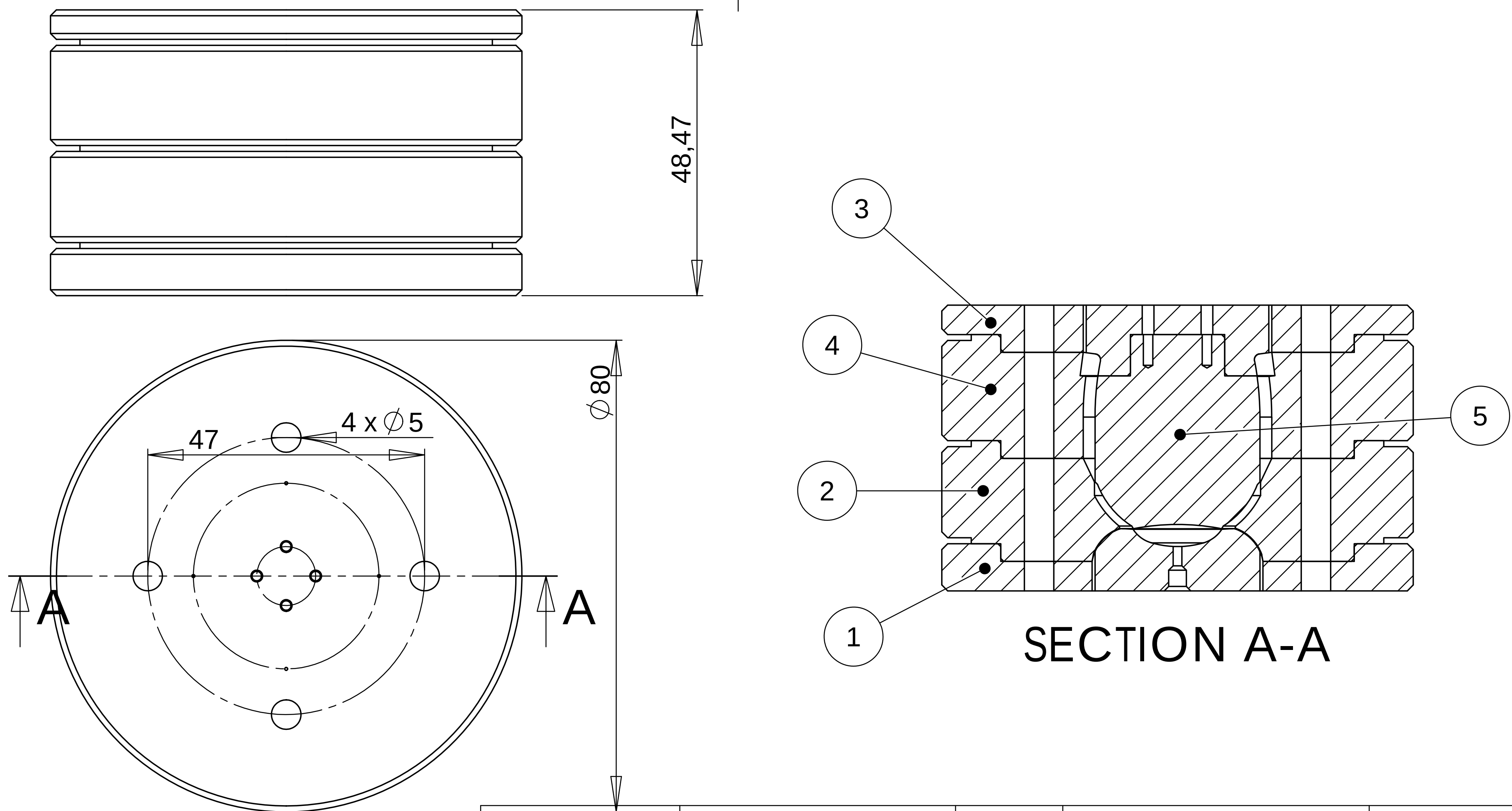
Deel 5

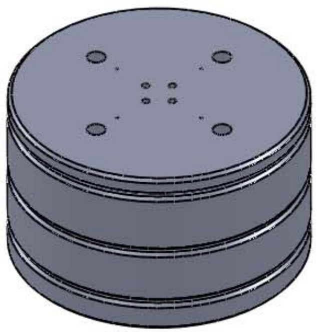
Rond 30 PMMA (33,03 → 36 mm)

1. Assembly gaten tappen (4 x M2)
2. Vertrapt deel maken op draaibank (is de inklemming voor CNC) en afsteken
3. Rondingen maken met de CNC draaibank

Assemblage

Vastschroefgaten boren (5 mm)





F-6

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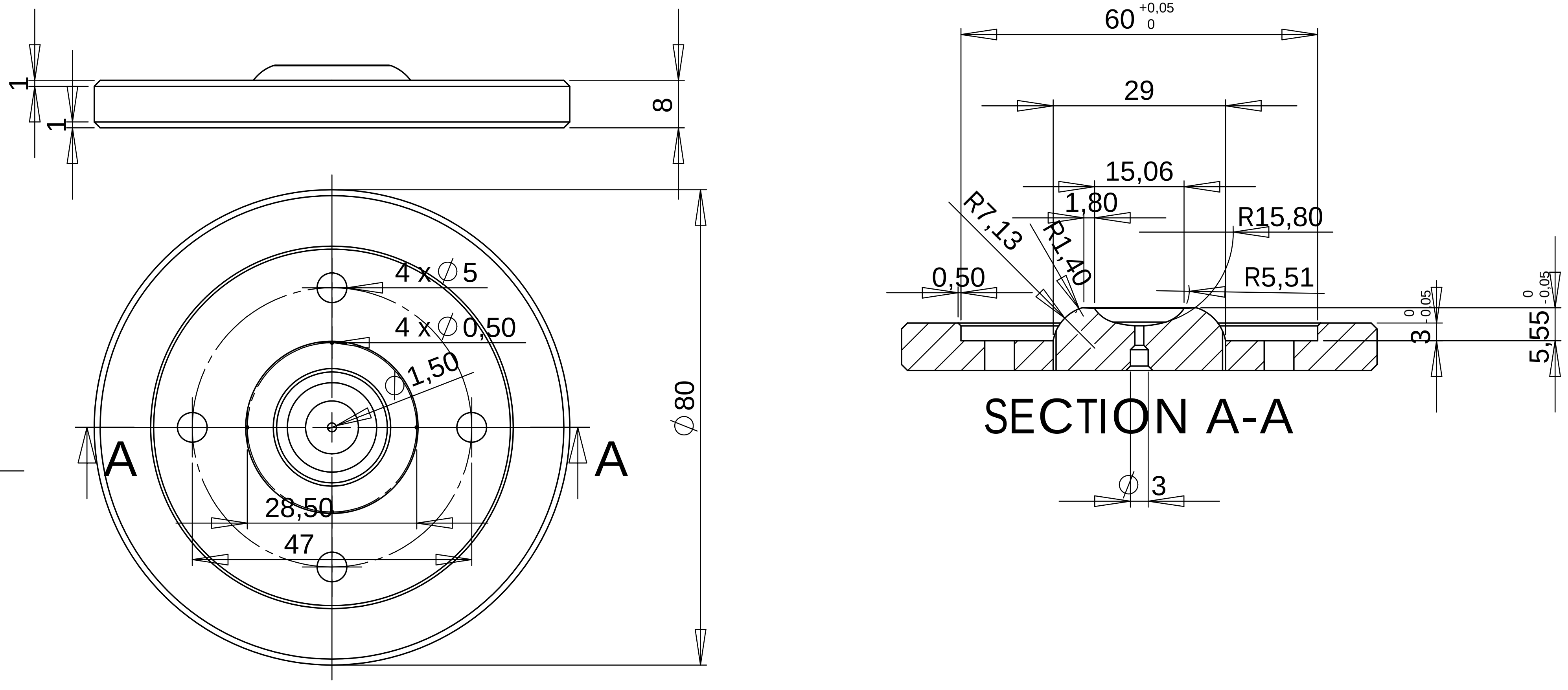

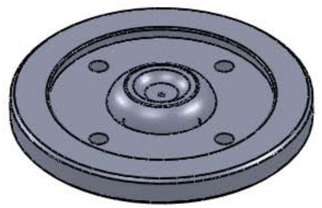

F-7

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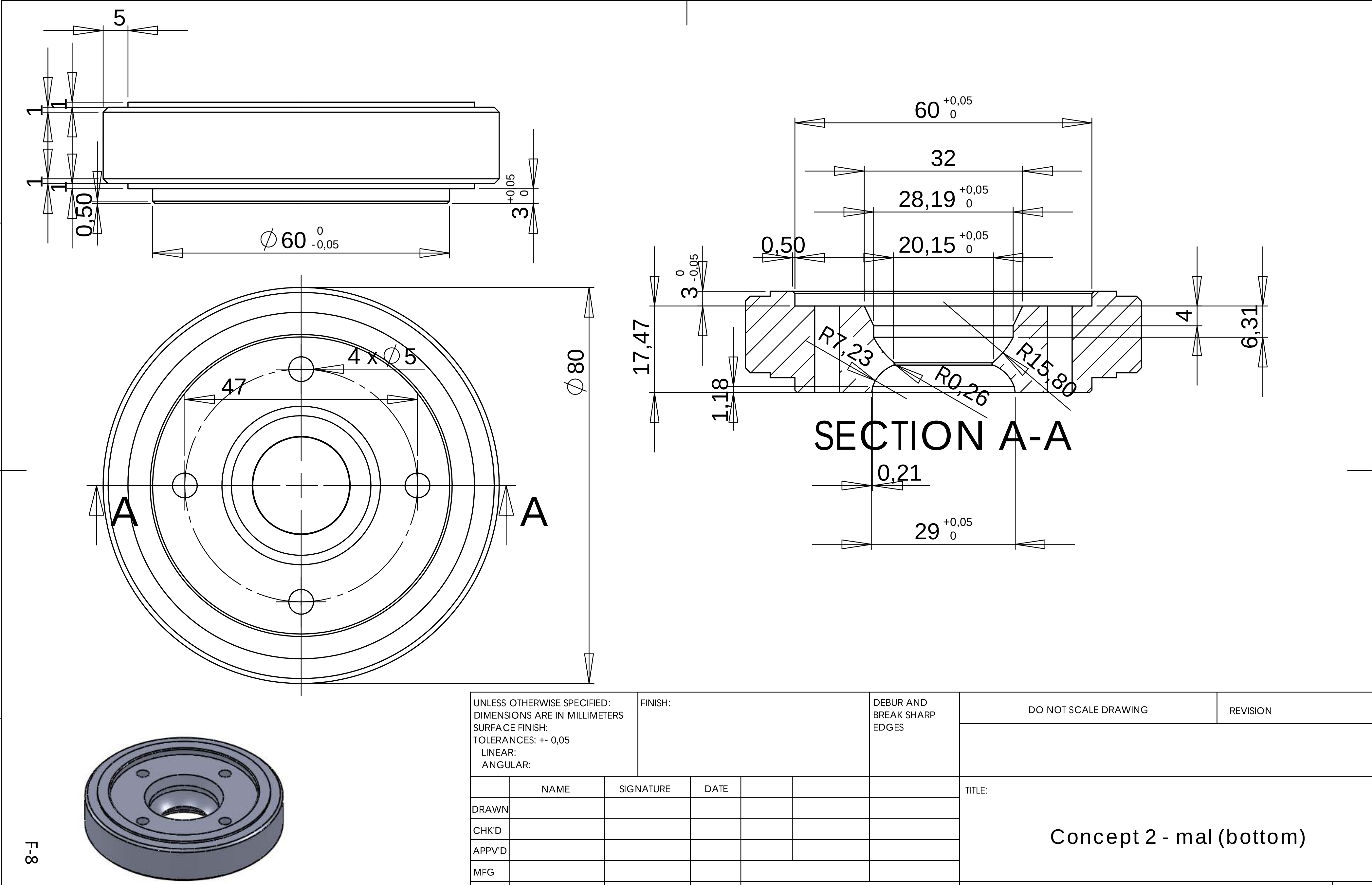

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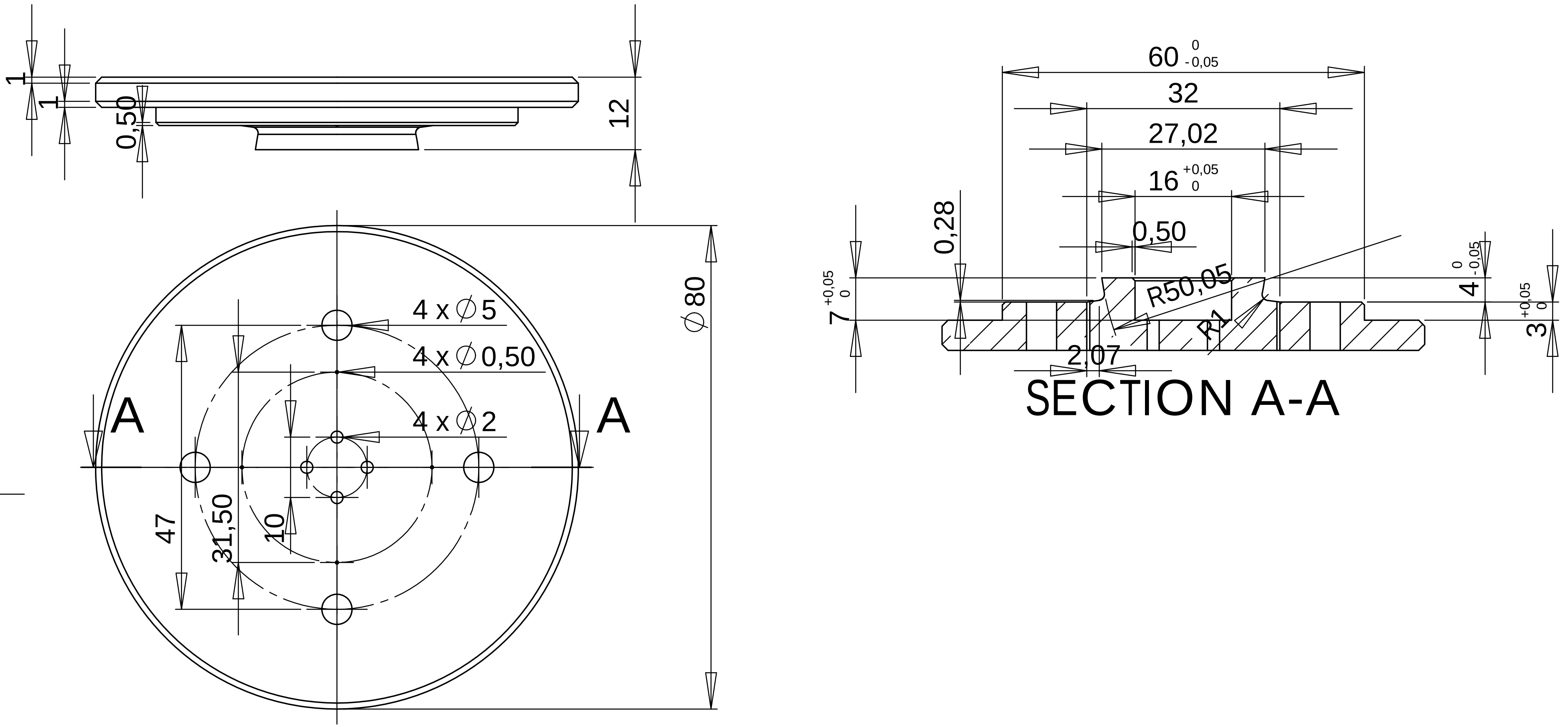

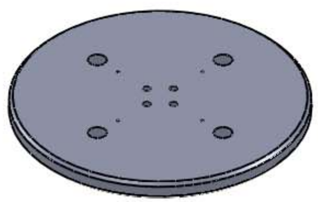

F-9

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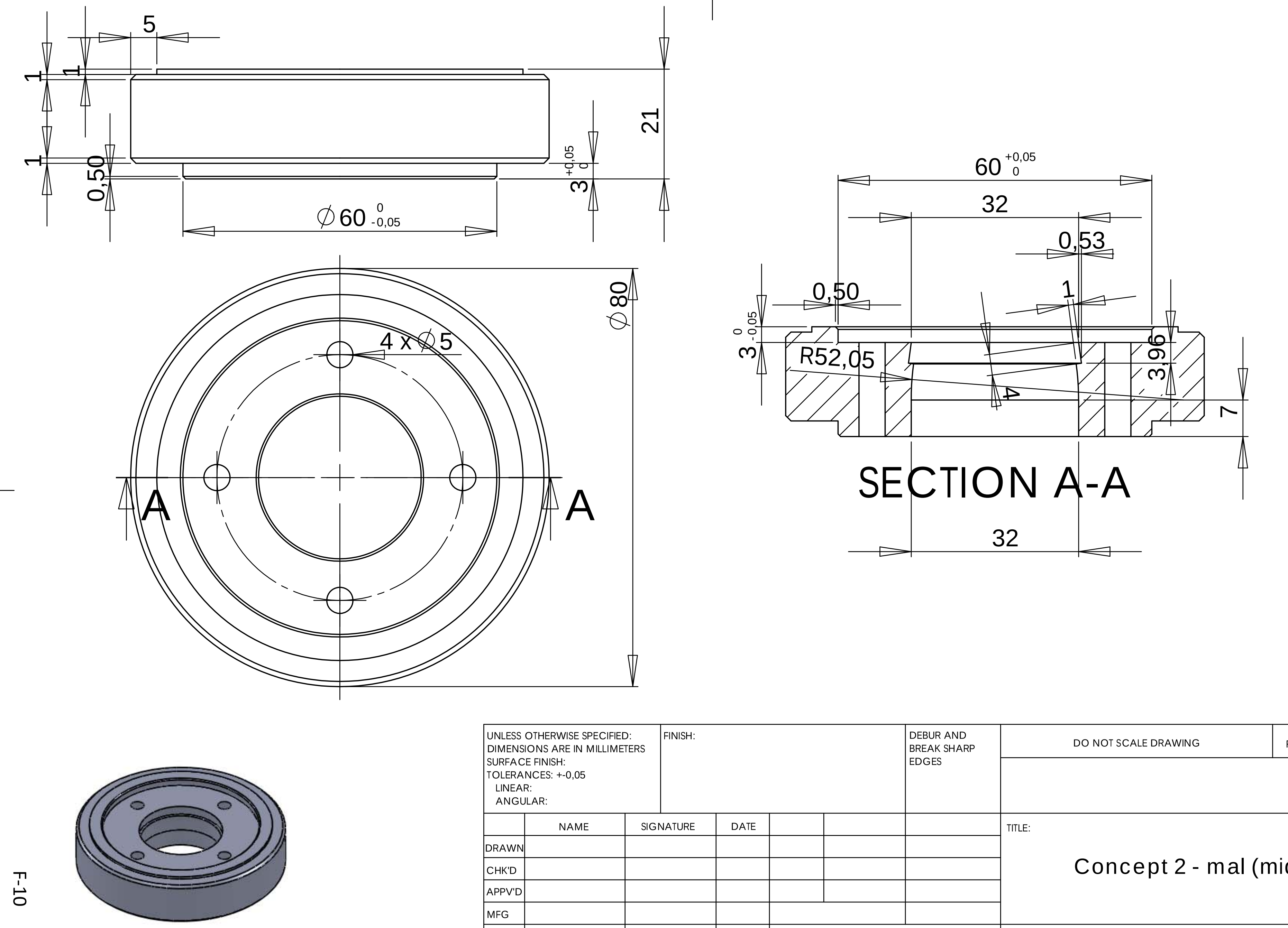

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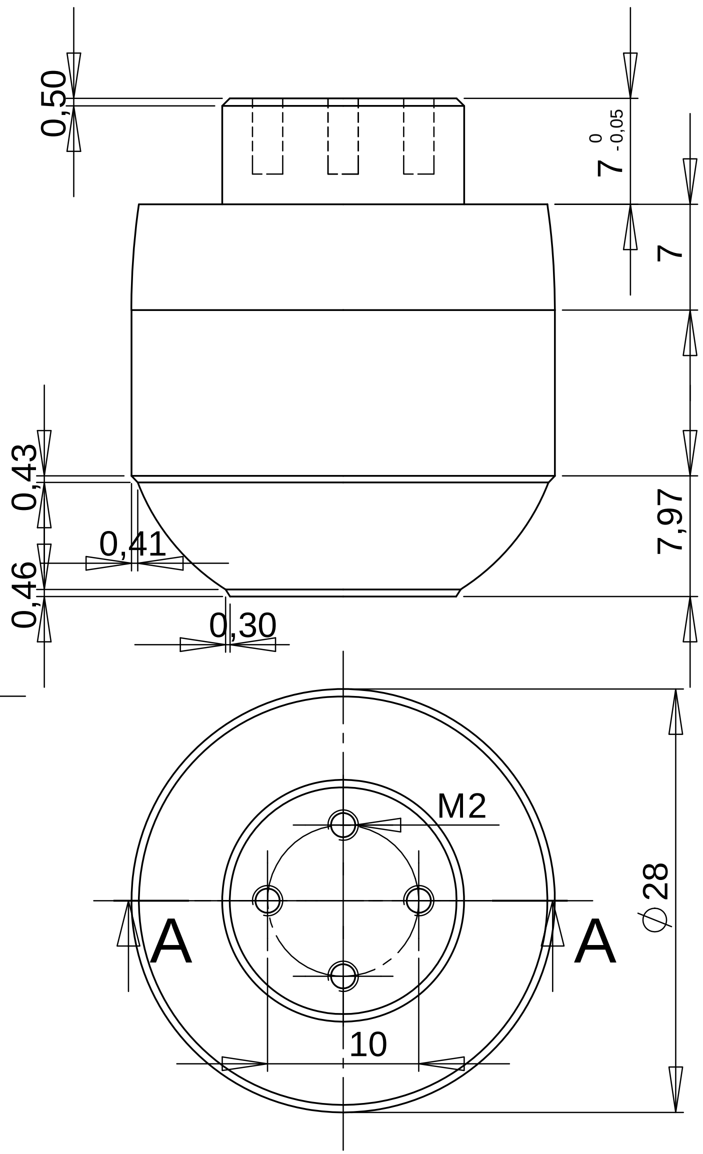
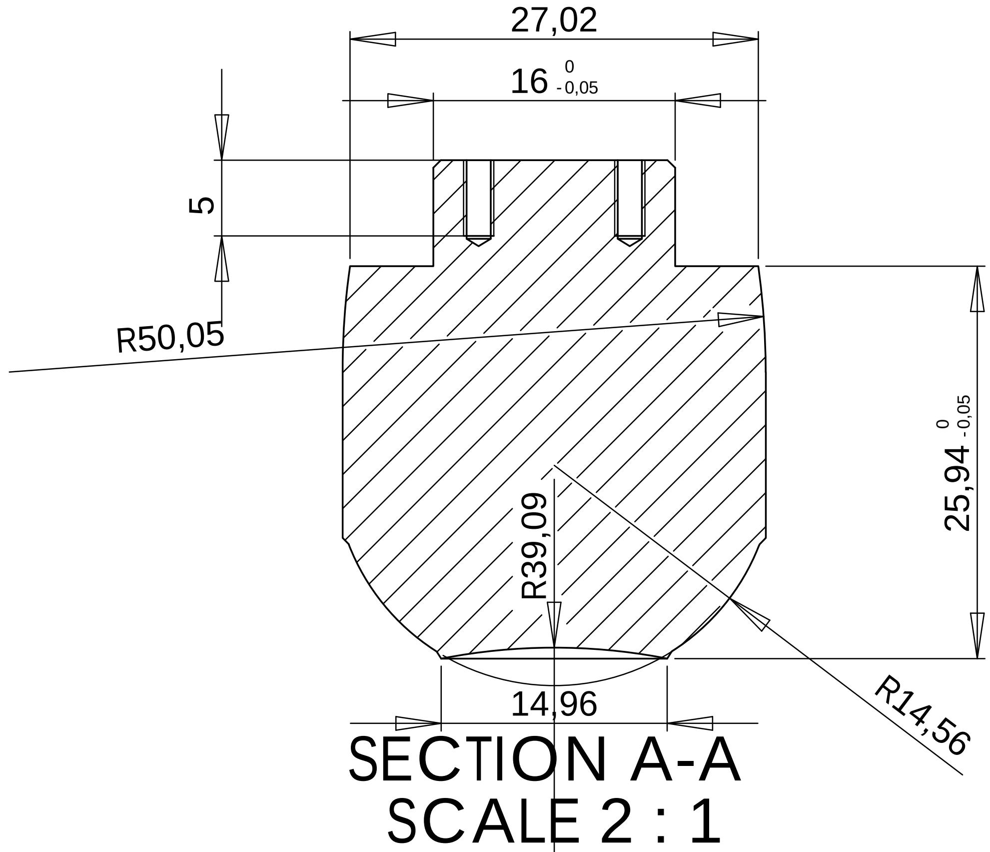
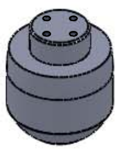
SHEET 1 OF 1





F-11



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APPV'D				
MFG				
Q.A			MATERIAL:	DWG NO. _Concept 2 - Cap - 5) Mould - core top — A4
			WEIGHT:	SCALE:2:1 — SHEET 1 OF 1

G Molding Protocol

This is the molding protocol for making prototypes for the Diabolo.

Materials

- Mould for the prototype: consisting of 5 parts
- 2 Metal rings, 4 screws and bolts
- Mould release spray
- Ordinary dish washing soap
- Container with dry ice
- Injection pistol
- Cartridge silicon rubber Principality Bellow Silicone Z001
- Pressure cylinder
- Shortened knife

Method

Preparation working area

- Put the silicone on the dry ice, put a sheet of plastic between the ice and the cartridge
- Clean the working area
- Put all the necessary tools on the working area
- Place a paper towel over the work area

Preparation mould

- Clean the mould with water and dishwashing soap
- Dry the mould with a paper towel
- Blow compressed air through the filling and air holes to remove any water drops and paper
- Cover the inner surface of the mould with a very thin layer of mould release spray (Figure G-1)
- Reassemble the mould, make sure the holes for the screws are in one line
- Put some pieces of paper (0,5 mm) between mould parts 1 and 2 (Figure G-2)
- Insert and tighten the screws through the metal ring to finish the mould (Figure G-3)
- Put the mould in the dry ice for about 15 minutes

Filling

- Prepare the injection pistol and push out a little silicone to remove air bubbles
- Fill the mould up without hesitation or haste to reduce the chance of bubbles (Figure G-5)
- Stop filling when it's visible that the mould is completely filled up or silicone comes out of the air holes (leave out-coming silicone where it is, it is easier to remove when it is cured)
- Check if the entire mould is filled up
- Wipe off the top of the cartridge straight, so the silicone is removed of the top. Put the cap of the cartridge back at the used cartridge and put the cartridge back in the container with dry ice
- Put the mould in to the pressure cylinder and close it properly (Figure G-4)

- Connect the cylinder to the air hose (make sure the valve is open) and pressure it up (7 bar). Close the valve and disconnect the hose.

Curing

- Place the cylinder with the mould in the oven and cure at 70 degrees for about 45 minutes
- Take the pressure off the cylinder by opening the valve, and remove the mould from the cylinder
- Gently pull the silicone spill on top of the air and filling holes. Stretch and cut off with a knife.
- Loosen the screws and gently open the mould with the shortened knife. Put the knife in between two parts of the mould and gently push them away from each other, be very careful and don't hurry; patience is the best way (Figure G-7)
- Use the sprues to release the membrane from its mould. Don't pull too hard. (Figure G-6)
- Remove the sprues from the product with a surgical knife
- Done!

Clearing up

Clean the mould with water and ordinary soap. Also clean the bench and remove the leftovers of cured silicon rubber. Put all the used tools back where they belong.

Figure G-1: put mould release spray on mould parts

Figure G-2: add pieces of paper between mould parts 1 & 2

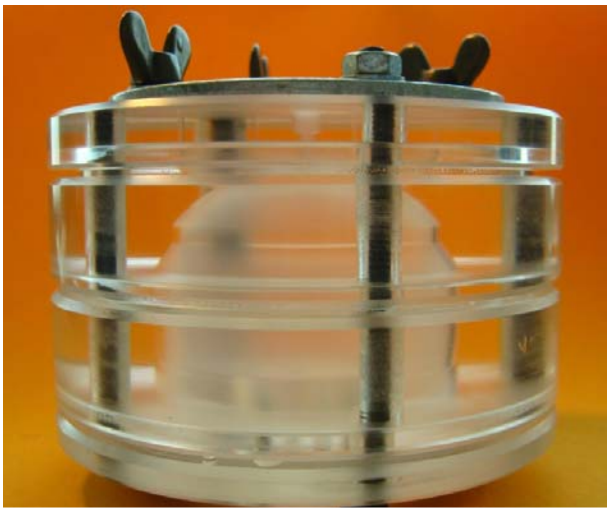


Figure G-3: reassemble the mould

Figure G-7: fill the mould

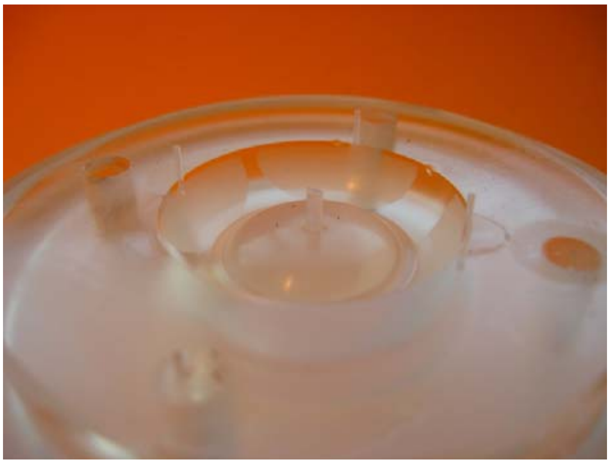


Figure G-4: use sprues to release membrane from its mould

Figure G-5: put shortened knife between mould parts

Figure G-6: mould in pressure cylinder

H Prototype List

Nr.	Photo	Result	Comments
1		Tear **Testable**	Forgot to cut away the surplus Cut away the whole membrane for testing
2		Tear Worse	Too little mould release spray <u>Breathing holes in sphere</u>
3		Good Worse	Added 0,1 mm paper between mould 1 & 2 <u>Added ‘ribs’</u>
4		Air bubbles	Added 0,2 mm, problem with cartridge

5		Good Worse	Added 0,2 mm Added ‘nobs’
6		Tear	0,3 mm. Tore when making breathing hole
From here every time 0,5 mm was added between mould part 1 and 2			
7		Tear	Tore when making breathing hole
8		Air bubbles **Good** **Good**	Large air bubble in the top Bubble filled with silicon, small tear in side Added ‘ropes’

9		**Good**	Small air bubble.
10		Air bubble **Good**	 Big bubble filled with silicon
11		**Good**	
From here every time a small tube was added as a sprue to remove air bubbles			
12		Tear	Small bubble in membrane tore

13		Air bubbles	
14		**Good**	Small bubble in top, side bubble filled
15		**Perfect**	
16		Perfect Worse	 <u>Added ‘ribs’</u>

17	 	Tear	Small piece tore from membrane
18	*No photo*	Tear	Small piece tore from membrane
19	*No photo*	Perfect Worse Worse	 <u>Added 'ribs'</u> <u>Cut small ring of membrane</u>
20	*No photo*	**Perfect**	

I In Vitro Testing

To evaluate the prototype, it's tested in vitro. The prototype is placed on the artificial lung (B.A.R.T) to measure its opening pressure, closing flow and breathing resistance (see Figure I-1). If these tests had shown that it's very likely to function on real patients, then the prototype would also be tested by real patients to get feedback on the functioning of the prototype.

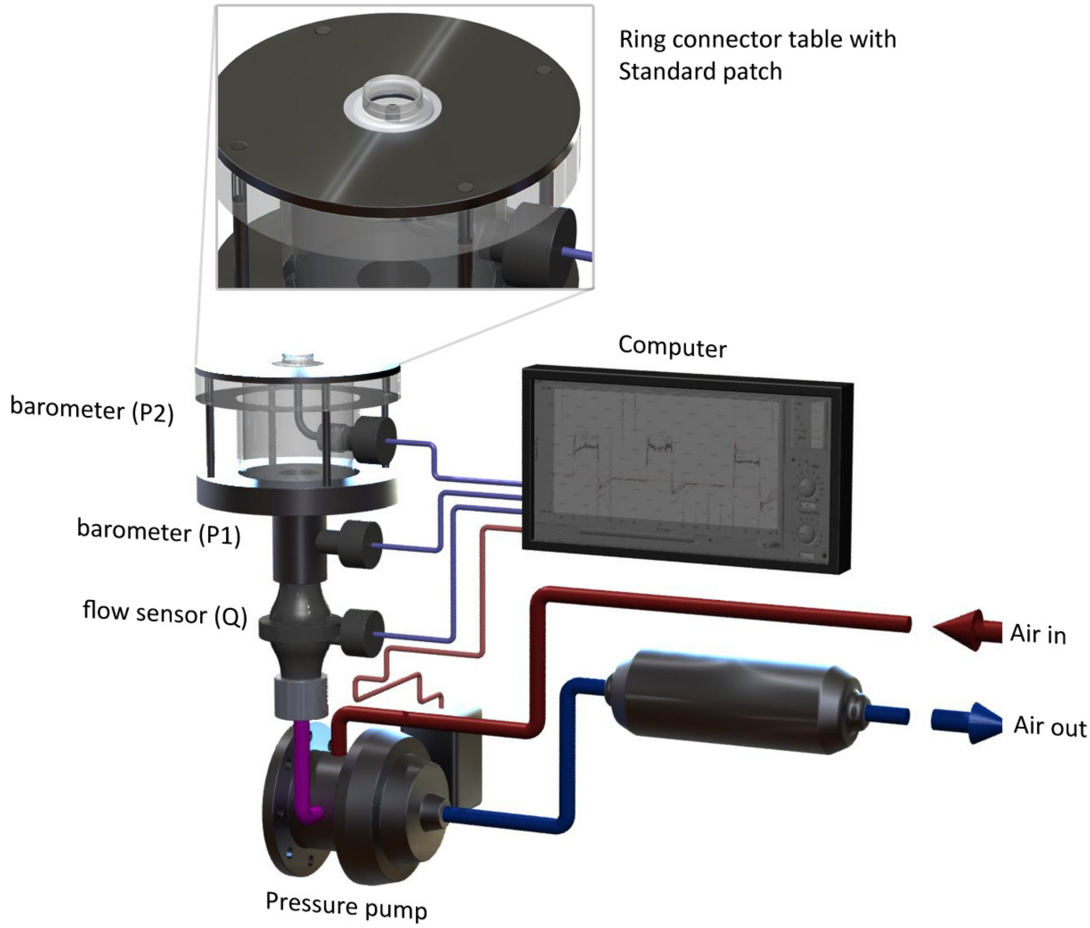


Figure I-1: schematic representation of the B.A.R.T and its parts.

The B.A.R.T. is a test set-up which makes it possible to put a certain pressure on a tube which ends in a standard patch. This pressure is controlled with a computer program and can be a function with time to mimic a normal breathing person. The flow of air is measured at the end of the pressure pump and two barometers measure the pressure in the tube. For the experiments described below, barometer P2 gives relevant results.

I.1 Closing flow

I.1.1 Aim

Aim of this test is to know if it's likely that a patient can use the Diabolo to talk. By executing this experiment more will be known about the required flow to close the prototype for talking.

I.1.2 Hypothesis

To close the Diabolo a strong inhalation flow is needed. Because of the resistance of the flow of air through the breathing holes a low pressure is created underneath the sphere, sucking the sphere inward, making it buckle. This means the required flow depends on the amount and size of the breathing holes. Charissa Roossien (2010) showed the closing flow isn't influence by the thickness of the sphere. With 4 breathing holes she measured a closing flow of -2,0 L / s for the UFO while the UFO was designed to close at a flow of -1,2 L / s.

Because the amount and size of the Diabolo's breathing holes are the same as in the UFO, it's expected to see the same closing flow. However, because the base (the cylinder) of the prototype is flipped inside-out, the sphere already has some pretension towards an opened position, so the closing flow is likely to be a bit higher.

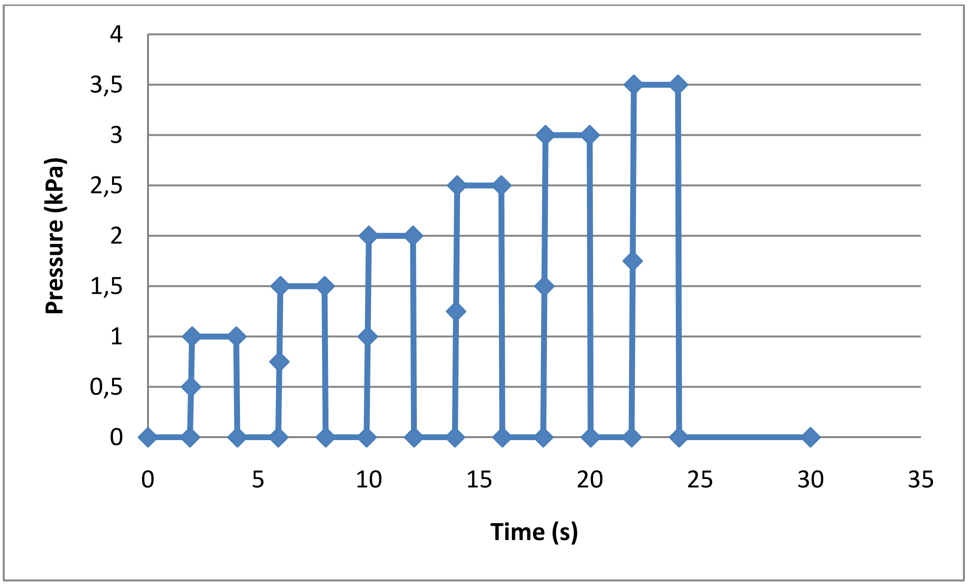
I.1.3 Materials and methods

The artificial lung is used to execute this measurement. Unfortunately it's only able to exhale air. To mimic inhalation, the end of the artificial lung can be put upside down (see Figure I-2). The prototype is placed on this downward and opened position. No HME-filter is used. The results is processed using Microsoft Excel 2007.

Figure I-2: the B.A.R.T. with a UFO placed in downward position

I.1.4 Procedure

For several times, the artificial lung will put a pressure on the prototype to mimic a short forceful inhalation. The amount of pressure is increased at every exhalation (as shown in the graph) until the prototype closes. If the prototype closes, the prototype is opened again and the test is repeated with increasingly smaller steps. On the screen of the connected computer the closing flow can be read from the graph. This is done 3 times for 4 identical versions of the prototype. When the pressure is set at zero kPa, the bias pressure and flow are noted to be subtracted from the measured values.



I.1.5 Results

The closing flow of the prototype is -2,31 ± 0,10 L / s, which corresponds with a vacuum pressure of 0,66 ± 0,03 kPa. The bias pressure and flow were respectively 0,05 kPa and 0,09 L / s.

I.1.6 Discussion

The aim was to have a closing flow of -1,2 L / s, but it's no surprise that it's close to the measured closing flow of the UFO. For people with normal functioning lungs, this should suffice as their peak inspiration flow is between -2,8 and -7,4 L / s (Depledge, 1985). However, the aim was to have a closing flow of -1,2 L / s, so to reach this value some adjustments should be made to the design of the prototype.

With the current setting, a too forceful inhalation is needed to create enough vacuum pressure inside the prototype to suck the sphere inwards. This required vacuum pressure is a constant and depends on the shape of the sphere and the connection to the rest of the prototype; the hinge. This shouldn't be adjusted as it is fully responsible for the opening pressure. Instead, the size of the breathing holes should be adjusted to change the closing flow. With the closing flow too high and the closing pressure being a constant, it can be said the resistance of the breathing holes is too low. So to decrease the closing flow, the breathing holes should shrink to create more resistance.

Just before closure, the resistance of the breathing holes is $0{,}66/2{,}31^2 = 0{,}12\ kPa\ \cdot s^2/L^2$. Assuming the vacuum pressure is constant, to reach a closing flow of -1,2 L / s, the resistance of the breathing holes should be increased to $0{,}66/1{,}2^2 = 0{,}46\ kPa\ \cdot s^2/L^2$ which is just at the limit of acceptable resistance. A solution should be found to have a parachute effect; until it unfolds it has only very little resistance, but unfolded it has a great resistance. The membrane could act like this when it is sucked inwards on strong inhalation to reduce the opening of the breathing holes.

I.1.7 References

Depledge, M.H. (1985). Peak Inspiratory Flow: Measurement Using a Modified Mini Wright Peak Flow Meter. *Thorax, 40*. 205-206.

Roossien, C. (2010). *Improvement of a tracheostoma valve*. (Unpublished graduation paper). Stenden Hogeschool, Emmen.

I.2 Opening pressure

I.2.1 Aim

Aim of this test is to know if it's likely that a patient can use the prototype to talk. By executing this experiment more will be known about the required pressure to open the prototype after talking.

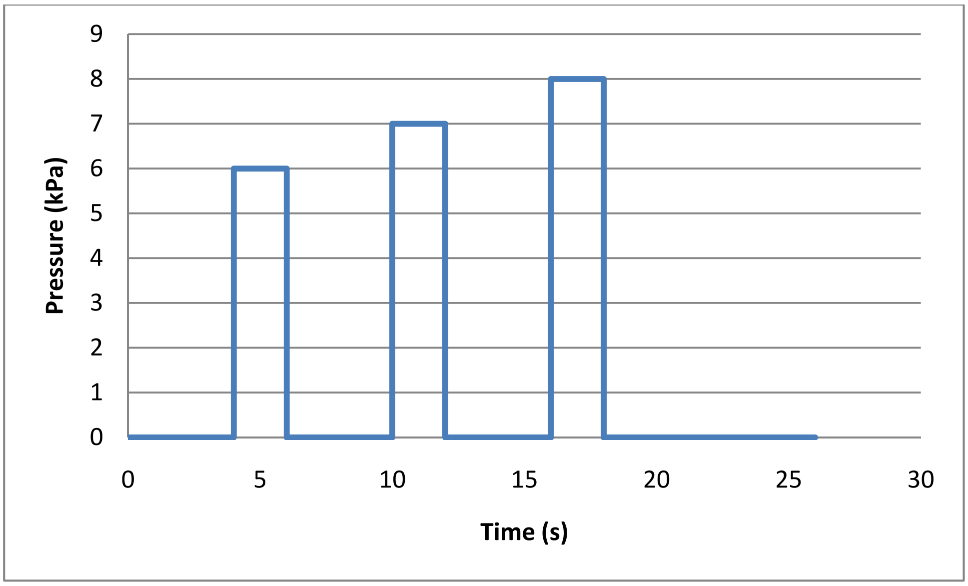
I.2.2 Hypothesis

In closed position, no exhaled air can flow through the Diabolo, so to open the Diabolo a strong exhalation pressure is needed. With enough pressure the sphere will buckle into its opened stable position. The opening pressure depends fully on the shape, diameter and thickness of the sphere and its hinges. Charissa Roossien (2010) showed that the UFO with a thickness of 1,24 mm has an opening pressure of 5,0 kPa. Because this is copied directly from the UFO it's expected to be similar.

The thin membrane, attached to the sphere, adds some rigidity to the sphere but is expected to be of little influence. This influence is probably compensated by the fact that the base of the prototype (the cylinder) is flipped inside-out which puts pretension on the sphere towards an opened position.

I.2.3 Materials and methods

The prototype is placed on the artificial lung in closed and upward position and the artificial lung puts a sudden pressure on the prototype which mimics a patient exhaling. This exhaling pressure is increased with every exhalation (as shown in the graph). Additionally, a linearly increasing pressure is put on the prototype to find out when it starts to leak.



The barometer P2 is placed just below the prototype because there the pressure differs from the pressure set by the computer. Again, no HME filter is used and Microsoft Excel 2007 is used to process the results.

I.2.4 Procedure

The opening pressure is measured by placing the prototype on the B.A.R.T. and putting increasing amounts of pressure on it. When the prototype opens, the experiment is finished and the barometer's last value before opening on which the prototype still didn't open is noted as the opening pressure. This is done 5 identical versions of the prototype.

To find the leaking pressure the graph of the flow is studied when a linearly increasing pressure (0,2 kPa / s) is set on the prototype. When the flow suddenly increases, it's clear that the prototype is leaking. The corresponding pressure is noted. This is done 3 times for 5 identical versions of the prototype.

I.2.5 Results

The measured opening pressure was 4,15 ± 0,16 kPa. The pressure upon which the prototypes started to leak was 3,96 ± 0,18 kPa.

nr.	**Leaking pressure (kPa)**			**Opening pressure (kPa)**		
	avg		*std*	*avg*		*std*
9	3,68	±	0,05	4,23		
11	3,90	±	0,08	4,28		
12	4,06	±	0,14	4,23		
14	4,00	±	0,06	3,88		
15	4,15	±	0,06	4,13		
	3,96	**±**	**0,18**	**4,15**	**±**	**0,16**

I.2.6 Discussion

The two measured values are very close to each other. This could be interpreted as that the prototype almost doesn't leak any air before opening. However, this isn't the case because it wouldn't explain the behavior of prototype number 14. The leaking pressure was measured with a linearly increasing pressure. When this pressure reached the previously found opening pressure, the prototype didn't open because the increase of pressure was too little. This means the opening pressure depends on the amount of time in which the pressure is put on the prototype. It's interesting to use different slopes in the increase of pressure, to find out what the influence is of time. With such an experiment a time depended opening pressure can be determined with unit Pa / s.

The measured opening pressure is close to the estimated 5,0 kPa. The fact that it's a little bit lower than the UFO is probably because the outside of the prototype is folded inside out which puts some tension on the sphere, pushing it into the opened position. It's possible that this has a larger influence than visible, but it's compensated by the extra rigidity the membrane gives to the sphere.

I.2.7 References

Roossien, C. (2010). *Improvement of a tracheostoma valve*. (Unpublished graduation paper). Stenden Hogeschool, Emmen.

I.3 Breathing resistance

I.3.1 Aim

Aim of this test is to know if it's likely that a patient can breathe comfortably with the prototype while talking. By executing this experiment more will be known about the breathing resistance of the prototype.

I.3.2 Hypothesis

Because exhaled air is blocked in closed position, 3 states remain: inhalation in opened position, exhalation in opened position and inhalation in closed position. In opened position air flows directly through the breathing holes so the breathing resistance only depends on the size and amount of breathing holes and the HME-filter. As this is expected to cause no problems these two measurements will not be done. However, the breathing resistance of the prototype for inhalation in closed position depends on the membrane blocking the breathing holes for exhaled air. This is interesting because test subjects mentioned this value to be too high for the UFO.

It's expected that the inhalation breathing resistance for the prototype in closed position is lower than for the UFO and is comfortable with a value below $500\ Pa \cdot s^2/s^2$. The resistance is expected to be lower at higher flow rates because then the membrane is folded away further.

I.3.3 Materials and methods

The prototype is placed on the artificial lung in downward (like in de closing flow test) and closed position and the artificial lung will put a continuous pressure on the prototype. Again the barometer is placed just below the prototype, no HME filter is used and Microsoft Excel 2007 is used to process the results. The breathing resistance (R) is calculated by dividing the measured pressure (ΔP) by the squared air flow (V^2).

I.3.4 Procedure

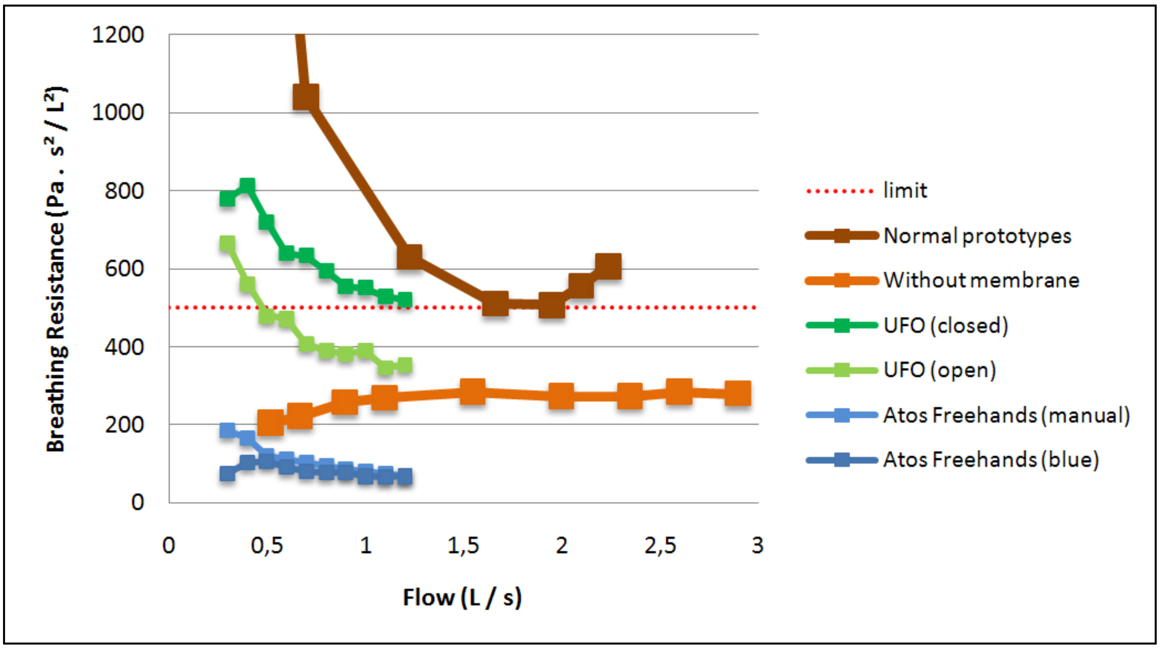
Because the artificial lung has an adjustable pressure, this is changed instead of changing the air flow which usually is done. Since the breathing resistance is expected to be below $500\ Pa \cdot s^2/s^2$, the pressure should be around

$$\Delta P = R \cdot V^2 = 500 \cdot 1{,}0^2 = 500\ Pa$$

For 9 different pressures (500, 600, 800, 1000, 1500, 2000, 2500, 3000, 3500 Pa) the pressure and flow is measured to calculate the breathing resistance. These measurements are done for 4 identical versions of the prototype. Additionally, one prototype is tested with the membrane cut away, to see what the influence of the membrane is on the breathing resistance.

I.3.5 Results

The breathing resistance of the prototype for inhalation in closed position is presented in the graph below. The dark red line represents the breathing resistance of the normal prototypes (n=4). Two points (flow = 0,1 and 0,2 L / s) are not incorporated because they were unrealistically high. The breathing resistance measured at 0,45 L /s was outside the scale of the graph (2,4 kPa · s^2 / L^2). The orange line represents the resistance of a prototype without a membrane. Results of previous measurements on the breathing resistance of the UFO and the Atos by Charissa Roosien (2010) are added to the graph.



I.3.6 Discussion

At a relatively low flow (below 1,0 L / s), the breathing resistance was measured to be extremely high. Two measurements were even excluded because it resulted in a breathing resistance of more than 100 kPa · s^2 / L^2. At these low flows the borders of the possibilities of the measurement equipment are reached so their deviations are of much influence. Nonetheless, it's not unlikely that the breathing resistance of the prototype is very high for low flows. The higher the flow, the further the membrane is pushed away resulting in a lower resistance. However, the graph shows a slight increase at even higher flows. This could be the result of a vibrating membrane. The membrane makes much sound at these high flows as it flaps against the inside of the prototype.

It's interesting to see that Charissa succeeded to make accurate measurements of the breathing resistance of the UFO at very low flows while the measurements of pressure and flow of the new prototype at similarly low flows seemed to be very inaccurate. Possibly the membrane of the new prototype has some strange influence on the flow of air which makes it fluctuate more.

To see the influence of the membrane, one prototype was tested with the membrane cut away represented with the nearly constant (261 ± 29 kPa $\cdot$ s^2 / L^2) horizontal orange line. The line makes the influence of the membrane on the breathing resistance very visible. The membrane not only makes the breathing resistance depended of the flow, it also almost doubles the resistance.

I.3.7 References

Roossien, C. (2010). *Improvement of a tracheostoma valve*. (Unpublished graduation paper). Stenden Hogeschool, Emmen.

J In Vivo Testing

With the results of the in vitro tests a proper estimation can be made towards the effectiveness of the prototype. If it's unlikely to function, or use of the prototype could be dangerous, then the in vivo tests will be skipped. If this is not the case at least 3 laryngectomees will be asked to test the prototype in comparison to the UFO and give their recommendations.

J.1 Aim

The aim of this use test is to get feedback from users to make recommendations towards the design of future versions and to be able to confirm decisions for the current design.

J.2 Variables

J.2.1 Dependent variables

In this test the appreciation of the user towards the design of the prototype will be tested. This means the following variables will be measured during the use test.

- <u>Difficulty of use</u>
  Measurement of number of tries and amount of required time to perform tasks in comparison to the UFO.
- <u>Usability</u>
  Observation while performing tasks and interview with test persons and comparison with the UFO.
- <u>Comfort</u>
  Interview with test persons with question about both comfort in use and comfort in wearing the TSVs.

J.2.2 Independent variables

The variables which are changed on purpose are the used Tracheostoma Valve (UFO vs. prototype) and the task performed by the test person. Additionally the prior knowledge of the test persons varies.

J.2.3 Environment variables (constants)

The order in which both TSVs will be tested will be the same for all test persons; first the UFO, then the new prototype. Test person's anxiety towards the new TSVs will be kept as low as possible to keep a low breathing pace. This will be done by first informing them about the project, explaining its functioning and taking the time to get used to using the TSVs.

J.3 Hypothesis

Since both the sphere and the breathing holes of the new prototype are copied from the UFO it's expected that test persons will notice only little difference in opening and closing the TSVs. However, the breathing resistance of the prototype in closed position should be lower than the UFO, and the test persons are expected to notice this.

J.4 Materials and methods

J.4.1 Task selection

An experienced doctor will check the TE-prosthesis. The researcher will place the droppatch around the tracheostoma and place the UFO and later the prototype. The researcher will ask the test person to perform a number of tasks and describe his feeling about it. In the end the researcher will ask the test person to answer some question about his experience with testing both TSVs.

J.4.2 Test persons

For this test, 3 test persons are asked to participate. All test persons have had a total laryngectomees, have a TE-prosthesis and are able to talk by manual occlusion. For this experiment it doesn't matter if they have any experience in talking hands free (by for example the use of Provox Handsfree HME-filter), because these new TSVs use inhalation instead of exhalation as activator. It is also irrelevant if they have participated in previous experiments with the UFO because this test is mainly focused on the comparison of the UFO and the prototype.

J.4.3 Set up

For every test person a droppatch, UFO (capseat and cap) and prototype (adjusted capseat and cap) will be prepared. No HME-filters will be used. During the test the researcher will note the time and amount of tries the test person need to perform the given tasks on a score form (see J.6 Score form). After the experiment the test persons are asked to answers questions from a questionnaire (see J.7 Questionnaire).

J.4.4 List of requisites:

- 1 doctor to check the TE-prosthesis
- 1 researcher
- 3 test persons
- 3 droppatches
- 3 UFO's (3 capseats, 3 caps)
- 3 prototypes (3 adjusted capseats, 3 caps)
- 3 score forms
- 3 questionnaires

J.5 Procedure

The test person is welcomed and the aim of this project and the procedure of the experiment are explained. He is also explained that he can take off the TSVs at any time. First the TE-prosthesis is checked to be sure the experiment can be executed safely. The droppatch will be placed around the tracheostoma and the capseat and cap of the UFO will be attached to the droppatch. The test person is asked to breathe normally, then to close the UFO by inhaling strongly and immediately opening it again. If the test person is able to do this without much trouble he is asked to close the UFO and to speak. During speech he is asked to breathe in without opening the UFO. After performing all these tasks, the UFO (cap and capseat) is removed and the new prototype (and the adjusted capseat) is placed. For the prototype the test person is asked to perform the same tasks.

While performing these tasks the researcher takes notes on the score form. When the experiment is done, the test person is asked to answer questions from the questionnaire about the prototype in comparison to the UFO.

J.6 Score form

Score form to be filled in by the researcher during the use test.

J.6.1 Administration

Date ______ - ______ - __________

Test person ____________________

Researcher ____________________

Doctor ____________________

J.6.2 Preparations

TE-prosthesis checked ❑

Droppatch placed correctly ❑

J.6.3 Tasks

	UFO			Prototype		
	Yes / no	Tries	Time	Yes / No	Tries	Time
1) Breathing without closing						
Comments						
2) Closing voluntarily						
Comments						
3) Opening voluntarily						
Comments						
4) Talking without opening						
Comments						

J.7 Questionnaire

J.7.1 Functioning

1) What is the difference in breathing through the UFO and the prototype? What do(n't) you like?

____

____

2) What is the difference in closing the UFO and the prototype? What do(n't) you like?

____

____

3) What is the difference in opening the UFO and the prototype? What do(n't) you like?

____

____

J.7.2 Talking

4) How is it to talk with the UFO? (Comfortable? Easy?)

____

____

5) How is it to talk with the prototype? (Comfortable? Easy?)

____

____

6) What is the difference with manual occlusion?

____

____

7) How is it to inhale while talking?

____

____

J.7.3 Design

8) How do you like the material?

____

____

9) What do you think about the appearance of the UFO and the prototype?

____

____

10) What do you think about the name 'UFO'?

____

____

11) What do you think could be improved in future versions?

____

____

K Umbrella

The membrane of the Diabolo needs some adjustments to make it function well. With a new membrane, called Umbrella, the problems should be solved and it should be possible to produce a working prototype.

In SolidWorks the moulds have been designed for this new membrane (Figure K-1). Only 2 parts are different from the original parts from the Diabolo: part 1 and 2 (Figure K-2).

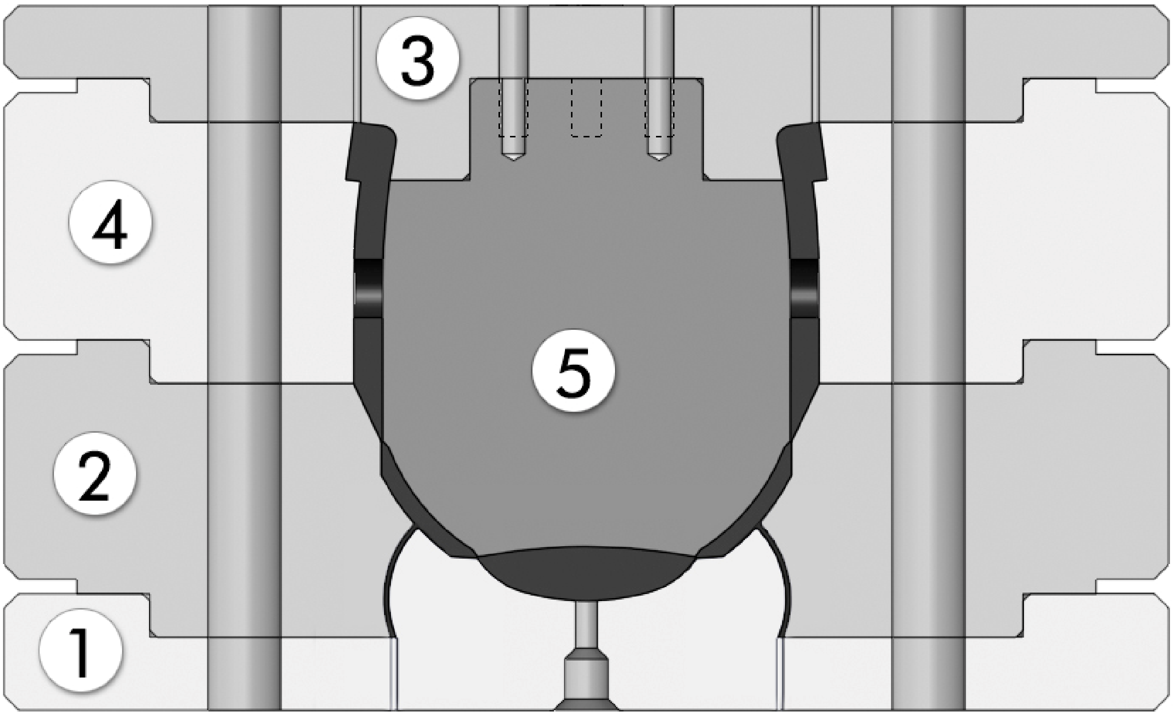


Figure K-1: cross-section view of the new mould parts. Only part 1 and 2 are different from the Diabolo.

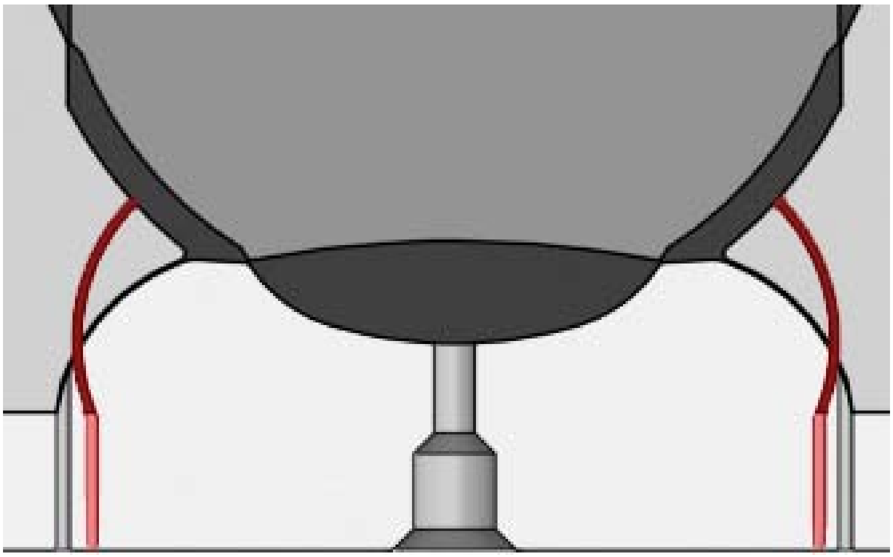


Figure K-2: the new membrane (red) is attached normal to the sphere whereas the Diabolo's membrane is attached tangent to the sphere.