Development of a membrane based
Voice Producing Prosthesis

A Bachelor assignment of the
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P. Stehouwer
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Study for improvement of a Voice Producing Prosthesis

Executed at:
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Biomedical Engineering Department

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Summary

In severe cases of laryngeal cancer it is sometimes necessary to remove the larynx (the voice box) completely, this is called laryngectomy. During this operation the windpipe (the trachea) is separated from the voice box and bypassed to an opening at the bottom of the neck through which the patient can breathe.
To be able to speak an air valve is placed between the windpipe and the gullet (the esophagus). In this study the commonly used Groningen Button is used. The valve allows air to flow to the mouth again but prevents food and drinks from reaching the lungs. The patient's voice after this kind of procedure often is of very low quality. At the University Medical Center Groningen (UMCG) a new kind of prosthesis has been developed which can be placed inside the Groningen Button and should improve the quality of the voice. Goal of these prostheses is to give laryngectomy patients a natural sounding voice again. The developed prosthesis is based on two parallel membranes which vibrate when the air passes between them; this vibration causes a certain sound. The pitch now created by the prostheses is however to high, especially to create a male voice.
By weighing the membranes the pitch can be lowered, first by using small weights; in a later phase Tungsten powder is used. The technique used to make the prototypes is too time-consuming to use in a large series.
The goal of assignment is to revise and improve both the sound properties and the production technique. (chapter 1)

There are several features which influence the frequency of the prosthesis. Some of which can be changed. The formula used to determine these features, the formula string under tension, is also used in the earlier development of this prosthesis. The formula is used to describe the influence of various features in the case of weights attached to the membranes and derived to a formula for a homogeneous membrane. Subsequently, the changeable properties, like elasticity, thickness and mass, are listed and elaborated. (chapter 2)
These variables, which could be used to lower the frequency, lead to some choices in material, configurations and production methods. A porous membrane is chosen made from polyurethane weighted with Tungsten powder. To make these membranes two methods are chosen: spreading and dipping. (chapter 3)

A selection of combinations in the variables of the membranes was made and tested to determine the influences of, for instance, the porosity on the elasticity and the effect of the different properties on the frequency. Due to a lack of available time in the lab in Enschede and failed membrane samples only part of the selection is made, these samples were later tested. (chapter 4)
The test results made it clear both techniques can be used to create very porous membranes with a relative high quantity of Tungsten powder. The elasticity of the membranes, at least the ones made by spreading, looks promising. (chapter 5)
No membrane was found which could fulfill the requirements. The test results have however clarified some aspects of the prosthesis and more specifically the ones with homogeneous membranes. The influence of the thickness of the membranes has, as now shown, primairaly effect on the pressure threshold needed for the membranes to vibrate. The influence of the thickness on the frequency seems small. Another thing that is shown in this study is the importance of the a well chosen base material: the two polymers did not only differ in viscosity and elasticity, but also in porosity and the amount of Tungsten powder which could be added without causing troubles. (chapter 6)

The possibilities for series production of the membranes are studied. But without an adequate membrane configuration a decision can not be made (chapter 7)
To make the design of the prosthesis suitable for series production a variety of concepts is developed. The possibilities to assemble the membrane got most attention because of the difficulties encountered during the assembling of the prototypes. A concept that consists of two housing halves between a conical-dipped membrane is clamped is chosen. (chapter 8)

Universiteit Twente
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Titel Bachelor eindopdracht:
Study for improvement of a Voice Producing Prosthesis

Uitgevoerd bij:
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Samenvatting

In ernstige gevallen van keelkanker is het soms noodzakelijk om de larynx (het strottenhoofd) in zijn geheel te verwijderen, dit noemt men laryngectomie. De luchtpijp (de trachea), die bij deze operatie wordt losgesneden van het strottenhoofd, wordt naar een opening onder in de nek wordt geleid waardoor de patiënt kan ademen.
Om te kunnen spreken wordt er een ventiel tussen de luchtpijp en de slokdarm (esofagus) geplaatst. In deze studie wordt uitgegaan van een veelvuldig gebruikt ventiel, de zogenoemde Groningen Button. Dit ventiel zorgt dat lucht weer bij de mondholten kan komen terwijl het voorkomt dat eten en drinken in de longen komt. Het stemgeluid dat de patiënt na deze ingreep heeft is echter van zeer lage kwaliteit. Aan het Universitair Medisch Centrum Groningen (UMCG) is gewerkt aan een prothese die in de Groningen Button geplaatst kan worden en die de kwaliteit van de stem verbetert. Het doel van deze prothese is om patiënten weer een natuurlijk klinkende stem te geven. De ontwikkelde prothese werkt door middel van twee paralel gespannen membranen die trillen als er lucht tussen stroomt, deze trilling veroorzaakt een zeker geluid. De toonhoogte die nu echter gerealiseerd wordt is te hoog, zeker om een mannelijke stem te vormen. Door het membraan te verzwaren kan de toonhoogte verlaagd worden, hierbij is eerst gebruik gemaakt van gewichtjes; in een later stadium van wolfraampoeder. De productietechniek die gebruikt is om de prototypes maken is te omslachtig om een grote serie mee te produceren.
Deze opdracht is bedoeld om zowel de geluidseigenschappen als de productietechniek te herzien en te verbeteren. (hoofdstuk 1)

Er zijn verschillende factoren die de frequentie van de prothese beïnvloeden. Sommigen hiervan kunnen veranderd worden. Hiervoor wordt gebruik gemaakt van de formule, voor een gespannen snaar, die tijdens onwikkeling van deze prothese ook is gebruikt. De formule is gebruikt om de invloed van verschillende factoren in de situatie met gewichtjes te beschrijven. Daarna is een afleiding gemaakt naar een voor een homogeen membraan. Vervolgens zijn de factoren die mogelijk aanpasbaar zijn, zoals elasticiteit, dikte en massa, benoemt en uitgewerkt. (hoofdstuk 2)
Deze variabelen, die voor frequentieverlaging kunnen zorgen, hebben vervolgens geleidt tot materiaalkeuzes, configuraties en productiemogelijkheden. Hierbij is gekozen voor poreuze met wolfraampoeder verzwaarde membranen van polyurethaan. Ook is de keuze gemaakt voor twee productietechnieken om de membranen te maken: smeren en dompelen. (hoofdstuk 3)

Verschillende samenstellingvariaties van de membranen zijn opgesteld en gemaakt om vervolgens te worden getest en de invloed van bijvoorbeeld de porositeit op de elasticiteit te meten en de uitwerking van de verschillende eigenschappen op de frequentie. Door gebrek aan beschikbare laboratoriumtijd in Enschede en mislukte membraanmonsters zijn echter slechts een deel van de beoogde membraanvariaties gemaakt, deze monsters zijn vervolgens getest. (hoofdstuk 4)
De resultaten van deze tests laten zien dat beide gekozen technieken zeer poreuze membranen met een relatief grote hoeveelheid wolfraampoeder kunnen vormen. De elasticiteit van de membranen, tenminste die gemaakt zijn door smeren, lijkt gunstig. De frequentietesten geven echter waarden die ver boven de eisen liggen. (hoofdstuk 5)
Er is geen membraan gevonden dat aan de eisen voldoet. Wel hebben de testresultaten geleid tot meer duidelijkheid omtrent de prothese en dan vooral de mogelijkheden om homogene membranen te gebruiken. Zo is naar voren gekomen dat de dikte van de membranen vooral van invloed is op de druk die nodig is om de membraan te laten trillen, de invloed op de frequentie zelf lijkt, zoals verwacht, beperkt. Ook is bevestigd dat de keuze van het basismateriaal belangrijk is: van de twee verschillende polymeren is niet alleen verschil in viscositeit en resulterende elasticiteit aangetoond, maar ook de porositeit en de hoeveelheid wolfraampoeder die zonder problemen kon worden toegevoegd varieerde. (hoofdstuk 6)

Vervolgens is er gekeken naar verschillende mogelijkheden voor serieproductie van de membranen. Zonder een goede membraan configuratie is hier echter geen beslissing in te nemen. (hoofstuk 7)
Om de vormgeving van de prothese voor serieproductie geschikt te maken zijn enkele concepten gemaakt. Hierbij is vooral gekeken naar een eenvoudiger bevestiging van de membranen in de behuizing, dit bleek tijdens het maken van de prototypes namelijk erg lastig. Er is gekozen voor een behuizing die uit twee delen bestaat waar een gedipt membraan tussen geklemd wordt. (hoofdstuk 8)

Contents

1 Introduction

1.1 The vocal folds

Speech is a complicated human skill which involves many mechanisms; important in creating a voice are the vocal folds or vocal cords. The vocal folds are positioned at the base of the voice box or larynx and consist of two membranes which are open during normal breathing but closed during speech or singing. When the air from the lungs passes through the elastic vocal folds it causes them to vibrate and produce a tone. The frequency of the tone depends on the tension of the folds and can be altered by muscles in the larynx. The sound travels through the vocal tract forming speech. The nasal and oral cavities transform the sound into vowels and words and thus speech.

1.2 Laryngectomy

Patients who suffer from advanced laryngeal cancer are often treated by removal of the larynx and thus the vocal folds (figure 1.1_A). The windpipe or trachea is diverted to an artificial opening at the base of their neck (figure 1.1_B). Speech is made possible by a valve, e.g. the Groningen Button, between the trachea and the esophagus (gullet) (figure 1.1_C). By closing the opening in the neck the air flows through the valve into the remaining soft tissue structures, causing the tissue to vibrate and producing a sound which can be used for speech. However, the quality of the voice is sometimes very poor and badly audible. This, of course, has a tremendous impact on the patients.

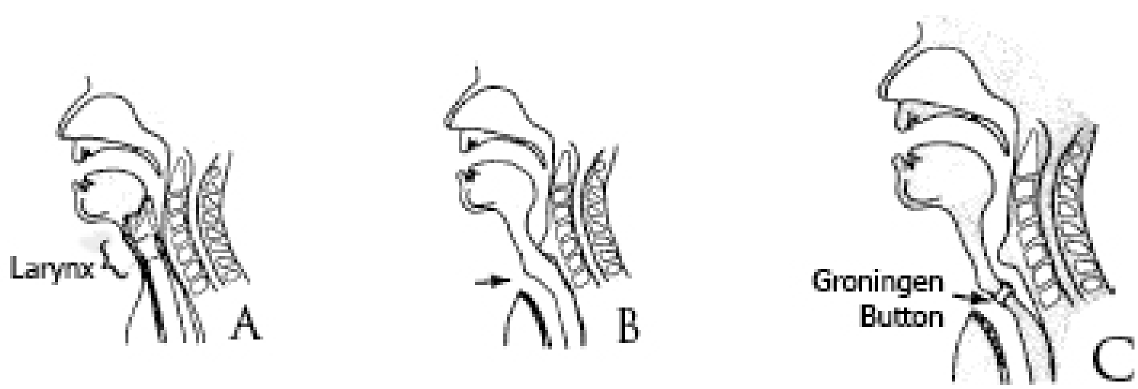

Figure 1.1: *Laryngectomy and Groningen Button*

1.3 Voice prostheses

In order to improve the voice of these patients several prostheses have been designed over the years. None of them create a good enough natural sounding voice or is without flaws.

At the Biomedical Engineering department of the University Medical Center Groningen (UMCG) a new kind of prosthesis has been developed. This prosthesis is based on two parallel membranes which vibrate when the air passes between them. The prosthesis is designed to fit inside the commonly used Groningen Button. This voice producing element or VPE, as the prosthesis is also called, has to produce a natural sounding voice with higher harmonics and possibilities for intonation and should function with long-pressures normal for the patients.

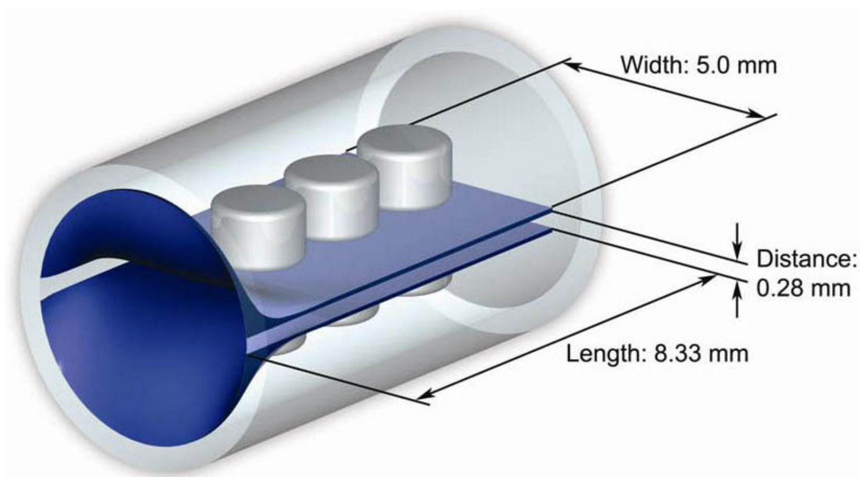

Figure 1.2: *Model of the voice prosthesis*

1.3.1 Functions of the voice prostheses

The main function of the prosthesis is to change energy of the air flowing from mechanical into acoustical energy. Another function is to enhance the voice in a way that allows the patient to articulate better and to generally improve his ability to speak. The patient should be able to alter his fundamental frequency and loudness of the voice by manipulating the airflow: an increasing airflow should result in a higher frequency and higher loudness. The prostheses must be reproducible with high quality and constant properties in a series production.

1.3.2 Physical requirements

The voice prosthesis will be placed inside a shunt valve (e.g. a Groningen button) which is located between the trachea and the esophagus. This shunt valve has an inner diameter of 5 mm and has a length of 5 to 11 mm depending on the thickness of the tissue wall in which it is placed with a median length of 10 mm, so 10 mm should be taken as a maximum for the prosthesis. An even smaller prosthesis would be even better. The used prototypes are 10 mm.

Figure 1.3: *Prosthesis placed inside a Groningen Button*

The membranes need to be kept stretched; this pre-strain has to be constant throughout the prosthesis's lifetime to maintain its voice characteristics. During the time the prosthesis is not used the membranes have a distance between them, these resting positions and set distance also have to be constant. The membrane has to be fixated on all edges, except the rear edge. The front edge has to be fixed to ensure the air flows only between the membranes. This is vital for the functionality of the prosthesis and for keeping the space between the membranes free from mucus.

1.3.3 Environmental restrictions

Due to a biofilm (remains of food and bacteria) forming on the esophageal side of the valve, the valve has to be replaced every 3 to 4 months. The biofilm could otherwise cause the valve to fail, keeping it permanently closed or open. The voice producing element must be able to function constantly and reliably for at least these 4 months, preferably for an even somewhat longer time.
The VPE itself is not to be expected to be subject to (major) biofilm formation, because it is located behind the one-way valve. However, mucus from the lungs, which enters the element during use, is considered to be an important threat to the oscillating mechanism of the VPE. The material of which the VPE will be made has to be resistant to the warm humid environment; a coating with a resistant material may also be possible.

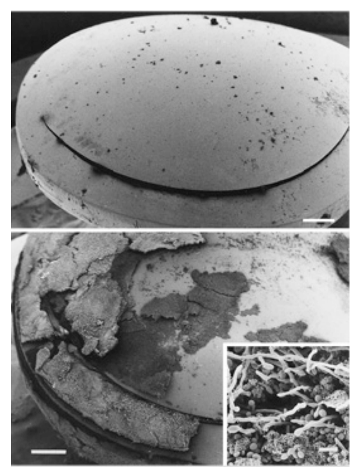

Figure 1.4: *Biofilm on Groningen Buttons (bars equals 1mm, 10 µm for inset)*

The materials used have to be strong enough to ensure save use. If (part of) the VPE would come loose, and would find its way to the lungs or elsewhere in the body, it must not cause major damage. It should therefore be made of a biocompatible and bio-stable material.

1.3.4 Functional requirements

In healthy people the driving lung pressure, necessary to produce a normal speaking voice, normally ranges from 0.2 to 1.5 kPa (lung pressure can reach levels above 3 kPa). The airflow ranges from 45 to 350 ml/s. The VPE should function under these conditions.
To produce a male voice a fundamental frequency (F_0) of 120 Hz is required; this is 210 Hz in the case of a female voice. Harmonics of the fundamental frequency (up to 4 kHz) should be present in the sound signal. This is to allow the pronunciation of distinguishable vowels. To make the voice sound natural, the VPE should provide the means for intonation during normal speech. For a natural intonation pattern the fundamental frequency and sound pressure level of the substitute voice should be controllable. For a healthy laryngeal voice, the frequency variation during normal phonation measures about 7 semitones (≈50%). The voice must have an appropriate sound pressure level. This level should lie in the range of 60 to 80 dB, measured at a distance of 0.3 m from the mouth.

Table 1.1: *Requirements for a voice prosthesis*

General requirements		
Fit inside a Groningen Button	Ø 5, length 10	mm
Produce an appropriate tone for males or females	120 or 210	Hz
Produce higher harmonics to the F_0	up to 4000	Hz
Function with a normal driving lung pressure	0.2 to 1.5	kPa
Function with normal airflow levels	45 to 350	ml/s
Produce an appropriate sound pressure level (measured 0.3 m from the mouth)	60 to 80	dB
Allow intonation	7	semitones
Function constantly and reliably	< 3	months
Be biocompatible		
Be biostable		
Withstand a humid, warm and possible acid environment		
May not cause injuries		
Housing specific requirements		
Allow air inflow		
Keep the membrane stretched (maintain pre-strain)	0 to 2%	
Maintain a constant membrane distance (at rest)	0.28	mm
Fixate the membrane lengthwise		
Fixate the membrane widthwise		
Be producible in series production		
Be reproducible with constant quality		
Have sufficient stiffness / strength		
Membrane specific requirements		
Low elasticity	< 3	Mpa
No strain relaxation	< 5%	
Tear resistant	> 2	kN/m

1.3.5 Development of the prosthesis

The Biomedical Engineering department of the UMCG has done research concerning the restrictions and possibilities of this prosthesis. This research was done in particular by J.W. Tack during his work for his doctor's degree.

An important issue in the development of the voice prosthesis is its fundamental frequency. The frequency range of a tracheo-esophageal voice is 60 to 90 Hz, which is very low. To create the wanted frequency (120 Hz for male and 210 Hz for female), a membrane with enough mass is needed; the tone would otherwise be too high. Tack attached weights to the membranes to achieve this. In the prototypes there are three weights that each measure 1.83 x 1.66 x 1.23 mm attached to both membrane halves. The membranes were made by dip molding. While using a magnet to keep the weights fixed on the mold they were enclosed inside the membrane. The magnet could be easily removed as the membrane was ready. This way the weights were captured inside the membrane on set positions.
Tack did several types of tests and came with a prototype which he used in in-vitro-experiments and eventually in-vivo-experiments. These prototypes were only tested on women because the frequency range of the prostheses was 180 to 300 Hz.

The in-vivo tests showed female patients can benefit considerably using the voice prosthesis; in many cases talking was easier with the prosthesis and the voice pitch and volume were much better.

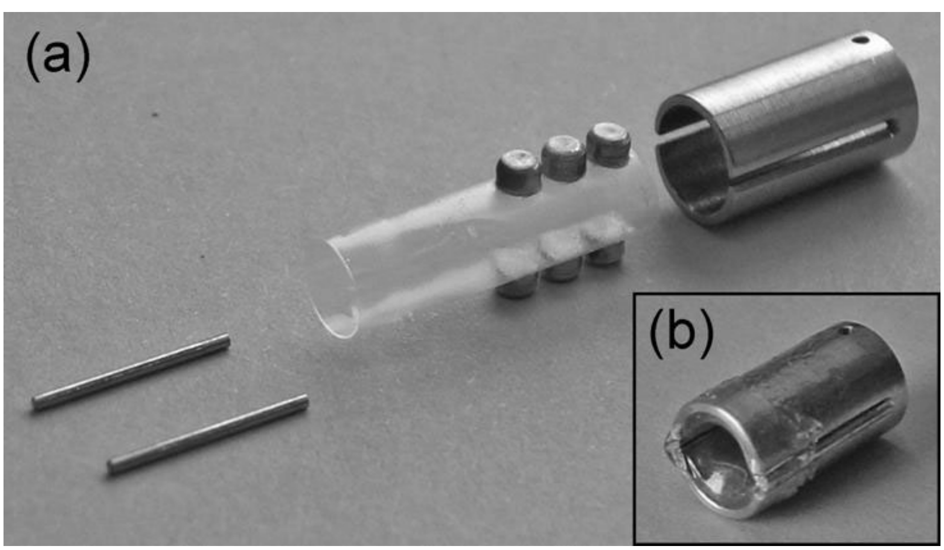

Figure 1.5: *Exploded view of voice prosthesis (a) and assembled prototype (b)*

The main problems that remained were the lack of prostheses for men and the possibility to make a series to extend the in-vitro testing. Due to the limited space inside the Groningen Button the prosthesis can only measure 5 mm in diameter and 10 mm in length. This limits not only the size of the membrane but also the size of the weights. Another disadvantage of the use of these weights is the time consuming and difficult production method of the prosthesis.

In a later stadium J.W. Douma, a student at the University of Twente, also worked on this product. In this study he tried to find another way to make a membrane with enough mass that would be easier to produce and which could create a fundamental frequency low enough to use in male prostheses.

The lead weights, enclosed during the casting of the membranes by the dipping process, proved to be time consuming and difficult. Douma tried mixing Tungsten powder with polymers and so integrated the mass inside the membranes. Tungsten is a material with a high density and is often used as an additive in various plastics applications. His results were promising and proved to be a good way for enlarging the weight of the membranes.

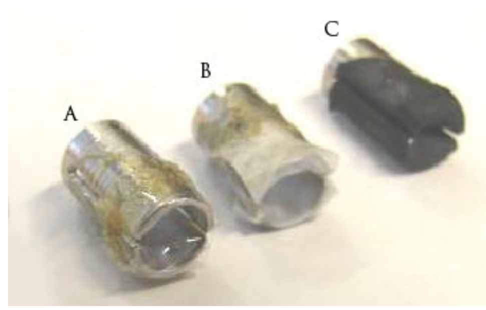

Figure 1.6: *Prototypes by J.W.Douma with Tecoflex membranes*
A: Solid B: Porous C: With Tungsten

Douma also looked at possibilities to produce a housing to hold the membranes and tested the possibilities to alter the tone using porous membranes with a lower elasticity. He used a solution of the polyurethane Tecoflex (EG-80A) weighted with Tungsten powder, which he spread out to a thin film. He made some samples with different percentages of Tungsten (0%, 20% and 33%). These membranes were tested on porosity, elasticity and the fundamental frequencies they produced when placed in a prototype.

Table 1.2: Test combinations and results by J.W. Douma

Nr	Solver-Mass% PUR:THF	Total-Mass% Tungsten	Thickness (µm)	Porosity (%)	Elasticity (at 10% elongation) (MPa)	F_0 (at 1 KPa) (Hz)
J1	5	0	40	5	5	2100
J2	10	0	40	12.5	2.9	1310
J3	10	0	100	12.5	2.9	
J4	10	20	65	35	3.9	
J5	10	20	70	35	3.9	
J6	10	33	70	52	2.9	790
J7	10	33	70	52	2.9	

Douma succeeded in making thin membranes weighted with Tungsten. The tests showed the frequencies produced by the made compounds were too high to use in voice prostheses. Further study was recommended, not only to examine the production possibilities but especially to attain a lower frequency.

1.3.6 Problem analysis

Redesigning the prostheses involves overcoming some obstacles, these are partly obstacles already encountered by my predecessors, mentioned in the first chapter.
The size of the prosthesis is not only a problem for the frequency; it also makes it harder to produce, handle and assemble. The membrane has to be flexible but also strong and tear resistant. Earlier prototypes show it is difficult to produce these membranes with the right properties necessary for a normal speech sound. The homogenous membranes should be easier to produce and assemble.

The resulting frequencies are far from the required frequency but the used techniques show possibilities to make this difference smaller.

There are strict limitations to the housing- and membrane material to use, not only to strength but also concerning biocompatibility and resistance to the (humid) environment in the throat. The Groningen Button in which the prosthesis is placed is replaced every three months so the prosthesis has to function for at least three months without clogging or tearing. A possibility to avoid problems concerning this environment is to develop a disposable prosthesis which the patient could replace himself every day. This however would probably raise even more problems and the costs would have to be significantly lower.
The housings of the prototypes were made of metal; tests show that plastic housings can also provide enough strength. For a series production this provides us with more possibilities.

The major difficulties however, lie with the membrane; the material and configuration to make a suitable membrane which can produce the right frequency are to be found.
To find the right properties to get this frequency is a challenge, especially a frequency for a male voice. Also the making and placing the membrane will need further attention.

1.4 Goal of the project

The main goal of this bachelor assignment is to design and make a new prototype of a voice prosthesis. The new prosthesis must have better results in fulfilling the requirements, especially the requirement for a lower frequency and series production.

Once a suitable prosthesis is found it will take much testing to fine tune the design and to establish a fundamental proof for its benefits. For that reason a test series of 100 prostheses to use in in-vivo testing is needed. Another goal of this project is therefore to find a production process to produce this series of 100 prostheses. Important for this process is to ensure the prostheses have a constant high quality and equal properties.

2 Theoretical methods to lower the frequency

The element consists of two parallel membranes fixed inside a tube. The air flows through the small opening between the membranes causing them to vibrate and periodically open and close the airway. As a reaction the air itself will start to vibrate in the same frequency which causes an audible tone.
An approximation for the fundamental frequency is given by J.W. Tack using the formula for a string under tension:

$$F_0 = \sqrt{\frac{4T_0}{md_m}}$$

Where m is the effective mass, d_m is the membrane width and T_0 is the elastic tension force used to stretch the membrane, defined as:

$$T_0 = EA_l\varepsilon_d = El_m t_m \varepsilon_d$$

with E is the modulus of elasticity (or Young's modulus) of the membrane, A_l the cross-sectional area of the membrane in lengthwise direction with length l_m and thickness t_m, and ε_d the membrane's pre-strain that is applied along the membrane width. This formula is tested to be an accurate formula to predict the fundamental frequency in case of a membrane configuration with loads (Fig 2.1).

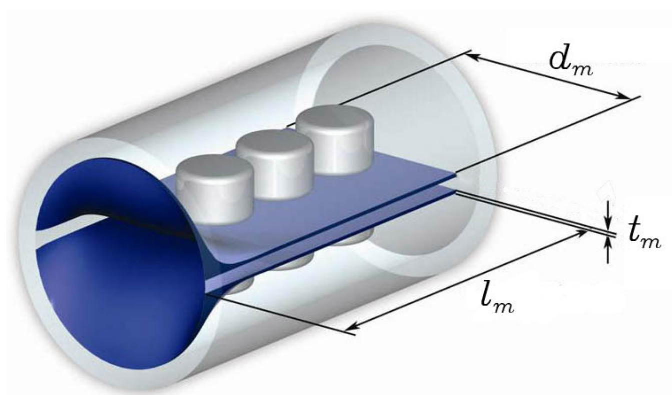

Figure 2.1: *Model of voice prosthesis with weigths*

The frequency created by the prototypes is, as said before, too high.
The given formula shows six different parameters (elasticity, pre-strain, length, width, thickness and mass) which can be altered in order to lower the frequency. However, in our case, not all of these parameters are easy to alter; the thickness for instance can't be too low, for it has to uphold certain strength. The membrane has to be strong enough to resist tearing and breaking.

2.1 Length, width, thickness and mass

In most cases where the desirable frequency is lower than the given frequency, up-scaling is used. A bass guitar for instance has longer, thicker and heavier snares in comparison to a normal guitar and will therefore produce lower tones. By making the snares longer the corresponding sound wave will also get longer and the frequency will lower. This is the basic principle of a guitar; shortening the snares results in a higher tone.
Heavier objects are harder to oscillate and also have longer sound waves. Mass is the product of density and volume (= length x width x thickness). The width and length of the membrane are set by the restrictions of the Groningen Button; only the thickness and the density of the membrane can be altered.

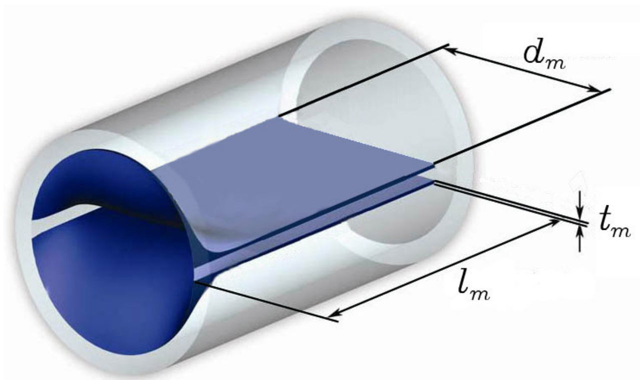

Figure 2.2: *Model of voice prosthesis with homogeneous membrane and without weights*

2.1.1 Homogeneous membranes

According to the formula the membrane should be kept as thin as possible. This is only the case when the mass is attained by attached loads instead of the mass of a homogeneous membrane. If we have a homogeneous membrane (Fig 2.2) the formula should be worked out and simplified. First by replacing T_0 for $El_m t_m \varepsilon_d$:

$$F_0 = \sqrt{\frac{4El_m t_m \varepsilon_d}{md_m}}$$

Then by replacing the mass (m) with density (ρ) multiplied by volume ($l_m t_m d_m$):

$$\sqrt{\frac{4El_m t_m \varepsilon_d}{\rho(l_m t_m d_m)d_m}} = \sqrt{\frac{4E\varepsilon_d}{\rho d_m^2}}$$

This would indicate that, in case of a homogeneous membrane, length and thickness do not influence the fundamental frequency; only the elasticity, pre-strain, width and the density of the homogeneous membrane do so. The elasticity and pre-strain will be discussed later. The membranes width has a very large impact on the frequency but can not be changed. The density can be changed and should be as high as possible. The influence of the membranes thickness is dismissed by this formula, it is however not certain this formula is correct. The influence of the thickness can be a key factor during the test track to check this.

2.2 Elasticity and pre-strain

The two membranes are stretched and fixed to the tube (Fig 2.2_A) with a certain pre-strain. When pushed aside by the airflow (Fig 2.2_B), the internal stiffness of the membranes will pull them back. The membranes will even move past their resting points (Fig 2.2_C) and are pulled back by their internal stiffness again; this time with help of the interrupted airflow. A higher stiffness results in a faster oscillation of the membrane and thus a higher tone. When the airflow stops the pre-strain will cause the membranes to fall back in their original position. Lowering the stiffness will lower the tone.

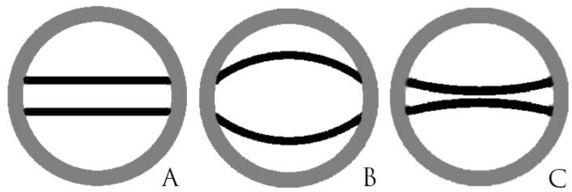

Figure 2.3: *Membrane positions*

Stiffness refers to the ability of the structure to resist changes in shape (for instance, to resist stretching, bending or twisting).
The formula for determining stiffness (k) due to an axial force is:

$$k = \frac{P}{\delta}$$

where P is the applied force and δ the deflection.

This resistance depends on a number of properties of an object.
The elasticity of the objects material exerts a great influence on the stiffness.
Elasticity is usually given by the modulus of elasticity (E):

$$E = \frac{kL}{A}$$

where k is the stiffness, L is the length of the element and A is the cross-sectional area. Eliminating k results in:

$$E = \frac{PL}{A\delta} = \frac{P}{A} \Big/ \frac{\delta}{L}$$

The ratio P/A is called stress whereas δ/L is called strain.
The SI derived unit of elasticity is Pascal (Pa); 1 Pa equals 1 N/m^2.
The elasticity is often given in MPa or GPa (1MPa = 1 N/mm^2).
A high modulus of elasticity means high rigidity whereas a low modulus results in a more flexible object. This elasticity is not a constant but is dependent on the extent to which a material is stretched.
The structure also influences the stiffness; this principle can be recognized in the shapes of beams (e.g. H-shape) and of corrugated fiberboard. The ease of bending these materials is greatly depending on the bending direction.

2.2.1 Porosity

Porosity has a great impact on the elasticity. A higher porosity means less material per cubic meter. An increase in porosity will result in an exponential decrease in elasticity; remember E is given in N·mm^{-2}. The relation between elasticity and porosity can be given by:

$$E \sim (1-\varphi)^2$$

where φ is the porosity. Porosity can be introduced by mixing the polymer with a substance which can be extracted directly after the membrane is made.
The porosity can be calculated by dividing the theoretical density minus the measured density by the theoretical density:

$$\varphi = \frac{\rho_T - \rho_M}{\rho_T} \quad \text{or} \quad \rho_M = (1-\varphi)\rho_T$$

where ρ_T is the theoretical density and ρ_M the measured density.
The porosity can help to lower the elasticity but may not result in a fragile membrane; it must be build to withstand the vibrations without tearing.

2.3 Divergence

J.W. Tack states in a numerical study that the frequency could be altered by placing the membranes under an angle, making the airflow path divergent.
The airflow capacity itself however should not be altered otherwise it will be more difficult to speak.

"Changing to a divergent profile results in reductions in frequency, flow rate and amplitude; the effect on the latter two quantities is substantial. A change of +0.5 resulted on average in a frequency change of -7.3%."

In these numerical computer tests the height between the two membranes was kept constant at the middle of the length of the membranes as the result of different angles were analyzed.

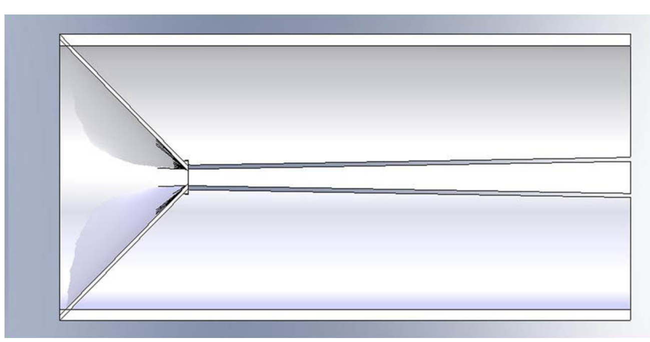

Figure 2.4: *Cross-section of a prosthesis model with membranes at an angle*

3 Membrane properties

Now we know more of the theoretical possibilities to make a prosthesis with a lower fundamental frequency. In this chapter we will look more closely at these possibilities, especially how this theory could be applied to come to a practical membrane, but first we will look at the possibilities to produce membranes.

3.1 Material properties of the membranes

3.1.1 Elastic material

An important factor in altering the F_0 of the VPE is the elasticity of the membrane. Besides making a choice based on biocompatibility, bio-stability and sufficient strength it is, therefore, important to choose a membrane material with low elasticity.
Elasticity can be calculated after a tensile test. Properties which can be determined directly with this test are, among others, tensile strength, elongation at break and stress at a given elongation.
The membrane will only be stretched slightly during its use so in our particular case the stress/strain ratio between 0 and 10% elongation is the most significant.

Silicone rubbers are biocompatible materials with a very low elasticity but also with low tensile strength. The range of tensile strength of silicone rubbers is 5 to 10 MPa, this makes it less suited for the prosthesis.
Polyurethane (PU) is a relatively inert and biocompatible polymer with a better tear resistance than silicone rubbers. Their tensile strength lies between 28 and 40 MPa. There are a variety of different polyurethanes with different elasticity's, densities and other properties. Many types of polyurethane have a low elasticity modulus. They are used in various biomedical applications, especially where a soft tissue is required, as in the VPE.
Other materials with higher tensile strength, bio-stability or good elasticity exist but the combination of these properties is found best in polyurethane.
Polyurethanes are the best choice to use as basic material for the membranes. There is however a wide diversity in PU's.

3.1.1.1 Polyurethane

A small group of biocompatible PU's with very low elasticity's which still provide enough strength were selected. Samples of these PU's, with are used in other medical products, were requested at their various producers: several grades of Evoprene, Tygon and C-Flex. Unfortunately these requests were denied so no new samples were acquired.
Tecothane and Tecoflex are available and provide good comparison possibilities.

Figure 3.1: *Polyurethane pellets*

Tecoflex (EG-80A) is a biocompatible polyurethane with a very low elasticity; the flexural modulus of this material is 6.895 kPa, its tensile strength 40.0 MPa. Tecothane (TT-1074A) has an even better biocompatibility and a slightly higher tensile strength. The flexural modulus of Tecothane is 8.963 kPa, the tensile strength 41.4 MPa.
Tecoflex and Tecothane are made by the same company (Lubrizol Advanced Materials, Inc.) which states they have been specifically formulated to have good biocompatibility, flexural endurance, high strength and processing versatility over a wide range of applications. Both polyurethanes are used in medical devices.
To use these materials in injection molding they can be melted; Tecoflex should be gradually heated to a temperature of 200° C before injecting it into a mold; Tecothane needs 210° C. Besides melting there are other ways to process these polymers. Both materials can for instance be dissolved in Tetrahydrofuran (THF) which is used as a solvent for many compounds. The THF is extracted in a later stadium of the membrane making process and will not remain in the membrane. THF is a hazardous liquid that irritates skin, eyes and airways. Pure THF can easily form peroxides which can result in explosion dangers and should always be handled with utmost care and under a fume hood.

3.1.2 Weight material

To lower the frequency the weight of the membranes can be increased. This can be done by adding a material with a high specific gravity or density. The elements with the highest density are Osmium (Os, atomic number 76) and Iridium (Ir, atomic number 77) with a specific gravity approximately 22.5 g/cm^3. These metals from the platinum family are however very rare and expensive. This is the case for most high density materials; especially Rhenium (Re, atomic number 75) which weighs 21,2 grams per square centimeter and costs 7.5 times more than Gold (Au, atomic number 79, 19.3 g/cm^3). Tungsten (W, atomic number 74) is a material with a very high density (19.25 g/cm^3), is resistant to corrosion and acids. Its density is practically the same as the density of gold, which is also very resistant, but Tungsten is cheaper

3.1.2.1 Tungsten

Tungsten is frequently used as an additive in various plastics applications. It has a high stiffness but when added as a powder to a polymer it will not raise the membrane's elasticity. Tungsten powder with a particle size of 0.60 to 1.00 microns will be used to weight the membranes. This powder is added after the solutions have been stirred for a couple of days and is stirred afterwards. The powder is not likely to have much influence on the elasticity of the membrane; the volume of Tungsten is because of its density relatively low. The viscosity of the solution will be higher as more Tungsten is added.

Figure 3.2: *Tungsten powder*

3.2 Structural properties of the membranes

3.2.1 Thickness

Chapter 2 showed that homogeneous membranes produce a frequency independent on the thickness. This was demonstrated by the derivation of the formula for a string under tension. Tack claimed this formula was also relevant for the frequency produced by the membranes of the voice prosthesis, in his case with attached weights. In a homogeneous membrane thickness affects both the stiffness and the mass and should therefore loose its influence.
This assumption must be proved and the influence of thickness should be tested.

3.2.2 Porosity

Phase separation molding has proven to be a useful technique to create a porous membrane; it is applied directly after the membrane is cast and can be used in combination with most production methods. The mentioned explanation for the principle of phase separation molding involves a membrane produced by spreading.

The polyurethane is dissolved in a solvent (e.g. tetrahydofuran) and spread out on a smooth Teflon coated plate, or on a mold if a structure is wanted (Fig. 3.3_A).
The membrane is then immersed in a non-solvent (e.g. ethanol) (Fig. 3.3_B).
The polyurethane will not react with the non-solvent but the solvent will mix with it and be replaced, leaving pores in the polyurethane membrane.
The ratio between the polymer and the solver determines the resulting porosity.
After the separation process the membrane will be placed in water to wash out (the rest of the solvent and) the non-solvent (Fig. 3.3_C) and to let the membrane solidify.

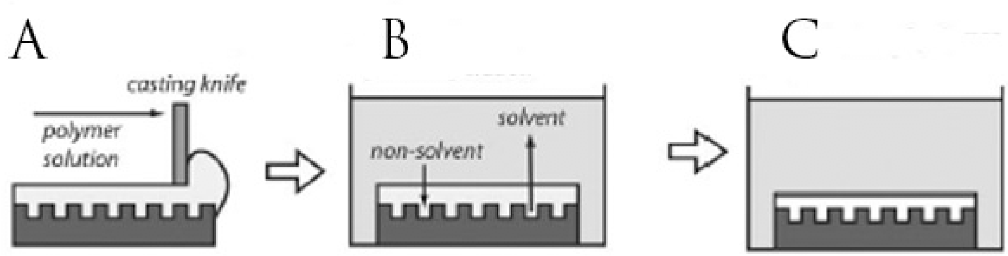

Figure 3.3: *Phase Separation of a spread membrane*

The membrane will shrink a little in this process so it will have to be clamped to make sure the membrane will stay in place. Shrinkage will take place in all steps of the membrane production, first during the solvent – non-solvent phase, secondly during the washing phase and finally in the drying phase. Shrinkage of the membrane has a negative effect on the porosity but will not eliminate it.

3.3 Production methods to make membranes

Besides the materials and structure of the membranes is the method of production an important choice to make, not only make samples to test the membrane properties but especially for the assembling of a series of prostheses

3.3.1 Spreading

This technique to produce plastic films is straight forward: molten plastic or a polymer solution is spread uniformly onto a smooth surface and let to dry. To ensure the membrane has a constant thickness the liquid plastic is spread with a special casting knife or casting rod which allows only a certain thickness.
The rods used to cast membranes have a small diameter difference between the middle section and the ends. This is a commonly used method to make films or membranes and is often used when phase separation is applied.
Because of a suspected shrinkage of the membranes this difference should be taken somewhat larger than the wanted thickness. Especially in combination with the phase separation process this shrinkage can be more than 60%.

3.3.2 Injection molding

This technique is often used in the plastic industry and can also be used to produce thin products like membranes. The process usually involves the melting of plastic pellets; the fluid polymer is then injected, under high pressure, into a mold. After the plastic is solidified the product is ejected and a new part can be made. In the case of small objects like membranes it is possible the mold has multiple cavities and will produce a number of membranes simultaneously.
The molds used to produce these membranes would be very expensive so only in the case of a large series can this be cost-effective. The combination with phase separation or another method to make porous membrane is possible but would mean an even more expensive production process. The viscosity is due to the Tungsten powder rather high for injection molding, which would mean the solution would have to be adjusted.

3.3.3 Flat-die extrusion

Similar to spreading but used to make much longer films is a variation on extrusion molding. This technique, that can be used to cast membranes, is known as flat-die extrusion. The plastic pellets are melted again but instead of injected into a mold or spread out by a knive the molten mass is forced through an extrusion-opening. These films are often cast directly onto carriers of paper or polyester film. The extrusion of high quality thin polyurethane films is however extremely difficult and porous membranes are probably not possible with this technique.

3.3.4 Dip molding

Another possibility is to make membranes is by dip molding or casting. Dip casting is used to make thin-walled products.
A dipping mold or mandrel (Fig 3.4_B) is introduced gradually into the polymer solution (Fig 3.4_A) until the mold is covered and withdrawn at a controlled rate that is consistent with the flow rate of the solution.
For some materials the mold has to be heated to allow the material to attach to it; for THF solutions this is not required.

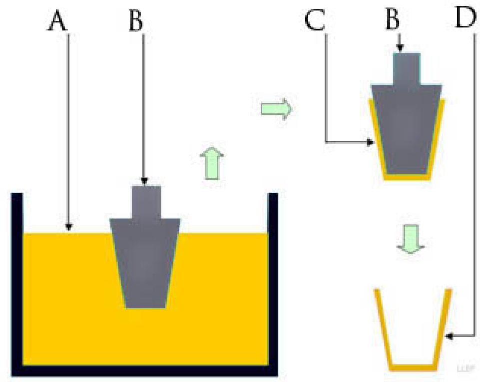

Figure 3.4: *Ordinary dip molding process*

The specific viscosity of the solution will determine the ease of application to the mold and the layer thickness. In order to create good membranes the viscosity of the solution can not be as high as solutions suitable for spreading; it can be lowered by using more THF in the solution.
After the mandrel is dipped in the solution it has a liquid coating which should be dried until a "skin" forms (Fig 3.4_C), subsequent dips should be dried likewise. For the membranes a cumulative drying time of 30 seconds per layer should be used. The wall thickness will be less on the top part of the membrane because the bottom part is relatively longer in the solution and due to gravity. To minimize this aspect of dip molding the mold can be held horizontal and slowly rotated during the drying stage of each layer.
To be sure of an equal thickness only the middle-section could be used.

With dip molding the phase separation process should be applied after layers are formed. Separating the THF per layer will not work, the solution will lose its coherency too fast and will drip from the mandrel, the original solution would also be polluted with ethanol. After all layers are applied, the phase separation and drying the thin-walled product (Fig 3.4_D) can be taken from the mold.

3.3.5 Selected methods

Making porous membranes with a flexible material like polyurethane is a highly specialized process. Although injection molding and extrusion are possibilities are the costs to produce the membranes that way extreme. The simpler methods of spreading and dipping are easier and less expensive nevertheless can result in high quality products. The high viscosity caused by the Tungsten powder makes it more difficult to cast, dipping and spreading are both still possible but the solutions used for dipping have to be more fluid. This can easily be done by adding more solver to the mixture.
The test samples in this project shall therefore be made by spreading an dipping. Dip molding is, because it can result in tube-like membranes, probably very useful to fixate the membrane into the housing, whereas spread samples are more practical to use in the tensile tests.

4 Membrane production and testing

In chapter 3 we have chosen materials to make the membrane as well as the structural properties the membranes should have to create a low frequency.
In this chapter we will put together combinations of these variables and describe the tests we use to test their independent influences.

4.1 Membrane variations

The tests in which these membranes will be used involve tensile tests to determine the elasticity and tests to determine the fundamental frequency. Tensile tests often use standardized dumbbell-shaped samples, which can be punched out of the flat membranes created with spreading. For the frequency tests tube-shaped membranes are wanted, these will be made by dipping.

A matrix of variations made by spreading was put together and for each material reference values were chosen.
For the Tecoflex samples this is a compound of:
- 60% Tecoflex / THF solution (1:9) mixed with 40% Tungsten and spread out with a thickness of 80 μm (sample S2)

The 'standard' for the Tecothane samples is:
- 40% Tecothane / THF solution (1:9) mixed with 60% Tungsten also spread to a thickness of 80 μm (sample S12)

The reason for putting more Tungsten to the Tecothane solution is the different viscosity of both solutions; Tecothane is more fluid and can therefore hold more Tungsten without causing major difficulties. These samples are made to test the influences on elasticity.

The percentages of added Tungsten mentioned in table 6.1 and the rest of this report is always the mass-percentage related to of the total solution (the Polyurethane, the Tetrahydrofuran and the Tungsten itself).

A different test series is prepared to test the influences on the fundamental frequency. These samples are made with the dip casting technique. The Tungsten powder makes the solution very viscous; it is not certain if it is possible to make good membranes this way, and these tests can clarify this.
Because of this viscosity the polymer solutions are made more fluid by adding more THF, this is necessary for the dipping process. The mass percentage of added Tungsten in the solutions is different in table 4.1_A from the percentages mentioned in table $4.1_{B.}$ This is to get membranes with a ratio, between Polymer and Tungsten, equal to the spread membranes (the 40% spread and the 29% dip samples should both result in a weight percentage in the membranes of 87%, the 60% spread sample would result in 94% and the 33% sample of Douma in 83%).

The standard values for the dipped membranes are:
- 71% Tecoflex / THF solution (3:50) mixed with 29% Tungsten, 4 layers (D3)
- 53% Tecothane / THF solution (3:50) mixed with 60% Tungsten, 4 layers (D6)

Table 4.1: *Membrane variations*												
A: *Spread membranes*												
Sample number	Material		Mass% Tungsten				Thickness (µm)			Pur:THF		
	Tecoflex	Tecothane	0	40	60	80	40	80	120	5%	10%	15%
S1	x		x					x			x	
*S2	x			x				x			x	
S3	x				x			x			x	
S4	x					x		x			x	
S5	x			x			x				x	
S6	x			x					x		x	
S7	x			x				x		x		
S8	x			x				x				x
S9	x		x					x				x
S10	x				x			x		x		
S11		x	x					x			x	
*S12		x			x			x			x	
S13		x			x		x				x	
S14		x			x				x		x	
S15		x				x		x			x	
B: *Dipped membranes*												
Sample number	Material		Mass% Tungsten				Layers			Pur:THF		
	Tecoflex	Tecothane	0	29	47	75	2	4	8	4%	6%	
D1	x		x					x			x	
D2	x			x			x				x	
*D3	x			x				x			x	
D4	x			x					x		x	
D5	x				x			x		x		
D6		x			x		x				x	
*D7		x			x			x			x	
D8		x			x				x		x	
D9		x				x		x		x		
¤D10	x			x				x				
* Standard values ¤ Sample made without phase separation												

Samples S10, D5 and D9 are different from the other samples because they deviate with two variables from their related standards. The samples have higher percentages of Tungsten powder in the solutions than the standard, which results in mixtures with a higher viscosity. These solutions have, to make them fluid and manageable again, also a higher percentage of THF. Only the spread sample S3 has more Tungsten powder in it than its standard without more THF being used.

4.2 Production methods

4.2.1 Making spread membranes

The casting of the membrane using this technique was done at the laboratory of the Membrane Technology Group of the University of Twente. The polymers were solved in the THF for a weekend and mixed with the Tungsten powder for another day. The mixtures were cast using pipettes. The available casting rods to spread the membranes had diameter differences to cast with a thickness of 200 µm, 300 µm and 400 µm; this is the size before shrinkage. The variation of thickness is less diverse but the number of varieties would not be altered. This method is used in earlier tests but not with Tecothane and not with these amounts of Tungsten, the are also more variations planned to get an clearer view on the influences of the components.

4.2.2 Making dipped membranes

The casting of the membrane using this technique was done at the Biomedical Engineering department of the UMCG.
More relevant using this technique is the settling of the Tungsten powder, because of its weight these small particles tend to sink to the bottom. And the solution had to be still during the casting itself and the mold is in contact with different 'levels' of the solution whereas casting with a pipette ensures a more homogeneousness mixture. The solution therefore has to be mixed intensively before each sample can be dipped to keep this to a minimum.

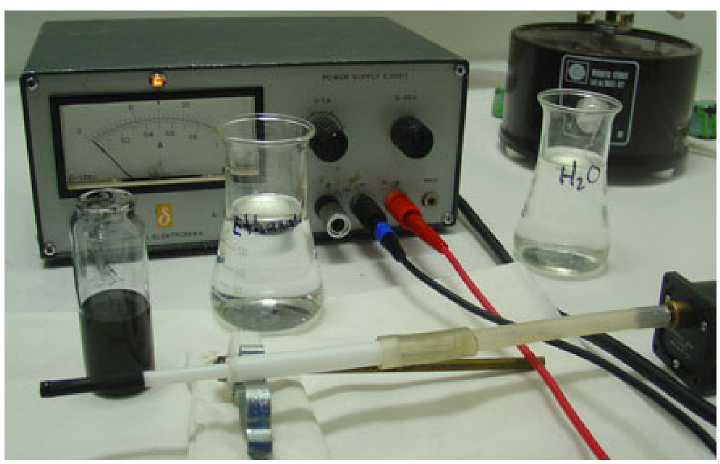

Figure 4.1: *Rotated drying after dip molding,*
with the Ethanol and water ready for the phase separation.

4.3 Measuring

4.3.1 Thickness

The thickness is not only one of variables of the membranes; it is also important to know the thickness for the porosity and elasticity. The measuring of the thickness is not easy with these elastic membranes. They are very thin and flexible, so there is a risk of compressing the membrane while measuring.

The UMCG has a machine at their disposal designed to tests the tensile and compressive properties of materials. The computer controlled machine was build for small objects and can accurately measure distances, deformations and forces. It slowly lowers a tool with a certain force, when the tool comes in contact with an object it gives a feedback on how much resistance it gets and stops when a certain value is reached. The compression limit can be tuned to a very low level so the tool will stop immediately when it touches the object; before compressing it. This way the machine can be used to measure the membranes thickness.

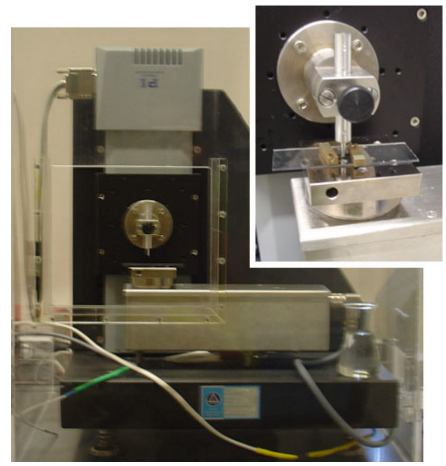

Figure 4.2: *The device used at the UMCG to measure the thickness*

Another possibility would have been to use a microscope or even a so called scanning electron microscope (SEM). With a SEM it is possible to take close-up-pictures of the membrane, the magnification is known so it is not hard to determine the thickness. To take these pictures the membranes first have to be frozen with nitrogen. The microscope (-pictures) could also be used to see if the Tungsten powder is divided evenly throughout the membrane and can show the porosity. This technique is however more complicated and time consuming; it was used in earlier membrane tests which indeed showed porous homogenous membranes.

4.3.2 Porosity

To determine the porosity of the spread membrane the theoretical density and the density of the membrane have to be calculated. For the theoretical density the known weight percentage of the PU and the Tungsten were used to calculate the volume and weight of the components. To find out the membrane density a piece was cut from the samples and the dimensions and weight were measured. The Tungsten percentage of the dipped membranes is somewhat harder to determine; although the solutions were mixed till moments before the dipping (and sometimes even in between), some Tungsten powder settled down to the bottom. To determine the porosity of a dipped membrane a sample was made without employing phase separation (letting THF evaporate slowly). This sample was compared with a membrane dip molded with the same solution but done with phase separation.

4.3.3 Elasticity

To create data comparable to earlier tests the same punches were used to punch the samples in a dumbbell shape (according to ISO 37 standards). These samples are tested in Enschede using the Zwick Z020 (also with ISO 37 standards). This machine is also used in the earlier tests and is built to do a variety of measurements simultaneously; it measures several tension abilities of the material. This machine is not especially suitable for these thin and delicate samples, another machine which could measure the E modulus more accurately was however out of order.

The samples were clamped at their ends and extension meters were placed at the thinner part to measure the distortion of the membrane as it was stretched up by the clamps. The thickness of the sample was inputted in the computer so the stress could be calculated.

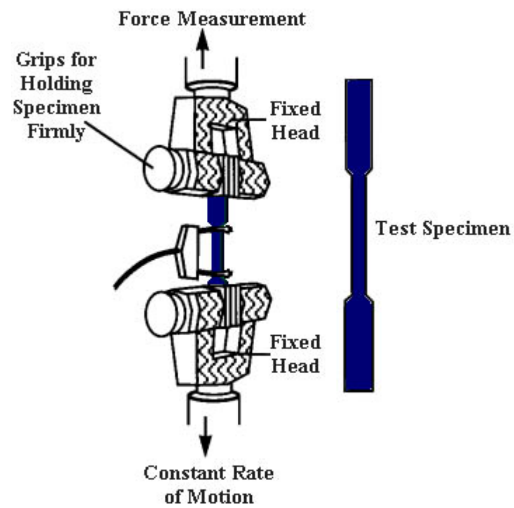

Figure 4.3: *Tensile test*

There were tree samples to test with, two samples of Tecothane with 60%Tungsten (S12) and one sample of Tecoflex with 40% Tungsten (S2).

This is not sufficient to produce hard results but might show a certain tendency using the earlier test results.

4.3.4 Frequency

To test the frequency of the VPE an experiment set-up was available at the Biomedical Engineering department of the UMCG (Fig. 4.4).

This is the same set-up Tack and Bouwma used in their earlier tests.

The set-up is a model of the physiological situation in a patient; it allows measuring various acoustical and aerodynamic parameters in-vitro. The vocal tract, lungs, and trachea present an acoustical load such that the required resonance frequencies can influence the fundamental frequency produced by the sound source. Therefore, physical models of the vocal tract, lungs and trachea were integrated, which closely resembled the acoustic properties of the altered airway geometry after Laryngectomy. These models consist of interconnected hard-walled tubes with specific lengths and diameters designed to obtain the proper resonance frequencies. The model representing the acoustical load of the lungs and trachea was fixed inside a large pressure reservoir, which was coated inside with a sound absorbing material. Via an air cylinder a flow of dry air at room temperature was supplied that was able to build up a pressure inside this reservoir. On top of the outflow opening of the lung model a VPE was placed inside a Groningen button shunt valve. To obtain the fundamental frequency a microphone is placed at a distance of 0.15 m from the VPE.

The data of the tests was analyzed with a computer using LabVIEW.

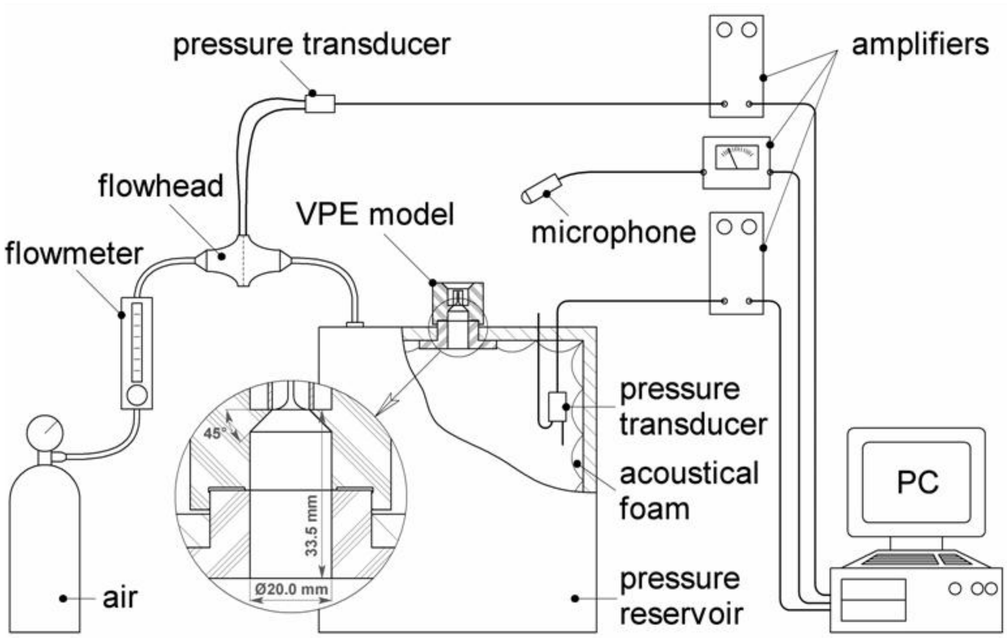

Figure 4.4: *Schematic representation of the in-vitro experimental set-up.*

The membranes had to be placed inside a prototype. This proved to be very difficult. It is unfortunate some membranes were damaged; the non-porous Tecoflex 29%Tungsten sample and the Tecothane 75%Tungsten sample ripped during the prototype assembling.

Because the samples were thicker than the earlier membranes two prototypes had to be altered to maintain the same space between the membranes.
The membrane tubes also varied in diameter but the membrane had to be fixated with the same pre-strain in the prototypes. As a result thicker and/or extra rods were placed to stretch the membranes. All the membranes were assembled in such a way that the length of the membrane in the prosthesis was 1 to 1.3% longer than the membrane in a relaxed state.

5 Results

5.1 Production methods

5.1.1 Spreading method

The resulting shrinkage was a bit less than expected and average membranes thicknesses was closer to 100 than to 80, the shrinkage not only resulted in thinner membranes but also in length and width. The mentioned thickness is an average; later sample parts used in other tests were measured separately. Few membranes were smooth films, several were wrinkled, others had small holes and some even a big gap.

Unfortunately after making the first eight samples there was no more time available in the lab in Enschede to make more samples using this spreading technique, this withheld me from making new variations and redoing the failed membranes.

Table 5.1: *Results Spread membranes*

Sample number	Material	Mass% Tungsten	Supposed Thickness (µm)	Pur:THF	Result	Real Thickness (µm)
S1	Tecoflex	0	80	10	Wrinkled membrane	
*S2	Tecoflex	40	80	10	Good membrane	122
S3	Tecoflex	60	80	10	Small and brittle membranes > too much Tungsten	
S4	Tecoflex	80	80	10	Not made because 60% already proved to be too much	
S5	Tecoflex	40	40	10	Not made due to lack of lab time	
S6	Tecoflex	40	120	10	Not made due to lack of lab time	
S7	Tecoflex	40	80	5	Not made due to lack of lab time	
S8	Tecoflex	40	80	15	Not made due to lack of lab time	
S9	Tecoflex	0	80	15	Not made due to lack of lab time	
S10	Tecoflex	60	80	5	Not made due to lack of lab time	
S11	Tecothane	0	80	10	Wrinkled membrane	
*S12	Tecothane	60	80	10	Good membrane	95
S13	Tecothane	60	40	10	Completely wrinkled membrane	
S14	Tecothane	60	120	10	Membrane to small to do tensile test	
S15	Tecothane	80	80	10	Not made due to lack of lab time	

*Standard values, in this case also the only membranes successfully cast

5.1.2 Dip mold technique

This technique resulted in fine thin-walled tube-shaped membranes.
Not all membranes were de-molded successfully; the membranes were rolled of the mold, in some cases however the membrane fused and could not be rolled out again. This was the case for instance for every sample of D2 attempted tough some samples were given a few days to harden.
Not all samples were made with the same mold, in a later stadium two more molds were found, probably ones Tack had used for his samples.
After determining the measurements of the samples the diameter proved to vary among the membrane tubes so all had to be measured.

Table 5.2: *Results Spread membranes*							
Sample specification					*Results*		
Nr.	Material	Mass% Tungsten	Layers	PU:THF (PU%)	Remarks	Ø (mm)	Real Thickness (µm)
D1	Tecoflex	0	4	6%	Sticky at first	5.8	75.6
D2	Tecoflex	29	2	6%	3 attempts, de-molding failed every time		
*D3	Tecoflex	29	4	6%	First attempt failed	5.4	126.8
D4	Tecoflex	29	8	6%	First 2 attempts failed	5.1	204.1
D5	Tecoflex	47	4	4%	Brittle yet sticky, de-molding fails		
D6	Tecothane	47	2	6%	Solution more fluid	5.0	85.5
*D7	Tecothane	47	4	6%		4.9	161.1
D8	Tecothane	47	8	6%	'thick' membrane	5.8	237.7
D9	Tecothane	75	4	4%	Very fragile	4.9	160.6
¤D10	Tecoflex	29	4	6%	Non-porous membrane	5.1	68

* Standard values
¤ Sample made without phase separation

5.2 Measurements

5.2.1 Porosity

Table 5.3: *Porosity*				
Sample number	**S2**	**S12**	**D10**	**D3**
Sample configuration	Tecoflex 40%Tungsten	Tecothane 60%Tungsten	Tecoflex 29%Tungsten No PS	Tecoflex 29%Tungsten PS
Technique used	spreading	spreading	dipping	dipping
Thickness (µm)	85.7	77.5	68	127
Area (mm^2)	123	174	92.5	99.21
Volume (mm^3)	10.51	13.4	6.27	12.60
Weight (g)	0.0146	0.0418	0.0363	0.0179
Density membrane ρ_M (g/cm^3)	1.39	3.12	5.79	1.42
Actual wt% Tungsten	87	94	87 (theoretically)	87 (theoretically)
Density Polyurethane	1.04	1.10	1.04	1.04
Density Tungsten	19.25	19.25	19.25	19.25
Theoretical density ρ_{Th} (g/cm^3)	5.88	9.50		
Porosity ($\frac{\rho_{Th}-\rho_M}{\rho_{Th}} \times 100\%$)	**76**	**67**	**0**	**76**

5.2.2 Elasticity

The first sample (Tecothane 60% Tungsten b) broke shortly after the test started, at an extension of only 9.5 %. The other two samples hold up much longer but neither one reached an elongation of 100% as earlier samples could. The results are plotted together with the results of an earlier test with the sample of Douma with the highest amount of Tungsten in it, also the tangents of all samples are plotted for the initial strain, the 5% strain and the 10%strain.

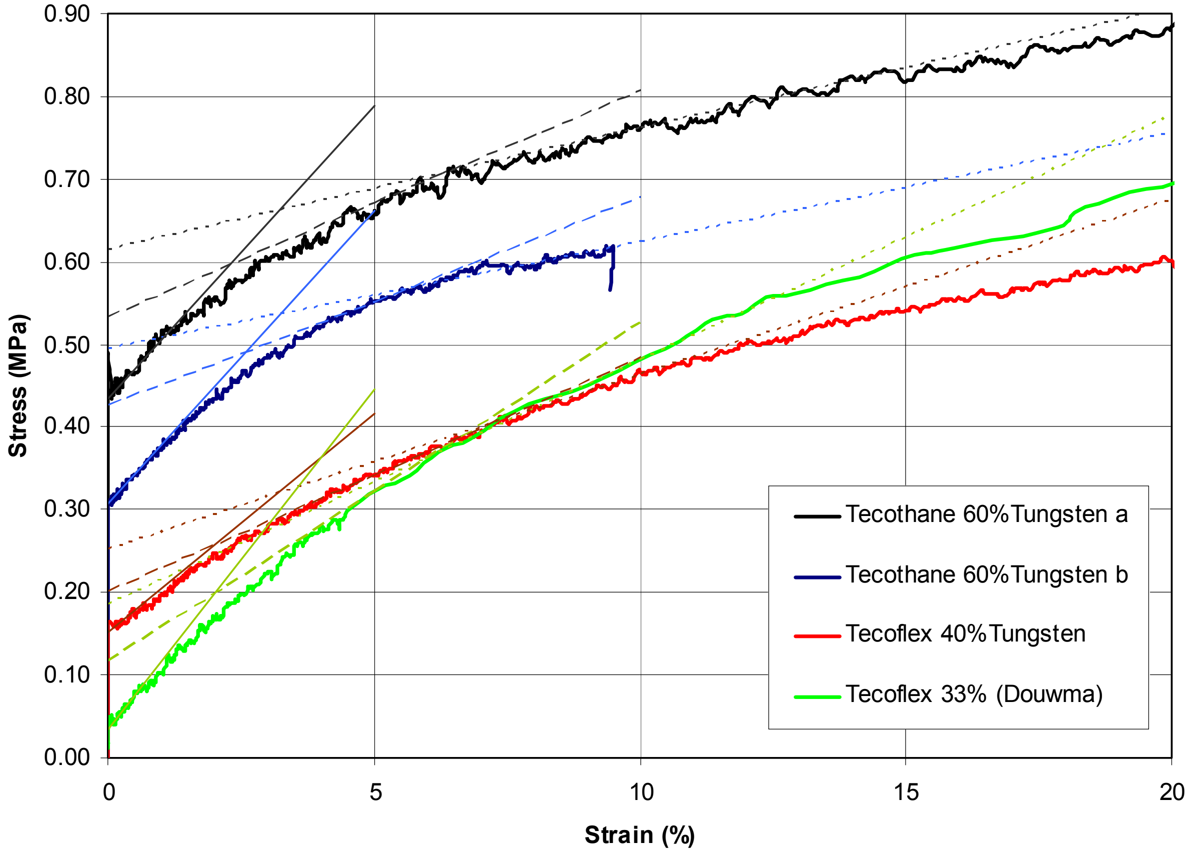

Figure 5.1: *Stress vs. strain, for different membrane samples, with tangents at 0, 5 and 10%*

Table 5.4: *E values at 0, 5 and 10% elongation*							
sample			Porosity (%)	E at 0%	E at 5%	E at 10%
Tecothane	60% Tungsten	S12a	67	7.10 MPa	2.74 MPa	1.46 MPa
Tecothane	60% Tungsten	S12b	67	7.09 MPa	2.53 MPa	1.31 MPa
Tecoflex	40% Tungsten	S2	76	5.30 MPa	2.83 MPa	2.11 MPa
Tecoflex	33% Tungsten	Douma	52	8.22 MPa	4.09 MPa	2.96 MPA

5.2.3 Frequency

The prototypes with the dipped samples all produced sound but some needed more pressure than anticipated. The membranes had higher frequencies which are needed for a natural sounding voice; only the fundamental frequencies are plotted and put in the table. The graph and table also contain old result of samples of Douma and Tack as a comparison to the new results.

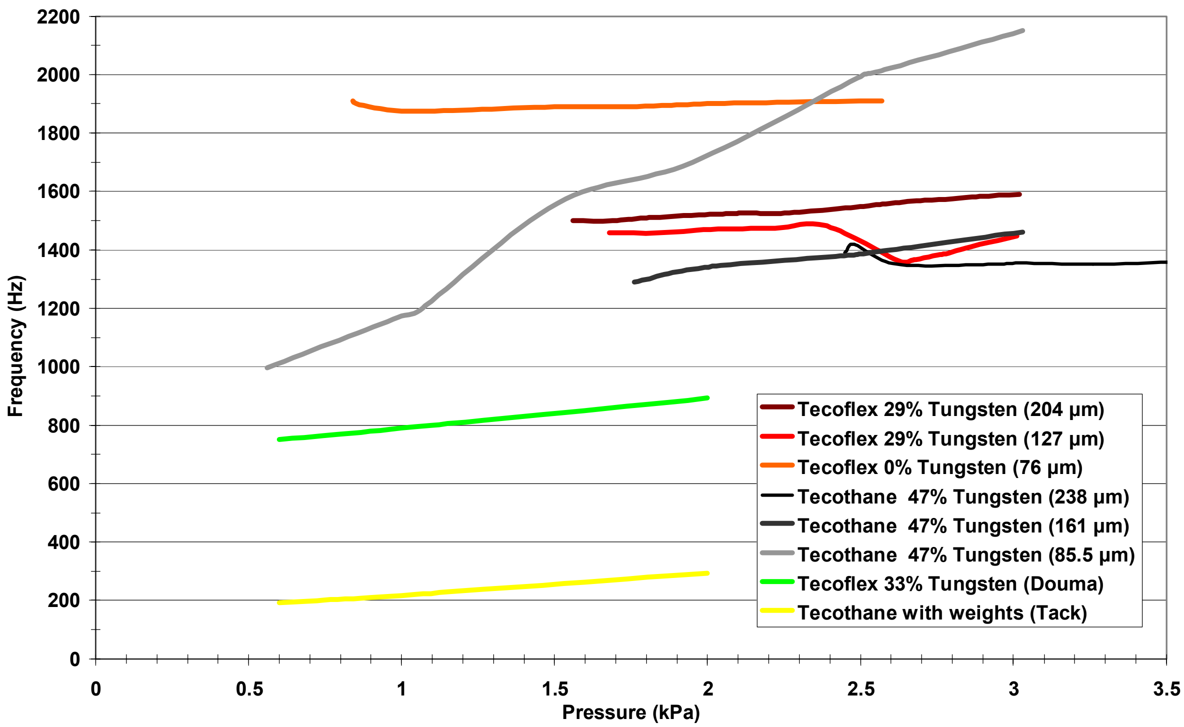

Figure 5.2: *Frequency vs pressure for different membrane samples*

Table 5.5: *Test results dipped membranes*

Sample number	Basic material	Tungsten	Layers	Thickness (µm)	F at 1 kPa (Hz)	F at 2 kPa (Hz)	F at 3 kPa (Hz)	Minimum pressure (kPa)
D4	Tecoflex	29%	8	204	-	1520	1589	1.56
*D3	Tecoflex	29%	4	127	-	1470	1445	1.68
D1	Tecoflex	0%	4	76	1875	1900	2590	0.84
D8	Tecothane	47%	8	238	-	-	1354	2.45
*D7	Tecothane	47%	4	161	-	1340	1460	1.76
D6	Tecothane	47%	2	85.5	1172	1720	2150	0.56
Douma	Tecoflex	33%	-	70	790	892	-	0.6
Tack	Tecothane	-	-	-	217	294	-	0.6

* Standard values

6 Discussions

6.1 Production methods

6.1.1 Spreading method

Making a good membrane proved to be not easy; especially with little experience in working in a lab. It took some time to get it right. The difficulty of making the membranes this way is mainly the fragility. The very thin sheet of polyurethane gets wrinkled very easy; it takes some time for the polymer to settle; if it sticks to itself before fully settled it will fuse and the membrane will be useless.
After several uses of the ethanol bath the phase separation failed because of too much THF in it. The bath of ethanol therefore has to be replaced after a couple of casts.

Some membranes had small holes, possibly due to the phase separation and shrinkage or to concentrations of THF in the solution. The bigger gaps in the middle of some membrane were likely due to touching of the two Teflon plates which were somewhat flexible and not perfectly flat.
The thickness of the membranes is slightly bigger than anticipated however there was not much variety in casting knives available and no time to redo the spreading.

The samples had to be smooth and at least 70 mm long to do tensile test similar to the ones done before, only two samples fit this requirements. The samples of Tecothane with 60%Tungsten and Tecoflex with 40% Tungsten could be used for further testing. Fortunately these are two samples suspected to result in a better elasticity compared with the earlier tests.

These successful samples made it clear it is possible to raise the level of Tungsten higher than done in earlier stages of the prosthesis development, so the membranes can be made heavier. Solutions were made with an even higher percentage of Tungsten but these proved to be too viscose to cast or resulted in brittle membranes. The maximum of adding Tungsten powder to the Tecoflex membranes is in all probability nearly reached with this sample although the higher percentage of THF was not applied to overcome the viscosity.

6.1.2 Dip mold technique

The procedure was somewhat easier than the spreading. The problem, also encountered with spreading, of fusing with itself when the membrane is not completely dried, is however also a big problem during dip molding. The most difficult part proved to be releasing the membrane from its mold without it fusing or without damaging it.
This problem can be partly overcome with a slightly conical dip-mold. The membranes would come free from the mold more easily. Of course, this would result in somewhat conical membranes. In combination with divergent membranes this would be a welcome consequence.

The thickness of the membranes can, because of the more fragile structure of the material, not be as thin as the membranes dipped without phase separation and added Tungsten like the ones made by Tack.
The results show a difference in the diameter of the membrane tubes.
The largest difference in diameter was 0.9 mm which corresponds with a difference in perimeter of almost 3 mm. On a small scale like the size of the prosthesis this is a significant variation. Besides the difference in diameter between the different molds (maximally 0.4 mm), the most logical reason for this variation is shrinkage of the membranes.

6.2 Measurements

6.2.1 Porosity

The porosity of the membranes proved to be very high. The two measured Tecoflex samples show a equal porosity (76%) though they made using different production techniques. The actual (theoretical) weight percentage of Tungsten of these samples was the same (87 wt-%) but the dipped membrane was made using more THF (94% instead of 90% of the PU:THF solution), the equal porosity is due to a higher shrinkage of the dipped membrane and/or perhaps less influence of the THF to the porosity. This could have been more clear when more samples were made.
The porosity of the Tecothane sample was 67%, this is not as high as the Tecoflex samples but still a high percentage, also compared with the samples Douma made (max 52%).
Only the porosity of three membranes was effectively determined but these results indicate that both methods I used result in a significant porosity.

6.2.2 Elasticity

The limited elongation of these samples, not much more than 60%, could very well be caused by the used percentages of Tungsten powder and porosity, which both lower the tear strength. It may also have been caused by impurities or weak spots or even other factors.
During use, the membranes will not be stretched to more than 20% of their length. The elasticity around 10% is for the membranes the most interesting.
The test results show that, although there is more stress needed to lengthen the Tecothane 60% samples to an elongation of 10%, the elasticity of these samples is lower than the Tecoflex samples at this point. According to the properties of the pure polymers this is odd; the Tecoflex should have the lowest elasticity, especially the Tecoflex 40% Tungsten sample since it also has a higher porosity.
Compared to the Tecoflex 33%Tungsten sample made by Douma, the Tecothane 60%Tungsten sample has only half the elasticity at 10% elongation. Furthermore, the weight of this sample is much higher. The E-values of these samples lie much closer together at the beginning of elongation. The Tecoflex 40% Tungsten sample has the most moderate plot; its elasticity however is higher than the Tecothane samples.

6.2.3 Frequency

It is unfortunate the membranes have a fundamental frequency higher than earlier tests. The main difference between these earlier tests are the fabrication methods; the new samples are porous and homogeneous made by dipping, the Douma sample was also porous and homogeneous but made by spreading whereas the Tack sample was also made by dipping but not porous and with weights (non-homogenous). Another possible cause for the high frequencies could be the pre-strain of the membranes. Although during assembling of the prototypes the pre-strain was attempted to be equal or even less than the earlier samples it was not always easy to establish. This pre-strain problem is, however present, not very likely since all new samples had to have higher pre-strains. Since the frequency is correlated to the exercised pressure the higher pressure could also be an influence on the high frequency. This high pressure threshold for the membranes to produce a tone is probably related to the higher thickness. This is best seen at the thickness variations of the Tecothane samples.

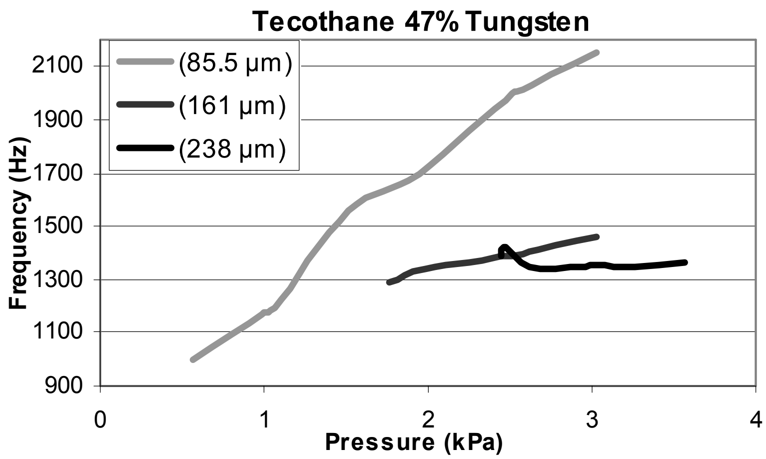

Figure 6.1: *Results of Tecothane membranes with different thickness*

The thinnest membrane started vibrating at a pressure of 560 Pa, the thickest needed almost 2500 Pa.
Another explanation for this threshold can be found in the results for the tensile tests. The minimum stress needed to stretch the membranes showed to be higher compared to the earlier samples. Patients usually do not have troubles reaching this pressure levels; phonation at a lower pressure level could still lead in a greater range of (lower) frequencies.

According to the simplified formula in chapter 2.1 the thickness would not influence the frequency. The thickness variation of the three Tecothane samples suggests that increasing the membrane thickness results in a lower tone. The two Tecoflex samples however show a decrease in thickness will lower the tone. More samples might have clarified this contradiction.
It can be said the thickness does indeed not change the frequency to a great extent. The biggest influence is clearly the impact on the required pressure. The thickness should therefore be kept low, between 70 and 100 µm.

7 Possibilities for series production of the membrane

In order to test the prosthesis on a larger scale a series of 100 prostheses is wanted. To make these one by one will take months; it is necessary to develop a method to accelerate this process. Equal quality of the prostheses is also important for accurate testing. The parts that are most difficult and time-consuming to make and assemble are the membranes; these are also the parts that are most important to control the quality of the prostheses.

As stated, there are several ways to make the membranes. Besides spreading and dipping, which proved to result in porous membranes, could injection molding and extrusion also be tried. These last two options are not yet tested and may not be possible to use these methods due to the high viscosity of the Tungsten/Polyurethane solution.
The two methods used in this report can both provide flexible and porous membranes with a mass that is relatively high.
In any case, it is vital for the constancy to keep the solution very well mixed.
Both can be used to produce multiple membranes at the same time.

The dipped membranes could be dipped simultaneous in a small series. Important in the process is the rotation of the molds between the dips; the molds have to be positioned horizontally during this rotation. Another problem with this technique is the de-molding of the membranes which should be easier using conical dip-molds.

Making a sheet of membrane material by spreading the solution, making it porous and letting it harden is for mechanical produced large series a good solution. The sheet can be cut into separate membranes and assembled in the prostheses. It is also possible to spread the solution over a raster of ‘molds’ to produce a large number of small membranes simultaneously. It is in this case important that the membranes will not float out of their cavities during the phase separation process and the shrinkage lengthwise and widthwise should be determined. A small-mesh wire netting could be used to prevent the floating.

8 Housing design

The prostheses consist of more than one component. The most important features are: the membranes, an inlet to guide the air, a housing to keep the parts in their place. Furthermore there are probably some parts needed to connect or fixate the other parts to the housing.
The outer geometry of the housing is set by the inner geometry of the Groningen Button in which the prosthesis will be placed. The most significant changes are therefore only possible in the air-inlet, the membranes and most importantly the fixation of the membranes. Assembling the prototypes was not easy; some membranes are ripped because of this. Problems were the small size of the prototypes and the strength of the membranes. Especially stretching the membrane around the prototype to create the air-inlet was a critical step. The ease of assembling should be an important factor in choosing the best concept.

8.1 Ways to fixate the membranes

The prosthesis will only work properly if the membranes are fixated on all edges except the rear edge. The membrane's pre-strain as well as the distance between the two membrane(part)s in resting position have to be constant. The front edge has to be fixed to the air-inlet to ensure the air flows only between the membranes. This is vital for the functionality of the prosthesis and keeping space between the membranes free from mucus.

8.1.1 Membrane cast directly on the housing(-parts)

This concept uses the possibilities of injection molding to bypass some problems concerning the assembling of the membranes. So further studies to whether injection molding is an real option to cast the membrane would be needed.
The housing will consist of an (symmetrical) upper and lower part which can be made by injection molding. The part can stay in the outer mold while housing is filled to the level where the membrane is wanted. This could be done using either some kind of wax or perhaps with a solid insert. The next step is to inject the layer which will form the membrane. It is cast directly onto the housing and is fixated this way. After the membrane is solid the filler can be removed. This concept requires much more study on the membrane composition especially concerning shrinkage. Little shrinkage can prove useful to obtain the needed pre-strain but the shrinkage will more likely exceed this 1^{+}%, so a solution should be found to either keep the shrinkage this low or to anticipate it before molding.

This solution requires expensive moulds but these do not necessarily be filled with machines or under great pressures. Only the outer mould can be used throughout the production line, each step will need a specific upper mould. The moulds can be provided with multiple cavities so multiple parts can be cast simultaneously. 2-k molding is also an option; this is used when a product is build up from multiple polymers which are cast in different stages.

8.1.2 To fixate the membrane(s) with rods

This solution is especially practical in combination with a tube-like membrane. The rods simultaneously keep the distance constant and the membrane tight. The rods can be made with steel wire, perhaps somewhat flattened to obtain the right distance. To keep the rods in place, the housing can be fitted with two parallel grooves. These grooves also help in fixating the distance of the membrane parts.

The first prototypes also use this principle (fig. 9.1). The air-inlet is created by the membrane which is stretched around the housing.

A tube-shaped membrane can be made by dip molding as was shown earlier, this is however not the only way. Extruded or injection molded membranes could also be tube shaped and it would be interesting to further examine the possibilities of these production techniques.

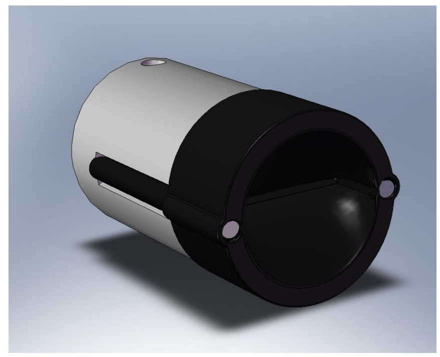

Figure 9.1$_A$: *Model of a prototype with dipped membrane with Tungsten*

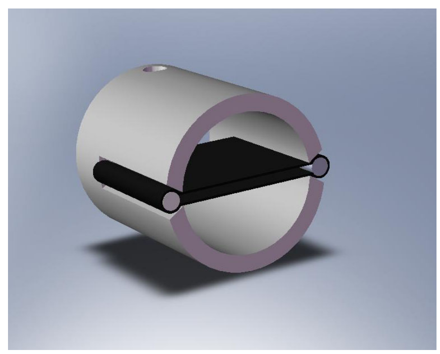

Figure 9.1$_B$: *Cross-section of the same prosthesis*

8.1.3 Fixation with glue and grooves

In this scenario the membranes are stretched through a groove and fixated on the outside of the housing with glue. The distance between the membranes is always equal to the width of the groove minus the combined thickness of the two membranes. The pre-strain can also be set on an accurate level.

It may be useful to use some kind of rods to make sure the mutual distance stays the same, and withhold the membrane to slide inside the housing when the glue might fail. Rods, however, mean extra parts that need to be assembled and can become loosened. The Groningen Button helps in this scenario to fixate the membrane. Spreading is in this case the most likely choice to cast the membranes.

8.1.4 Two dipped membranes

Another possibility is to use two dipped tube-like membranes in combination with the groove concept. Instead of using rods, the membranes are stretched using the housing itself, similar to the earlier concept with glue. The grooves set the mutual distance and the friction with the Groningen Button helps to maintain the pre-strain. Assembling this concept should be much easier. The air-inlet has to be created separately, integrated in the housing or as an extra part.

The tube shaped membranes could be produced by other techniques yet to be examined.

8.1.5 To fixate the membranes by clamping

The prosthesis will be placed inside the slightly bigger tube of the Groningen Button. Because of the small difference in radius the Groningen Button can be used to keep the parts of the prosthesis in place and properly connected to each other.

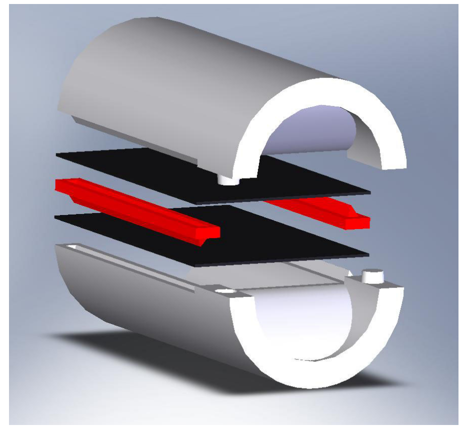

Figure 9.2: *Exploded view of a prosthesis*

The housing is build up from different elements, an upper and lower part, and parts (red in fig. 9.2) to fixate the membrane which can be clamped in between them.
The pre-strain of the membranes is set during assemblage; this is probably not particle to do at the same time as the prosthesis is placed inside the Grongen Button (which is already placed inside the patient). The prostheses can be assembled and put inside another tube, from which it can be inserted inside the Groningen Button. The pre-strain is in this case set in the fabrication phase of the prostheses. This would involve an extra tool, but could mean a more practical way of placing the prosthesis in general.
The membranes could be made by both dipping and spreading. To place the dipped membranes with the right pre-strain it is useful to use an instrument similar to tweezers but used to stretch instead of pinch.
It is, relative to other concepts, easy to include an angle in placing the membranes. The numerical study predicts this would further lower the frequency. Although there are more parts involved, upper and lower parts do not have to be different in geometry and can be made with the same mould.

8.2 Recommendation for concept

Although this study to redesign the geometry of the voice producing prosthesis was only short, a couple of recommendations can be made. The assembly of the prototypes proved to be a big problem; it was both time-consuming and difficult. The first option is far fetched but would make large series a lot easier, as said only after intensive study to overcome other problems.
A better concept to overcome problems present in the current prototypes is the prosthesis which uses clamping. This concept, with a house that consists of two parts, is recommended for further development.
The membranes should preferably be placed under a slight angle of 1° to get a lower frequency. The membranes can be made by dipping with a conical dip mold and placed as described above. The housing parts and probably the space-separators/ pre-straining parts can be made using injection molding. The small sizes allow the mold to hold several parts which can be made in one cast.

9 General discussion and recommendations

9.1 Discussions

9.1.1 Membrane choices

One of the main problems of the voice producing prosthesis at the start of this project was the high frequency it produced. The element producing the tone is the membrane; to lower the fundamental frequency it was determined which characteristics of the membrane influence this frequency. The influence of thickness was not certain because of the used formula, which was the formula for a string under tension. Characteristics that could alter the frequency significantly were the membrane width, elasticity and density.
The width of the membrane could not be altered due to the restrictions of the Groningen Button and could therefore not be used to lower the frequency.
The elasticity should be low; this would be achieved by a porous material with a low Young's modulus. The density of the membrane material should be as high as possible.

A range of membrane variations was set up in order to test the influences of the different parameters.
The two basic materials used for these samples were polyurethanes. These were chosen because of their low elasticity modulus in combination with sufficient tear strength and furthermore for the possibility of PU to make a porous material. Porosity should lower the elasticity, and with it the frequency, even more. Both selected polyurethanes were used to successfully make porous membranes. There are however more materials that can be made porous using the same method.

To increase the weight of the membrane Tungsten powder was added. This was done before by Douma and proved to be promising. The made samples show that the mass percentage of the added Tungsten powder can be increased to high levels. The samples made will likely be close to the maximum; compounds with higher percentages of added Tungsten either failed at the production or at the assembling of the membranes. An important characteristic to choose polyurethane materials was, as said, their acceptable tear strength. The tensile tests made clear that the tear strength is compromised due to the adding of the Tungsten powder and the porous structure. The samples tested on elasticity snapped as they were extended for only 60 to 70%. This can also be due to impurities in the tested membranes, but it is that certain the tear strength was lowered because of the named influences. The membranes should probably function as required because the extension during use will not be higher than 20%. The tear strength is also important in the production and assembling of the membrane, these are complicated by the current materials, techniques and configurations.

9.1.2 Tests

Unfortunately only a few samples could be made to determine their elasticity, the frequency of these spread samples was not established. The samples with different percentages of Tungsten and THF that were not made would have given more information about their influences. They were, as said, not made due to a lack of lab facilities; technically most of these membranes could have been made with the given configurations.
The frequency was determined with dipped membranes. These frequencies were much higher than anticipated. Although both the weight and the porosity were higher than the samples based on Tecoflex and Tungsten made by Douma, the frequencies were higher too. The reason for this is not clear, partly because of the little amount of samples tested.
This amount of samples is not nearly enough to attain strong proof or hard figures, the tests give only an indication of the influence of the different variables.

Both techniques can successfully be used to make the membranes. Neither the porosity nor the amount of Tungsten powder used seems to differ; the dipping required more THF but resulted in similar membranes.

The influence of the added Tungsten powder is positive; it lowers the frequency and seems to have no unwanted influence on the elasticity. The Tecothane solutions used contained high percentages of Tungsten and resulted in fine membranes. The adding of the Tungsten powder lowered the maximum elongation of the membranes but kept enough elongation possibility and with a good elasticity.

The choice of membrane material proved to be more important than anticipated. Before the test phase the Tecoflex was supposed to result in the lowest frequency because it had a lower elasticity. But because the Tecothane was stronger and was less viscose when mixed with the THF it could hold more Tungsten powder which resulted in lower frequencies. The porosity of the Tecothane membranes was, probably, even lower than the Tecoflex membranes.

The impact of the different degrees of porosity on the elasticity is not established. No samples with the same materials were made to compare the tested membranes with. Only the result of an earlier sample was there as a comparison, this was also made with a 1:10 Tecoflex:THF solution but not only the porosity was higher in the new Tecoflex sample; also the a amount of added Tungsten was different. This could suggest a positive influence of the Tungsten on the porosity but could have been caused by multiple other reasons.

The influence of the membrane thickness is primarily the pressure threshold to produce a tone; the tone itself is far less dependant on the thickness (if at all).

9.1.3 Production method for the prosthesis

Another goal of this thesis was to design a production method to produce a series of 100 prostheses. Some recommendations were made, but due to the lack of a successful membrane configuration, no real conclusions or guidelines were made on this part. No homogeneous membranes were made which could produce the required frequencies, another configuration or variation on this prosthesis will probably require its own production method.

9.1.4 Housing design

After a short study of the possibilities to produce a series of prostheses a new configuration is presented: a prosthesis that consists of two housing halves between which the conical dipped membrane and its space-separator are clamped. The Groningen Button is used to keep the parts together and in place. The housing parts could be made using injection molding. It should be assembled together with the membrane and its space-separator and placed inside a holding tube with an inside diameter similar to the Groningen Button. When the voice prosthesis is placed it can be pushed from the holding tube into the Groningen Button.

9.2 Conclusions

The results of the different tests do not provide a membrane with the required properties. The tested membranes had all got a fundamental frequency too high to use in voice prostheses for men or even women.

Adding weight using the Tungsten powder proved to be possible, even for dip molding the membranes. It is also established porous membranes can be made using the dip mold technique.
The tear strength is somewhat compromised because of both the porosity and the added Tungsten which makes the membranes brittle.

To allow a tone at a pressure level beneath 1 kPa, the thickness of the membranes should probably be kept between 60 and 100 microns. The influence on the frequency is, according to the anticipations and the frequency tests, trivial. It is however important to maintain sufficient strength, the thinner membranes tore easily and were difficult to assemble as was the Tecothane sample with the higher percentage of Tungsten powder which tore and could not be tested.
The most important chance to reach a good frequency, using homogeneous membranes, is to acquire a suited proportion between mass and porosity.

There are few possibilities to improve the design of the prostheses with the given restrictions. It is possible to ease the production and especially the assembling process by choosing a two-part housing. An angle between the membrane parts can easily be introduced. It is said the frequency could drop with 7.3% if the membranes are placed under an angle; this is not tested but should be taken in account to determine a new prosthesis design.

9.3 Recommendations

9.3.1 Membranes

The membrane needs more research to fulfill the requirements.
Since results show it is possible to lower the frequency using Tungsten and porosity it might be worthwhile to further study these possibilities.
The influence of the added THF could be examined further, perhaps even in combination with more Tungsten.
The elasticity tests that were not possible during this project could be tried to make sure the Tungsten has no influence on the elasticity; the porosity of the other samples could then be taken into account.
The elasticity is normally independent on the thickness of the membranes; thicker membranes are only interesting if it leads to more porous membranes.
Other basic materials can be tried as well as other combinations of solver and non-solver to alter the porosity. As was shown does a basic material with a lower elasticity not always result in a membrane with a lower elasticity, the strength and viscosity are also important factors. It is not likely a better material can be found to add weight considering the high density of Tungsten.

A specific study of the membrane, and only the membrane, would be useful. This should be done by a chemistry student or someone more specialized in making chemical solutions and casting thin plastic structures. This way a broader study can be done with more samples. If more samples are used the results will be more significant and useful.

9.3.2 Series production of the membranes

Before a large test series of prototypes for in-vivo testing is made, the membranes need to satisfy the requirements as set in the first chapter. Since this is not the case for the membranes made so far the search for the best configuration and production method for the membrane is still unresolved.
Spreading will be easier to produce large numbers of membranes.
The dipped membranes are easier to fixate with a known pre-strain.

9.3.3 Housing design

The geometry of the prosthesis should be studied more extendedly; especially before a series is put in production. Due to the limited time of this study not enough attention was given to the design of possible new prostheses. In further studies the transition from air-inflow to membrane and membrane fixation should elaborated on.
The width of the membrane has an important influence on the frequency. Making prostheses with both voice element and shunt valve function may bypass the restrictions of the Groningen Button. Studies to reduce the forming of bio-film on the Groningen Button can be used to make prostheses with a longer lifetime.
This study should be separated from the search for a better functioning membrane.

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