Manufacturing development of the **Voice Producing Element** Redesign and manufacturing a cheap and high quality voice producing element

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Abstract

Patients with advanced laryngeal cancer are treated by total removal of the larynx, including the vocal folds and epiglottis. The most radical change experienced by the patients after the operation is the loss of the ability to produce a voice. An alternative sound source is realized by placing a shunt-valve through the trachea and the esophagus. While the tracheostoma is closed, the air stream from the trachea can flow via the shunt into the esophagus. This causes a vibration of the surrounded tissue in the esophagus, which produces a sound that can be used for speech. However, the produced sound has relatively a low fundamental frequency and for some patients a poor quality, which makes it hard for patients to express themselves. Therefore a voice producing element (VPE) is needed. One of the possible methods is the VPE as designed by J.W. Tack. This VPE is based on a double membrane concept and can be described as a mass spring system. When air passes the VPE the membrane oscillate and produces a fundamental frequency with higher harmonics. In this VPE, masses are needed for lowering frequency. This VPE is difficult to process. Therefore a redesign is needed to get a cheap and high quality VPE.

This VPE can be divided in three basic elements, housing, membrane and masses. These different basic elements have there own possible shapes, materials and production processes. Different solutions are researched and described.

The production method for the VPE is tested. The results therefore have to been seen as a first step in founding a design and production process that makes producing a high quality VPE cheap and reliable.

We found however a promising direction which can results in cheap quality and high quality VPEs. A porous membrane is used, which has a lower stiffness than a solid membrane. This results in a lowering of the fundamental frequency. This membrane can be manufactured by Phase Separation Micro Molding. Porosity can be regulated by this method. Adding tungsten powder in this porous membrane, the fundamental frequency approach the fundamental frequency such as needed for males or females laryngectomized patients. The housing can be made by RTM. Epoxy is advised for the housing cause the stiffness.

After further research, a cheap and high quality VPE can be produced by the method as described in this report.

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Introduction

Patients with advanced laryngeal cancer are treated by total removal of the larynx, including the vocal folds and epiglottis. The trachea is sutured to an opening in the skin in the neck. Therefore a tracheostoma is formed so it is possible for the patient to breathe. The most radical change experienced by the patients after the operation is the loss of the ability to produce a voice.



Figure 1 laryngectomized

An alternative sound source is realized by placing a shunt-valve through the trachea and the esophagus, see Figure 1. While the tracheostoma is closed, the air stream from the trachea can flow via the shunt into the esophagus. This causes a vibration of the surrounded tissue in the esophagus, which produces a sound that can be used for speech. However, the produced sound has relatively a low fundamental frequency and for some patients a poor quality, which makes it hard for patients to express themselves. Therefore, this is not a good alternative for all the laryngectomized. Especially for females - compared to males- the low fundamental frequency is very disturbing, because a healthy female larynx produces a relatively higher fundamental frequency than a male larynx.

There are other ways to create a new voice for these patients, by means of a Voice Producing Element (VPE) as designed by J.W. Tack at the University Medical Center Groningen. VPE prototypes are currently tested in patients.

The test results are promising. From prototype to commercial usage a large scale examination with more than 200 patients is needed. Producing 200 VPEs in the current manufacturing method is very time consuming. Therefore we are looking for a better way to manufacture VPEs. This method should produce cheap and high quality VPEs with a constant quality.

First the current model will be discussed and also an explanation of the disadvantages of the present production method. Chapter one will describe the demands as required for the VPE. In chapter two the different concepts are presented with the manufacturing method which is tested in chapter three. This report will end by a general discussion with conclusions and recommendations.

Current VPE

VPE

To allow speech again, J.W. Tack developed the Voice Producing Element (VPE) concept as described in his article 'In-vitro evaluation of a double-membrane based voiceproducing element for laryngectomized patients' (2006):

"The double membrane as a sound-generating principle was developed in a previous study using up-scaled models. The VPE based on this concept consists of two elastic membranes placed parallel to each other inside a circular

housing, see Figure 2. A constant flow of air from the lungs Figure 2 VPE in body can be led between the membranes, which then start to vibrate via aerodynamic forces, and thereby generate a complex sound. The underlying working principle is comparable to the oscillating lips of a musician playing a brass instrument, but also to the avian vocal system, the srinx, in which the membranous sections at the junction of the two avian bronchi interact with the airflow from the lungs, producing a frequencymodulated sound. An advantage of the double-membrane VPE over the reed- and lipbased VPEs is that the double-membrane concept is expected to be less sensitive to blockage by mucus, since the exhaled air has to pass the lumen between the membranes, thus removing the mucus. Moreover, the membranes can be pushed away from each other to create a larger through-flow opening for passing mucus, while afterwards the membranes will always return to their initial position because of their attachment to the housing. The sound produced by the prototypes should contain a fundamental frequency suitable for producing a male (mean 120 Hz) or female voice (mean 210 Hz)."

This VPE can be described by a mass-spring system (Figure 3). The membrane has a specific stiffness. The weight of the membrane together with the masses on the membrane forms the total mass. The damper is dependent on the air in the housing, and hysteresis of the material. The fundamental frequency (F₀) can be calculated by stiffness (k) and mass (m) in the following equation: $F_0 = \sqrt{k/m}$.



Figure 3 M/K model

The VPE as designed by J.W. Tack is build up by four different components:

- 1. Housing of stainless steel
- 2. Tube (membrane) of Polyurethane (1x)
- 3. Weights of silver steel
- 4. Stainless steel rods

The function of the housing is membrane stretching. Without the weights, the fundamental frequency is too high. The rods are used to fix the membrane into stainless steel housing.



Figure 4 Elements



Figure 5 Weights on membrane



Figure 6 Current VPE front side



Figure 7 Current VPE back side



(6x)(2x)

(1x)

The optimal present values for each component are presented in table 1

Table 1 VPE sizes		Width: 5.0 mm
Part	Value in mm	
Membrane distance	0.28	
Membrane thickness	0.06	Distance:
Membrane length	0.833	0.28 mm
Inner diameter	5	Length: 8.33 mm
Outer diameter	6.0	
Weight length	1.83	
Weight width	1.66	
Weight high	1.27	Figure 8 Current VPE

"The membranes were comprised of a medical grade polyurethane, and manufactured via dip molding. The process can described as follows: it is necessary to get a thin polyurethane film around the weights, this could be received after a few times dipping. Next step is placing the weights in a mould and dip again. A membrane thickness of 60µm is received by dipping six's times. After this dipping process the membrane will be placed in the housing by hand. The metal discs were comprised of steel (AISI 02; density = 7.85 g/cm³), and dipped in the polyurethane as well. The result of the dipping process was a polyurethane housing, with the six weights incorporated in the polyurethane, as shown in Figure 2a. The elastic housing was stretched by two stainless steel pins that fit into the slits on both sides of the stainless steel housing to obtain two pre-stressed, parallel membranes. The strain of the membranes was 1.8%. The protruding portion of the housing was folded over the outside of the housing, and glued with medical grade cyanoacrylate glue (Tack, 2006)". The current VPE is shown in Figure 8.

The elements and the production method are shown in Figure 3-6.

The VPE as designed and developed by Ir. Tack is complex to produce; it is very difficult to create similar VPE's. Therefore a redesign has to be made, including the optimal manufacturing process(es). Disadvantages of the current method are:

1. Membrane producing

- Inhomogeneous membrane thickness
- Time-consuming
- 2. Assemblage
 - Irreproducible membrane stretching

The membrane is in the current method the bottleneck by assemblage and causes irreproducibility. Therefore another membrane shape is needed. This redesign have consequences for the other elements in the VPE.

Aim

For getting a better producible VPE the next aim is formulated:

The aim of the study is creating a viable production method for the VPE, which results in a VPE produced for acceptable prices and constant quality. It is allowed to redesign the current VPE prototype if it is necessary.

The VPE should be produced in mass production. Therefore it is necessary to have a reproducible VPE which can be easily assembled. For a better design it is necessary to know which parameters are variable and invariable and also describe the functions which should be fulfilled by the VPE. Chapter one gives an overview of the demands. Chapter two describes the concepts. Chapter three described tests as execute with the redesigned VPE. After this there is a general discussion and conclusions.

1. Functions and requirements of the VPE

Concepts can only be accurately examined by right requirements. Therefore it is necessary to have knowledge of the requirements which the VPE should fulfill. For getting a list of just requirements, the functions will be described and likewise the requirements. After this the parameters will be investigated. Which results in summarized requirements.

1.1 Functions and requirements

1.1.1 Functions

The functions the VPE has to fulfil are:

- Creating sound
- Increasing frequency with increasing airflow

1.1.2 Restrictions by environment.

The prosthesis is placed in a shunt valve. This valve is made out of silicone rubber and has an inner diameter of 6 millimeters and an outer diameter of 7 millimeters. The average length of the valve around the 10 millimeter and is dependent of the wall thickness. When it is much longer compared to the prosthesis, it sticks out in the trachea.

The shunt valve is replaced every three months on average. The valve is placed between the esophagus and the trachea. On the esophagus side, food glides along the valve. So bacteria and food rests sticks on the valve and create a biofilm. After a long period the lid sticks and stays open or closed. The valve is unusable when leakage occurs.

It is possible that mucus from the lungs comes between the membranes of the prosthesis. Therefore it is necessary to design the prosthesis so mucus has no negative influence. When the prosthesis or parts of it come loose, it comes in the stomach or in the lungs. In the lungs the prosthesis may not cause any damage. Biocompatible material is needed.

The prosthesis is placed in a warm and moist environment. The prosthesis has to fulfill the functions for a period of three months. With a disposable prosthesis the life time could be shorter¹. In spite of this environment the prosthesis should work constantly and should be reliable.

1.1.3 Functional requirements

- Creating a voice source with a F_0 of 120 Hz for male
- Creating a voice source with a F_0 of 210 Hz for female
- Create flow inlet
- Stretching membrane
- Fit into a Shunt valve
- Biocompatible
- Biostable
- Safely

¹ A disposable prosthesis is not designed because not all the patients are able to replace the VPE. In further stadium a disposable prosthesis should be designed for patients which are able to replace the VPE.

1.1. 4 Production requirements

The first series (null series) is a small series, around the 500 units. When the prosthesis is tested successfully, there is a need of 10.000 pieces per year in the Netherlands. The maximum price is 100 euro per unit. For a disposable prosthesis the price may not be higher than one euros per unit.

Of course the product has to fulfill all the requirements as mentioned above. There are some more requirements which are not described above:

- Mechanical producible components
- Suitable mechanical assembling
- Costs low as possible
- Suitable for consistent mass production
- Ability to have a retail price which is up to 4 times the cost price.

1.1.5 Invariable and variable parameters

Invariable parameters

-	Membrane distance	Air pressure needed for generating membrane oscillations.
-	Length of the membrane	For generating the right frequency
-	Height of the weights	May not touch the housing inside
-	Outside diameter	Fit in shunt valve

Variable parameters

Membrane thickness

-

-

Strong enough

-	Mass dimension	Higher mass results in lower F ₀
-	Membrane stiffness	Produce a lower frequency in a natural way
-	Mass weights	Higher mass results in lower frequency
-	Number of weights	Smaller weights results in a better natural wave

- Length of the housing Between 1 and 3.5 centimeter
- Membrane shape The membrane has to create af frequency, this is possible by different shapes
- Material

Material is justified when it fulfils the requirements

1.2 Requirements by component

The prosthesis has to

- Work by an air pressure between 0.2 to 1.5 kPa
- Work by an airflow rate of ca 45 to 350 ml/s.
- Produce a F_0 of 120 or 210 Hz with higher harmonics.
- Sound Pressure level (SPL) between 60-80 dB over a distance of 30 centimeter from the mouth.

The VPE can be divided in three basic elements; the housing, the membrane and masses. The housing has to be able to perform a number of functions and therefore a special geometry is required. The requirements for all these different basic elements are described below:

Housing shape

- Stretching the membrane.
- Create an flow inlet when the membrane doesn't form the flow inlet as in the current model.
- Keeping the membrane distance constant.
- Fit in the shunt valve.
- Fasten the membrane linear direction.
- Create stiffness of the VPE
- Producible by two mould parts.

Groove

- Fixating membrane in the linear direction.
- Fixating membrane in width direction.
- Create a constant membrane distance.

Membrane fixation and stretching

- Pre-strain between 0 and 2%.
- Membrane may not come loose.

Membrane at flow inlet

- Smooth switch from housing to membrane.
- Laminar air stream.
- Creating an flow inlet (not necessary if housing can fulfil this function)

Membrane

- Possibility to place weights on it if necessary.
- Possibility for fixation on housing.
- Have to oscillate by a constant flow of air from the lungs, thereby periodically closing off the airway

Masses

- May not hit the housing by vibrating
- May not lead to a degradation of the membrane stiffness.

There are more requirements as well. All the materials should be biocompatible and survive for three months in a gastric acid environment. The requirements are placed in the table 2:

 Table 2 requirements.

Membrane material requirements	Reason	Value
Mechanical properties		
High ultimate elongation	Great tear strength	>400%
Low young modulus	Lower young modulus results in a lower frequency	<3 MPa
No strain relaxation	Constant frequency	< 5%
Mechanical properties		
Good impact strength	May not tear of degrade by vibration	
Tear resistance high as possible	May not tear by strain of a little gap	>2 kN/m
Environment resistance		
No gradient by oxidation	Airflow from longs pass the VPE, $(CO_2 \text{ and } O_2)$	
No water absorption and or degradation	Damp environment (mucus, saliva)	
Chemical resistance		
Base	Blood, saliva	pH 7.5 ²
Acid	Gastric acid	pH 1 ³
Housing material requirements		
Physical properties		
Density high as possible	For the weights, high density lower frequency	Min 7.8 Kg/m ³
Environment resistance		
No dangerous oxidation	Oxidation gives Fe ₂ O what can come in longs	
Chemical resistance		
Base	Blood, saliva	рН 7.5 ⁴
Acid.	Gastric acid	pH 1 ⁵

² www.ortholon.com/catalog/article_info.php?articles_id=15 250406
 ³ www.vrom.nl/pagina.html?id=10147 250406
 ⁴ www.ortholon.com/catalog/article_info.php?articles_id=15 250406
 ⁵ www.vrom.nl/pagina.html?id=10147 250406

Glue material requirements

Physical properties		
Elasticity	May not break or tear by strain	0.05 mm
Resilience normal	May not break by a bit elongation	05 mm
Mechanical properties		
Strong as possible	Hold the membrane on the just place	<2%
Environment resistance		
No gradient by oxidation	Damp environment (mucus, saliva)	
No water absorption and or degradation	Mucus and saliva	
Chemical resistance		
Base	Blood, saliva	pH 7.5 ⁶
Acid	Gastric acid	pH1 ⁷

⁶ www.ortholon.com/catalog/article_info.php?articles_id=15 250406 ⁷ www.vrom.nl/pagina.html?id=10147 250406

2. Concepts.

The present VPE form is derived from its functions. By creating a VPE in a more professional context with more production possibilities totally other shapes are possible. Although the function may not perish there is freedom for redesign.

In this first section we will discuss the housing. After these concepts, different kinds of materials are displayed. Finally the production methods are shown. This order is also applied to the membrane and the masses.

The requirements that are needed to evaluate these concepts are presented in the previous chapter. In the next chapter we will show you some concepts and evaluate these concepts.

2.1 Housing

The function of the housing is membrane stretching, guarantee a constant membrane distance. The housing should be fitted in the shunt valve. By the housing the VPE is handily. Housing concepts are described in the following text even as the production method and material.

2.1.1 Concept housings

Housing shape

The shape of the outer housing is defined by the shunt valve. For a proper fixation in the shunt valve a round shape is needed with a maximum outer diameter of six millimeters. There are many ways to form a round housing but in this particular case two possible concepts are viable: housing made by one or two parts. Some concepts are visualized in Figure 9.

Membrane distance

A groove is one of the solutions for membrane distance and membrane stretching. This groove is saved in the housing. The groove has two main functions:

- Fixing the membrane
 - Linear direction (keep the membrane over the flow inlet)
 - Breadthways (the membrane may not flip through the groove into the housing.
- Guarantee a constant membrane distance

A groove in the housing generally leads to a lower stiffness of the housing. There are three possibilities to increase the housing stiffness: material with a high stiffness, or a closed groove. A closed groove had two closed ends at both sides, contrary to an open groove with one open end. An open groove is presented in Figure 10. There is, however, another solution: fixing the membrane by means of metal rods. This way housing stiffness will largely be maintained.

Membrane attachment and stretching

The membrane is the key element in the VPE, therefore it is important to consider all the concepts and possibilities for fixating it. For optimal results, the membrane is fixed in the housing without tension on it. This way the frequency is lowered. To build the housing out of two parts there are a few realistic options

- A small elliptic border, the membrane is fixed on this border by glue (Figure 11)
- Straight groove, the membrane is glued at the border (Figure 12).









Figure 11 Elliptic border





Figure 13 Enveloping

- Third, the housing is enveloped by the membrane (Figure 13).
- Two small rods are in the closed membrane and stretch the membrane by the housing. These rods can have have every possible shape, but cylinders are the most common (figure 14).

The first three concepts use two parts to stretch the membrane, the last one uses four.

A completely different way of stretching the membrane is shown in Figure 15. Two bars enclosed by the membrane are bent in the right shape, stretching the membrane creating an flow inlet. The membrane can be held on the inside of the housing by grooves.

Membrane to flow inlet opening transition

A smooth transition from the flow inlet created by the housing to the membrane is necessary to prevent whirls at the end. The design of a special flow inlet is needed.

In the first side view the air collides with the membrane (figure 16)

Second view(Figure 17) a complex deepening prevents from collision.

The third concept is the opposite of the second shown in Figure 17

The fourth solution presented in Figure 19. The membrane goes under the flow inlet that is created by the housing. The membrane is stretched at the end, so there is more fixation.

When the housing is fitted with a straight groove, one can lead the membrane downward by means of an extra element.



Figure 14 Rods



Figure 15 Stretch by bars



Figure 16 Collapse



Figure 17 Deepening



Figure 19 Over flow inlet



Figure 20 Underneath

2.1.2 Housing Material

The housing should consist of a biocompatible material with a high stiffness. Two biocompatible materials with a high stiffness are SAN and PMMA. SAN has a high stiffness.

"Styrene-acrylonitrile (SAN) medical products are transparent, with the level of optical clarity dependant on the grade used. Typical properties include good surface gloss, high rigidity, hardness, and chemical resistance. With its flow characteristics and processability, SAN enables the production of thin-section moldings with high strength and dimensional accuracy. The combination of processability and transparency, makes SAN well suited to medical applications such as reaction chambers for automated diagnostic units. In this instance, the clarity of the specimen-housing carriers and the nonspecific bonding characteristics of SAN enhance the accuracy of automated diagnostic tests. Other applications include ampoules, measuring beakers, drip chambers, and line joints."

(From: www.medicaldesign.com/articles/ID/856)

"Lustran® ABS (acrylonitrile-butadiene-styrene) and SAN (styrene acrylonitrile) resins provide an excellent balance of properties for molded medical parts. Lustran ABS 348-1002 natural, 2002sno-white and other selected colours meet FDA- modified ISO 10993-I requirements (see 'Biocompatibility'). SAN resins can exhibit 'water clear' optical clarity. SeveralLustran SAN resins for the medical market comply with USP 23 Class VI. Both Lustran ABS and SAN resins offer excellent chemical resistance and are sterilizable by EtO or gamma."

(In according to:www.newmaterials.com/news/2481.asp)

A totally different material is epoxy. Epoxy is a thermo labile material. Epoxy is made by mixing two components. Epoxy is known as very rigid material. In a lot of articles epoxy is used to create a biocompatible film around products.

"After assembly, the entire tag is coated with a 1 mm layer of medical grade epoxy (Epo-Tek 302-3M, Epoxy Technology, Billerica, MA). (...)It has been chosen to use a biocompatible epoxy resin (EPO-TEK 30 1-2) as encapsulating material, as it confers to the package the right degree of stiffness."

(From: Designing an Archival Satellite Transmitter for life deployments on oceanic vertebrates: The life history transmitter, Horning, Hill, R.D. 2005)

"The microprobe has been assembled on a ceramic substrate, packaged by injection dispenser with a biocompatible epoxy resin and connected by flexible wires to the external measurement instrumentation."

(From: Impendance microprobes for myocardial ischemia monitoring, Benvenuto, A., 2000).

The advantage of epoxy is its high stiffness and the relative easiness of processing. Another great advantage for using epoxy is the small shrinkage. There is only chemical shrink. This results in high exactnesses.

2.1.3 Production method for housing

The two processes most used for the materials as described are 'injection molding' for SAN and PMMA and for epoxy 'transfer molding'. Both process are described in the following text.

Injection moulding (IM) "The highest volume method of forming objects from granular or powdered thermo sets and thermoplastics, in which the material is forced from an external heated chamber through a sprue, runner or gate into a cavity of a closed mold by means of a pressure gradient, independent of the mold's clamping force. Flaws may occur at fiber ends which tend to induce brittle failure. For a given fiber volume, long fibers are preferred because they introduce fewer ends to the composite than do short fibers. Long fibers with their higher aspect ratios are more prone to be preferentially







oriented in a composite matrix, providing improvement in properties." Definition from CRC Press LLC Copyright ©1989. These process is schematically shown in Figure 21.

"The most common equipment for molding thermoplastics is the reciprocating screw machine, shown schematically in the Figure. Polymer granules are fed into a spiral press where they mix and soften to a dough-like consistency that can be forced through one or more channels ('sprues') into the die. The polymer solidifies under pressure and the component is the ejected. Thermoplastics, thermosets and elastomers can all be injection molded. Co-injection allows molding of components with different materials, colours and features."

(From CES edupac injection molding)

Resin Transfer moulding (RTM)

"Definition: A closed-mold pressure injection system which allows for faster gel and cure times as compared to contact molded parts. The process uses polyester matrix materials systems association with cold-molding and most reinforcement material types such as continuous strand, cloth, woven roving, long fiber and chopped strand. Also known as resin-injection process." (Figure 22) Definition given by CRC Press LLC Copyright ©1989.

"Resin Transfer Moulding (RTM) allows manufacture of complex shapes in fiber-reinforced composites without high tooling costs. It uses a closed mould in two or more parts, usually made of glass-reinforced polymer or light metal alloys, with injection points and vents to allow air to escape. Reinforcement is cut to shape and placed in the mould, together with any inserts or fittings. The mould is closed and a low viscosity thermosetting resin (usually polyester) ins injected under low pressure (roughly 2MPa) through a mixing head in which hardener is blended with the resin. The mould is allowed to cure at room temperature. The moulding is allowed to cure at room temperature. The fluidity of the

Process Schematic





resin and the low moulding pressure guarantee long tool life at low cost."

(From: CES edupac Resin Transfer Moulding)

"Advantages of Transfer Molding

- Provides more product consistency than compression molding
- Cycle times are shorter than compression molding
- Better than compression molding for rubber-to-metal bonding

Disadvantages of Transfer Molding

- The transfer pad is scrap
- Cycle time is longer than injection molding
- Product consistency is poorer than injection molding."

(From: www.molders.com/transfer_molding.html)

"The benefits of RTM are impressive. Generally, dry preforms for RTM are less expensive than prepreg material and can be stored at room temperature. The process can produce thick, near net-shape parts, eliminating most post-fabrication work. It also yields dimensionally accurate complex parts with good surface detail and delivers a smooth surface finish on all exposed surfaces. It is possible to place inserts inside the preform before the mold is closed, allowing the RTM process to accommodate core materials and integrate "molded in" fittings and other hardware into the part structure during the molding process. Moreover, void content on RTM'd parts is very low, measuring in the 0 to 2 percent range. Finally, RTM significantly cuts manufacturing cycle times and can be adapted for use as one stage in an automated, repeatable manufacturing process for even greater efficiency, reducing cycle time from what can be several days required for hand layup to just hours -- or even minutes."

(According to: www.compositesworld.com/sb/ov-rtm)

2.2 Membrane

The VPE need a specific fundamental frequency. In the current model a membrane without weights does not approach the right fundamental frequency. Lowering the F_0 of the VPE can be realized by using a material with a low modulus of elasticity (E) by equation $F_0 = \sqrt{k/m}$. A lower E must be accompanied by a sufficient tear strength for the membrane to hold together. Another possible solution is a thinner membrane. It is also possible to increase the mass. This concept is described in chapter 2.3.

2.2.1 Membrane concepts

The membrane is the key element in the VPE, however its shape can be changed while preserving its functioning. Creating elastic parts on the sides of the membrane is the first concept. Flexible parts on the sides of the membrane gives a more flexible membrane as shown in Figure 23. The borders can stretch more than in the normal situation.

A way around these problems may be a found in a different way of creating the flexible parts. Two ribs near each other with a thinner area in between can create a small gap with relative great closed surface between the other two ribs as shown in Figure 24. This result in a lowering of E.

Another idea is porosity. A higher porosity will probably results in a lower stiffness of the membrane the stiffness will decrease more than the tensile strength



Figure 23 Flexible edge



Figure 24 Flexible parts

2.2.2 Membrane material

The selection of the membrane materials starts with stating what kind of mechanical properties the membrane requires; low elastic modulus and high tensile strength. CES edupac is a program with an extended database of materials. For this case materials are selected by tensile strength and elastic modulus, CES gives for these requirements the next graph (displayed in Figure 25);



Looking at this plot, there can be concluded that polyurethane is the best material that can be used in the VPE. Natural rubber has the same mechanical properties, but is not biocompatible. The table below confirms this conclusion. Silicone had a low elastic modulus, but the tensile strength is not high enough. Table 3 gives an overview of the properties of different materials.

Table 3 Material properties

Test	Polyurethane	Silicone	Latex
Tensile (psi)	3000-5500	800-1500	4400-4900
Elongation (%)	400-1000	600-1100	800-1200+
Tear strength (pli)	330-380	100-280	340-370
S tear (pli)	150-250	50-100	100-190
Tensile set a 300%	2-10%	1-5%	None
UV resistence	Good	Good	Poor
Chemical resistance	Good	Good	Poor
Bondability	Good	Moderate	Poor
Allergic reaction	No	No	Yes
		1 1 1 1 1 1	1.1 1. 10110110

(From www.devicelink.com/mddi/archive/01/04/002.html)

It seems that polyurethane is the best material. CES edupac and datasheets of polyurethane confirm the choice for polyurethane.

"Polyurethanes are thermoplastic rubbers made from isocyanates and are designated aromatic or aliphatic on the basis of the chemical nature of the diisocyanate component in their formulation. Aromatic and aliphatic polyurethanes share similar properties that make them outstanding materials for use in medical devices:

- High tensile strength (28-69 MPa).
- Wide range of durometer (72 Shore A to 84 Shore D).
- Good biocompatibility.
- High abrasion resistance.
- Good hydrolytic stability.
- Ability to be sterilized via ethylene.
- Ability to retain elastomeric properties at low temperature."

(In according to: www.devicelink.com/mddi/archive/01/04/002.html)

"Chemical and environmental resistance Polyether and polyester urethanes each have specific chemical resistance characteristics, such as resistance to hydrocarbons, chemicals, ozone, bacteria, fungus, and moisture, as well as skin oils. Urethane may be sterilized with ethylene oxide without yellowing and with gamma sterilization in cases where a limited amount of yellowing is acceptable.

Sterilization depend on the formulation selected, urethanes can offer excellent resistance to a wide range of hydrocarbons, chemicals, ozone, fungus, moisture, and sterilant gases such as ethylene oxide.

Fabrication versatility Urethane is easy to work with. It can be fabricated in many ways with many different substrates, enhancing design versatility. Sheet can be fabricated with urethane tubing to provide the benefits of urethane to an entire product system, such as in linked bladder applications"

(From: www.stevensurethane.com/medical/performance.html)

CES edupac gives a lot of manufactures who produce polyurethane. By searching on the internet, for products and manufactures, the datasheets of specific polyurethanes are available and can put together in the table 4 below:

Table 4 Material overview

	Product	Durometer	Specific	Flexural	Tear	Ultimate	Ultimate	Tensi	le at	remark
Manufacture		(shore	gravity	modulus	strength	tensile	elongation	100	300	
		hardness)	kg/m ³	MPa	Kn/m	MPa	%	MPa	MPa	
Estane	TT-1074A	75A	1.10	9	-	41	550	3.5	7.6	
Estane	TT-1085A	85A	1.12	20.68	-	48	450	5.5	11	
Estane	EG-80A	73A	1.25	8.3		35	710%	2.8	6.2	
Estane	EG-80A	72A	1.04	6.8	-	39	660	2.1	5.5	Not biostable
Noveon	PC-3575A	73A	1.15	4.3	-	36.5	470	2.7	6.2	
Rogers Corporation	PORON 4708 soft cushioning	120	.0223	-	0.5	.276	-	-	-	
Rogers Corporation	PORON 4708 soft supporting	170	.02976	-	0.9	0.517	-	-	-	
Rogers Corporation	PORON MF energy absorbing	66 OO	.272	-	1.8	.612	-	-	-	
Rogers Corporation	PORON MSRVF (dark jade 80)	82 OO	.240	-	2.1	690	-	-	-	
Dow	Pellethane 2103-80AE	-	1.13	-	105	34.5	600	5.5	11.7	
Dow	Pellethane 2354-45D	46D	1.19	68.9	119	39.6	500	9.0	19.0	
Dow	Pellethane 2354-65D	65D	1.22	-	208	40	430	19.3	25.8	
<u>AlphaGary</u>	Evoprene G618	-	1.18	-	163	3.7	550	0.9	-	
AlphaGary	Evoprene Cogee 632	52A	1.08	-	24	3.7	280	2.5	3.6	
<u>AlphaGary</u>	Evoprene Super G 948	44	1.08	-	20	7.4	510	1.4	3.7	
Vi-Chem	Uravin 901-65 FR-7759	69	1.219	-	1.6	9.9	433	6.0	8.5	
Corporation										
Vi-Chem	Uravin 901-80	75	1.230	-	8.5	-	484	2.0	6.5	
Corporation										
Stevens	Stevens urethane MP-1880	87A	1.12	-	70	48.2	450	6.90	13.8	
Stevens	Stevens urethane MP-189	90A	1.14	-	87.5	55.2	450	10.3	20.68	
Cytec	Vytaflex 10	10A	1.00	-	5	28	1000			Not biocompatible
Cytec	Conathane RN-3360	60A	1.07	-	33	30	600	1.5	2.4	Not biocompatible
	CES Urethane ⁸	-	1.18-1.2	1.8-3.2	-	29-32	680-720	-	-	

⁸ CES edupac (2006) polyurethane properties

Conathane contains a lot of material properties stated before, but it is not biocompatible. TT-1085A is used in the current VPE. At a relative low stiffness EG-80A is a good alternative. EG-80A has a lower tensile stress and a high ultimate strength. However EG-80A is not biostable and therefore, with the membrane placed in the body, the frequency generated in the VPE is not constant over a long period of time, but possible for a disposable VPE. The biostability test is described below. This research is executed by the manufacturer.

"All Tecothane® and Carbothane® implant samples were punched from 0.5 mm thick extruded tape using an ASTM D-1708 die. The approximately 1 cm x 3 cm samples were ETO or chemically sterilized prior to implantation. The samples, along with USP-polyethylene controls, were placed at the dorsal sites above the paravertebral muscle of mature New Zealand white rabbits. Each rabbit received 2 controls and 6 test implants (4 left side, 4 right side). Tecothane® and Carbothane® samples were explanted after 30 and 90 days. The explants were evaluated in terms of ultimate tensile strength, ultimate elongation and surface appearance. Tensile and elongation measurements of the explants were tested with control samples conditioned in the same manner but not implanted. The explant samples were examined by scanning electron microscopy to determine if the surface of the material showed signs of degradation."

Material	Mem	Hemolysis	USP Class	30-day	90-day	Ames
	Elution		VI^9	implant	implant	mutagencity
EG-	Pass	Pass	Pass	Pass ¹⁰	-	Pass
A80A						
TT1075A	Pass	Pass	Pass	Pass	Pass	-
TT-	Pass	Pass	Pass	Pass	Pass	-
1085A						

Table 5 biocompatibility and stability test

(This information comes from: Biocompatibility/biostability Noveon 2003/2004)

After 30 days of implantations the reaction of the immune system to the EG-80A samples was so intense that the samples had to be removed. EG-80A can be made more resistant to the human body by adding barium sulphate, but we prefer a clear grade polymer. A clear grade polymer react possible less with the immune system. More materials in the membrane can lead to more problems.

⁹ USP Class VI includes three tests:

^{1.} Systemic injection of 4 extracts; 2. Intracutaneous injection of 4 extracts 3. Intramuscular implantation for 7 days 10 Macroscopic observation of 30-day subcutaneous explants passed gross observation criteria for inflammation, encapsulation,

hemorrhaging, necrosis and discolouration.

2.2.3 Production method for membranes

It is hard to create a membrane with a thickness of 60 micrometer by extrusion. The polymer has a high viscosity by the long chains. With this production method an enormous pressure is needed. Because of the small wall thickness blow extrusion is not possible. The slim wall thickness can only be achieved at a high diameter. Calendar (making a plate thinner by putting it door roles with a specific distance) is only profitable when there are kilometers of membrane to produce. The profitable way to make a small series of membranes is: Phase Separation Micro Moulding (PSµM), spraying, rotating and dip molding.

Phase Separation Molding (PSµM)

Vogelaar et al, (2005) describe this process:

"A schematic representation of the PSµM process is given in Figure 26. In PSµM a polymer solution is applied on a mold with a micrometer-sized relief structure on the surface. The application of the solution on the mold is performed most of the time by casting, using a casting knife to spread out the solution into a thin film. When the thickness of the layer of polymer solution is a critical parameter, a set-up is used in which the height of the casting knife can be adjusted by micrometer positioners, thereby ensuring the accuracy of the film thickness."



Figure 1. Schematic representation of the phase separation micromolding process. A layer of polymer solution is applied to a mold having a micrometer-sized relief profile on the surface. The polymer solution is solidified by either thermally induced (change of temperature of the solution) or liquid-induced phase separation (immersion in a nonsolvent). During the solidification the polymer assimilates the profile of the mold. The polymer microstructure is easily released from the mold.

Figure 26 PSµM

"Phase separation can lead to three basic types of morphology:

- 1. Completely dense structure;
- 2. Porous substructure with dense skin layer;
- 3. Completely porous structure.

The morphology that is obtained depends on the dynamic path in the ternary diagram that is followed during phase separation. This is related to a large range of parameters, including temperature, composition of the polymer/solvent/non-solvent system, casting thickness and pre-treatment prior to immersion (e.g. solvent evaporation, contact with non-solvent vapor). Since these conditions can be controlled, the final morphology can be tailored to suit the application. Pore sizes can range from 0 (dense) to several microns, covering separation processes from gas separation to microfiltration. The maximum achievable porosity is not limited by the process itself but rather by the mechanical stability of the obtained film"

(New Replication technique for the fabrication of thin polymeric microfluidic devices, de jong, ankone).

Spraying

By spraying, granulate will be mixed in the solvent and sprayed by gas at the surface. The thickness of the film around the subject can precisely be determined.

- "Spraying should be accomplished with high quality industrial equipment.
- Solution viscosity should be adjusted for uniform spray output.
- Spray coated components should be deaerated for 24 hours prior to handling."

(From: Processing Information www.estane.com 03/04)

Some tips which are given by dipping are also relevant for spraying:

- "Mandrels of the desired shapes should be cleaned with acetone prior to use.
- In many cases, elevated temperature can facilitate lacquer application. Recommended starting temperatures are 55°C for the mandrel and 65°C for the lacquer solution. These temperatures should be used only with DMAC. THF and MC do not require heating.
- Test runs are necessary to optimize the solids content and viscosity required for application.
- The eventual thickness of each layer will be determined by the solids content, whereas the ease of application will be determined by the viscosity.
- The mandrel should be introduced gradually into the lacquer until the mandrel is completely covered, and then withdrawn at a controlled rate that is consistent with the flow rate of the lacquer.
- Each coating should be air or oven dried until a "skin" forms. Subsequent dips should be dried likewise.
- Once the desired thickness is attained, the part should be
- allowed to deaerate for at least 24 hours prior to demolding or handling."

(From: Processing Information www.estane.com 2003/2004)

Rotation molding

Another way to create a membrane is by rotating molding. The mold is filled with polymer of low viscosity. A membrane with slim walls can be made by rotating the mold. This polymer is applied in a line over the length of the mold while the mould is rotating fast. The homogeneity is achieved by the centrifugal forces. The process of rotation molding is schematically represented in Figure 27.



Dip molding

The membrane in the current VPE is made by dipping. Dipping is a method were the mould is dipped a few times in the solution. The solvent can evaporate and the polymer stays on the mould. The thickness can be regulated by the dipping time and the number of dipping times. The method is time consuming in small series. An example of dip molding is presented in Figure 28.

Figure 27 Rotation Molding



Figure 28 Balloon dipping

2.3 Masses

2.3.1 Mass Concepts

Weights can be used for lowering the natural oscillation of the membrane, if the membrane self doesn't produce the needed F_0 . In the mass spring system, results a higher mass in a lower frequency. A lower stiffness is also possible; this is described in chapter 2.2.1. Differently shaped weights are considered for use in the VPE. Among others rectangles or trapezium. Space between the weights

is needed to prevent collision between the weights yet maintaining **Figure 29** Weight shapes Flexibility. Options are shown in Figure 29.

Scattering powder over the surface eliminates this predefined position. The powder can be placed between the layers, but it is also possible to mix the polyurethane, the solvent and the powder and spread this mixture over the surface. Both possibility's are shown in Figure 30 and 31.

Mass in the middle of the membrane, however, has a much higher impact on the F_0 than mass at the border of the membrane, and is therefore inefficient.





Figure 30 Powder in layers



Figure 31 Homogenous distribution

2.3.2 Mass Material

Selecting a mass-material for the VPE is not simple. The most important requirements are the bio stability, biocompatibility and high density.

Gold and platinum are inert materials, so they are biocompatible and have a high density; gold 19 gr/cm³ and platinum 21 gr/cm³. The costs are respectively 14.500 and 29.500¹¹ euros per kilogram. For a female voice the element needs approximately 150 milligram, and for a male voice there is a need of approximately 210 milligram. The costs of gold weights are respectively 3.05 and 2.18 euros, for platinum respectively 6.20 and 4.43 euros. This material can be recycled but it is not practical, due to administration costs. Therefore another high density material needs to be found.

CES-edupac had a database with a high number of different metal and alloys. Based on density and price, Figure 32 represents the plot as given by CES Edupac. The price is plotted against density.



This figure indicates that tungsten has a low price and a high density. The density of pure tungsten is 19.3 gr/cm^3 and the costs are 80 euros per kilogram. Tungsten powder is available worldwide.

The fine tungsten powders produced from Buffalo Tungsten typically have a minimum purity of 99.95%, with average particle sizes up to 10 microns. The remaining 0.05% is described in attachment A. Possible particle sizes are shown in table 6.

Table 6 Tungsten powder

Туре	Avg. particle size microns
C3	0.60-0.99
C5	1.00-0.39
C6	1.40-1.99

Tungsten powder is not biocompatible, however when encapsulated in polyurethane is it safe to use in the VPE membrane. Encapsulation can be done by mixing the powder in the polyurethane solution.

2.3.3 Production method for masses

Tungsten is a very tough material and therefore hard to process. One of the methods of processing tungsten-powder is sintering (Figure 33). Fortunately this is not the only way. Other processing possibilities are described in the following text.

Sintering

"Sintering is a method for making objects from powder, by heating the material (below its melting point) until its particles adhere to each other. Sintering is traditionally used for manufacturing ceramic objects, and has also found uses in such fields as powder metallurgy. Sintered bronze in particular is frequently used as a material for bearings, since its porosity allows lubricants to flow through it. In the case of materials with high melting points such as Teflon and tungsten, sintering is used when there is no alternative manufacturing technique. In these cases very low porosity is desirable and can often be achieved.





Advantages of this technology, which is schematically shown in Figure 25, include:

- the possibility of very high purity for the starting materials and their large uniformity
- preservation of purity due to the restricted nature of subsequent fabrication steps
- stabilization of the detail of repetitive operations by control of grain size in the input stage
- absence of sintering of segregated particles and inclusions (as often occurs in melt processes)."

Technon Powder

"Tungsten Heavy Powder Inc. in California discovered a new way to process tungsten. (...) There has never been a more economical, flexible, and versatile method to attain such high density. The process is suitable for most applications where added weight is the objective. Technon powder with a binding agend densities of 15 gr/cc can achieved. By sintering tungsten component a typical density of 17g/cc is achieved. Such relatively smalladded density is economical considering the sintering costs as well as the additional costs for machining, fitting, and attaching (From: www.wikipedia.org/wiki/Sintering)



Figure 34 Technon

the sintered part. This method will enable to manufacture a high-density item in a factory without any additional capital investment. The necessities are shown in Figure 26." This method is shown in Figure 34.

(From: www.tungsten-heavy-powder.com/Tungsten_Heavy_Powder)

After sintering Tungsten has a very rough surface. To make the material bio compatible it can be dipped into a gold bath. Gold attaches very well to the rough surface of tungsten.

Laser Cutting

Another way to get the right shape is laser cutting. However, due to the high melting point of tungsten, laser cutting is not recommended. Mechanical cutting is very expensive because of the great hardness of tungsten alloys.

Tungsten polyurethane mix

When tungsten powder is processed in the polyurethane solution it is better to use pure tungsten powder. A tungsten alloy gives a lower density than pure tungsten. Pure tungsten powder can be used in a polyurethane solution. When tungsten powder is mixed by a polyurethane solution, the mixture has a high enough viscosity to be used in a mould. After the solvent has evaporated, a mass will remain that is easily fixed to the membrane.

However it is important to know the size of the pores in the polyurethane. The tungsten powder should have such an average particle size that the polyurethane pores are smaller than the particles. Another possibility is the chemical binding to polyurethane. One of these is needed to prevent tungsten powder loosing.

2.4 Morphologic scheme.

A combination of the different concepts as described above are presented in a morphologic scheme (Figure 35). A combination of different solutions lead to differents VPE concepts as swon in Figure 36-40.

Figure 35 morphologic scheme



Concept 1

- Membrane enveloped housing
- Membrane slides in deepening
- One piece housing
- Flat membrane
- Open groove
- Membrane created by rotation
- Housing created by injection molding
- Weights on top of the membrane

Concept 2

- Membrane is stretched by glue
- Membrane over flow inlet
- Flat membrane
- Ellipsoid groove
- Two half housings
- Membrane created by $PS\mu M$
- Housing created by injection molding
- Weights are pyramid shaped.

Concept 3

- Membrane is stretched by rods
- Membrane slides under flow inlet
- Sealed membrane
- Open groove
- One piece housing
- Sealed membrane created by PSµM
- Housing created by RTM
- Powder in membrane

Concept 4

- Membrane is stretched by swelling
- Membrane at flow inlet
- Round membrane
- Closed groove
- Whole housing
- Membrane produced by spraying
- Housing created by RTM
- Weights as layers in membrane

Concept 5

- Membrane clamped by housing
- Plate membrane
- Open groove
- Whole housing
- Membrane created by spinning
- Injection molded housing
- Double row of weights.

In contrast to other concepts this VPE has only one membrane.



Figure 36 concept 1



Figure 37 Concept 2



Figure 38 Concept 3



Figure 39 Concept 4



Figure 40 concept 5

2.5 Discussion of production process

The housing as shown in Figure 22 seems easy to assemble but it is hard to create a good VPE by this housing. The parts should precisely fit each other and two injection points are needed to create this shape. A second injection point is however more expensive. The housing as shown in concept five has a hard time coming out of its mould. When the groove is open the housing can deform to come off the mould. A closed groove results in great circular tension because of shrinkage. Another disadvantage of this shape is the complex mould that is needed. These two parts should shove by each other. When the temperature rises, the two parts expand unequally much so the mould might break. To produce a closed groove one can make inserts in the mould. The disadvantage of these inserts are the costs, around 5.000 euros each.

Injection molding is an expensive process. The mould price is around 25.000 euros. Injection molding is profitable when more than 10.000 products are produced of one mould. A null-series mould can be produced for 10.000 euros. This can produce seven products in succession. After these seven products the mould need cooling down time. The First two product in this session are starter-ups and therefore unusable. The mould should have a dummy product or more VPEs in the mould, because the small volume. Van Dijk advices to produce the null-series housings by resin transfer molding. The equipment used for this process is cheaper and therefore more profitable at low numbers. By resin transfer molding is it also possible to create models with more complex geometry and higher tolerances. The price for these moulds are around 2.000 euros. Epoxy resin can be used in the process of resin transfer molding, one advantage of epoxy resin is its high stiffness and the low shrinkage. The material prices are a little bit higher, around six euros per kilogram, in contrast to SAN which is used for injection molding, this material costs three euros per kilogram.

SAN is biocompatible and has a high stiffness. The injection point should be located at the thickest part of the housing.

Rotating is an interesting option to create a round membrane. The disadvantage of this process is the time it takes to produce a lot of membrane this way.

When the membrane is produced as a plate, $PS\mu M$ is the most attractive production method. A porous membrane will probably result in a lower frequency. The porosity can not be regulated by spraying or spinning therefore $PS\mu M$ is advised.

 $PS\mu M$ also has the ability to produce a membrane with tungsten powder inside. Attaching weights to the membrane is hard and takes a lot of time. Therefore $PS\mu M$ with evenly spread tungsten powder inside is the best method of creating a membrane. This membrane needs to be sealed or glued in the next step of production to create a rounded shape.

To be able to stretch the membrane creating two swollen rods in the membrane (as shown in Figure 20) is the best solution. These rods make assembly easy and housing stiffness is guaranteed and so is the membrane distance. The groove that goes with this membrane is straight and has a special shape to trap the rods inside the housing. The membrane will at the flow inlet be placed under the flow inlet create by the housing.

2.6 Selection

The requirements as presented in chapter 1 are usable for evaluating these concepts. A whole housing is preferred above a housing formed by two parts. Two parts is more expensive by manufacturing and more difficult by assemblage compared with a housing made by one part.

A closed groove does not come easily loose of the mould by stress cause the shrinkage. Therefore an open groove is need. To guarantee the membrane distance, the material should be stiff enough. Also the membrane or another element can help for a constant membrane distance. The membrane can guarantee the distance by swellings which fit in the groove. Another possible solution is rods in the membrane, which stretch the membrane and guarantee the membrane distance. In that case the membrane is fixed in al directions. The dimension of the membrane determines the pre stress. It can be regulated. The tungsten powder has possible the less influence on the membrane stiffness. The flow inlet as shown in figure 20 gives the best smooth transition.

After an extended study, three materials, TT-1074A, TT-1085A and EG80A, met the stated requirements and can therefore be used to produce a prototype. This prototype will have a porous membrane that will vibrate at a low frequency. This membrane can easily be created by $PS\mu M$. Another advantage of this method is the possibility to mix tungsten powder through the polymer mixture in order to further lower the frequency. We requested different samples of Buffalo Tungsten INC of 100 grams each. C3 and C6 can be used for a prototype.

The most reliable way of producing the housing is RTM. A biocompatible epoxy can be used to create this housing. The advantages are low mould costs, high achievable tolerances and high material stiffness.

The recommend concept is shown in figure 41 and 42. this concept fullfils the requirements which are drawed up in chapter 1. To test the viability of the concept a prototype, can now be created. This tests stands in chapter 3.





Figure 42 cross section presented concept

Figure 41 presented concept

3. Prototype research

The ultimate goal is to manufacture a prototype of the best concept and to measure its performance. When the prototype is tested and the results are know, further recommendation should be done.

For manufacture a prototype membranes are produced with Phase Separation Micro Moulding. The Aim of these membranes are eventually to produce a prototype with the proper frequency, produced on the recommend way as described in chapter 2.6. A few sub aims are therefore necessary. First, it will be tested whether it possibility to make a porous membrane using EG-80A. When these tests are positive, further research will be done on mixing tungsten powder in the membrane. Finally the tensile stress at elongation will be tested. For evaluating the tungsten powder in the membrane some SEM pictures are made for demonstrating the porosity and the homogeneous distribution. Another important aim is the usage by a prototype testing the functionality.

3.1 Membrane manufacturing

3.1.1 Material

The membranes consist of a medical grade polyurethane (Tecothane EG-80A, Noveon Inc., Cleveland, OH, USA).

THF (Tetrahydrofuran)

Tungsten powder (FTP C3, Buffalo Tungsten Inc., Depew, USA) Tungsten powder (FTP C6, Buffalo Tungsten Inc., Depew, USA)

Six different configurations are made using these materials:

- 5% weight solution PUR:THF
- 10% weight solution PUR:THF -
- (10% Weight solution PUR:THF):25% Tungsten powder C3
- (10% Weight solution PUR:THF):25% Tungsten powder C6
- (10% Weight solution PUR:THF):50% Tungsten powder C3
- (10% Weight solution PUR:THF):50% Tungsten powder C6 -

Percentages are based on the weight of the materials, related to the weight of the entire solution. These solutions are mixed by a magnetic stirrer until all the polyurethane is solved in the THF and forms a viscous homogenous mix (Figure 43).

3.1.2 Method

The THF solution is placed on a Teflon coated plate in a fume cubboard by a pipette. Best membranes, produced by Phase Separation Micro Moulding, are produced by using a Teflon coated plate, which should be cleaned by acetone first. The solution should spread out with an equal thickness by the special metal rod as shown in Figure 44. After spreading the membrane over a Teflon coated plate it will be placed in a bath of ethanol for about four hours (Figure 45). THF will be replaced by ethanol. After this bath the membrane is put in water, from where it becomes more and more solid in a period of three days.

It may look odd inserting an extra step into the process: placing the membrane in ethanol, but while putting it directly in water, the membrane is not usable anymore. So, in order to get a porous membrane, the bath of ethanol is necessary.

After this ethanol bath another Teflon coated plate will be put above the other with three pieces of tape between this two plate's. This construction will be clamped and put in water for minimal three

days, in order to get between the two plates. This method works for Figure 47 Rotation all six different solutions. While trying to create a membrane by

rotation molding the viscosity of the solution was too high. So this method is proven unsuccessful because of a high viscosity. This method is shown in figure 47.



Figure 43 Mixture



Figure 44 spreading



Figure 45 ethanol bath



Figure 46 water bath



3.1.3 Results

 $PS\mu M$ results in a porous film, characterized by its white colour. Because of light diffraction. Which occurs in a porous membrane (Figure 48 and 49)

A membrane which is cures by air, results in a transparent membrane as shown in Figure 49.

Membranes encapsulated with tungsten powder (Figure 45) are porous but black. These membranes are more manageably because of the less stickiness.

3.1.4 Discussion

The membranes as produced using $PS\mu M$ are inhomogeneous. Air bubbles and heterogeneous thickness lead to low quality. Membranes with a higher quality are achieved when using a lower viscosity (by adding more THF).

A better spreading method will also lead to a more

homogenous membrane. The possibility of making a porous membrane encapsulated with tungsten powder has been proven.



Figure 48 Porous membrane



Figure 49 Membranes

3.2 SEM pictures

3.2.1 Material

Two samples are used for the SEM pictures:

- Porous membrane with tungsten powder (C3) 25%
- Porous membrane with tungsten powder (C6) 50%

3.2.2 Method

The samples were frozen in nitrogen $(-190^{\circ}C)$ and broken. By this process the porosity is preserved. Both broken sides are fixed in a holder and placed in a vacuum oven $(30^{\circ}C)$ for two days. The samples are coated with gold for conduction

3.2.3 Result

Figure 50 and 51 shows the membrane with 25 % mass C3. This film is a not very porous. The cross section view shows some tungsten powder clots. However, Figure 52 and 53 shows the membrane produced by 50% mass C6. This membrane is more porous and shows logically more tungsten powder particles. The tungsten powder subsided a little bit by the gravity field, but is properly surrounded by the polyurethane. The powder does not come out of the membrane.



Figure 50 C3 25% cross section



Figure 52 C6 50% cross section



Figure 51 C3 25% bottom



Figure 53 C6 50% bottom

Even not when put in water when the membrane is stretched. This sample is made out of the same membrane as sixth sample in the tensile test with the very low stiffness. The C3 sample is made of another membrane than is used in the tensile tests.

The pores in the C6 25% membrane seems very small. The pores in the cross section view seems smaller than the pores at bottom side. The pores in the cross section view are two till three micrometer in diameter. It seems that the pores are collapsed. In the C6 50% membrane more pores are visible. These pores seem also two rill three micrometer in diameter. The tungsten powder is in Figure 52 lumped. Other particles are homogenous divided in the membrane. Gravity has no visible influence on the particle position in the membrane. It seems that there is no chemical binding; the particles are encapsulated by the polyurethane.

3.2.4 Discussion

The high porosity of C6 is explicable by the nucleation point. This point is important for the phase separation. The gravity has a little effect on the tungsten powder position but not dramatically. The tungsten powder is fixed in the polyurethane and is in general reasonably scattered through the film.

3.3 Porosity tests

Goal of the membranes manufactured by $PS\mu M$ was a porous membrane. The porosity is shown on the SEM pictures in 3.2, but can also approach by calculating. For knowing the porosity.

3.3.1 Material

Micrometer tolerance of 0.25 μ Balance tolerance of 0.1 mg

3.3.2 Method

The membranes were divided in parts of 15mm x 15mm. These parts were weighted and the thickness was measured. Results are presented in table 7. The following porosity calculation is used.

First the density of the solution is calculated. This density can be calculated by knowing the density of each component. When the THF is not (longer) present in the solution and only polyurethane (and tungsten powder) stay(s) has the solution another density. This density can be calculated by knowing the mass and the volume of both components. This density is the density of a solid membrane of pure polyurethane and tungsten powder when it is added. When this density is compared with the measured density there is a difference. This difference induce porosity. This porosity is calculated by the following equation:

theoretical density – measured density Theoretical density ·100% = Porosity (%)

3.3.3 Results of different densities EG-80A

Table 7 Density

	Thickness μm	Weight mg	Density g/cm ³	Average density gr/cm ³
Solid	42.5	0.00949	0.99	0.99
Porous	48	0.00967	0.91	0.91
C3 25%	50.3	0.02440	2.07	2.1
C6 25%	49.3	0.02298	2.1	2.1
C3 50%	49	0.02805	2.1	2.4
C6 50%	103	0.05453	2.4	2.4

For calculating the membrane density as manufactured by $PS\mu M$ the next values are needed:

Density THF = 0.886 gr/cm^3 Density EG80A = 1.04 gr/cm^3 Tungsten = 19.4 gr/cm^3 For further calculating the porosity the next table (8) is filled in:

Table 8 Porosity

	Solid	Porous	25% tungsten	50% tungsten
Gram PUR (gr.)	1	1	1	1
Gram THF (gr.)	9	9	9	9
Gram tungsten (gr.)	0	0	2.5	5
Total mass (gr.)	10	10	12.5	15
Total volume (mL)	11.12	11.12	11.25	11.38
Density (gr/mL ³)	0.90	.90	1.11	1.32
Total mass minus THF mass	1	1	3.5	6
Total volume – volume THF (mL)	0.96	0.96	1.09	1.22
Measured density (gr/cm ³)	1.04	1.04	3.21	4.92
Practical density (gr/cm ³)	0.99	0.91	2.1	2.4
Porosity (%)	5	12.5	35	52

3.3.4 Discussion

The first remark is the statistic inaccuracy. The solid and the C6 (25%) density is based on one sample. The samples were cut in pieces by a knife; a less precise method. The density of the membranes with 25% and 50% of tungsten powder result in the same density, so it's not depending on a particular size. This make sense and causes preciseness to be less important.

The porosity rises up when there is more tungsten powder in the membrane. This process can be explained by the nucleation point. This is a point where the non-solvent has more solidity to stay into the membrane and is it better possible for the non-solvent to keep the membrane porous.

3.4 Tensile tests

3.4.1 Material

Samples of the membrane are made as described above. Finally seven samples are made an overview is given in table 9.

Table 9 Sample properties

	Property	Thickness
1	Solid	40µm
2	Porous	40µm
3	Porous	100µm
4	Porous + C3	65µm
5	Porous + C3	70µm
6	Porous + C6	70µm
7	Porous + C6	70µm



Figure 54 Punch

The sample used, is the standard ISO 37 (type 2, 28 mm by 4mm). The stress machine (Z020, Zwick GmbH & Co, Ulm, Germany) was equipped by extensometers, these extensometers measure the tensile stress¹². The tensile stress test is execute according to ISO 37, test speed 60mm/min.



Figure 55 Samples

3.4.2 Method

The samples are formed by a punch as shown in Figure 54 results of these punch are shown in Figure 55. These samples are placed in a tensile tester as shown in Figure 56, 57 and 58. This tensile tester displays measures over the tensile stress at elongation and maximal elongation. The tensile test begins by a zero stress value and stretches out the membrane until it breaks. The E modulus is independent of the thickness. Therefore the particular difference does not matter. Sample 2 and 3 comes out the same membrane even as samples 4 and 5 these are also punched out the same membrane.



Figure 56 Tungsten membrane



Figure 57 Porous membrane



Figure 58 Solid membrane

¹² Machine data: 020SND WN:130567. Crosshead travel monitor WN: 130567. Load cell ID:0 WN:802349 500 N. Multisens WN: 130571

3.4.3 Results

The results are shown in the plot 1 and 2 below.

Plot 1 Tensile stress 0-450%

Tensile stress by Strain





The membranes are made by EG-80A. The manufacturer gives the values in the datasheets as shown in table 10. The measured values are compared whit the given values in the table below:

Table 10 Tensile stress

Material	Tensile stress at 100%	Tensile stress at 300%	Ultimate tensile		
	MPa	MPa	%		
EG-80A (datasheet)	2.1	5.5	660		
EG80A solid	2.0	6.4	426		
EG80A porous	1.36	4.42	286		
EG80A C3	1.38	3.3	373		
EG80A C6	1.4	1.8	287		

The E – modulus can be calculated by the derivative which can be read from the plot. E = tensile stress / strain

Table 11 E-modulus

Material	E at 5 e	longation	E at 10% elongation			
	MPa/%		MPa			
EG-80A (datasheet)	?		?			
EG80A solid	3.33	0	5	0		
EG80A porous	2.5	- 25%	2.9	- 42%		
EG80A C3	3.8	14%	3.9	- 22%		
EG80A C6	3.8	14%	2.9	- 22%		

3.4.4 Discussion

The results from this test gives only a small (actually, more samples are needed) indication for the tensile stress at elongation. However, the quality of the samples is plainly disputable. The width is inhomogeneous even as the thickness which is expiring.

The rough plot is caused by bad samples. Plot 2 is most relevant by the small strain that is in the VPE. Plot 1 is usable for the tensile strength. The E-modulus is lower by the porous membranes than by the solid membrane. As the SEM picture shows the C6 membrane's seems more porous and results more a lower F_0 . Based on the E-modulus as presented in table 11 there can be conclude that a porous membrane had a lower stiffness than the membranes with tungsten powder in it. But the absolute tensile stress is lower in the membranes with tungsten powder.

The E-modulus of a porous membrane is lower than the E-modulus of a solid membrane, at 5% strain and 10% strain. When tungsten powder is added in the porous membrane, the E-modulus increase 22% at 10% strain. But the absolute value of the tensile stress by strain is in a porous membrane with tungsten powder lower than all the other membranes. Therefore the membranes with tungsten powder will lead to a decrease of the frequency. This hypothesis will test in the next chapter.

3.5 VPE frequencies tests

3.5.1 Material

Three different types of membranes are used for a prototype to test the F_0 :

- Solid membrane
- Porous membrane
- Porous membrane with Tungsten powder C6 (50%)

Goal of the tests is to discover the different frequencies produced by the different VPEs. It is suspected that the solid membrane produces a high frequency compared with the other. The tungsten powder membrane shall properly made the lowest F₀.



Figure 59 VPE models

3.5.2 Method

The experimental set-up is the same as Tack described in 'In-vitro evaluation of a doublemembrane based voice-producing element for laryngectomized patients (2006)':

"The experimental set-up shown in Figure 59 is a model of the physiological situation in a patient; it allowed us to measure various acoustical and aerodynamic parameters invitro. Physical models of the 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 housings 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 prototype was placed inside a Groningen Button shunt valve."

The VPEs as used for these test are made by hand and the membranes are fixed with hobby glue.



Figure 60 experimental set up

3.5.3 Results

The plot below shows the different F_0 values at different pressures. This plot gives an overview of the fundamental frequencies of the different membranes. The VPE with the solid membrane produced not the needed frequency. As expect the porous membrane with tungsten powder has a lower frequency than the porous membrane. The last VPE is the prototype of J.W. Tack, this frequency is minimally needed for a female voice. For a male voice sound further lowering is necessary. The higher harmonics as needed for producing different vowels are present in the produced sound.

Remark: the solid, porous and tungsten membranes are made by EG-80A and the VPE prototype membrane is made by TT-1085A.



Frequency versus pressure

 $\frac{F_0 \text{ (solid membrane)} - F_0 \text{ (other membrane)}}{F_0 \text{ (solid membrane}} \cdot 100\% = \text{frequency lowering}$

 Table 12 Frequencies

	F ₀ at 0.6 KPa (Hz)		F_0 at 1 KPa (Hz)		F ₀ at 2.0 KPa (Hz)		
	L	owering F ₀	L	owering F ₀	Lowering F ₀		
Solid membrane	1859	0%	2100	0%	2700	0%	
Porous membrane	1040	44%	1310	38%	1767	35%	
Porous membrane with	750	60%	790	62%	892	67%	
50% tungsten powder							
VPE prototype	192	90%	217	90%	294	90%	

3.5.4 Discussion

Therefore the results give an indication of the possible frequencies but are not accurate. The pre stretch of the membrane in the housing was not was not zero (sometimes more, sometimes less). Also the flow inlet was not always stretched properly. These can result in slightly different frequencies.

The conclusion is: a porous membrane result in a large decrease of the frequency (average 39% compared with a solid membrane). When tungsten powder is added, the frequency lowered 63% compared with a solid membrane. These tests are promising.

3.6 Housing manufacturing test

3.6.1 Material

A mould is made at Fe360. The housing is made by two components (PS 105, polyservice, Krimpen aan de ijssel, the Netherlands).

3.6.2 Method

Both component are mixed and will be placed in the mould (Figure 61). After one hour the components are hardened. A groove is not in the mould, so this element should be created after moulding.

3.6.3 Results

It is possible to make a housing by a mould that is created by hand. However the stiffness created by a housing made by polyurethane is too low. The wall thickness is 0.5 mm and poly urethane as used is not stiff enough to form a solid housing. A wall thickness of 0.5 mm can manufactured by this method. The results are shown in Figure 62 and 63.

3.6.4 Discussion

It is necessary to found the good method for producing so air bubbles has no influence. A mould with more precisely dimension a more professionals skills for filling will result in good housing. The method works, but better material is needed.



Figure 61 RTM Mould



Figure 62 RTM housings



Figure 63 RTM Housing

4. General Discussions

The prototype as designed by J.W. Tack is difficult to process; therefore VPE redesigning was needed. This report gives alternatives for redesigning and tests results of the selected concept .

We like to note that the experiments were not satisfying, we only tested a static not realistic. Moreover, the prototypes were mostly made by hand and are not perfect in shape and function.

The results therefore have to been seen as a first step in founding a design and production process that makes producing a high quality VPE cheap and reliable. We found however a promising direction which can results in cheap quality VPEs. A porous membrane is used, which has a lower stiffness than a solid membrane. This results in a lower frequency. This membrane can be manufactured by Phase Separation Micro Molding. Porosity can be regulated by this manufacturing process. After adding tungsten powder in this porous membrane, the fundamental frequency decrease more. The fundamental frequency such as needed for male and female laryngectomized patients, can achieved. The housing can be made by RTM. When the tube is made by epoxy the tube has a high enough stiffness and fulfilled the tolerances.

5. Conclusions

We redesigned the VPE using a porous membrane. This design passed the tests successfully. A porous membrane with tungsten powder lead to a decrease of the fundamental frequency. This membrane can easily manufactured by Phase Separation Micro Molding. The housing, that is needed for membrane stretching and guaranteeing the membrane distance, can be produced by Resin Transfer Molding. Epoxy is the best material choice for this housing by the high stiffness low shrinkage.

The concept tested is promising and will result in a cheap high quality Voice Producing Element. Therefore the concept as presented at the end of chapter three can be used.

6. Recommendations

The VPE concept, as presented at the end of chapter three, is promising but further research is needed, especially the membrane. Another solution proportion can result in a more porous membrane, even as another method. Other methods are adding salt, which can wash out, or inserting gas. The tungsten powder have an enormous influence on the nucleation point, this determine among other the porosity.

This research can be execute by a student studying Chemical Technology. It is worthwhile to produce a porous round membrane. A round membrane is cheaper because the sealing is not needed and the swelling can manufactured in it. When the VPE is assembled a round membrane is cheaper and easier.

A total other concept is the membrane shape. With Ansys it is possible to modulate a special membrane shape (ribs, holes etc.) to approach the needed fundamental frequency with enough strength.

It is considerable to use a non-biocompatible membrane. Or research the biocompatibility of these materials. Some of these materials have a lower stiffness than the biocompatible polyurethanes.

Two last remarks:

- Consider a disposable VPE and tools for replacing
- Adapt the shunt valve so the VPE can easily be fixed in the valve

7. Acknowledgments

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8. Referees

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Manufacturing of membranes

Plastic process adviser

Tensile Tests

Plastic specialist

Tungsten powder deliver

RTM contact person

Appendix A

TO: I	W Douma	l	CERTIFICATE OF ANALYSIS:							
Beneluxlaan 99			Date: 2006-05-25							
H	olland	iseneue		Quantity: LBS						
Customer's Order No.				TYLER SHOWALTER Quality Control Manager						
LOT NO. WS-C3 and C6 MATERL					ERIA	L: TU	NGSTI	EN P	POWDER	
CHEM	IICAL and	SPECTRO	GRAPHIC			PHYS	ICAL			
ELEM.	%	ELEM.	%	Fisher No.		As Supp	olied	Lab. Milled		
Al	0.007	NH ₃		Av. Microns		3.32	,		2.25	
As		Na	0.002	Porosity		.610)		.467	
Bi		Ni	0.0075	Scott Densit	76.4	4	gm/cu. in.			
C _T	0.437	O/LOR	0.411	Tap Test7.69gm/c					m/cc.	
C _F		Р	0.0015							
Ca	0.014	Pb	< 0.001							
Cd		S		PAR	RTIC	LE SIZE	DISTR	IBUT	TION	
Со	0.088	Sb				BY MAI	LVERN			
Cr	0.0156	Si	0.0025							
Cu	< 0.001	Sn	< 0.001	Micron Range	Wt. %		Micron Range		Wt. %	
Fe	0.0080	Та	0.006	0-1		6	7-8		4	
K	< 0.001	Th		1-2		11	8-9		5	
Mg	0.0055	Ti	0.003	2-3		8	9-10		5	
Mn	0.0016	W	99.4	3-4		7 10-1		5	14	
Мо	0.002	V	<0.001	4-5	4-5 5		15-20		11	
N		Zn	< 0.001	5-6 5		5	20-25		13	
				6-7 6						
				SCREEN ANALYSIS						
				MESH SIZE Wt. %				t. %		
				-100 All						

- Average Particle Size (Fisher Sub-Sieve ASTM B-330)

- Apparent Density (Scott Volumeter ASTM B-329)]
- Particle Size Distribution (Photelometer ASTM B-430, Sedigraph, or Malvern Mastersizer)

- Chemical Impurity Analysis

www.buffalotungsten.com/html/fine.html