34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

Advantages of Voice Reproduction and the Development of a Biomimetic Self-Regulating Double-Clack Valve for a Prosthesis of the Larynx - A Feasibility Study

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Abstract — **The human larynx is a versatile organ. Main functions are phonation, protection and regulation of the air ways. Patients suffer severely from the diagnosis of a laryngeal carcinoma of the stages T3 and T4. In most cases this diagnosis will lead to a total laryngectomy, which is usually dissatisfying in the sense of postoperative rehabilitation. The postoperative consequences include the loss of the native voice, the loss of regular air ways via mouth and nose, sense of smell, and the inability to build up an abdominal pressure.**

In this paper we focus on the feasibility of a modular larynx prosthesis which enables the laryngectomee to talk with his native voice, to breathe via the regular air ways, and to build up abdominal pressure. In particular we will give insights for a postoperative solution - a modular prosthesis based on a biomimetic self-regulating double clack-valve and on a voice reconstruction module, a so called *vocoder*. The *vocoder* is a device to reproduce the natural human voice. Most important for the use is an additional device required to analyze, conserve and manage voice characteristics of the patient before surgery. The self-regulating double clack-valve is designed to build up an abdominal pressure e.g. to cough. Therefore, our valve-system is working in both directions – a two-way valve system. By bridging the gap of the regular air ways lost by laryngectomy, the sense of smell and taste are restored. In the following we will present details and characteristics of these two main components required for a modular prosthesis of the larynx in laryngectomees.

I. Introduction

The laryngeal carcinoma is a common malignant tumor of the head-neck region. The incidence of laryngeal carcinoma worldwide is approx. 160.000 [1]. The worldwide mortality is approx. 90.000 individuals per year. In Germany 4000 individuals are suffering from laryngeal carcinoma; about 3000 people per year have their larynx removed completely [2]. Although the incidence and mortality are slightly decreasing since the 1990s for male individuals incidence and mortality in women are still increasing [2]. The main risk factor for laryngeal carcinoma is smoking, alcohol ingestion, and work-related exposure to dust and chemicals like halogenated hydrocarbons [3].

According to the cancer stage different ways of therapy are initiated such as laser treatments, partial resection of the larynx in early stages or total resection of the larynx in advanced stages as well as radiation therapy. At the cancer stages T3 and T4 total laryngectomy and implantation of a tracheostoma is performed thus leading to a permanent loss of the voice and the regular air ways [4, 5].

Current rehabilitation methods after total laryngectomy include a training of the esophageal voice using the gullet for phonation. Additional methods include an implantation of a vocal fistula using valve vocals, or the use of electrolaryngeal speech aids. These kinds of voice production are rather unsatisfying for the patient as such a voice sounds either rattling or like a monotonous robot voice. Furthermore a huge disadvantage is the colonization of the artificial valves-system used in vocal fistulas by fungus and bacteria which lead to local infections [6 - 8].

In general the state of rehabilitation is dissatisfying to the patient and contains a significant loss of quality of life. Still today there is neither an existing therapy nor prosthesis to face this. In our work we are introducing such a prosthesis to preserve the own voice, restore the ability to smell by restoring the regular airways, and the ability to build up abdominal pressure.

II. Modular Prosthesis for the Larynx

The larynx (voice box) is situated between the pharynx (fauces) and the upper end of the trachea (windpipe) with its main function being phonation (Fig. 1). It consists of a skeleton of cartilages which are connected to multiple muscles. The *rima glotti*, located in the middle of the larynx, is formed by two opposing vocal folds. This complete organ of phonation is called glottis. According to the length of the vocal cords the voice pitch is high or low. The resilience of the vocal folds, which is influenced by specific groups of muscles, is used to vary the pitch of tones produced by air which streams through the narrowed glottis. While multiple muscles are involved in closing the glottis, mainly one pair of muscles can significantly open the glottis. This pair of muscles, *M. crycoarytenoideus* (in short "Posticus"), has a major influence on the pitch. Thus, according to the degree of contraction, the muscles are able to open the glottis maximally for forced inspiration or slightly for minor

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978-1-4577-1787-1/12/$26.00 ©2012 IEEE

changes of the pitch. The Posticus muscle is innervated by the *N. laryngeus recurrens*, a nerve which arises from the 10th cranial nerve, *N. vagus* [9]. These two nerves or the Posticus muscle, if still existent after tumor surgery, are planned to be used for the neural or myogenic interface of our modular prosthesis.

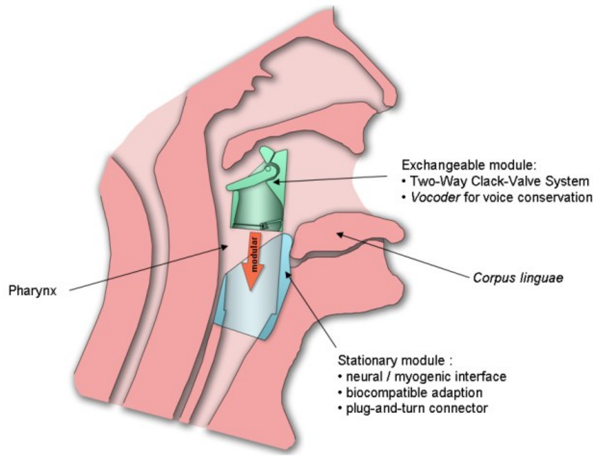

Figure 1: Modular prosthesis of the larynx. In our studies we focus on two main parts of the prosthesis: A prosthesis for the epiglottis acting as a valve system and a *vocoder*, which is responsible for voice reproduction. In the figure a simple epiglottis prosthesis is shown, later in our work we will also present a biomimetic approach for a double-way valve: A biomimetic self-regulating double clack-valve system.

A radiation therapy is often necessary to destroy remaining tumor cells after laryngectomy. An implantation of the laryngeal prosthesis would not be possible after radiation therapy as the tissue is harmed by ionizing radiation (radiation fibrosis, ulcerations) which will impede the engraftment of the laryngeal prosthesis [10, 11]. Implantation of the laryngeal prosthesis before radiation therapy is not feasible, either, due to the radiation doses. Doses vary from 30 to 70 Gray and severely harm electronic components made out of semiconductors where radiation can generate high currents in the circuitry leading to a permanent destruction [12, 13]. Furthermore, a permanently implanted electronic device can become useless by aging, especially the batteries, or component failure. In the case of component failure or the necessity of a hardware update, or in the case of a mechanical failure the whole prosthesis would have to be explanted meaning further straining surgery to the patient.

To overcome these limitations the laryngeal prosthesis has to be divided into a stationary and an exchangeable module (Fig. 2). Stationary and exchangeable modules are made up of a biocompatible, fungicidal and bactericidal material. The stationary module has interfaces to connect the laryngeal recurrent nerve to the prosthesis and another interface to connect the exchangeable module's electronic devices. The exchangeable module is inserted into the stationary module by a simple plug-and-turn connector. The exchangeable module contains the valve appliances, the electronic devices plus power supply, the interface to the stationary module, and the epiglottis prosthesis. After the surgical removal of the larynx the stationary module is implanted permanently. A second so-called dummy module that excludes the aforementioned electronic devices and power supply but includes the valves system and the artificial epiglottis, is inserted into the stationary module for radiation therapy, thus allowing the patient to breath via mouth and nose and to swallow without the danger of choking until the radiation therapy is completed.

Afterwards, the dummy module is replaced by the fully equipped module. In the case of a mechanical or electronic component failure or if hardware update is required, the defective module is replaced by an additional functional module. The replacement is done via the opened mouth of the sedated patient without the requirement of surgery. Hence, the modular solution minimizes the complexity of servicing and replacing the laryngeal prosthesis and avoids the danger of damage to the laryngeal prosthesis by ionizing radiation.

The epiglottis prosthesis is located on the cranial part of the laryngeal prosthesis which is sutured with the pharynx and trachea (Fig. 1). The epiglottis prosthesis is made up of a biocompatible, fungicidal and bactericidal material and replicates the anatomic features and sizes of the native epiglottis. The epiglottis prosthesis protects the cranial aperture of the trachea from chyme being choked and is pressed down by the tongue during swallowing. When the chyme has passed a coil spring puts the artificial epiglottis back into its home position [9, 14].

In case of an emergency intubation of the patient the coil spring of the artificial epiglottis gives way to the laryngoscope, thus facilitating access to the trachea.

III. VOICE CONSERVATION AND ELECTRONICS

One of the most valuable characteristics of the laryngeal prosthesis is the reproduction of the patient's native voice. An electronic device inside the prosthesis (Fig. 1) receives input from the *N. laryngeus recurrens* and *N. phrenicus* and generates the voiced parts of speech using the native voice of the patient as a template.

Voice in general consists of voiced and unvoiced parts. Voiced parts are generated by pressured airflow from the lung leading to vibrating vocal folds inside the larynx. Unvoiced parts are sounds that are not generated by the vocal folds. Unvoiced parts can be generated by air flow passing tongue and teeth. The individual voice gets its uniqueness from the shape of the larynx, neck, mouth, tongue and teeth – and mostly from the shape, thickness and length of the vocal cords [15]. This is referred to as the vocal tract which is removed in total laryngectomy.

Nowadays, telecommunication systems, e.g. cellular handsets, commonly use algorithms to emulate vocal tracts. *Vocoders* are electronic devices that are utilizing mathematical models to reproduce the vocal tract [16]. The original reason for using *vocoders* in telecommunication is to save bandwidth for data transmission. A v*ocoder* can also be used to emulate the vocal tract in a laryngeal prosthesis, thus generating speech with the patient's native voice.

Most *vocoders* have implemented *Adaptive Multi-Rate Codecs (AMR)* or other speech encoding methods that are based on Code-Excited Linear Prediction codec (CELP), which is an extension of Linear Prediction based codecs (LP) [16]. LP based algorithms are using aligned tubes of different lengths and radiuses as a model of the vocal tract (Fig. 2). Input to the decoder consists of a variable part and a fixed part. The variable part describes the change in loudness and pitch of the voice during speech. The fixed part describes unique parameters to program the vocoder with which represent the basic characters of the patient's native voice. The laryngeal prosthesis takes input from the *N. laryngeus recurrens* and the *N. phrenicus* and calculates the necessary variable parameters for the *vocoder* (Fig. 3) whereas the fixed parameters are given by hardware programming, e.g. firmware.

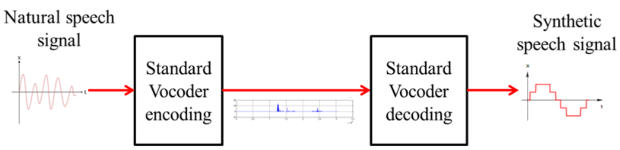

Figure 2: *Vocoder* in telecommunication applications. The natural speech is encoded and transmitted to a standard *vocoder* (mobile phone). Here a synthetic voice is produced.

Due to the uniqueness of an individual's vocal tract, i.e. in shape and size and other characteristics, the voice of a human being is like a distinct fingerprint. From digital signaling point of view, the uniqueness of a voice fingerprint lies in the shape, pitch and location of formants of each voiced sound. The calculation is based on the patient's individual voice characteristics which were conserved earlier. In order to speak with the original patient's voice, it is necessary to capture and conserve the patient's voice characteristics as accurately as possible.

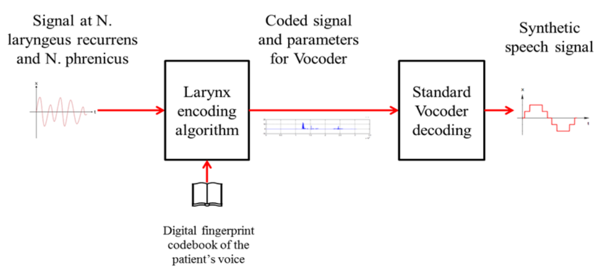

Figure 3: *Vocoder* in laryngeal prosthesis. Transferred to our feasibility study, the natural speech can be encoded and conserved before a total laryngectomy. Based on this data the *vocoder* is able to reproduce the synthetic speech in the modular prosthesis. The voice signal is re-coded by nerve potentials from the *recurrent laryngeal nerve*.

Therefore the approach includes the method to capture individual voice characteristics before resection. This includes recording of the voice while the patient is performing a set of voiced sounds and hereby trains the system. The training set is chosen in a way that covers most parts of the patient's voice spectrum. The algorithm in the laryngeal prosthesis recalculates the neural signals to input parameters for the *vocoder* so that formants are placed and shaped to reproduce the patient's native voice.

IV. BIOMIMETIC SELF-REGULATING DOUBLE CLACK-VALVE

For our feasibility study we analyzed a biomimetic self-regulating double clack-valve system. The self-regulating double clack-valve has to ensure abdominal pressure e.g. to cough. It also has to bridge the gap in the regular air ways caused by laryngectomy using a valve system. This valve system enables smelling and tasting again. To build up abdominal pressure, e.g. when lifting heavy objects, the vocal folds and false vocal folds will shut, thus trapping air in the lungs and increasing pressure. This valve system has to be robust and mimic all anatomical functions, especially opening and closing. Our biomimetic self-regulating double clack-valve system, which meets these requirements is characterized by simulation and a testing demonstrator.

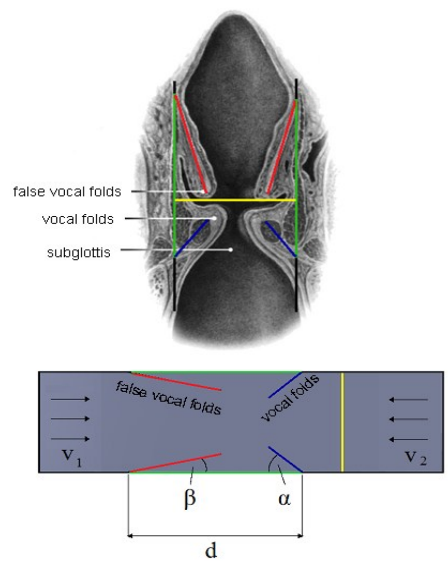

Figure 4: Anatomic and schematic model and parameterization of the larynx for the performed simulation. Top: Anatomical model of the larynx, including the reference lines (reworked from [1]). **Bottom**: parameterization and flow direction of the flow simulation. The red and blue lines are representing the false- and vocal folds, respectively. The openings angles α and β the distance d and the flow directions $v_{1,2}$ were varied. The yellow line is the scale factor (reference line) referring to the upper image.

Figure 4 shows the anatomic and biomimetic model of a self-regulating double clack-valve system. All simulations were performed in 2D flow chamber using the tool *FloExpress* of *Solid Works*. We tested various opening angles and distances of the false and vocal folds depending on the inlet velocity and inlet-geometry. For the opening geometry we analyzed a planar inlet covering the full surface and a circular inlet (hole like structure) in the size of the human larynx. Figure 5 shows a typical flow profile in the flow chamber. For this particular simulation we used opening angles of $v_{inlet} = 1.2$ ms^{-1}, $\alpha = 50°$ and $\beta = 17°$. The distance between the false and vocal folds is varied in figure 5. The upper images refer to an inlet with a planar inlet, while the lower one applies to a circular-shaped one.

In summary of our simulation, we varied all parameters and characterized them by the gravity of induced vortices.

The velocity was changed up to coughing velocities of about 1.2 ms^{-1}. We found severe vortex-formation at opening angles of more than $\alpha = 50°$ and $v_{inlet} \approx 0.2$ ms^{-1} for planar inlets. For circular inlets vortices were significantly reduced and the opening and closing of the folds were more stable when operating with these parameters.

To integrate such a biomimetic self-regulating double clack-valve into the prosthesis, we found that the planar system was closing the false vocal folds under a stream with the direction of v_1 in contrast to the circular shaped ones, which closed the vocal-folds (Fig 4) and vice versa (v_2). Our simulation could be also verified by experimental testing with the help of a demonstrator. A possible explanation could be the Bernoulli Effect versus the first Newtonian Law.

In the case of the planar system the particles of the air are pushing against the folds resulting in an opening of the false vocal fold and closing the vocal folds simply by directed force. This effect can be also the origin for higher appearance of induced vortices at different parametric setups.

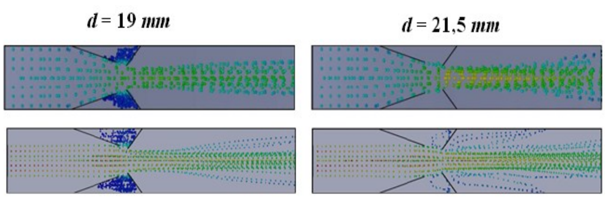

Figure 5: Simulated flow profile in the model of the larynx. In the upper images the flow is distributed over the complete inlet area. In the lower image the flow mimics more the inlet of the natural airway. In general less vortex-formation could be found in the setup used for the upper simulation. In both images the flow is in the direction of v_1 (inhalation).

When using a circular-shaped inlet the Newtonian force is small and the competing Bernoulli Force dominant. This leads to a closing of the false vocal folds. Also, this mechanism is more likely and closer to the principle of nature. In conclusion, such a biomimetic self-regulating double clack-valve should reduced inlet and the opening angles and the distance should be set individually based on our model and simulation as each larynx varies in shape and size.

V. CONCLUSION

The further development of the laryngeal prosthesis demands fundamental research in various areas, such as neurophysiology, neural-interface design and durability of foreign material in the head-neck region. Facing the requirement for a prosthesis, we developed a biomimetic self-regulating double clack-valve for aspiration and inhalation a *double-way* clack-valve. Additionally, our approach avoids any electronic control, which makes our system highly reliable and very robust. More than that, by using titanium or surgical steel as a material our system will be also working during radiation therapy. By using a modular and exchangeable system we also solved the problem of voice conservation by a *vocoder*. Integrated into a modular prosthesis this prosthesis will overcome most disadvantages of today's rehabilitation methods. Due to the benefits of the modular prosthesis laryngectomee can be adequately rehabilitated by the restored ability to talk with the natural voice, to breathe via the regular air ways, and to build up an abdominal pressure. Nevertheless, early stage detection of cancer always prevents total laryngectomy and would be in any case the golden solution.

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