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Modular prosthesis of the larynx: Visions and feasibility

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Abstract— Purpose: A total laryngectomy, usually performed after the diagnosis of a laryngeal carcinoma of the stages T3 or T4 in cases where a radiation therapy is not indicated, still leads to radical restrictions of the patient. The postoperative consequences include the loss of the voice, the loss of the regular air ways via mouth and nose, thus also leading to the loss of the sense of smell, and the inability to build up an abdominal pressure. The feasibility of a larynx prosthesis which enables the laryngectomee to talk with his or her usual voice, to breathe via the regular air ways, and to build up abdominal pressure is discussed here.

Materials and methods: The autonomous prosthesis consists of a device to reproduce the natural human voice, a device to reproduce the natural air ways including an artificial epiglottis to avoid choking, and a system of valves to build up an abdominal pressure e.g. to cough. The prosthesis consists of two modules: a stationary module and an exchangeable module. This is necessary to avoid a destruction of the electronics during possible radiation therapies and to easily replace components in case of a breakdown.

Conclusions: Regarding the present possibilities of rehabilitation the modular prosthesis of the larynx for use in patients after laryngectomy means a medical and ethical benefit for the postoperative course in rehabilitation of laryngectomees.

Keywords— Larynx carcinoma, laryngectomy, nervus laryngeus recurrens, larynx prosthesis, rehabilitation

I. INTRODUCTION

A. Pathology

The laryngeal carcinoma is one of the more common malignant tumors of the head-neck region. The number of newly diagnosed cases of laryngeal carcinoma worldwide is approx. 157.000 individuals per year and the worldwide mortality is approx. 84.000 individuals per year. Incidence and mortality have been steady since 2002. Incidence peaks in the 5th to 7th decade of life and recently is showing an increase in persons younger than 40 years of age due to

increased smoking at younger ages. Carcinoma of the larynx ranks 21st making it far less common than the top 3 carcinomas, lung, breast, and colorectal, but still more common than Hodgkin's lymphoma or multiple myeloma. Also, it has a higher incidence in men than in women (rank 14 vs. rank 24) and a higher incidence in less developed regions than in developed regions (99.000 vs. 58.000) [1].

A fundamental risk factor for laryngeal carcinoma is smoking, often combined with alcohol ingestion, and work-related exposition to dust and chemicals like halogenated hydrocarbons [2].

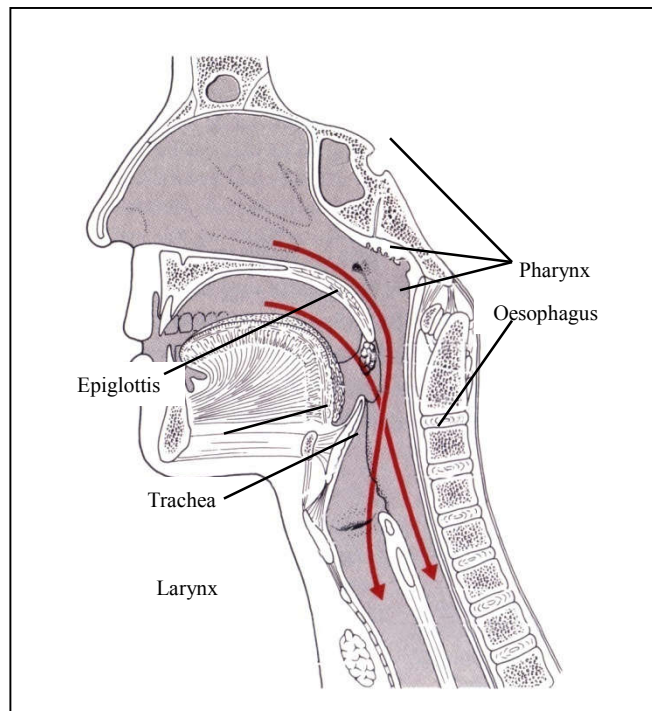


Fig. 1 Anatomy

Since 2010 cancer of the larynx is listed among the recognized occupational diseases by the International Labor Office (ILO) [3].

B. Anatomy

The larynx is an organ of phonation which is located at the upper end of the trachea (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 plicae vocales, the vocal cords. This complete organ of phonation is called the glottis. Depending on the length of the vocal cords the voice pitch is high or low. The resilience of the vocal cords, which is influenced by specific groups of muscles, is used to change the pitch of tones produced by air which streams through the narrowed glottis. While multiple muscles are included in closing the glottis, only one pair of muscles can significantly open the glottis. This pair of muscles, *Musculus crycoarytenoideus*, 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 changes of the pitch [4]. The pair of muscles is innervated by the *Nervus laryngeus recurrens*, the laryngeal nerve, a nerve which arises from the 10th cranial nerve, *Nervus vagus* [5].

C. Present therapy and ways of rehabilitation

Depending on the cancer stage an adequate therapy is initiated. Therapy includes laser treatments, partial resection of the larynx in early stages and total resection of the larynx in advanced stages as well as radiation therapy. Cancer in the stages T3 and T4 are still treated by laryngectomy and lead to the permanent loss of the voice and the regular air ways by placement of a permanent tracheostoma [6].

The present state of rehabilitation includes the training of the esophageal voice using the gullet for phonation, the implantation of a vocal fistula using valve vocals, or the use of electrolaryngeal speech aids. Depending on the use of a valve or an electrolarynx the produced voice sounds either rattling or monotonous (robot voice). Artificial valves used in vocal fistulas are often colonized by fungus and bacteria which lead to local infections, thus making regular replacements of the valve necessary [7].

The state of rehabilitation therefore is dissatisfying to the patient: the consequences of cancer therapy mean the loss of the voice, the loss of the regular air ways, and consequently the inability to smell and to build up an abdominal pressure.

II. MATERIALS AND METHODS

A. Present technical capabilities of electronics and information technology to be used in the prosthesis

This paper presents a prosthesis of the larynx which gives the laryngectomee the ability to talk with his or her native voice. The prosthesis is build up out of two modules and includes a device to reproduce human voices, a neural interface to receive the impulses on the laryngeal recurrent nerve, a processing unit to decode the neural impulses and to translate them into the individual voice characteristics of the patient, a voice output, and a power supply.

The individually customized prosthesis is placed between the pharynx and the trachea during laryngectomy [8, 9]. It is made up of a biocompatible, fungicidal and bactericidal material, that adheres, once sutured with the trachea [10]. The processing unit consists of a microprocessor and the audio component. The audio component's main circuitry consists of a filter-component with multiple fixed and adjustable filter coefficients to determine the voice characteristics dynamically within a given range. The given range of the fixed filter components is defined by preoperative voice recordings and analyses of the patient's natural voice. The audio component's adjustable filter components can be dynamically altered by the microprocessor in real-time for the generation of situational voice characteristics. The audio component's main circuitry is a vocoder chip comparable to the vocoders used in regular digital cellular phones which are usually based on signal processing methods like the Linear Code Prediction (LPC) to reproduce human voice adequately [11, 12].

The information on the recurrent laryngeal nerve correlates with the pitch of the speaker's voice, thus delivering data to the microprocessor and eventually to the filter-components to be set accurately to imitate the patient's natural voice. Muscle potentials from the cricoarytenoid muscle can be used for input as well, if the muscle can be salvaged during cancer surgery [13].

Therefore, the prosthesis contains a neural interface to connect the laryngeal recurrent nerve, a programmable microprocessor using Fuzzy logic, a RAM, an EEPROM containing the firmware, and the audio component [14, 15, 16]. The prosthesis also contains a preamplifier to amplify the neural impulses, an audio signal amplifier, and a customized speaker. The power is supplied by lithium polymer batteries which are charged by an inductive collar while respecting the limits of tolerable inductive energy transfer through the skin [17]. A transponder unit is used for bidirectional communication between the prosthesis and a service computer (e.g. for firmware updates, adjustment of fixed filter values, status information of the prosthesis,

battery lifetime etc.) using technologies like low power RF, e.g. Bluetooth® technology.

B. Conserving and administration of voice characteristics

The system to digitally conserve and administrate the voiced and unvoiced portions of the patient's native voice characteristics contains a digital recording unit, an analyzing unit including the identical filter components like used in the prosthesis, and an audio database [12]. After being digitally recorded, the patient's voice is analyzed by frequency, structure and range of voiced portions, in particular the tessitura.

The analyzing unit uses Fast Fourier Transform (FFT) to transform the voice signal from the time domain into the frequency domain. After spectrum analysis the analyzing unit compares the digitally recorded native voice with the output of its digital filter units to approach the highest similarity in the input signal and the reproduced signal. A regular computer with specific software controls the recording unit, the analyzing unit and its digital filters. Audible control is provided by loudspeakers connected to the system. The generated data for filter settings of the voiced portions will then be transferred to the prosthesis via the transponder unit.

In case the voice of the patient has already been affected too much by tumor growth, i.e. the voice is too hoarse, and no recording of the original voice can be done prior to surgery, the digital recording unit can also process old recordings of the patient's voice, e.g. tape recordings, video recordings to create an acoustic fingerprint of the patient's voice. If no voice recordings should be available at all, another way is to try an approach to the original voice by manually setting the filter values after the implantation of the prosthesis step by step until the patient's replicated voice resembles his or her original voice which will make audio tests by the patient and also by e.g. family members or friends necessary.

C. Epiglottis prosthesis

The epiglottis prosthesis is located on the cranial part of the laryngeal prosthesis which is sutured with the pharynx and trachea (Fig. 2). 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 [8, 18, 19, 20].

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.

Special attention to the selection of the used materials for the coil spring and epiglottis replica, e.g. titanium, latex, is required in terms of durability as these parts of the prosthesis are under permanent strain by constant swallowing.

D. Valve engineering

The valve appliance replicates the natural air way functionality and is located in the caudal part of the laryngeal prosthesis (Fig. 2). The valve appliance's width is that of a regular trachea's inner diameter from 1,0 to 1,5 cm, and its height is from 1,0 to 1,5 cm. It is made up of titanium and covered by a biocompatible, fungicidal and bactericidal material [9, 10]. The valve appliance consists of a device to build up air pressure and a pressurizing device.

The hatches of the air pressure device will suddenly be hermitically closed in forced expiration. When air pressure abruptly exceeds a defined limit the pressurizing device opens a pressure relief valve explosively. In the opposite case of falling air pressure - during inspiration - the hatches of the air pressure device return to their home position by pivot bearings, thus allowing both to breathe calmly and to forcibly exhale which will lead to an immediate increase of the abdominal pressure due to the closing valve [21]

The air pressure device's hatches can be pushed in caudal direction to allow intubation by a tube if the patient needs to be mechanically ventilated [9, 20].

E. Stationary and exchangeable module

A radiation therapy can be necessary to destroy remaining tumor cells after laryngectomy. The implantation of the laryngeal prosthesis is not possible after radiation therapy as the tissue is harmed by ionizing radiation (radiation fibrosis, ulcerations) which impedes the engraftment of the laryngeal prosthesis [22, 23]. Implantation of the laryngeal prosthesis before radiation therapy is not doable, either, as the doses used for radiation therapy vary from 30 – 70 Gray which will severely damage electronic components made up of doped silicon. Further damaging solid-state physical effects include the Compton effect and the generation of high currents in the circuitry during radiation [24]. Also, a permanently implanted electronic device will eventually break down by aging or component failure. In the case of component failure or the necessity of a hardware update, or in the case of a

mechanical failure a non-modularly built prosthesis would have to be completely explanted.

It is therefore useful to divide the prosthesis into a stationary and an exchangeable module (Fig. 2). Stationary and exchangeable module are made up of a biocompatible, fungicidal and bactericidal material. The stationary module has at least one interface connecting the laryngeal recurrent nerve to the prosthesis and at least one contact to the exchangeable module's electronic devices. The exchangeable module is inserted into the stationary module by a plug-and-turn connector. The exchangeable module contains the valve appliance, the electronic devices with their power supply, the contact to the stationary module, and the epiglottis analog. After the resection of the larynx the stationary module is placed permanently between pharynx and trachea. A dummy module 'B' which excludes the electronic devices and power supply but includes the valves and the artificial epiglottis is inserted into the stationary module for radiation therapy.

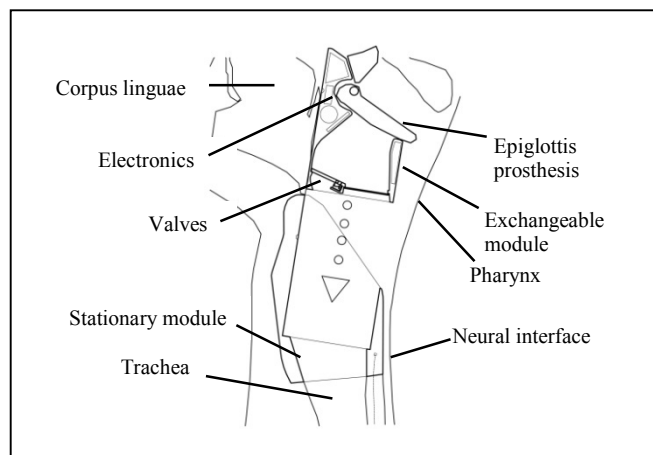


Fig. 2 Inserting the exchangeable module into the stationary module

After the radiation therapy the dummy module 'B' is replaced by the fully equipped module 'A'. In the case of a mechanical or electronic component failure or if hardware update is required, the defected or serviced module 'A' is replaced by a functional module 'A'. The replacement is done via the opened mouth of the sedated patient without the requirement of an operation.

This modular solution minimizes the complexity of servicing and replacing the laryngeal prosthesis and avoids the danger of a damage to the laryngeal prosthesis by ionizing radiation.

III. CONCLUSIONS

The mentioned materials and methods, namely the neural interface, the audio component, the transponder unit, the system to digitally conserve and administrate the voiced and unvoiced portions, the epiglottis prosthesis, and the valve appliance represent components that can be realized by present technology and together with the already existing results [13, 21] are a strong sign that this prosthesis is realizable.

The comparison of this prosthesis with the present form of rehabilitation leaves a disappointing and dissatisfying mark as the rehabilitated patient still is vastly hindered after his therapy and rehabilitation [6, 7]. In contrast, due to the benefits of the modular prosthesis of the larynx the hitherto severely disabled laryngectomee will be adequately rehabilitated by the ability to talk with his or her natural voice, to breathe via the regular air ways, and to build up an abdominal pressure.

The implementation of the laryngeal prosthesis still requires further intensive research in the fields of neurophysiology, neural interface design, and the implantation and durability of foreign material in the head-neck region, but very promising results [13, 21] encourage us to continue with our research and we would also like to ask scientists worldwide to consider research in the aforementioned fields, especially in the fields of biocompatibility of implants in the pharynx, and in the analysis of the information on the laryngeal recurrent nerve and the muscle potentials on the cricoarytenoid muscle respectively and thus to realize this prosthesis one day.

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