Recent promising technological developments on hearing restoration

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ABSTRACT

The purpose of this paper is to review some of the promising technological developments related to hearing restoration part of ENT practice. If successfully implemented in product or procedure form, these technologies are likely to simplify surgical procedures related to hearing restoration and improve the condition of patients. The developments are compiled from scientific sources as well as from recent patent documents and they are not yet commercially available.

Keywords: Ear Nose and Throat; ENT; Ossicular Replacement Prosthesis, ORP; Ossiculoplasty; Active Ossicular Prosthesis; Cochlear Implant

1. INTRODUCTION

It is very well known in medical community that technological developments benefit surgical and medical procedures directly. Many technological innovations in medical field eventually find its way into a product or a procedure that affects the well being of human beings. Due to this, technical innovations are eagerly awaited by medical community more than any other field [1,2].

Ear nose and throat (ENT) related ailments plague a very high percentage of society and as a result, any technological improvements in this arena find reflections into the well being of many millions of patients in the world [3]. In this study authors review some of the technological developments in the area of hearing restoration which looks promising and may find their ways into surgical procedures and medical products during the coming years.

A word of warning may be necessary at this stage. Obviously good ideas do not necessarily guarantee successful products; as success of a product is as much to do with marketing process as the innovative aspects of the product. Engineering community know too well that the best selling processor in the market may not necessarily be the best processor technically. Sometimes suc-

cessful products are doomed because of marketing errors and on the same token, some mediocre products may turn into commercial successes because of successful marketing [4]. Walking along this line of thought, it is not possible to claim that the technologies reviewed in this study will definitely be successful. But they certainly have potential to be successful if the products are designed and marketed properly.

The technological developments reviewed in this paper are categorized in the following groups;

- 1) Developments related to reconstruction of the sound bridge inside the middle ear.
- Cochlear implant related technological developments.

2. DEVELOPMENTS RELATED TO RECONSTRUCTION OF THE SOUND BRIDGE INSIDE THE MIDDLE EAREASE OF USE

The middle ear contains chain of three bones which are linked to each other extending from tympanic membrane to oval window of the inner ear. These bones are known commonly as the malleus, incus and stapes. This chain of bones is called ossicular chain or auditory ossicles [5]. The **Figure 1** shows the bones of the osscicular chain which starts with malleus which engages the ear drum (membrane tympani) and transfers the vibrations of tympanic membrane through incus and stapes bones. These bones are connected to each other through joints and transfer vibrational movement from one bone to the other. Stapes is the last bone of this ossicular chain and transfers vibrations to the cochlea of the inner ear which is located in the vestibule.

When movement of the ossicular bones is impeded for some reason which may be due to deterioration of one of the bones or the joints, the chain is reconstructed using artificial bone which is called Ossicular Replacement Prosthesis (ORP) [6].



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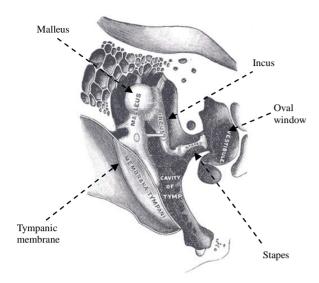


Figure 1. Structure of the middle ear and ossicular chain components.

Ossicular chain reconstruction surgery involves reconstitution of sound conduction bridge of osscicular bones by removing the dysfunctional elements of the chain and replacing it by Ossicular Replacement Prosthesis (ORP) [7].

Ossiculoplasty is the type of the surgical operation where ORP prosthesis is implanted into the middle ear cavity using a surgical procedure where an incision is made through the ear canal and prosthesis is placed. Replacement of incus and stapes in the chain is called Total ORP (TORP), and replacement incus bone is called Partial ORP (PORP) [8,9]. Both prosthesis touches the remnant of tympanic membrane or newly created tympanic membrane. Ossicular Replacement Prosthesis is expected to have low mechanical inertia, low mechanical damping, as well as being durable and biocompatible [10]. Currently ORP's are attached to the ossicular chain using wires, springs and cement. Since size of the ossicular chain components may be different for different individuals, manufacturers usually manufacture several different sizes to accommodate whole range of patients. Some manufacturers make the components of ORP in such a way that the size of the components can be altered by cutting down the size of the components.

Ossicular chain of bones has a complex mechanism of connection which transmits vibrations of the eardrum to the inner ear. However, in case of large displacement which is due to unusually loud sound or pressure differences, the joints absorb the excessive mechanical displacement, so that neither the ossicular bones nor the sensitive inner ear cochlea is damaged during the process. Current state of the art ORP prosthesis use spring elements to absorb these additional shocks due to pressure differences or loud sounds although many experts

find their performances unsatisfactory. In technical language, the vibrations due to sound are called dynamic sound pressure variations; whereas vibrations due to ambient pressures change or changes due to loud sounds are called static and quasi-static sound pressure variations respectively. Displacements due to static and quasistatic sound pressure variations may be 10,000 times more than the typical displacements encountered with conversational dynamic sound pressure variations [11]. Such high energy and displacement generated by static and quasi-static sound pressures are likely to damage sensitive inner ear components of hearing. Although current state of the art ORP prosthesis perform satisfactorily under dynamic sound pressure variations, their performance under static and quasi-static sound pressure variations has been less than ideal.

There are several promising developments in the area of ORP prosthesis which addresses these complicated issues. One such invention is disclosed in a recent patent document where ORP prosthesis is designed with deformable joints in such a way that normal vibrations are transmitted from eardrum to the oval window without hindrance with minimal acoustic attenuation [12].

In this particular design, the deformable coupling between the ossicular components is designed to absorb the additional changes under ambient pressure. The components act rigid during regular dynamic load circumstances but become soft under large static or quasi-static loads.

The design uses non-Newtonian fluids between the couplings of the ossicular chain prosthesis components. There is a special category of non-Newtonian fluids which are called thixotropic fluids. Thixotropy is the property of certain gels or fluids that are thick (viscous) under normal conditions, but flow (become thin, less viscous) over time when shaken, agitated, or otherwise stressed. These fluids are also called "shear thinning fluid" which displays decreasing viscosity with increasing shear rate [13].

There are some fluids used in industry which make use of this property of thixotropic fluids. The drilling mud is an example of thixotropic fluid which becomes fluid under pressure, yet thickens when pressure is removed. It is the ideal fluid to be pumped to the depth of thousands of meters through drilling pipe to cool down the drill tip as well as removing rock cuttings from the locality of the drill tip. Since drilling mud becomes fluidic under pressure, it can be pumped to immense depth with reasonable pressure.

The state of the art prosthesis designed with this technology uses an artificial synovial fluid between the joints of the prosthesis to achieve the similar affect. **Figure 2** shows the principle of operation of the component. The device resembles a piston and cylinder as-

sembly where the piston fits loosely having a gap between the piston and the cylinder wall. The cavity inside the cylinder is filled with thixotropic fluid which is forced to move as the piston inside the cylinder moves. The piston and the cylinder are covered by a spring like casing which not only confines the thixotropic fluid within the cylinder but also acts like a spring when the piston is moved.

The operation of the unit can be described as follows. Under regular dynamic vibration conditions, the thixotropic liquid inside container is viscous enough to force the piston and the cylinder to act as one rigid unit with no relative movement between the two parts. Under these conditions, the prosthesis acts like a rigid rod. When a loud sound is encountered, the piston is pushed with higher force toward the cylinder which increases the pressure on the thixotropic fluid contained inside the cylinder. Under increased pressure, the viscosity of the thixotropic fluid decreases and becomes more fluid. As a result of this, the fluid can escape through the loose fitting between the piston and the cylinder. Under these conditions, the piston and the cylinder is not rigid anymore and movement of the piston is absorbed by the prosthesis. When pressure is removed, the spring like outer casing returns the piston and the cylinder to their original position. In this sense, the device acts like a special shock absorber similar to shock absorbers connected to wheels of a vehicle.

Figure 3 shows the three dimensional view of the cylinder and the piston assembly where the spring-like shroud with compliance capability is shown as wire frame for clarity. **Figure 4** shows the three dimensional view of the middle ear with incus bone is replaced by the prosthesis (PORP).

3. DEVELOPMENT OF ACTIVE OSSICULAR REPLACEMENT PROSTHESIS

Another promising technological development is the development of active ossicular prosthesis concept [14]. Ossicular prosthesis replaces one of the ossicular bones in the ossicular chain which transmits vibration of the sound signal received by ear drum to the oval window of the inner ear which converts the vibrations to sound signals. As it is explained in the previous section in detail, replacement of one of the bones or the whole ossicular chain is ossicular replacement prosthesis operation. In this particular innovation, one of the bones of the ossicular chain is replaced by an active ossicular replacement component which not only carries vibrations forward just like an ordinary ossicular bone, but also can actively amplify the vibrations through a tiny actuator built inside the prosthesis. Because of its active nature, this active component can not only amplify vibrations but can also

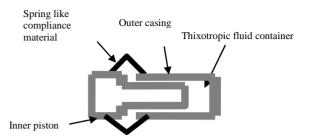


Figure 2. Cross sectional view of the prosthesis member.



Figure 3. Perspective view of the cylinder and the piston assembly.

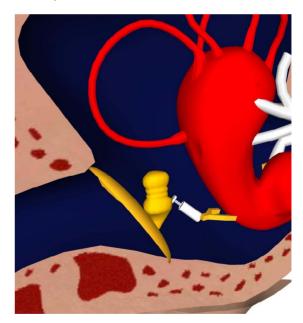


Figure 4. State of the art OSP prosthesis incorporating shock absorbing ossicular elements.

dampen them in case it is required.

Active ossicular replacement prosthesis is not intended to replace the whole chain of ossicular bones but replace one of them. Having more than one active ossicular prosthesis in the ossicular chain is not recommended. In this particular case, any one of the ossicular bones can be replaced by the active component. However, the developers of the technology recommend replacement of the incus bone by the active component

more than any other bone in the chain. Incus bone is located between malleus and stapes ossicles and it is the most suitable bone to be replaced by this prosthetic bone since connection of prosthesis to bones is easier surgically than connection to tissue. The prosthesis is supposed to be surgically placed in the ossicular chain through an incision made in the ear drum. The prosthesis is a self contained unit with no wire coming out or going into the unit. The prosthetic device receives its signal and energy through optical connection from a transmitter placed in the outer ear canal. **Figure 5** shows the location of the transmitter which transmits its signal and energy via optical means.

The design details of the prosthesis are shown in Fig**ure 6**. The unit is a self-contained one which receives its energy through a photovoltaic cell placed in front of the device facing eardrum. The same source that transmits power through light spectrum also transmits the signals in a different frequency of the spectrum. The sound signals are received by a microphone placed in the outer ear canal, processed by a special processor and converted into optical spectrum. The processor is expected to filter out loud noises and other unwanted signals during the processing phase and transmit only what is valuable. The power and the signal are transmitted in photonic spectrum in the form of light and can pass through the eardrum which is translucent. Even though the signal is attenuated partially, the experiments indicated that what is received by the unit inside the middle ear is sufficient to power the prosthesis to operate.

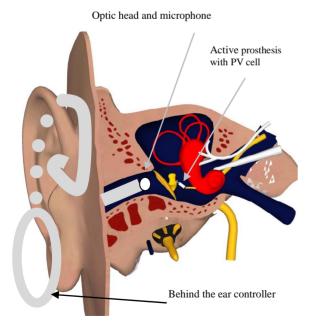


Figure 5. Placement of controller and optic head inside the outer ear canal.

Photovoltaic cell to receive power and signals

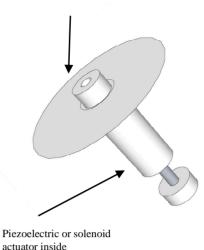


Figure 6. Active prosthesis and its parts.

Actuation of the prosthesis is achieved by piezoelectric or solenoid actuators. Piezoelectric actuators contain crystals which can change shape under electric field. The crystals used in commercial piezoelectric actuators are optimized to change shape along one axis which causes the crystal to elongate lengthwise. Solenoid actuators are made up of a solenoid coil and a suitable core material which can be magnetic or nonmagnetic. As current passes through the solenoid coil, the magnetic field generated inside the coil moves the core in and out. The signal received by the prosthesis is converted into voltage or current form to activate the actuator, which in

4. DEVELOPMENT OF A LESS INVASIVE COCHLEAR IMPLANT SYSTEM

return vibrates the ossicular chain components and oval

window which carries the signals to the brain.

Cochlear implant has been a very valuable innovation for patients who suffer hearing loss due to neurological problems in the inner ear [15]. A typical cochlear implant has electrode implanted on the cochlea and controlling electronics placed in the temporal bone. Electronic unit receives its power and signal through an RF coil placed under the skin. Using a suitable power source, power is delivered to the electronics embedded inside the temporal bone through wireless means. The sound signal is picked up by an external microphone and sound signal is processed and converted into electrical form which is suitable for feeding into the cochlear electrode in contact with the cochlea. Cochlear implant has provided a solution to thousands of severely hearing impaired who otherwise, would not have an idea about hearing sense whatsoever. A typical cochlear implant is

shown in Figure 7 below.

Although cochlear implant has been a wonderful device, there are some aspects of the device and the implementation which are less than desirable. The existence of RF coils and electronics either prevents or makes it difficult for the cochlear implant patients to go through MRI imaging process. And other undesirable aspect of the current costlier implant is the level of invasiveness of the surgical procedure. Part of the temporal bone has to be cut out or emptied to make room for the electronics which in return weakens the temporal bone. Making wire connections from temporal bone to cochlear electrode is not an easy process. Yet another difficulty is maintaining connection with the internal RF coil placed under the skin and external unit placed over the skin. External microphone unit that picks up the signal provides little information about the direction where the sound comes from [16].

Currently there is a significant innovation which may get rid of many undesirable aspects of the classical cochlear implant system [17,18]. This system uses optically energized electronics as well as optically provided signals. A simple behind the ear external unit picks up sound signals through the microphone placed inside the external auditory canal. This technique provides highly directional sound signals. The sound signals are processed and converted into optical signals in the light spectrum. The processor unit which is located inside the behind the ear unit generates signals which are suitable for feeding into the cochlear electrode. The electronic signal is converted into photonic signal by an ordinary LED, light emitting diodes which is placed inside the external

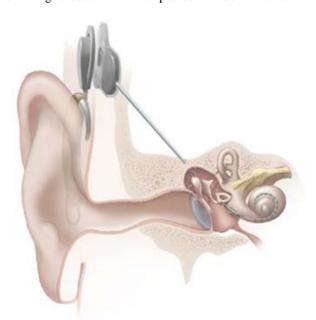


Figure 7. Typical cochlear implant and location of processor.

auditory canal in close proximity to the microphone. The light signals penetrate and pass-through the translucent eardrum with little impairment. The internal unit of the cochlear implant is located inside the middle ear cavity. This unit has a photovoltaic sensor facing eardrum for receiving power which is transmitted in the form of light by the external unit placed in the ear canal.

In addition to the photovoltaic sensor, there are additional light sensors mounted on the middle ear unit of the optical cochlear implant to receive excitation signals transmitted in different light wavelengths. The optical signals are encoded using suitable optical techniques to provide signals with adequate fidelity to the internal unit of the optical cochlear implant.

This new way of implementation of cochlear implant is likely to simplify the surgical process since it does not require placement in the temporal bone. The internal electronic part of the cochlear implant is implemented using suitable nonmagnetic material which causes no interaction with the MRI imaging process. Since excitation of the cochlea through the cochlear electrode requires very little power, power transmitted through photovoltaic means is likely to be sufficient for powering the internal electronics. The placement location of the internal unit is the middle ear which is normally occupied by ossicular bone chain. Placement surgery most probably requires making an incision on the eardrum and emptying the middle ear cavity to house the inner unit of the cochlear implant. The Figure 8 indicates the location of the inner and outer units of the optical cochlear implant.

5. CONCLUSIONS

We presented several new promising technologies related hearing restoration in this study. The technologies

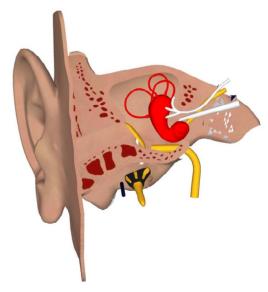


Figure 8. Optically coupled cochlear implant.

are invented quite recently and it may take some time for the products to appear on the commercial market. The information about the technological developments is compiled from scientific documents as well as patent filings. Authors have neither commercial interest nor connections to any of developers of the technologies whatsoever. Authors are not responsible for the accuracy of claims in the referenced documents.

The information is collected and presented in good faith for the purpose of informing ENT community about the recent developments and encouraging practitioners' and inventors to think and invent out of the box.

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