New bone conduction hearing aid passed long term endurance test

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Professor Bo Håkansson regularly meets with the patients who participates in the clinical study to follow how the new hearing aids work. Here Anders Salonen visits the hearing lab at Chalmers. Credit: Malin Ulvarson

For how long time can an implant function inside the body without losing performance? That is one of many questions researchers want to have answers to when new implants are developed, before they eventually can be approved for general use in healthcare.

Patients who are suffering from conductive or mixed hearing loss can gain normal hearing with a new implant that replaces the middle ear. Over 200 000 people worldwide have this type of hearing aids that uses the skull bone to transmit sound vibrations to the inner ear via so-called bone conduction.

The Bone Conduction Implant (BCI) is a new type of hearing aid with several improved features developed by researchers at Chalmers´ department of signals and systems, in collaboration with Senior Physician Måns Eeg-Olofsson and his team at the ENT department, Sahlgrenska University Hospital. The first patient received the BCI implant in December 2012 in Gothenburg, and it is today worn by 16 patients in a clinical study.

Milestone celebrated

Recently, a milestone was reached on the way to the goal of launching the BCI to the market in the future. The bone conduction implant has been kept "listening" to radio in an age-acceleration test chamber that accelerates the exposure time with a factor of approximately six times.

"The performance of the implant has been verified and monitored corresponding to ten years of normal usage time for patients who are using the hearing aid for eight hours on a daily basis", says Professor Bo Håkansson, originator of the bone conduction hearing aids and a pioneer in the field with 40 years´ research experience.

Credit: Chalmers University of Technology

The long term endurance test shows that the life span of the implant is longer than the desired minimum time for implants in the human body, often considered to be ten years.

"Once a month, for twenty months, we have monitored the implant performance at different frequencies", says PhD-student Karl-Johan Fredén Jansson, who is responsible for these validations, which also is an important part of his coming doctoral thesis. "We are pleased to note that we during this time haven't seen any impairment in the implant function."

Simulating conditions in the human body

The test chamber was constructed about two years ago by the student Helga Jóna Harðardóttir, who started the project during her master thesis project at Chalmers.

To simulate the real conditions in the human body, the temperature in the test chamber is kept at 37 degrees Celsius. The Swedish national radio P1 has proved to be the best radio channel to use in the test, since the broadcasts resemble a good mix of the sounds you are exposed to during an ordinary day at work, comprising both spoken words and other sounds.

The researchers can whenever they want connect and listen how the sound would be perceived inside of the head of the patient using the implant, through a so called skull simulator.

Valuable meetings with patients

Credit: Chalmers University of Technology

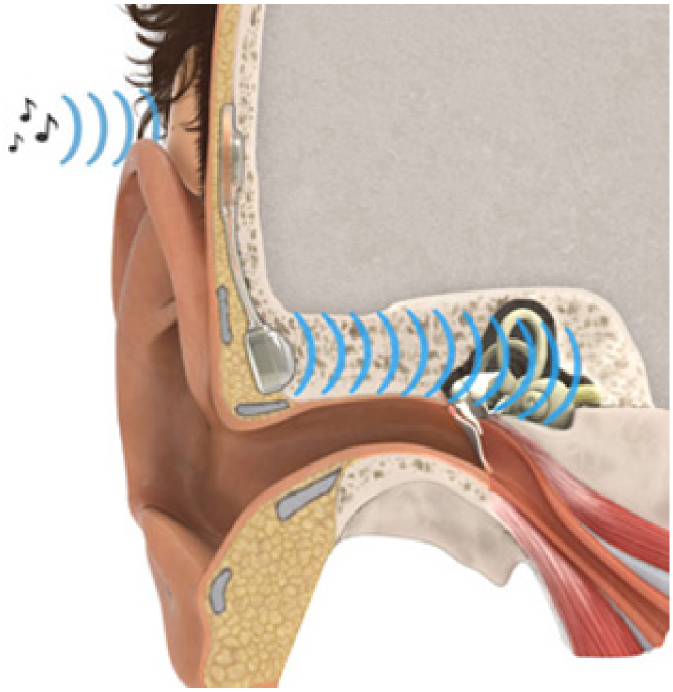
Evaluations are also done concerning how the patients in the study experience the life with their new hearing aid and they regularly come to Chalmers to do follow-up visits and hearing tests.

"So far we have received good responses from the participants and haven't had any serious complications", says Professor Bo Håkansson. "To meet grateful patients, who feels a higher quality of life, gives us a very strong motivation to carry on with our work."

Heading for long term goal

In the meantime the implant continues to "listen" to radio in the test chamber. The aim is to collect more data, which gives information about how the implant reacts if the hearing aid is used for more years and over eight hours on a daily basis.

The long term goal is to get CE-mark in the EU and approval from the US Food and Drug Administration, FDA. Important information to qualify for these requirements, concerns for example safety issues towards the patient, technical function and hearing rehabilitation. These are essential steps on the way of launching the BCI as a new hearing aid for general use in healthcare, and to offer improved hearing rehabilitation for more people.



Credit: Boid/Chalmers

The implant is slightly less than six centimeters long. By a surgical procedure, it is implanted in the skull bone under the skin at a position behind the ear. Sound is transmitted wirelessly from an externally worn sound processor to the implant by an induction link, comprising one transmitter coil in the sound processor and one receiver coil in the implant. The patient can easily attach or remove the sound processor from the head as it is magnetically attached over the implant.

The audio signal is transmitted to a tiny quadratic loudspeaker anchored to the bone near the auditory canal. The speaker generates sound vibrations which reaches the sensory organs of the cochlea, and is further by the brain interpreted as sound.

In comparison with the convention Bone Anchored Hearing Aid (BAHA), the wireless link keeps the skin intact because there is no titanium screw needed through the skin.

Thanks to a new type of transducer technique, the BCI transducer can be made small, but as powerful as a BAHA, and at the same time avoid complications related to a titanium screw through the skin.

Provided by Chalmers University of Technology