

Fully Implantable Middle Ear Hearing Devices (ACROSS) in KOREA

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The conventional hearing aid is widely used for rehabilitation for hearing impaired person. But, It still has some limitations to apply in the serious hearing loss cases. They are acoustic feedback (howling effect), bad cosmetic, sound distortion, ear canal occlusion and foreign body sensation, etc..

The IMHD (implantable middle ear hearing device) is developed to overcome the limitation of air conduction hearing aids. The IMHD catch the sound, the sound is changed to vibration, and the vibration is transferred to oval-window. There are two types IMHD, one is semi-implantable middle ear hearing device such as P-MEI system and Vibrant Soundbridge. The other is fully-implantable middle ear hearing device such as Carina and ACROSS. We are researching transducers and system for middle ear hearing device until 1995. Over the last 6 years, a Korean research team at Kyungpook National University (KNU) has been developed an FIMEHD called ACROSS based on a differential floating mass transducer (DFMT). The main research focus was functional improvement, biocompatibility, miniaturization, and a low-power operation of the fully implantable middle ear hearing device.

We have developed a DFMT (differential floating mass transducer) for generation of vibrating force. It consists of a vibration membrane, two titanium covers, driving coils, and two bonded magnets with the same poles facing each other and located inside the driving coil. To design the DFMT with the maximum actuating force and proper frequency response to a normal middle ear, the optimum design specifications of the DFMT can be obtained on the basis of the FEA (finite element analysis) simulation.

The microphone of ACROSS v1.8 consists of a small electret condenser microphone (ECM), titanium case, and vibrating membrane. The vibrating membrane made of very thin titanium foil that is a 20 um-thick flexible titanium foil. It has a wider area than the ECM, because, the sensitivity of microphone increase under the skin. As the materials of electret like piezoelectric, silicone oxide, silicon nitride, or ferrite generally have no bio compatibility, hermetic sealing and bio compatible material of case are very

important. For safety, we focused on the laser welding and feed-through in titanium microphone case.

The implant system of ACROSS v1.8 consists of the main body, transducer, implantable microphone, and communication coil. The specifications of ACROSS v1.8 are +23 dB pre-amplifier for microphone, secure the all material's bio-compatibility wireless charging, wireless control and low power consumption u-controller.

In order to investigate the effectiveness of the ACROSS v1.8, the performance of the ACROSS v1.8 was measured using human fresh temporal bones in Stanford university. Through the experimental results in Stanford University, the effectiveness of ACROSS v1.8 was verified.

For secure safety, the ACROSS v1.8 was tested by Korea Testing & Research Institute, Korea Electric Testing Institute and Korea Testing Laboratory. As all test result, the ACROSS v1.8 has bio-compatible.