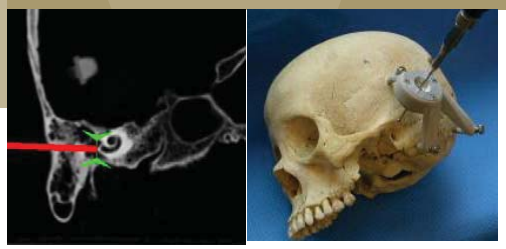
VANDERBILT

OFFICE OF TECHNOLOGY TRANSFER AND ENTERPRISE DEVELOPMENT

Percutaneous Cochlear Implantation



On the left is a CT scan of the temporal bone. The cochlear is the snail shaped structure and the purposed drill path is shown in red with green indicating the target. On the right is the C-in™ system consisting of a custom made drill-guide, unique for each patient.

Summary

Vanderbilt inventors have developed and tested a device (C-in™) and method that would shift the current invasive, risky surgical procedure of cochlear implantation to a less invasive outpatient procedure.

Description

Building on expertise in image-guided surgery, Vanderbilt researchers have developed a device and methodology for obtaining cochlear access in a minimally-invasive fashion based on use with a microsurgical platform (by FHC, Inc.). This technique, or alternatives that Vanderbilt has developed, will allow cochlear access to be obtained in an out-patient procedural suite in under 30 minutes. The concept (see Figure) uses radiographic guidance to drill directly from the surface of the skull directly to the cochlea without injuring vital structures. The device that accomplishes this (the C-in™, see Figure above right) is a drill guide that is custom-made for each patient based on pre-operative CT scans. This concept has been presented nationally and published in peer-reviewed articles.

IRB-approved human validation trials are underway at Vanderbilt University Medical Center, and IRB-approved human validation trials will continue at VUMC and are to begin at other leading medical centers in April 2007. The procedure has been performed on 2 patients at Vanderbilt, one of which has been validated with very successful results.

Value Proposition

This new surgical technique offers at least 3 significant advantages over the current technique:

(1) Time and cost savings. The C-in™ will allow cochlear implantation to be performed in a procedural suite under local anesthesia in less than 30 minutes. This time savings translates to large cost savings.

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(2) Precise, yet individualized placement. The C-in™ places the device is a standardized fashion eliminating the variable of surgical technique on outcome. Furthermore, as patients are awake for the procedure, auditory feedback from the patient will permit fine tuning of depth of implantation (e.g. “Mrs. Smith do you hear better in position 1 or position 2?”).

(3) Patients can be fitted in a single day. This is a dramatic improvement from the current standard of care where patients wait 2-3 weeks before activation of the cochlear implant after surgical edema has resolved.

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Potential Market Size

The cochlear implant market has sustained double-digit growth over the past decade. In the United States, as many as 738,000 patients could benefit from cochlear implants, and the international market consists of multiple millions of patients, with emerging markets in Asia and Latin America.

Current Competitive Product(s)

Currently surgical access to the inner ear is needed to perform cochlear implantation. This surgical procedure takes approximately 2-3 hours and requires a highly skilled surgeon. Even with such skill, the surgery is risky due to several vital structures residing in such close proximity to the cochlear, including the facial nerve, jugular vein and the carotid artery.

Three companies have FDA approval to sell cochlear implant systems—Cochlear Corporation (Melbourne, Australia), MED-EL Corporation (Innsbruck, Austria) and Advanced Bionics Corporation (Valencia, CA). Advanced Bionics was recently purchased by Boston Scientific for $740 million dollars, with expectations of $82 million in sales for 2005 and $128 million in 2006.

Investment Needed

Significant research funding is already in place to further test and validate patients at 3 other clinical sites under IRB-approved protocols. Investments to commercialize this technology will be required for transferring knowledge of the procedure, marketing and to productize a surgical kit for FDA-approved sales.

Intellectual Property Status

The intellectual property includes pending patents on the method of percutaneous cochlear access, components of the drill guide, software algorithms crucial to the registration of radiographic images to surgical anatomy and novel safety controls ensuring accurate travel of the drill.