Emerging Technology List  
Semi-implantable, Middle Ear Hearing Aids  

| Technology: | Semi-implantable, middle ear hearing aids |
| Manufacturer: | The Direct System (SOUNDTEC™ Inc., Oklahoma City; US) |
| Purpose: | In adults, to compensate for moderate to severe deafness due to disorders of the auditory nerve. |
| Current Regulatory Status: | In 2001, The Direct System was licensed by Health Canada and also received approval for marketing from the US Food and Drug Administration. |
| Description: | The semi-implantable Direct System consists of a sound processor that is worn either behind the ear or in the ear canal, an earmold coil that fits inside the ear and a tiny magnet that is implanted in the middle ear. As the manufacturer's product brochure explains, the sound processor "receives and amplifies sound vibrations and transforms them to electrical signals." These signals are picked up by the earmold coil assembly which converts them to electromagnetic energy that is transmitted to the magnetic implant, causing the small bones of the ossicular chain to vibrate. "These vibrations pass through the cochlea, stimulating the hair cells and nerves that send impulses to the brain that are interpreted as sound." |

Such devices are intended to alleviate some of the disadvantages of conventional hearing aids, such as: inadequate amplification in the high frequency range, acoustic feedback, problems in the fit of the earmold, external otitis causing discomfort and sound and voice distortion. Semi-implantable hearing aids are indicated for use in adults with moderate to severe sensorineural hearing loss who need an alternative to externally worn, acoustic hearing aids. SOUNDTEC recommends that individuals try an appropriately fitted conventional hearing aid before considering a semi-implantable device. 

The implantation surgery for The Direct System takes about 30 minutes and can be performed as an outpatient procedure. About two months after the surgery the audio processor is fitted and programmed by an audiologist to suit the individual's specific hearing loss. 

| Cost: | The Canadian distributor for SOUNDTEC provided the following prices for The Direct System: |
| | • Sound processor in the ear canal: C$7,495 for the first ear and C$5,975 for the second ear |
| | • Sound processor worn behind the ear: C$6,799 for the first ear and C$5,599 for the second ear (Ingo Mueller, President, SoundTec Canada Inc., Vancouver: personal communication, 2002 Dec 11). |

The life expectancy of the device is about four years if used for about eight hours a day. The battery life is three to four weeks.
The Direct System was tested in the US in a multicentre, Phase II clinical trial of 103 patients. The approach taken was single subject repeated measures, with patients acting as their own controls and a comparison being made with their pre-implant experience with acoustic hearing aids. In material submitted to the FDA on 95 patients with 20-week follow-up, statistically significant improvements were found in the usable range of hearing (functional gain), Articulation Index score (audibility) and speech recognition in quiet. There was no significant difference in speech recognition in a noisy environment. With respect to subjective measures, 84 of 94 patients preferred the semi-implantable system to their acoustic hearing aid. Patients also reported statistically significant reductions in feedback and occlusion (the feeling of speaking into a tunnel or barrel when using a hearing aid) and perceived improvements in sound quality. In 85 of 95 patients residual hearing was not significantly affected. The most common adverse effects associated with the device (ear pain, outer ear irritation and device noise) resolved in the majority of patients.

Semi-implantable middle ear hearing aids are contraindicated for patients with active or recurrent middle ear infections, perforated ear drums and tinnitus or hearing loss due to other conditions such as conductive hearing loss. Because the implants contain magnets, patients with semi-implantable hearing aids must not undergo magnetic resonance imaging (MRI). Other procedures such as diathermy, electrosurgery or electroconvulsive therapy are also contraindicated. The manufacturer notes that the effects of certain diagnostic and treatment procedures on the implant, for example, cobalt treatments, positron emission (PET) scans, transcranial diagnostic ultrasound and linear accelerator therapy, are not known.

A variety of conventional, acoustic hearing aids are available. New developments in this area include disposable devices, such as the SongBird Digital Disposable hearing aid. Another device recently approved for marketing in the US is the Adapto voice-activated hearing aid (Oticon Inc., Somerset, NJ). The Adapto uses a microchip that distinguishes and amplifies human speech as opposed to background noise.

A second semi-implantable hearing aid system, the Vibrant Soundbridge (Symphonix Devices, Inc.) also received regulatory approval in Canada, the US and Europe, but the company recently closed down. The MET (Middle Ear Transducer) from Otologics, another semi-implantable hearing aid, is currently available in Europe and is undergoing trials in the US. Several fully implantable devices are awaiting regulatory approval in North America or are under development.

Semi-implantable hearing aids may be an option for those with moderate to severe hearing impairment who experience difficulties with conventional hearing aids. Limited available data suggest that the technology is effective and safe, though data on long-term outcomes in larger groups of patients are needed.

Health professionals require special training (provided by the manufacturer) to learn how to make the deep-canal impressions required for fitting the device.
A disadvantage with this technology is the need for a surgical procedure. Morbidity associated with this procedure has yet to be established, although results from the small studies to date are encouraging.

References:


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This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

These summaries have not been externally peer reviewed.