Surgical Treatment of Sensorineural Hearing Loss: A Semi-Implantable Active Magnetic Middle Ear Implant

Ian S. Storper, MD1 and Omid B. Mehdizadeh, MD2
1New York Head and Neck Institute/North Shore LJI Health System  2New York University School of Medicine

Abstract

Objective: To present surgical technique, indications for and results of the senior author’s experience with a semi-implantable active middle ear device.

Study Design: Retrospective chart review of all patients undergoing this procedure from September, 2012 through October, 2014 by the senior author

Setting: Tertiary referral center, outpatient hospital

Patients: 16 patients with severe sensorineural hearing loss who were not receiving adequate benefit from hearing aids

Intervention: Surgical placement of this middle ear implant and fitting of external auditory canal processor

Main Outcome Measures: Postoperative hearing level and functional gain

Results: Postoperative hearing levels are compared to preoperative hearing levels. Patient use and complications are discussed

Conclusions: This middle ear implant can offer significant hearing improvement for properly-selected individuals who have not achieved adequate benefit from hearing aids.

Methods and Materials

A retrospective chart review was performed for all patients undergoing MAXUM® middle ear implant between September, 2012 and October, 2014. Patients with disabling tinnitus, need for repeat MRIs, CPA or middle ear pathology, cortical concerns and/or conductive component of hearing loss were not offered a device. All patients had neurologic evaluation including MRI. All patients underwent split-coil surgical technique (6,7).

Preoperative and postoperative threshold and speech discrimination scores. Postoperative hearing was recorded in a sound field with a tent plug placed in the external auditory canal of the unoperated ear. Functional gain was assessed by frequency; preoperative and postoperative pure-tone averages were also assessed. All data were harvested without patient identifying information. This study was approved as EXEMPT by the NS-LU IRB. The authors have no disclosures.

Introduction

Semi-implantable middle ear devices have been available for over a decade as a treatment option for sensorineural hearing loss (1-5). These devices are typically used for patients with moderate to severe hearing loss who have not achieved adequate benefit from hearing aids despite being optimized.

The device being studied is a system in which a neodymium-iron-boron magnet encased in titanium is affixed to the stapes capitulum by heat-sensitive Nitinol wire and cement. The patient wears an integrated processor in the ear canal which consists of microphone, speech processor and transducer to drive the magnet. This allows for large amounts of energy to be delivered to the stapes, thereby providing increased amplification and improved scores in speech discrimination. As the electromagnetic oscillations are silent, there is no feedback, which can be a limiting factor in amplification. The distortion and occlusion effect generated by some hearing aids is also reduced.

It was our purpose to examine the preoperative and postoperative hearing results of all patients undergoing this procedure by the senior author from September, 2012 through October, 2014. Functional gain is examined as well as changes in speech discrimination in an effort to understand the degree of hearing improvement and patient benefit which this device provides. To the best of our knowledge, this is the first publication of hearing data obtained from patients with this device.

Results

• 19 Operations performed on 16 patients, one bilateral
• Age range 31-93; 8 men, 8 women. Twelve right ears, 7 left ears.
• PTA decreased on average 16 dB at 250 Hz, 23 dB at 500 Hz, 34 dB at 1 KHz, 36 dB at 2 KHz and 29 dB at 4 KHz. This is shown in Fig. 1.
• Functional gain was clear at all frequencies. This is shown in Fig. 2.
• Postoperative improvement in speech discrimination score varied from -4 to 60 percent with mean increase of 25 percent.
• Postoperative speech reception threshold improvement ranged from 55 dB to -5 dB with mean improvement of 21 dB.
• Figure 3 is a scattergram showing word recognition scores and pure tone averages for the studied patients before surgery.
• Figure 4 is a scattergram showing change in word recognition score and pure tone averages after surgery.
• Two patients had missing data and these were not included.
• Two patients had extrusions: 1) Pt. with hobby using high-powered magnets. Device was replaced with excellent result. He no longer does this. 2) Pt. with Eustachian tube dysfunction who increased smoking and autoinsufflation. Replaced with excellent result and then became nonfunctional again. Undergoing workup.
• Remainder are wearing their devices, to best of our knowledge.

Discussion

• Our experience with 19 procedures on 16 patients was described. There was significant functional gain at all tested frequencies but it was greatest in the middle to high frequencies.
• As can be seen from the scattergrams, there was a high incidence of hearing improvement both for pure tones and speech discrimination.
• Particularly encouraging is the improvement of a number of patients who had poor preoperative speech discrimination scores.
• Aside from the two patients with extrusions (one presumably related to magnet use) there were no complications.
• Two patients—one with autoimmune inner ear disease and one with congenital hearing loss have suffered progression of their conditions, but are still using their implants.
• Positive attributes of this study are that there was one surgeon and all were performed at the same institution. Limiting factors were variety of diagnoses and missing speech discrimination on two pts.
• This device was derived from the SOUNDTEC Direct® system, which was available from 2001-2004. It offered significant hearing improvement, but some patients complained of a knocking sound. While newer surgical techniques remedied this, the device was withdrawn by the manufacturer when ways to improve it were identified. In the current device, the integrated processor and transducer, digital signal processing and no need to disrupt the incudostapedial joint are the major advances which appear to contribute to its success.

Conclusions

A semi-implantable electromagnetic hearing device for treatment of sensorineural hearing loss has been studied. Results obtained are extremely encouraging. Further investigation will help elucidate the benefit of this device in patients with moderate to severe sensorineural hearing loss to determine its best position between hearing aids and cochlear implants.

Contact

Ian S. Storper, MD
New York Head and Neck Institute, North Shore-LIJ Health System
Email: istorper@nshs.edu
Website: www.nyhni.org
Phone: 212.434.4500

References