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REVIEW

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# Implantable Hearing Aids: Where are we in 2020?

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## Abstract

Beginning in the late 20th century, implantable hearing aids were developed and used as an alternative for individuals who were unable to tolerate conventional hearing aids. Since that time, several devices have been developed, with four currently remaining on the international market (Med-el Vibrant Soundbridge, Envoy Esteem, Ototronix MAXUM, and Cochlear Carina). This review will briefly examine the history of middle ear implant development, describe current available devices, evaluate the benefits and limits of the technology, and consider the future directions of research in the field of implantable hearing aids.

**KEYWORDS**

active middle ear implants, Cochlear Carina, Envoy Esteem, implantable hearing aids, MED-EL vibrant Soundbridge, middle ear implants, Ototronix MAXUM, sensorineural hearing loss

## 1 | INTRODUCTION

Hearing loss affects 23% of individuals over the age of 12 in the United States,[1,2] with prevalence estimates over 80% for those over the age of 80.[1] Despite the pervasiveness of hearing loss in the aging population and the emerging research on its independent contribution to the development of cognitive impairment,[2] the adoption rate of conventional hearing aids remains quite low. Estimates of hearing aid utilization range vary across studies, but even the highest estimates still suggest only one-third of individuals who would benefit from hearing aids report using them.[3] Additionally, once hearing aid candidates are identified, studies report patients may delay up to 10 years before adopting amplification devices.[4,5]

Several factors have been identified as barriers to technology access, including lack of perceived benefit, financial burden, appearance, device mechanics and handling, health care professionals' attitudes, and personal and situational influences.[3,6,7] Other factors such as race,[3,4] socioeconomic status,[4] and gender[4] also play a role, not only in the decision to adopt hearing aids, but also in the delay of seeking treatment.

Implantable hearing aids were developed primarily to address many of the concerns preventing widespread adoption of conventional hearing aids. These devices bypass the external ear canal, thus circumventing issues related to suboptimal acoustics from the occlusion effect and problems related to chronic otitis. Additionally, by directly stimulating the cochlea through coupling to the long process of the incus, stapes suprastructure or footplate, or round window membrane, implanted hearing aids have the potential to overcome gain limitations and address acoustic issues related to distortion, feedback and high output levels. This review will briefly examine the history of middle ear implant development, describe current available devices, evaluate the benefits and limits of the technology, and consider the future directions of research in the field of implantable hearing aids.

## 2 | HISTORY OF IMPLANTABLE HEARING AIDS

Implantable hearing aids are devices with a surgically placed component that replaces the receiver of a conventional hearing aid and directly stimulates the ossicular chain, round window, or cochlear fluid. The term active middle ear implant is used to refer to the

implanted component but can also be used to describe the entire device. The end component that delivers energy to the auditory system for all implantable hearing aids is a mechanical transducer, either a piezoelectric or electromagnetic-based actuator.

Early investigation into mechanical stimulation of the middle ear focused primarily on electromagnetically driven transducers. The first experiments were conducted in 1935 by the Finnish physicist Alvar Wilska, who placed iron pellets on the eardrums of subjects and generated an oscillating magnetic field by placing a small electromagnetic coil into the ear canal.[8] A similar experiment was conducted in 1959 by Rutschmann in New York, who glued small magnets to the malleus umbo of patients and drove current through a coil in the external ear canal. Subjects successfully perceived tones from 2 to 10 kHz, with two additionally reporting hearing broadcasted programming via the magnet.[9]

Researchers at Case Western Reserve University in 1986 began investigating several prototypes of implantable electromagnetic hearing aids, ultimately settling on a contactless device in which the magnetic implant was placed on the incus and physically separated from the driving induction coil. This device was known as the semi-implantable middle ear electromagnetic hearing device (SIMEHD system).[10,11] Though approval for clinical trial by the United States FDA was granted in 1996,[10] no additional data has been published regarding this device.

A second similar set of devices was developed by the Michigan Ear Institute and Smith & Nephew Richards Company. In seeking approval for a clinical trial from the FDA, it was determined that a three-phased study would be required. In phase I, a small target magnet (known as the electromagnetic ossicular augmentation device, or EOAD) was temporarily affixed to the lateral surface of the eardrum of patients with sensorineural hearing loss. In phase II, the target magnet was incorporated into the ossicular chain prosthesis (known as the electromagnetic ossicular replacement device, or EORD) for use in patients with mixed hearing loss. The final phase III involved implanting the EOAD on the lateral surface of the eardrum of patients with sensorineural hearing loss. These devices were driven by an electromagnetic coil incorporated into a custom mold, similar to an in-the-ear style hearing aid.[12,13] Though early outcomes in a report of the long-term EORD results in Denmark seemed promising, none of the nine original cohort patients used their implanted device long-term, citing poor fit of the driver in the canal and prosthesis extrusion or dislocation as the primary reasons.[14] While initial outcomes for the EOAD appeared to demonstrate non-inferiority in comparison with conventional hearing aids,[12,13] the company eventually lost funding and the device is no longer in use.[8]

The Direct Acoustic Cochlear Stimulator (DACS) was developed as collaboration between Cochlear and Phonak Acoustic Implants as a power-driven stapes prosthesis. The device was designed for treatment of moderate to severe mixed hearing loss and intended primarily for use in advanced otosclerosis. In the original design, an electromechanical DACS transducer is coupled to a conventionally placed stapes prosthesis and powered via an external auditory processor secured in placed with a percutaneous plug. In the original clinical trial, four patients underwent device placement with a second prosthesis placed in parallel and coupled to the incus as in traditional stapedotomy.[15] Phonak Acoustic Implants refined the original design to develop the DACS-PI (Partial Implant) system, which contained a similar electromagnetic transducer, but replaced the percutaneous processor with a magnetically coupled button device.[16] Though promising results have been shown in otosclerosis patients with severe to profound mixed loss,[17] only a few studies have been published and have been none reporting long-term outcomes, and the continued availability of this device is questionable.[18]

The Cochlear Carina device began development as a partially-implantable electromagnetic transducer at Washington University in St. Louis in the 1970s.[19] Known initially as the Middle Ear Transducer (MET) Ossicular Stimulator, the device demonstrated promising attributes in its relatively linear input-output function and flat frequency response. The original Otologics MET system consistent of an implanted electromagnetic transducer mounted in a titanium bracket anchored to the mastoid and an external button processor used to provide transcutaneous electric signal and internal device power.[20-23] The fully implantable Carina combined the external and internal components into a single device with a rechargeable battery, a digital signal processor, a microphone, a transducer, a magnet, and a receiver coil.[20,21,24-28]

The MET device was originally designed to be coupled to the incus body. Surgical preparation for implantation required a cortical mastoidectomy and atticotomy approach. Once the body of the incus was well visualized, a 0.5 × 0.75 mm deep hole was laser drilled into the center of the body of the incus to accommodate the actuator tip.[29] In later developments of the Carina, the laser drilled hole was abandoned a variety of different actuator terminals were manufactured (including a tipped spherical shape, a cylindrical shape, a basket-type, and a ball tip) in order to allow coupling of the transducer to alternate locations in addition to the incus, such as the stapes, footplate, or round window membrane.[24] Surgical approach varied depending on the desired coupling location.

The Otologics MET technology was sold to Otologics in Boulder, CO[8,24] and phase 1 clinical trials in the United States in 1996 were not completed,[22] but the device was approved for use in Europe[30] and South America.[31] The technology was later adapted into a fully-implantable system known as the Carina, which received European Union CE mark for treatment of moderate to severe sensorineural hearing loss in 2006 and mixed loss in 2007.[8,24] The Carina was subsequently acquired by Cochlear Corporation.[24] Despite its demonstrated potential to treat patients with severe mixed or sensorineural hearing loss, distribution of the device was stopped in May 2020.

While use of electromagnetic devices predate incorporation of piezoelectrics in early studies of mechanical stimulation of the middle ear, the principles of piezoelectricity were first described much earlier by Jacques and Pierre Curie in the 19th century. They noted that particular solid substances would both develop an electrical charge under mechanical stress and deform with application of an electric current. Knowing that the physical changes in piezoelectric materials are voltage-dependent, small crystals can be used in middle ear implants to create predictable micro-oscillations to drive the ossicular chain.[8]

In the late 1970s, researchers in Japan developed a piezoelectric middle ear implant, known as the RION device. A fully-implantable version was successfully tested with long-term outcomes in cats,[32] and a partially-implantable device began clinical trials in humans in 1984, ultimately being approved for commercial use in 1993.[33] Though some initial complications required device optimization prior to development of a second generation model, most patients reported good hearing outcomes with the implant; however, the device was discontinued in 2005 secondary to limited and insufficient reimbursement in the Japanese socialized medical system.[8]

The first fully implantable piezoelectric middle ear implant was developed in Germany beginning in the early 1990s. The totally-implantable cochlear amplifier (TICA LZ3001) device received the European Union CE Mark in 1998, becoming the first approved completely implantable middle ear device.[8,34,35] The device had three components: a membrane sound sensor, a piezoelectric transducer, and an internal processor that also houses the device battery. The implant battery was rechargeable and powered transcutaneously with an induction coil.[34,35] Though there were some issues noted with feedback that were assumed to be due reverse transmission of signal through the ossicular chain and to the subcutaneous location in the ear canal,[8,34] 17 of 20 subjects in the phase 3 clinical trial demonstrated improvement in speech recognition and localization metrics.[35] Unfortunately, the company developing the device went bankrupt, the intellectual property rights were purchased by Cochlear Corporation, but was not brought to the commercial market for implantation.[8]

## 3 | CURRENT DEVICES

Several companies have developed active middle ear implants, undergoing clinical trials and are currently available for commercial use (see Table 1 for review). The MEDL-EL Vibrant SoundBridge, the Ototronix MAXUM system, and the Envoy Esteem have received FDA approval and are widely used in the United States and Europe. Though the Cochlear Carina device underwent initial clinical trials in the United States, the generation of device use proved unreliable and it did not receive FDA approval. A newer, more reliable generation of the transducer was available in Europe and South America until May 2020, when Cochlear ceased distribution of the implant.

### 3.1 | The MED-EL vibrant soundbridge

The Vibrant SoundBridge (VSB), a semi-implantable device, was introduced into clinical practice by Geoffrey Ball working in the research laboratory of Richard Goode in 1994.[36,37] The device was manufactured and commercialized by Symphonix, Inc. (San Jose, CA, USA). The device was initially designed for coupling to the incus long process in patients with sensorineural hearing loss, with the first surgery performed in 1996.[38,39] The VSB was the first middle ear implant to be approved for use by the Food and Drug Administration (FDA) in the United States in the August of 2000.[38,40] Since its initial development, the device has been adapted for coupling on other middle ear structures, such as the round window, expanding the potential indications to include conductive and mixed hearing losses as well.

The VSB is composed of both an internal implant and a wearable external component. The implanted portion of the device, also known as a vibrating ossicular replacement prosthesis (VORP), is composed of a receiving coil, a magnet, a demodulator, a conductor link, and a floating mass transducer (FMT). The external component, or audio processor, includes a microphone, an audio processor, a battery, a transmitter coil, and a retention magnet. Sound is picked up by the microphone on the externally worn audio processor, held in place over the internal device via the retention magnet. The signal is transmitted across the skin via the coil. The FMT is comprised of two electromagnetic coils around a small magnet that are sealed in a titanium housing.[38,39,41] The FMT converts the electric signal to mechanical vibrations via electromagnetic induction, with displacements on the order of 0.1 to 0.001 μm.[38] The frequency response of the VSB ranges from 100 to 10 000 Hz with a coupling-dependent average gain of 30 to 55 dB.

Since its initial entry into the market, several modifications have been made to the device. As performance with middle ear implants is critically dependent on sufficient coupling to avoid energy loss, several different couplers have been produced specific to various middle ear structures in order to optimize FMT coupling. The internal magnet on the newest generation of the VORP is MRI-compatible up to 1.5 Tesla, and the new digital audio processor features adaptive directional microphones and several sound processing strategies.

**TABLE 1** Types of Implantable Hearing Aids

| Device | Company | Coupling | Transduction mechanism |
|---|---|---|---|
| Vibrant SoundBridge | Med-El | Incus long process or body, stapes head or footplate, round window, oval window, cochlea | Electromagnetic |
| Esteem | Envoy Medical Corporation | Incus (sensor)<br>Stapes head (driver) | Piezoelectric |
| MAXUM System | Ototronix LLC | Stapes head | Electromagnetic |
| Carina | Cochlear Corporation | Incus long process or body, stapes head or footplate, round window, oval window | Electromagnetic |

### 3.2 | The Ototronix MAXUM system

Development of the Ototronix MAXUM System, formerly the SOUNDTEC Direct Drive Hearing System, began with experimentation at the Hough Ear Institute in Oklahoma the 1980s,[8] and, in 2001, it ultimately became the second middle ear implant to obtain FDA approval in the United States.[42] The original SOUNDTEC device consisted of a magnetic implant, a behind-the-ear sound processor, and an earmold-coil assembly.[43] The updated MAXUM system also includes a surgically-implanted magnet, but the sound processor and electromagnetic coil have been combined into a single unit that is worn in the ear canal and known as the integrated processor and coil (IPC).[44] Sound is picked up by the microphone in the IPC, processed and amplified. The resulting electrical signal is passed through the magnetic coil in the IPC, creating an electromagnetic field that is radiated into the middle ear, oscillating the implanted magnet that transmits as mechanical signal to the inner ear.[8,43,44]

The procedure for implantation is one of the less invasive surgeries for placement of middle ear implants. Via a transcanal approach, the incudostapedial joint is fully visualized with curetting of the posterosuperior medial canal wall as necessary. The implant magnet, which is housed in a titanium cylinder and attached to an open wire-form ring, is gently coupled to the stapes by placing the open portion of the attachment coil around the incudostapedial joint and securing in place with a low-temperature heating device.[8,44] The previous generation of the implant required incudostapedial joint separation to allow placement of the retention ring over the stapes capitulum and around its neck[43]; however, this step has been simplified with the incorporation of the heat-sensitive memory-alloy nitinol clip.[44]

Prior to development of the newer generation MAXUM device, the SOUNDTEC Direct Drive system was voluntarily pulled from the market in 2004 in order to investigate the source of an audible rattle perceived by some implantees when the sound processor was not in use. This was believed to be related to movement of the implant magnet at its fixation point and has not been a reported issue with the MAXUM system.[8,45] One additional issue with this device relates to MRI compatibility and use in locations with strong electromagnetic fields. Since the implant itself is a magnet, linear and torsional forces on the implant from the MRI machine could potentially cause implant displacement or ossicular chain disruption, as well as heating of the magnet or demagnetization of the implant. While there have been reports of patients tolerating MRI up to 0.3 Tesla strength, for patients in whom MRI is necessary, positioning or use of fast spin echo sequence may be valuable, or the implant may need to be temporarily removed and reimplanted.[44]

### 3.3 | The Envoy Esteem

The Envoy Esteem is a nonrechargeable, battery-powered completely implanted hearing device, consisting of a sensor, an implanted sound processor, and a driver. The Envoy Medical Company was founded in 1995, with initial device development in Europe and United States FDA approval beginning in 2010.[46] It is currently approved only for sensorineural hearing loss, though some studies have evaluated device benefit in mixed hearing loss.[47]

The Esteem is composed of two piezoelectric transducers; one, coupled to the incus body, serves as a sensor by converting ossicular vibrations into electrical signal, and the second, coupled to the stapes, serves as a driver by transducing electrical signal to mechanical vibrations. The implanted sound processor receives the signal from the sensing lead and filters and amplifies the acoustic signal.[48-54]

The unique feature of this device is the utilization of the tympanic membrane as the "microphone" of the system, allowing the device to be completely implantable.[55] Unfortunately, this utilization of the intact middle ear system as a microphone pick up source necessitates a healthy eardrum and ossicular chain, limiting indications to patients with normal middle ear anatomy[53] (see Table 2). Other limitations of the procedure include the non-rechargeable battery, which must be replaced at regular intervals.[49,53,54] The company suggests battery life is between 4.5 and 9 years,[50] and with one study reporting an average time of 4.9 years before battery replacement is required.[56]

An additional concern regarding the Esteem device is related to the surgical procedure itself. In order to prevent feedback, the intact ossicular chain must be disarticulated, resulting in a new conductive hearing loss on top of baseline sensorineural dysfunction.[54] In the event of device failure or explanation for non-use, an additional reconstructive procedure would be required to re-establish baseline hearing function.

Since its initial release, modifications and updates have sought to improve upon the device profile to improve ease of surgical placement.[46] Additionally, modifications have been made to improve the frequency response and extend gain above 3 kHz.[54]

## 4 | OUTCOMES STUDIES AND LIMITATIONS

Several outcomes studies have been published evaluating the benefits of implantable hearing aids. While only a few provide direct comparison between performance with conventional hearing aids,[45,49,57] most of the investigations have demonstrated improvement in hearing performance over the unaided condition,[45,52,57] low complication rates,[49,52] and high subjective satisfaction scores.[22,24,25,54,58]

Single-institution reviews have been completed for each of the above-mentioned individual devices. For a summary of these studies, see Table 3. In analysis of 14 individuals implanted with the SoundBridge, high-frequency audibility and speech discrimination scores in quiet and in noise were significantly better when compared with performance in open-fit hearing aids.[57] Other studies of Soundbridge have shown similar benefit of implantable devices over conventional aids.[59,60] A similar study in six patients with severe high-frequency sensorineural hearing loss who were implanted with the MAXUM device demonstrated superior functional gain and word recognition scores in quiet compared to optimally fitted hearing aids.[45] Studies of the Esteem have shown both

**TABLE 2** FDA Premarket Approval (PMA) Criteria for Implantable Hearing Aids

| Device | Vibrant P/Vibrant D SoundBridge System | Esteem Totally Implantable Hearing System | SOUNDTEC Direct System (MAXUM System) |
|---|---|---|---|
| *Company* | Med-El | Envoy Medical Corporation | Ototronix LLC |
| *Approval Date* | 10/27/2000 | 03/17/2010 | 09/07/2001 |
| *Criteria* | - 18 years of age or older<br>- Moderate to severe SNHL<br>- Desire alternative to acoustic HA | - 18 years of age or older<br>- Stable bilateral SNHL<br>- Moderate to severe bilateral SNHL defined by PTA<br>- Unaided speech discrimination ≥40%<br>- Normally functioning Eustachian tube<br>- Normal middle ear anatomy<br>- Normal tympanic membrane<br>- Adequate space for implant determined by hi-res CT scan<br>- Minimum of 30 days of experience with appropriately fit hearing aids | - 18 years of age or older<br>- Moderate to severe SNHL<br>- Unaided AC threshold upper limits: 60 dB HL at 250 Hz, 70 dB HL at 500 Hz, 85 dB HL at 1 kHz, 100 dB HL at 2-6 kHz<br>- Desire alternative to acoustic HA |
| *Additional recommendations* | Prior to implantation, it is recommended patients have experience with appropriately fit hearing aids | | Prior to implantation, it is recommended patients have experience with appropriately fit hearing aids |

**TABLE 3** Review of Implantable Hearing Aid Outcomes

| Authors | Year | n (ears) | Devices Tested | Conventional Hearing Aid Comparison | Objective Tests | Subjective Benefit | Significance Reported |
|---|---|---|---|---|---|---|---|
| Matthews[43] | 2002 | 95 | SOUNDTEC | Yes | Favored IHA | Favored IHA | Yes |
| Chen et al[54] | 2004 | 5 | Esteem | Yes | Favored IHA | Favored IHA | No |
| Jenkins et al[22] | 2007 | 20 | Carina | Yes | Favored CHA | Favored IHA | Yes |
| Bruschini et al[20] | 2010 | 8 | Carina | No | Favored IHA | Favored IHA | Yes |
| Boeheim et al[57] | 2010 | 14 | SoundBridge | Yes | Favored IHA | Favored IHA | Yes |
| Gerard et al[52] | 2012 | 13 | Esteem | No | Favored IHA | Favored IHA | No |
| Kam et al[58] | 2012 | 6 | Carina | Yes | Equivocal | Favored IHA | Yes |
| Bruschini et al[24] | 2016 | 32 | Carina | No | Favored IHA | Favored IHA | Yes |
| Hunter et al[45] | 2016 | 6 | MAXUM | Yes | Favored IHA | N/A | Yes |
| Savaş et al[25] | 2016 | 9 | Carina | Yes | Equivocal | Favored IHA | Yes |
| Lee et al[60] | 2017 | 34 | SoundBridge | Yes | Favored IHA | Favored IHA | Yes |
| Barbara et al[50] | 2018 | 41 | Esteem | Yes | Favored IHA | N/A | Yes |
| Shohet et al[49] | 2018 | 172 | Esteem | Yes | Favored IHA | N/A | Yes |
| McRackan et al[66] | 2018 | 91 | MAXUM | Yes | Favored IHA | N/A | Yes |
| Spiegel et al[59] | 2020 | 45 | Soundbridge | Yes | Favored IHA | Favored IHA | No |
| Uhler et al[61] | 2016 | 50 | Carina | Yes | Equivocal | Favored IHA | Yes |

Abbreviations: CHA, conventional hearing aid; IHA, implantable hearing aid.

improvement in speech perception compared with unaided conditions[52] as well as increased benefit with speech understanding compared with best-fit conventional aids.[49,54] The largest review of patients fit with Esteem also confirmed surgical safety with minimal reported adverse events as well complete resolution of tinnitus for many patients after implantation.[49] Results for Carina have been mixed. Though improvement over unaided speech performance has been demonstrated,[20,22,24,25,55] several direct comparisons with conventional hearing aids have equivocal results,[25,58,61] with one study reporting slightly better performance with preoperative conventional hearing aids.[22] Additionally, several patients fit with earlier models have described problems with excessive feedback, resulting in device non-use and need for revision surgery in one case.[20] Despite some mixed results, patients typically report high satisfaction with the Carina in subjective performance metrics.[22,24,25,58]

A few attempts have been made to complete metanalyses of implantable hearing aid performance compared with both conventional hearing aid and unaided performance. Most independent investigations could not be directly compared because of a lack of standardization in performance outcome measures.[26,47,48] Though no statistical analyses could be completed in these larger reviews, all studies did demonstrate improvement in outcome performance when compared with unaided conditions and a subjective improvement in quality of life.[26,47,62]

Despite the consistent report of high patient satisfaction and subjective preference over conventional hearing aids in many cases, implantable hearing aids have not gained significant market penetrance. While some patients may prefer conventional aids over an implantable device requiring surgery and associated risks of anesthesia and manipulation of the middle ear, additional factors may contribute to lack of widespread adoption. Few insurance companies are willing to cover the cost of surgery for implantable hearing aids. In some cases, additional surgery or revision procedures may be necessary, which may discourage third-party payers from reimbursing the surgeries. Additionally, the lack of Current Procedure Terminology (CPT) codes to precisely describe the implantation procedures may give surgeons reason to hesitate as they may risk inadequate reimbursement.[49]

Cost-effectiveness of middle ear implants has been demonstrated in a handful of studies[63-65] with cost per quality-adjusted life year estimated in a range similar to that seen for cochlear implants and conventional hearing aids.[64] High cost-utility has been demonstrated for traditional candidates with pure sensorineural hearing loss,[63,65] as well as those with chronic otitis externa for whom consistent use of conventional hearing aids may prove challenging.[64] The potential for significant quality of life improvement,[63-65] coupled with relative low complication rates,[49,52,63,64] suggest that future investigation of the middle ear implant performance and continues device development and optimization provide an important alternate treatment option to conventional hearing aids.

## 5 | FUTURE DIRECTIONS

The companies that have developed implantable hearing aids continue to work towards device improvement. Both the SoundBridge and Carina have been adapted since their initial design for coupling to the ossicular chain or directly to the inner ear in several different ways, expanding the potential indications for surgery to include a variety of conductive pathologies. Further improvements in design are aimed at miniaturizing device components to allow use in more challenging otologic cases and work towards other fully implantable options.

Investigation of multiple prognostic factors, including age at hearing loss, age at implantation, sex, ear implanted, whether a hearing aid had been previously used, whether bilateral hearing aids had been used, or years of hearing aid use, has yet to identify any positive correlation with implanted device benefit.[49] Few studies have attempted to stratify patients to determine which criteria may be used to identify populations that are more likely to benefit from implants over conventional aids,[66] and future investigation may be beneficial not only in targeting patients most likely to benefit, but also potentially in pushing for third-party reimbursement for implantable devices and the surgeries requirement for placement.

The impetus for the development of implantable hearing aids was improving upon limitations of conventional hearing aids, including suboptimal acoustics related to distortion, feedback and high output levels, gain limitations, removal of canal occlusion for patients with chronic otitis, and lifestyle limitations due to the need for an externally worn device. While some of these goals have been addressed, particularly related to perceived subjective benefit, data regarding acoustic performance improvement is mixed and a clear objective performance benefit remains elusive. Additionally, the advantage of removal of canal occlusion and externally worn aids remains incompletely realized as none of the currently available devices are completely implantable and patients must still wear external processors. Future research of middle ear implants must address these concerns with continued innovation, as well as demonstrate reliable long-term performance outcomes. Though still relatively nascent in the field of auditory rehabilitation and hearing technology, middle ear implants have the potential to overcome many limitations of conventional hearing aids.

## CONFLICT OF INTEREST

No potential conflict of interest was reported by the authors.

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