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Advances in hearing preservation in cochlear implant surgery

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Abstract

Purpose: Advancements in cochlear implant (CI) surgical approaches and electrode designs have enabled preservation of residual acoustic hearing. Preservation of low-frequency hearing allows CI users to benefit from electroacoustic stimulation which improves performance in complex listening situations such as music appreciation and speech understanding in noise. Despite the relative high rates of success of hearing preservation, post-operative acoustic hearing outcomes remain unpredictable.

Recent findings: Thin, flexible, lateral wall arrays are preferred for hearing preservation. Both shortened and thin, lateral wall arrays have shown success with hearing preservation and the optimal implant choice is an issue of ongoing investigation. Electrocochleography can monitor cochlear function during and after insertion of the electrode array. The pathophysiology of hearing loss acutely after CI may differ from that involved in delayed hearing loss following CI. Emerging innovations may reduce cochlear trauma and improve hearing preservation.

Summary: Hearing preservation is possible using soft surgical techniques and electrode arrays designed to minimize cochlear trauma; however, a subset of patients suffer from partial to total loss of acoustic hearing months to years following surgery despite evidence of residual apical hair cell function. Early investigations in to robotic-assisted insertion and dexamethasone eluting implants show promise.

Keywords

Cochlear implant; hearing preservation; electroacoustic stimulation; residual hearing

Introduction:

Cochlear implants (CI) have revolutionized hearing care with their ability to restore open set speech perception for patients with severe to profound hearing loss. CIs bypass the natural mechano-transducer of the inner ear and provide electrical stimulation directly to auditory neurons. Traditionally reserved for patients with minimal natural acoustic hearing, advancements in CI design and surgical techniques have made preservation of residual hearing after surgery possible (1). This has expanded CI candidacy to include individuals

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with preoperative functional residual low frequency hearing (2). Patients with preserved hearing following CI can benefit from electroacoustic stimulation (EAS) which also confers improvements in speech understanding, particularly in background noise, music appreciation and sound localization (3–8). Hearing preservation is therefore a desirable outcome and is the focus of significant research and development over the past two decades. Despite these significant advancements, hearing outcomes following CI are highly variable and the goal of achieving reliable hearing preservation after CI remains elusive.

Damage to residual hearing after CI appears to occur in a biphasic manner. The first phase occurs in the immediate postoperative period and is thought to be linked to surgical and insertional trauma. A second delayed phase has been noted to occur months to years post-operatively in a subset of patients with occasional progression to total loss of residual acoustic function (9, 10). The pathophysiologic mechanism(s) of this latter phase of delayed loss is under active investigation and likely involves an inflammatory response and fibrosis (9–12). To date, most efforts directed towards improving hearing preservation have focused on minimizing cochlear trauma and inflammation. Alterations in surgical technique, development of new electrode designs, active monitoring of cochlear function, and anti-inflammatory drug delivery have all demonstrated varying degrees of success in improving hearing preservation outcomes.

In this article, we will attempt to review the most relevant literature pertaining to hearing preservation after CI surgery. We will provide a general overview on the major findings in the field over the past two decades and highlight recent findings of interest. We will then conclude by discussing promising future avenues for hearing preservation research and technological development.

Surgical considerations

Lehnhardt et al. and Gantz et. al pioneered the use of “soft” techniques for CI surgery in the 1990s (13). The proposed approach emphasized drilling a small cochleostomy anteroinferior to the round window without disrupting the endosteum, irrigating the surgical field prior to opening the endosteum, slow controlled insertion of the CI, and achieving an adequate seal after insertion. The principles of soft surgery were developed in an effort to mitigate cochlear trauma and have since become widely accepted as the standard of care in CI surgery. Evidence from animal and human temporal bone studies supports the use of soft surgical techniques by highlighting the negative impacts of traumatic insertion on hearing preservation and cochlear structural integrity (12).

Electrode Array Design

CIs are generally classified as either lateral wall or peri-modiolar electrodes (14). This classification is based on where the respective electrodes are intended to sit in the scala tympani after insertion. Peri-modiolar arrays are rigid and pre-curved and tend to hug the modiolus and stay in close proximity to the neural element. This position is thought to limit electrode channel cross-talk and provide higher specificity of electric stimulation (14). Lateral wall arrays designed for hearing preservation purposes are straight, flexible and tend to float in the scala tympani closer to the lateral wall of the cochlea. Straight lateral wall arrays cause less insertion trauma and are preferred for hearing preservation applications (15, 16). In this section, we will discuss two types of straight CI electrodes that have been developed for hearing preservation and EAS purposes: 1) shortened electrode arrays and 2) thin straight electrode arrays.

Shortened electrode arrays

Alterations in electrode array design with the goal of preserving hearing first began in the late 1990s. Gantz and colleagues proposed a shortened electrode array that would not be advanced beyond the basal turn of the cochlea with the goal of preserving low-frequency acoustic hearing for use in combined EAS (1). Since that time, several clinical trials with different iterations of shortened electrode arrays have been completed. Shorter electrode arrays are typically reserved for individuals with low frequency hearing of 60 dB or better and high frequency hearing of worse than 80dB. Most recently, the S12 hybrid implant (10-mm, 10 electrode contacts) was evaluated in a multicenter clinical trial (17)*. 85% of subjects enrolled in this trial maintained functional low-frequency hearing at 12 months, defined as pure tone average (PTA) at 125, 250 and 500 Hz of ≤ 85dB. More importantly, CNC word scores and AzBio sentence recognition scores significantly improved for most patients in the trial when compared to scores with bilateral hearing aid use preoperatively. Patients implanted with the S12 had similar hearing preservation outcomes when compared to those implanted with the S8 (10mm, 6 electrode contacts) which showed an ~83% hearing preservation rate (18) but fared better than individuals implanted with the slightly longer L24 (74% hearing preservation) electrode (16mm, 22 electrode contacts) (19). These studies support the notion that electrode length and depth of insertion could be an important factor in maintaining low frequency hearing. Furthermore, long term outcomes showed that a significant portion of L24, S8 and S12 users demonstrated functional low frequency hearing up to 15 years after initial implantation (20).

Although many studies demonstrate fairly high hearing preservation rates overall, a subset of these patients go on to develop progressive hearing loss in the months following surgery, resulting in loss of the acoustic component and, perhaps, suboptimal cochlear coverage with the electric only component (9, 19). Interestingly, a postmortem histopathologic temporal bone case study in a patient with progressive hearing loss after CI revealed no significant change in hair cell or spiral ganglion neuron counts suggesting alternative mechanisms of hearing loss (11). Altered intracochlear mechanics due to fibrosis, endocochlear potential dysregulation and deficits in synaptic transmission have all been proposed as potential mechanisms of delayed hearing loss in these patients (21, 22). A recent clinical electrocochleography study by Tejani et al (10)* points towards synaptic pathology as a potential contributing factor. This study included seven L24 hybrid implant recipients who had complete loss of acoustic hearing (Thresholds > 115 dB at frequencies 125–8000 Hz) several months post-operatively. These patients had preserved cochlear microphonic responses to low frequency cochlear stimulation despite loss of auditory nerve neurophonic responses. These findings suggest that despite total loss of audiometric and auditory nerve responses, functional apical hair cells were present but were unable to transmit signals to the auditory nerve. This disconnect between hair cells and auditory nerve fibers suggests a synaptic pathology(23).

Thin straight electrode arrays

Thin straight electrode arrays have emerged as a potential way of compromising between the potential need for greater electrode coverage and hearing preservation. These arrays are characterized by an intermediate length (20–26 mm) and very thin diameter that tapers off towards the apex (0.3–0.6mm). Van Abel et al. published a retrospective review of 52 patients who received thin straight electrodes and found that functional low frequency hearing (PTA at 125, 250 and 500 Hz of ≤ 85dB) was achieved in 47% of participants at 6 months (24). Moran et al. performed a similar study on 139 patients and found that of those with functional preoperative low-frequency hearing (<70dB at 250 and 500 Hz) 39.5% retained it (25). More recently, Lenarz et al published a retrospective series using the SlimJ electrode and showed promising short term hearing preservation results (26). In this study of 20 subjects, 85% experienced preservation of low-frequency hearing within 30 dB of their pre-operative thresholds.

Overall, these patients appear to have decreased rates of hearing preservation when compared to those with shorter arrays. It is difficult to draw strong conclusions regarding hearing preservation outcomes from these studies as many are retrospective, have variable definitions for hearing preservation and are performed by surgeons with varying training backgrounds and institutional practices. Ultimately, it appears that hearing preservation with lateral wall arrays is an achievable goal regardless of electrode length. Further prospective randomized studies are needed. Surgeon preference, patient clinical characteristics and institutional practice dictate electrode choice in the current clinical landscape.

Corticosteroid use in CI surgery

The use of corticosteroids perioperatively has been touted as a potential way to reduce the cochlear inflammatory response to surgery and improve hearing preservation. Multiple studies have assessed the use of systemic, intratympanic and topical round window corticosteroid use on hearing preservation and produced highly variable results (27–29). Recently, O'Leary et al published results from a randomized placebo-controlled trial looking at the effects of systemic methylprednisolone administration on hearing preservation outcomes and found no difference between the experimental and placebo groups (30). A limitation of this study is that all patients, regardless of randomization assignment, received a single dose of dexamethasone perioperatively as part of the institution's practice to reduce postoperative nausea and vomiting. Therefore, despite the well-conceived design of the study, it is difficult to discern the individual impact of systemic corticosteroids on hearing preservation.

Corticosteroid eluting CIs have also emerged as a potential method of reducing inflammatory responses after surgery. Corticosteroid elution from CIs has been shown to decrease inflammation, fibrosis and lower electrode impedances in a guinea pig model of CI (31). In a recent study on normal hearing non-human primates, dexamethasone eluting implants lowered auditory brainstem response threshold shifts and reduced electrode impedances when compared to conventional CIs up to 6 months post-implantation (32). Histologic analyses in this study also showed reductions in intracochlear fibrosis and new bone formation in the experimental group. Briggs et al. reported results of a clinical study that examined electrode impedance measurements using a novel dexamethasone eluting peri-modiolar CI compared to a commercially available peri-modiolar CI (33)*. They found that in the experimental group, electrode impedances were significantly lower and more stable up to 24 months post-operatively. Stable low impedances are indicative of a reduction in the inflammatory response to CI. These results suggest that corticosteroid eluting implants may successfully result in long-term suppression of the local inflammatory response which may translate to improvements in hearing preservation.

Robotic-assisted insertion

Speed and steadiness of insertion is widely accepted as an important factor related to reducing intraoperative trauma and may improve post-operative hearing outcomes. Speed/steadiness of insertion can vary widely based on surgical expertise, patient anatomy and electrode type. Robotic-assisted CI placement has emerged as a tool that holds the promise of standardizing insertion speed and trajectory during CI surgery. Kaufmann et al. compared robotic vs manual insertion using a novel robotic platform on human cadaveric temporal bones and found that robotic assistance decreased insertion forces and variability of force between insertions (34). X-ray microscopy of implanted specimens also showed reduced cochlear trauma in robotic-assisted insertion with reduction in inter-scalar translocation and disruption of the osseus spiral lamina. Barriat et al. also performed a pilot study in five patients using robotic assisted insertion and concluded that it was safe and feasible to perform this in the clinical setting (7). This is a very exciting area which promises unparalleled control over CI insertion mechanics and more research is needed to understand its clinical impact on hearing preservation.

Future directions:

To this point, we have discussed the most prominent recent technological advancements in the field of hearing preservation. In this section, we will attempt to forecast the next wave of technologies that may shape the future of this field. Chiefly among these in our view are image-guided CI insertion, electrode array coatings and anti-inflammatory therapeutics.

Image and electrophysiologically-guided CI surgery

The trajectory/depth of insertion and final scalar location of CI array is difficult to control and can vary widely depending on patient anatomy and surgeon experience. Image guided CI surgery using CT has been studied recently as a way of more carefully planning the vector and depth of insertion. Image guidance allows for the use of patient specific anatomic parameters to make decisions regarding the ideal insertion vector and track depth of insertion in real time (35). Labadie et al. developed a system for image-guided CI surgery whereby preoperative CT images are registered to fiducial surface markers and the CI is inserted in a minimally invasive manner through a mastoidotomy using a manual roller wheel (36). An integrated system that combines image guidance and robotic assisted insertion can provide unprecedented control over insertion dynamics and is the logical next step for this technology. Likewise, real-time integration of precisely controlled electrode insertion dynamics enabled by robotics with active electrophysiological electrocochleography monitoring will likely lead to reduced trauma and improved outcomes.

Electrode array coatings

CI design modifications for hearing preservation have largely focused on the thickness, length and configuration (pre-curved vs. straight) of electrode arrays. CI electrodes are embedded in a silicone polymer casing (37) which is susceptible to biofilm formation and universally elicits a foreign body inflammatory/fibrotic response (38). This foreign body response results from cell interactions with the surface properties of silicone polymers (39). The use of hydrophilic “hydrogel” coatings to improve the mechanical and anti-fouling properties of silicone-based devices has garnered attention from biomaterials researchers. For instance, our group is studying zwitterionic hydrogel coatings as potential CI coatings for these purposes (40). Zwitterionic hydrogels show promising results and decrease protein, cell, and bacterial adhesion in vitro but have not yet been studied in in vivo CI models (41, 42) Importantly, these coatings significantly decreased the force of CI electrode array insertion in cadaveric human cochleae, suggesting they may also help mitigate acute insertion trauma (43). Other protein repellent coatings such as hyaluronic acid and sPEG hydrogels have also been developed and tested in a limited capacity for CI (44, 45). Further in vivo and clinical work is needed to demonstrate the utility and durability of hydrogel coatings.

Anti-inflammatory therapeutics

As discussed previously, local and systemic corticosteroid use has been extensively studied in CI surgery with mixed results. Emerging evidence from animal studies suggest that other anti-inflammatory medications may also prove to be beneficial for hearing preservation. Evidence from guinea pig studies has shown that systemic administration of etanercept, a TNF-α inhibitor, and lipoic acid is associated with less pronounced hearing threshold shifts after CI placement when compared to controls (46, 47). Other pharmacologic agents such as antioxidants, thrombolytics and apoptosis inhibitors have also showed some benefit in hearing preservation in animal models (48–50). To our knowledge, none of these pharmacologic agents have been tested clinically. Ultimately, this is an area that we believe is likely to be fruitful as pharmacologic targets will continue to emerge with our increased understanding of cochlear trauma, inflammation, healing and the foreign body response.

Conclusion:

Hearing preservation during CI surgery is an attainable goal and should be the intent in all patients who have functional preoperative low frequency hearing. Outcomes for hearing preservation remain highly variable regardless of implant design or length and continued clinical, electrophysiological and histological studies are invaluable. Further developments in electrode design such as the incorporation of robotics assistance, image guidance, novel electrode coatings and anti-inflammatory therapeutics are exciting prospects.

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Key points:

- Preservation of residual acoustic hearing using soft surgical techniques and appropriate electrode arrays provides many benefits to patients receiving cochlear implants.
- Electrocochleography can be used to monitor cochlear function during and after cochlear implantation.
- Preclinical and early clinical studies on image guidance, robotic assistance and corticosteroid eluting implants show tremendous promise.