# Critical Review:
# Is ipsilaterally combined electro-acoustic stimulation an effective alternative to hearing aids or cochlear implants alone when treating individuals with severe to profound high-frequency hearing loss?

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High-frequency sensorineural hearing impairments are among the most common configurations observed in the adult population. These impairments are more than often treated with acoustic amplification or cochlear implantation, both of which have benefits and pitfalls that need to be considered. This critical review will examine the effectiveness of ipsilaterally combined acoustic and electric hearing in an attempt to exploit the perceptual merits of each. A literature search was conducted and the resulting articles were critically appraised on the basis of their methodology, validity and level of evidence. Overall, the data reviewed suggest significant improvements on related measures of speech perception when electro-acoustic stimulation is compared to both acoustic and electric stimulation in isolation. The benefits and limitations of each study are discussed, and future research suggestions are offered as they relate to the clinical implications of this treatment.

## *Introduction*

Most adults that present with hearing impairments exhibit a configuration in which the high-frequency thresholds are significantly elevated compared to the low-frequency thresholds. The impact of a high-frequency sensorineural hearing loss on speech perception will vary depending on the severity of the loss. An individual with a severe to profound high-frequency hearing loss will have great difficulty perceiving speech cues associated with manner and place of articulation. The substantial loss of inner hair cells in the high-frequency region of the cochlea prevents the transmission of temporal and spectral cues to the brain (Turner, Reiss & Gantz, 2008). This will inhibit the neural coding of these speech cues that define various English phonemes.

Traditionally, individuals with high-frequency sensorineural hearing losses are treated with amplification in the form of hearing aids (HAs) or with cochlear implants (CIs). With HAs, appropriate low-frequency amplification is often attainable. In cases of severe to profound high-frequency hearing losses, however, appropriate high-frequency amplification is frequently not possible due to device limitations. Further, the provision of high levels of acoustic stimulation needed to overcome such losses has been shown to result in no improvement in speech perception, given the inner hair cell damage associated with losses of this degree (Turner, Gantz & Reiss, 2008; Turner, 2006).

Alternatively, a CI may be recommended in an attempt to restore high-frequency audibility to the user. This results from the CIs ability to overcome the physiological limitations of the cochlea (i.e., to by-pass the damaged inner hair cells) and stimulate the auditory nerve directly. Unfortunately, the CI is limited in its ability to provide adequate frequency resolution when compared to a HA. Turner, Reiss and Gantz (2008) have demonstrated that the degree of frequency resolution attainable with a CI is significantly reduced when compared to the resolution provided by natural low-frequency acoustic hearing in the presence of high-frequency hearing loss.

Recent emphasis has been placed on the potential perceptual benefits that can occur when low-frequency acoustic hearing and high-frequency electric hearing are combined in the same ear. This method attempts to exploit the advantages of both acoustic and electric hearing in that the low-frequency acoustic hearing will provide adequate resolution of frequency and waveform fine structure to supplement high frequency audibility provided through electric listening.

## *Objectives*

The primary objective of this paper is to critically analyze the existing body of literature evaluating the effectiveness of ipsilaterally combined acoustic and electric hearing. The discussion will focus on treating the speech perception deficits that individuals with severe to profound high-frequency hearing losses experience.

## *Methods*

*Search Strategy*

Two primary Internet based databases were used: Medline Ovid® and Scopus®. For both databases, an

independent search was conducted for the terms "cochlear implant" and "hybrid". Using the AND Boolean operator, the independent searches were combined. The search was limited to articles written in English. Additional literature was obtained by reviewing the works cited by the authors of a given publication.

*Selection Criteria*

The studies that were selected for inclusion in this critical review were required to investigate any method that combined electric and acoustic listening as a treatment for adults with severe to profound high frequency hearing loss. There were no limits applied to the outcome assessments used to measure the efficacy of the treatments.

*Data Collection*

The literature review, based on studies that met the aforementioned selection criteria, resulted in three types of articles: Within-groups design (repeated measures) [3], a non-randomized clinical trial (mixed design) [1] and a single-group (post-test only) design [1]. The articles to be reviewed represent the work of three independent research groups.

## *Results*

A study conducted by Kiefer et al. (2005) used a within-groups (repeated measures) research design to assess the efficacy of combining an in-the ear hearing aid and a long-electrode CI with a shallow insertion depth. Pre-operative speech recognition measures (e.g., Frieburg test for monosyllabic words, HSM sentences) in quiet and in noise were measured in all thirteen participants who wore bilateral HAs. The same speech recognition measures were taken post-operatively across a number of conditions: CI alone (modified depth), ipsilateral HA alone, ipsilaterally combined CI + HA. The results of the study showed significant improvements in sentence recognition in quiet and in noise in the combined condition compared to the pre-operative condition after one year of use. However, there were no significant improvements in performance on the monosyllabic word test in the combined condition when compared to the CI alone condition.

Given the invasive nature of the experimental manipulations, the authors effectively controlled for such variables as age, age at implantation, duration of hearing impairment and CI insertion depth. There was considerable variability across participants in post-operative pure-tone thresholds, especially in the low frequencies. Further, low-frequency pure-tone thresholds worsened after the surgical intervention. Specifically, mean post-operative thresholds increased by an average of 14 dB in the frequencies from 125 to 1000 KHz. For some individuals, performance might have been limited because they no longer had the ability to derive benefit from a HA due to poor low-frequency audibility.

The details of the participant eligibility criteria are clearly outlined by Kiefer et al. (2005). The methodology and outcome measure parameters were presented, including the protocol used to fit patients with HAs and CIs. This description would allow others to easily replicate this study. Appropriate baseline measures were taken and the design of the study allowed each participant to act as their own control permitting reasonable certainty and causal inferences when analyzing treatment effects. The authors' choice to report the data at a time interval of one-year was valid given that during the first few years of use, electric pitch perception often shifts in frequency and early pitch sensations have been correlated with speech reception performance (Reiss, Turner, Erenberg & Gantz, 2007).

Due to the small number of participants, the data were appropriately reported using group mean percentages, and significant differences were quantified using t-tests for repeated measures. The group data should be interpreted cautiously given the limited power associated with t-tests and AB experimental designs that fail to exhibit repeated copresence. Overall, the level of evidence provided by this study is moderate due to the carefully controlled experimental manipulations, data analyses and measurement of functional benefit using valid outcome assessments.

Gantz, Hansen, Turner, Oleson, Reiss and Parkinson (2009) also used a within-groups design to evaluate the efficacy of Cochlear Corporation's Nucleus 10-mm Hybrid implant in treating severe to profound high-frequency sensorineural hearing loss. It is important to note that this specific implant is a standalone hybrid device composed of a HA and short-electrode CI that only stimulates the basal portion of the cochlea.

A total of 61 adult patients with useful low-frequency acoustic hearing and severe to profound high-frequency sensorineural hearing loss were implanted with the hybrid device. Pre-operative measures of speech discrimination in quiet (CNC monosyllabic word test) and in noise (BKB-SPIN) were taken while using bilateral HAs. The same measures were taken post-operatively with the hybrid implant after 3, 6, 9 and 12 months of use. The results revealed that 74% and 48% of individuals showed improvements on one or both discrimination measures, respectively. A multiple regression analysis was conducted that yielded a set of predictor variables. An appropriate model to fit these variables was selected using the AIC method. The model indicated that pre-operative CNC scores and

duration of deafness collectively accounted for 29% of the variance in the data.

The authors stated the candidacy criteria with explicit detail, which is necessary given that the treatment is not suitable for all hearing loss configurations. A description of the programming and fitting protocol used when fitting the HAs and Hybrid CIs was provided. This process ensured that there was consistency in the way these devices were optimized for each individual, thus removing any potential pre- and post-treatment confounds. The methods were described in sufficient detail and could reasonably be replicated if required.

The chosen outcome measures are known to be reliable and are commonly used in audiological practice when quantifying speech discrimination performance. The CNC word test is valid and appropriate in this context as the lists were constructed so that words have a minimum frequency of occurrence in the English language (Peterson & Lehiste, 1962). By reducing the range of frequencies over which the words of each list occur in the English language, the items are made more discriminating for acoustic factors (Peterson & Lehiste, 1962). Also, the large number of lists negated the impact of practice effects when administering the test in both the baseline and treatment conditions. The authors gave no indication whether the lists associated with the speech materials were counterbalanced or randomized across participants, which may be problematic if a replication study is undertaken.

Gantz, Hansen, Turner, Oleson, Reiss and Parkinson (2009) presented only group mean percentage scores. Given the large sample size, a two-factor repeated measures analysis of variance (ANOVA) may have been a more powerful statistical test to demonstrate significant change. However, the authors graphically presented data for each individual participant displaying whether their performance in the hybrid condition was significantly improved using the criteria associated with the specific speech test. Although no direct comparisons can be made to other studies, the data analyses presented can be considered appropriate, as this is a controlled clinical trial. Overall, a large sample size and a two-variable baseline and treatment measure provide a moderately high level of evidence.

Another group of authors, Buchner, Schussler, Battmer, Stover and Lesinski-Schiedat (2009), used a single-group (post-test only) design to evaluate Cochlear's Nucleus Hybrid implant. A total of 22 participants who were all previous HA users were implanted with the hybrid device. Speech reception thresholds were determined 6 months post-operatively using the Oldenburger Sentence test in 3 conditions: CI alone, ipsilateral HA alone, Hybrid (ipsilateral CI + HA). A subset of the participants (n=17) were tested under the same 3 conditions using the HSM sentence test with a fixed signal-to-noise ratio of 10 dB. The results suggest that for both measurements there is a highly significant performance increase in the hybrid condition compared to both the CI and HA alone conditions.

The study's subject eligibility and inclusion criteria were omitted from the article. However, subject demographics such as age, duration of hearing loss, age at onset of HA use and duration of HA use were reported for each participant. Although the experimental methodology is rather straightforward, it may be difficult to replicate this study without knowing the criteria the authors used as a basis for inclusion.

Buchner, Schussler, Battmer, Stover and Lesinski-Schiedat (2009) did not complete any baseline measurements, and it is uncertain whether any treatment effect represents a significant change from pre-treatment performance. The statistical tests were appropriate as the authors used a non-parametric Wilcoxon test, which may be a more powerful statistic given that the small sample size may not be normally distributed. However, the authors do not state if this was actually the case. Post-hoc statistics were computed with Bonferonni corrections for multiple comparisons, which is beneficial as it will reduce the probability of a type I statistical error.

It is also evident that the authors analyzed the HSM sentence in noise data for only a portion of their participants. The authors do not clarify their reasoning for doing so and do not comment as to whether the specific choice of participants was randomized. Although the results of this analysis were statistically significant, an intention-to-treat analysis may be more appropriate to compensate for the participants that were treated but not included in the analysis.

The lack of a baseline measure or matched control group makes it difficult to demonstrate any type of treatment effect. The statistics used were appropriate; however, the sample size was inconsistent across analyses and no clear rationale for this was provided. The findings of this study should be interpreted with caution and inferences about causality should be limited. Given these limitations the level of evidence provided by this study is considered low.

Turner, Gantz, Vidal, Behrens and Henry (2004) conducted a two-part study evaluating speech recognition in noise performance across individuals with traditional long electrode CIs and hybrid CIs. The first experiment was a within-groups design. Fifteen adults with normal hearing were asked to identify a spondee in a background of competing talkers and filtered white noise while their contralateral ear was

occluded. The spondee was presented in three conditions: unprocessed, processed to simulate a 16-channel CI and processed to simulate a Hybrid CI. In comparison to performance for the unprocessed spondee, the traditional CI and hybrid CI simulations resulted in an SNR disadvantage of 13.5 dB and 8.6 dB, respectively. These results were significant as confirmed by a 2-way ANOVA. The second experiment was a non-randomized clinical trial (mixed) design. The same procedure and unprocessed stimuli from experiment 1 were used with 20 adults implanted with a long electrode CI and 3 adults with Hybrid implants. A mixed-model ANOVA with follow-up t-tests indicated that the Hybrid implant users significantly outperformed the traditional users only in a background of competing talkers. Further, when the Hybrid and traditional CI participants were matched to have comparable speech recognition scores in quiet, the same statistical outcome was observed.

For both experiments, the participant eligibility criteria were clearly stated, including pertinent information related to hearing sensitivity. The nature of the speech recognition and competing background materials were clearly described, which included details related to filtering characteristics and presentation parameters (e.g., intensity, duration). Further, the adaptive procedure used to assess outcome was outlined in sufficient detail. The amount and detail of procedural information given by the authors would permit an accurate replication of this study.

A baseline was established for participants in the first experiment, where each individual acted as their own control. No baseline information was provided for individuals participating in experiment 2; however, an attempt was made by the authors to match the two groups of implant users. The outcome measures used were appropriate to assess whether the treatment had any impact on speech recognition in the presence of noise.

The authors controlled for any unwanted order effects by randomizing the conditions of experiment 1 across subjects. The statistics used were appropriate, including the necessary *post-hoc* analyses to determine the underlying factors responsible for any significant main effects or interactions. It should be noted that the two groups submitted to the ANOVA in experiment 2 were non-uniform in number, which may have reduced the power of the test, especially since the Hybrid group consisted of only 3 participants. Turner, Gantz, Vidal, Behrens and Henry (2004) were adept in identifying any extraneous variables that could account for the results and re-analyzed their data accordingly.

This study can be considered to provide a high level of evidence for the use of Hybrid implants for several reasons. The study was conducted using a strong experimental and methodological basis. The statistics and *post-hoc* analyses used were appropriate; however, a replication using a larger sample size may be warranted. Also, the results of the two experiments corroborate each other lending evidence to the fact that there is an explicit treatment effect.

### *Discussion*

A number of observations can be made after critically reviewing the studies discussed above. The provision of ipsilaterally combined acoustic and electric stimulation did not reduce the speech recognition/discrimination abilities of any of the participants involved. It was evident that simultaneous electro-acoustic stimulation resulted in significantly improved performance on a variety of speech measures when compared to traditional long electrode CIs or HAs. However, this improvement was not universal and was often dependent on the specific stimuli used. For instance, more improvement was observed for materials that used sentences rather than isolated monosyllabic or spondaic words. Interestingly, combined electro-acoustic stimulation lead to consistent improvements across studies when the stimuli were presented in a background of competition.

A survey of the evidence clearly indicates that there is some benefit when acoustic and electric hearing are combined in the same ear. It is important to recognize that these results need to be considered in light of the advantages and disadvantages of each of the studies reviewed. Further, there are a considerable number of factors that make comparisons across studies unreliable.

The studies were non-uniform in the experimental design they employed leading to differences in the confidence with which the researchers make causal inferences. Participant factors such as variability in duration of hearing loss or duration of HA use also need to be considered. Research has demonstrated that there are cortical and cognitive changes associated with prolonged deafness and duration of HA use, which may have a significant impact on treatment outcomes. Methodological inconsistencies such as the actual device and outcome measures used are also important to consider. In the articles reviewed, electro-acoustic stimulation was provided with either a Hybrid (short electrode) CI or a traditional (long electrode) CI with a shallow insertion depth. These two methods differ in that the hybrid CI has a constant insertion depth of approximately 10 mm, whereas the study that employed the traditional CI had a range of shallow insertion depths in excess of 10 mm. It is uncertain what the optimal insertion depth is and whether one method is more advantageous than the other. Also, each study used a different speech recognition/discrimination task, which differed in the

type of stimuli, the nature of the competing background and how performance was quantified. Finally, the status of the contralateral ear when measuring outcome varied across studies. Specifically, some studies measured outcome with the contralateral ear occluded whereas others provided a HA for that ear. In this situation it is difficult to determine the impact of ipsilateral electro-acoustic stimulation on performance when audibility is established in the contralateral ear. Only after these aforementioned concerns are addressed will it be possible to make comparisons across studies permitting a reliable determination of the efficacy of ipsilaterally combined electro-acoustic stimulation.

### *Clinical Implications*

The data presented would seem to suggest that ipsilateral electro-acoustic stimulation is a viable alternative to traditional HAs or CIs alone when treating adults with severe to profound high-frequency sensorineural hearing loss. However, much work needs to be done before this treatment is clinically implemented and approved for use other than for research purposes. Prior to clinical implementation additional research in many areas needs to be undertaken, and should be done so by other institutions and networks of researchers. Most of the research to date has been completed by a single group of authors (Gantz et al.).

Evidently this is not an appropriate treatment for anyone with a hearing impairment. The specific candidacy criteria needs to be outlined to ensure that audiologists and otolaryngologists have the necessary information to make appropriate referrals and ensure that their patients will benefit from electro-acoustic stimulation. Further, the associated surgical risks, which may result in further decreases in hearing sensitivity, need to be weighed against advances in digital signal processing such as HAs with frequency lowering capabilities. More information related to all of these factors is warranted and will assist in making appropriate clinical decisions when this treatment becomes available to hearing health care practitioners.

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