How to **Counsel** Hearing Aid Users About Their Prospective Candidacy for a **Cochlear Implant**

By Terry Zwolan, Ph.D.

Multichannel cochlear implants (CIs) have progressed significantly since they first received FDA approval for adults in 1984 and for children in 1990. This includes enhancements in design of the surgically implanted electrode arrays, improvements in surgical tools and techniques used to implant the electrode array, advances in sound processing strategies used to convey important speech information, and improvements in the function, usability, and cosmetic appeal of the externally worn sound processor. These enhancements have led to improved outcomes: Cochlear implants provide most adult recipients with significantly improved speech recognition skills when compared to preoperative scores obtained with hearing aids (e.g. Sladen et al., 2017; Runge et al., 2016). Additional benefits of CIs include improvements in self-reported quality of life (Crowson et al., 2017; Cohen et al., 2004) and improvements in socialization, self-esteem, communication, and relations to friends and family (Orabi et al., 2005).

Despite these demonstrated benefits, CI utilization remains low for both adults and children in the United States. Sorkin and Buchman (2016) recently reported that pediatric utilization ranged from a low of 50% in the United States, compared to a high of 97% in Australia, and blamed the low incidence rate in the US on lack of an appropriate referral system. The utilization rate reported for adults is low everywhere – it is estimated that only 10% of adults who qualify for a CI receive one. Sorkin and Buchman feel the lack of adult utilization is due to the absence of routine hearing screenings for adults. They additionally

cite that many primary care physicians and audiologists are unfamiliar with current CI candidacy criteria and outcomes and, therefore, fail to make appropriate referrals.

Some patients are hesitant to proceed with a CI evaluation, even when they experience grave difficulty with their hearing. There are many reasons for such hesitancy, including a fear of surgery, lack of understanding of what the evaluation process will entail, lack of understanding of insurance coverage of CIs, and inappropriate understanding of how the device works and the expected outcomes. In this article, we provide suggestions of when patients should be referred for a CI evaluation, and we also provide recommendations regarding how to present such a recommendation to patients, in order to facilitate their attendance at a CI evaluation.

Referring **Patients** for a **CI Evaluation**

When they were first introduced, CIs were only considered for patients with bilateral profound sensorineural hearing loss who scored 0% on open-set tests of sentence recognition, making it easy for clinicians to identify and refer potential candidates for a CI. These patients were often highly motivated to consider a CI as it was the only option available for them to obtain access to hearing.

Over the years, FDA-approved indications for CIs have expanded as the benefits of this technology have become proven across the age range. Such indications typically include statements regarding speech recognition with appropriate hearing aids as well as statements regarding the audiometric configurations that typical candidates should demonstrate. FDA-approved indications can be confusing, however, as they vary depending on the device manufacturer and the make and model of the electrode array. For example, the most lenient FDA-approved criteria are for hybrid/EAS arrays as they are more likely to preserve hearing than more traditional electrode arrays. Audiometric indications for the Nucleus® Hybrid L24 device state that the typical preoperative hearing of candidates for this device range from normal-to-moderate hearing loss in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz), with severe-to-profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz greater than or equal to 60 dB HL) in the contralateral ear (Nucleus® Hybrid L24 cochlear implant professional package insert, 2014). Conversely, subjects who qualify for more traditional cochlear implant systems, such as the Nucleus® CI512 and the Nucleus® CI532, typically demonstrate a bilateral moderate to profound sensorineural hearing loss. Audiometric configurations of CI candidates for the devices mentioned above are provided in Figure 1 on page 20.

Food and Drug Administration (FDA) indications for currently available devices also vary in regard to speech recognition requirements. Again, the most lenient indications are for the Nucleus Hybrid, which state that candidates' preoperative CNC word recognition score should fall between 10% and 60% in the ear to be implanted and be less than or equal to 80% correct in the preoperative contralateral aided condition (Package insert, Nucleus Hybrid L24, 2014). This was one of the first FDA-approved indications to base candidacy on a word recognition score; previously approved indications for CIs have always utilized a sentence recognition score. This expanded candidacy can be contrasted with more traditional speech recognition requirements, such as those published for the Nucleus CI512 (Nucleus® CI512 cochlear implant professional package insert, 2016) which state that candidates should demonstrate scores less than or equal to 50% correct on recorded sentences in the ear to be implanted and less than or equal to 60% correct on sentences in the best aided condition. The change to utilization of word scores for Nucleus Hybrid indications should be applauded as non-CI audiologists are more likely to administer word recognition tests than sentence recognition tests, making it easier for professionals to recognize patients that should be referred for a CI evaluation.

Theoretically, anyone whose audiogram falls within the indications listed listed in Figure 1 on page 19 could be considered for a CI evaluation. However, not all patients whose hearing falls in this range will meet either the FDA indications or their insurer's candidacy requirements regarding speech recognition. Some patients whose audiograms fall within the shaded audiometric indication area are best suited to receive a hyrbrid/EAS device while others are best suited to receive a traditional CI. Additionally, some who meet these audiometric criteria may not meet speech recognition indications, or they may meet indications but choose to continue using hearing aids.

It should also be noted that many clinics across the country are actively participating in clinical trials that enable patients to receive a CI even if they do not meet FDA indications. Additionally, many clinics are receiving approval from insurers to provide CIs to patients who do not meet FDA or insurer indications. Such "off label" devices are often provided to patients with asymmetric hearing losses where the

better-hearing ear would preclude a patient from meeting indications while the poorer-hearing ear is suitable for a CI. Such decisions are based on data showing improved speech recognition when use of an implant is combined with use of a hearing aid in the contralateral ear (Ching et al., 2004; Dunn DD, Tyler RS, Witt SA, 2005; Devocht et al., 2017).

At the University of Michigan clinic, we have noted that many professionals will only refer a patient for a CI evaluation if they are highly confident that the patient will qualify for a CI. Unfortunately, this means that some professionals refrain from making a referral if they think there is a chance the patient will not qualify. Below we provide suggestions regarding when a patient should be considered for a CI evaluation. It is our hope that, after reading this article, professionals will recognize that there are very few inappropriate referrals and that most patients, even if they do not qualify for a CI, will feel that their participation in such an appointment was valuable and worthwhile. This article will focus on referral of patients who may qualify for a more traditional, non-hybrid device. Information regarding referral of patients who may qualify for a hybrid/EAS device are outlined in a separate article in this edition.

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Referring **Patients** for a Cochlear Implant **Candidacy** Evaluation

As stated previously, FDA-approved indications for traditional CIs typically base candidacy on both audiometric and open-set sentence recognition criteria, and one problem with such indications is that many referral sources, such as audiologists who dispense hearing aids, do not regularly administer sentence tests to their patients, making it difficult for them to know if a patient will qualify for a CI. Many professionals do, however, administer word recognition tests as part of routine unaided audiometric testing or as part of the hearing aid fitting/verification process. Thus, we propose that scores obtained on such word recognition tests, along with the results of audiometric testing, be used as a guide for determining if a patient should be referred for a CI evaluation.

Gubbels et al. (2017) examined the medical records of patients who were seen at their clinic over a five-year period, in order to determine if findings from routine unaided audiometric tests could be used to predict the results of a more formal CI candidacy evaluation. They found that 86% of patients with monosyllabic word recognition scores at or below 44% met CI candidacy requirements for private insurance. In their study, candidacy decisions were based on the use of AzBio Sentences (Spahr et al., 2012) or older test materials that included HINT Sentences (Nillson et al., 1994). If predictability had been based solely upon subjects' AzBio Sentence scores, it is likely their data would have revealed a slightly higher monosyllabic word score. Additionally, many clinics today determine candidacy based on AzBio sentences administered in the presence of background noise, which would have yielded an even higher monosyllabic word score to predict candidacy.

We recently performed a similar review of data obtained on all adults who received a CI at our facility over the past two years. Monosyllabic word scores used in our analyses to predict CI candidacy were obtained from a careful chart review and included unaided word scores obtained at the referral site or at our site during preoperative testing. For this analysis, we based candidacy on the FDA-approved indications used most often in our clinic, which included a score of less than 60% correct on open-set sentence recognition in the patient's best aided condition when recorded AzBio sentences were presented to a soundfield at a level of 60 dB SPL using a signal to noise ratio of +10 dB. Because CI candidacy is most often based on the patient's best-aided performance, we elected to use subjects' "best" unaided monosyllabic word score when scores for the left and right ears were compared. To reflect scores being obtained in various clinics, we included all available unaided scores obtained for the right and left ears, and included scores obtained on the NU-6 monosyllabic words test (Tillman & Carhart, 1966), the CID W-22 test, and the CNC Monosyllabic words test (Peterson & Lehiste, 1962). Additionally, we included scores obtained using either recorded materials or presented live voice.

Of 249 adults referred for a CI evaluation, 157 (63%) qualified for a CI, while 90 (36%) did not qualify for a CI based

on the criteria cited above. Unfortunately, because Medicare has different criteria than the FDA (i.e. beneficiaries must obtain a score less than 40% correct on open set sentences in the best aided condition), some of the patients who met these candidacy requirements were unable to receive a CI.

Unaided monosyllabic word scores were available for 84 subjects who met candidacy requirements for a CI. We analyzed our dataset similar to the procedure used by Gubbels et al (2017) and found that CI candidates obtained a best unaided monosyllabic word score that ranged from 0 to 82% correct. The 86% threshold for our patients was much higher than the 44% monosyllabic word threshold reported by Gubbels et al (2017). We found that 86% of the patients who qualified for a cochlear implant at our facility obtained a best unaided monosyllabic word score of 60% or less.

Based on these scores, we recommend professionals consider referring a patient for a CI evaluation if he/she obtains a score of approximately 60% correct or less on an unaided monosyllabic word test for their better hearing ear, especially if the patient also demonstrates a bilateral moderate to profound sensorineural hearing loss. It should be noted that 12 of our patients scored above this threshold score of 60% yet still qualified for a CI. Thus, some patients who are candidates for a CI may have preoperative unaided word recognition scores higher than this recommended score of 60%.

Other **Factors** to **Consider**

For both hybrid and traditional candidates, there are other factors that are often taken into consideration when deciding if a patient is a suitable candidate for a CI. These factors include motivation, dissatisfaction with current amplification, recent experience (or lack of) with appropriate amplification, ability to function/hear at work, and ability to function/hear in social situations, to name a few. We feel that asking patients about these factors can provide insight that can be used to help determine if a patient should be referred for a CI evaluation.

What if They're **Not** a **Candidate**?

It's important for professionals to recognize that most patients feel the CI candidacy evaluation is worthwhile, even when the results indicate they are not a candidate. This is because the evaluation typically includes verification of their hearing aid settings (a necessary step prior to speech recognition testing), discussion of their difficult listening conditions, counseling regarding their candidacy/non-candidacy, and recommendations for future follow-up. In our experience, most patients who are not candidates leave the appointment grateful that their referring audiologist considered them for this evaluation.

Discussing the Referral for a CI Evaluation with the **Patient**

Receiving a recommendation from a professional, to consider a CI evaluation, may be difficult for some patients. Therefore, such recommendations should be handled with care to ensure the patient understands the reason for the recommendation. We find the following steps helpful when communicating with patients about a referral.

Description of their audiogram

It is important for patients to understand their audiogram as this will facilitate understanding of what their current hearing technology can or cannot do for them (as described below in regards to functional gain). For all potential CI recipients, it is helpful for them to know if their hearing loss meets the audiometric requirements for a cochlear implant as stated in the FDA indications. For this purpose, we provide an audiogram that includes the traditional CI indications. We recommend professionals consider overlaying the patient's thresholds on this audiogram, as doing so can help support a recommendation for a CI evaluation and help explain the audiometric indications for a CI.

Functional Gain

Although the standard of care for determining the optimal fit of amplification is real ear verification (AAA 2013, AAA 2006), it may be helpful to perform functional gain testing with patients you are considering referring for a CI evaluation. When displayed graphically, aided thresholds can serve as a useful counseling tool to help illustrate the sounds of speech that the patient does or does not have access to when using optimally-fit amplification. Overlaying this information on an audiogram that shows both speech and environmental sounds (such as the audiogram in Figure 1 on page 19 of the previous article) helps patients understand what their current technology is, or is not, providing them in regard to sound detection. Additionally, including a visual representation of the detection skills that CIs typically provide (20-25 dB HL 250-4000 Hz) can have a positive effect on how they will view the CI. It is important to keep in mind that that the most thorough objective verification and booth testing only provides you with a glimpse of how your patient performs in idealized settings. It is important to listen to your patient

when he describes difficulties and challenges. It may be that a CI could potentially help him to overcome some of these perceived difficulties.

Speech Recognition

It will also be helpful to provide the patients with information regarding their speech recognition test results, and to inform patients of recent outcomes with typical CI users. For example, one could cite recent publications on adults, such as the study of Runge et al. (2017), where adults demonstrated significant improvements in word scores in quiet, sentence scores in quiet, and sentence scores in noise when compared to preoperative scores obtained with hearing aids. Adults in this study obtained mean improvements in speech recognition (12-month post-operative score minus pre-operative score) of 51.2% for words and 58.1% for sentences in quiet. We additionally counsel patients about the range of scores obtained by patients as this helps clarify that CI patients demonstrate a variety of outcomes and that patients may score well above or below these typical scores. We then discuss factors that may impact performance with a CI, including their length of deafness, age at implant, history of hearing aid use in the ear to be implanted, cognitive factors, and any medical conditions that may hinder performance, such as abnormal cochlea(e) and/or cochlear ossification.

Quality of Life

It is important to inform patients that several studies indicate that CI use frequently results in improvements in self-reported quality of life (Hinderink et al., 2000; Mo, Lindbaek, & Harris, 2005; Orabi et al.,2005). Such studies cite improvements in socialization, self-esteem, communication, and relations to friends and family, following intervention with a CI.

Providing Information

Patients who are considering a cochlear implant frequently conduct a great deal of investigative work on the topic of CIs prior to participating in an evaluation. It is important for them to access accurate and reliable information. Unfortunately, there is a great deal of misinformation on the internet regarding CIs, their outcomes, and the risks associated with surgery. We recommend audiologists provide prospective patients with web addresses for the three CI manufacturers who provide devices in the United States: www.advancedbionics.com, www.cochlear.com, www.medel.com. These websites provide important information regarding candidacy, electrode arrays, device reliability, and patient experiences. They additionally provide prospective patients with the ability to connect with CI users to learn first-hand about their experiences with their CIs.

What Not to Do

In our experience, referral sources have a large impact on a patient's willingness to participate in a CI evaluation. In addition to encouraging patients to seek a CI evaluation, some audiologists unknowingly discourage patients from considering this important next step. Below we provide examples of some of the things our patients have shared with us regarding the discussions they have had with well-meaning audiologists.

If a child is born with a bilateral profound sensorineural hearing loss, we do not recommend the family be counseled to "try hearing aids first to see if they work". When parents hear these words, they frequently hold out hope that the hearing aids will "work" and that their child will not need surgery. It is well known that children with profound losses who receive CIs obtain better spoken language skills than children with profound losses who continue to use hearing aids (Bittencourt et al., 2012). Thus, it may be more appropriate to ask the parent if they have the goal of spoken language for their child. If they respond that they do, they should be informed that the best chance for successful development of spoken language skills is with early implantation with a CI. They should be encouraged to establish consistent hearing aid use, but for reasons other than to "see if they will work". Benefits of early hearing aid use include access to sound, establishment of a device-wearing routine, and that, in some cases, insurers may require a hearing aid trial before they will provide preauthorization for a CI.

We recommend that professionals refrain from referring to the CI as a "last resort". Such a reference often increases the grief and dread that some patients or parents may feel about a CI for themselves or their child. Referring to the CI as a last resort causes potential patients and parents to worry about hypothetical situations, such as what will happen if the CI is not successful.

Do not wait until you feel a patient IS a candidate to refer them for a CI evaluation. Frequently, patients who are seen in our clinic likely qualified for a CI much sooner. If you have questions regarding the appropriateness of a referral, we recommend you contact the CI center directly and ask them to review your test results. The additional benefit of such contact is that the CI Center can alert you of any studies they are participating in that may have more lenient criteria than those of the FDA-approved devices. When such

communication occurs, the patient seems to find comfort knowing that the referring audiologist took an extra step to ensure the evaluation would be worthwhile and that the CI center is familiar with their case.

Do not assume the patient has too many "other issues" that would make him/her a poor candidate for a CI. Cochlear implant centers frequently provide implants to patients with additional disabilities. This includes adults with cognitive or physical disabilities and/or children with cognitive and/or developmental delays. Frequently, providing the patient with improved communication can have a large, positive impact on the ability to diagnose and treat other health issues.

Summary

Dispensing audiologists play a key role in referring patients for CI evaluations. However, determination of when to refer someone is not always a straightforward decision. Based on data obtained at our clinic we recommend dispensing audiologists consider referring patients when they demonstrate an unaided monosyllabic word score that is less than or equal to 60% correct. In this paper, we have provided suggestions that you may find helpful when communicating with your patients regarding your recommendation for a CI evaluation. Without referrals from their dispensing audiologist, many of the patients who currently use CIs would still be receiving inappropriate benefit from hearing aids. Instead, many of these patients are receiving great benefit from a CI and are grateful their dispensing audiologist had the knowledge and foresight to recommend such an evaluation. ■

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References

American Academy of Audiology (2013). American Academy of Audiology Clinical Practice Guidelines: Pediatric Amplification. Retrieved from: http://audiologyweb.s3.amazonaws.com/migrated/PediatricAmplificationGuidelines.pdf_539975b3e7e9f1.74471798.pdf

American Academy of Audiology Task Force (2006). Guidelines for the audiological management of adult hearing impairment. Audiology Today 18(5), 32-36. Retrieved from: http://audiology-web.s3.amazonaws.com/migrated/haguidelines.pdf_53994876e92e42.70908344.pdf

Bittencourt AG, Giantomassi AA, Torre D, Bento RF, Tsuji RK, deBrito R. Prelingual deafness: Benefits from cochlear implants versus conventional hearing aids. Int Arch Otorhinolaryngol. 2012 Jul; 16(3): 387–390.

Ching TY, Incerti P, Hill M (2004). Binaural benefits for adults who use hearing aids and cochlear implants in opposite ears. Ear and Hearing, Feb; 25(1): 9-21.

Crowson MG, Semenov YR, Tucci DL, Niparko JK. Quality of Life and Cost-Effectiveness of Cochlear Implants: A Narrative Review. Audiol Neurootol. 2017 Dec 21;22(4-5):236-258.

Cohen SM, Labadie RF, Dietrich MS, Haynes DS. Quality of life in hearing-impaired adults: the role of cochlear implants and hearing aids. Otolaryngol Head Neck Surg. 2004 Oct;131(4):413-22.

Dunn DD, Tyler RS, Witt SA (2005). Benefit of wearing a hearing aid on the unimplanted ear in adult users of a cochlear implant. Journal of Speech Language Hearing research, Jun; 48(3): 668-80.

Devocht EMJ, Janssen AML, Chalupper J, Stokroos RJ, George EL. The benefits of bimodal aiding on extended dimensions of speech perception: Intelligibility, Listening Effort, and Sound Quality. Trends Hear. 2017 Jan-Dec; 21.

Gubbels SP1,2, Gartrell BC2,3, Ploch JL4, Hanson KD5. Can routine office-based audiometry predict cochlear implant evaluation results? Laryngoscope. 2017 Jan;127(1):216-222. doi: 10.1002/lary.26066. Epub 2016 Oct 31.

Nilsson M1, Soli SD, Sullivan JA. Development of the Hearing in Noise Test for the measurement of speech reception thresholds in quiet and in noise. J Acoust Soc Am. 1994 Feb;95(2):1085-99.

Peterson GE, Lehiste I. Revised CNC lists for auditory tests. J Speech Hear Disord. 1962 Feb;27:62-70.

Hinderink JB, Krabbe PF, Van Den Broek P. Development and application of a health-related quality-of-life instrument for adults with cochlear implants: the Nijmegen cochlear implant questionnaire. Otolaryngol Head Neck Surg. 2000 Dec;123(6):756-65.

Mo B, Lindbaek M, Harris S. Cochlear implants and quality of life: a prospective study. Ear Hear. 2005 Apr;26(2):186-94.

Nucleus® Hybrid L24 cochlear implant professional package insert, 2014

Nucleus® CI512 cochlear implant professional package insert, 2016

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Orabi AA1, Mawman D, Al-Zoubi F, Saeed SR, Ramsden RT. Cochlear implant outcomes and quality of life in the elderly: Manchester experience over 13 years. Clin Otolaryngol. 2006 Apr;31(2):116-22.

Runge CL, Henion K, Tarima S, Beiter A, Zwolan TA. Clinical Outcomes of the Cochlear™ Nucleus(®) 5 Cochlear Implant System and SmartSound™ 2 Signal Processing. J Am Acad Audiol. 2016 Jun;27(6):425-40.

Sladen DP, Gifford RH, Haynes D, Kelsall D, Benson A, Lewis K, Zwolan T, Fu QJ, Gantz B, Gilden J, Westerberg B, Gustin C, O'Neil L, Driscoll CL. Evaluation of a revised indication for determining adult cochlear implant candidacy. Laryngoscope. 2017 Oct;127(10):2368-2374

Sorkin DL, Buchman CA. Cochlear Implant Access in Six Developed Countries. Otol Neurotol. 2016 Feb;37(2):e161-4.

Spahr AJ1, Dorman MF, Litvak LM, Van Wie S, Gifford RH, Loizou PC, Loiselle LM, Oakes T, Cook S. Development and validation of the AzBio sentence lists. Ear Hear. 2012 Jan-Feb;33(1):112-7.

Tillman TW, Carhart R. An expanded test for speech discrimination utilizing CNC monosyllabic words. Northwestern University Auditory Test No. 6. SAM-TR-66-55. Tech Rep SAM-TR. 1966 Jun:1-12.

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References

Boothroyd, A. (2008). CasperSent: A program for computer-assisted speech perception testing and training at the sentence level. *Journal of the Academy of Rehabilitative Audiology*, 41, 30-50.

Henshaw, H., & Ferguson, M. A. (2013). Efficacy of individual computer-based auditory training for people with hearing loss: a systematic review of the evidence. Plos One 8, e62836.doi:10.1371/journal.pone.0062836

Humes, L. E., Burk, M. H., Strauser, L. E., & Kinney, D. L. (2009). Development and efficacy of a frequent-word auditory training protocol for older adults with impaired hearing. *Ear and hearing,* 30(5), 6613.

Moore, D.R., Rosenberg, J.F., & Coleman, J.S. (2005). Discrimination training of phonemic contrasts enhances phonological processing in mainstream school children. *Brain and Language*, 94(1), 72-85.

Savignon, S.J. (1972) Communicative competence: An experiment in language teaching. (Vol. 12). Marcel Didier.

Sommers, M. S., Tye-Murray, N., & Spehar, B. (2005). Auditory-visual speech perception and auditory-visual enhancement in normal-hearing younger and older adults. *Ear and Hearing,* 26(3), 263-275.

Sweetow, R. W., & Palmer, C.V. (2005). Efficacy of individual auditory training in adults: A systematic review of the evidence. *Journal of the American Academy of Audiology, 16*(7), 494-504.