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Re-focussing on the clinical targets

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The objective of this presentation is to re-examine the clinical targets for hearing aid recommendation and processing. The main clinical target is the damaged cochlea, and the main measure discussed will be the many patterns of clinical word recognition across level. Study of human temporal bones allows appreciation of the underlying damage to the cochlea in hearing aid cases, with somewhat surprising implications. Primarily, it is necessary to allow for and respond to, a model of depletion of the sensory epithelium (as in macular degeneration). There is an important difference between reverse-engineering the audiology results and providing maximum information to a depleted receptor array. Diagnosis using word recognition, recommendation criteria, and implications for delivering optimal hearing aid output and for studying the results will be discussed.

WHO IS IN THE WAITING ROOM AND WHAT DO THEY NEED?

Figure 1 shows the sites of lesion of cases arriving in the author's waiting room in the U.S.A. over one year based on the diagnosis codes listed for each case. (U.S. Dept. HHS, ICD-9-CM, 2003) "Sensorineural" cases are treated as cochlear by the author unless otherwise indicated by the patients' history and presentation. This approach allows progress beyond the view that nothing is known about the site of lesion when air matches bone. For example, study of human temporal bones shows the clear majority of losses with no air-bone gap not only show cochlear disease, but sufficient cochlear disease to account for the loss (Merchant and Nadol, 2010). Modeling sensorineural hearing loss as a function of cochlear damage has demonstrable, practical use in diagnosis, amplification and counseling in this clinical population. It is reasonable to proceed as if the damaged cochlea is what is wrong with the majority of our patients requiring hearing aids, and to test such modeling against the measurable behaviour of these patients. A framework for doing this will be presented below.

Interaction with this population in the clinic brings forward a set of needs which are not often discussed. These patients are told by hearing professionals (and advertisements) that everyone with "hearing loss" will receive life-improving benefit from amplification (Kochkin, 2011). Their friends, some of whom are careful, trusted observers, tell them that, in many instances, hearing aids "don't work". For the purpose of this discussion, both of these sets of observations will be treated as

useful. What if patients and their families are applying a more stringent criterion than that of the industry before deciding that hearing aids "work"? To address this possibility, this discussion will be limited to the most tangible positive effect: the provable increase in word recognition provided by amplification under good conditions. This variable is clear to patients (and their families) and is measurable clinically using well-accepted methods.
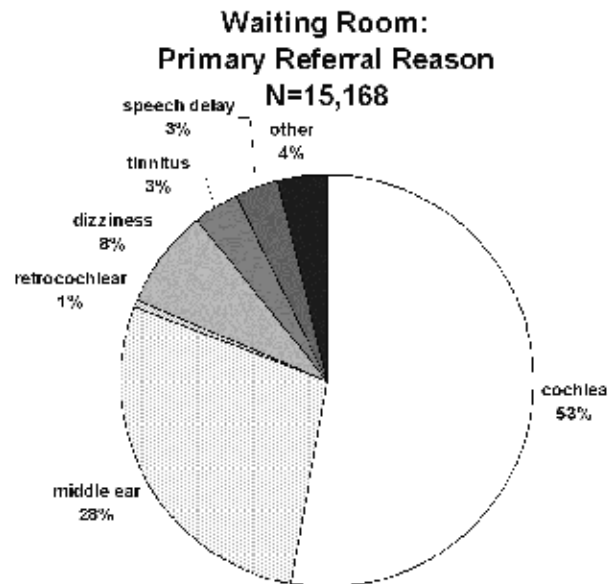
Waiting Room: Primary Referral Reason
N=15,168

Fig. 1: Sites of lesion for patients arriving in the author's waiting room during one year. These were derived using their ICD9 codes.

Improvement in word recognition operates differently from satisfaction and other such measures. Satisfaction can be manipulated by fixing patient complaints and by other factors, but doing so may not also result in a measurable increase in a performance variable like word recognition. Monosyllables in quiet are used here because they scale maximum performance limits in a way which may be compared across many cases and clinics. Clinical word recognition does not empirically address every real-life situation, but it does show the upper limits imposed by cochlear disease, from which further difficulties in noise can be anticipated. In this discussion, no attempt is made to present a model which includes the effects of complex noise-handling algorithms, and the claims that technology can deliver the patient's constantly-changing listening target will be left to others. The goal of this discussion will be to carry the straightforward facts of the word recognition limits imposed by individual cochlear disease, all the way through clinical diagnosis and amplification. If this is seen as simplistic or as a failure to provide all possible benefits, it nonetheless remains true that these patients currently have full access to a hearing industry with a much more liberal approach and very wide recommendation

criteria. Year after year however, these patients and their families choose not to make full use of this. Of those who have chosen to purchase hearing aids, performance in noise remains the highest reported complaint (Kochkin, 2005). The current answer these patients feel they always receive is: "Yes, you have hearing loss. Lets try hearing aids, you never know". This discussion will propose that these patients have developed a clear need for the opposite: "No, we cannot prove that hearing aids will give you substantial benefit". In this discussion, clear (but possibly difficult to accept) criteria will be proposed which link the observations of the patients with the clinical data in an attempt to increase general trust in the work of providing hearing aids. The more conservative approach presented here, treating only the effects of amplification on word recognition, represents an attempt to respond to the information performance limitations being encountered by this clinical population, and to treat their observations as useful. In short, the argument will be that we should turn from measuring a problem (hearing loss) to proving that increased acoustic power is a statistically verifiable solution. The difference between these two concepts is larger than many believe, and this drives some of the most intractable problems in the work of providing hearing aids.

AMPLIFICATION FOR THE DAMAGED COCHLEA

The damaged cochlea is the primary target we are stimulating with a hearing aid. While this is obvious, the discrepancy between current methods, which are often called "fitting the audiogram" (Keissling, 2001) and addressing cochlear damage is very large as can be appreciated in figure 2. Pure tone threshold audiograms are on the top in each case. On the bottom is the NAL-NL1 formula response with 60 dB speech input (Verifit Audioscan 3.0.11). These audiograms have been properly "fit". These cases are actually from the U.S. National Temporal Bone Repository [http://temporalboneconsortium.org] and so the state of each cochlea can be shown using well accepted methods. (Merchant and Nadol, 2010) Below the audiograms are cytocochleograms obtained by counting cells by light microscopy. Inner and outer hair cell populations (v. normal) are shown using horizontal bars, along with stria vascularis and auditory neurons, which are presented on the frequency-to-millimeter map which relates the cochlea to the audiogram. The black regions in each bar indicate missing cells of each type. The first (leftmost) case is fairly sensible clinically in that the example speech is inaudible without gain, although it should be noted that the expected aided outcome (in information terms) is likely to be limited by the specific type of cochlear damage. A large proportion of the outer hair cells are gone and the hearing aid user, with much broadened tuning etc. is not expected to do better than is indicated by the 40% word recognition score which was found in this case, even though the frequencies can be made audible.

The next two cases are more problematic. In the center case, the discrepancy between the model implied by the audiogram and that of the cochlea is easy to see. Here, there are threshold responses above 1 kHz which look just like a graded "loss" of gradually increasing severity on the audiogram but in fact there is a sharp boundary just above 1 kHz beyond which there are practically no inner hair cells.

The threshold responses arise from the tails of the tuning curves of surviving remote cells and from a small patch around 3 kHz. Here it is possible to appreciate the difference between graded threshold effects of tuning curve tails and the sharp absence of cells able to provide speech information. This difference does not require post-mortem evaluation, but is available clinically by evaluating a binary test (pure tone detection) versus an information-intensive test (word recognition). (Carhart, 1946; Halpin and Rauch, 2009a) Of greater interest for hearing aid work is the effect of using a gain formula based on the audiogram. In the center case, the frequency bands where gain exceeds 20 dB are enclosed by the rising dotted lines. What can be seen is that responding to the audiogram is practically the opposite of responding to the cochlea in that the action of the hearing aid is maximal in the region where the cochlea is too damaged to pass information. Because of this patient's insensitivity to low frequency sounds, there is reason to believe that a broadband hearing aid would provide benefit, but it would be necessary to form a useful model of the cochlea at the time of clinical evaluation (as opposed to post-mortem in this case) to see the need for this.
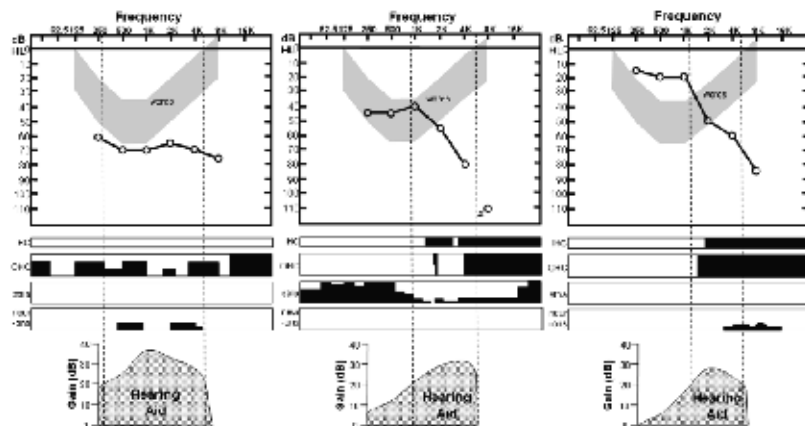

Fig. 2: Fitting hearing aids on temporal bones. The top three panels are pure tone audiograms. Below them are bars known as cytocochleograms in which cells are denoted as absent (black) or present by light microscopy. On the bottom of each panel is an NAL-NL1 frequency spectrum (60 dB SPL input) calculated using the audiograms above. [Reprinted with permission from Halpin and Rauch 2009b].

Finally, the most controversial finding: the far right case shows the cochlear apex completely normal and the base completely de-populated of inner and outer hair cells. The clinical question is "which region should we now stimulate with gain?" The answer in this discussion is: neither, the normal regions don't need it and the dead regions can't use it. The unfortunate standard answer can be found in the hearing aid response at the bottom where the hearing aid is set to act nearly entirely on regions with no receptors. This patient has very significant problems, particularly in noise but the severity of these problems does not provide a rationale for a solution

using formula-based spectral gain. He is, however, accurately "fit". The implication of these cases is that the clinical question should move from quantifying the problem (using tone detection) to proving that the remaining cochlea allows a solution (using words). These are the cases where the patients' report that the hearing aid "does not work" should be taken seriously, even in the presence of an abnormal threshold audiogram and substantial difficulties in noise.

COCHLEAR DIAGNOSIS USING WORD RECOGNITION

In order to diagnostically apply the differences in detection v. information, a familiar tool is used: the Speech Intelligibility Index (SII; ANSI S3.5 1997). The SII integrates the audibility of speech across frequency bands and arrives at the available speech information (from 0.0 to 1.0). This can then be used to predict the score on a test (here CID W-22 monosyllables) for normal ears under that condition. Clinically then, this calculation can be repeated for all levels from 0 to 110 dB HL, resulting in the entire performance / intensity function for any audiogram as if there is no cochlear depletion (all frequency bands contribute normally as their thresholds are exceeded). This is shown in figure 3 as the curve (marked "predicted") in the left-side "speech intelligibility" boxes. This is not done to predict the actual outcome, but serves as a model (like 0 dB HL) against which the information effects of cochlear damage can be seen. The audiogram can be thought of as actual surviving cells with a layer (of tuning curve reception regions) obscuring them. The SII allows the clinician to further evaluate the non-normal frequency regions to see if the cochlear cells are really still there and are contributing as expected to word recognition (Halpin and Rauch, 2009a).

Figure 3 shows the clinical threshold and word recognition patterns for two different clinical cases. In the first case, panel A shows a low-level list (40 dB HL) which provides stimuli shown as the empty 40 dB HL spectrum on the audiogram. In this condition, only frequencies below 1500 Hz are audible. The SII ("predicted" line) predicts a maximum of 80% correct using only these frequencies, and the patient's actual score is 72% correct. The normal thresholds and near-match to SII prediction support a conclusion that this region of the cochlea (250-1000 Hz) is healthy in terms of speech. The higher level word recognition test (gray spectrum, 70 dB HL) adds the important frequencies from 2-4 kHz and, as the prediction line shows, it would now be possible to achieve near 100% correct. This is not what happens in this case: The high level score (74% correct) is not significantly improved by adding these regions. Another way to model this cochlea is shown in panel B. Here, the frequencies from 1500-8000 Hz are forced to out-at-limits. This is, of course, acoustically impossible from the standpoint of pure tone detection since such damping is not available on the basilar membrane. On the other hand, it may accurately reflect the information transmission capacity of the cochlea (as in figure 2, right case). The SII predicted performance / intensity curve is re-calculated, showing that the patient's entire word recognition performance across level could be achieved using only the low frequency regions. Such modeling using word recognition at high and low levels has been shown to apply to low frequency,

cookie-bite and "inverted V-shaped" cases as well (Halpin *et al*., 1994; Halpin, 2002; Vinay and Moore, 2010).
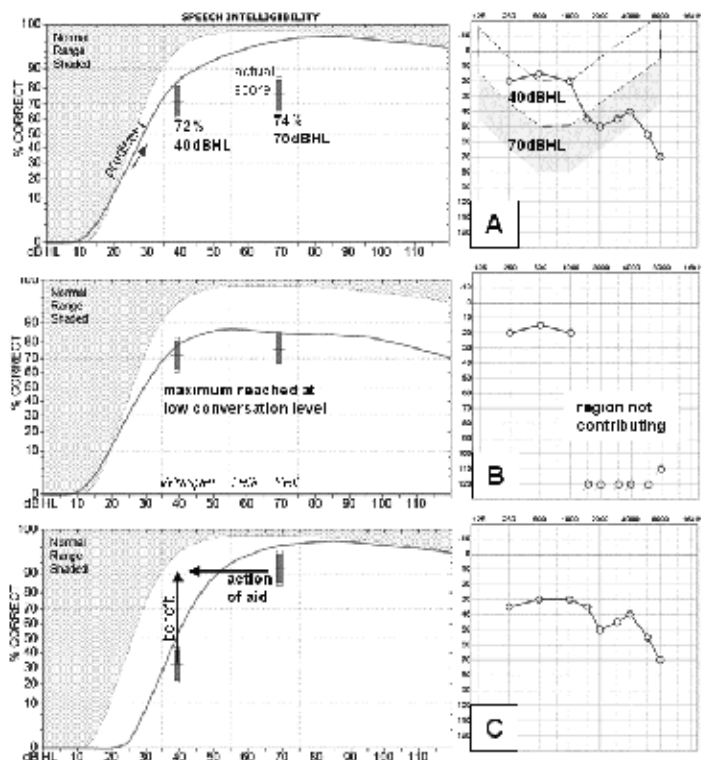

Fig. 3: Diagnosing the cochlea and recommending hearing aids. The standard pure tone audiogram is on the right (right ear symbols show sensory loss). On the left is a performance / intensity graph of word recognition where the rising curve is the best possible performance predicted by SII (ANSI, 1997). Actual scores (CID W22; Hirsh recording 50 item) are shown as the central tic in the rectangular symbol and the 95% critical differences (Thornton and Raffin, 1978) are shown by the extent of each bar. This construct allows evaluation of the amount of information (re: full SII importance) being contributed under each condition.

What is shown by using this approach in the clinic is that patients' information bandwidth is often much smaller than their detection bandwidth. This is expected due to the different characteristics of the detection v. word recognition tasks. The threshold audiogram remains clinically useful as a map, primarily of healthy areas. The word recognition data is not place-specific, but can be added to the audiometric map data to evaluate the surviving ability of the non-normal sensory epithelium. In sloping loss cases then, the audiogram is used as a filter to separate two conditions

(regions) by level. In flat audiogram cases, a general information-loss model of the disorder affecting the whole cochlea is sufficient to move forward (i.e. figure 2 left case). A very important aspect for clinical work is to continue to apply the implications of depleted (rather than attenuated) sensory receptors though the provision of hearing aids. Depletion results in intractable limits on the information which can pass. Once the remaining receptors have all the available speech information, then the limit is reached and this limit may very well be reached at low conversational levels. The rationale of any hearing aid assumes that louder sounds increase speech information in an ear with elevated thresholds, and this is clearly not true in cases such as the case in panel A-B and the right-hand case in figure 2.

RECOMMENDING AIDS: PROVING IMPROVEMENT (v. 40 dB HL)

After the evaluation described in panels A and B of figure 3, two important limits are shown. First, there is no expectation of significant improvement in word recognition with amplification (increasing level from 40 to 70 dB HL). The second limit is that, though the patient's performance never rises above 74%, this maximum performance is achieved at a low conversational level (40 dB HL). The patient may seek hearing aids based on severe problems understanding, particularly in noise, but will notice the same word recognition ability with or without them. The depleted cochlea acts somewhat like an analogous disease of the eye: macular degeneration. There is a severe reduction in the effective bandwidth of the receptor and there is no input strategy which will allow this bandwidth limitation to be exceeded. Macular degeneration patients are not abandoned. They are provided with high-contrast visual materials, family support and other strategies. On the other hand, they are not asked to pay more because a certain pair of glasses is more "advanced". The patient in panel A-B should not be recommended amplification. If this approach were adopted by hearing care providers, it would not reduce the actual number of instruments sold since patients already apply a similar criterion [unpublished data currently in review], but it would give patients something they clearly need: a clinically measurable "no" point. If the answer is always "yes", it is a weaker answer than one based on a firm insistence on proof of improvement in the clinic. The industry would benefit from a stronger reputation by the same token. Both recommendation and non-recommendation would be based on a clear clinical boundary and the "hearing aids don't work" cases would be treated as valuable observations, providing a shared frame of reference for clinician and patient in this very important decision.

Panel C shows a good case for recommending amplification. The audiogram may not seem very different from that in panel A. However, more frequencies lie outside the normal range and the summed effect is to move the word recognition performance / intensity curve in the speech box (both predicted and measured) towards the right and out of the normal range. In addition, high level word recognition testing (70 dB HL) shows that this cochlea will allow 92% correct under good conditions. Since the corresponding test at a low conversation level (40 dB HL) shows only 32%, then a large improvement in performance has been

demonstrated with amplification. Here, difficulty with soft or distant speech can be addressed by making the input sound loud. In terms of the speech graph in panel C, the hearing aid acts to move the demonstrated high level performance back to the left (see "action of aid") such that soft speech is now loud and the ~90% word recognition condition is achieved artificially (see "benefit"). This clinical finding of improvement stands in clear contrast versus both the case from panel A and the current state of hearing aid recommendation. Instead of hoping that amplification might "give back" specific frequencies from an abnormal audiogram, the clinician now has proven that this cochlea will allow significantly improved word recognition with amplification. This improvement will be clear to the patient and family as well. Hearing aid providers would be glad to have a such a known improvement in hand before beginning the many additional challenges of a hearing aid case.

PROVIDING AMPLIFICATION: PRESERVING IMPROVEMENT

Amplification may be conservatively modeled as providing benefit as seen in figure 4 ("benefit" arrow). This means that, whatever combination of depletion and attenuation is imposed by ear disease, the cochlea in question has been shown to allow improvement in word recognition performance from a low conversational level (40 dB HL) to a higher level. Words which are missed now (here below 65 dB HL) could be recognized (under good conditions) if they were made loud. To do this in a straightforward way, the cochlea depletion model indicates that a simple (loud) provision of all possible word information would be a useful first step (Halpin and Rauch, 2009b). Instead of reacting to the audiogram as attenuation, un-distorted broadband words would be provided at those higher levels shown to be beneficial. An un-distorted broadband approach preserves all the inherent component relationships for appreciation either at the place of excitation, or remotely, including appreciation of naturally-occurring distortions and interactions. The engineering approach to this would be similar to that used by audiophiles. No audiogram, frequency gain spectrum or fitting formula is used and the reason for this can be seen in figure 2. Provision of benefit in this sort of case is easy to demonstrate, but it is not easy to preserve in the real conditions encountered by the patient. The actual provision and relationship between benefit (provided by increased power) versus complaints (also caused by increased power) as is shown by adding the "complaint" arrow in figure 4. Note that while most would agree that response to complaints reduces the output power by some amount (horizontal scale), the effects on the patients' word performance (vertical) are not always considered.

If an accurate (flat broadband), loud sound is delivered to patients, they complain about several things, beginning with low frequencies ("the boom"). Gain at these frequencies nearly always must be reduced for acceptance. This could be said to drive the gain spectrum in the direction of the complement of the common high frequency loss. However, this complaint is likely related to the spread of energy and other perceptual difficulties (i.e. their own voice) but is not likely due to a direct spectral gain relation to their audiogram (as seen in figure 2). Directional microphones, occlusion handling, noise algorithms, feedback cancellers and

compression all act in some way along the dimension of the "complaint" arrow in figure 5. An example of how compression may act not only to reduce power, but to remove information is proposed in the bottom panel of figure 4. Basically, the assumption that the patients' loudness scale will respond to re-mapping by using smaller increments may not be supportable since those increments do not change with hearing loss (Stillman, *et al.*, 1993). This and other issues with information lost using compression have been reported (Plomp, 1988; Souza, *et al.*, 2007).
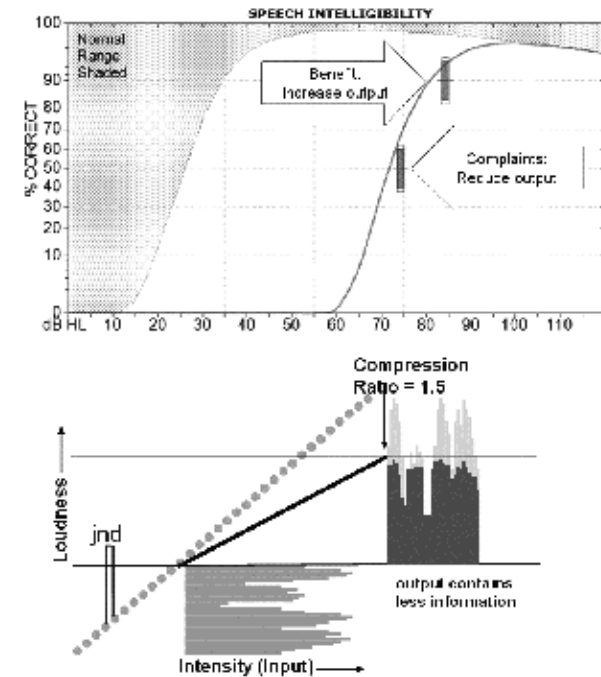

Fig. 4: Preserving benefit. In the upper panel, the opposition dynamic of benefit versus complaint fixes is shown in the word recognition space. The effect of lowering MPO, gain etc. by 10dB is shown to reduce monosyllable score from 90 to 50%. The lower panel shows A standard depiction of compression, except that the implication of the discrete steps (jnd) is shown on the main diagonal. Given discrete loudness steps, fewer steps are available and so information is lost.

Application of complaint-fixing strategies may be necessary given the patients' reports, but it is important to recognize the information effects of each reduction in either the strength or accuracy of the hearing aid's ability to deliver the signal. In the top panel of figure 5. a clinician might apply 30 dB of broadband gain to speech and preserve the amplitude excursions with an MPO of 120+ in order to achieve performance consistent with 90% correct monosyllables ("benefit" arrow). If the patient complains, and the MPO and gain are reduced by 10dB, the expected word recognition performance falls to around 50% correct ("complaint" arrow). In

general, reaction to complaints might be approached minimally order to preserve the maximum amount of word recognition improvement available to the patient. Results are surprisingly positive (in this author's experience), though neither these reports, nor their audiograms should be lumped together to predict the behaviour of the next clinical case arriving in the waiting room.

WORK: THE GAME WE CAN WIN

Patients are not well served by presenting hearing loss in terms of communication success and failure. In fact, they do not often fail. They eventually find ways to determine what is said, or they learn to avoid challenging situations. The social consequences for missing words are very bad (Preminger, 2007), and patients do not put themselves in position to move from failure to failure. This means that to tell them that hearing aids will stop their many failures of communication may not be effective, particularly when the various cochlear limitations described above are added to the considerations. Patients may not accept a failure/success rationale, but they and their families are nearly always willing to accept that hearing impairment adds a substantial amount of work to multiple verbal exchanges throughout the day (Mulrow, *et al.*, 1990). Once this is agreed, the clinician can show that the work required for success can be tangibly reduced by a hearing aid turned up loud and worn constantly. This may seem simplistic, but it reduces the need to require that the hearing aid sound "good " or "natural" (when it does not) nor that the limits imposed by the ear (i.e. in noise) be reliably exceeded. The "work" rationale is only that, if the patient wears the hearing aid all day, particularly in instances where they would succeed (with difficulty) they will finish the day with tangibly more energy. Control is returned to the patient in two ways: first, they decide when they would like to trade loudness for work (using the volume control), and second, all the energy not expended because of their ears becomes energy they can use for other things. This is a very conservative, straightforward view of hearing aid benefit and few would argue that hearing aids cannot do this.

STUDYING PEOPLE AND THEIR HEARING AIDS

Studying the hearing aid market, by definition, involves the study of people who do not have hearing aids. The standard view of the market is that of a single large group (everyone with "hearing loss") who would all benefit from wearing hearing aids and simply need better inducement. If the arguments presented here are carried through, the current "market" and the patients who benefit are actually two different groups along the dimension of a provable increase in word recognition (v. 40 dBHL). There is a group who do not improve and who actually form a large portion of the currently-conceived "market". When studying marketing approaches, these differences (figure 3A vs. C) may affect the applicability of the findings.

Some of the concepts discussed above may be applied to studies of hearing aids and their parameters. One suggestion would be not to start by using a comparison with another hearing aid at all, but to allow into experiments a "null" processing condition in which sounds were treated very well (i.e. the audiophile approach),

made loud, but not manipulated. Improvements over such a null, very high quality condition would be useful and the results transferable to the clinic. Also, forming groups by audiogram thresholds is problematic as suggested by figure 2. Both the center and right case would be included in many "high frequency loss" groups with predictably variable results. It may not be necessary to form groups at all, but to allow patients to distribute along one dimension, (i.e. maximum word recognition in quiet) indicative of the information bandwidth of the cochlea, and then plot the variable in question versus that dimension. Clinicians often do not benefit from descriptions of lumped groups as much as from a "slide rule" approach where they can find their current patient along one axis, and then see how well they might be expected to perform on some variable or task on the other. Finally, the use of normal subjects should be approached with great caution. While any set of bad results can be achieved in normals using noise etc., the normal system is not one in which improvement is as highly limited as the damaged cochlea. Such comparisons do not take into account a depletion model where there simply is much less cochlear epithelium (and will never be more). Giving bad sound to good ears is not the same as giving good sound to bad ears, even if the starting scores can be made to match. Overall, what will not change is the patients' need to recognize words. What can be improved is the clinician's ability to determine the cochlear limits, to prove improvement with amplification when that is possible, and to preserve that improvement in the patients' real world experience.

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Electric-Acoustic Stimulation in Cochlear-Implant Subjects

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Today, cochlear implantation is the treatment of choice in cases of severe to profound hearing loss, but the speech understanding of many recipients in noisy conditions is still poor and the overall sound quality and ease of listening requires improvement. Residual low-frequency hearing has been shown to improve hearing performance in cochlear implant patients, especially in difficult listening environments (i.e. cocktail parties). It seems that low frequency information can enhance the segregation of competing voices which leads to better speech understanding in noise. For this reason, more and more subjects with low frequency residual hearing are being implanted with so called Hybrid or Electric-Acoustic-Stimulation (EAS) cochlear implant systems to preserve the residual hearing in the ear to be implanted. Results from more than 100 subjects with hybrid cochlear implant systems will be presented. Additionally, a group of more than 80 subjects with conventional cochlear implant systems on one side and residual acoustic hearing on the contralateral side will be demonstrated. Both groups show highly significant improvements in adverse listening environments when using the hearing aid additionally to the cochlear implant system. In this context, indication criteria for the use of acoustic amplification in cochlear implant subjects will be discussed.

INTRODUCTION

Cochlear implants are starting to enter the domain of conventional hearing aids. Subjects generally achieve significant open speech understanding using cochlear implants. Subsequently, more and more candidates with usable residual hearing are being implanted nowadays, as postoperative hearing performance especially in conjunction with low-frequency acoustic hearing is most remarkable. Different research groups showed that cochlear implant subjects with some degree of residual hearing on the contralateral ear benefit significantly by the combination of the acoustic and electric hearing (Ching *et al.*, 2004; Kong *et al.*, 2005; Dorman, 2007). Also, simulations of combined electric and acoustic hearing presented to normal hearing subjects demonstrated superior performance over the simulation of electric hearing alone (Turner *et al.*, 2004; Dorman *et al.*, 2005).