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## Bimodal hearing or bilateral cochlear implants? Ask the patient

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### Abstract

**Objective:** The objectives of this study were to assess the effectiveness of various measures of speech understanding in distinguishing performance differences between adult bimodal and bilateral cochlear implant (CI) recipients and to provide a preliminary evidence-based tool guiding clinical decisions regarding bilateral CI candidacy.

**Design:** This study used a multiple-baseline, cross-sectional design investigating speech recognition performance for 85 experienced adult CI recipients (49 bimodal, 36 bilateral). Speech recognition was assessed in a standard clinical test environment with a single loudspeaker using the minimum speech test battery for adult CI recipients as well as with an R-SPACE<sup>TM</sup> 8-loudspeaker, sound-simulation system. All participants were tested in three listening conditions for each measure including each ear alone as well as in the bilateral/bimodal condition. In addition, we asked each bimodal listener to provide a yes/no answer to the question, "Do you think you need a second CI?"

**Results:** This study yielded three primary findings: 1) there were no significant differences between bimodal and bilateral CI performance or binaural summation on clinical measures of speech recognition, 2) an adaptive speech recognition task in the R-SPACE<sup>TM</sup> system revealed significant differences in performance and binaural summation between bimodal and bilateral CI users, with bilateral CI users achieving significantly better performance and greater summation, and 3) the patient's answer to the question, "Do you think you need a second CI?" held high sensitivity (100% hit rate) for identifying likely bilateral CI candidates and moderately high specificity (77% correct rejection rate) for correctly identifying listeners best suited with a bimodal hearing configuration.

**Conclusions:** Clinics cannot rely on current clinical measures of speech understanding, with a single loudspeaker, to determine bilateral CI candidacy for adult bimodal listeners nor to accurately document bilateral benefit relative to a previous bimodal hearing configuration. Speech recognition in a complex listening environment, such as R-SPACE<sup>TM</sup>, is a sensitive and appropriate measure for determining bilateral CI candidacy and also likely for documenting bilateral benefit relative to a previous bimodal configuration. In the absence of an available R-SPACE<sup>TM</sup> system, asking the patient whether or not s/he thinks s/he needs a second CI is a highly sensitive measure which may prove clinically useful.

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### INTRODUCTION

Dorman and Gifford (2010) reported that approximately 60% of adult cochlear implant (CI) candidates have aidable residual hearing, mostly in low frequencies, in one or both ears. A more recent report by Holder and colleagues (2018) suggested that 72 to 85% of CI candidates have aidable residual hearing, depending on the chosen definition of "aidable". This residual hearing alone is not sufficient to allow high levels of communicative performance in everyday life—as evidenced by the fact that the individuals involved were pursuing preoperative evaluation for cochlear implantation.

Aidable acoustic hearing, though of little use alone, can provide significant benefit when paired with a CI (e.g., Dunn et al., 2005; Gifford et al. 2007; Sheffield & Gifford 2014; Zhang et al., 2010). Indeed, in the best cases, combining the acoustic hearing of the non-implanted ear with a CI in the opposite ear (bimodal hearing) produces higher speech understanding scores and better sound quality than can be provided by the CI alone. Many successful bimodal listeners report that the electric signal of the CI provides the base for their speech understanding, but the contralateral acoustic signal provides a richer, fuller, and more natural sound that provides information not delivered electrically (Berrettini et al. 2010). Furthermore, the addition of acoustic hearing to the CI has been shown to yield significantly better music perception on tasks of chord, melody, and melodic contour recognition as well as timbre recognition as compared to the CI alone (e.g., Kong et al., 2004; Dorman et al., 2008; El Fata et al., 2009; Gfeller et al., 2012; Kong et al., 2012; Prentiss et al., 2015; Crew et al., 2015).

#### Bimodal hearing versus bilateral cochlear implants

Irrespective of hearing configuration, two ears provide significant advantages over single ear listening across various conditions. As mentioned previously, bimodal listening is significantly better than CI alone or HA alone for tasks of speech in quiet and noise (e.g., Dunn et al., 2005; Gifford et al., 2014; van Hoesel, 2012; Zhang et al., 2010). The degree of bimodal benefit afforded by binaural summation varies widely among listeners (e.g., Schafer et al., 2007, 2011; Zhang et al., 2013, 2014; Illg et al., 2014; Kokkinakis and Pak, 2014; Gifford et al., 2014, 2015; Blamey et al., 2015; Dorman et al., 2015; Crew et al., 2015). In fact, many listeners with acoustic hearing in the non-CI ear receive little to no bimodal benefit from ears that were labeled the "better hearing ear" during the preoperative evaluation (Dorman et al. 2015, Illg et al. 2014). Bilateral cochlear implants also yield significant benefit over either CI alone for speech recognition both in quiet and noise (e.g., Litovsky et al. 2006; Buss et al., 2008; Aronoff et al., 2010; van Hoesel, 2012; Gifford et al., 2014). However, bilateral CI users may exhibit similar or even less binaural summation than bimodal listeners on tasks of speech recognition in quiet or in co-located noise (e.g., Gifford et al., 2014, 2015). This is thought to be due to complementary, yet different information provided across ears in a bimodal hearing configuration (van Hoesel, 2012). Nevertheless, both bimodal and bilateral CI recipients demonstrate binaural summation.

Head shadow (or better-ear listening) may also differ across bimodal listening and bilateral CI stimulation. Head shadow is primarily dependent upon interaural level differences (ILDs) yielding frequency dependent differences in the signal-to-noise ratio (SNR) across ears. For

this reason, many bimodal listeners with sloping high-frequency losses and/or severe-toprofound hearing loss in the high-frequency region will not obtain equivalent head shadow for each ear. Several papers have demonstrated asymmetry in head shadow for individual ear conditions as well as for the bimodal condition for listeners demonstrating interaural asymmetry in audible bandwidth and/or speech understanding (e.g., Ching et al., 2004; Dunn et al., 2005; Gifford et al., 2014; Morera et al., 2005; Potts et al., 2009; Pyschny et al., 2014). In these cases, the poorer hearing ear—typically the HA ear—will derive little-to-no benefit from head shadow. Conversely, bilateral CI users generally exhibit symmetrical head shadow across ears due to the availability of ILDs (e.g., Litovsky et al., 2006; Buss et al., 2008; Grantham et al., 2008; Pyschny et al., 2014; Gifford et al., 2014).

Binaural unmasking of speech—commonly referred to as binaural squelch—is not available for bimodal listeners and not robust for bilateral CI users. Binaural unmasking of speech is dependent upon sensitivity to interaural time difference (ITD) cues allowing the listener to compare the timing differences of noise at the two ears thereby "squelching" the noise. This squelch effect is thought to allow for a higher internal SNR. While ITDs are present in both temporal fine structure and the temporal envelope, fine structure ITD resolution is generally more sensitive than envelope-based ITD resolution. Bimodal listeners do have access to temporal fine structure via acoustic hearing in the non-CI ear; however, fine structure is not well transmitted by the CI (e.g., Francart et al., 2009, 2011) and is thus not available across hearing modalities for bimodal listeners. Bilateral CI users also have limited access to fine structure ITDs outside of controlled laboratory conditions (e.g., Laback et al., 2004; Majdak et al., 2006; Grantham et al., 2008; Francart et al., 2009). The reason is that amplitude modulated pulse trains lack temporal fine structure given the high, fixed channel stimulation rates used in CI signal processing, interaural spectral mismatches, and lack of processor synchronization. Envelope ITDs, while present, are also limited due to processor asynchrony, the potential for variable channel and overall stimulation rates across ears, and channel interaction (e.g., van Hoesel, 2004; van Hoesel et al., 2008; Kerber and Seeber, 2013; Kan et al., 2015). Nevertheless, there have been reports of binaural unmasking of speech in bilateral CI users, though estimates have been small in magnitude (e.g., Schleich et al., 2004; Litovsky et al., 2006; Buss et al., 2008; Eapen et al., 2009; Verhaert et al., 2012; Gifford et al., 2014; Kokkinakis and Pak, 2014).

Spatial release from masking is another phenomenon for which hearing with two ears provides significant benefit. Spatial release from masking is thought to be due to a combination of both head shadow and binaural unmasking of speech, depending on the spectral and temporal characteristics of the signal and distracter(s) as well as the spatial location of signal and distracter(s). Research has shown that both bimodal and bilateral CI users derive benefit from spatial release from masking with similar degrees of benefit (e.g., Gifford et al., 2014; Weissgerber et al., 2017).

Finally, spatial hearing abilities may differ for bimodal and bilateral CIs users. Bimodal localization abilities are highly variable with conflicting reports regarding bimodal benefit. Specifically, some studies have demonstrated significant bimodal benefit for horizontal plane localization (e.g., Choi et al., 2017; Potts et al., 2014) and other studies have shown little-to-no benefit over unilateral hearing alone (e.g., Dorman et al., 2016; Potts & Litovsky, 2014).

Localization for bilateral CI users has been shown to be significantly better than either unilateral CI alone (e.g., Grantham et al., 2007; Potts & Litovsky, 2014; Dorman et al., 2016) and generally better than bimodal hearing can afford (Potts & Litovsky, 2014; Dorman et al., 2016). The mechanism driving bilateral CI benefit for both speech understanding and localization is thought to be ILD cues (van Hoesel and Tyler, 2003; Laback et al., 2004; Seeber and Fastl, 2008; Grantham et al., 2008; Dorman et al., 2013, 2014; Loiselle et al., 2016). Bimodal listeners generally do not have access to ILDs given the presence of sloping hearing losses and/or the severity of high-frequency thresholds—as ILDs are most robust for high-frequency stimuli (e.g., Macauley et al., 2010). Bimodal listeners with high-frequency audibility in the non-CI ear likely have access to ILDs and hence better localization abilities; however, there is a need to document the range of audiometric thresholds over which bimodal listening could confer localization abilities on par with bilateral CI users.

As described here, there are many listening conditions and associated auditory tasks for which there may be performance differences between bimodal and bilateral CI users. For the purposes of the current experiment, we chose to focus on *binaural summation*. The reason is that in most clinical environments, CI recipients are assessed on measures of speech recognition for each ear individually as well as in the bilateral/bimodal condition—whether that is bimodal or bilateral CI. That is, clinical convention for assessment inherently provides information regarding binaural summation. Thus, binaural summation is a clinically relevant concept holding diagnostic potential for determining bilateral CI candidacy.

#### **Current study**

It is often a simple decision for an individual to pursue unilateral cochlear implantation given poor speech understanding and a high degree of communication difficulty. However, it is much more difficult to make a decision about whether to continue use of a hearing aid (HA) in the non-CI ear or to pursue a second CI. Ideally, this decision would be based on a dataset derived from an examination of performance in realistic listening conditions for patients using bimodal and bilateral CI fittings. Such a dataset does not currently exist. In fact, clinical experience demonstrates that many adult sequential bilateral CI recipients obtain a second implant simply because the patient expressed desire for a second CI. In some cases, patients have requested a second CI despite clinicians' hesitations regarding the likelihood of obtaining bilateral CI benefit compared to the bimodal condition and/or concerns about loss of function should acoustic hearing preservation not be possible (Gifford et al. 2015). Consequently, it is more often the case that bilateral implantation for adult CI recipients in the U.S. is patient driven rather than data driven; however, there may be underlying audiologic data that point to patients' motivations for pursuing a second implant.

The current clinical assessment battery in the U.S., the minimum speech test battery (MSTB) for adult CI users (MSTB, 2011), includes monosyllabic words and AzBio sentences to be presented in quiet as well as in multi-talker babble. Though the MSTB does not specify a recommended configuration for the speech and noise stimuli, most US-based audiology clinics use a single loudspeaker delivering co-located speech and noise. In this

testing environment, there is no evidence that a second CI yields greater benefit than a bimodal CI configuration (Cullington and Zeng, 2011; Gifford et al., 2014, 2015; Dorman et al., 2015; Yoon et al., 2015; Luntz et al., 2014; Potts & Litovsky, 2014). Thus it is unclear whether those self-selecting for bilateral implantation are actually achieving better outcomes than the previous bimodal hearing configuration. Further it is unclear whether we can rely on these measures to help determine one's candidacy for a second implant.

The perceived usefulness of an intervention depends on the tests and listening environments used to measure it. Current clinical test measures and environments are likely not sufficient for assessment of outcomes for any configuration of bilateral hearing (e.g., van Hoesel, 2012). In this paper, we describe experiments in which we obtained estimates of speech understanding performance for 49 adult bimodal listeners and 36 adult bilateral CI recipients in both a standard clinical test environment and in a more realistic listening environment with semi-diffuse noise.

The overarching goal of this study was to determine whether testing in a semi-diffuse noise environment reveals differences in performance between bimodal and bilateral CIs that are not found when testing in a standard clinical test environment. Our primary hypothesis was that there would be no difference between bimodal or bilateral CI performance or binaural benefit (i.e. binaural summation) in a clinical test environment with a single loudspeaker, but that differences would arise in a complex listening environment using multiple loudspeakers and semi-diffuse noise. Our secondary hypothesis was that bilateral CI recipients would derive greater overall performance and binaural summation as compared to bimodal listeners in the complex listening environment.

### MATERIALS AND METHODS

#### Participants

Participants were 85 adult CI recipients who were recruited and participated in the research activities in accordance with Institutional Review Board approval. Participants' ages ranged from 19 to 90 years with a mean of 60.3 years. Study inclusion criteria required CI experience of at least 6 months with each implanted ear as well as full-time use of the most recent generation CI sound processor at the time of experimentation, i.e., the Advanced Bionics (AB) Harmony, the Nucleus N5 (CP810), and the MED-EL Opus 2. Additionally, bimodal participants were required to be full-time users of both their CI and HA technology.

Of the 85 participants, 49 were bimodal listeners and 36 were bilateral CI recipients. Mean CI experience with the implanted ear (or first implanted ear of the bilateral recipients) was 5.1 years with a range of 0.7 to 20.8 years. Mean bilateral CI experience for the 36 bilateral recipients was 3.1 years with a range of 0.7 to 9.0 years. Complete demographic information is provided in Tables 1 and 2 for the bimodal and bilateral participants, respectively. All 49 bimodal listeners exhibited significantly higher speech recognition in the CI ear as compared to the HA ear based on the binomial critical difference statistic for monosyllabic words (Thornton & Raffin, 1978). Thus, for all bimodal listeners in the current study, the CI ear was the better hearing ear. For the 36 bilateral CI users, however, just 9 participants exhibited significant interaural asymmetry in performance for monosyllabic word

recognition based on a binomial critical difference statistic (Thornton & Raffin, 1978) with 6 of the 9 exhibiting significantly higher performance with the first implanted ear (bilateral participants 6, 7, 9, 17, 32, and 36). The 9 bilateral CI users who exhibited interaural asymmetry in speech recognition are indicated via shading in Table 2.

Figure 1 displays individual and mean audiometric thresholds for the non-implanted ears of the 49 bimodal participants obtained on the day of study enrollment and assessment as well as the preoperative audiometric thresholds for the second implanted ears of the bilateral CI recipients-or the better hearing ear for simultaneous bilateral recipients-obtained from the medical records. All hearing losses were sensorineural; that is, bone conduction thresholds, while not displayed in Figure 1, were within 10 dB of air conduction thresholds at all octave frequencies from 500 through 4000 Hz. Individual audiometric thresholds ranged from the limits of normal hearing to a severe-to-profound hearing loss in the low-frequency range for both groups. Thresholds in the high-frequency range were all consistent with a severe-toprofound hearing loss. In order to calculate low-frequency pure tone average (LFPTA, mean threshold across 125, 250 & 500 Hz) and pure tone average (PTA, mean threshold across 500, 1000, and 2000 Hz), thresholds documented as "no response" were logged as 5 dB above the limits of the audiometer for insert earphone testing. For the bimodal participants, the mean LFPTA was 57.3 dB HL (range: 16.7 to 96.7) and the mean PTA was 84.3 dB HL (range: 53.3 to 110.0). For the second implanted ears of the bilateral CI recipients (or the better hearing ear in cases of simultaneous bilateral implantation), the mean LFPTA was 69.4 dB HL (range: 31.7 to 97.5 dB HL) and the mean PTA was 91.8 dB HL (range: 66.7 to 113.3 dB HL). A one-way analysis of variance was completed for LFPTA and PTA across participant groups (bimodal vs. bilateral). There was a significant main effect of participant group for LFPTA  $[F_{(1, 83)} = 10.53, p < 0.0001]$  and PTA  $[F_{(1, 83)} = 7.0, P = 0.01]$ . That is, although there was considerable overlap in audiometric thresholds between the participant groups, audiometric thresholds for the second CI ear (or better CI ear for simultaneous recipients) of the bilateral CI users were significantly poorer than the non-CI ear thresholds for the bimodal participants.

#### Hearing equipment

The HA settings for the non-implanted ear of all bimodal participants were verified to be providing NAL-NL1 target audibility for speech at 60 and 70 dB SPL (within 3 dB of NAL-NL1 targets), ensuring audibility for all presentation levels used here. If an individual's HA was not meeting NAL-NL1 targets (n = 7), the HA was reprogrammed prior to experimentation. All hearing aids were verified to be using an omnidirectional microphone setting and all front-end processing features were disabled prior to experimentation to provide as much across-subject consistency using the technology with which each listener was most accustomed. Hearing aid manufacturers were as follows: Phonak (n = 21), Unitron (n = 7), Oticon (n = 6), GN Resound (n = 4), Starkey (n = 3), Siemens (n = 3), Audibel (n = 3), and Widex (n = 2). Because we did not have access to the Audibel hearing aid software, the 3 Audibel users were reprogrammed using a loaner HA (Phonak Naida III UP without nonlinear frequency compression). For all 7 listeners for whom the HA was programmed, there was no acclimatization period provided. That is, testing commenced immediately following real-ear verification of hearing aid settings.

Page 7

CI audibility was verified using aided audiometric detection thresholds for frequency modulated pure tones to ensure thresholds were in the range of 20 to 30 dB HL for frequencies between 250 and 6000 Hz (Firszt et al. 2004; James et al. 2002; Skinner et al. 1999; Holden et al. 2007; Skinner et al. 1997). Preprocessing for CI programs was limited given the time frame over which these data were collected (late 2010 through early 2013). All AB and MED-EL CI recipients were tested using an omnidirectional microphone with AB recipients using T-Mic only—as neither AB or MED-EL had directional settings when data collected commenced. All Nucleus CI recipients were assessed using a standard directional microphone configuration with the addition of Autosensitivity Control (ASC) and Adaptive Dynamic Range Optimization (ADRO; James et al. 2002) as suggested by Wolfe and colleagues for use in background noise (Wolfe et al. 2009). All 85 participants reported full-time bilateral device usage—whether that be bilateral CI or CI plus contralateral HA.

#### Methods

This study was completed in a sound treated booth using either a single loudspeaker placed at a distance of 1 m from the listener, per standard clinical protocols for MSTB sound field testing, or the Revitronix R-SPACE<sup>TM</sup> system (Braintree, VT). For the R-SPACE<sup>TM</sup> system, each of the eight loudspeakers surrounded the listener circumferentially in a 360-degree arc with 45-degree separation between speakers. Each speaker was situated at a distance of 24 inches from the listener's head with speakers at the height of the listeners' ears. This was accomplished using an adjustable height chair.

To obtain a clinical-based estimate of speech recognition, each participant was administered the MSTB (MSTB, 2011) for each individual ear alone as well as in the bimodal or bilateral CI conditions. The MSTB includes Consonant Nucleus Consonant (CNC; Peterson & Lehiste 1962) monosyllables, AzBio sentences (Spahr et al. 2012) in quiet and in multi-talker babble at +5 dB SNR. Though the MSTB also recommends the use of the Bamford-Kowal-Bench Speech In Noise test (BKB-SIN; Etymotic Research, Elk Grove Village, IL), we did not administer the BKB-SIN in this experimental test battery; instead, we chose to use a truly adaptive measure to determine a speech reception threshold (SRT) for the purposes of time, greater accuracy, and better test-retest variability. The recorded target speech stimulus was always presented at 60 dB SPL (A weighted). For MSTB administration, all listeners were administered one 50-word list for CNC and one 20-sentence list for each AzBio condition, consistent with clinical protocol. The practice run was used for both CNC and AzBio sentences prior to assessment for each of the listening conditions.

To obtain a laboratory-based estimate of speech recognition in the presence of a semi-diffuse noise, the recorded Hearing In Noise Test (HINT; Nilsson, Soli and Sullivan, 1994) sentences were presented from a loudspeaker placed at 0 degrees while the R-SPACE<sup>TM</sup> proprietary restaurant noise (Compton-Conley et al. 2004) was presented from all eight loudspeakers. The restaurant noise was fixed at a level of 72 dB SPL (A weighted) with each speaker calibrated to a level of 63 dB SPL [72 – 10\* log(8)]. The level of the HINT sentences was varied adaptively using a 1-down, 1-up tracking procedure to provide an

estimate of 50% correct to obtain a SRT. For the first two reversals, the step size was 4 dB. For the remaining reversals, the step size was 2 dB. SRT was expressed in terms of the SNR, in dB, required to yield 50% correct.

For all speech recognition testing, participants were instructed to look forward at the speaker placed at 0 degrees and to repeat what they had heard following each sentence. Participants were encouraged to guess if not completely certain. A transmitting microphone was clipped on the upper torso as close to the participant's mouth as possible (lapel or collar). The experimenter wore a monaural earphone connected to the transmitting microphone ensuring that the spoken responses were audible and that ambient noise levels in the laboratory did not interfere with sentence scoring. The experimenter scored the participants' responses in real time during the study visit. Prior to each experimental session, all stimuli were calibrated in the free field using the substitution method with a Larsen Davis SoundTrack LxT or 800B sound level meter.

Subjective estimate of technology: Do you think you need a second CI?—In

addition to the speech recognition testing described above, following informed consent—and prior to commencing any testing—all bimodal participants were asked, "Do you think you need a second CI?" Participants were instructed to answer with a single response of either "yes" or "no". For the few participants who attempted to clarify their response with additional verbiage such as, "I can get by without a second CI so I technically do not 'need' a second CI," or, "Sometimes I think I do, but I'm not sure," we supplemented our original question with, "Do you think you would achieve better outcomes with a second CI?"

### RESULTS

#### MSTB

Individual and mean speech recognition scores for each individual ear as well as the bilateral condition (bimodal or bilateral CI) are shown in Figure 2 for CNC, AzBio and AzBio at +5 dB SNR. Circles represent bimodal data points and inverted triangles represent bilateral CI data points. In an attempt to describe outcomes for individual ear and bilateral/bimodal conditions, we characterized performance according to the HA, CI, and bimodal condition for the bimodal listeners and poorer CI, better CI, and bilateral CI condition for the bilateral CI recipients. The HA ear afforded speech recognition scores that were either equivalent to or poorer than the CI ear for all 49 bimodal listeners. For bilateral CI users who did not show a difference in performance between ears, we characterized the better and poorer ears according to the listener's subjective preference. All listeners reported having a "better hearing ear".

All statistical analyses were completed using SPSS version 25 (IBM, 2017). Statistical analyses for speech recognition scores were completed using linear mixed model analyses with participant group (bimodal vs. bilateral) and listening condition [poorer ear, better ear, and bilateral/bimodal] as the independent variables and speech recognition, in percent correct, as the dependent variable. Post hoc analyses were completed using the Holm-Sidak statistic. In addition to statistical analysis for speech recognition performance across conditions, we also completed one-way ANOVA for bilateral/bimodal benefit on each

measure. Benefit was calculated both in terms of percentage point benefit conferred by listening with two ears (bilateral or bimodal) minus the score obtained with the better ear alone as well as normalized benefit which takes into account the score for the better hearing ear. For example, standard bimodal benefit for an individual scoring 55% in the bimodal condition and 50% in the CI alone condition would be 5-percenage points with normalized benefit being 5%. Compare that to another individual scoring 100% in the bimodal condition and 95% in the CI alone condition for whom standard bimodal benefit would 5-percentage points with normalized benefit being 100%. The equation used to calculate normalized benefit was as follows:

[(Bilateral/bimodal – best ear alone) ÷ (100 – best ear alone)] x 100

#### **CNC** monosyllabic word recognition

For bimodal listeners, CNC word recognition ranged from 0 to 64% in the HA ear (mean 17%), 38 to 98% in the CI ear (mean 76%), and 48 to 98% in the bimodal condition (mean 81%). For bilateral CI users, CNC word recognition ranged from 22 to 90% with the poorer CI (mean 62%), 48 to 98% with the better CI (mean 76%), and 40 to 98% in the bilateral CI condition (mean 82%). Statistical analysis via linear mixed model revealed a significant effect of participant group  $[F_{(1,249)} = 60.5, p < 0.0001, \eta^2 = 0.33]$ , a significant effect of condition  $[F_{(2,249)} = 177.0, p < 0.0001, \eta^2 = 0.59]$ , and a significant interaction  $[F_{(2,249)} = 56.5, p < 0.0001, \eta^2 = 0.31]$ . Post hoc analyses revealed a significant difference in CNC scores for the bilateral and bimodal groups *for the poorer ear alone* (t<sub>249</sub> = 13.2, p < 0.0001). For the bilateral/bimodal condition and for the better ear alone, there was no difference in CNC scores between groups. Collapsed across participant group, there was a significant difference in CNC scores hetween the poorer and better ears (p < 0.0001) as well as the poorer and bilateral/bimodal condition (p < 0.001) for CNC words. There was no significant difference between the better ear and bilateral/bimodal condition (p = 0.14) for CNC words.

Bimodal/bilateral benefit, or binaural summation, for CNC word recognition ranged from -16 to 26-percentage points (mean 4.3) for the bimodal listeners and -8 to 20-percentage points (mean 5.4) for the bilateral CI users. Normalized bimodal/bilateral benefit for CNC word recognition ranged from -25 to 93% (mean 19.8) for the bimodal listeners and -50 to 69% (mean 20.7) for the bilateral CI users. Statistical analysis via one way ANOVA revealed no significant difference between participant groups for either standard bimodal/bilateral benefit [ $F_{(1, 83)} = 0.25$ , p = 0.62,  $\eta^2 = 0.003$ ] nor for normalized benefit [ $F_{(1, 83)} = 0.02$ , p = 0.88,  $\eta^2 = 0.0002$ ].

#### AzBio sentence recognition in quiet

For bimodal listeners, AzBio sentence recognition ranged from 0 to 88% in the HA ear (mean 27%), 48 to 99% in the CI ear (mean 86%), and 46 to 100% in the bimodal condition (mean 89%). For bilateral CI users, AzBio sentence recognition ranged from 37 to 99% in the poorer ear (mean 77%), 56 to 100% in the better hearing ear (mean 87%), and also 56 to 100% in the bilateral CI condition (mean 91%). Statistical analysis via linear mixed model revealed a significant effect of participant group  $[F_{(1,249)} = 76.9, p < 0.0001, \eta^2 = 0.24]$ , a

significant effect of condition  $[F_{(2,249)} = 146.1, p < 0.0001, \eta^2 = 0.54]$ , and a significant interaction  $[F_{(2,249)} = 65.6, p < 0.0001, \eta^2 = 0.35]$ . Post hoc analyses revealed a significant difference in AzBio scores for the bilateral and bimodal groups for the poorer ear only (t<sub>249</sub> = 14.4, p < 0.001). Similar to the CNC results, there was no difference in AzBio sentence recognition between groups for either the better ear alone or the bilateral/bimodal condition. Collapsed across participant group, there was a significant difference between the poorer and better ears (p < 0.0001) as well as the poorer ear and bilateral/bimodal condition (p < 0.0001) for AzBio sentences in quiet. There was not, however, a significant difference between the better ear and the bilateral/bimodal condition (p = 0.99) for AzBio in quiet.

Bilateral/bimodal benefit, or binaural summation, for AzBio sentence recognition in quiet ranged from –16- to 24-percentage points (mean 2.6) for the bimodal listeners and –4- to 15-percentage points (mean 3.0) for the bilateral CI users. Normalized bimodal/bilateral benefit for AzBio sentence recognition in quiet ranged –18 to 100% (mean 34.5) for the bimodal listeners and –57 to 100% (mean 31.0) for the bilateral CI users. Statistical analysis via one-way ANOVA revealed no significant difference between participant groups for either standard bimodal/bilateral benefit [ $F_{(1, 83)} = 0.42$ , p = 0.52,  $\eta^2 = 0.005$ ] nor for normalized benefit [ $F_{(1, 83)} = 0.21$ , p = 0.64,  $\eta^2 = 0.003$ ].

#### AzBio sentence recognition at +5 dB SNR

For bimodal listeners, AzBio sentence scores at +5 dB ranged from 0 to 41% in the HA ear (mean 7%), 8 to 95% in the CI ear (mean 52%), and 12 to 99% in the bimodal condition (mean 62%). For bilateral CI users, AzBio sentence scores at +5 dB ranged from 8 to 78% with the poorer CI (mean 36%), 17 to 87% with the better CI (mean 54%), and 26 to 95% with bilateral CIs (mean 63%). Statistical analysis revealed a significant effect of participant group [ $F_{(1,249)} = 22.7$ , p < 0.0001,  $\eta^2 = 0.08$ ], a significant effect of condition [ $F_{(2,249)} = 111.7$ , p < 0.0001,  $\eta^2 = 0.47$ ], and a significant interaction [ $F_{(2,249)} = 15.1$ , p < 0.0001,  $\eta^2 = 0.11$ ]. Post hoc analyses revealed a significant difference in AzBio sentence recognition for the bilateral and bimodal groups for the poorer ear only ( $t_{249} = 7.2$ , p < 0.001). As reported for the other measures, there was no difference in AzBio sentence recognition. Collapsed across participant group, there was a significant difference between the poorer and better ears (p < 0.0001), the poorer ear and bilateral/bimodal condition (p < 0.0001), as well as between the better ear and the bilateral/bimodal condition (p = 0.003) for AzBio at +5 dB.

Bilateral/bimodal benefit, or binaural summation, for AzBio sentence recognition at +5 dB ranged from -13 to 52-percentage points (mean 10.1) for the bimodal listeners and -15 to 25-percentage points (mean 8.6) for the bilateral CI users. Normalized bimodal/bilateral benefit for AzBio sentence recognition at +5 dB ranged -20 to 80% (mean 24.2) for the bimodal listeners and -21 to 77% (mean 23.3) for the bilateral CI users. Statistical analysis via one-way ANOVA revealed no significant difference between participant groups for either standard bilateral/bimodal benefit [F<sub>(1, 83)</sub> = 0.40, p = 0.53,  $\eta^2 = 0.005$ ] nor for normalized benefit [F<sub>(1, 83)</sub> = 0.03, p = 0.86,  $\eta^2 = 0.0004$ ].

#### Summary of results for clinical measures

For the tests of speech understanding included in the MSTB, presented via a single loudspeaker at 0 degrees, we found 1) no significant differences in performance between bimodal and bilateral CI listeners in the better ear alone and bilateral/bimodal conditions, and 2) no significant differences in the degree of binaural summation as compared to the better ear alone.

#### Adaptive HINT SRT in the R-SPACE<sup>™</sup> test environment

For the adaptive HINT SRT obtained in the R-SPACE<sup>™</sup> listening environment, there were a number of conditions for which the bimodal listeners were unable to complete the task at any SNR. In order to complete statistical analyses on the entire sample, we assigned an SRT of 25 dB SNR for such outcomes, representing the maximum presented SNR in the adaptive track. In the HA-only condition, 34 of 49 (69.4%) listeners could not complete the task. In the CI only condition, just one listener could not complete the task. In the bimodal condition, all 49 listeners were able to complete the task. For bimodal listeners, adaptive HINT SRTs ranged from 7 to 25 dB in the HA ear (mean 21.6 dB), 3 to 25 dB in the CI ear (mean 9.5 dB), and 0.7 to 25 dB in the bimodal condition (mean 8.5 dB).

For bilateral CI users, adaptive HINT SRTs ranged from 4 to 18 dB with the poorer CI (mean 10.9 dB), 3 to 16 dB with the better CI (mean 9.3 dB), and 0 to 12 dB with bilateral CIs (mean 6.4 dB). Thus, all bilateral CI users were able to complete the SRT task in each tested condition. The interquartile range (IQR) for the bilateral CI users in the bilateral CI condition was 4.8 to 8.8 dB SNR—a range that will be used later in the paper.

Statistical analysis via linear mixed model revealed a significant effect of participant group  $[F_{(1,249)} = 69.9, p < 0.0001, \eta^2 = 0.22]$ , a significant effect of condition  $[F_{(2, 249)} = 110.12, p < 0.0001, \eta^2 = 0.47]$ , and a significant interaction  $[F_{(2,249)} = 32.3, p < 0.0001, \eta^2 = 0.21]$  for HINT SRT, in dB SNR. Post hoc analyses revealed a significant difference in HINT SRTs for the bilateral and bimodal groups for both the poorer ear ( $t_{249} = 11.4, p < 0.001$ ) *as well as for the bilateral/bimodal condition* ( $t_{249} = 2.3, p = 0.02$ ). As reported for the other measures, there was no difference in HINT SRTs between groups for the better ear alone. Collapsed across participant group, there was a significant difference between the poorer and better ears (p < 0.0001), the poorer ear and bilateral/bimodal condition (p < 0.0001), and the better ear and bilateral/bimodal condition (p = 0.03).

As completed with the MSTB measures, we also performed statistical analysis for the degree of bimodal/bilateral benefit obtained on the adaptive HINT across participant groups. Due to the adaptive nature of this task, only standard benefit (in dB) could be calculated. Bimodal/bilateral benefit for the adaptive HINT SRT ranged from -5 to 8 dB (mean 1.0) for the bimodal listeners and 1 to 8 dB (mean 4.9) for the bilateral CI users. Statistical analysis revealed a significant difference between participant groups bimodal/bilateral benefit on the adaptive HINT [F<sub>(1, 83)</sub> = 50.3, p < 0.0001,  $\eta^2 = 0.38$ ].

### Summary of results for R-SPACE™ testing

For tests of adaptive sentence recognition in the presence of restaurant noise via 8 loudspeakers, we found 1) significant differences in performance between bimodal and bilateral CI listeners in the bilateral/bimodal condition (bimodal vs. bilateral CI), and 2) significant difference between groups in the degree of binaural summation as compared to the better hearing ear alone. Specifically, the bilateral CI group exhibited significantly better performance in the bilateral/bimodal condition and significantly greater summation as compared to the better ear alone.

#### Do you think you need a second CI?

As discussed in the Methods section, at the time of study enrollment, all bimodal participants were posed the question, "Do you think you need a second CI?" Individual answers to this question are displayed in Table 1. Nineteen of 49 (39%) bimodal listeners reported that they felt they needed a second CI and 30 of 49 (61%) reported that they did not need a second CI. To understand which variables contributed to a patient's bimodal SRT and bimodal benefit for SRT, a stepwise regression was completed to assess the degree of association between bimodal SRT or bimodal benefit (dependent variables) and the following independent variables: age, LFPTA, aided SII at 60 dB SPL, degree of interaural asymmetry in SRT between CI and HA ears (in dB), and the participant's answer to the question, "Do you think you need a second CI?"

For bimodal SRT (in dB SNR), the stepwise regression model included the following variables ordered from greatest significance: answer to the question (yes or no), age, and SRT interaural asymmetry. That is, neither LFPTA nor aided SII provided significant value to the regression model for bimodal SRT. A significant regression equation for bimodal SRT was determined with the answer to the question (yes or no), age, and SRT interaural asymmetry  $[F_{(3,45)} = 9.13, p < 0.0001]$  with a correlation coefficient of 0.62 and a corresponding r<sup>2</sup> value of 0.38. That is, bimodal listeners answering "yes" to needing a second CI, who are older, and who have greater interaural asymmetry in SRT across ears exhibited significantly higher (i.e. poorer) bimodal SRT values.

For bimodal benefit in SRT (in dB), the stepwise regression model included the following variables ordered from greatest significance: SRT interaural asymmetry, answer to the question (yes or no), and LFPTA. That is, neither age nor aided SII provided significant value to the regression model for bimodal benefit in the HINT SRT. A significant regression equation for bimodal benefit was determined with interaural asymmetry, answer to the question (yes or no), and LFPTA [ $F_{(3,45)} = 17.57$ , p < 0.0001] with a correlation coefficient of 0.73 and a corresponding r<sup>2</sup> value of 0.54. That is, bimodal listeners with greater interaural asymmetry in SRT, answering "yes" to needing a second CI, with poorer LFPTA in the non-CI exhibited significantly lower bimodal benefit.

Figure 3 displays both bimodal SRT and bimodal SRT benefit as a function the participants' answer to the question regarding bilateral CI. On the left-hand side of Figure 3, individual and mean bimodal SRTs are displayed, in dB SNR, stratified by the participants' answers to the question. Error bars represent the 95% confidence interval for each distribution. The gray

shaded region represents the IQR for the 36 bilateral CI listeners on this measure and the dotted horizontal line indicates the bilateral CI median. This shaded region is labeled "equivocal" given that bimodal listeners achieving scores within the bilateral IQR would likely achieve similar scores should they pursue a second CI—in other words, this is the range of SRTs over which we may not expect bimodal listeners to demonstrate significant benefit *on this measure* with a second CI based on bilateral CI users' performance in this study. Individuals scoring below (i.e. better) this range are better suited with a bimodal hearing configuration and those scoring above (i.e. poorer) than this range are more likely to achieve better outcomes with a second CI. The arrows labeled *bimodal* and *bilateral* on Figure 3 represent this logic.

An unpaired t-test (Student's test) was completed comparing bimodal SRT for those answering "yes" and those answering "no" to the bilateral question. There was a significant difference in bimodal SRTs between the groups (t = -3.91, two-tailed p = 0.0003) with those answering "no" to a second CI achieving significantly lower (i.e. better) bimodal SRT (mean 6.8 dB) as compared to those answering "yes" to a second CI (mean 11.3 dB).

For the 19 bimodal listeners answering "yes" to needing a second CI, 11 (58%) scored more poorly than the 75<sup>th</sup> percentile for bilateral CI users and thus correctly identified the lack of benefit obtained from the non-implanted ear. Eight of the 19 bimodal listeners (42%) answering "yes" to a second CI scored within the bilateral IQR and thus may not obtain better auditory only speech recognition in noise should they pursue a second CI. None of the 19 bimodal listeners answering "yes" to a second CI achieved better scores than the bilateral 25<sup>th</sup> percentile. Thus, the "yes" respondents were quite accurate in their reporting.

For the 30 bimodal listeners answering "no" to needing a second CI, 23 listeners (77%) scored either within the bilateral IQR (n = 16) or better than the 25<sup>th</sup> percentile (n = 7) for bilateral CI recipients. Thus over <sup>3</sup>/<sub>4</sub> of the "no" respondents correctly rejected bilateral CI candidacy as it is highly unlikely that they would achieve significantly better outcomes with bilateral implants. However, 7 of the 30 "no" respondents (23%) scored more poorly than the 75<sup>th</sup> percentile for bilateral CI recipients in this sample. Thus for "no" respondents, the use of this question would potentially miss 23% of those who would be better served with a second CI.

In the right-hand panel of Figure 3, individual and mean bimodal benefit (bimodal minus CI alone) for adaptive HINT SRT is plotted as a function of the listeners' responses to the question regarding a second CI. An unpaired t-test (Student's test) was completed comparing bimodal SRT benefit across the yes/no respondent groups. There was a significant difference in bimodal benefit between the respondent groups (t = -3.60, two-tailed p = 0.0008) with those answering "no" to a second CI achieving significantly greater bimodal benefit (mean 2.1 dB) compared to those answering "yes" to a second CI (mean benefit -0.8 dB). On the basis of this analysis of bimodal SRT benefit (Figure 3, right panel), we can conclude that those patients indicating need for a second CI are generally accurate in their reporting lending support to the fact that we are currently offering sequential bilateral implants to bimodal listeners who express a desire for bilateral implantation.

#### Patient-specific variables explaining bimodal performance

Additional unpaired t-tests were completed for the bimodal SRT data stratified by a "yes" or "no" answer for each of the following variables: LFPTA and PTA of the non-implanted ear, HA and CI alone scores for all speech measures, and interaural asymmetry in speech scores for all speech measures [CNC, AzBio (quiet and +5), and adaptive HINT]. Statistical analysis found no difference between yes/no respondents for the following variables: CI only scores (p > 0.25 for all comparisons), interaural asymmetry for CNC words (p = 0.14), and interaural asymmetry for AzBio sentences at +5 dB (p = 0.23). Statistical analysis revealed a significant difference between yes/no respondents for the following variables: LFPTA (t = 2.0, p = 0.048), PTA (t = 2.5, p = 0.02), HA only SRT (t = 3.9, p = 0.0003), HA only CNC (t = 3.2, p = 0.003), HA only AzBio in quiet (t = 3.7, p = 0.0006), HA only AzBio at +5 dB (t = 2.6, p = 0.011), interaural asymmetry for HINT SRT (t = 2.3, p = 0.03), and interaural asymmetry for AzBio in quiet (t = 2.6, p = 0.013).

Figure 4 displays bimodal SRT, in dB SNR, plotted as a function of all variables deemed significantly different across the respondent groups. Those answering "yes" and "no" are represented by filled and unfilled symbols, respectively. The solid black line in each panel represents linear regression across all data for both respondent groups. Linear regression revealed no relationship between bimodal SRT and LFPTA (p = 0.26), PTA (p = 0.16), HINT SRT interaural asymmetry (p = 0.67), and AzBio quiet interaural asymmetry (p = 0.74). That is, the distributions of bimodal SRTs for "yes" and "no" respondents were nearly completely overlapping across LFPTA, PTA, and interaural asymmetry for HINT SRT and AzBio quiet. Thus we cannot use these variable to guide clinical-decision making regarding which patients should get a second CI on the basis of LFPTA, PTA, or interaural asymmetry in HINT SRT and AzBio quiet.

The slope of the regression function was significantly different than a horizontal line for bimodal SRT regressed against all HA-alone scores as follows: CNC:  $F_{(1,47)} = 7.1$ , p = 0.01; AzBio quiet:  $F_{(1, 47)} = 8.5$ , p = 0.005, AzBio +5:  $F_{(1, 47)} = 6.3$ , p = 0.02, and HINT:  $F_{(1, 47)} = 6.3$ 19.5, p < 0.0001. Shading was added to these figures displaying a significant relationship such that the darker gray shading represents the region of overlap between yes and no respondents and the lighter shading was provided to help highlight the range of HA-alone scores over which we could expect either a "yes" or "no" answer regarding a second CI. On the basis of this dataset, we would not expect a bimodal patient to request a second CI if their HA only score exceeded 30% CNC, 45% AzBio in quiet, or 18% AzBio at +5 dB. For R-SPACE<sup>TM</sup> adaptive HINT, these results suggest that bimodal patients with a HA-alone SRT better than 25 dB SNR—a criterion threshold representing an inability to complete the task—would not pursue a second CI. Note that these data do not suggest that individuals with HA-only scores above 30% CNC, 45% AzBio quiet, 18% AzBio at +5 dB, or better than 25 dB SNR for adaptive HINT would not achieve better performance with bilateral CIs. Rather, these data suggest that these HA-only scores may separate patients who would voluntarily request a second CI from those who may express that they do not need a second CI.

### Ask the patient: clinical application

In order to quantify the clinical appropriateness of using this simple question, the "yes" and "no" responses were characterized according to hit, miss, false positive, and correct rejection in a contingency table (Table 3). For bimodal data points falling within gray zone of uncertainty in Figure 3, we characterized these responses as "correct" for both "yes" and "no" responders. We recognize that while this is not an entirely accurate approach, we argue that this is an appropriate choice in this situation given that 1) we do not know the true incidence of bilateral CI candidacy for existing adult bimodal listeners and 2) there is no widely accepted criterion for determining bilateral CI candidacy. Thus we maintain that if a bimodal listener's SRT falls within the zone of uncertainty (i.e. within the bilateral IQR), because we cannot state whether that patient's SRT would be most likely to improve or decline following bilateral implantation, we are assuming that the patient's intuitive response was accurate.

As shown in Table 3, the sensitivity (or hit rate) of this simple question is extremely high with 100% of the "yes" respondents' SRTs falling within the bilateral IQR or above (poorer than) the bilateral 75<sup>th</sup> percentile. Correspondingly, the false positive rate was 0% as none of the "yes" respondents had SRTs lower than (better than) the bilateral 25<sup>th</sup> percentile. The specificity, or correct rejection rate, of this question was moderately high with 77% of the "no" respondents' SRTs falling within the bilateral IQR or below (better than) the 25<sup>th</sup> percentile. The false negative rate was moderately low with 23% of the "no" respondents scoring more poorly than the bilateral 75<sup>th</sup> percentile.

### DISCUSSION

We are currently making clinical decisions regarding bilateral cochlear implant candidacy based on limited clinical information. Many adults obtaining a second implant are those individuals who actively pursue this intervention-often despite having significant residual acoustic hearing in the non-CI and measurable bimodal benefit (e.g., Gifford et al., 2015). Thus it is common practice for adult bilateral implantation to be patient driven, rather than data driven. For this reason, we were motivated to complete this study to investigate whether bimodal listeners self-selecting for bilateral implantation may be expected to achieve better outcomes following bilateral implantation using a multiple-baseline, cross-sectional study design. Our hypotheses were as follows: 1) there would be no difference between bimodal or bilateral CI benefit (i.e. binaural summation) in a clinical test environment with a single loudspeaker, but that between-group differences would be evident in a complex listening environment using multiple loudspeakers and semi-diffuse noise, and 2) bilateral CI recipients would derive greater overall performance and binaural summation than bimodal listeners in the complex listening environment. An exploratory goal of this project was to investigate the subjective accuracy of bimodal listeners' perception regarding whether or not they needed a second implant.

The results of the current study revealed that bilateral/bimodal or "two-eared" performance was not significantly different between the bimodal and bilateral CI listeners for any of the clinical MSTB measures, supporting our primary hypothesis. This finding was consistent with similar reports in the literature for both between-subjects (Gifford et al., 2014;

Kokkinakis and Pak, 2014) and within-subjects (Luntz et al., 2014; Potts and Litovsky, 2014; Gifford et al., 2015) comparisons of bimodal and bilateral CI outcomes on clinical tests of speech recognition. Thus, we may not be able to reliably use our current clinical measures of speech understanding, when presented via a single loudspeaker, to determine bilateral CI candidacy for bimodal listeners or to determine whether a bilateral CI user has demonstrated significant benefit relative to his or her own bimodal hearing configuration. However, a recent study of 22 sequential bilateral adult CI users revealed significantly higher bilateral CI scores for CNC words and AzBio sentences in quiet (Yawn et al., 2018). Thus, it is possible that a larger scale, longitudinal investigation of sequential bilateral CI recipients may prove clinically valuable for determining bilateral CI candidacy.

In the current study, bilateral/bimodal performance on the adaptive HINT in R-SPACE<sup>TM</sup> was significantly better for the bilateral CI recipients. This finding provides supporting evidence for our secondary hypothesis and suggests that we may be able to use a complex listening environment, like that offered by the R-SPACE<sup>TM</sup> system, to determine bilateral CI candidacy and to determine whether a bilateral CI user has obtained significant benefit relative to his or her own bimodal listening condition. Indeed, we previously demonstrated that speech recognition in the R-SPACE<sup>TM</sup> system was the only measure for which 8 sequential bilateral CI recipients—all of whom exhibited above-average performance in the bimodal condition—demonstrated significant improvement relative to his/her own bimodal condition (Gifford et al., 2015).

### R-SPACE<sup>™</sup> to determine bilateral CI candidacy

Using the IQR for the 36 bilateral CI users in this study, we could reasonably recommend a second CI to bimodal listeners whose bimodal SRT was higher (i.e. poorer) than 8.8 dB SNR—a score representing the 75<sup>th</sup> percentile for bilateral CI users. In other words, bimodal listeners with SRTs higher (i.e. poorer) than 8.8 dB, would stand a 75% chance of achieving better auditory only speech recognition in complex noise environments with a second CI as compared to a bimodal hearing configuration. Indeed, a similar method using the third quartile for PTA and resultant speech recognition outcomes has been proposed for determining pediatric CI candidacy for children whose audiometric thresholds are outside labeled indications (Leigh et al. 2016).

On the other end of the spectrum, we could reasonably discourage bilateral candidacy for bimodal listeners with SRTs lower (i.e. better) than 4.8 dB SNR—a score representing the 25<sup>th</sup> percentile for bilateral CI users. In other words, bimodal listeners achieving SRTs below 4.8 dB would only stand a 25% chance of achieving better auditory only speech recognition in complex listening conditions and would thus be advised to retain bimodal hearing. For bimodal listeners obtaining SRTs between 4.8 and 8.8 dB SNR, we cannot reasonably make predictions regarding whether they might be expected to benefit from a second CI. Thus this region has been shaded in gray on Figure 3 and is labeled equivocal as it is represents a "gray zone" of uncertainty.

The use of the adaptive HINT in the R-SPACE<sup>TM</sup> environment would allow clinics to make data-driven recommendations regarding sequential bilateral cochlear implantation for existing adult bimodal patients. This is a quick evidence-based recommendation given that

the adaptive HINT SRT takes approximately 6 minutes to both administer and score. However, many clinics will not have the space, time, nor the funding to obtain and routinely use an R-SPACE<sup>TM</sup> system. For these clinics, an alternative method for making a recommendation is necessary. In such circumstances, asking the patient whether s/he believes s/he needs a second CI may prove clinically useful.

#### Ask the patient

All bimodal participants were asked the question, "Do you think you need a second CI?" Nineteen of 49 (39%) reported they felt they would benefit from a second CI. Of the 19 listeners reporting need for a second CI, 11 (58%) scored more poorly than the 75<sup>th</sup> percentile for the bilateral CI users and the remaining 8 scored within the IQR for bilateral CI users on this task. Thus all 19 "yes" respondents were somehow aware of the benefit, or lack of benefit, from a bimodal hearing configuration. Thus the sensitivity (or hit rate) of this question was perfect in this sample with a correspondingly perfect false positive rate. The specificity of this question was also high as 23 of the 30 "no" respondents (or 77%) scored within the bilateral CI IOR or better than the bilateral CI 25<sup>th</sup> percentile. Based on the current dataset, the primary concern with this question is the false negative rate. Specifically, 7 of the 30 "no" respondents (or 23%) scored more poorly than the 75<sup>th</sup> percentile for bilateral CI users. It is quite possible that these 7 bimodal listeners may have placed greater internal weight on acoustic hearing for a multitude of possible reasons including natural sound quality, music perception, music appreciation, fear of acoustic hearing loss, etc. The results of the current study cannot speak to the participants' internal reasoning or motivation for their answer to the question, "Do you think you need a second CI?" Future investigation is needed in this area.

While we recognize that bilateral CI candidacy for adults cannot be definitively determined on the basis of this study, we can conclude that for this group of 85 CI recipients, asking the 49 bimodal patients whether they needed a second CI would have been a satisfactory alternative to advanced, laboratory-based experimentation with multiple loud speakers. These results provide evidence in support of current clinical trends. That is, current clinical practice is consistent with a patient-driven model of bilateral implantation as compared to a data-driven model of determining bilateral candidacy. The results from this study would suggest that this patient-driven model is likely appropriate and that patient perception regarding need for a second CI is largely consistent with laboratory-based results in a complex listening environment.

#### Limitations

We recognize that the differences observed between groups could be, in part, due to relatively small sample sizes and an uneven sample across the two groups. For this reason, additional investigation is warranted with larger sample sizes and current generation hearing technology. We also recognize that differences in HAs across the bimodal listeners could have influenced the outcomes. At the time of study development, we originally felt that it would be best to assess each listener with his/her familiar HA settings; however, future experimentation will include identical HAs across bimodal listeners for consistency. Relatedly, although we removed all front-end processing and programmed omnidirectional

microphone settings for all HAs in an attempt to provide between-subject consistency, it is possible that this could have also influenced outcomes. Future investigation using front-end processing and/or directional microphones could prove valuable for determining differences across hearing modalities. Furthermore, though all 85 study participants reported full-time use of both hearing devices, this study was completed prior to the widespread availability of datalogging verification of device wear time. Because wear time has potential to impact performance, and not all bimodal listeners may use their HA on a full-time basis (Neuman et al., 2017), this is a limitation of the current study. Further investigation is needed with objective verification of device wear time for all hearing technology.

Another possible reason for the between-group differences in performance is interaural asymmetry in speech understanding for the bimodal listeners. Though we would argue that this is a driving factor for the superiority of the bilateral CI users' performance and bilateral benefit, this may be due to sampling. Specifically, more individuals with asymmetric hearing losses are pursuing unilateral cochlear implantation resulting in greater interaural symmetry in audibility and speech recognition in the bimodal hearing configuration (e.g., Firszt et al., 2012; van Loon et al., 2017; Sladen et al., 2018). In the current dataset, all 49 bimodal participants had severe-to-profound hearing loss in the high frequencies and all exhibited significant interaural asymmetry in monosyllabic word understanding using binomial critical difference table for monosyllabic word recognition (Thornton & Raffin, 1978). In contrast, just 9 of 36 (25%) of bilateral CI users exhibited significant interaural asymmetry for monosyllabic word recognition.

Listener age may also be factor. Specifically, none of the five youngest bimodal participants (aged 32 to 45 years) in this sample stated a need for a second implant. This is not likely an issue that the youngest individuals also had better audiometric thresholds in the non-CI ear, as there was no correlation between listener age and LFPTA in the non-CI ear (r = 0.11, p = 0.45). This finding could be due to sampling as there were bimodal participants in their mid-to-late 40s who expressed a need for a second CI. Nonetheless, listener age should be studied more systematically in future studies as related to bimodal/bilateral candidacy.

As described in reference to Figure 1, there was a significant difference in audiometric thresholds between the non-CI ear for the bimodal listeners and the preoperative audiograms for the second implanted ear (or better hearing ear) of the bilateral CI users. Specifically, the bilateral CI users had significantly higher (i.e. poorer) audiometric thresholds, on average. This is consistent with a recent prospective study of 287 preoperative CI candidates of whom those self-selecting for sequential bilateral implantation had significantly poorer preoperative audiometric thresholds in the second implanted ear as compared to the group of individuals who had chosen to retain bimodal hearing (Holder et al., 2018). Despite significant differences at the group level, there was still considerable overlap in audiometric thresholds between the two groups—both in the current study as well as in Holder et al. (2018). This degree of overlap coupled with the fact that there was no significant association between either LFPTA or aided SII in the non-CI ear and bimodal performance for the 49 bimodal participants in the current study warrants further investigation into the reliability of audiometric threshold in determining bilateral CI candidacy. Put another way, this is a major clinical problem because these two groups of patients are clinically similar with respect to

audiometric threshold and speech understanding thereby offering the clinician little distinguishable difference between those who are likely bilateral CI candidates versus those who would fare better with bimodal hearing. It is important to note here that all bimodal listeners in the current study had aidable low-frequency hearing and severe-to-profound hearing loss in the high-frequency region. Further all 85 participants had normal inner ear anatomy. Thus we cannot necessarily generalize these findings to bimodal listeners with better high-frequency hearing or individuals who have cochlear anatomical anomalies.

Prior to commencing experimentation, all bimodal participants were asked whether they felt they needed a second CI. This question was posed verbally to each of the participants requesting a verbal answer. We recognize that asking the patient in person as opposed to presenting a written question could have biased the participants' answers. Future studies should investigate whether there may be differences between verbal and written responses and whether either of these methods would be best used in a clinical CI practice. Further we did not provide a reference for this question. That is, we did not ask the participant to consider speech recognition, sound quality, spatial hearing, music listening, or any particular outcome. We felt this to be an organic method for posing the question given that many adult sequential bilateral CI users received a second implant following self-selection of bilateral candidacy. However, we recognize that it is possible that the participants' answer to this question may be different when considering various circumstances. This may be particularly true for tasks of music perception and appreciation for which acoustic hearing yields significant benefit over electric hearing alone (e.g., Kong et al., 2004; Dorman et al., 2008; El Fata et al., 2009; Gfeller et al., 2012; Kong et al., 2012; Prentiss et al., 2015; Crew et al., 2015). Further we did not document the underlying etiology of hearing loss for our participants. Depending on a known etiology, particularly one associated with rapid progression, this could influence the patient's answer to this question as well as shaping clinical recommendations for bilateral CI candidacy.

Another issue is the fact that some listeners' scores on MSTB metrics were affected by ceiling effects. CNC word recognition and AzBio sentences in quiet were particularly affected for the bilateral/bimodal condition (Figure 2). Scores for AzBio sentences at +5 dB, however, did not have the same issue with ceiling effects yet, the trends were the same; that is, there was no difference between bimodal and bilateral CI performance nor binaural summation obtained between the listener groups for AzBio at +5 dB. As CI recipient performance continues to improve over time, we will need to re-evaluate our clinical test battery to ensure that our measures are largely unaffected by floor and ceiling effects as this could negatively impact clinical decision making.

Finally, we recognize that a cross-sectional study design does not afford the same level of experimental control that a longitudinal, within-subjects study of sequential bilateral CI users would offer. That is, we cannot accurately predict where our bimodal listeners would perform with respect to the scores for the bilateral CI population. Furthermore, there was such a broad range of performance scores and degrees of binaural summation in both groups of listeners—highlighting the clinical difficulty of determining bilateral CI candidacy for the individual patient. Thus there is great need for a large scale, longitudinal assessment of

outcomes for sequential bilateral CI recipients on clinical and laboratory measures of speech recognition, sound quality, and subjective estimates of communication and quality of life.

#### Summary

This dataset provides us with additional information regarding the range of HA-only scores over which we might expect a bimodal patient to request evaluation for a second implant. Referencing the clinical MSTB measures, the upper cutoff for those expressing need for a second implant was 30% CNC, 45% AzBio quiet, and 18% AzBio in noise at +5 dB SNR. There is a precedent for choosing 30% CNC word recognition for determining ear specific CI candidacy as two North American multi-site studies—Nucleus Freedom (Balkany et al. 2007) and Cochlear Revised Indications Study (Sladen et al. 2017)-both used 30% CNC word recognition in the ear to be implanted as the criterion guiding CI candidacy. Furthermore, both studies demonstrated significant speech recognition benefit for the CI recipients using this criterion. It is critical to note here that we are not suggesting that individuals scoring above 30% CNC, 45% AzBio in quiet, and 18% AzBio at +5 dB SNR in the HA ear would not benefit from obtaining a second implant. Rather, we are stating that individuals scoring above these levels in the HA ear may not be expected to actively pursue a second CI nor may they be amenable to considering a second CI per clinician recommendation. More research is needed in this area with larger sample sizes and broader ranges and configurations of audiometric thresholds in the non-implanted ear to definitively define indications guiding bimodal and bilateral CI candidacy. We also need to investigate efficacy of newer CI and HA processing and preprocessing strategies to determine whether differences may be seen with current systems. Further we need large prospective studies of bimodal listeners with various degrees of hearing thresholds and speech recognition performance in the HA ear to fully describe the expected benefit from a second CI as well as the true incidence of bilateral CI candidacy amongst modern-day, adult bimodal listeners.

### CONCLUSION

Any view of the usefulness of an intervention depends on the tests used to measure it. In this project, we compared clinical tests of speech recognition in quiet or co-located noise as well as speech recognition in laboratory-based, complex listening environments. The outcomes of this research can impact clinical decision making regarding bilateral candidacy for adult bimodal listeners. The results of this study suggest the following:

- Clinical measures of speech recognition with a single loudspeaker are not sensitive enough to distinguish between bimodal and bilateral CI performance nor binaural summation.
- An adaptive speech recognition test in high level, semi-diffuse noise using the R-SPACE<sup>™</sup> system identified performance differences between bimodal and bilateral CI patients, with bilateral CI recipients achieving significantly lower (i.e better) SRTs.
- The patient's answer to the question, "Do you think you need a second CI?" held high sensitivity for identifying potential bilateral CI candidates and

moderately high specificity for correctly rejecting bimodal listeners likely best suited with a bimodal hearing configuration.

- Thus, in the absence of an R-SPACE<sup>TM</sup> system in a clinical setting, asking the patient whether or not s/he thinks s/he needs a second CI may be sensitive for determining bilateral candidacy.
- For this 85-participant sample, the question would have been a satisfactory alternative to R-SPACE<sup>TM</sup> testing for determining bilateral CI candidacy.
- Using both a quantitative measure of speech recognition in a complex listening environment as well as a qualitative patient-derived response regarding bilateral candidacy would jointly yield the most accurate, evidence-based recommendation regarding adult bilateral candidacy.
- The current clinical practice of offering a second CI to adult bimodal listeners expressing desire and/or need for a second CI appears to be an accurate and evidence-based protocol.

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### Figure 1:

Individual and mean audiograms for the non-implanted ear of the 49 bimodal listeners and the second implanted ear for the bilateral CI recipients in the current study. For bilateral CI users obtaining both implants in the same surgery, thresholds for the better hearing ear are displayed. Error bars represent  $\pm 1$  standard error.

Page 27



#### Figure 2:

Individual and mean speech recognition scores for CNC words, AzBio sentences in quiet, AzBio sentences at +5 dB, and R-SPACE<sup>TM</sup> adaptive HINT. Circles and inverted triangles represent bimodal and bilateral CI recipients, respectively. Red symbols represent the poorer hearing ears, yellow symbols represent the better hearing ears, and green symbols represent the bilateral/bimodal condition for each group. Statistical significance *across listening conditions* is indicated by brackets and asterisks above the symbols. Statistical significant

*across participant groups* is indicated by dashed brackets underneath the tick labels on the x-axis. Error bars represent  $\pm 1$  standard error.



#### Figure 3:

Individual bimodal SRT (dB SNR, left) and bimodal benefit (dB, right) stratified by the bimodal listeners' responses to the question, "Do you think you need a second CI?" The gray shaded region on the left-hand figure represents the interquartile range (IQR) for the bilateral CI users' in the bilateral CI condition with black dotted line representing the median SRT for the bilateral CI group. The error bars indicate the 95% confidence interval for each distribution.

Gifford and Dorman

Page 30



#### Figure 4:

Individual bimodal SRTs, in dB SNR, as a function of the variables found to be significantly different across yes (filled circles) and no (unfilled circles) respondents: LFPTA, PTA, interaural asymmetry (R-SPACE<sup>TM</sup> adaptive HINT and AzBio quiet), and HA-alone scores for all speech recognition measures (CNC, AzBio quiet, AzBio +5, and R-SPACE<sup>TM</sup> adaptive HINT). Solid black lines represent linear regression. For each panel demonstrating a significant regression function (bimodal SRT vs. HA-alone scores), the dark gray section encompasses the range of overlap between yes/no respondents and the light gray section helps define the HA-alone range of scores over which we would expect either a yes or no answer to the question, "Do you think you need a second CI?"

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Bimodal participant	Gender	CI manufacturer	CI ear	Age at testing, vears	CI exp, vears	Non-CI ear, aided SII, 60 dB SPL	LFPTA dB HL	Do you need a 2 <sup>nd</sup> CI?	HA CNC. % correct	CI CNC	Bimodal CNC. % correct
				2						% correct	
1	male	Cochlear	R	76	3.4	26	58.3	No	22	54	80
2	male	Cochlear	Г	82	2.3	51	41.7	No	28	64	48
3	female	Cochlear	R	39	5.9	21	53.3	No	38	84	96
4	male	Cochlear	Г	74	5.4	4	96.7	Yes	0	84	84
5	male	AB	К	64	3.1	22	58.3	No	0	80	90
9	male	AB	Я	66	2.7	10	83.3	Yes	0	90	90
7	female	AB	Я	58	6.8	19	56.7	Yes	0	90	78
8	male	Cochlear	L	70	5.9	28	70.0	No	0	90	86
6	female	Cochlear	L	82	2.9	22	56.7	Yes	2	68	60
10	male	AB	L	65	2.3	12	85.0	Yes	0	06	80
11	male	Cochlear	Г	LL	1.7	29	58.3	No	24	84	84
12	female	Cochlear	Г	76	2.1	17	61.7	Yes	14	50	09
13	female	Cochlear	R	34	1.9	36	76.7	No	10	80	84
14	male	Cochlear	Г	06	2.0	36	53.3	No	20	74	84
15	female	AB	Г	50	1.3	40	66.7	Yes	30	88	88
16	male	AB	L	76	13.2	18	66.7	No	9	74	74
17	female	Cochlear	R	47	10.7	15	61.7	Yes	9	72	82
18	female	AB	Г	41	3.2	L	70.0	No	0	88	82
19	male	Cochlear	R	52	0.8	43	20.0	No	54	86	86
20	female	Cochlear	Г	64	0.8	20	55.0	Yes	8	84	86
21	male	Cochlear	Г	88	4.9	22	46.7	Yes	2	52	68
22	male	AB	Г	69	2.1	35	55.0	No	26	92	06
23	male	Cochlear	L	74	5.9	15	58.3	Yes	0	80	76
24	male	Cochlear	Г	62	0.9	16	91.7	Yes	10	50	72
25	female	MED-EL	L	84	7.3	9	58.3	No	0	78	68

Bimodal CNC, % correct	72	06	88	64	84	80	84	94	78	78	86	80	86	86	96	86	54	84	86	58	56	82	86	06	80.7	
CI CNC, % correc	46	94	92	38	68	74	76	91	60	70	74	86	72	06	06	88	56	82	82	56	48	84	94	06	76.4	15 0
HA CNC, % correct	0	18	9	22	0	18	0	30	34	64	54	14	50	50	9	36	0	44	24	20	14	30	10	4	17.3	176
Do you need a 2 <sup>nd</sup> CI?	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes	No	No	No	No	No	No	Yes	No	No	No	No	Yes	N/A	
LFPTA dB HL	83.3	80.0	48.3	50.0	36.7	65.0	58.3	35.0	58.3	56.7	36.7	46.7	76.7	61.7	56.7	16.7	63.3	28.3	48.3	71.7	66.7	43.3	26.7	35.0	57.3	175
Non-CI ear, aided SII, 60 dB SPL	15	12	82	33	23	37	15	28	38	51	54	21	35	39	40	32	22	21	31	20	29	30	18	15	25.2	11.0
CI exp, years	0.7	6.4	5.3	0.8	1.9	3.5	3.4	2.2	10.7	6.5	0.8	5.9	4.6	8.0	5.1	1.3	4.4	2.5	7.5	1.7	0.9	1.1	5.3	4.9	4.0	° c
Age at testing, years	62	68	72	86	68	68	72	73	79	59	52	47	64	36	68	58	88	45	58	67	77	61	70	49	65.8	C 7 I
CI ear	Г	R	Г	Г	Г	Г	Г	Г	R	Г	R	R	R	R	R	R	Г	Г	R	R	R	Г	R	R	N/A	
CI manufacturer	MED-EL	Cochlear	MED-EL	Cochlear	Cochlear	AB	Cochlear	Cochlear	Cochlear	MED-EL	Cochlear	Cochlear	MED-EL	Cochlear	AB	Cochlear	AB	MED-EL	Cochlear	MED-EL	AB	Cochlear	Cochlear	Cochlear	N/A	
Gender	male	male	male	male	male	female	male	male	male	male	female	female	female	female	male	female	male	female	female	male	female	female	male	male	N/A	
Bimodal participant	26	27	28	29*	30	31	32	33	34	35*	36*	37	38	39	40	41	42	43	44	45	46	47	48	49	MEAN	стреи

#### Table 2.

Participant demographics for 36 adult bilateral CI recipients including gender, implant manufacturer, first ear implanted, age at testing (in years), duration of bilateral CI experience (in years), and CNC word recognition for the 1<sup>st</sup> CI ear, 2<sup>nd</sup> CI ear, and in the bilateral condition. Shaded columns indicate the 9 participants demonstrating significant differences between ears based on the binomial critical difference tables for monosyllabic words using a 50-item list. AB = Advanced Bionics; SIM = simultaneous bilateral

Bilateral participant	Gender	CI manufacturer	1 <sup>st</sup> CI ear	Age at testing (years)	Bilateral CI experience (years)	1 <sup>st</sup> CI: CNC, % correct	2 <sup>nd</sup> CI: CNC, % correct	Bilateral CI: CNC, % correct
1	female	Cochlear	L	50	2.6	88	80	84
2	female	Cochlear	R	69	9.0	76	72	72
3	male	Cochlear	L	56	2.9	88	80	84
4	male	AB	R	46	4.0	66	50	78
5	female	Cochlear	R	59	4.6	56	72	90
6	female	AB	L	52	2.4	80	44	92
7	female	Cochlear	R	59	7.4	60	22	70
8	male	Cochlear	R	53	2.5	74	80	84
9	female	Cochlear	SIM	22	3.1	98	72	94
10	male	Cochlear	SIM	19	1.5	98	90	98
11	female	Cochlear	L	47	2.8	60	50	80
12	female	Cochlear	R	19	3.7	74	66	92
13	male	Cochlear	L	75	1.3	76	76	86
14	female	Cochlear	L	63	1.2	66	88	94
15	female	AB	L	51	1.2	80	78	92
16	male	Cochlear	L	48	1.5	80	68	84
17	female	AB	L	62	1.4	70	48	80
18	male	AB	R	59	0.7	82	70	90
19	male	Cochlear	L	67	1.2	92	84	92
20	male	AB	R	65	3.0	96	82	96
21	female	Cochlear	L	62	2.9	36	56	58
22	male	MED-EL	R	60	2.1	74	74	78
23	male	Cochlear	L	37	0.9	94	90	96
24	female	Cochlear	L	55	1.9	74	88	92
25	male	AB	L	29	8.1	55	48	70
26	male	Cochlear	L	62	1.1	48	30	50
27	male	Cochlear	R	68	2.3	32	72	72
28	female	MED-EL	R	31	0.9	38	88	92
29	male	MED-EL	SIM	66	7.5	56	46	72
30	female	AB	L	81	1.7	76	78	76
31	male	MED-EL	SIM	45	8.5	84	78	86
32	female	MED-EL	SIM	62	8.2	84	66	90

Bilateral participant	Gender	CI manufacturer	1 <sup>st</sup> CI ear	Age at testing (years)	Bilateral CI experience (years)	1 <sup>st</sup> CI: CNC, % correct	2 <sup>nd</sup> CI: CNC, % correct	Bilateral CI: CNC, % correct
33	female	MED-EL	SIM	58	3.0	48	40	40
34	female	MED-EL	R	35	1.4	48	36	58
35	male	Cochlear	L	54	1.0	86	92	94
36	female	Cochlear	R	56	0.7	80	60	84
MEAN	N/A	N/A	N/A	52.8	3.1	71.5	67.1	81.7
STDEV				15.1	2.5	17.9	18.6	13.7

Contingency table for the 49 bimodal listeners' responses to the question, "Do you think you need a second CI?"

Do you think you need a 2 <sup>nd</sup> Cl?	"YES"	"NO"
Bilateral Cl candidate R-SPACE™ HINT SRT > 8.8 dB	<b>Hit</b> 100% n = 19	False negative 23% n = 7
Not bilateral Cl candidate R-SPACE™ HINT SRT < 8.8 dB	False positive 0% n = 0	Correct rejection 77% n = 23