Title: Evaluating recommended audiometric changes to candidacy using the Speech Intelligibility Index

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Abstract: The National Institute of Health and Care Excellence (NICE) has derived candidacy guidelines for cochlear implants (CI) in the UK based on audiometric thresholds (90 dB HL or above at 2 and 4 kHz; hereafter referred to as the 90 dB HL criteria). Recent research has proposed that these criteria should be changed to 80 dB HL at 2 and 4 kHz (hereafter referred to as the 80 dB HL criteria) in the ear to be implanted. In this study, we analysed aided SII scores derived for different hearing loss profiles falling within the current 90 dB HL criteria and equivalent profiles falling within the new 80 dB HL criteria. The aided SII scores demonstrated that the majority of potential hearing configurations falling within the new proposed 80 dB

HL criteria have aided SII values of less than 0.65 (a recommended cut-off point below which there is not sufficient audibility to receive adequate benefit through hearing aids). This supports the proposed change to the 80 dB HL criterion level and also highlights the additional value of the SII score in supporting candidacy decisions for CI, especially for borderline candidates.

Keywords: Speech Intelligibility Index, SII, Cochlear Implant, implant candidacy criteria, 80 dB HL criteria

Introduction

Assessing adequacy of hearing aid (HA) fitting for a child can be difficult because children are not always able to report their perceived benefit and may not cooperate with speech testing (Bagatto et al. 2010). To optimise amplification in children, recent HA fitting guidelines recommend use of probe microphone measurements to estimate the audibility of speech and match to prescription targets (Bagatto et al. 2010). Prescriptive formulae derive target values for HA gain based on long-term average speech spectrum (LTASS) and for swept tones near the maximum output of the HA (McCreery et al. 2013).

The closeness of the HA fitting to prescription targets is indicative of the audibility of speech (McCreery et al. 2013). This is a key factor in predicting subsequent rate of speech and language development; if the child cannot hear sufficient components of the speech spectrum, their spoken language and, later literacy, outcomes are compromised (Stiles, 2012). Studies also show that children require greater levels of audibility, as well as greater bandwidth and better signal-to-noise ratio, than adults to reach age-appropriate levels of speech understanding (Stelmachowicz et al. 2004) and word learning (Pitman, 2008). Quantifying audibility is therefore crucial to ensuring children have adequate access to acoustic cues for spoken language development.

As speech recognition is challenging to assess with young children, clinicians use indirect estimates of speech audibility derived from acoustic measurements of the HA output, based on the aided Speech Intelligibility Index (SII: American National Standards Institute [ANSI] S3.5–1997).

The SII is a measure of the proportion of the information in the speech signal that is audible to the listener with their hearing impairment and hearing aid. The SII is a numerical estimate of audibility across the frequency range of speech and is calculated by estimating the audibility of an average speech signal based on the listener's hearing thresholds or level of background noise, whichever is greater. The calculation is completed for a discrete number of frequency bands, which are each assigned an importance-weight based on the known contribution of that frequency band to speech recognition (Studebaker and Sherbecoe, 1991). Audibility is multiplied by the importance weight for each band and the weighted audibility of all bands is summed to create a number between 0 and 1. An SII of 0 implies that none of the speech information is available and an SII of 1 that all the speech information in a given setting is audible for a listener. Based on the SII score, levels of speech recognition can be predicted, e.g. as the SII increase the listener's speech understanding will also increase (McCreery and Stelmachowicz, 2011).

Aided SII results of children with HAs have been shown to predict functional outcomes, including language development and speech understanding. Stiles et al. (2012) reported that children with mild to moderately severe hearing loss with an aided SII of less than 0.65 demonstrated greater delays in vocabulary development than children with higher aided SII scores. The aided SII therefore provides a more valid estimate than the pure tone average audiogram (PTA) of the child's access to speech and consequently potential benefit from current HA amplification in real-world environments.

For children with profound hearing loss, it may be extremely difficult to achieve the prescribed target gains and hearing aids do not supply sufficient aided audibility. These children, who will have very low aided SII scores, are however within the audiometric criteria for cochlear implantation. Cochlear implants (CI) have the potential to give them better, clearer and more consistent access to spoken language across the speech frequency range than HAs.

According to McCreery et al (2013), for many children with a moderate to severe loss adequate amplification may be achieved in terms of proximity to prescription targets; however, if the level of aided audibility for the speech spectrum is too low for good phoneme discrimination it could impact on understanding and these children may not reach the expected developmental level for spoken language.

This group of children with hearing loss configurations in the moderate to severe range are currently outside the 90 dB HL criteria recommended by NICE for CIs and are receiving, over time, inconsistent and sub-optimal access to sound through their HAs. They consequently experience limitations in access to and perception of linguistic input, which essentially leads to reduced language exposure and an overall poorer language experience.

The importance of consistent auditory experience over time cannot be underestimated; without this the gap in language development between children with hearing loss and their normal hearing peers will further widen. Tomblin et al. (2015) demonstrated that this gap widens in children who did not have good audibility early on and incurred language development difficulties at a later age. In their study, children's audibility scores were grouped in quartiles according to their SII regardless of their hearing thresholds. The two lower audibility groups were found to have language scores which did not develop as rapidly as those children in the better audibility groups. By the age of 6 years the cumulative effect of poor audibility resulted in the children in the top quartile having language abilities considerably greater than children in the bottom quartile, indicating that effect of audibility over 4 years was large.

Current research indicates that NICE CI criterion should be relaxed, with the cut-off changed to the 80 dB HL criteria. Lovett et al. (2015) investigated if the current UK 90 dB HL criteria are appropriate for candidacy of bilateral CIs. Seventy one children were tested, 28 with bilateral CIs and 43 with bilateral HAs. Using an odds ratio of 3:1 these measures suggested a candidacy cut-off of 80 dB HL (at 2 and 4 kHz) and with a 4:1 ratio a cut-off somewhere between 80 and 85 dB HL (at 2 and 4 kHz). The audiometric procedure for estimating thresholds has a 5 dB step size and is known to have a 5 to 10 dB HL critical difference (Schmuziger et al, 2004, Stuart et al 1991) so the practical implementation of recommendations ought to take this into account.

The aim of our study was to conduct an analysis of potential configurations of hearing loss that would fit in the proposed 80 dB HL criteria amendment to candidacy and to determine the level of audibility for speech through HAs. For the aided SII, values less than 0.65 were considered to be less than optimal, based on data from Stiles et al. (2012), Tomblin et al. (2015) and normative SII data from Bagatto et al. (2011) as the level of SII required (0.65) for children to achieve good language development. The

0.65 cut-off proposed by these authors is based on extensive work with the SII and its relationship with HA outcomes.

Methods

Sixteen potential hearing loss configurations were derived and HA fitting targets generated. Probe microphone measures were conducted using averaged coupler derived approach (Real-Ear-to-Coupler Difference (RECD)) to estimate the acoustic characteristics of a 6 year old child's occluded ear. HA verification was then simulated in the 2cc coupler. AURICAL® FreeFit software calculated aided and unaided SII for the simulated audiograms, using the International Speech Test Signal (ISTS) presented at 65dBSPL (average speech), 50 dBSPL (soft speech) and 80 dBSPL (loud speech), following ANSI S3.5 (1997) with Crest factor set to 15. A swept pure tone at 85dBSPL was used when measuring the maximum output. The obtained fitting data were then compared to the prescriptive targets of the Desired Sensation Level v5.0 (DSL) for each input level and the proximity to DSL target was met following British Society of Audiology (BSA) guidelines on tolerances to the prescription rationale of +/- 5 dB at frequencies of 250, 500, 1000 and 2000Hz, and of +/- 8dB at 3000 and 4000Hz.

Eight of the hearing loss configurations were within the current 90 dB HL criteria and eight met the proposed 80 dB HL criteria. Only thresholds at 500Hz and 1kHz were modified and it was assumed that there was no measurable hearing above 4kHz.

Results:

All hearing loss configurations and the correspondent SII are shown in Table 1. All hearing loss configurations (A to H) which met the current 90 dB HL audiometric candidacy criteria showed SII values lower than 0.65. The remaining eight hearing loss configurations (I to P) which represented children with hearing thresholds within the proposed 80 dB HL criteria also had SII values equal or lower than 0.65.

Table 1 – Hearing loss configurations and corresponding SII values. Configurations A to H are in line with current 90 dB HL audiometric candidacy. Configurations I to P represent the proposed 80 dB HL criteria.

	Thresholds (dB HL)			
Configuration	0.5 kHz	1 kHz	2 and 4 kHz	SII
A	20	20	90	0.57
B	30	30	90	0.56
C	40	40	90	0.55
D	50	50	90	0.53
E	60	60	90	0.51
F	70	70	90	0.46
G	80	80	90	0.40
H	90	90	90	0.33
I	20	20	80	0.65
J	30	30	80	0.65
K	40	40	80	0.63
L	50	50	80	0.62
M	60	60	80	0.57
N	70	70	80	0.53
O	80	80	80	0.47
P	90	90	80	0.42

These results are also illustrated in Figure 1.

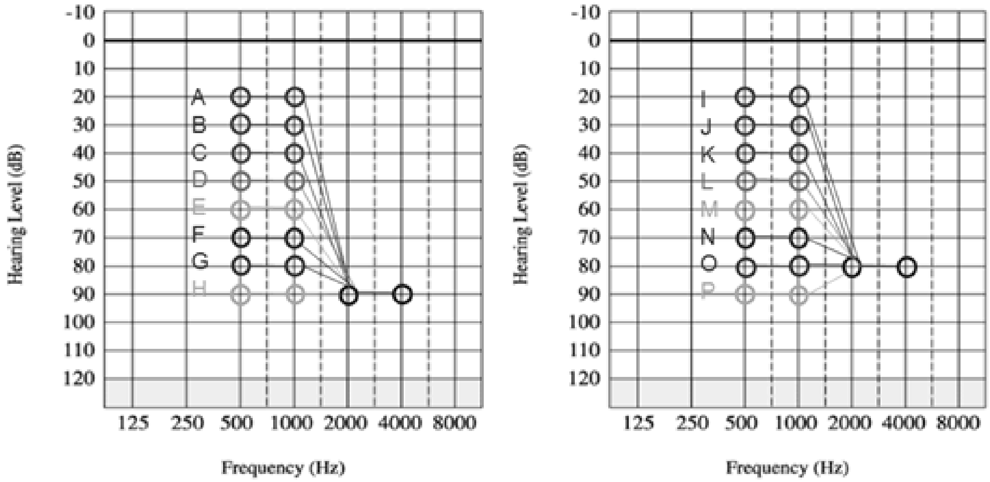

Figure 1 – Hearing loss configurations and corresponding SII values. Configurations A to H are in line with current 90 dB HL audiometric candidacy. Configurations I to P represent the proposed 80 dB HL criteria.

Discussion:

The aim of the study was to determine if the proposed change to candidacy could be validated with SII rules and whether the SII could be useful clinically for adding to the candidacy assessment toolbox for informing appropriate clinical decision making. Stiles et al. (2012) and Tomblin et al. (2015) showed that the SII was a useful tool in predicting language outcome for children and that the lack of audibility earlier in life can have cumulative negative effects on language development of children with hearing loss. The SII can provide powerful information for the clinician so that they can look beyond the audiogram, in particular for those borderline CI candidates, those individuals with a range of hearing loss configurations which are currently not considered by NICE and to identify children at an early stage who will potentially not benefit from HAs. These children can then be promptly referred for CI to reduce the impact of their hearing loss on language development.

The recommended 0.65 cut-off proposed by the Stiles et al. (2012), Tomblin et al. (2015) and normative SII data from Bagatto et al. (2011) as the level of SII required (0.65) for children to achieve good language development is based on work looking at the relationship between the SII and HA outcomes. To further explore the appropriateness of this cut-off value for evaluating borderline CI candidates the data from Lovett et al. (2015) will be re-analysed using the SII calculations for the pre-operative audiogram.

McCreery (2014) reported that if audibility is poor despite best efforts to adjust the amplification, CI should be considered as an intervention, even if audiometric thresholds are better than those typically expected for CI. However, in the UK, making a case to proceed with implantation for individuals outside audiometric criteria is complicated and requires individual funding applications.

The existing UK 90 dB HL criteria for implantation is strictly enforced, resulting in many children and adults who would benefit from implants not being considered even though they have poor access to speech sounds with best fitting HAs. Fitzpatrick et al. (2006) suggested CI as an appropriate intervention for selected children with hearing losses outside current candidacy criteria. In addition, it is well known that the critical difference (the expected variation of a measure when tested on two different occasions) for pure tone audiometry is between 5 and 10 dB for a given threshold (Schmuziger et al., 2004; Stuart et al., 1991) which means that even for current guidance, the cut-off point ought to be 80 dB HL at 2 and 4kHz. Clinical experience and emerging research shows that without making appropriate treatment decisions early, children may not develop language optimally.

Lovett et al. (2015) proposed relaxing audiometric candidacy criteria in the UK. Based on this work, the proposal is to change current guidance levels to be 80 dB HL at 2 and 4 kHz to address the issue of hearing-impaired children and adults who under existing guidelines are not considered for CI being given the appropriate intervention.

The SII values obtained for all eight hearing loss configurations representative of the new candidacy 80 dB HL criteria were equal to or below 0.65. According to Stiles (2012), if these audiograms related to children, they would be considered at risk of vocabulary delay. In addition, the deprivation from sufficient audibility may prevent these children from closing the developmental gap with their hearing peers in receptive language tasks (Toblin, 2015). Considering all these implications and the extensive research done with SIIs and HAs, we suggest that the SII can provide powerful information for CI audiologists so that they can look beyond the audiogram, in particular for those borderline CI candidates and children with a range of hearing loss configurations which are currently not considered by NICE.

Further research is necessary to establish if the 0.65 cut-off value is an appropriate one to be used in the recommended guidelines for CI.

Conclusion:

Current NICE audiometric criteria are thought to result in some individuals (adults and children) not receiving CIs when they could genuinely benefit from the intervention. In our study, the SII values for the 90 dB HL and 80 dB HL criteria were computed to determine if they fell below the 0.65 suggested cut-off point for hearing aid benefit proposed by Stiles et al. (2012), Tomblin et al. (2015) and normative SII data from Bagatto et al. (2011); all of the configurations evaluated produced an SII below this criteria value. This adds further support to the suggested amendment to candidacy criteria and shows the potential value of adding the SII to the assessment toolbox for supporting decisions about CI candidacy, in particular for borderline candidates and children with a variety of hearing loss configurations. To determine if this value appropriate for recommendation of CIs, the data from Lovett et al. (2015) will be re-analysed using the SII calculations for the pre-operative audiogram.

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