Canadian Audiologist
The Official Publication of the Canadian Academy of Audiology

Keeping Amplification Levels Safe for Children with Hearing Loss

Published February 27th, 2021

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Hearing aids are fitted to children with hearing loss to enhance the audibility of the acoustic cues necessary for communication, social, and academic functioning. Children with hearing loss who have access to these cues have better speech recognition,[1] language growth[2,3,] and academic outcomes[4] than peers with reduced access. Although audibility is critically important, keeping the output of hearing aids at a safe level is also critical to not increase the risk for damage to the auditory system. Hearing-aid verification provides an essential tool for improving audibility while maintaining safe amplification levels, but previous research raises questions about whether these practices are sufficient to prevent further hearing loss.

Macrae's early research used case examples of school-age children with hearing loss to demonstrate the potential harms of over-amplification.[5,6] Children with hearing loss in these studies often used hearing aids that were not fitted using verification methods, and as a result, often had amplification that was 20–30 dB higher than what would be prescribed for their degree of hearing loss. Poorer audiometric thresholds were reported over time, sometimes with thresholds shifts up to 25 dB. This early work was informative for promoting probe microphone measures to ensure that the output of hearing aids is safe.[7]

Since that time, hearing aids and verification practices have fundamentally changed. The hearing aids in early studies used linear amplification schemes that created trade-offs between enhancing audibility and maintaining safe listening levels, particularly for children with severe-to-profound hearing loss. With the widespread availability and implementation of nonlinear, wide dynamic range compression, audiologists could use signal processing to support audibility while maintaining comfort and safety more easily than with linear amplification.[8,9] Hearing-aid prescriptions and verification practices were also modified to reflect nonlinear hearing aids and promote conservative estimates of maximum output in hearing aids to minimize the likelihood of over-amplification.[10,11] These changes also led to the need to re-evaluate questions related to safe amplification levels for children.

Along with hearing-aid technology changes, the age of identification with hearing loss and age at first hearing aid fitting was reduced from around 2.5 years[12] to approximately 6 months.[13] This rapid progress meant that hearing aids were being fitted frequently during infancy.[14] This was an

essential development for improving language outcomes for children with hearing loss. However, it also raised questions about the potential safety of providing amplification in the smallest ear canals, where sound levels can be considerably higher than in older children and adults.

Based on those since the earlier work of Macrae,[6] Ching and colleagues used modelling to make predictions about the potential for over-amplification in children who were fitted based on nonlinear prescriptive formulae,[15] Desired Sensation Level version 5,[10] and the National Acoustics Laboratory – Nonlinear version 2.[11] In that study, Ching and colleagues used 57 audiograms from children with hearing loss who had participated in their studies to simulate the output levels for DSL v. 5 and NAL-NL2 for each audiogram.[6] Using the safety criteria that Macrae developed,[6] the researchers compared the levels indicated by each prescriptive approach for varying degrees and configurations of hearing loss. NAL-NL2 generally prescribes lower outputs than DSL v. 5, particularly for listeners with greater degrees of hearing loss. By comparing the modelled outputs for each prescription, children fitted with DSL v.5 who had thresholds above 70 dB HL were determined to be above the risk criteria for over-amplification NAL-NL2 fittings were below those criteria until children had thresholds that were greater than 90 dB HL. The conclusion was that using the outputs prescribed by DSL v.5 for children with severe or profound degrees of hearing loss could put them at risk for amplification-induced hearing loss like the children in previous studies by Macrae.

Ching and colleagues' findings raised concerns among pediatric audiologists, particularly in North America where most pediatric hearing-aid users (e.g., > 95% of children in two large cohort studies) are fitted to the DSL v.5 Child prescriptive formula.[1,15,16] Furthermore, there were some significant limitations of Ching and colleagues' study that required further investigation.[15] The main limitation of any study that relies entirely on models is that those models need to be empirically validated. However, researchers would have difficulty prospectively assessing safety limits for amplification in infants and young children due to ethical concerns. Institutional Review Boards that oversee human subjects research generally do not allow children's random assignment to an amplification condition that could make their hearing worse. The lack of ability to prospectively evaluate the modeling research results created a potential conundrum for pediatric audiologists and researchers alike.

Another significant limitation of the modelling study by Ching et al. was the fact that the safety limits derived in the study were based on dB HL thresholds.[15] Due mainly to variations in ear canal size and acoustics, the ear canal's sound pressure level can vary by 15–20 dB among infants and young children for the same dB HL threshold.[17] This variation in ear canal acoustics rendered the amplification safety limits in dB HL from that paper virtually useless without additional information about how ear canal acoustics affected the hearing aid's output in the child's ear canal. Not only would the risk criteria for over-amplification vary across children, but the risk of over-amplification might vary over time depending on the effects of ear canal growth and related acoustics on the output of the hearing aid in the ear canal.

Around the same time that the Ching et al. study was published, our research team was conducting a 10-year longitudinal study of auditory and language outcomes in children with hearing loss.[15] As part of that study, we collected hearing threshold, ear-canal acoustics, and hearing-aid verification

data from over 300 children with hearing loss who were fitted with hearing aids at clinics around the United States.[1] Though many of the children in the study had amplification settings that did not provide adequate audibility. Others had fittings that exceeded prescriptive targets. It would have been unethical to intentionally over-fit hearing aids in children in our study to test the modelling assumptions from earlier studies. However, the presence of a group of children who were overfitted in our sample provided an opportunity to study the effects of over-amplification on hearing thresholds. The ear-canal acoustics data would allow us to address a limitation of previous research by accounting for the effects of individual variability in ear-canal acoustics on the risk for over-amplification.

For the analyses, we evaluated the hearing aid output and threshold changes for 292 children between 6 months and 8 years of age who had multiple audiograms, did not have known risk factors for progressive loss (e.g., congenital cytomegalovirus), and wore their hearing aids for at least 8 hours per day. Approximately 15% of the children in the sample had hearing-aid fittings where the output exceeded prescribed targets for an average speech input by at least 5 dB at one or more frequencies, with some children over-fitted by as much as 20 dB. We developed risk criteria for dB HL thresholds and thresholds in dB SPL in the ear canal, based on the modelling published by Ching and colleagues and the previous work by Macrae.[5–7,15] Audiometric thresholds for children who met or exceeded these risk criteria based on their measured hearing aid output were compared to children who fell below the risk criteria for dB HL or dB SPL.

One key finding of the analysis was that the dB HL risk criterion overestimated the risk of over-amplification compared to the risk criterion that accounted for individual differences in ear-canal acoustics (i.e., dB SPL risk criterion). Previous risk criteria were appropriately conservative in estimating the potential for over-amplification based on the audiogram. However, these results suggest that many children deemed to be at-risk for over-amplification based on the previously reported dB HL criteria were not above those limits when their ear-canal acoustics were incorporated.

Perhaps surprisingly, the children who were over the risk criteria for dB HL or dB SPL did not experience significant threshold shifts over the years that they participated in the study compared to children who were below the risk criteria for over-amplification, despite wearing their hearing aids for over 8 hours per day on average. The only changes in thresholds observed in the study were a slight worsening of dB SPL thresholds over time for both groups associated with increased ear-canal volume and reduced real-ear-to-coupler differences that generally occur as children get older.

These analyses support using best-practices for hearing-aid verification for children to ensure that signals are audible and well-matched to prescriptive targets. There is no compelling evidence at present to fit hearing aids above prescribed levels to attempt to provide additional speech audibility, even if children in the current study who were fitted above prescriptive targets did not experience significant threshold shifts. These results suggest that very few children with mild-to-severe degrees of hearing loss will fall above published risk criteria for over-amplification if fitted to the DSL prescriptive approach. Instead, the larger risk in this sample was that nearly half of the children were fitted below prescriptive targets, limiting audibility and the potential for language growth.[2] Pediatric audiologists who follow verification best practices provide a strong foundation for language development by delivering consistent audibility and ensuring that the output of the

hearing aids is safe to prevent further shifts in hearing threshold from over-amplification.

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