

THE Hearing Review

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Our Bionic Future

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A 10-Year Review of the Earlens System

Part 2: Direct Drive: Sound Quality and Preference Evidence from the Earlens Device

By SUZANNE CARR LEVY, PhD, and DREW DUNDAS, PhD

This 3-part series is intended to serve as a high-level review of the data that has accumulated across more than 10 years of clinical research with the technology at the heart of the Earlens system. In Part 1, we dove into the speech understanding data and how increasing the bandwidth of processed audibility results in improved speech understanding performance from a number of perspectives. In Part 2, we discuss the perceptual benefits to naturalness and overall sound quality. Finally, in Part 3, we'll take a deep dive into the restoration of audibility, and how the Earlens approach to overall audibility improvement is reliably achieved via direct drive.

Anecdotal reports of superior sound quality and superior speech understanding have been common since the first clinical evaluations of the Earlens system. As noted in Part 1 of this article series,¹ clinicians from early studies were persuaded by persistent participant testimonials that Earlens had better sound quality than acoustic devices. However, one question of great speculation has taken years to answer: "Given our clinical experiences attempting to provide broadband audibility with acoustic devices, why aren't Earlens patients complaining of tinny and harsh sound quality when as much as 60 dB

of insertion gain is needed to restore high frequency audibility?"

To this day, we meet clinicians who express skepticism regarding the value of broadband audibility. After all, pushing the limits of conventional devices to extend the audible bandwidth into the high frequencies commonly leads to reports of harshness and a quick request to "turn it down, please!" rather than exclamations of delight and reports of a dramatic improvement in sound quality. So, while we would all agree that research shows that delivering a broader bandwidth of audibility is "better" in terms of potential speech perception benefits, those benefits will not be realized if sound quality or preference issues lead users to leave their devices in the drawer or force the clinician to turn the gain down.

Summary of Sound Quality and Subjective Preference Studies

Repeated studies utilizing subjective preference questionnaires demonstrate that the sound delivered by the Earlens system is perceived as being clear and natural, with exceptional sound quality. Subjective reports of superior speech understanding and improved satisfaction relative to acoustic hearing aid performance have also been documented.^{2,3} Using a blinded comparison approach, Folkeard et al,⁴ showed a significant preference for the sound of wide-bandwidth speech, demonstrating that the provision of high-frequency audibility does not degrade sound quality. Vaisberg et al⁵ further demonstrated that extending the high frequency audible bandwidth from 5kHz to 10kHz produced consistently superior ratings of the sound

quality of both speech and music.

Despite this accumulation of evidence, many clinicians remain surprised that Earlens patients seem to not only tolerate, but consistently prefer, a level of high-frequency amplification and audibility that an acoustic hearing aid patient *may not be* willing to leave the office with, even if it were possible!

So, is there something "magical" about direct drive? Is the reason purely extended bandwidth? Or is there something else?

Is the Improvement Only About Broader Bandwidth?



Is the "magic" simply broader audible bandwidth? This paper focuses on sound quality and how subjective preference for a direct drive device can be explained by an amplification approach that balances loudness throughout the cochlea. There may be other factors that contribute to the sound quality of a direct drive device, including the elimination of direct acoustic path interactions with the direct drive path, allowing for delivery of the broadband digitally processed signal with no relative time delay between direct acoustic sound and amplified sound—and these concepts will be explored separately at a later time.

"The Pedestal of the Lows"

Over the years, we've gained insight into some of the reasons why Earlens users enthusiastically accept high-frequency audibility. In short, it may correlate with Earlens' ability to provide low frequency output while maintaining a widely vented configuration—which is possible due to the unique mechanism of action of directly driving the eardrum. This low-frequency energy provides the pedestal that is required to generate acceptance of the high frequencies.



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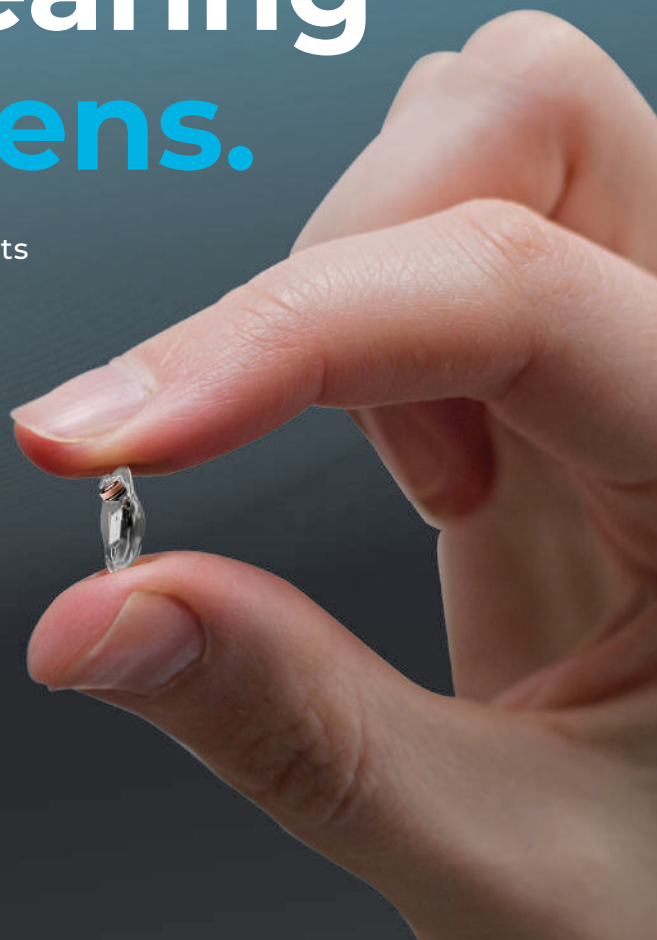
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32% improvement in speech understanding in noise

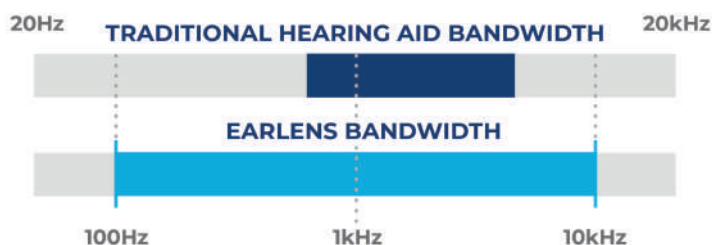


16x closer to normal hearing in the high frequencies



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Earlens transmits sound information without an acoustic signal by gently vibrating the eardrum to activate the hearing system. As a result of its novel mechanism of action, Earlens nearly doubles the usable bandwidth of hearing aids, offering incredible sound quality without the limitations of conventional hearing devices.



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The importance of the low frequencies and the ability to achieve them through the direct drive mechanism is perhaps most evident in comparisons of streamed audio sound quality. Even while vented, the Earlens streaming program can supply ample low-frequency output to provide rich bass sounds, which creates a significant streaming sound quality advantage over vented acoustic hearing aids.^{6,7}

But does the low frequency advantage apply in other listening situations outside of streaming? Moore and Tan⁸ showed in normal-hearing listeners that, when you start with a bandwidth which approximates that of a conventional hearing aid (313-4455 Hz), sound naturalness ratings are poor. Simply extending only the lows or only the highs does not appreciably increase naturalness. However, extending *both* the lows (down to 55 Hz) and the highs (up to 10,869 Hz) dramatically increases the perception of naturalness.

The Vaisberg study⁵ built on Moore and Tan's methods and illuminated a similar effect in hearing-impaired listeners wearing Earlens—showing that extending processed audibility into both the lows and the highs improved sound quality. Importantly, it also suggests that an even broader bandwidth is perceived through Earlens than the claimed 125-10,000 Hz range. In Folkeard et al⁴ the extension of amplified bandwidth downwards from 313 to 123 Hz had a significant impact on loudness perception, illustrating that the lows are definitely present and perceptible with the Earlens device even when widely vented.

Based on the results presented in Vaisberg et al⁵ and Folkeard et al⁴ we can draw two main conclusions:

- 1) The stimuli are being perceived through Earlens at suprathreshold levels in both the lows and the highs, as the ratings changed when these frequencies were present; and
- 2) Participants preferred the sound quality of broader audibility, as ratings increased when audible bandwidth was extended.

The strategy to effectively combat the perception of tinnitus in high-frequency amplification while maintaining maximum benefit for the patient is this: the perceptual loudness of the highs must be balanced with that of the lows in order to achieve the benefits of exceptional performance while simultaneously maintaining exceptional sound quality.

What is CAM2 and Why Does Earlens Apply It?

The CAM2 fitting algorithm was selected for implementation in Earlens in an effort to achieve exceptional sound quality and performance. Why CAM2 and not NAL or DSL?

CAM2 was developed in Dr Brian Moore's lab at Cambridge University with an idealistic goal: making as much of the speech spectrum audible, over the broadest possible range of frequencies, while maintaining normal overall loudness for soft, average, and loud speech.⁹ It generates targets from 125 Hz to 10 kHz. Simply put, the goal is to equalize the loudness perceived in various frequency regions for a soft speech input (ie, equalize *specific loudness*) while simultaneously keeping the overall perceived loudness of speech to a level that is similar to what would be experienced by a normal-hearing listener (ie, normalized *overall loudness*). The model also seeks to normalize the overall loudness of loud speech, and prescribes compression ratio targets so that for the hearing-impaired listener, soft speech sounds like soft speech, and loud speech sounds like loud speech.

When compared to other fitting algorithms that make tradeoffs to maximize benefit within the constraints of the performance envelope of conventional hearing devices, this idealistic approach generates a differ-

CAM2 and Experienced/Inexperienced Users

CAM2 was developed with two prescriptive variants: one for "experienced" and another for "inexperienced" hearing aid users. Earlens initially implemented the experienced user setting as the first-fit prescription. The two large studies con-



ducted to secure FDA clearance generated achieved gain and subjective outcome data from nearly 100 participants. The results were evaluated and summarized in Arbogast et al.² In their studies, the "first-fit" prescription was the CAM2 experienced user algorithm, and clinicians were permitted to fine tune to participant preferences. On average, participants did prefer slightly less high-frequency gain than the full CAM2 prescription at initial fitting, but even after fine tuning, high-frequency audibility for speech was maintained. In 2019, Earlens modified the fitting software to prescribe high-frequency gain according to the inexperienced variant of CAM2, as this prescription closely approximated the average fine-tuning adjustments described in Arbogast et al.²

ent balance of low- and high-frequency energy. For example, NAL-NL2 is likely to boost the mid frequencies, while rolling off the low and high frequencies in order to maximize speech understanding while maintaining normal overall loudness. However, this pattern of loudness is perceived as unnatural by listeners. CAM2's approach yields naturalness and acceptance of broad-spectrum amplification up to 10 kHz on a first fit, but only if the targets can be achieved in the low, mid, *and* high frequencies. For that reason, CAM2 and Earlens direct drive technology are a perfect pair—as a vented acoustic configuration would not be able to provide the low-frequency output that CAM2 prescribes (even for those with normal low-frequency hearing), nor the substantial high-frequency gain prescribed, without the risk of feedback.

Summary

It seems then that broad spectrum audibility extending to 10 kHz can produce exceptional sound quality, but it must be implemented on a platform that can provide a balanced sound experience. If you have great headphones and an amplifier, you can do this acoustically. To implement this on an ear-worn device is more challenging, which is why the direct-drive platform has a huge advantage and results in a very different fine-tuning experience than with conventional acoustic technology. We have actually heard clinicians say that fitting an Earlens is similar to fitting a BAHA for a pure conductive loss, in that you can basically click "first fit" and do very little fine tuning. It is this balanced approach and subjective preference for the superior sound quality of the extended bandwidth that allows users to benefit from the corresponding speech understanding improvements described in Part 1.

Part 3 will explore audibility and its implications for those who may benefit from Earlens technology. ►



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REFERENCES can be found in the online version of this article at: hearingreview.com