Multiflex Tinnitus Pro: New Tools to Help Hearing Professionals Fit Tinnitus Maskers

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Executive Summary

- *Starkey's new Multiflex Tinnitus Pro technology arms hearing professionals with the ability to better personalize the tinnitus stimulus (aka 'masker'), based on the audiogram or on masking thresholds.*
- *Acoustic therapy for tinnitus need not be the same for every patient.*
- *This paper presents evidence of patient benefits of Multiflex Tinnitus Pro.*

Introduction

It is not rare for individuals with hearing impairment to experience bothersome, chronic tinnitus (Lewis et al., 2020; Nondahl et al., 2011). For these patients, hearing professionals must manage, not only the hearing loss, but also the tinnitus.

Comprehensive tinnitus management strategies, such as Tinnitus Retraining Therapy (Jastreboff, 2000) and Progressive Tinnitus Management (PTM) (Henry et al., 2010), involve a combination of counseling and acoustic therapy (aka "sound stimulation" or "sound therapy") for patients with persistent, bothersome tinnitus (Tunkel et al., 2014). Acoustic therapy may be achieved using sound amplification via a hearing aid, sound stimulation using a tinnitus masker (aka "tinnitus stimulus"), or both.

Once a decision has been made to use a tinnitus masker, the hearing professional still needs to select an appropriate masker and to fit this masker to the patient. While 'white' (flat-spectrum) noise is commonly used, today's hearing aids also allow hearing professionals to select other types of stimuli, with spectral characteristics tailored to the patient's hearing and tinnitus.

Starkey's Multiflex Tinnitus Pro provides hearing professionals with tools to facilitate the fitting of personalized hearing-aid generated tinnitus maskers. These were described in detail in a previous publication (Reinhart & Micheyl, 2020). They include an 'audiogram-shaped noise', the level-per-band of which increases across frequency in relation to the hearing loss, and a 'custom noise', the level-per-band of which is determined based on tinnitus masking levels (MMLs). The often-used 'white noise' masker option remains available; this noise has a nominally flat level per band (when measured in a 2-cc coupler) regardless of the hearing loss.

Here, we outline results of a preliminary investigation into actual usage of these maskers in patients with tinnitus and hearing impairment over an 8-week field trial. The results show significant improvements in self-reported tinnitus severity starting after 1 week, and they illuminate differences in masker preference and masker usage among patients. When given a choice between the three masker types, roughly half of the participants declared a preference for, and used preferentially, the audiogram-shaped or custom masker over white noise. Lastly, results indicate that custom maskers, containing less sound energy in the low frequencies, can yield less speech masking than a white-noise masker

Methods

Participants

Thirty-one participants (mean age = 61.3 years, standard deviation = 8.0 years; 26 males, 5 females) with tinnitus enrolled in the field trial. At the start of the study, participants presented with mild to severe tinnitus, as quantified by the 100-point Tinnitus Handicap Inventory (THI; 0-16 = no or slight handicap; 18-36 = mild handicap; 38-56 = moderate handicap; 58-76 = severe handicap; 78-100 = catastrophic handicap) (Newman et al., 1996). Participants had low-, mid-, and/or high-frequency hearing loss ranging from mild to severe, as indicated by pure-tone hearing thresholds (Figure 1). To limit the potential effects of novel sound amplification on tinnitus (e.g., Surr et al., 1985), only experienced hearing aid users were recruited (mean = 4.4 years; standard deviation = 3.3 years). To limit the potential effects of previous masker experience biasing perception of the study maskers, individuals who currently used a tinnitus masker with their personal hearing aids were excluded from the study. Individuals with hyperacusis, as indicated by a cumulative score >4 on the Sound Tolerance section of the Tinnitus and Hearing Survey, were excluded from the study (Henry et al., 2010).

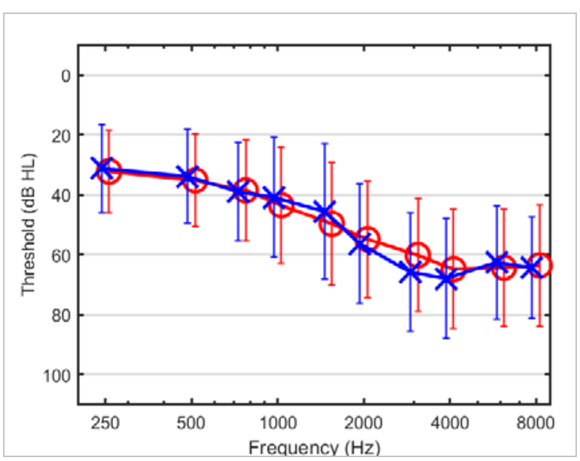

Figure 1: Mean hearing loss across the 31 participants. Blue curve: left ear; red curve: right ear. Error bars represent +/-1 standard deviation.

Procedure

Visit 1: Baseline and Hearing Aid Fitting. At Visit 1, participants completed an audiometric assessment including case history, pure-tone audiometry (Figure 1), and THI. Participants were fit with study hearing aids—6 participants received Livio Edge AI BTE devices with custom earmolds, and 25 participants received Livio Edge AI rechargeable RIC devices with either open (3/25), closed (19/25), or power domes (3/25), depending on audiometric configuration. All fittings were bilateral, except for one participant with unilateral hearing loss.

The hearing aids were programmed with four memories using Starkey Inspire X fitting software. Hearing aids were fit to NAL-NL2 (Keidser et al., 2011) prescriptive formula and adjusted based on participant feedback. The default memory (memory one) was programmed without any tinnitus masker (i.e., amplification alone); the order of the three subsequent memories was randomized for each participant and programmed with the three different tinnitus maskers (white noise, audiogram-shaped, and custom). Each masker was initially generated to Tinnitus Target Match, and the levels were then adjusted to be just below the level at which their tinnitus was completely masked (Jastreboff, 2000). Figure 2 shows the white noise, audiogram-shaped, and custom noise spectra following the fitting process for one participant. Note that noise band levels better track pure-tone thresholds for the audiogram-shaped noise than for the white noise. To some extent, noise band levels lower than the pure-tone thresholds can be accounted for in terms of loudness summation (Hawkins et al., 1987). For this participant, the Custom noise that was generated based on the measured detection and tinnitus-masking thresholds contained only mid- and high-frequency bands.

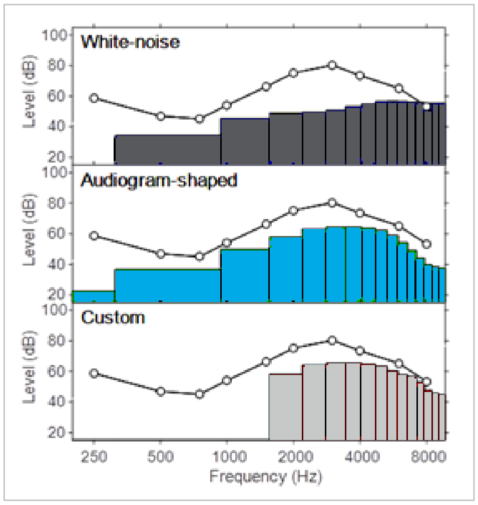

Figure 2: Example white noise, audiogram-shaped, and custom noise spectra (blue histograms, respectively). Histogram-bar heights correspond to predicted real-ear SPL per auditory-filter bandwidth. Empty circles show pure-tone thresholds for that ear, converted to minimum audible SPL. Note that noise band levels better track pure-tone thresholds for the audiogram-shaped noise than for the white noise. For this participant, the custom noise that was generated based on the measured detection and minimal masking level thresholds contained only mid- and high-frequency bands.

After fitting the maskers, the ear-to-ear tinnitus volume control was enabled, so participants could adjust the masker volume level in 4 dB increments via the right hearing aid rocker switch. Participants were also issued a 2.4 GHz Remote accessory with hearing aid volume control. Participants could change memories via either the 2.4 GHz Remote or the left hearing aid rocker switch.

Visit 2: Fine-tuning and Speech Testing. One week after Visit 1, participants returned for a follow-up visit. Participants completed the THI to reassess the tinnitus handicap since starting the field trial. If requested, the amplification and masker levels were fine-tuned based on participant feedback. The hearing aid datalogging was reset.

Laboratory testing was also completed to assess speech intelligibility using the Hearing-in-Noise Test (HINT) (Nilsson et al., 1994; Vermiglio, 2008). The HINT was administered in quiet in four aided conditions: amplification alone, amplification plus white noise, amplification plus audiogram-shaped noise, and amplification plus custom noise. Testing was conducted in a free-field sound booth with target sentences presented at 0° azimuth. Each condition was presented twice, and results were averaged. Final scores for each condition were speech reception thresholds indicating the minimum level (dB SPL) at which participants could recognize 50% of the speech.

Visit 3: Final Assessment and Study End. Seven weeks after Visit 2, participants returned for their final visit. At this visit they completed their final THI assessment, and study hearing aids were collected so that final datalogging results could be extracted. One participant was lost to follow-up and failed to complete Visit 3.

Results

Datalogging

Average hearing aid use was 9.2 hours (standard deviation = 4.6 hours) during the field trial. On average, 68.8% of that time was reported to be in the default memory (i.e., amplification alone). The remaining time was distributed across the three masker memories. Figure 3 shows the distribution of percentage time using the white noise (panel A), audiogram-shaped (panel B), and custom (panel C) maskers. All three maskers had similar medians (white noise = 8.0%, audiogram-shaped = 4.0%, custom = 5.3%) with right-skewed distribution. Overall, these results indicate that maskers were similarly utilized by participants with several instances of participants spending a substantial percentage of their hearing aid use time (40%+) utilizing a specific masker.

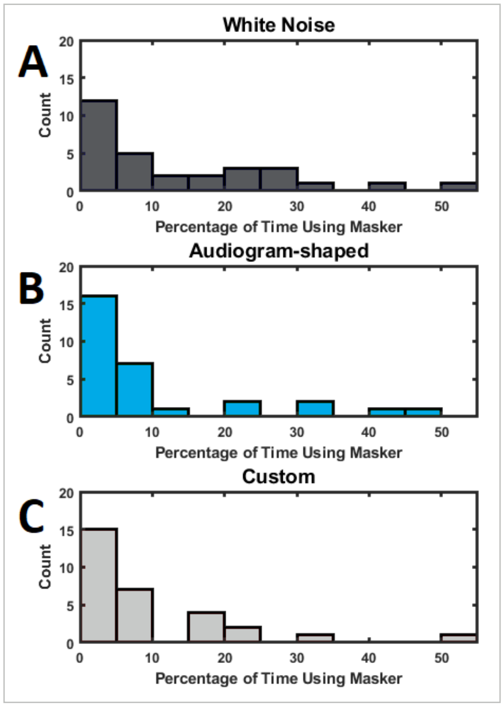

Figure 3: Datalogging results showing distribution of percentage time participants used White Noise (panel A), Audiogram-shaped (panel B), and Custom (panel C) maskers.

Tinnitus Handicap Inventory

Given that participants utilized the three maskers to different extents, participants were categorized based on their most utilized masker to examine the THI results. Using this method, 15 participants were categorized as "White Noise", 7 were categorized as "Audiogram-shaped", and 7 were categorized as "Custom". Results of the THI are depicted in Figure 4.

Based on the results of repeated-measures analysis of variance test, average THI scores decreased (i.e., improved) significantly over the first week ($p < .001$), although not between weeks 1 and 8 ($p = .363$). Although the average decrease in THI score appears larger for the custom masker group, than for the other two groups (an effect perhaps related to the baseline THI score being visibly larger in the former group), no statistically significant difference in THI scores or in THI improvements over time across the three maskers was found ($p = .215$ and $p = .353$, respectively).

Speech Masking

To examine the speech masking effects of each noise, HINT speech reception thresholds (SRTs) measured with amplification plus masker were subtracted from the SRT measured with amplification alone (no masker). Using one-sample t-tests, average SRT measured in the presence of the white noise masker was significantly higher (i.e., worse) than performance measured with amplification alone (mean = 1.67 dB, $p = .041$), indicating that the white noise masker caused a significant decrease in speech-perception performance. By contrast, the custom masker did not cause a significant elevation in SRTs relative to amplification alone (mean = .28 dB, $p = .654$), due probably to it containing less energy at lower frequencies. The audiogram-shaped masker failed to cause a significant elevation also ($p = .063$), but its mean effect on SRTs was almost as large as that of the white noise (mean = 1.53 dB).

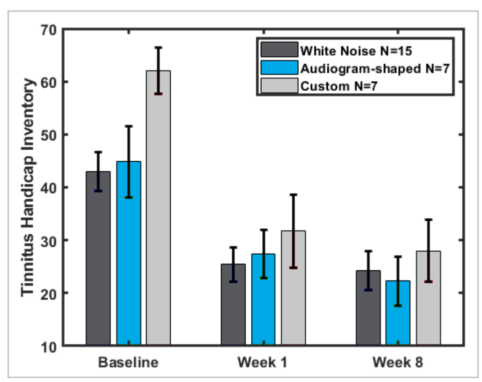

Figure 4: Tinnitus Handicap Inventory (THI) scores measured at Baseline, Week 1, and Week 8 with participants categorized based on their most used masker. Error bars represent +/-1 standard error.

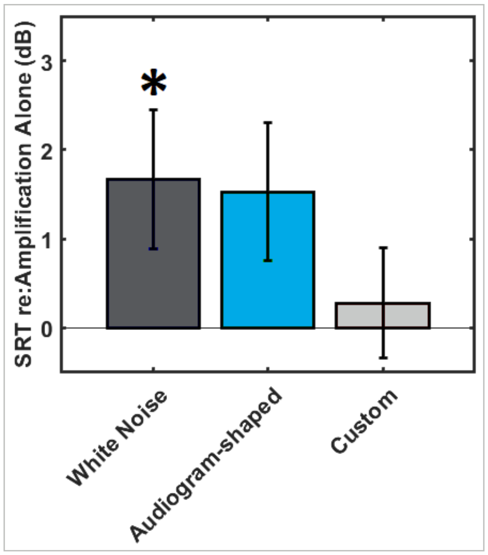

Figure 5: Speech reception thresholds of the three maskers relative to performance with amplification alone. Asterisk (*) represents that the performance for that condition significantly differed from performance with amplification alone (p < .05). Error bars represent +/-1 standard error.

Discussion

The results of this study underscore that a "one-size-fits-all" approach to acoustic therapy of tinnitus is not optimal. When provided with an opportunity to try each of the three automatically generated maskers in Multiflex Tinnitus Pro (white noise, audiogram-shaped, and custom), participants utilized them to varying extents, with different participants preferring different maskers. The drivers for such individual preferences remain uncertain but may include differences in perceived effectiveness of the maskers, perceived intensity (related to loudness), perceived sound quality (related to timbre), and/or masking of environmental sounds (related in particular to low-frequency energy). Importantly, with participants allowed to choose which masker they used and when, THI scores were found to improve significantly over the first week of masker use, for all three masker types; this was observed, even though all participants had protracted prior experience with amplification.

It would be convenient if hearing professionals could predict which type of masker a patient is likely to prefer. One factor that may affect their preference is the slope of their hearing loss. While the groups have similar thresholds in the low- and mid-frequencies, the white noise group had lower (i.e., better) thresholds than the audiogram-shaped and custom groups at 2000 and 4000 Hz. For individuals with significant high-frequency hearing loss, the white noise masker may have been sub-threshold in the high frequencies where energy was needed to mask their tinnitus. Due to the nominally flat spectrum of white noise, increasing the overall level to provide sufficient high-frequency masking would have increased the low-frequency energy and become uncomfortable. In these cases, the spectra of the audiogram-shaped and custom maskers can be shaped to provide high-frequency masking without additional low-frequency energy.

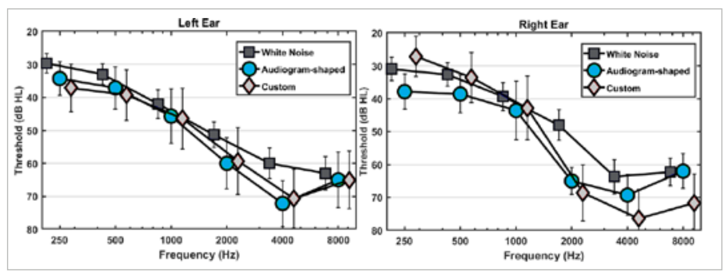

Figure 6: Average audiograms for the White Noise, Audiogram-shaped, and Custom preference groups. Error bars represent +/-1 standard error.

The custom masker may prove advantageous for patients who intend to use a masker while engaged in active listening. During laboratory testing, participants had significantly improved speech perception when using the custom masker compared to the white noise masker: while the white noise increased SRTs by approximately 1.7 dB (an estimated 17 percentage-point worsening in correct word-recognition scores according to Vermiglio, 2008) relative to the amplification-alone condition, the custom masker caused no significant SRT elevation.

The custom masker is generated based on psychoacoustic measurements of minimum masking level (MML) which are used to determine the frequency regions at which masking is most effective. Once these frequency regions are identified, masking energy is primarily applied there, and frequency regions that are ineffective at masking tinnitus are excluded from the custom noise spectrum. Thus, for some patients, the custom noise may be a more efficient masker than white noise or the audiogram-shaped noise, due to its lacking excess energy at low frequencies that predominantly acts as energetic masking when listening to speech, while still masking tinnitus; by definition, a white noise masker always has a broadband spectrum that provides energetic masking across frequencies critical for speech perception. If a patient reports experiencing intrusive tinnitus during conversation, then a hearing professional may prioritize fitting a custom masker for that individual.

A key factor in fitting any tinnitus masker is fitting the overall masker level. Starkey Inspire X software generates tinnitus maskers at a starting level (Tinnitus Target Match), which is based on the audiogram (for white noise and audiogram-shaped maskers) or the measurements captured with the Stimulus Personalization tool (for the custom masker). However, due to individual differences in tinnitus perception and masking, this initial level may require fine-tuning in order to be set at the desired level relative to their tinnitus. Common approaches include setting the masker level to just below, at, or slightly above the patient's minimum masking level (Jastreboff, 2000; Henry et al., 2016; Tyler et al., 2012). Ultimately, it is at the discretion of the hearing professional to verify that the masker level is consistent with the goals of acoustic therapy. While this initial level is set in a clinical setting, it may require subsequent fine-tuning to reflect fluctuations in tinnitus severity and/or comfort considerations. These subsequent adjustments can be made in a follow-up visit or remotely. With Starkey's synchronous remote programming (Live Sessions), a hearing professional can adjust the masker level remotely for hearing aid users who currently have a masker enabled. Regardless of whether fine-tuning is required, patients often need to be re-instructed regarding use of the tinnitus-stimulus volume control and its distinction from the hearing aid gain volume control; the Thrive app can make this distinction easier.

Conclusion

Tinnitus patients can differ along multiple dimensions, including their audiogram, the maskability of their tinnitus across frequency, and their subjective sound preferences. By providing tools to facilitate the fitting of personalized tinnitus maskers based on the audiogram and/or masking levels, Starkey's Multiflex Tinnitus Pro makes it easier for hearing professionals to explore options for acoustic therapy beyond white-noise maskers. For patients, having an option to try different tinnitus maskers may allow them to find one that is most effective and/or least intrusive.

The results described above reveal that, when given a choice between three different acoustic stimulus options, about half of the tinnitus patients tested expressed a preference for a more personalized stimulus than white noise. Moreover, statistically significant reductions in self-reported tinnitus impact on daily life (as measured using the THI questionnaire) were observed across all three maskers, including audiogram-shaped noise and custom noise. Lastly, the results confirm that noises that contain less energy at lower frequencies than white noise can yield significantly less masking of speech, which may be advantageous when the tinnitus stimulus is being used while listening to speech or other environmental sounds.

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