CLINICAL VALIDATION OF MULTIFLEX TINNITUS TECHNOLOGY

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Introduction

Sound therapy, or use of any sound for the purpose of tinnitus management, is widely accepted as a management tool for reduction of tinnitus complaints. The rationale for the use of sound is minimizing the patient's perception of tinnitus by effectively reducing the perception of tinnitus relative to environmental sounds (Del Bo & Ambrosetti, 2007; Folmer & Carroll, 2006). Despite this common rationale, approaches to sound therapy have varying goals, as described by Tyler (2006), including "reducing the attention drawn to the tinnitus, reducing the loudness of the tinnitus, substituting a less disruptive noise (background sound) for an unpleasant one (tinnitus), and giving the patient some control."

In developing Multiflex Tinnitus Technology, a central goal was to create a product that was capable of accommodating the unique preferences of individual tinnitus patients and providing multiple options for various sound therapy approaches for tinnitus management (Galster, 2013). Multiflex Tinnitus Technology is available within the Xino™ Tinnitus product. Xino Tinnitus offers such advanced hearing aid features as PureWave Feedback Eliminator, Voice iQ^2, InVision Directionality and Spectral iQ. Memories within the device may be configured with hearing aid only functionality, hearing aid and Multiflex Tinnitus functionality, or Multiflex Tinnitus functionality only. Multiflex Tinnitus Technology generates a broadband noise signal that can be adjusted by the professional in the Inspire® fitting software using 16 independent frequency bands. All hearing aid settings and features can be configured independent of the settings of Multiflex Tinnitus Technology. An optional modulation setting controls the rate of periodic changes in the amplitude and frequency response of the noise signal over time, resulting in an auditory perception similar to ocean waves or a breeze. Additionally, SoundPoint Tinnitus, a feature available within the Inspire fitting software, allows the tinnitus patient to become an active participant in the fitting process by enabling him or her to tailor the noise signal to their preference. As the patient explores the SoundPoint Tinnitus interface on the screen via a mouse or touchscreen, the overall level and frequency shape of the noise changes in real time. Thus, the patient has the opportunity to select the settings that may be most pleasant or beneficial.

A critical part of the product development process is the clinical validation of new features. The goal of this clinical validation process is to ensure that new features not only function as designed but also provide benefit to patients. The specific purposes of this investigation into Multiflex Tinnitus Technology were twofold: to investigate the effects of Multiflex Tinnitus Technology on tinnitus handicap and severity and to investigate participants' preferences for settings of Multiflex Tinnitus Technology.

Methods

Nineteen individuals, 12 males and seven females, with tinnitus were selected to participate in the study. The mean age of all participants was 64.4 years. Eighteen of 19 participants had hearing impairment ranging from mild to severe. Mean audiometric data, as well as group minimum and

maximum thresholds, are displayed in Figure 1. Seven of the participants had previous experience with hearing aids, but none of the participants had previous experience with any form of sound therapy for tinnitus. Prior to the start of the study, psychoacoustic measures of tinnitus were completed with each participant, including pitch matching, loudness matching and minimum masking levels. Additionally, all participants reported clinically significant tinnitus as defined by a score of 20 or more points on the Tinnitus Handicap Inventory (THI; Newman, Jacobson, & Spitzer, 1996; Newman, Sandridge, & Jacobson, 1998).

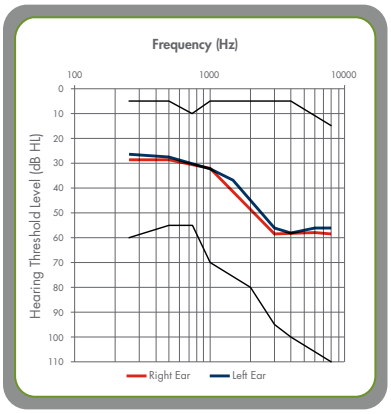

Figure 1: Mean audiometric thresholds for the right and left ears, indicated by red and blue lines, respectively, and minimum and maximum thresholds, indicated by the black lines.

Part I: Investigation of Benefit from Multiflex Tinnitus Technology

Prior to the start of the study, participants completed the THI and the Tinnitus Functional Index (TFI; Meikle et al., 2012). The THI, developed by Newman, Jacobson and Spitzer (1996), measures a patient's tinnitus handicap based on responses to 25 questions. A score of 100 on the THI indicates maximal tinnitus handicap, indicating that the patient's tinnitus has a significant negative effect on his or her daily life. The TFI was developed by Meikle and colleagues (2012) and is designed to evaluate the severity and the negative impact of tinnitus on a patient's life. Similar to the THI, the TFI has 25 self-report items, with a maximum possible score of 100. In addition to these standardized questionnaires, participants were asked to rate the effect of their tinnitus on their lives on a scale of zero to 10, with zero representing no effect and 10 representing a significant effect. Participants were also asked to indicate the percentage of time they were aware of and the percentage of time they were disturbed by their tinnitus.

At the final study session, participants were again asked to complete the THI and the TFI, to rate the effect of their tinnitus on their lives, and to rate the percentage of time they were aware of and disturbed by their tinnitus. Additionally, at the conclusion of the study, participants were asked to rate the effect of Xino Tinnitus on their tinnitus on a five point scale: worse, no effect, mildly better, moderately better, or significantly better.

Part II: Investigation of Participants' Preferences for Multiflex Tinnitus Technology Settings

Participants were seen for a minimum of four visits over the course of a six- to eight-week field trial. At session one, the participants were fit with Xino Tinnitus. As a part of the fitting process, the research audiologist fit Multiflex Tinnitus Technology based on Best Fit settings, making adjustments to the level and frequency response of the noise stimulus. Initially, the mixing point, or level at which the participants reported an interaction between his or her tinnitus and the noise signal, was found. However, most participants reported that this level was slightly loud, thus, further adjustments were made to ensure participant comfort, while maintaining audibility of the noise signal. In a different memory within the device, participants used the SoundPoint Tinnitus feature to select their preferred level and frequency response settings for Multiflex Tinnitus Technology. In addition to these two memories, participants used a memory in which Multiflex Tinnitus Technology was disabled, but all hearing aid functionality was enabled. Participants evaluated these three different settings during the

initial portion of the study. After this evaluation period, they were asked to indicate whether they preferred the hearing aid only, audiologist programmed or SoundPoint settings. In addition to this comparison, participants compared the available modulation settings for Multiflex Tinnitus Technology: off, slow, medium and fast, and indicated their preferred modulation settings.

Results

Part I: Investigation of Benefit from Multiflex Tinnitus Technology

Mean ratings of the effect of tinnitus on the participants' lives, ranging zero to 10, are displayed in Figure 2. At the beginning of the study, the mean rating was approximately 5.6 points. By the end of the study, the mean rating had decreased by approximately 3.0 points, a significant improvement ($p<0.001$). Figure 3 displays mean reported percentage of time participants were aware of and disturbed by their tinnitus. From the beginning to the end of the study, mean percentage of time participants were aware of their tinnitus decreased by nearly 30 percent and mean percentage of time participants were disturbed by their tinnitus decreased by nearly 20 percent. Both of these changes represented statistically significant improvements ($p<0.05$).

Figure 4 displays mean THI and TFI scores. Comparison of pre- and post-treatment results indicated statistically significant improvements in both THI and TFI scores ($p<0.01$). In addition, at the end of the study, participants were asked to indicate the degree of change, if any, in their tinnitus, ranging from worse to significantly better. Individual results for this and for the changes in THI and TFI scores are displayed in Table 1. For the THI, a clinically significant improvement for an individual is defined as a decrease in score of 20 or more points (Newman, Sandridge & Jacobson, 1998). For the TFI, a clinically significant improvement is defined as a decrease of 14 or more points (Meikle et al., 2012). Examination of these individual results reveals that 11 of 19 participants reported both an improvement in their tinnitus and exhibited a clinically significant improvement in either THI or TFI score. An additional four participants reported an improvement in tinnitus but did not exhibit a clinically significant improvement in THI or TFI score during the field trial.

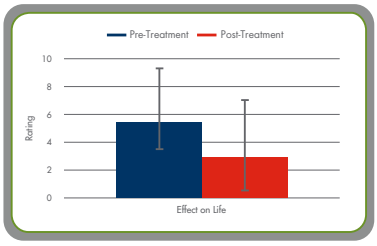

Figure 2: Mean ratings and standard deviations of the effect of tinnitus on participants' lives on a scale from zero to 10 (zero represents no effect and 10 represents a significant effect).

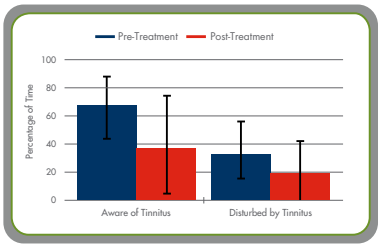

Figure 3: Mean percentage of time participants were aware of and percentage of time participants were disturbed by their tinnitus with standard deviations.

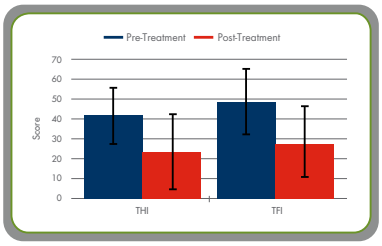

Figure 4: Mean pre-treatment and post-treatment Tinnitus Handicap Inventory and Tinnitus Functional Index scores and standard deviations.

Participant	Change in Tinnitus	THI Change	TFI Change
1	Moderately Better	-22.0	-18.8
2	Moderately Better	-6.0	-14.4
3	Mildly Better	-12.0	1.6
4	No Effect	-32.0	-4.4
5	No Effect	-20.0	-27.2
6	Mildly Better	-34.0	-27.2
7	Mildly Better	-20.0	-15.6
8	Moderately Better	-22.0	-6.8
9	Mildly Better	-10.0	-2.8
10	Significantly Better	-10.0	-17.6
11	Moderately Better	12.0	-7.2
12	Moderately Better	-28.0	-34.0
13	Moderately Better	-4.0	-54.4
14	Mildly Better	-8.0	-8.4
15	No Effect	-30.0	-15.6
16	No Effect	0.0	-26.0
17	Significantly Better	-36.0	-57.2
18	Moderately Better	-20.0	-24.0
19	Significantly Better	-28.0	-25.2

Table 1: Individual results for the participant-reported change in tinnitus and the changes in THI and TFI scores. A negative number indicates an improvement in tinnitus handicap or severity in the post-treatment score relative to the pre-treatment score. Changes of 20 or more on the THI and of 14 or more on the TFI are considered clinically significant.

Part II: Investigation of Participants' Preferences for Multiflex Tinnitus Technology Settings

Participants were asked to compare various Multiflex Tinnitus Technology settings during the field trial. They were instructed to use each of the three device memories as part of their six- to eight-week field trial: one with amplification only, one with Multiflex Tinnitus Technology settings as programmed for the patient by the research audiologist and one with Multiflex Tinnitus Technology settings as selected by the participant using SoundPoint Tinnitus. Figure 5 displays the preferred settings for all participants. Sixteen of the participants indicated that they preferred one of the memories with Multiflex Tinnitus Technology over the amplification only memory. Of those 16 participants, nine participants preferred the noise signal as programmed by the audiologist and seven participants preferred the noise signal selected using SoundPoint Tinnitus.

The 16 participants who preferred Multiflex Tinnitus Technology to amplification only were then asked to indicate their preferred modulation settings. These results are displayed in Figure 6. Seven participants preferred modulation off. Among those participants who preferred modulation enabled, preference for the modulation setting was divided approximately evenly across the slow, medium and fast rates.

Discussion

In this study, 58 percent of the 19 participants were successful with Xino Tinnitus after six to eight weeks of use; these participants reported benefit from Xino Tinnitus and exhibited clinically significant improvement in tinnitus on at least one of the two standardized questionnaires. A review of literature revealed that these results are consistent with results obtained with other combination hearing aid and sound therapy devices. Parazzini, Del Bo, Jastreboff, Tognola and Ravazzani (2011) used both open canal hearing aids and sound generators as a part of a Tinnitus Retraining Therapy program. After six months of use of either hearing aids or sound generators, 62 percent of participants exhibited a significant reduction in THI score. Sweetow and Sabes (2010) evaluated the effectiveness of a combination hearing aid and sound generator and found that, after six months of use, 43 percent of participants exhibited a significant improvement on either the Tinnitus Reaction Questionnaire or the THI. Interestingly, both studies found that success rate increased over time; that is, as time elapsed, more participants exhibited clinically significant improvements in tinnitus as measured by standardized questionnaires. Considering this, it is possible that success rate with Xino Tinnitus may have exceeded the measured 58 percent if participants had used the devices for more than six to eight weeks.

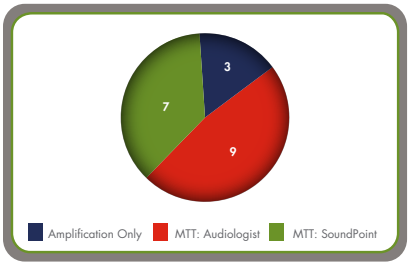

Figure 5: Number of participants who preferred each setting after comparing memories with amplification only, Multiflex Tinnitus Technology (MTT) with settings programmed by the research audiologist and Multiflex Tinnitus Technology with settings selected by the participant using SoundPoint Tinnitus.

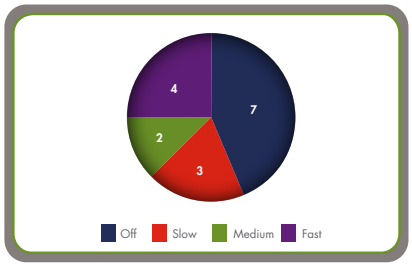

Figure 6: Number of participants who preferred each of the available modulation settings: off, slow, medium or fast.

Conclusions

As discussed, this clinical validation process is critical to the development of new products. Evidence-based design requires that patient benefit and patient preferences be investigated when developing new technologies. Results from this study indicate that Multiflex Tinnitus Technology can provide significant patient benefit, reducing the effect of tinnitus on patients' lives and reducing the amount of time patients are both aware of and disturbed by their tinnitus. Additionally, this benefit can be measured via standardized measures like the THI and TFI. Information regarding patient preference is used to validate the design of the product and ensure patient comfort and satisfaction. The results from this examination of patients' preferences revealed that patients have varied preferences, but Multiflex Tinnitus Technology provided the flexibility necessary to meet the needs of a majority of participants. The clinical validation of Multiflex Tinnitus Technology demonstrated that the feature can provide relief from tinnitus and can be tailored to meet the varied needs of patients with tinnitus.

References

Del Bo, L. & Ambrosetti, U. (2007). Hearing aids for the treatment of tinnitus. In B. Langguth, G. Hajak, T. Kleinjung, A. Cacace, & A.R. Moller (Eds.), *Progress in Brain Research: Volume 166. Tinnitus: Pathophysiology and Treatment.* Amsterdam: Elsevier.

Folmer, R.L. & Carroll, J.R. (2006). Long-term effectiveness of ear-level devices for tinnitus. *Otolaryngology-Head and Neck Surgery, 134*, 132-137.

Galster, E.A. (2013). Sound therapy for tinnitus: Multiflex Tinnitus Technology. *Innovations, 3*, 4-9.

Meikle, M.B., Henry, J.A., Griest, S.E., Stewart, B.J., Abrams, H.B., McArdle, R., et al. (2012). The Tinnitus Functional Index: Development of a new clinical measure for chronic, intrusive tinnitus. *Ear & Hearing, 33*, 153-176.

Newman, C.W., Jacobson, G.P., & Spitzer, J.B. (1996). Development of the Tinnitus Handicap Inventory. *Archives of Otolaryngology-Head & Neck Surgery, 122*, 143-148.

Newman, C.W., Sandridge, S.A., & Jacobson, G.P. (1998). Psychometric adequacy of the Tinnitus Handicap Inventory (THI) for evaluating treatment outcome. *Journal of the American Academy of Audiology, 9*, 153-160.

Parazzini, M., Del Bo, L., Jastreboff, M., Tognola, G., & Ravazzani, P. (2011). Open ear hearing aids in tinnitus therapy: An efficacy comparison with sound generators. *International Journal of Audiology, 50*, 548-553.

Sweetow, R.W. & Sabes, J.H. (2010). Effects of acoustical stimuli delivered through hearing aids on tinnitus. *Journal of the American Academy of Audiology, 21*, 461-473.

Tyler, R. S. (2006). Neurophysiological models, psychological models, and treatments for tinnitus. In R.S. Tyler (Ed.), *Tinnitus Treatment* (p. 11). New York, NY: Thieme.

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