

## Introduction

Sound therapy, or use of any sound for the purpose of tinnitus management, is widely accepted as a management tool for tinnitus. The rationale for the use of sound in the management of tinnitus is to minimize the patient's perception of tinnitus by effectively reducing the signal-to-noise ratio between the tinnitus and ambient or environmental sounds<sup>1,2</sup>. Despite this common rationale, approaches to sound therapy have varying goals, as described by Tyler<sup>3</sup>:

- "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 multiple sound therapy approaches for tinnitus management. Multiflex Tinnitus Technology generates a broad-band stimulus that can be adjusted by the professional in the Inspire fitting software using 16 independent frequency bands. The hearing aid settings and the Multiflex Tinnitus Technology settings can be configured independently of one another. An optional modulation setting controls the rate of periodic changes in the amplitude and the frequency response of the noise over time, resulting in an auditory perception similar to ocean waves or a breeze.

The purposes of the current study were as follows:

- to investigate patient preference for settings of Multiflex Tinnitus Technology and
- to investigate the effects of Multiflex Tinnitus Technology on tinnitus handicap and severity.

## Methods

- 19 adults, 1 with normal hearing and 18 with varying degrees of hearing impairment, participated in this study. See Figure 1 for audiometric data.
- Participants, 12 males and 7 females, had a mean age of 64.4 years.
- 12 participants were new hearing aid users and 7 participants were experienced hearing aid users.
- All participants had clinically significant tinnitus as indicated by a score of 20 or greater on the Tinnitus Handicap Inventory (THI)<sup>4</sup>.
- All participants were fit bilaterally with receiver-in-canal hearing aids, featuring Multiflex Tinnitus Technology, and were seen at least 4 times over the course of 6 to 8 weeks.
- Participants completed both the THI and the Tinnitus Functional Index (TFI)<sup>5</sup> to assess tinnitus handicap and severity at the beginning and end of the study.
- Participants were also asked to rate the change in their tinnitus by the end of the study and to indicate their preference for various hearing aid settings, including hearing aid only, hearing aid with a steady-state tinnitus stimulus, and hearing aid with a modulated tinnitus stimulus.

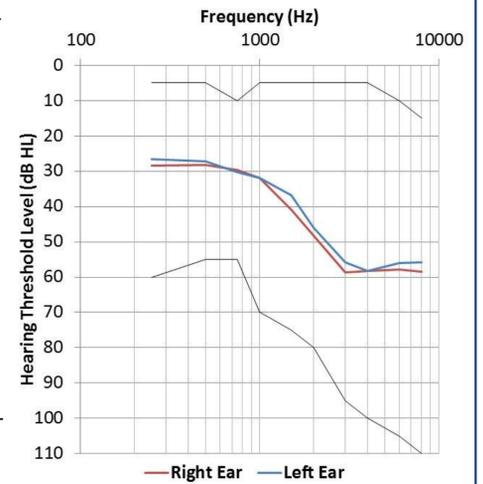


Figure 1. Mean audiometric data for right (red) and left (blue) ears. Black lines represent minimum and maximum thresholds for all participants.

## Results

Figures 2 and 3. Figure 2 (left) displays participant preference for hearing aid only or the hearing aid plus Multiflex Tinnitus Technology. Figure 3 (right) displays preference for modulation settings (off, slow, medium, or fast) among those who preferred hearing aid plus Multiflex Tinnitus Technology over hearing aid only.

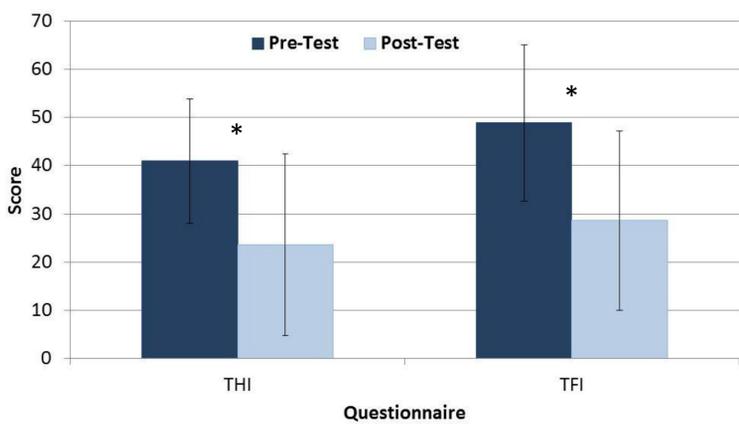
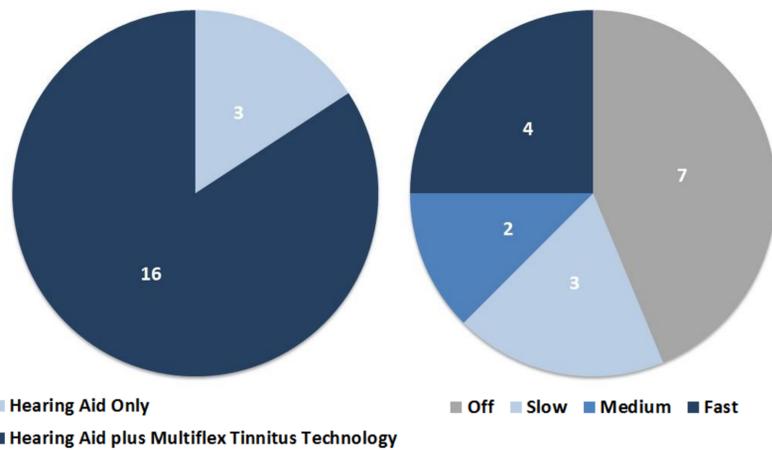


Figure 4. Mean THI and TFI pre-test and post-test results. THI score improved by approximately 17 points and TFI score improved by approximately 20 points. Error bars indicate  $\pm 1$  standard deviation. As indicated by the asterisks, both changes were statistically significant ( $p < 0.01$ ).

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. Subjective results for all participants. Participant ratings of change in tinnitus by the end of the study are displayed in the second column. Changes in THI and TFI scores are displayed in the third and fourth columns, respectively. Negative values in these columns indicate an improvement in tinnitus handicap or severity. A clinically significant change on the THI is 20 or more points and on the TFI is 14 or more points. Clinically significant changes are indicated by red text.

## Conclusions

- 16 of 19 participants indicated preference for the hearing aid plus Multiflex Tinnitus Technology settings over the hearing aid only settings.
- Approximately half of the participants preferred modulation on and approximately half preferred modulation off. Of those participants who preferred modulation on, preference for rate of modulation was split evenly across the slow, medium, and fast settings.
- There was a statistically significant improvement in tinnitus handicap and severity as measured by comparing the mean THI and TFI pre-test and post-test scores.
- 11 of 19 participants reported an improvement in their tinnitus by the end of the study and exhibited a clinically significant improvement on at least one of the two standardized questionnaires.
- An additional 4 participants reported an improvement in their tinnitus by the end of the study, but did not exhibit any clinically significant improvement on either questionnaire.
- Results indicate that Multiflex Tinnitus Technology may be used successfully as a part of a sound therapy program for tinnitus patients.

## References

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