

Treatment of tinnitus with a customized, dynamic acoustic neural stimulus: clinical outcomes in general private practice

Objectives: The purpose of this study was to:

1. Determine whether the outcomes reported with the Neuromonics Tinnitus Treatment in the controlled clinical environment would translate to the “real world” setting of private practice clinics.
2. To evaluate the relative effectiveness of the Neuromonics Tinnitus Treatment for various categories of patients found in the private practice setting.

Design: The Neuromonics Tinnitus Treatment is a treatment approach that combines the use of an acoustic stimulus with a structured program of counseling and support by a clinician trained in tinnitus management. The individually customized acoustic stimulus was designed to provide stimulation to auditory pathways deprived by hearing loss, engage positively with the limbic system, and allow intermittent, momentary tinnitus perception within a pleasant and relaxing auditory sensation, thereby facilitating desensitization to the tinnitus perception.

In previously reported clinical studies, the Neuromonics Tinnitus Treatment provided rapid and large improvements in tinnitus symptoms for a large majority of patients who met suitability criteria.^{1,2} In one study, after 6 months of treatment, 91% of patients with clinically significant tinnitus disturbance reported an improvement in disturbance of at least 40%.¹ In another controlled study, the Neuromonics Tinnitus Treatment resulted in greater efficacy (66% mean improvement reported after 6 months) than treatment protocols using counselling alone or with broadband noise (15% and 22% mean improvement, respectively, after 6 months).²

The present study reports on the clinical outcomes for the first tinnitus patients to undertake the Neuromonics Tinnitus Treatment in 7 “real world” private practice clinics in Australia. In this study, 552 patients (72% male) began treatment. The mean age was 56 ± 13 years (range: 19 to 88 years). The length of time since tinnitus onset ranged from 0.1 to 63 years, with a mean of 11.1 ± 12.4 years. The level of tinnitus disturbance before treatment, as measured by the Tinnitus Reaction Questionnaire (TRQ) score, varied from negligible (TRQ=1) to maximum disturbance (TRQ=104), with a mean pretreatment TRQ score of 41.7 ± 23.5. Patients were assigned to 1 of 3 cohorts based on criteria that defined their relative suitability for Neuromonics Tinnitus Treatment.

1. Tier 1 (n=237). Patients did not display any of the nonstandard or complicating factors by which the following 2 cohorts were determined. These were the most suitable patients.
2. Tier 2 (n=223). Patients exhibited one or more of the following: a high level of apparent psychological disturbance (n=111), a low reported level of tinnitus-related disturbance (TRQ<17) (n=82), and/or a moderately severe or greater hearing loss in the worse-hearing ear (n=42).
3. Tier 3 (n=92). Patients exhibited 1 or more of the following: “reactive” tinnitus, i.e., reported tinnitus that was exacerbated by even low levels of sound (n=25), continued exposure to high levels of noise without effective hearing protection during the period of treatment (n=17), active pursuit of compensation (n=14), multitone tinnitus (n=12), English-language comprehension difficulties (n=12), pulsatile tinnitus (n=11), Meniere’s disease (n=8), and/or a hearing loss of greater than 50 db for the 4-frequency (0.5, 1, 2 and 4 kHz) average in the best-hearing ear, i.e., in both ears (n=4).

Patients began the treatment protocol with a device-fitting appointment followed by a 2-week post-fitting review. They were instructed to listen to their acoustic stimulus for at least 2 hours per day, particularly during periods of tinnitus disturbance. For the first 2 months, they were instructed to listen to the stimulus in a manner that provided a high degree of relief from tinnitus. At approximately 2 months after the fitting, the patients had a “transition appointment”, and were instructed to achieve an intermittent level of interaction, i.e. to use the stimulus in a manner that covered up their tinnitus during the intensity peaks and allowed perception during the intensity troughs. All patients were offered the option of seeing a clinical psychologist (“tinnitus coach”) if they felt they needed additional assistance for relaxation or to address depression or anxiety.

The principal measurement instrument was the TRQ. Other measurements included tinnitus awareness, loudness discomfort levels (LDLs), and broadband noise minimum masking levels (MMLs).

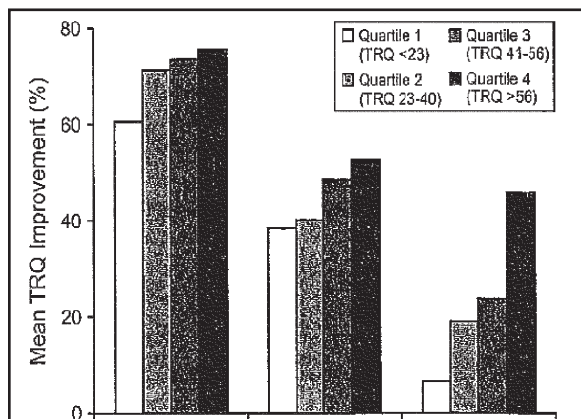
Results: Of the first 552 patients who began treatment, 470 patients progressed with treatment and 62 (11%) chose to discontinue treatment and receive the full refund on offer over the initial stages of treatment. An additional 20 patients were lost to contact after their initial fitting appointment.

Improvements in Tinnitus-Related Disturbance. Statistically significant improvements in tinnitus disturbance occurred in all 3 cohorts, although the degree and consistency of improvement varied across the 3 cohorts. The best outcomes were achieved for patients in the Tier 1 cohort, i.e., the most suitable patients. The “success rate,” defined as the proportion of patients who experienced a reduction in TRQ score of at least 40%, was 92% for Tier 1 patients, 60% for Tier 2 patients, and 39% for Tier 3 patients. The mean improvements in these 3 groups were 72%, 49%, and 32%, respectively.

Improvements in tinnitus, as measured by the TRQ score, was found to be least for patients with the lowest level of pretreatment disturbance, and highest for patients with the highest levels of pretreatment disturbance. (See **Figure 1**.)

Improvements on Other Measures. A high proportion of patients reported significant improvements in tinnitus awareness and in MML and LDL levels. The improvements were statistically significant for each measure for all 3 cohorts (p<0.001).

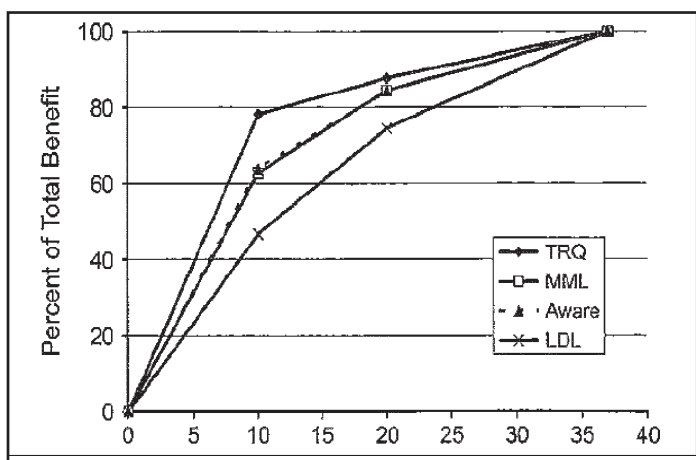
Figure 1. Improvements in Tinnitus Reaction Questionnaire (TRQ) Scores



Bars correspond to mean reduction in TRQ score among patients within each suitability cohort whose pretreatment TRQ score fell within each severity quartile, defined by scores ranging between 0 and 22, 23 and 40, 41 and 56, and 57 and 104.

Time Frame of Achievement of Benefits. Large benefits were achieved in the early stages of treatment. Relative to the total mean improvement in TRQ achieved at the completion of treatment, 78% of the improvement had been achieved by the transition appointment, which took place on an average of 10 weeks after beginning treatment. (See Figure 2.)

Figure 2.
Rate of Improvements in Tinnitus Disturbance, Awareness, MML and LDL



Rate of improvements in tinnitus disturbance (as measured by reduction in TRQ score), awareness (Aware), MML, and LDL. Depicted are proportions of total mean improvement that were reported at each key point in treatment protocol, as determined for all patients who progressed with treatment.

Discussion: Relation between Suitability and Clinical Outcomes.

A clear relationship was observed between the achievement of positive clinical outcomes and the suitability of the patient for treatment. Among the most suitable patients, 92% exceeded the minimum threshold for clinical success. The mean improvement in disturbance was 72% for these patients; the discontinuance rate was 4%. For the other cohorts, the success rates and mean improvements were somewhat lower (Tier 2: 60% and 49%, respectively; Tier 3: 39% and 32%, respectively), and the discontinuance rates were higher (Tier 2: 16%; Tier 3: 17%).

Less consistently positive outcomes were reported by patients who were actively pursuing compensation, presented with active Meniere’s disease, were challenged with English-language comprehension difficulties, or were subject to ongoing noise exposure without adequate hearing protection during the period of treatment. These relationships may provide guidance for health-care providers when setting patient expectations based on the degree of the patient’s suitability for treatment.

Relation between Tinnitus Disturbance and Clinical Outcomes.

Within each of the patient suitability cohorts, a clear relationship was observed between the level of disturbance improvement reported after treatment and the degree of tinnitus disturbance before treatment. For example, patients with Tier 3 suitability and a low level of tinnitus disturbance had the least positive prospects, while those with Tier 3 suitability and a high degree of tinnitus disturbance had relatively better prospects for successful treatment. This relationship can provide guidance for the health-care professional when determining which patients are more likely to experience successful results with the Neuromonics Tinnitus Treatment.

Limitations of Study Design. With no control or placebo group, there was no internal reference group to gauge the degree of improvement that might have been due to a placebo effect, an intervention effect, or other non-treatment-specific effects. However, findings in prior studies strongly support the contention that the acoustic stimulus provided as part of the Neuromonics treatment contributed in large part to the clinical benefits reported by patients in the present study. In one study, patients who received the Neuromonics treatment reported a significantly greater and more consistently positive benefit than those patients who received a counselling and support program, with or without a broadband noise stimulus.² Another study demonstrated a clear dosage effect, i.e. a relation between clinical efficacy and dosage (amount of treatment time per day) over the first 4 months of treatment.¹

Also, it is possible that the reported positive outcomes may have been influenced by the fact that the patients paid for treatment out of their own pockets. However, the stress associated with the financial outlay may at least partly offset this effect. In any case, patient payments mirror the situation that most patients are likely to encounter with “real world” clinical treatment.

Conclusions: The results of this study showed that the Neuromonics Tinnitus Treatment is an effective treatment for suitable patients in the private practice setting. Treatment resulted in rapid and consistent improvement in patients who satisfied various predefined suitability criteria, and in those who had previously tried other treatments without success. Improvement was achieved with a modest investment of clinician time over the course of treatment and of patient time per day, and patients found the treatment pleasant and easy to use. These results provide guidance for health-care providers in setting patient expectations based on the degree of suitability for treatment.

References

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3. Wilson PH, Henry J, Bowen M, Haralambous G. Tinnitus reaction questionnaire: psychometric properties of a measure of distress associated with tinnitus. *J Speech Hear Res.* Feb 1991;34(1):197-201.