Treatment of Tinnitus With a Customized, Dynamic Acoustic Neural Stimulus: Clinical Outcomes in General Private Practice

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Objectives: We evaluate the relative effectiveness of a newly available tinnitus treatment approach for different categories of patients in general private practice.

Methods: This was a cohort study, sponsored by Neuromonics, involving the first 470 patients to undertake the Neuromonics Tinnitus Treatment in 7 Neuromonics tinnitus clinics. All patients were provided with a dynamic acoustic neural stimulus, customized to each patient’s audiometric profile, for daily use as part of a structured rehabilitation program. Tinnitus disturbance was assessed before, during, and after treatment with the Tinnitus Reaction Questionnaire.

Results: The outcomes displayed a relation with patients’ suitability according to predefined criteria: among the most suitable patients (tier 1 cohort), 92% exceeded the threshold for success (defined as a reduction in tinnitus-related disturbance of at least 40%), and the mean improvement in tinnitus disturbance was 72%; the discontinuance rate was 4%. For other suitability categories, the success rates and mean improvements were somewhat lower, and the discontinuance rates higher (tier 2: 60%, 49%, and 16%, respectively; tier 3: 39%, 32%, and 17%, respectively).

Conclusions: The results showed that the treatment is effective for suitable patients in the private practice setting, and they provide health-care professionals with guidance as to what patients might expect from treatment, depending on their degree of suitability.

Key Words: acoustic stimulation, cohort study, rehabilitation, tinnitus.

INTRODUCTION

Recent advances in the understanding of tinnitus pathogenesis have highlighted the importance of changes within the auditory system and within the associated systems that control attention and the emotional reaction to tinnitus perception.1,2 Targeting the emotional reaction, counseling-based therapies are often recommended, and there are reports of significant (albeit modest) quality-of-life improvements with such approaches — for example, with cognitive behavioral therapy3 and group educational counseling.4 Other commonly recommended therapies combine counseling with acoustic therapy, usually in the form of noise generators or hearing aids.1 Three such approaches, tinnitus masking, tinnitus retraining therapy, and cognitive behavioral therapy with noise generators, have recently been shown to yield modest outcomes over treatment periods extending up to 18 months.5,6 Whether the acoustic stimulation used in such approaches provides incremental benefit over counseling has been questioned by some researchers,6-9 and there are reports of patient acceptability problems with such devices.6,10

The Neuromonics Tinnitus Treatment was developed with the intention of providing clinicians with a treatment option that offers more consistent efficacy, is more efficient to administer, and is more acceptable to patients than previous approaches.11,12 As detailed elsewhere,13 this approach provides stimulation to auditory pathways deprived by hearing loss through administration of a broad-frequency stimulus customized for each patient’s individual audiometric profile. The stimulus, which has been described elsewhere,13-16 also incorporates relaxing music. This serves the dual objectives of engaging positively with the limbic system (the involvement
of which contributes to the disturbing effects of tinnitus\(^1\) and making the stimulus pleasant to listen to, thereby promoting compliance with treatment. In addition, the dynamics of the stimulus allow intermittent, momentary tinnitus perception within a pleasant and relaxing listening experience, thereby facilitating desensitization to the tinnitus signal. This stimulus is provided in conjunction with a clinician-administered support program that shares key elements with counseling programs in general use and applies the principles of systematic desensitization and cognitive behavioral therapy.\(^1\)

Previously reported clinical studies undertaken by the treatment’s developers have shown that Neuromonics Tinnitus Treatment provides rapid and large improvements in tinnitus symptoms for a large majority of patients who meet suitability criteria. In a recent study, after 6 months of treatment, 91\% of patients with clinically significant tinnitus disturbance reported an improvement in the disturbance of at least 40\%, with a mean improvement of 65\%; much of the improvement was evident over the first 2 months of treatment.\(^1\) The suitability criteria for that study were a lack of a significant hearing loss in the speech range, defined by a 4-frequency (0.5, 1, 2, 4 kHz) average hearing threshold level worse than 50 dB in the best-hearing ear; a lack of ongoing compensation claims related to tinnitus; a lack of clinically significant psychosocial, depression, cognitive incapacity, or insufficient English-language abilities; an absence of significant factors that cause tinnitus to be aggravated, such as loud noise exposure, ototoxic medication, and disease processes; and an absence of concurrent treatment of tinnitus (including recent onset of hearing aid usage exceeding 1 hour per day). That study also demonstrated the benefit for patients of the customization process, as it allowed patients to cover up (and hence gain relief from) their tinnitus perception at a listening volume that was much lower (16 dB lower on average) than an equivalent noncustomized stimulus. A high proportion (more than 90\%) of patients reported that they found the acoustic stimulus pleasant and easy to use. Another controlled study demonstrated the greater efficacy of Neuromonics treatment (66\% mean improvement reported after 6 months) as compared with other treatment protocols utilizing counseling plus broadband noise or counseling only (22\% and 15\% mean improvement, respectively, after 6 months).\(^1\)

The Neuromonics Tinnitus Treatment was first made available to the general tinnitus patient population in a private practice setting in Australia in 2004. The current study was performed to determine whether the clinical outcomes reported in the controlled clinical trial environment would translate to the “real world” setting of private practice clinics, and to evaluate its relative effectiveness for different categories of patients in that setting. The present study, which was sponsored by Neuromonics, reports on the clinical outcomes for the first 470 such patients to undertake the Neuromonics Tinnitus Treatment in 7 of these clinics.

**MATERIALS AND METHODS**

**Patient Selection and Characteristics.** This study concerns all of the first 470 fee-paying patients to undertake treatment in any of 7 Neuromonics tinnitus clinics in Australia (ie, in Sydney, Melbourne, Perth, Brisbane, Canberra, Newcastle, and Launceston). Before commencing treatment, all patients underwent a standardized assessment to gauge their relative suitability for treatment and to check for the presence of any conditions that might have required medical intervention. All patients were recommended for otolaryngological evaluation whenever appropriate.

The 470 patients who progressed with treatment were drawn from 552 patients who had commenced treatment. Of these 552 patients, 62 elected to take advantage of a return-for-refund policy that was on offer over the initial stages of treatment. A further 20 patients were lost to contact after their initial fitting appointment, ie, before their first follow-up appointment; these patients were excluded from the data set for outcomes analysis.

Of the 552 patients who commenced treatment, 72\% were male. They ranged in age from 19 to 88 years, with a mean of 56 years (SD, 13 years). They displayed a wide range of audiometric profiles and tinnitus types and experiences. The length of time since tinnitus onset ranged from 0.1 to 63 years, with a mean of 11.1 years (SD, 12.4 years). Forty-nine percent had previously tried various other treatments (including hearing aids, maskers, counseling, Tinnitus Retraining Therapy, music therapy, acupuncture, and herbal treatment) with limited success.

The level of tinnitus disturbance before treatment, as measured by the Tinnitus Reaction Questionnaire (TRQ\(^1\)) score, varied from negligible (TRQ score of 1) to maximum disturbance (TRQ score of 104). The mean pretreatment TRQ score across the 552 patients was 41.7 (SD, 23.5; 95\% confidence interval for mean, 39.8 to 43.7), which corresponds to a moderate to severe level of disturbance.\(^1\) This mean TRQ score corresponds to a Tinnitus Handicap Inventory (THI\(^2\)) score of approximately 55.9, if the previously described TRQ/THI transform function\(^1\)
is applied (95% confidence interval for mean, 53.7 to 58.0).

The patients were assigned to 1 of 3 cohorts on the basis of their degree of satisfaction of the criteria defining relative suitability for Neuromonics Tinnitus Treatment. These criteria had been defined on the basis of the clinical experience over a series of clinical trials conducted before the release of the treatment in a private-practice setting. The 3 cohorts and the distribution of patients among them were as follows.

The tier 1 cohort (237 patients) were the most suitable patients, who did not display any of the nonstandard or complicating factors by which the following 2 cohorts were determined.

The tier 2 cohort (223 patients) exhibited one or more of the following: a high level of apparent psychological disturbance (111 patients), a low reported level of tinnitus-related disturbance, as indicated by a TRQ score below 17 (82 patients), and/or a moderately severe or greater hearing loss in the worse-hearing ear, ie, a greater than 50-dB 4-frequency (0.5, 1, 2, and 4 kHz) average (42 patients).

The tier 3 cohort (92 patients) exhibited 1 or more of the following: “reactive” tinnitus, ie, reported tinnitus that was exacerbated by even low levels of sound (25 patients), continued exposure to high levels of noise without effective hearing protection during the period of treatment (17 patients), active pursuit of compensation (14 patients), multitone tinnitus, ie, reported 2 or more prominent tinnitus tones that were disturbing (12 patients), English-language comprehension difficulties (12 patients), pulsatile tinnitus (11 patients), Meniere’s disease (8 patients), 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, ie, in both ears (4 patients).

It is apparent from this breakdown of patients by category that there were a number of patients who opted to proceed with treatment even though they exhibited characteristics that were believed to make them less-than-ideal candidates. This was especially true for the tier 3 patients. These patients were informed of their relatively lower suitability for treatment, but opted to proceed regardless of this, typically on the basis that they had tried other treatments without success and were prepared to “give it a try.” They proceeded in the knowledge that they could later opt to discontinue treatment under a return-for-refund policy. The tier 2 patients were also advised that their “nonstandard” profile might be reflected in a somewhat lesser responsiveness to treatment or success rate. Included among these patients were a sizeable number who reported a level of tinnitus-related disturbance that was below the threshold for clinically significant disturbance that had been defined by the developers of the TRQ (ie, a TRQ score of less than 17). It is noted that their decision to proceed with treatment was entirely at their discretion, and their decision indicates that notwithstanding a low overall score reported on the TRQ, the tinnitus was sufficiently intrusive on at least some aspects of their life (eg, sleep, concentration) that they felt the effort and investment in a treatment was warranted for them.

Among the 552 patients were 83 (15%) who used hearing aids for hearing and communication or had used hearing aids previously for management of their tinnitus. Those patients whose hearing loss was sufficient to warrant it were encouraged to use their aids for general hearing and communication purposes, then take their hearing aids out at those times of the day when they wished to use their Neuromonics treatment (especially at those times of the day when their tinnitus was usually most disturbing, for example, quiet periods, or when trying to go to sleep). As the earpiece of the Neuromonics device sits in the concha bowl of the ear, it is physically not possible to use the Neuromonics treatment and hearing aids at the same time. Patients whose hearing thresholds were found at assessment to exceed the recommended maximum 4-frequency (0.5, 1, 2, 4 kHz) average of 50 dB in both ears were recommended to proceed with hearing aid fitting in preference to progressing with the Neuromonics Tinnitus Treatment.

**Acoustic Stimulus.** The Neuromonics acoustic stimulus and the principles underlying its use have been described in detail elsewhere. In summary, it consists of a broad-frequency (up to 12 kHz) combination of broadband noise and relaxing music that is customized by spectral modification to account for each individual’s particular hearing loss profile by use of proprietary algorithms. The stimulus was designed with the objective of addressing the neurologic processes underlying the condition, that is, the auditory, attentional, and emotional processes that lead to clinically significant tinnitus-related disturbance. Use of the stimulus is intended to provide a broad-frequency stimulus to address the effects of auditory deprivation, to promote relief and relaxation with the intention of reducing the engagement of the amygdala and the autonomic nervous system, and to apply the principles of systematic desensitization (taking advantage of the dynamic properties of music) to address the attentional processes underlying the condition.

**Treatment Protocol.** As described elsewhere,
the patients were instructed to listen to their acoustic stimulus for at least 2 hours per day, particularly at those times when their tinnitus was usually disturbing. They were instructed in how to achieve a high level of interaction with their tinnitus perception for the first 2-month period using the first phase of treatment, ie, to listen to the stimulus in a manner that covers up a large proportion of their tinnitus perception and hence provides a high degree of relief from their tinnitus. Then, during the subsequent 4-month period, the patients were given the second phase of treatment and instructed to achieve an intermittent level of interaction, ie, to use the stimulus in a manner that allows their tinnitus to be covered up during the intensity peaks in the dynamic stimulus and to be perceived during the intensity troughs. A structured program of monitoring and support by clinicians was also provided throughout the treatment program. The standard protocol comprised a device fitting appointment, a 2-week postfitting review, a “transition appointment” at approximately 2 months after the fitting (at which the stimulus and instructions were changed from “high interaction” to “intermittent interaction”), and additional review appointments at approximately 4 and 6 months after the fitting.

The standard clinical protocol outlined above comprises approximately 4½ hours of clinician-patient face-to-face time in total (excluding the pretherapy assessment). In addition, the patients were offered the opportunity for time with a clinical psychologist (described to them as a “tinnitus coach”) if they or their clinician felt that additional assistance would be helpful with such issues as depression, anxiety, or inability to relax. Of the patients with a high apparent degree of psychological disturbance (95 in tier 2 and 20 in tier 3), 79% accepted the offer of time with a psychologist, and 61% had more than a single session (median, 2.5 hours among those who spent time with a psychologist). Among the other 355 patients who progressed with treatment, 24% were seen by a psychologist, and 61% had more than a single session (median, 1.0 hours); for these patients, this time with the psychologist was most commonly focused on providing further assistance with relaxation and sleep management techniques.

The present study followed formal clinical trials of the treatment, which had been conducted with ethics committee and Institutional Review Board approval. The present study’s focus was to evaluate the efficacy of the treatment for those who preselect themselves as patients in the “real world” environment of general private practice. The patients were provided with comprehensive written materials outlining what they could expect from treatment, as well as the risks and hazards. These were discussed with each patient before the commencement of treatment to ensure that their decisions to progress with treatment were adequately informed. The patients were also informed that they could discontinue treatment at any time, and would receive a full refund if they did so over the initial stage of treatment. Ethical issues associated with data collation and presentation were also addressed appropriately in line with the preceding university-based studies.

Measurement Devices. The TRQ, with its well-established psychometric properties,19 was adopted as the principal measurement instrument, in line with the previous clinical studies of the Neuromonics treatment. The TRQ summates the degree of tinnitus distress over 26 items that are indicative of the extent of lifestyle disturbance, and yields a composite score with a maximum possible distress level of 104. Each patient completed the questionnaire with reference to the effects of the tinnitus in the week before each clinical visit. The “pen and paper” forms were completed by the patients, so they were not subject to any rater bias. In analysis of TRQ results, a threshold for a clinically significant improvement was set at 40% of pretreatment TRQ, in line with prior clinical studies of this technique.14

Audiometry and measurement of minimum masking levels (MMLs) were based on the Oregon Health Sciences University Tinnitus Clinic protocol,22 using a Maico MA53 audiometer and Sennheiser HD200 headphones. The 10 and 12.5 kHz hearing level values were calibrated according to ISO TR/389-5. The MMLs were determined ipsilateral to the dominant tinnitus percept (contralateral in instances of tinnitus in a “dead ear”) by initially measuring the patient’s hearing threshold with broadband noise, and then increasing the noise intensity to the point at which it just fully masked perception of the tinnitus; the sensation level value was determined by subtracting the hearing threshold from the masking level. Measurement of loudness discomfort levels (LDLs) was adapted for safe use with tinnitus patients as described previously.14 This was performed separately for each ear at 0.5, 1, and 4 kHz, and the 3-frequency average was determined for each ear; the lowest average LDL was taken as the patient’s LDL at each time point.

Awareness was assessed by asking the patients the following question within written questionnaires administered at the assessment appointment and at subsequent review appointments: “Over the past week, what percentage of the time while awake were you aware of your tinnitus (eg, 100% aware = all the time, 25% aware = ¼ of the time)?”
Audiological Staff. Treatment was administered by 9 university-qualified audiologists with training in tinnitus and the Neuromonics treatment.

Statistical Analysis. The statistical methods used for descriptive statistics were frequencies and percentages. For inferential analyses, 1-way analyses of variance of the change between pretreatment and final posttreatment measures were used, and t-tests and confidence intervals were used for pairwise comparisons. Backwards stepwise regression was used to determine which factors were important in predicting change in disturbance (TRQ) scores.

Role of Funding Source. Employees of the study sponsor were involved in all aspects of this study, including clinical service provision, data collection and analysis, and manuscript preparation.

RESULTS

Discontinuance Rate. We consider the proportion of patients who chose to discontinue treatment and receive the full refund on offer over the initial stages of treatment as providing a metric of patient dissatisfaction with treatment. Among the first 552 patients to commence treatment, 62 (11%) chose to discontinue the treatment in this fashion.

The discontinuance rate varied among the various suitability cohorts: 4% (10 of 237 patients) among tier 1 patients, 16% (36 of 223) among tier 2 patients, and 17% (16 of 92) among tier 3 patients.

A further 20 patients (4%) were lost to follow-up after the initial device fitting appointment, but did not seek a refund. Those patients were excluded from the outcomes analysis reported herein. Any patients who were lost to follow-up after having attended at least 1 further review appointment after device fitting were included in the outcomes analysis on a “last value carried forward” basis.

Improvement in Tinnitus-Related Disturbance. The outcomes achieved on the primary measure of tinnitus disturbance, the TRQ, are displayed in Table 1. It shows that the degree and consistency of improvement varied across the 3 suitability cohorts, with the best outcomes achieved for the most suitable patients. “The success rate,” defined as the proportion of patients who reported an improvement in tinnitus disturbance (ie, reduction in TRQ score) of at least 40%, was 92% among tier 1 patients, 60% among tier 2 patients, and 39% among tier 3 patients. The mean improvements for patients in these 3 cohorts were 72%, 49%, and 32%, respectively. In all 3 suitability cohorts, the improvements in tinnitus disturbance were statistically significant. The differences between tier 1 and the other suitability cohorts were statistically significant.

Figure 1 displays the distribution of outcomes among the patients in each suitability cohort. TRQ — Tinnitus Reaction Questionnaire.

Table 1. Improvement in Tinnitus Disturbance (TRQ Score) for Each Suitability Cohort

<table>
<thead>
<tr>
<th>Patients who progressed with treatment</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pretreatment TRQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>40.1</td>
<td>41.8</td>
<td>46.2</td>
</tr>
<tr>
<td>SD</td>
<td>17.0</td>
<td>28.5</td>
<td>22.7</td>
</tr>
<tr>
<td>Posttreatment TRQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>11.1</td>
<td>21.2</td>
<td>31.3</td>
</tr>
<tr>
<td>SD</td>
<td>9.7</td>
<td>21.5</td>
<td>20.6</td>
</tr>
<tr>
<td>Improvement in TRQ (mean)</td>
<td>72%</td>
<td>49%</td>
<td>32%</td>
</tr>
<tr>
<td>Patients with &gt;40% improvement in TRQ</td>
<td>92%</td>
<td>60%</td>
<td>39%</td>
</tr>
<tr>
<td>Significance of differences before vs after treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>t Statistic</td>
<td>-29.1</td>
<td>-20.6</td>
<td>-14.9</td>
</tr>
<tr>
<td>p</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Significance of differences vs other tiers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>t Statistic</td>
<td>8.45*</td>
<td>5.75†</td>
<td>14.20‡</td>
</tr>
<tr>
<td>p</td>
<td>&lt;0.001*</td>
<td>0.066†</td>
<td>&lt;0.001‡</td>
</tr>
</tbody>
</table>
| TRQ — Tinnitus Reaction Questionnaire.
*Versus tier 2.  
†Versus tier 3.  
‡Versus tier 1.
characteristics that they exhibited. Table 2 displays the mean disturbance (TRQ score) improvement, SD, and success rate (ie, proportion with reduction in TRQ score of at least 40%) for each of these subcategories (ordered by success rate for each tier). The success rates indicated for the tier 2 subcategories “high level of hearing loss in one ear,” “low reported level of disturbance,” and “high apparent psychological needs” were determined in relation to only those patients categorized overall as tier 2. They exclude patients with those attributes who were categorized overall as tier 3; those patients were included in the subcategories corresponding with their tier 3 characteristics. The sum of categories within each cohort exceeds the cohort total because some patients were assigned to more than 1 subcategory.

In order to assess any relation between pretreatment severity and posttreatment outcomes, we divided patients into quartiles based on their TRQ score. For the 470 patients who progressed with treatment, TRQ scores of 23, 41, and 57 defined the second, third, and fourth quartiles by tinnitus severity. Within each of the 3 suitability cohorts, the mean improvement in TRQ score was determined for the patients in each of these severity quartiles. As illustrated in Fig 2, improvement in tinnitus disturbance as measured by the TRQ score was found to be least for patients with lowest levels of pretreatment disturbance (quartile 1), and highest for patients with highest levels of disturbance before treatment (quartile 4). Statistically significant differences were observed between quartiles (F statistic F(3, 464) = 131.28; p < 0.001), and these held irrespective of tiers.

### Improvement on Other Measures

Figure 3 displays the consistency of improvement on other measures: the amount of time patients report they are generally aware of their tinnitus (“awareness”), the MML, and the LDL. A change in LDL was determined as the difference between the lowest-ear 3-frequency (0.5, 1, 4 kHz) average before treatment and that after treatment. On each measure, a high proportion of patients reported a significant improvement, with some variation among suitability cohorts. The improvements were statistically significant for each measure for all 3 cohorts (for t-tests, tiers 1, 2, and 3, p < 0.001 for all 3 measures). The mean improvements on each measure for each of the suitability cohorts are outlined in Table 3.

### Time Frame of Achievement of Benefits

Figure 4 depicts the time frame over which benefits were achieved on each of the key outcomes measures for all 470 patients who progressed with treatment. It shows that large benefits were achieved in

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**Table 2. Improvement in Tinnitus Disturbance for Each Patient Subcategory**

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>No. of Patients</th>
<th>% of Patients With Reduction in TRQ of at Least 40%</th>
<th>Mean Improvement in Disturbance (TRQ Score Reduction; %)</th>
<th>SD of TRQ Change (% of Pretreatment Mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>217</td>
<td>92</td>
<td>72</td>
<td>41</td>
</tr>
<tr>
<td>Tier 2 (high level of hearing loss in one ear)</td>
<td>32</td>
<td>72</td>
<td>55</td>
<td>39</td>
</tr>
<tr>
<td>Tier 2 (low reported level of disturbance)</td>
<td>62</td>
<td>61</td>
<td>39</td>
<td>71</td>
</tr>
<tr>
<td>Tier 2 (high level of apparent psychological needs)</td>
<td>95</td>
<td>57</td>
<td>49</td>
<td>40</td>
</tr>
<tr>
<td>Tier 3 (multitone)</td>
<td>10</td>
<td>60</td>
<td>52</td>
<td>54</td>
</tr>
<tr>
<td>Tier 3 (pulsatile)</td>
<td>9</td>
<td>56</td>
<td>53</td>
<td>59</td>
</tr>
<tr>
<td>Tier 3 (reactive)</td>
<td>17</td>
<td>53</td>
<td>36</td>
<td>56</td>
</tr>
<tr>
<td>Tier 3 (high level of hearing loss in both ears)</td>
<td>4</td>
<td>50</td>
<td>31</td>
<td>38</td>
</tr>
<tr>
<td>Tier 3 (pursuing compensation)</td>
<td>14</td>
<td>36</td>
<td>24</td>
<td>45</td>
</tr>
<tr>
<td>Tier 3 (active Meniere’s disease)</td>
<td>6</td>
<td>33</td>
<td>33</td>
<td>38</td>
</tr>
<tr>
<td>Tier 3 (comprehension issues)</td>
<td>9</td>
<td>22</td>
<td>30</td>
<td>46</td>
</tr>
<tr>
<td>Tier 3 (ongoing noise exposure, unprotected)</td>
<td>16</td>
<td>13</td>
<td>9</td>
<td>30</td>
</tr>
</tbody>
</table>

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**Fig 2.** Improvements in tinnitus disturbance for patients in TRQ score quartiles. 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.
the early stages of treatment. Relative to the total mean improvement in tinnitus disturbance (ie, TRQ) achieved at the completion of treatment, 78% of the improvement had been achieved by the transition appointment, which took place in practice at an average of 10 weeks after commencement. The proportions of total overall benefit achieved by this time were somewhat lower on the other measures. The mean “duration” of treatment, defined as the period between device fitting and the formal completion appointment, was 37 weeks across the 470 patients (median, 32 weeks; SD, 18 weeks). Excluding those patients who did not attend formal completion appointments (86 of the 470), the mean “duration” was 39 weeks (median, 34 weeks; SD, 17 weeks).

**DISCUSSION**

**Limitations of Study Design.** As a cohort study, the present study compares clinical outcomes reported for 470 patients, divided among 3 different cohorts according to their degree of satisfaction of various predefined suitability criteria. In the absence of a control or placebo group, there was no internal reference group with which to gauge the degree to which the reported improvements might have resulted from a placebo effect, an intervention effect, or other non–treatment-specific effects. It is recognized from other studies that these effects can be significant, and hence there are limitations around the interpretation of results from cohort studies of the type described herein.

However, in a prior study undertaken by the developers of this approach, its performance was assessed relative to relevant controls, comprising a matched counseling and support program with or without a broadband noise acoustic stimulus. That study found a significantly greater and more consistent positive benefit reported by patients who received the Neuromonics treatment as opposed to those patients who received a counseling and support program with or without a broadband noise stimulus. Further, in another study undertaken by the treatment’s developers, a clear dosage effect was demonstrated whereby patients who received the same treatment reported results that displayed a relation between clinical efficacy and dosage or amount of treatment time per day over the first 4 weeks.
months of treatment. These prior findings provide strong support for our 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, as opposed to placebo or other nonspecific effects.

It warrants comment that the patients in the present study typically paid for their treatment out of their own pockets. Accordingly, it is possible that this may have contributed to the positive reported outcomes by virtue of the emotional investment that accompanies payment for treatment. However, it is our view that this is at least partly offset (for some patients, and therefore in aggregate across the patient population) by the stress associated with the financial outlay and the fear of having made a financially poor decision. Such concerns were mentioned proactively by a number of these patients, and can be expected to be counterproductive to treatment success, given the influence that general stress levels can have on tinnitus. In light of these considerations, together with the similarity in outcomes reported by suitable patients in the present study and those reported in previous formal clinical trials,14,18 it is our view that any impact of payment on treatment outcomes is not so material as to have distorted the reported outcomes. In any case, it is noted that having patients pay for their treatment mirrors the situation in which most patients are likely to be presented with the treatment in the broader clinical context. That patients commonly pay for their treatment in this setting can be argued as simply another aspect of the many attributes with which each patient presents when seeking treatment from a clinician.

Relation Between Suitability and Clinical Outcomes. Backwards stepwise regression analyses were used to identify any significant predictors of change in disturbance ratings using a 5% removal criterion. Excluding pretreatment TRQ, the factors tested were tier, age, time since onset, time since disturbance, gender, previously tried other treatments, hearing thresholds (4-frequency average for 0.5, 1, 2, and 4 kHz) in better and worse ears, percent awareness, MML, LDL, decreased sound tolerance, tinnitus pitch, and time with tinnitus coach. The minimal acceptable (final) model ($R^2 = 0.23$) included the following as significant factors: tier ($p < 0.001$), gender ($p = 0.006$; with women showing slightly greater improvement than men), percent awareness ($p < 0.001$; with greater pretreatment awareness associated with greater improvement), and time since tinnitus became disturbing ($p = 0.007$; with shorter time associated with greater improvement). No other factors displayed significant effects.

A clear relationship was observed between the clinical outcomes achieved and patient suitability for treatment, based upon fit with various predefined suitability criteria assessed before treatment. This was the case for the rate of success (defined as the percent of patients who reported an improvement in TRQ score of at least 40%), the mean level of benefit on various measures, and the discontinuance rate. Among the most suitable (tier 1) patients, the largest of the suitability cohorts, 92% of patients exceeded the minimum threshold for clinical success, and the mean improvement in disturbance was 72%; the discontinuance rate was low at 4%. The success rates and mean improvements were somewhat lower, and the discontinuance rates higher, for the other suitability cohorts (tier 2: 60%, 49%, and 16%, respectively; tier 3: 39%, 32%, and 17%, respectively). This provides health-care professionals who may consider offering the treatment or referring patients for assessment with guidance as to what patients might expect from treatment depending on their degree of satisfaction of those measures.

Surprisingly, the outcomes for one of the tier 3 subcategories (multitone tinnitus) were comparable with those of tier 2 cohort patients (and surpassed those of the high apparent psychological needs subcategory). The results for patients who presented with pulsatile and reactive tinnitus were only marginally less positive than those for tier 2 patients. The worst outcomes were reported for 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.

Relation Between Tinnitus Disturbance and Clinical Outcomes. A clear relationship was observed between the level of disturbance improvement reported after treatment and the degree of tinnitus disturbance before treatment, within each of the patient suitability cohorts. This relationship was most pronounced among the tier 3 patients, in whom the mean improvement ranged from as low as 7% for the patients in the least severely disturbed quartile (TRQ score of less than 23) to as high as 46% for the patients in the most severely disturbed quartile (TRQ score of more than 56). For the tier 2 and tier 1 cohorts, the corresponding ranges were 38% to 52% and 61% to 75%, respectively. This relationship further enhances the guidance for health-care professionals. For example, patients who present with tier 3 suitability characteristics and a low level of tinnitus disturbance have the least positive pros-
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There was rapid and consistent improvement among the patients who satisfied various predefined suitability criteria. This was also the case for the patients who had previously tried other treatments without success. This improvement was achieved with a modest investment of clinician time over the course of treatment and of patient time per day, with a treatment that patients reported as being pleasant and easy to use. The results provide health-care professionals with guidance as to what patients might expect from treatment, depending on their degree of suitability.