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Research Article

A Series of Case Studies of Tinnitus Suppression With Mixed Background Stimuli in a Cochlear Implant

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Purpose: Background sounds provided by a wearable sound playback device were mixed with the acoustical input picked up by a cochlear implant speech processor in an attempt to suppress tinnitus.
Method: First, patients were allowed to listen to several sounds and to select up to 4 sounds that they thought might be effective. These stimuli were programmed to loop continuously in the wearable playback device. Second, subjects were instructed to use 1 background sound each day on the wearable device, and they sequenced the selected background sounds during a 28-day trial. Patients were instructed to go to a website at the end of each day and rate the loudness and annoyance of the tinnitus as well as the acceptability of the background sound. Patients completed the Tinnitus Primary Function Questionnaire (Tyler, Stocking, Secor, & Slattery, 2014) at the beginning of the trial.
Results: Results indicated that background sounds were very effective at suppressing tinnitus. There was considerable variability in sounds preferred by the subjects.
Conclusion: The study shows that a background sound mixed with the microphone input can be effective for suppressing tinnitus during daily use of the sound processor in selected cochlear implant users.

Chronic tinnitus can be very debilitating (Tyler & Baker, 1983), often affecting the primary functions of emotions, hearing, sleep, and concentration (Tyler et al., 2006). Several therapeutic approaches—including counseling and behavioral therapy (Andersson & McKenna, 2006; Cima, Andersson, Schmidt, & Henry, 2014; Tyler, Stouffer, & Schum, 1989; Wilson, Henry, Andersson, Hallam, & Lindberg, 1998), the provision of hearing aids (Kochkin & Tyler, 2008; Kochkin, Tyler, & Born, 2011; Searchfield, Kaur, & Martin, 2010; Shekhawat, Searchfield, & Stinear, 2013), and sound therapy devices (Hoare, Searchfield, El Refaie, & Henry, 2014; Tyler, Stocking, Secor, & Slattery, 2014)—can be effective for many people.

New approaches are being explored for patients with unilateral hearing loss and severe tinnitus, including cochlear implants (CIs; Hansen, Gantz, & Dunn, 2013; Van de Heyning et al., 2008), brain stimulation through transcranial magnetic stimulation (Langguth & De Ridder, 2013; Piccirillo et al., 2011; Vanneste, Walsh, Van de Heyning, & De Ridder, 2013), and brain stimulation (De Ridder, Vanneste, Menovsky, & Langguth, 2012). However, at present, there is no "cure" for tinnitus.

Early reports by House (1976) and Cazals, Negrevergne, and Aran (1978) noted the potential benefit of CIs in reducing tinnitus (for an early review, see Kuk, Tyler, Rustad, Harker, & Tye-Murray, 1989). Laboratory trials indicated that electrical stimulation of the cochlea could suppress tinnitus in many sufferers (Hazell, Graham, & Rothera, 1985; Kuk et al., 1989), which has been further confirmed in recent investigations (Di Nardo et al., 2007; Zeng et al., 2011).

CIs have been shown to reduce tinnitus in about 80% of the patients presenting with tinnitus (Demajumdar, Stoddart, Donaldson, & Proops, 1999; Gibson, 1992; Harris, Parker, Fields, Frewin, & Baguley, 2011; Ito, 1997; Ito & Sakakihara, 1994a, 1994b; Kloostra, Arnold, Hofman, & Van Dijk, 2015; Kompis et al., 2012; Mo, Harris, & Lindbaek, 2002; Olze et al., 2011; Olze, Grabel, et al., 2012; Olze, Szczepek, et al., 2012; Quaranta, Wagstaff, & Baguley, 2004; Souliere, Kileny,

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Zwolan, & Kemink, 1992; Tyler, 1994, 1995; Tyler & Kelsay, 1990; Van de Heyning et al., 2008; Yonehara et al., 2006).

Pan et al. (2009) administered the Tinnitus Handicap Questionnaire (Kuk, Tyler, Russell, & Jordan, 1990) to tinnitus sufferers before and after they received a CI and observed that scores on the Tinnitus Handicap Questionnaire reduced for most patients. In addition, patients who reported they could hear better with their CIs typically showed large reductions in their tinnitus. The few patients reporting worsening of their tinnitus after cochlear implantation had a minimal preimplant tinnitus handicap. This could have been caused by activation of the device. However, cochlear trauma and/or medications provided during or after surgery might have also caused tinnitus or might have contributed to worsening of mild preexisting tinnitus.

Patients with unilateral hearing loss are excellent candidates for tinnitus treatment with a CI, as it has the potential to improve binaural hearing as well as suppress tinnitus (Arndt et al., 2011; Hansen et al., 2013; Punte, De Ridder, & Van de Heyning, 2013; Punte et al., 2011; Ramos et al., 2012; Song, Punte, De Ridder, Vanneste, & Van de Heyning, 2013; Van de Heyning et al., 2008). Trials in patients with unilateral hearing loss who were using an extracochlear stimulation device (Frachet, Wable, Vormes, Repetto, & Gallego, 2004; Péan, Cazals, Rosanis, & Frachet, 2010; Wenzel et al., 2014) were not as successful as the trials with multichannel CIs. At this stage, CIs for unilateral hearing loss are only reimbursed in a few countries (e.g., Canada and Germany) but are not yet reimbursed in the United States. It is anticipated that patients with tinnitus and unilateral hearing loss are willing to accept and pay for implants to treat their tinnitus (Tyler, 2012) and that public reimbursement in other countries will be forthcoming. It is likely that those with occupationally induced or accident-induced tinnitus will have the right to receive the best possible treatment for their tinnitus, which very well might be a CI.

CIs and the surgical techniques to implant them are becoming less traumatic, and CIs are now implanted in patients with residual low-frequency hearing (Gantz et al., 2009; Lenarz et al., 2013). Eventually, if hearing can be completely or partially preserved, electrical stimulation might become a treatment option for patients with tinnitus and normal or mild hearing loss (Tyler, 1997). Some individuals might be willing to risk an additional mild hearing loss in one ear if there was a highly probable chance of reducing their tinnitus.

It is clear that for many patients who receive a CI for their hearing loss, the electrical stimulation to the cochlea also reduces their tinnitus. These CI patients typically report that their tinnitus comes back when the implant is switched off or when there is no external sound in their environments. In this article, we explore whether the use of background sound added to the sound captured by the microphone of the CI can alleviate tinnitus in CI patients with tinnitus. Thus, patients perceive speech and environmental sounds mixed with a continuous background stimulus intended to suppress their tinnitus. The technologies that are described should be important in the development of a CI for hearing loss and tinnitus, or even for tinnitus alone.

Method

We sought volunteers from our CI patients with tinnitus. They first came in for a laboratory visit where they listened to a variety of different sounds (see Table 1) and selected 2–4 sounds for the trails. They were asked to choose

- sounds that were likely to reduce the magnitude of their tinnitus;
- sounds that they would likely find acceptable if they were to listen to them all day long; and
- sounds that were very different from each other, as long as they met the above two criteria.

In the trial, they were provided with a portable sound file player (iAudio9; Cowon, Seoul, South Korea) that they could wear and attach via a cable to their CI. This particular player was selected because it had a gapless loop playback function. This was considered important so as not to introduce annoying breaks when sound files are played back endlessly. The sound file outputs were mixed with the signal from the external microphone. Whatever external sound was received (noise, speech, music, and environmental sounds) was mixed with the tinnitus suppression sound. That is, the sound picked up by the external microphone and the tinnitus suppression signal was presented on the same electrodes. We use the term *suppression* here to indicate that the subjects report a reduction in their tinnitus perception, and we do not want to imply that the neural activity associated with tinnitus percept is reduced.

Subjects were instructed to change the tinnitus suppression sound each day. They were instructed to adjust the level of the suppression sound on the sound file player so that it was effective at reducing the tinnitus loudness and/or annoyance and would be acceptable to listen to in their daily life.

They were made aware that the researchers did not know what level they were using, and it was for them to modify and adjust it as necessary. They were instructed to adjust the level if they thought they wanted to try a different level, or if the effectiveness or acceptability of a level changed during the day. They were instructed to leave the suppressor on all day. At the end of each day, they were required to log onto a secure website to rate on a scale of 0%–100% for the loudness and annoyance of their tinnitus as well as the acceptability of the background sounds:

In general, for today

- Rate the loudness of your tinnitus on a scale of 0–100 (0 = *no tinnitus*, 100 = *loudest tinnitus you can imagine*).
- Rate the annoyance of your tinnitus on a scale of 0–100 (0 = *no annoyance*, 100 = *most annoying tinnitus you can imagine*).
- Rate the acceptability of listening to this background sound on a scale of 0–100 (0 = *unacceptable*, 100 = *extremely acceptable*).

We consider this investigation a series of case studies.

Table 1. Pretrial tinnitus suppression signals offered to subjects.

Sound	Description
Noise	• Flat spectrum broadband noise • Noise designed to deliver equal amplitude on all electrodes • OLSA noise (10–8000 Hz with low-frequency and midfrequency emphasis < 3000 Hz [speech weighted]; Wagener & Brand, 2005) • ICRA noise (10–8000 Hz with low-frequency emphasis [speech-weighted and speech-like temporal properties]; Dreschler et al., 2001) • Modulated broadband noise (20% amplitude modulated)
Sine waves	• 1000-, 2000-, and 4000-Hz pure tones • Frequency modulation ◦ 2000 Hz; 100-Hz frequency modulation ◦ 4000 Hz ; 200-Hz frequency modulation ◦ 2000 Hz; frequency modulation varying between 0 and 100 Hz ◦ 100 Hz; frequency modulation varying between 0 and 100 Hz • Amplitude modulation ◦ 100 Hz; 10% ◦ 2000 Hz; 10% ◦ 4000 Hz; 10%
Music	• Four different background melodies played by an ensemble of flutes, piano, violin, guitar, and chimes (Melodies 1, 2, 3, and 4)
Environmental sounds	• Ocean, raindrops, waterfall, and spa music (tonal combinations varying slowly in amplitude and frequency: the different combinations are referred to as Spas 1, 2, 3, and 4)

Note. OLSA = Oldenburg Sentence Test; ICRA = International Collegium for Rehabilitative Audiology.

Seven subjects ranging in age from 55 to 64 years participated in this study. Subject characteristics—including age, gender, duration, and location of tinnitus—and CI characteristics are detailed in Table 2. One subject participated twice (with a 7-month interval in between) and is listed twice (Subjects 2 and 7). Note that Subject 1 had worse tinnitus in the left ear while the CI was in the right ear.

Table 3 shows the pretrial results from the Tinnitus Primary Function Questionnaire (Tyler et al., 2014). The Tinnitus Primary Function Questionnaire was designed to assist tinnitus treatments (such as tinnitus activities treatment; Tyler et al., 2006) and to be responsive to treatments in clinical trials. It focuses on the four primary areas that are potentially affected by tinnitus (thoughts and emotions, hearing, sleep, and concentration). This will assist other researchers conducting clinical trials to compare tinnitus severity between subjects. It might be noteworthy that Subjects 3, 5, and 6 were only mildly bothered by their tinnitus.

Results

Subject 1

Subject 1's pretrial tinnitus loudness was 50%, whereas this subject's pretrial annoyance was 70%. Subject 1 selected the following stimuli for the trial: 2-kHz frequency-modulated (FM) stimulus, 20% amplitude-modulated (AM) noise, Spa 1, and the ocean sound. Subject 1's results for loudness, annoyance, and acceptability are shown in Figures 1A–1C. There was a near-complete reduction of tinnitus loudness for all four stimuli. Similarly, the annoyance reduced dramatically for all stimuli. However, the sounds varied in terms of their acceptability. Subject 1 found Spa 1 to be most acceptable followed by the 2-kHz-FM stimulus. The 20% AM noise and the ocean sound were rated as less acceptable (<50%) by this subject. It is noteworthy that Spa 1 was consistently rated higher than the other stimuli. The subject reported that this sound was "just easier and pleasant to listen to," particularly when there was no need to communicate.

Subject 2

Subject 2 had unilateral hearing impairment and had only a mild, high-frequency hearing loss in the nonimplanted ear. Pretrial tinnitus loudness was 90%, and tinnitus annoyance was 80%. The average tinnitus loudness for the "no-sound" condition (81%) was relatively consistent with the pretrial tinnitus loudness level that indicated a stable tinnitus. The subject selected to listen to the 2-kHz-AM sound, the unmodulated noise, and the ocean stimulus during the trial. Tinnitus loudness decreased 26% with the 2-kHz-AM sound, 29% with the unmodulated noise, and 44% with the ocean stimulus when compared with the control condition (see Figure 2A). Tinnitus annoyance also decreased 29%, 38%, and 49% in response to the 2-kHz-AM stimulus, the unmodulated noise, and the ocean sound, respectively, when compared with the control condition (see Figure 2B). Results indicated that tinnitus loudness and annoyance ratings had decreased for all stimuli with varying levels of acceptability (see Figure 2C).

Subject 3

Subject 3's pretrial loudness and annoyance levels were rated at 30% and 20%, respectively. This subject

Table 2. Subject characteristics.

Subject	Age (years)	Gender	Duration of tinnitus (years)	Duration with CI (years)	Percept	Location of tinnitus	Implant ear	CI array	CI processor	Processing strategy	Active channels
1	58	M	38	12	Ring; "Shhh"; hiss	Both ears; worse in left	Right	Nucleus CI24M	CP810-5	CIS	6
2	58	M	7	1	"Shhh"	Left ear	Left	Nucleus CI422	CP810-5	ACE	18
3	56	F	21	8	"Shhh"	Both ears equally	Right	Nucleus EAS3	Freedom Hybrid	ACE	6
4	64	M	29	5	"Shhh"	Right ear	Right	Nucleus Hybrid S12	Freedom Hybrid	ACE	10
5	55	M	12	6	Hum	Left ear	Left	Left: Nucleus CI24RE(CA); Right: Nucleus CI422	CP810-5	ACE	Left: 22; Right: 18
6	64	M	40	2	Locust	Middle of the head	Right	Nucleus Hybrid L24	Freedom Hybrid	ACE	18
7	59	M	8	1	"Shhh"	Left ear	Left	Nucleus CI422	CP810-5	ACE	18

Note. Subject 5 had bilateral cochlear implants (CIs) but was stimulated unilaterally for tinnitus suppression. M = male; F = female; CIS = Continuous Interleaved Sampling; ACE = Advanced Combination Encoder.

Table 3. Tinnitus Primary Function Questionnaire scores.

Subject	Emotions	Hearing	Sleep	Concentration	Total
1	13	28	0	28	18
2	52	90	67	57	66
3	10	30	0	10	10
4	17	40	33	33	31
5	20	20	0	10	10
6	10	20	25	3	15
7	37	80	62	75	63

Note. Subject 2 and Subject 7 (same subject) took the questionnaire twice, about 7 months apart.

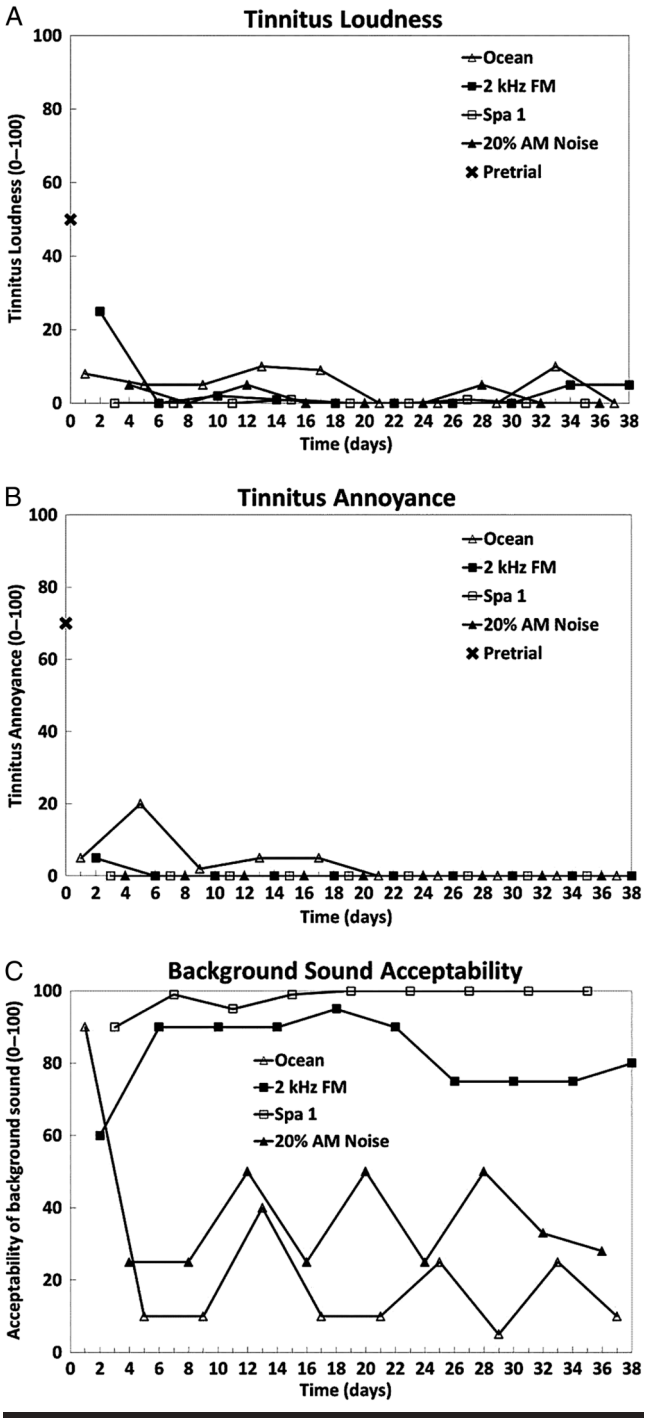
selected the 1000-Hz-AM stimulus, Oldenburg Sentence Test (OLSA, http://www.hoertech.de/web_en/produkte/audiotests/olsa.shtml; Brand & Kollmeier, 2002) unmodulated noise, Spa 4, and the ocean sound for testing. After the commencement of the study, we thought it might be useful to include days without any background sound. Therefore, for Subject 3, we intentionally included days on which a tinnitus-suppression signal was not presented. Results for loudness, annoyance, and acceptability are shown in Figures 3A–3C. All four stimuli were successful in reducing tinnitus loudness. During the no-stimulus days, the loudness of the tinnitus increased. All four stimuli were also successful in reducing tinnitus annoyance for many of the days (see also the no-sound condition on Day 9).

Note that on Day 9, the subject reported a drop in the tinnitus loudness, even without a suppressing stimulus. This finding might be influenced by at least three factors. First, it may be due to variability in the subject's ratings. Second, it may be some cumulative effect of using suppression stimuli on previous days. We have observed in previous laboratory trials (Rubinstein, Tyler, Johnson, & Brown, 2003) that prior stimuli, even presented with > 30-min rest periods, can have a cumulative effect on the perception of the tinnitus. Third, it might represent a placebo effect—the subject simply thought the tinnitus was reduced because of participating in the trial.

The acceptability ratings showed differences across stimuli. One stimulus, the 1000-Hz-AM tone, was unacceptable, and the subject stopped using this stimulus after the first few days. The subject observed that the similarity (in terms of pitch and tonal quality) between the suppression signal and the tinnitus made this stimulus (1000-Hz-AM tone) less desirable.

The subject stated that it was important to have the option to turn off the tinnitus suppression signal and to control its volume. The subject also noted that wearing the additional hardware of the MP3 player made it difficult to function with ease at work and to use the telephone. When we asked this subject how likely she would use background stimulation with the current equipment on a scale ranging from 1% (*least likely*) to 100% (*most likely*), the subject said 25%. We also asked how likely she would use the tinnitus suppression stimuli if embedded in her CI. Her response was 80% (on the same scale as above). She reported that some of the stimuli were "calming."

Figure 1. Subject 1: A. Loudness of tinnitus. B. Annoyance of tinnitus. C. Acceptability of background stimuli. FM = frequency modulated; AM = amplitude modulated.



Subject 4

For Subject 4, both pretrial tinnitus loudness and tinnitus annoyance levels were rated at 30%. The subject selected three stimuli (Spa 1, Spa 2, and OLSA modulated 20%) for

Figure 2. Subject 2: A. Loudness of tinnitus. B. Annoyance of tinnitus. C. Acceptability of background stimuli. AM = amplitude modulated.

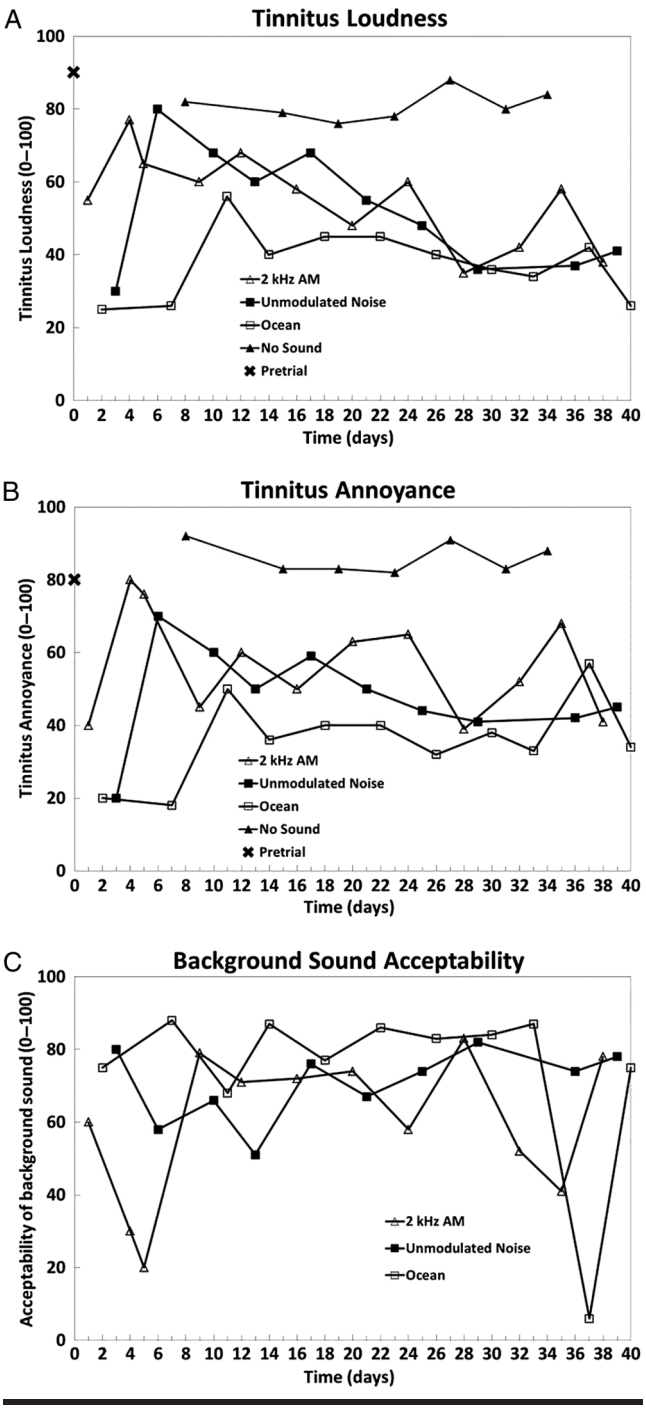
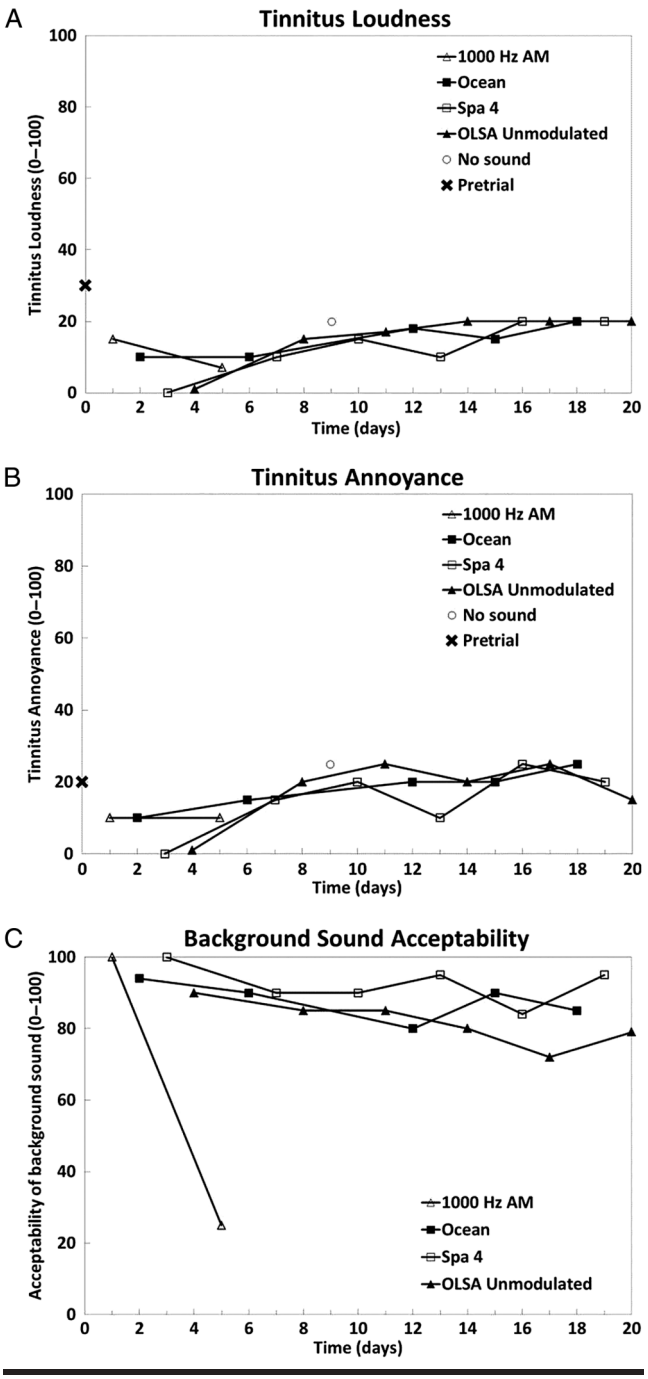


Figure 3. Subject 3: A. Loudness of tinnitus. B. Annoyance of tinnitus. C. Acceptability of background stimuli. AM = amplitude modulated; OLSA = Oldenburg Sentence Test.



the take-home trial. All selected stimuli were successful in reducing tinnitus loudness (see Figure 4A) and annoyance (see Figure 4B) and demonstrated high acceptability levels near 70% (see Figure 4C). The take-home trial provided a 10% reduction in tinnitus loudness and annoyance (see Figures 4A and 4B). Note that tinnitus loudness decreased steadily with time in response to all stimuli.

Subject 5

Subject 5 reported pretrial tinnitus loudness level to be 40% and tinnitus annoyance to be 10%. Subject 5 selected

Figure 4. Subject 4: A. Loudness of tinnitus. B. Annoyance of tinnitus. C. Acceptability of background stimuli. OLSA = Oldenburg Sentence Test.

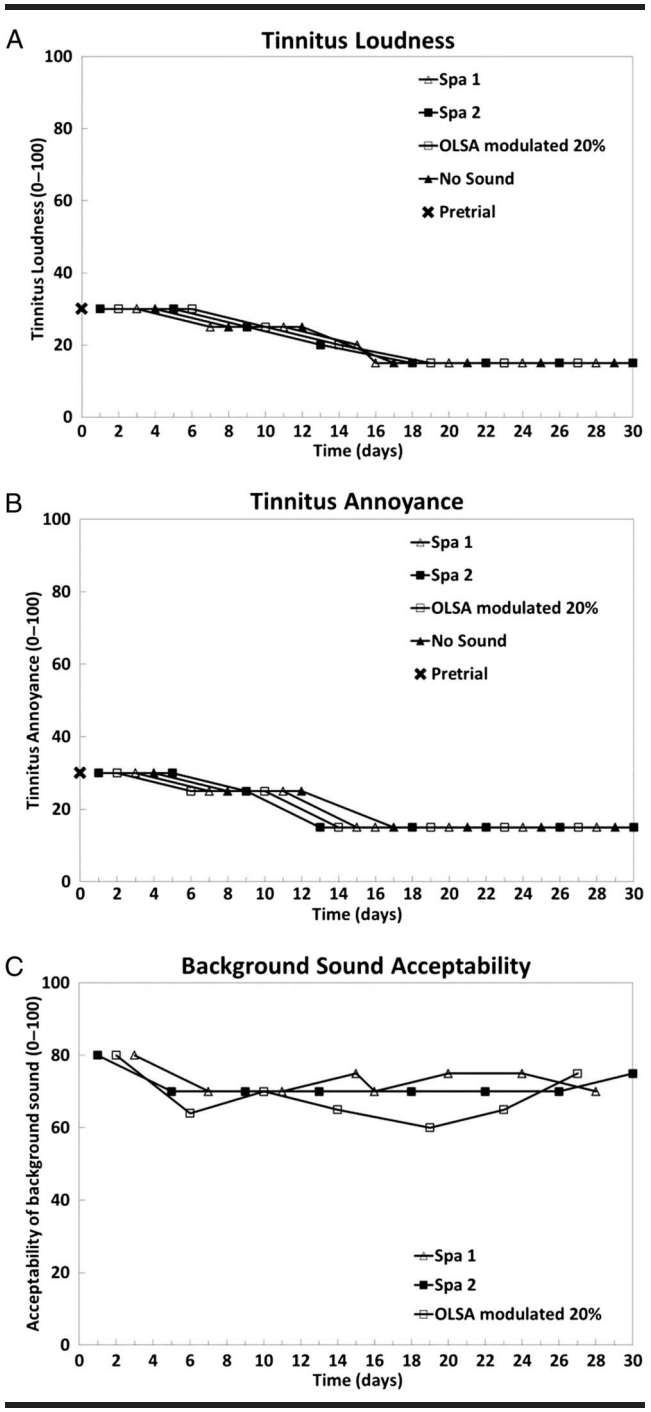
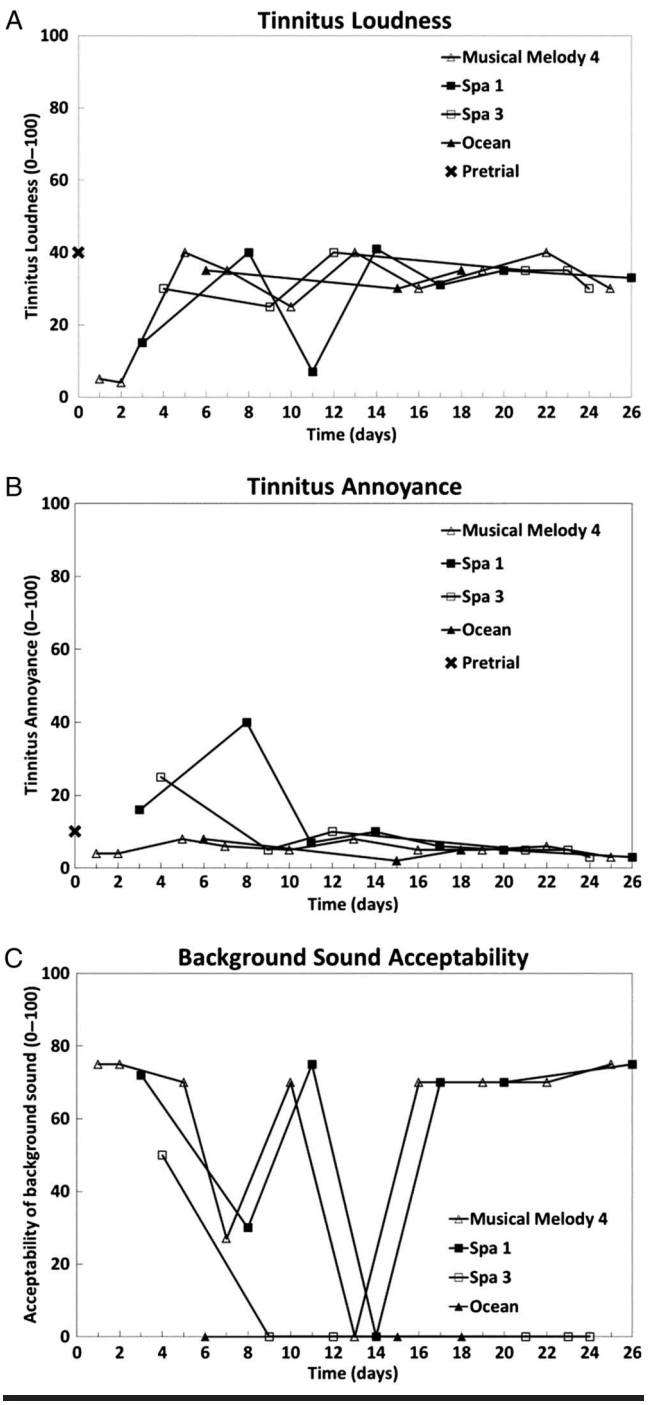


Figure 5. Subject 5: A. Loudness of tinnitus. B. Annoyance of tinnitus. C. Acceptability of background stimuli.



Musical Melody 4, Spa 1, Spa 3, and ocean stimuli for the take-home trial period. Levels of tinnitus loudness decreased from the pretrial measurement for all stimuli used (see Figure 5A). Comparable levels of reduction were observed in response to Musical Melody 4 (28%), Spa 1 (30%), Spa 3 (32%), and ocean (33%) stimuli. Reduction in tinnitus annoyance for this subject was minimal (see Figure 5B), likely because of the low pretrial annoyance level. This subject demonstrated adequate acceptance for Musical Melody 4 and Spa 1 stimuli (see Figure 5C). Effects on tinnitus loudness were observed for the Spa 3 and ocean stimuli; however, these stimuli were not considered acceptable by this subject.

Subject 6

Subject 6 rated his pretrial tinnitus loudness as well as annoyance at 70%. This subject selected only two stimuli: the 2-kHz-AM stimulus and the ocean stimulus. A comparison of average data from the take-home portion of the study indicated a reduction in tinnitus loudness (see Figure 6A) and tinnitus annoyance (see Figure 6B) for the ocean stimulus. No decrease in tinnitus loudness or annoyance was observed for the 2-kHz-AM condition; however, only three recordings were made in the 2-kHz-AM condition compared with 20 recordings for the ocean stimulus. This is attributed to patient confusion with trial instructions. The ocean stimulus initially had minimal effect on tinnitus loudness and annoyance, but over time the patient demonstrated diminished annoyance effects (see Figure 6B). It is possible that, with further listening, greater effect of tinnitus annoyance or loudness reduction would be observed in the 2-kHz-AM condition. Subject 6 found the ocean stimulus to be generally acceptable (60%–70%) throughout the duration of the study (see Figure 6C).

Subject 7

Subject 7 rated his pretrial tinnitus loudness at 82% and tinnitus annoyance at 85%. This subject selected three stimuli: Band-Filtered Noise 1, low-pass noise < 1000 Hz, and broadband noise. All stimuli were effective at reducing tinnitus loudness (see Figure 7A). The no-sound condition was ineffective. The reduction of tinnitus annoyance (see Figure 7B) was also about equally effective for all stimuli. Acceptability was similar for all stimuli, at about 60% (see Figure 7C).

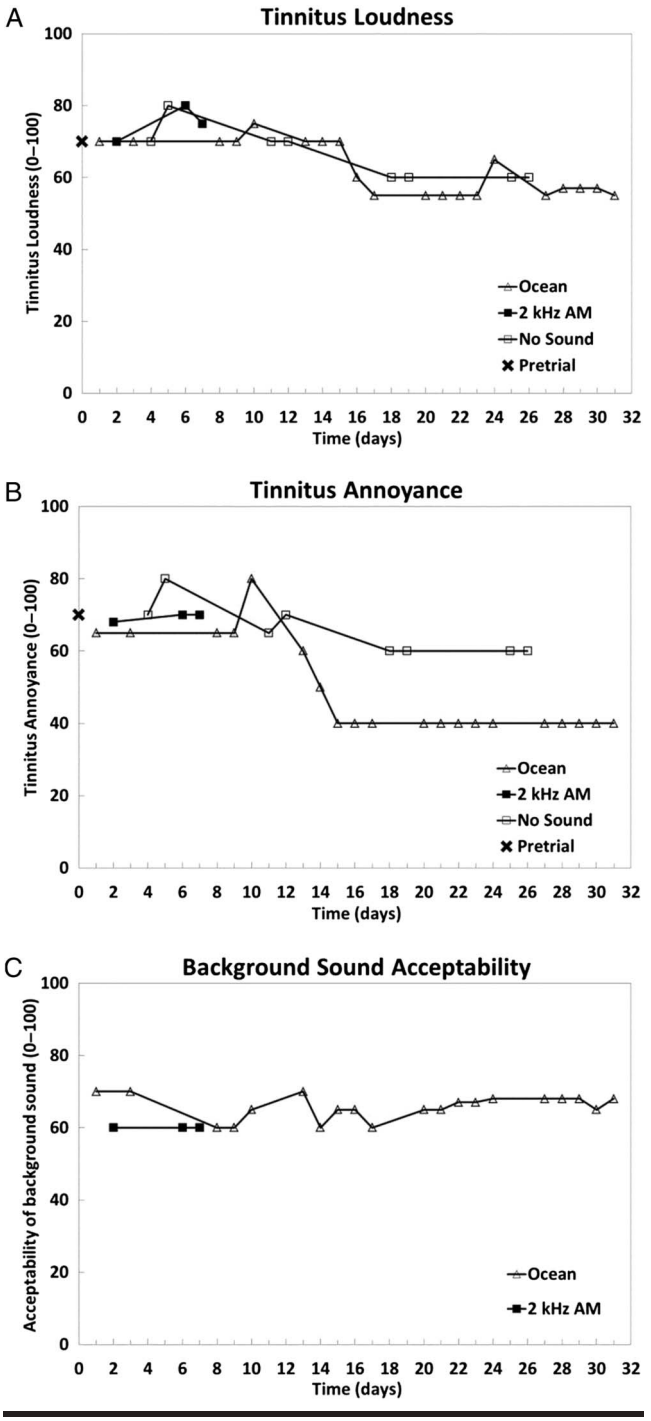
Summary of Findings

Table 4 shows loudness, annoyance, and acceptability ratings for subjects for each stimulus. Average results are shown for the entire trial.

In Table 5, the sounds are grouped in broad categories, and patient preference for different sounds is summarized. Again, there is a lot of variability across subjects. Most subjects prefer a noise and/or environmental sounds. (This generalization depends on the description of the categories and to what extent subjects differentiated these four categories in the same way. It might be, for example, that in some cases the environmental sounds are very close to noise.)

In Table 6, we show average results for the ocean, 2-kHz-FM, and Spa 1 background stimuli (the percentage change relative to the baseline). These were the three stimuli that were chosen by 3–5 of the subjects. There were no large differences among the three.

Figure 6. Subject 6: A. Loudness of tinnitus. B. Annoyance of tinnitus. C. Acceptability of background stimuli. AM = amplitude modulated.

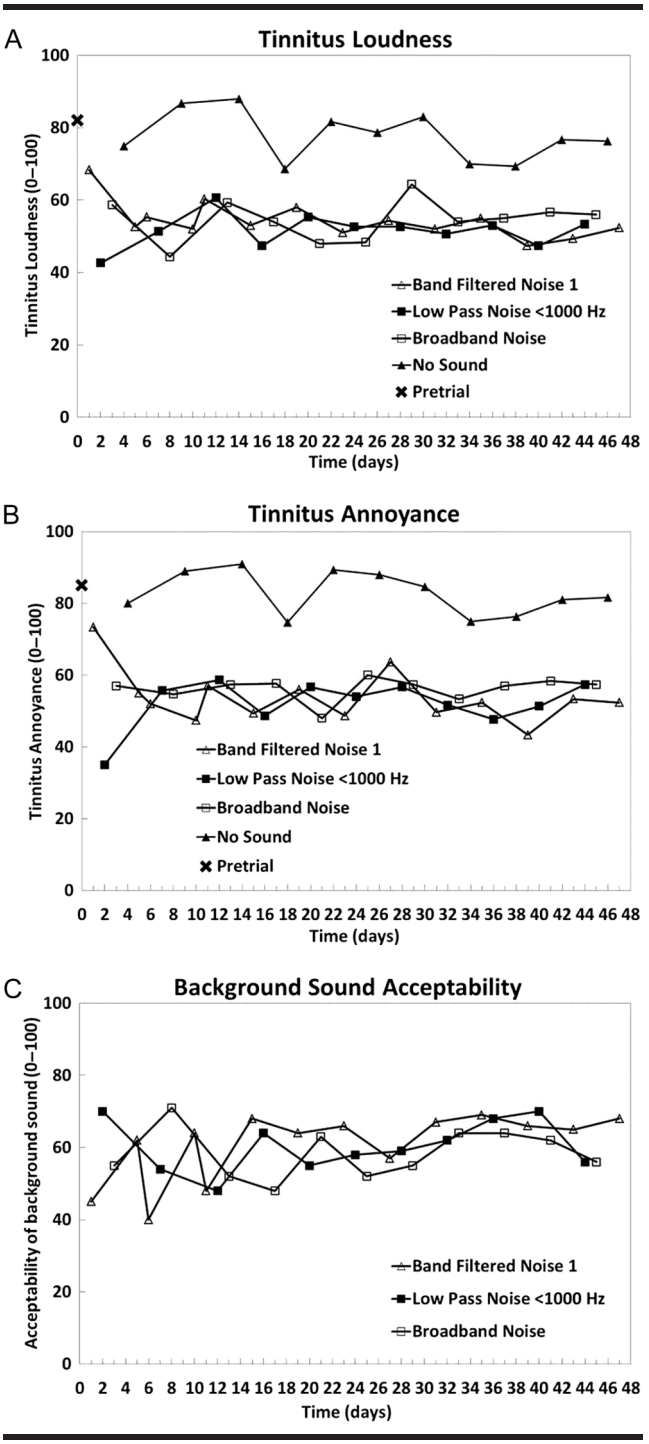


Discussion and Conclusions

Loudness, Annoyance, and Acceptability of Sounds for Daily Listening

A wide range of responses was observed across subjects. In some, the tinnitus loudness was reduced to magnitudes less than 10%. In others, there was no effect. In two subjects (Subjects 4 and 6), tinnitus loudness reduced during the several days of the trials. This cumulative effect has been observed over short time periods in previous experiments (Rubinstein et al., 2003).

Figure 7. Subject 7: A. Loudness of tinnitus. B. Annoyance of tinnitus. C. Acceptability of background stimuli.



Annoyance of the tinnitus was reduced in five of the seven subjects. In some subjects (e.g., Subject 6), annoyance clearly decreased during the duration of the study, perhaps as they got accustomed to listening to the sound or adapted the input to a more acceptable level. In contrast, for Subject 3, although the annoyance was reduced during the first few days, it later increased to its initial magnitude. It might be that this patient had high expectations, and after it became evident that the tinnitus was not going to be completely suppressed, it was more difficult to tolerate the sound. Furthermore, this patient scored low on tinnitus loudness, annoyance, and the Tinnitus Primary Function Questionnaire.

Acceptability of sounds was highly variable across and within subjects. Although the acceptability of sounds was generally stable over time, for Subject 5, acceptability changed up and down for some sounds. At this stage, it is unclear to what extent this is related to the level of the input signal.

There is a large range of preferences across subjects in terms of the sounds they prefer and the effectiveness of the sounds. For some subjects (e.g., Subject 2), there was a clear difference in the effectiveness of the various sounds. It is clear that there would be an advantage to having multiple sounds or shapeable sounds (e.g., spectral and modulation shaping) available for patients to choose their preferred sounds. This might change depending on the actual sound environment or behavioral state (e.g., conversing, working, driving a car, falling asleep) of the patient. By allowing subjects to choose among several options, they might be even more committed to the treatment.

It will be equally important to provide counseling to patients about setting realistic expectations. They need to know that the tinnitus will likely not be completely suppressed. Tyler, Witt, Dunn, and Perreau (2008) have suggested field trials for fitting CIs, similar to ones for fitting hearing aids, in which patients alternate daily between options before making a decision of an optimal program. This same strategy, as used in the current experiment, could be applied clinically.

No-Sound Condition

We initially decided not to include a no-sound condition because we were concerned that carry-over effects from previous days might actually affect the tinnitus. We have observed this before in laboratory studies when stimuli lasting 20 min produced poststimulus tinnitus reductions for several hours. This means that results of a day with "no stimulus" might actually include effects from the stimulus used the previous day. It also means that, at least for some subjects, the switching from day to day might not have provided sufficient relief from the previous stimulus. Later in the trials, we decided to include the no-sound conditions. Subjects 4 and 6 reported a reduction in tinnitus loudness in the no-stimulus condition compared with the pretrial baseline condition. This could have been a placebo effect or an actual reduction in tinnitus resulting from the prior days of stimulation. It might be desirable in future trials to have a 2- or 3-day no-trial condition. Requiring rating at bedtime and upon waking might also be insightful.

The CI for Tinnitus

From our data, it is clear that many CI patients might experience an acceptable reduction in their tinnitus

Table 4. Ratings of tinnitus loudness, annoyance, and acceptability.

Subject	Stimulus	Loudness	Annoyance	Acceptability
1	Before	50	70	
	2-KHz-FM	4	1	82
	Spa 1	0	0	98
	20% AM noise	2	0	35
	Ocean	5	4	24
2	Before	90	80	
	2-kHz-AM	55	57	60
	Unmodulated noise	52	48	71
	Ocean	38	36	74
3	Before	30	20	
	1000-Hz-AM	11	10	63
	OLSA unmodulated	16	18	82
	Spa 4	13	15	92
	Ocean	15	18	88
4	Before	30	30	
	Spa 1	20	19	73
	Spa 2	21	20	72
	OLSA modulated 20%	21	20	68
5	Before	40	10	
	Musical Melody 4	28	5	60
	Spa 1	29	12	56
	Spa 3	33	9	8
	Ocean	33	5	0
6	Before	70	70	
	2-kHz-AM	75	69	60
	Ocean	62	49	66
7	Before	82	85	
	Band-Filtered Noise 1	54	54	61
	Low-pass noise < 1000 Hz	52	52	60
	Broadband noise	54	56	58

Note. The rating refers to the situation before starting the trial and during the use of suppression sound (Subjects 2 and 7 are the same person). FM = frequency modulated; AM = amplitude modulated; OLSA = Oldenburg Sentence Test.

when a tinnitus suppression signal is mixed on all electrodes with the incoming stimulus from the CI microphone. Individual differences regarding the magnitude of the tinnitus reduction will be large. There will also be large differences in the choice of background sound. It would be desirable if the background sound reduced the tinnitus loudness. However, even if this was not the case, as long as the background sound reduced the annoyance of the tinnitus, then this alone would be valuable. In addition to tinnitus loudness and annoyance, it is important that the patient finds the suppressing sound acceptable.

In this concept of acceptability, one should consider the context under which the CI user would be listening. This could include the following:

Table 5. Patient choices for categories of background sounds.

	Noise		Tones			
Subject	Modulated	No modulation	Modulated	No modulation	Music	Environmental sounds
1	1		1			2
2		1	1			1
3		1	1			2
4	1					2
5					1	3
6			1			1
7		3				
Total	2	5	4	0	1	11

Note. Subjects 2 and 7 are the same person; when this subject was tested a second time, he had already experienced other sounds.

Table 6. The mean loudness and annoyance values, together with the percentage of change relative to baseline, for subjects who used that stimulus.

Variable	Loudness	Annoyance	*n*
Baseline	56	50	5
Ocean	31	22	5
% decrease	25	28	
Baseline	70	73	3
2-kHz-FM	45	42	3
% decrease	25	31	
Baseline	40	37	3
Spa 1	16	10	3
% decrease	24	26	

Note. FM = frequency modulated.

- when listening to speech,
- when in a quiet background (e.g., while alone in a quiet room) without a critical need for other listening, and
- when in a noisy background (e.g., while alone driving a car) without a critical need for other listening.

It will be desirable for some patients to have several different tinnitus suppression stimuli that they can select from in their wearable device. This should include an option to turn the tinnitus suppression signal off.

Another important consideration is to allow patients to change the level of the tinnitus suppression stimulus, independent of the level of incoming external stimuli. Some subjects indicated the need to adjust the volume level of the stimulus throughout the day. Using automated data logging could document levels and frequency of changes.

It is important to note that the tinnitus does not have to be totally masked, analogous to the acoustic partial masking of tinnitus (e.g., Tyler & Bentler, 1987). The sound level at which a subject wishes to set the suppressor sound presumably is a compromise between reduction of tinnitus loudness and annoyance, acceptability of the suppressor sound, and the ability to communicate. Thus, again, the loudness may depend on the context in which a subject is using the CI.

It is noteworthy that patient reactions to the background sound sometimes changed over the period of the 30-day investigation. Some patients whose expectations of efficacy are not met after several days might eventually become disappointed with the approach. Other patients might require time to accommodate to and accept the background sound. Counseling regarding these two concerns will be important.

There is presently no pharmacological or surgical tinnitus treatment that reduces the tinnitus magnitude that has been approved by any government agency. Further controlled field trials are needed by independent laboratories before the CI for tinnitus can gain health care acceptance.

Limitations of the Study

Connecting an external device via external auditory cable to the processor is cumbersome and does not provide patients with an adequate tool to implement the device. One subject volunteered that the likeliness of using a tinnitus suppressor was much greater if it was built into the CI speech processor. Signal generation by the signal processor or connection via wireless streaming would be less obtrusive and more comfortable.

We did not measure speech perception with the background tinnitus suppression signal present. No subject complained of a decrement in speech perception or spatial hearing, but this should be tested.

Some of the patients reported that when they participated in the trial, their tinnitus became more annoying because they were thinking about it every day. Clinically, in tinnitus activities treatment (Tyler et al., 2006), we tell them that "the more you are thinking about your tinnitus, the more you are thinking about your tinnitus!" Thus, just trying to reduce tinnitus has a risk of making it worse.

A small sample size was reported here. We were not looking for the "best" stimulus on average but just wanted to establish whether a stimulus could be found that would be effective. With a larger sample size, we might be able to find a specific stimulus that would be statistically the best for the group. However, this was not our primary goal.

Additional metrics could also be added in future studies. The estimates of loudness and annoyance often followed the same pattern, and we have noted previously that louder sounds are generally more annoying. It was clear that the various sounds can be equally efficacious in reducing loudness and annoyance but not equally acceptable.

One concern with our design is the carry-over effects. Listening to a background sound all day can apparently affect some patients' tinnitus for several hours and perhaps even days. This might require a 2- or 3-day rest period with no background stimuli. Again, individual differences will be important.

The Next Steps

When developing background stimuli in a CI for tinnitus, researchers should consider the following points:

- It will be important to consider the acceptability of listening to the background sound, not just its ability to reduce tinnitus loudness and annoyance.
- Individual differences are critical, and having a variety of sounds available will be essential.
- It might be helpful to have a systematic field trial (e.g., ABCABC . . .) to select the most desirable background stimuli for an individual. Tyler, Rubinstein, et al. (2008) suggested such field trials to assist with the selection of signal processing options for hearing aids and for CIs.
- Patients should be allowed to adjust the level throughout the day.

We also suggest that it might be useful to ask the subjects to take the Tinnitus Primary Function Questionnaire at the end of each day and perhaps also at the end of the

trial while allowing them to listen to each of their selected stimuli.

We do believe that single-subject designs are preferred because they are flexible and highlight individual differences. The in-depth pictures we got from those individuals were informative. We want to explore how individual characteristics interact with the stimulus, which may lead us to establish a new or more effective stimulus.

It is exciting to know that many patients with CI might benefit from suppressor sounds, which can be added to an existing implant with relatively simple technology. In this article, we explored the use of sound devices that were connected to the implant's speech processor with a cable. The results could likely be improved by relatively simple technologies involving a wireless link or software built into the speech processor. Thus, the approach to suppress tinnitus taken in this article may be applicable in a large portion of the current CI users. A previous survey indicates that many tinnitus patients who do not have CIs are ready for such a treatment and are willing to pay for it (Tyler, 2012).

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