

## Worldwide experience with sequential phase-shift sound cancellation treatment of predominant tone tinnitus

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### Abstract

**Objective:** To report clinical data from six centres in the US, Western Europe and Asia which have used phase-shift sound wave cancellation for treatment of predominant tone tinnitus, from the first treatment in 2000 to 2009.

**Method:** Clinical data were obtained from New York City, London, Erie (Pennsylvania, USA), Antwerp, Grottamare (Italy) and Kuala Lumpur, and summarised.

**Results:** A total of 493 patients were treated. A reduction in tinnitus volume (defined as  $\geq 6$  dB) was seen in 49–72 per cent of patients.

**Key words:** Tinnitus; Sound; Therapy; Acoustic Stimulation

### Introduction

It is postulated that tinnitus is perceived in the auditory cortex. Several studies have demonstrated metabolic activation chiefly in the left auditory cortex during tinnitus perception, using single photon emission computed tomography, positron emission tomography (PET) and functional magnetic resonance imaging (MRI).<sup>1–6</sup> Anderson *et al.* demonstrated subsidence of cortical activity in response to lidocaine reduction of tinnitus.<sup>7</sup> Baguley *et al.* showed that severing the vestibular nerve did not abolish tinnitus.<sup>8</sup> Gerloff used external magnetic energy applied over the brain to treat tinnitus.<sup>9</sup>

In 2000, one of the authors (DC) hypothesised that using a tinnitus patient's self-assessed pitch and volume wave, shifted sequentially  $6^\circ$  for 30 seconds (over 30 minutes), would cancel the neuronal complex in the auditory cortex responsible for predominant tone tinnitus (Figure 1). This concept was based on the commercial availability of successful sound-cancelling devices, which cancel or modify low frequency ambient road or aircraft noise by radiating a sound wave  $180^\circ$  reciprocal to the incident sound wave. However, since the time-space locus of a patient's tinnitus wave is unknown, it is not possible to create an opposing,  $180^\circ$  reciprocal wave. The solution was to take the patient's self-perceived sound wave and deliver it (i.e. its pitch and volume) to the brain at sequential phase-shift intervals of  $6^\circ$  every 30 seconds for  $360^\circ$  (over 30 minutes). It can be proven mathematically that the patient's endogenous tinnitus wave is cancelled for one-third of this time, i.e. 10 minutes. Sequential phase-shifting negates

the absence of knowledge of the time-space locus of the patient's own tinnitus wave – analogous to shooting at a flight of geese with a shotgun instead of a rifle.

A controlled, prospective, group substitution study was performed, involving rotation of 35 patients through two sham-control groups (A and B), and through a  $6^\circ$  sequential phase-shift group (group C). Group A received a sound wave of 1000 Hz at 77 dB for 30 minutes. Group B patients received their self-perceived tinnitus frequency wave at 77 dB for 30 minutes. Group C patients received their self-perceived tinnitus frequency and volume with a  $6^\circ$  phase shift every 30 seconds, for 30 minutes. Pitch levels were self-determined five times in groups B and C, both before and after treatment.

Every patient was rotated through each group. There were thus 105 patients in each of the three groups.

Each patient self-assessed their tinnitus volume five times.

Patients comprised 21 men and 14 women, aged from 35 to 66 years. All had sonograms showing auditory loss above 4000 Hz, and all had normal brain MRI scans. All patients had suffered bilateral tinnitus for more than one year, and all had tried various treatments (e.g. masking, Tinnitus Retraining Therapy (TRT) or drugs) without benefit.

In this early study,<sup>10–13</sup> a variable proportion of patients reported a reduction in tinnitus volume of 6 dB or more, as follows: group A, 24 per cent; group B, 27 per cent; and group C, 82 per cent ( $p > 0.01$ ) (Figure 2).  $p$  values relates to the difference between the 27% (B) and 83% (C).

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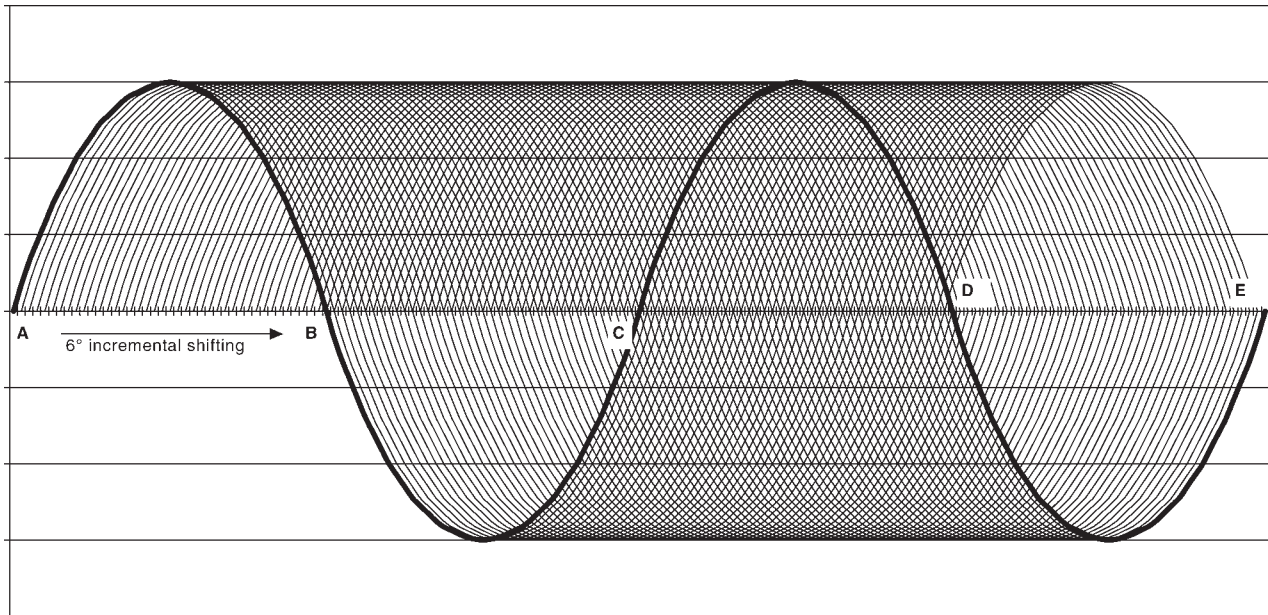


FIG. 1  
Phase-shifting of sound wave.

**Methods**

Following this earlier study, and after receiving Food and Drug Administration (FDA) approval, research groups were established in New York, Erie (Pennsylvania, USA), London, Antwerp, Grottamare (Italy) and Kuala Lumpur. Our objective was to collect clinical data from diverse centres around the world,

in order to abolish author bias and to assess whether findings from other centres would support our original data.

Our tinnitus treatment centres in New York and London supplied all other participating centres with tutorials, programmable computers and patient treatment devices (Figure 3).

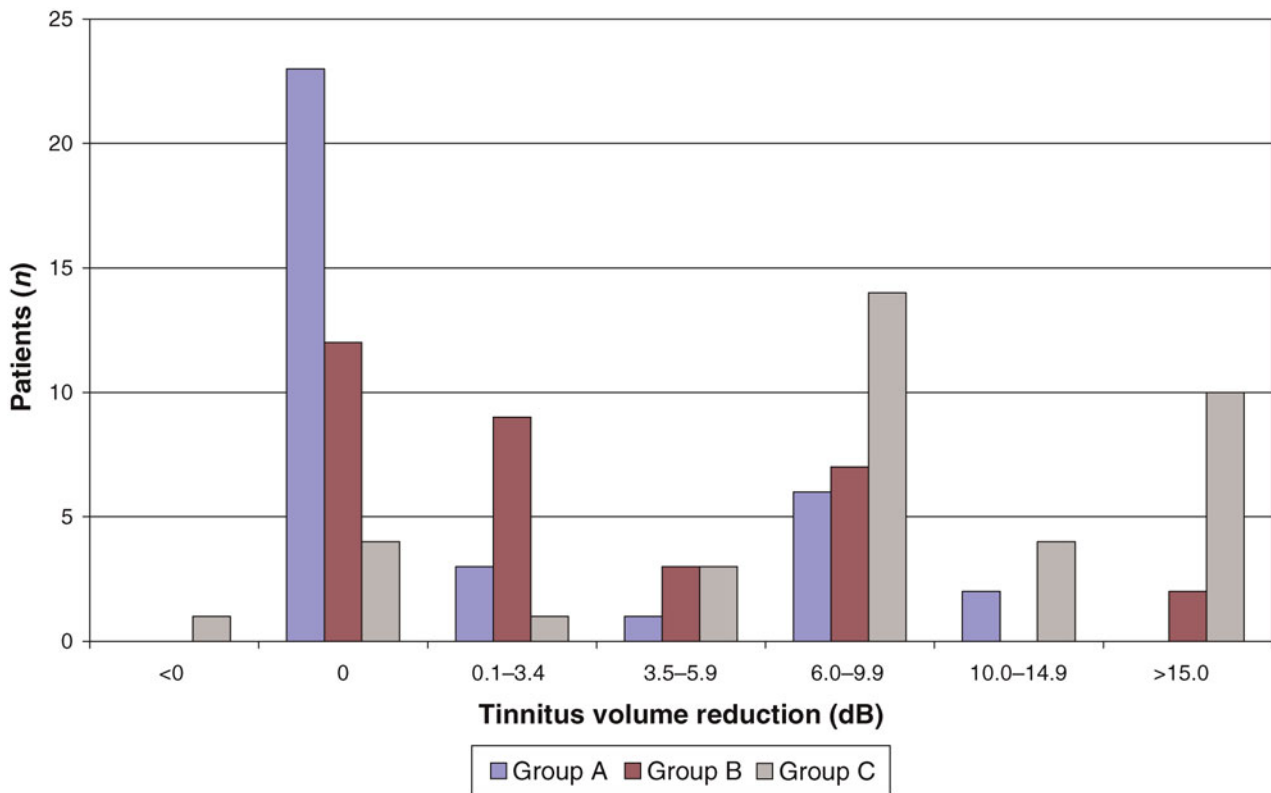


FIG. 2  
Patients' perceived reduction in tinnitus volume.



FIG. 3  
Treatment equipment.

Investigators used the computers to determine each patient's self-perceived tinnitus pitch and volume. From an earphone input, patients selected a sound with a pitch most closely resembling their tinnitus. Tinnitus volume was similarly determined. This assessment was performed a total of five times to maximise accuracy. The selected pitch and volume were then fed into the patient treatment device, which automatically converted the signals into a sequential 6° phase shift for 30 seconds, through 360° (over 30 minutes). This sound was then delivered to the patient's ears via headphones. At the end of each 30-minute treatment, the patient self-assessed their new tinnitus volume five times. Each treatment sequence was repeated three times per week. At the end of the three treatments, if the patient's tinnitus volume had decreased by at least 6 dB (i.e. 50 per cent), they were supplied with a patient treatment device for continued self-treatment at home, three times per week.

The patient treatment device was programmed to cease functioning after six months, thus obliging the patient to return to the ENT centre for reassessment. (At this point, 10 per cent of patients were found to have an altered tinnitus pitch.) The patient treatment device (re-programmed if

necessary) was then returned to the patient for another six months of treatment. This cycle of treatment and assessment was repeated every six months.

### Results and discussion

From the six centres in the US, Europe and Asia, 493 patients were enrolled. All patients underwent sequential phase-shift sound wave treatment for predominant tone tinnitus. Based on a minimum of 6 dB tinnitus volume reduction, a total of 301 patients (61 per cent) responded to treatment. Response rates at individual centres ranged from 49 to 72 per cent (Table I).

Of the 211 patients treated in the New York centre (age range 20–82 years; 161 men and 50 women; tinnitus frequency range 100 to 13 400 Hz), 140 (66 per cent) responded. Three of these 140 patients experienced total resolution of tinnitus for between 18 and 54 months, while two had resolution of tinnitus for one week, three for two weeks and one for three weeks. Sixty patients reported a reduction in tinnitus volume of 6–10 dB, while 80 reported a reduction of more than 10 dB, lasting between three and four weeks.

TABLE I  
RESULTS OF TREATMENT

Centre	Pts ( <i>n</i> )	Total pts responding ( <i>n</i> (%))	Pts not responding* ( <i>n</i> )	Pts responding ( <i>n</i> )	
				6–10 dB	>10 dB
New York	211	140 (66)	71	60	80
London	104	51 (49)	53	32	19
Erie	58	33 (57)	25	9	24
Kuala Lumpur	56	35 (63)	21	32	3
Antwerp	35	21 (60)	14	21	–
Grottamare	29	21 (72)	8	21	–

\*Less than 6 dB response. Residual inhibition was seen in all centres, ranging from 3 to 43 days. Further reductions in tinnitus volume were seen in 12 of 17 patients assessed at six months (3–31 dB reduction seen in six patients), 12 months (21 dB reduction seen in one patient) and 18 months (10 dB reduction seen in three patients and 20–23 dB reduction seen in two patients); thus, continued home treatment is definitely of value.

To the best of our knowledge, prolonged tinnitus inhibition of this magnitude has not been reported following tinnitus treatment with masking, Tinnitus Retraining Therapy (TRT) or other methods.

Ongoing home therapy led to a continued reduction in tinnitus volume in 16 out of the 17 patients, followed for six, 12 and 18 months, indicating continued benefit with prolonged therapy. The 17 patients were those who were selected responders based on a >6 Db drop after treatment. The patients elected to purchase PTD's for home therapy. These devices were calibrated at the average pitch that the patients self selected during therapy. The volume knob on the PTD is adjustable. Patients are taught to use these devices 3x weekly in a quiet room for 30 minute treatments. They are able to adjust the volume to match their own tinnitus volumes. The PTD's (patient treatment device) are programmed to stop functioning at six months. Patients are therefore obliged to return for recalibration of pitch. It has been our experience that 10% of patients experience a change of pitch at six months. If this occurs the PTD's are recalibrated accordingly. No side effects of therapy were encountered.

Sequential phase-shift sound wave treatment is a promising new therapy for predominant tone tinnitus. It is based on three postulates: (1) tinnitus originates in the brain; (2) specific frequencies and volumes are generated; and (3) it is possible to reduce or modify the perceived tinnitus sound wave by delivering to the patient via headphones the same wave, phase-shifted sequentially.

- **This study reports clinical data for phase-shift sound wave cancellation treatment of predominant tone tinnitus, from six centres worldwide**
- **A total of 493 patients were treated. A reduction in tinnitus volume (defined as  $\geq 6$  dB) was seen in 49–72 per cent of patients**
- **Sequential phase-shift sound wave treatment of predominant tone tinnitus is a viable and successful method of treatment, which is reproducible in a range of centres**

In order to further test these hypotheses, we plan to perform serial brain imaging, using functional MRI and/or PET, before and during the above-described treatment. A 20 patient, double-blind study is nearing completion at a prominent European university. Our group would be interested in expanding our study, and invites other prominent ENT groups around the world to join us.

## Conclusion

A favourable response to sequential phase-shift sound wave treatment of predominant tone tinnitus was seen in 489 patients in six separate ENT centres worldwide. A response to treatment of patients is based on a requirement of when a >6db reduction of volume occurs. This result verifies this technique

as a viable and successful method of tinnitus treatment, which is reproducible in a range of centres.

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