Evaluation of Implanted Tinnitus Suppressor Based on Tinnitus Stress Test


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Abstract: An electrical tinnitus suppressor developed at the Hokkaido University was implanted in two women and five men, aged 44–77 years old. To evaluate the efficacy of the suppressor, a self-administered tinnitus stress test (TST), annoyance index (AI), and tinnitus intensity index (TII) were conducted 1.1–3 years after implantation of the device. Residual inhibition results found at outpatient clinics and at the homes of patients with implanted suppressors were closely correlated except in one patient in whom the device’s electrode was free from the promontorium tympani.

The AI registered at a severe level in five patients and a moderate level in two patients before implantation of the suppressor. However, the AI improved after the operation, being moderate in three patients and mild in two, and achieving no level in two patients. After the operation, the TST improved except in one patient whose device had electrode trouble.

The TII registered as extreme in all patients before implantation of the suppressor, although the intensity of tinnitus varied from patient to patient according to the loudness balance test. After device implantation, the TII did not register any level in two patients, was mild in another two patients, was moderate in yet two more patients, and was severe in a patient whose device had electrode trouble.

After the operation, at TST, AI, and TII results were positively correlated (p = .01), though there was no correlation among these parameters before the operation.

Keywords: tinnitus stress test; annoyance index; tinnitus intensity index; implanted tinnitus suppressor; electrical stimulation

There is a clear agreement among implant groups that the majority of patients can experience tinnitus suppression while using an implanted electrical tinnitus suppressor [1]. However, implantation for tinnitus suppression previously was not performed in patients with nearly normal hearing because of the cost and potential damage to the cochlea.

An electrical tinnitus suppressor incorporating the use of an extracochlear stimulator has been developed at Hokkaido University [2]. This device is likely to result in minimal damage to the cochlea because the stimulating electrode is near the round window. In addition, the small size of the implanted chip coil (6 mm wide, 5 mm thick, and 10 mm long) in the mastoid contributes to the avoidance of injury risk [3,4]. This device was implanted in two female and five male tinnitus patients.

Although we often speak of tinnitus as if it were a single entity, tinnitus actually consists of sensory and affective components [5]. The sensory component is a sound sensation, whereas the affective components are many, including insomnia, annoyance, anxiety, and interference in communication capability [6]. The severity of the affective component is not always commen-
urate with the severity of the sensory component. Some patients can accept tinnitus with little affective disorder, although they still perceive a tinnitus sensation. However, some patients are disturbed by affects (especially the severe disabling type of tinnitus).

The differences in the degree of affective disorders that patients perceive are explained by a stress model for tinnitus [7]. It is hypothesized that both the hippocampus and the amygdala of the medial temporal lobe system are significant for transition from the sensory to the affective component. The transition is purported to be modulated by the influence of stress, according to the level of cortisone [7]. The location of cortisol control under stress is considered to be in the hippocampus, not in the hypothalamus [8].

Such affects as insomnia, annoyance, anxiety, and interference in communication capability that are induced by tinnitus would constitute stress that is highly associated with patients' quality of life. The existence of tinnitus itself also may be a major cause of stress. Therefore, a good assessment of the impact of tinnitus on patients' lives should be based on the amount of stress induced by tinnitus.

Few questionnaires are available to ascertain the degree of tinnitus that would affect patients' lives [9,10]. The tinnitus stress test (TST) is a tool for monitoring the efficacy of treatment, control, and relief procedures for tinnitus. The higher the score on this test, the greater is the stress associated with tinnitus. The objective of this article is to evaluate benefits of the implanted tinnitus suppressor on the basis of the TST.

PATIENTS

Patient 1

Patient 1, a 57-year-old woman, complained chiefly of bilateral hearing loss and tinnitus in the left ear. She has suffered from chronic otitis media that has resulted in bilateral eardrum perforations. Audiography reveals profound mixed deafness, as shown in Figure 1. The patient uses a behind-the-ear type of a hearing aid in the left ear. She visited our outpatient clinic with concerns about the discharge from both ears and increased hearing loss in the left ear. Tinnitus in the left ear was reported. The frequency of the left-ear tinnitus was 250 Hz at an intensity of 95 dB 1 month after the first visit (September 18, 1992). Because we were afraid that the operation would worsen a preexisting hearing loss in the left ear, the suppressor device was implanted in the patient's right ear.

Patient 2

Patient 2, a 61-year-old woman, complained chiefly of bilateral hearing loss and right-ear tinnitus at the first consultation. She has a history of congenital syphilis, and her syphilitic serum titer was 80. The right-ear tinni-

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Figure 1. Audiogram from Patient 1. There was tinnitus in the left ear. The device was implanted in the right ear on March 8, 1994. On August 11, 1992, the patient had visited our outpatient clinic with complaints of ear discharges and bilateral hearing loss. Filled symbols show the air conduction hearing thresholds. Bone conduction hearing thresholds before and after the operation also are shown <and> show the bone conduction hearing thresholds on June 1994; [and] on August 11, 1992.
tus ensued from sudden deafness in the right ear. Audiography revealed profound mixed deafness in the right ear and slight sensorineural deafness in the left ear. Frequency of the tinnitus was 2 kHz at an intensity of 75 dB. The device was implanted in the patient’s right ear.

**Patient 3**

A 74-year-old man, Patient 3 is the oldest of our male patients. Audiography demonstrated bilateral sensorineural hearing loss. The tinnitus described by this patient was white noise at an intensity of 95 dB in the right ear and 75 dB in the left ear. The suppressor device was implanted in the patient’s right ear.

**Patient 4**

Patient 4, a 73-year-old man, complained chiefly of bilateral hearing loss and tinnitus. Bilateral hearing loss was demonstrated at higher frequencies on audiography. The frequency of right-ear tinnitus was 4 kHz at an intensity of 85 dB and the frequency of left-ear tinnitus, 4 kHz at an intensity of 85 dB. The device was implanted in the patient’s right ear.

**Patient 5**

Patient 5, a 67-year-old man, was chiefly concerned with bilateral hearing loss as a result of ear infections in childhood and tinnitus in both ears. Right mastoidectomy was performed nearly 40 years ago to relieve chronic otitis media. The audiogram showed combined deafness in both ears. The frequency of the tinnitus was 125 Hz at an intensity of 50 dB in the right ear and 125 Hz at an intensity of 65 dB in the left ear. The device was implanted in the patient’s left ear.

**Patient 6**

Patient 6 is a 53-year-old man. Audiography showed slight hearing loss in both ears. The frequency of the tinnitus was 6 kHz at an intensity of 75 dB in the right ear and 55 dB in the left ear. Right-ear suppressor device implantation was performed.

**Patient 7**

In Patient 7, a 44-year-old man, audiography showed moderate hearing loss in the right ear due to Meniere’s disease. The frequency of the tinnitus was 8 kHz of band noise at an intensity of 80 dB. Endolymphatic shunt surgery was performed 2 years before implantation of the tinnitus suppressor but failed to improve this patient’s hearing loss or to decrease the number of vertigo attacks. The device was implanted in the patient’s right ear.

**METHODS**

**Configuration of the Device**

The electrical tinnitus suppressor consists of an external coil inside a behind-the-ear type of hearing-aid case and an implanted coil in the mastoid [3]. The implanted, silicon-covered coil is 11 mm long, 12 mm wide, and 6 mm thick. The electrical stimulator weighs approximately 300 g, and the electrical pulse is provided by 100-V alternating current. The stimulus frequency consists of a 10-kHz sinusoidal wave modulated at 100 Hz. The duration of stimulation varies. If patients choose a timer switch, the device works automatically for 30 minutes. Patients use the device while they are in bed or sitting.

**Implantation of the Device**

The operation for device implantation was similar in all patients. We have reported our surgical method elsewhere [3]. Briefly, the silicon-covered coil is implanted in the mastoid after mastoidectomy using a postauricular incision. The Pt-Ir ball electrode, covered with polyalcoholic gel, is placed on the promontorium tympani, and the return electrode is fixed to the subcutaneous tissue at the tip of the mastoid.

Maximum stimulus intensity was set at 70 μA in Patient 1, 200 μA in Patient 2, 300 μA in Patient 3, 500 μA in Patient 4, 600 μA in Patient 5, 600 μA in Patient 6, and 100 μA in Patient 7, using a limiter on the chip coil. These subjects did not report any auditory sensation evoked by electrical stimulation.

**Questionnaires**

Seven patients in whom a tinnitus suppressor was implanted received three self-evaluative tests in April 1996: the TST, the tinnitus intensity index (TII), and the annoyance index (AI). These patients mailed back to us within a month their answers to the test questionnaires. The duration of device usage varies from 1 1/2 to 3 years, as shown in Table 1.

For the TST, there are two different scoring procedures. In procedure A, each of 16 questions was equally weighted and scored on a 5-point rating scale. In procedure B, scoring was accomplished using a weighted scale. Ten items—questions 1, 2, 4, 5, 7–9, 12, 14, and 15—were given zero points for a response of “not at all,” 1 point for “a little bit,” 2 points for “moderate,” 3 points for “quite a bit,” and 4 points for “extremely.” The remaining seven items—questions 3, 4, 6, 10, 11,
Table 1. Patient Profiles

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Gender</th>
<th>Age (yr)</th>
<th>History</th>
<th>Duration of Tinnitus (yr)</th>
<th>Duration of Usage (yr)</th>
<th>Side of Tinnitus Implantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>57</td>
<td>COM</td>
<td>10</td>
<td>3</td>
<td>Lt.</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>61</td>
<td>Sudden deafness</td>
<td>&gt;10</td>
<td>2.5</td>
<td>Rt.</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>74</td>
<td></td>
<td>7</td>
<td>2</td>
<td>Both</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>73</td>
<td></td>
<td>10</td>
<td>2</td>
<td>Both</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>67</td>
<td>COM</td>
<td>50</td>
<td>2</td>
<td>Lt.</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>53</td>
<td>Meniere's disease</td>
<td>40</td>
<td>2</td>
<td>Rt.</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>44</td>
<td></td>
<td>6</td>
<td>1.5</td>
<td>Rt.</td>
</tr>
</tbody>
</table>

COM = chronic otitis media.
Note that the side of the implantation (rt. ear) in Patient 1 was opposite the ear with tinnitus (lt. ear).

13, and 16—received double the points for each category. These categories addressed standard of living, socialization, coping with anger, depression, and fear. These items were considered to be the most important for stress. The maximum number of points obtainable is 96. The higher the score, the greater is the stress associated with tinnitus. We used procedure B for scoring.

The TIl test was distributed to all patients. The index was rated by each individual as 0 for no tinnitus and 7 for the loudest imaginable. The TII was rated by each individual as mild (1 or 2), moderate (3, 4, or 5), or severe (6 or 7).

Annoyance refers to interference in lifestyle—that is, vocational, recreational, and social activities as well as sleep. The AI was rated by each individual as mild (1 or 2), moderate (3, 4, or 5), or severe (6 or 7).

RESULTS

Residual Tinnitus Inhibition at Outpatient Clinics and with the Implanted Suppressor

Tinnitus in six patients disappeared for several hours to a half-day after electrical promontory stimulation at the outpatient clinic Table 2. The duration of residual tinnitus inhibition with the implanted suppressor was similar to that at the outpatient clinic except in one patient in whom the electrode broke free from the promontory. Tinnitus in Patient 6 did not disappear even after the operation. This finding is consistent with that obtained at outpatient clinics. It is of interest to note the outcome of bilateral tinnitus in four tinnitus patients. Tinnitus in the ears opposite the device implantation site in patients 4 and 5 completely disappeared.

Table 2. Residual Inhibition at Outpatient Clinic and with Implanted Suppressor

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Duration of Tinnitus Inhibition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At Clinic</td>
</tr>
<tr>
<td>1</td>
<td>Several hours</td>
</tr>
<tr>
<td>2</td>
<td>Several hours</td>
</tr>
<tr>
<td>3</td>
<td>Several hours</td>
</tr>
<tr>
<td>4</td>
<td>Several hours</td>
</tr>
<tr>
<td>5</td>
<td>Half-day</td>
</tr>
<tr>
<td>6</td>
<td>Suppressed moderately for a half-day</td>
</tr>
<tr>
<td>7</td>
<td>Half-day</td>
</tr>
</tbody>
</table>

Figure 2. Results of tinnitus stress test. Filled bars show the level on the tinnitus stress test before the operation, whereas open bars indicate postoperative levels. No level was registered postoperatively for patients 1, 4, and 7.
Tinnitus Stress Test for Implanted Tinnitus Suppressor


Annoyance Index

Tinnitus Intensity Index

Figure 3. Results of the tinnitus intensity index and annoyance index. Filled bars show the scores on the tinnitus intensity index and annoyance index before the operation, whereas open bars indicate postoperative scores.

TST, and only one patient still reported an extreme level on this test. In the latter patient, the stimulating electrode broke free from the promontory.

Results of the TII and AI

All patients reported an extreme score on the TII before device implantation, although the intensity of tinnitus varied from patient to patient based on the loudness balance test. After the operation, results of the TII reveal no level in two patients, a mild level in two other patients, a moderate level in two patients, and a severe level in a single patient (Figure 3). Tinnitus in two patients who registered as no level disappeared for the entire day, although tinnitus reappeared if the patient suffered from a common cold or was severely tired. The two patients with a mild TII level sometimes perceive tinnitus, indicating that the effects of one-time stimulation sometimes were not long-lasting enough to relieve tinnitus altogether.

The TII finding revealed the loudness of tinnitus as perceived by the patients before and after the operation; the implanted tinnitus suppressor was effective for improving the sensory component in all patients. Only Patient 6 did not experience tinnitus disappearance, although the intensity was diminished relative to that before the operation. Patient 2, in whom the electrode was problematic, still perceived her tinnitus as the loudest imaginable because the suppressor did not work well.

The AI scores revealed a severe level in five patients and a moderate level in two patients before device implantation. The AI improved in six patients postoperatively (see Figure 3). Three patients were at a moderate level, two were at a mild level, and two registered no level after the operation. In Patient 2, the AI results worsened after the operation (from moderate to severe), owing to the electrode problem.

Correlations Among TST, AI, and TII

Data were analyzed to determine the relationship among TST, TII, and AI. The results of this analysis are displayed in Table 3. A positive correlation after the operation (at the .01 level of significance using the t-test) was observed although no correlation was observed among those tests before the operation.

Table 3. Correlations Among TST, AI, and TII

<table>
<thead>
<tr>
<th></th>
<th>Preoperative Values</th>
<th>Postoperative Values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$r^2$</td>
<td>$p$ (t-test)</td>
</tr>
<tr>
<td>TST and AI*</td>
<td>0.019</td>
<td>.7668</td>
</tr>
<tr>
<td>TST and TII</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>AI and TII</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

*TST = tinnitus stress test; AI = annoyance index; TII = tinnitus intensity index.

Note that dashes indicate that the correlation cannot be computed.
Tinnitus Suppression and the Results of TST, AI, and TII

Patient 1 experienced a small amount of persistent tinnitus in the left ear all day after device implantation in the right ear, although tinnitus reappeared during a common cold and when the patient was very tired. Hence, this patient’s TII, AI, and TST scores highly improved after the implantation.

Patient 2 abandoned use of the stimulator because of the electrode trouble she experienced in 1996. Therefore, her TST score worsened relative to that before the implantation.

Patient 3 experienced tinnitus disappearance for several hours in the implanted ear after 30 minutes of stimulation. Tinnitus in the unimplanted ear sometimes disappeared simultaneously. The TII was lower than that before the implantation because tinnitus that reappeared was weaker than the preoperative condition. However, this patient’s TII still was higher than that of other patients.

Patient 4 has experienced no tinnitus in the unimplanted ear after usage of the suppressor. Tinnitus usually disappears also in the implanted ear after several daily stimulations. Tinnitus did not disappear in the implanted ear when the patient suffered from a common cold or was very tired. This patient’s AI and TII dramatically improved after implantation of the suppressor. He also reported hearing improvement after use of the suppressor.

In Patient 5, tinnitus in the unimplanted ear has completely disappeared, and tinnitus in the implanted ear usually disappears after several electrical stimulations per day. Tinnitus did not disappear in the implanted ear if the patient was suffering from a common cold or was very tired. He had trouble with hearing because of chronic otitis media since childhood. This patient reported hearing improvement after using the suppressor. The duration of the residual inhibition was so much longer than that of other patients that the number of uses per day (once or twice) is smaller than that of other patients. Patient 5 felt that the intensity of his tinnitus was the loudest imaginable preoperatively, although it annoyed him only slightly. After use of the suppressor, the tinnitus annoyed him far less, indicating that the suppressor might be beneficial even to those patients in whom tinnitus is only slightly annoying. This patient was more satisfied with hearing improvement than with tinnitus relief. Therefore, the TST, AI, and TII dramatically improved after device implantation.

Patient 6 had never experienced relief from tinnitus since the first consultation at our outpatient clinic. The tinnitus weakened so dramatically after the operation that he was satisfied with the suppressor. Therefore, this patient’s TST, AI, and TII improved after the implantation.

After use of the suppressor, hearing in Patient 7 improved to normal (Figure 4) and tinnitus completely disappeared except when he was suffering from a common cold or from extreme tiredness. Dizziness also was controlled by the suppressor. Therefore, the TST, AI, and TII dramatically improved in this man after device implantation.

Complications

No rebound tinnitus was reported in any patient. No vertigo, ear blockage, headache, or worsening of residual hearing level was reported either. No patient experienced extrusion of the wire under the external skin, although the stimulating electrode has broken free from the promontorium tympani in one patient.

DISCUSSION

We recommended two female and five male tinnitus patients for implantable tinnitus suppressors. For patient selection, we emphasized the evaluation of residual tinnitus suppression after transtympanic electrical stimulation. The degree of tinnitus suppression using the implanted device was consistent with that reported

Figure 4. Audiogram from right ear of Patient 7 with improvement in hearing. Thresholds were recorded on June 29, 1994 (before the operation); on December 22, 1994 (approximately 2 weeks after the operation); and on March 16, 1995 (3 months after the operation). In August 1997, the hearing threshold still is within normal limits.
from outpatient clinics, as shown in Table 2; that is, the duration of residual inhibition using the suppressor was not longer in home users of the device than at outpatient clinics, but tinnitus intensity improved.

Patients selected for the implantable suppressor should have experienced tinnitus disappearance for more than a few hours after electrical promontorium tympani stimulation at an outpatient clinic. Patient 6 never experienced the disappearance of tinnitus at an outpatient clinic, and so in this patient we could not guarantee tinnitus disappearance even if he continued to use the implantable device. As expected, Patient 6 did not experience tinnitus disappearance after use of the implanted suppressor.

In addition, the intensity of alternating current stimulation for tinnitus relief was emphasized because the stimulator is designed to be portable. The maximum intensity of alternating current necessary to make tinnitus disappear at outpatient clinics was less than 100 µA for patients, except for Patient 3, for whom the intensity was 200 µA. Especially in patients 1 and 7, the intensity of the current needed to make tinnitus disappear was less than 40 µA, so that the maximum current was set at 70 and 100 µA, respectively. For others, the maximum current was set at less than 600 µA owing to the requirement for a more intense current to make tinnitus disappear. Because of the limitations of the stimulator, the maximum current delivered to the promontorium tympani, however, appeared to be less than 300 µA. Patients reported that tinnitus did not disappear if they were suffering from a common cold or were very tired. Taking into account such situations as a common cold or tiredness, we should select for suppressor implantation those patients in whom less than 200 µA of maximum current is necessary to make tinnitus disappear.

Previously, we reported the outcome of treatment of tinnitus with an implanted tinnitus suppressor in 3 of 7 patients considered in this study [11]. In our earlier report, Patient 1 still experienced slight tinnitus all day after using the device, and tinnitus reappeared during a common cold or when the patient was tired. Those results are consistent with the scores of the AI, TII, and TST after the operation.

For Patient 2 in the earlier report, we noted that the effect on tinnitus suppression was unstable. When the patient began using the device, she experienced little tinnitus all day after 1 hour or more of stimulation two or three times daily. The patient was becoming so dependent on the device that the stimulation time extended to four or more times per day. Eventually, she used the device for several hours every day. Initially, this apparent dependency was attributed to the patient’s personality, not to problems with the electrode, which were the actual cause. The patient reported that she was apt to pay too much attention to the existence of the implanted coil in the mastoid. She reported trying to push down the switched button of the stimulator repeatedly, but her tinnitus was not reduced. Finally, the patient abandoned use of the stimulator and felt despair because she thought that she could not escape from tinnitus. The patient’s desperation caused her to feel impatient, and she registered an extreme score on the TST. We now are able to see the electrode tip through the eardrum and are aware that the decreasing efficacy of the suppressor was caused by problems with the electrode trouble, not by the patient’s personality. After the patient was supplied with an upgraded stimulator and the free electrode again touched on the eardrum, the patient’s TST score leveled off to her preoperative level.

The third report in our earlier publication (concerning Patient 6 from the present study) noted that the patient experienced tinnitus all day despite using the stimulator twice daily. The patient did report, however, that his tinnitus was weakening. This comment was in accord with the TII of Patient 6 postoperatively. The AI showed that he was satisfied with the result from using this device.

A discrepancy was demonstrated among these patients regarding the degree of annoyance and tinnitus intensity before the operation. All patients before the operation thought that the intensity of tinnitus was the loudest imaginable. However, not all patients were severely affected by tinnitus even while reporting that it was the loudest imaginable. Hence, the AI did not correlate with the TII preoperatively [12]. Nonetheless, a positive correlation at the .01 level of significance was observed among the postoperative TII, AI, and TST scores [12]. This finding indicates that patients can so much more easily manage tinnitus after use of the stimulator than before such use that tinnitus no longer scares patients.

Subjective improvement in hearing was reported in the ear with tinnitus relief after combination therapy of tinnitus masking and external electrical stimulation, although no change in the hearing threshold was demonstrated by audiometric testing [13]. Patient 5 also reported improvement in his hearing, but the hearing threshold did not improve after use of the implantable suppressor. However, improvement in the hearing threshold was observed in patients 1, 2, and 7. See, for example, the audiogram of Patient 1 shown in Figure 1. The bone conduction threshold improved postoperatively. In patients 1 and 2, the effects of middle-ear infection on the hearing threshold were taken into account. However, in Patient 7, we should not dismiss improvement in the hearing threshold (see Figure 4), although we also could not ascertain the reason for hearing threshold improvement in the ear with the implanted device. Approximately 9 months after the im-
was a response in the form of ataxia or destruction-type nystagmus. In the period 1989–1992, the number of instillations was limited to four (the so-called quadruple method) [6,7]. Alternatively, the dual strategy was used as suggested by Magnusson and Padoan [8] in 1991, in which gentamicin is instilled on 2 consecutive days and thereafter the patient’s condition is observed and drug is administered as needed; if there is a substantial caloric loss or the vertigo attacks cease, no more gentamicin is instilled. With both the dual method [8] and the quadruple method [7], one must be prepared to administer additional drug after 1 or several months. Even if the initial therapeutic regimen almost always causes a unilateral caloric loss, and some relapses occur that necessitate additional instillations of gentamicin.

The patients have been investigated with electronystagmography, dynamic posturography, pure-tone audiometry, and speech audiometry before and after the gentamicin treatment. The follow-up period spans 2–17 years. Intensive physiotherapy was used in all cases [9].

RESULTS

This article is intended to present the auditory results after gentamicin treatment. It should be noted, however, that among the 69 patients involved in this study, only 3 failures of the vertigo treatment were seen. One patient had a labyrinthectomy, and 2 others had vestibular nerve sectioning after the gentamicin treatment failed.

Six patients were given three instillations, whereas 25 patients were given four instillations (either according to the quadruple method or via a repeated dual method). Only occasional patients were given more than eight doses of gentamicin (Figure 1).

With use of the initial method of daily drug instillation until the effect was obvious, three ears became deaf. On the quadruple drug regimen, one ear became deaf. With use of the dual method, no ear has lost hearing, but one ear that was re-treated and ultimately received a total of four doses of gentamicin experienced a pure-tone threshold increase of 65 dB.

For patients treated by the original unlimited method, the mean hearing loss after treatment was 12 dB. The quadruple method caused a mean hearing loss of 8 dB, whereas in the patients treated by the dual strategy, no mean hearing loss was noted. In the latter group, there was a mean 0.3 dB gain and a median hearing improvement of 5 dB. It should be noted that even during the era of unlimited numbers of gentamicin instillations, some patients had a nystagmus response after two, three, or four instillations (Figure 2) [10,11].

We wished to determine whether the pure-tone threshold level was predictive of the hearing result after

![Figure 1. Number of doses given to the patients (e.g., 25 patients received four gentamicin instillations).](image)
Gentamicin's Impact on Hearing


Figure 2. Change of pure-tone mean threshold caused by gentamicin treatment. Above the line indicates hearing improvement. Number of doses indicated on the bars. For number of patients, see Figure 1.

treatment. In Figure 3, a comparison is made between the pure-tone threshold before treatment and the change in pure-tone average after treatment. No correlation exists between the pretreatment level and the change in threshold after gentamicin treatment.

DISCUSSION

After gentamicin treatment, the endolymph-producing dark cells in the stria vascularis are damaged and, possibly, their function is diminished [12,13]. Also, the vestibular epithelium is damaged or destroyed, causing a unilateral vestibular loss that results in a destruction type of nystagmus and caloric loss [14]. With vestibular rehabilitation, there is no more ataxia or vertigo. The head-shaking test may unveil a unilateral vestibular loss, but other clinical tests will be negative. Broad-frequency rotatory testing using pseudorandomized stimulation unveils the asymmetry that is not obvious in sinusoidal tests [15].

Dynamic posturography reveals that in the weeks immediately subsequent to gentamicin treatment, an ataxia is present that gradually disappears and, after 3 months, is no longer detectable [16].

Without vestibular rehabilitation and physiotherapy, there is a risk for some permanent ataxia and slight vertigo. Also, if a full effect of gentamicin is not experienced with a few instillations of the drug, a risk for vertigo attacks remains. Additional drug dosing will solve this problem.

In addition to the shunt operation, other surgical procedures such as labyrinthectomy or vestibular nerve sectioning might be performed. The labyrinthectomy offers relief from the attacks of vertigo but also abolishes hearing totally and so should not be used. Vestibular nerve sectioning is associated with a 20% risk for added hearing loss, which exceeds the risk for hearing loss that is associated with gentamicin treatment. Furthermore, if vestibular nerve severing is not performed by an extremely experienced surgeon, the complications can be severe.

In patients treated with gentamicin, vertigo should be cured. If correctly applied, gentamicin treatment is the method of choice and should be attempted before destructive surgery is even considered. The risk for co-
chlear damage is minimized if the dual method of gentamicin administration is used. The risk for hearing loss should, however, be explained to the patient. Gentamicin should be used particularly in patients who suffer a significant and severe hearing loss, and these patients should be warned about the possibility of additional hearing deficit. Although relief from tinnitus cannot be promised, the world literature indicates that most patients suffer less severe tinnitus after gentamicin treatment [17].

REFERENCES