

Signia Notch Therapy: A Novel Approach Clinically Proven to Reduce the Perception of Tonal Tinnitus

Whitepaper

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Introduction

Hearing instruments (with or without a sound generator component) are a current mainstay of the audiological management of tinnitus (1). In 2014, the American Academy of Otolaryngology created evidence-based recommendations for clinicians treating tinnitus patients. The guidelines included the use of hearing instruments as a tinnitus treatment (2). MarkeTrak VIII revealed nearly 2 out of 3 subjects reported hearing aids relieved their tinnitus most of the time to all of the time, while 3 out of 10 reported that hearing aids alleviated their tinnitus all of the time (3). A retrospective study by Searchfield et al (2010) concluded that amplification plus counseling provided twice the reduction in tinnitus handicap over counseling alone (4). Habituation through acoustic therapy (which usually includes wearing hearing instruments) can be applied to all types of tinnitus and, therefore, is the treatment method of choice for many hearing care professionals.

For individuals who present with *Tonal Tinnitus*, that is the perception of a near-continuous sound or overlapping sounds with well-defined frequencies (5), an alternative to habituation therapy is available. Tonal tinnitus is present for the majority of individuals with tinnitus. A joint comprehensive tinnitus study conducted by the Kresge Hearing Research Laboratory and the University of Oregon Health Sciences Center Tinnitus Clinic revealed that tinnitus pitch falls largely into two broad categories: tonal and noise. More than half of the subjects, or 59%, reported tonal tinnitus; 25% reported noise-type tinnitus; and, 16% presented with a combination. The subjects were further classified based on frequency of the tinnitus. A near two-thirds, or 63%, indicated perceiving tinnitus between 2000 and 7000 Hz. Only 21% had low-tone tinnitus below 2000 Hz and 16% above 7000 Hz. (6). New research supports attempts to mitigate tonal tinnitus from its anatomic origin utilizing spectral notching rather than treating the effects of tinnitus through traditional habituation noise therapy. This paper will discuss a novel approach of utilizing notch-modified hearing instruments to treat patients with tonal tinnitus.

Acoustic trauma has been linked with changes in synaptic inhibition in the damaged areas of the cochlea. The auditory deprivation creates an excitation-inhibition imbalance throughout the central auditory pathway, most likely from a weakening of the inhibitory network in this area (7). Lateral inhibition is a process in which the most active sensory nerve fibers in a bundle inhibit action potentials in adjacent fibers from the periphery of the stimulus area (8). It has been proposed that providing additional stimulation to the affected area (hearing loss frequencies) - effectively "evens out" the imbalance and reduces the perception of tinnitus (9). However, even with the advanced hearing instruments available today, providing adequate stimulation to achieve this goal is not always possible. As an alternative, efforts to reduce the loudness perception of tonal tinnitus turned to the use of music therapy. Okamoto introduced a notched-music method for which subjects listened to self-chosen, enjoyable music notched to remove energy in the frequency range surrounding the tinnitus frequency. The theory behind notched music therapy contends that music, modified with a spectral notch, reduces cortical activity corresponding to the center frequency (CF)

of the perceived tinnitus pitch and fosters an increase of lateral inhibition in that area. The approach is called Tailor-Made Notched Music Therapy or TMNMT (10).

One limitation to TMNMT is that the individual is required to spend 1-3 hours on a daily basis listening to the notched music therapy (10). This involves dedication to the program and disrupts normal daily routine. Further, TMNMT fails to address the amplification needs of the patient.

Signia Notch Therapy

Signia introduces Notch Therapy (NT), a new and proprietary sound therapy approach. Based on the concept of “re-attracting” lateral inhibition (7), Notch Therapy uses spectral notching and applies it to the principles of traditional amplification with hearing instruments. We know that amplification has been clinically proven to reduce patient scores on the Tinnitus Handicap Inventory and subjectively reduce the impact of tinnitus in their daily lives (11, 12). Therefore NT aims to attack tinnitus on two fronts: 1) enhancing the auditory environment by amplification to compensate for the patients hearing loss; and, 2) suppressing the tinnitus associated neural hyperactivity with enhanced lateral inhibition.

Strauss and colleagues conducted a double-blinded study to determine the subjective and objective efficacy using notched environmental sound technology (NEST), the original name of NT, with individuals reporting tonal tinnitus (13). Subjects included 20 individuals with mild hearing loss and distressing tinnitus, as defined by the Tinnitus Questionnaire 12 (TQ12), an assessment questionnaire that identifies *tinnitus*-related psychological distress (14). Mean age was 53 years. Subjects were randomly assigned to one of two groups: Group 1 was fit with commercially available behind-the-ear hearing instruments, or amplification only, and Group 2 was fit with the same instruments, but with the notched environmental sound technology activated. The TQ12 was administered at the beginning of the study and repeated at 3 weeks to assess the subjective effects of NEST.

Results indicated a more predominant improvement for the NEST approach, as defined by an improvement in the TQ12 score. This improvement was clearly noticeable after only 3 weeks (13). This efficacy study shows that this approach positively impacts the tinnitus sufferer by increasing habituation and decreasing distress levels within a 3-week pre/post therapy window (see Figure 1).

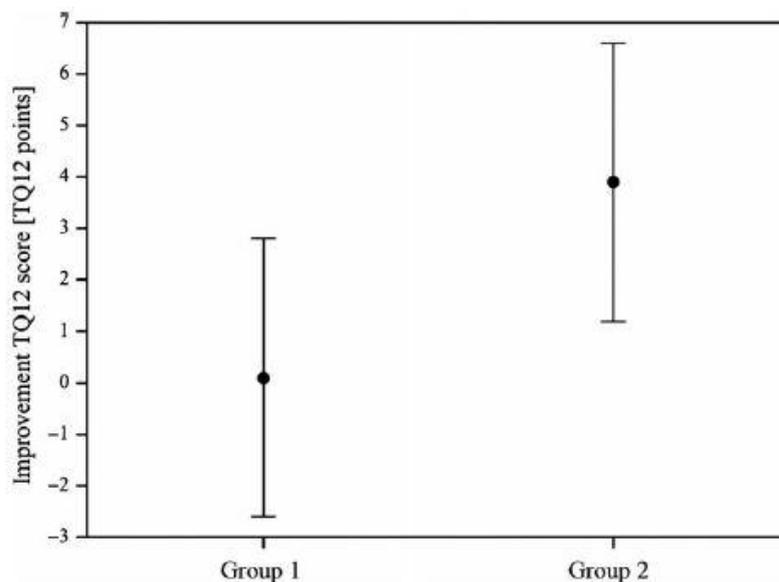


Figure 1. Tinnitus Questionnaire 12 (TQ12) represents the change in points from pre-study evaluation score to the post-study outcome score. Group 1 (control) showed virtually no improvement with an average point improvement score of zero, while Group 2 (NT) showed an average improvement of 4 points.

A follow-up, double-blinded study was conducted to determine the long-term effectiveness of Signia Notch Therapy. Subjects included 34 individuals with mild-to-moderate hearing loss and well-documented, subjective chronic tinnitus. Mean age was 56.5 years. Subjects were divided into two groups. The control group was fit with commercially available, digital-processing behind-the-ear hearing instruments and target group with the same hearing instruments, but with the frequency response spectrally notched at the individual's matched tonal tinnitus frequency. All subjects completed the Tinnitus Questionnaire 52 (TQ52) at the beginning of the study, after 3 months and after 6 months. Like the TQ12, the TQ52 assesses tinnitus severity, but in a more comprehensive manner (14). Results indicated a prominent improvement in the TQ52 scores at the 3-month evaluation for the target group with notched environmental sounds approach. An improvement in the TQ52 score translates to a reduction of tinnitus-related distress. Results show strong improvement of the target group, relative to the control group, and how the improvement is maintained at the 6-month evaluation (see Figure 2).

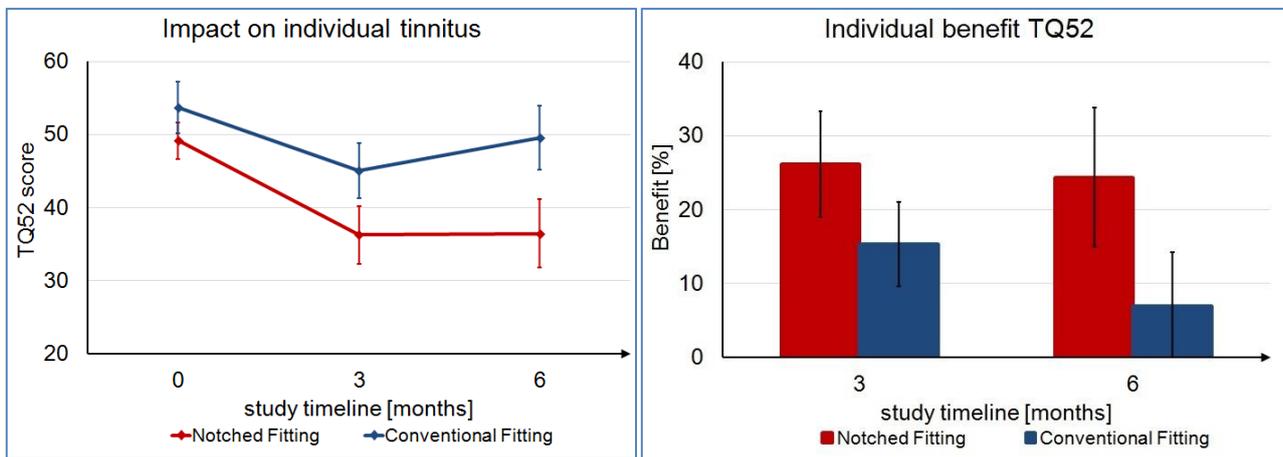


Figure 2 *Left panel*: Average reduction of Tinnitus Questionnaire 52 (TQ52) scores for individuals with Conventional Fitting and Notch Fitting. A reduction of the TQ52 score corresponds to an improvement in tinnitus perception and relief. The Conventional Fitting group demonstrated a maximum improvement at 3 months, lessening at 6 months. The Notched Fitting group demonstrated a significant improvement in TQ52 scores at 3 months and this improvement sustained through the 6-month study period. *Right panel*: Percent benefit based on Tinnitus Questionnaire 52 (TQ52) scores at 3 and 6 months. The Notched Fitting group achieved roughly 10 % more benefit at 3 months, which was maintained through the 6 month completion of the study.

Conclusions of the study were as follows:

- 1) The study shows a therapeutic advantage of utilizing Notch Therapy (NT) compared to hearing instruments with conventional amplification.
- 2) There is no need set aside dedicated time for NT. Its effects become apparent by simply wearing the hearing instruments every day.
- 3) NT was shown to be effective for patients with mild-moderate hearing loss and tonal tinnitus.
- 4) NT was shown to be effective for patients suffering from severe chronic pure tone tinnitus (13).

Hearing aids are considered the initial and primary treatment to help the tinnitus patient manage tinnitus, even when their hearing loss is mild (15). Other therapies such as TMNMT require the patient to spend a considerable amount of time listening to music independent of wearing hearing aids to compensate for hearing loss the remainder of the day. Signia Notch Therapy combines the best of both therapies into one convenient method. With Notch Therapy, the notched environmental sounds provide the therapeutic effect of spectrally modified acoustic stimulation integrated into the wearer's daily routine.

Implementation of Notch Therapy

Signia primax hearing instruments offer NT as software-based tinnitus therapy option through the Connex 8.2 fitting software, in addition to the traditional Tinnitus Therapy signals that can be activated to assist in habituation to tinnitus. In order to activate NT, the clinician needs to determine the placement of the notch by a simple pitch matching procedure. Connex offers three options for determining and entering the pitch that most closely represents the patient's internal tinnitus tone. The simplest method is to utilize the Automatic Matching procedure. The clinician simply plays two tones (A & B) to the patient through their primax hearing instruments (Figure 3). The patient indicates which tone is closer to their internal tinnitus tone. This process is repeated several times as Connex automatically narrows down the frequency range to find the most appropriate pitch match.

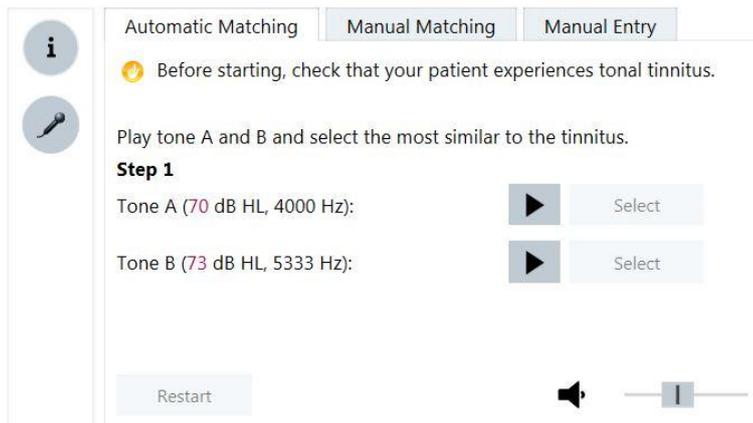


Figure 3. Screen view of the three tinnitus pitch matching procedures available in the Connex 8.2 fitting software. Shown is the Automatic Matching selection.

The second approach available is Manual Matching (Figure 4). In this procedure the clinician presents tones through the primax hearing aids to obtain a pitch match in a more traditional pitch matching procedure (16, 17). Simply manipulate the frequency and intensity of the presented tone through the software similar to the operation of an audiometer.

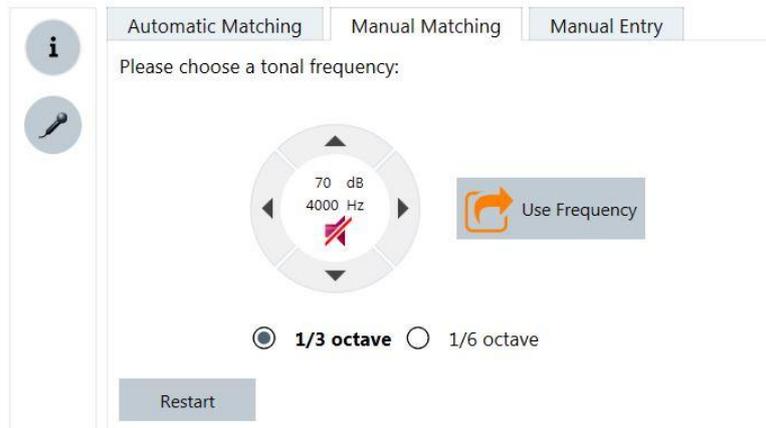


Figure 4. Screen view of the three tinnitus pitch matching procedures in Connex 8.2 fitting software. Shown is the Manual Matching selection.

The third method, Manual Entry, allows the clinician to simply enter an already determined tinnitus frequency as the pitch match (Figure 5). Some clinicians may have performed a tinnitus pitch match either with their audiometer or with some other form of equipment designed for this assessment. For those clinicians, Connex Manual Entry option allows the choice of 31 different frequencies. The clinician should choose the frequency closest to the tinnitus frequency they have already identified and select "Use Frequency" as seen in Figure 6.

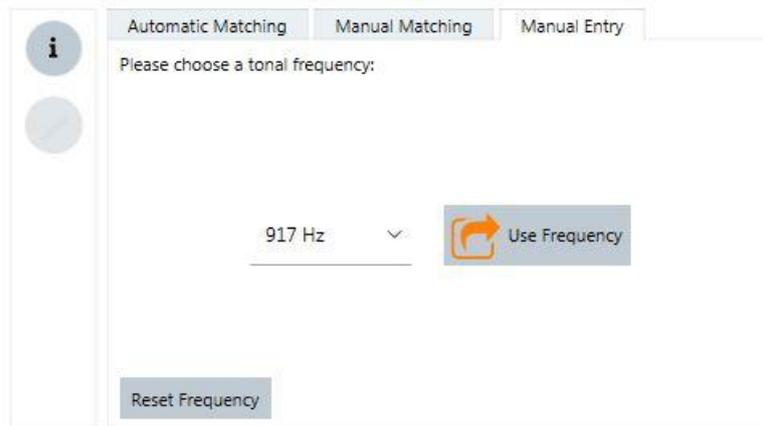


Figure 5. Screen view of the three tinnitus pitch matching procedures in Connex 8.2 fitting software. Shown is the Manual Entry selection.

In order to confirm an appropriate pitch match was found, Frequency Check needs to be completed prior to initiation of the notch. This Frequency Check is also located within the Connex software (Figure 6).

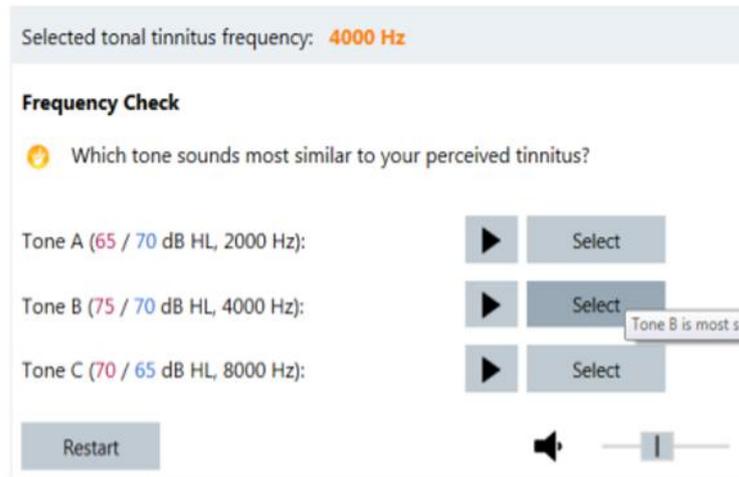


Figure 6. Screen view in Connexx 8.2 software showing the Frequency Check.

Once the frequency is confirmed with the Frequency Check, the clinician selects in which programs to activate the notch. A complete screenshot of the Tonal Tinnitus screen is seen in Figure 7. For more details on the workflow in Connexx, refer to (18).



Figure 7. Tonal Tinnitus Therapy screen in Connexx 8.2 showing a Manually Entered pitch match as 3333 Hz, with the Frequency Check completed and the notch activated in all three listening programs.

Conclusion

Hearing aids such as primax offer a variety of tinnitus treatment options to meet the individual needs of any patient. It's up to the clinician to decide the best course of treatment for each individual based on their type of tinnitus and various additional factors. NT is a new tool which has been proven effective for treatment of tonal tinnitus. However, if your patient requires a more traditional habituation approach, primax offers various static therapy signals to choose from: White noise, Pink noise, Speech noise, High Tone noise, and Brownian noise, which can all be further individually customized with respect to frequency content, as well as 4 modulated Ocean Wave signals. This allows the clinician even more flexibility to find

therapy signals that fit the needs of any habituation protocol. By adding a Notch Therapy option, Signia raises the bar for tinnitus treatment offering the most flexible combination device in the hearing instrument market.

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Dr. Munhões dos Santos is an audiologist and the Product and Marketing Manager of Signia in Brazil. She holds a Ph.D. in Sciences and a Master's degree in Experimental Pathophysiology from the University of São Paulo. She has been providing sound therapy for tinnitus patients since 1998. She is experienced in a variety of tinnitus relief approaches including TRT (Tinnitus Retraining Therapy) and TAT (Tinnitus Activities Treatment) and has presented lectures on tinnitus relief within Brazil and internationally. She founded and is responsible for a support program for tinnitus patients in Signia retail stores in Brazil.



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Dr. Powers is an Education Specialist for Signia. She trains customers and staff on products, software, and services. In this role, Leanne has given several lectures at AudiologyNOW! and numerous state conventions on a variety of topics. Leanne practiced in a variety of hearing healthcare settings for 16 years prior to joining the Signia team. Most recently, she operated two hearing aid offices in the Chicago area. Leanne received her undergraduate degree from Northern Illinois University, her graduate degree from RUSH University in Chicago, and her doctorate from A.T. Still University of Health Sciences in Arizona.

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