A MANUALLY OPERATED DEVICE FOR THE TREATMENT OF RESIDUAL MIDDLE EAR EFFUSION AND EUSTACHIAN TUBE DYSFUNCTION

By

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ABSTRACT
Following recovery from otitis media, middle ear function might not have been restored completely, and annoying symptoms like sound distortion, blockage or fullness in the ear can persist. The continuation of symptoms can be explained by residual effusion and persisting Eustachian tube dysfunction, which prevents the middle ear to adjust to fluctuations of atmospheric pressure. Residual symptoms can be addressed successfully by gently unblocking the middle ear with a pocket sized manually operated device called the N300 (Enttex GmbH, Hannover, Germany). It has been developed to specifically unblock the middle ear as is often associated with air travel and diving. Tubotympanometry and vestibular evoked myogenic potentials (VEMPs) before and after N300 application were employed to objectively assess Eustachian tube function.
Key words: Otitis media, tubotympanometry, vestibular evoked myogenic potentials, N300, Eustachian tube dysfunction, middle ear effusion.

INTRODUCTION
Following recovery from otitis media, middle ear function might not have been restored completely. Symptoms such as fullness, blockage in the ear or discomfort and sound distortion as well as difficulties in speech perception might continue for weeks, and despite a normal pure tone audiogram or tympanogram. The continuation of symptoms can be explained by residual effusion and persisting Eustachian tube dysfunction, which prevents the middle ear to adjust to fluctuations of atmospheric pressure. Tympanometry can fail to demonstrate a suspected Eustachian tube dysfunction so that special tests need to be employed. Morimitsu et al. introduced tubotympanometry and documented this technique to accurately measure residual Eustachian tube dysfunction (1). In this test Eustachian tube dysfunction is detected by the inability to return to the initial middle ear pressure level following Valsalva manoeuvre and frequent swallowing. Recently Wang et al. added vestibular evoked myogenic potentials (VEMPs) to detect residual middle ear conduction impairment (2). Typically it shows a delay in the latencies P13 and N23 while the interpeak latencies remain normal.
We have gained experience in gently unblocking persisting fullness in the ears by employing a pocket sized manually operated device called the N300 (Enttxe GmbH,
Hannover, Germany). It has been developed to specifically unblock the middle ear as is experienced with air travel and diving.
The N300 operates by applying mild negative pressure to the sealed external ear canal. This helps to unlock the Eustachian tube, and thus facilitating middle ear ventilation when swallowing (Fig. 1). The N300 has a safety valve that prevents creating excessive pressures in the external ear canal, and not exceeding 350-400mmH₂O.

MATERIAL AND METHOD
Twenty patients with persisting ear fullness sensation in one ear following otitis media were randomly subdivided into two groups of ten. Pure tone audiometry, tympanometry and stapedial reflexes were normal in these subjects. Group A consisted of 7 males and 3 females, mean age 36.9 years, and group B consisted of 6 males and 4 females, mean age 41.5 years. All subjects have previously been treated with the usual medical regime for otitis media (nasal decongestants, non-steroidal anti-inflammatory drugs, antihystamines and antibiotics).

Subject’s fullness in the ear was quantified through the Visual Analogue Scale (VAS). The audiological assessment was performed by an audiologist (MV) and consisted of:

- Pure Tone Audiometry
- Tympanometry
- Stapedial Reflexes
- Tubotympanometry
- Vestibular Evoked Myogenic Potentials (VEMPs)

For VEMPs, the same techniques were employed as previously described (3). The following parameters were of particular interest: presence or absence of response, latency of first positive (P13) and negative (N23) peaks, interpeak latencies (P13-N23), and peak-to-peak amplitudes (P13-N23).

Group A was subjected to no further treatment following recovery from otitis media and after the clinical and audiological assessment (Control Group). Group B subjects were asked to use the N300 three times a day, for at least 5 minutes each time and every day for a week.

Each group was clinically and audiologically reassessed after a week, and VAS repeated.
RESULTS
At the beginning of the study the mean value of fullness in the ear as measured by VAS were 8.68 in group A and 9.2 in group B. Tubotympanometry revealed residual Eustachian tube dysfunction in 9 subjects in group A and in all subjects in group B. VEMPs were delayed in all subjects comparing the normal ear to the affected ear. In normal subjects right/left differences for P13 and N23 are expected to be less than 1msec (3). In group A, right/left differences for P13 were prolonged to 1.6msec and in group B to 1.7msec.

After one week group A showed a VAS score of 6, tubotympanometry remained abnormal in 7, and right/left latency differences remained prolonged with 1.4msec (Fig. 2). These values did not reveal a significant improvement (p>0.005).

After one week of treatment with the N300 the VAS score was 2, tubotympanometry was abnormal in only one subject, and right/left latency differences were 0.8msec (Fig. 3). These values revealed a significant improvement (p<0.001).

DISCUSSION
Acute otitis media runs its normal course over a period of three weeks. Despite the application of medication residual symptoms may persist thereafter being responsible for the annoying symptoms of sound distortion, fullness and blockage in the ear or even severe discomfort.

Valsalva manoeuvres are not always helpful as the tissue tugor of the Eustachian tube is raised during its action locking the tube even further. The Toynbee manoeuvre can also fail as during the latter phase of its action, when the soft palate resumes its normal position, suction is exercised on the pharyngeal end of the Eustachian tube, which has an adverse effect on middle ear ventilation.

The application of negative pressure in the sealed external ear canal results in adjusting reduced middle ear pressure to the pressure in the outer ear canal and reducing the pressure gradient across the tympanic membrane. This also has the effect of unlocking the Eustachian tube. With a reduced pressure gradient across the tympanic membrane and an unlocked Eustachian tube, middle ear ventilation is facilitated during swallowing.
The N300 creates pressures that do not exceed 350-400mmH$_2$O. These pressures are safe and are routinely used in assessing middle ear function with tympanometry.

The application of negative pressure in the external ear canal, however, is only effective provided the middle ear is not completely filled with incompressible fluid and residual air is present in the middle ear. We therefore suspect that the application of the N300 in serous otitis media will possibly be successful when residual air is present in the middle ear. Tympanometry and otoscopy will assist in the correct assessment of the middle ear condition.

**CONCLUSION**

Despite normalization of pure tone audiometry and tympanometry following otitis media, ear fullness may persist for weeks and can be resistant to common treatment regimes. With the N300, negative pressure is applied to the sealed external ear canal. This unlocks the Eustachian tube and facilitates middle ear ventilation when swallowing and restoring normal middle ear function.

**REFERENCES**

The N300 is a pocket size device that is manually operated. Negative pressure, not exceeding 350-400mmH₂O, can be applied to the external ear canal with the effect of unlocking the Eustachian tube and facilitating middle ear ventilation when swallowing.
Fig. 2

VAS score, tubotympanometry and VEMPS revealed an insignificant improvement in this group. VAS: Visual Analogue Scale; TUBOTYMP: tubotympanometry; P13 latency: right/left difference in msec.
Fig. 3

The N300 was able to restore middle ear function within a very short period of time. VAS: Visual Analogue Scale; TUBOTYMP: tubotympanometry; P13 latency: right/left difference in msec.