Modern acoustic reflectometry: Accuracy in diagnosing otitis media with effusion

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Abstract
We conducted a study of 80 patients to evaluate the accuracy of a commercially available acoustic reflectometer in identifying the presence or absence of otitis media with effusion (OME). This device assesses bilateral tympanic membrane mobility and, by inference, middle ear status. We found that it was most accurate in patients with normal and grossly fluid-filled ears. We recommend screening with this acoustic reflectometer to rule out OME in adult and pediatric patients.

Introduction
Acoustic reflectometry was introduced in 1984 as a method of improving the diagnosis of otitis media with effusion (OME), particularly in children. However, this technology has not been widely accepted in clinical practice. In this article, we describe our evaluation of the accuracy of a commercially available acoustic reflectometer for detecting OME in adults and children.

Patients and methods
We conducted a study of patients who had undergone bilateral diagnostic audiometry at the Department of Head and Neck Surgery at the Kaiser Permanente Medical Center in Oakland, Calif. Exclusion criteria were the presence of a tympanic membrane perforation and/or a pressure equalization tube and a failure to undergo all testing, which included diagnostic audiometry (including tympanometry), pneumatic otoscopy, and acoustic reflectometry.

A total of 80 patients—47 adults, aged 15 to 88 years (mean: 50.9), and 33 children, aged 1 to 12 years (mean: 4.0)—met the inclusion criteria and were entered into the study. Diagnostic audiometry was administered by a certified audiologist (R.D.W.). The other three authors were blinded to the audiometry results.

Pneumatic otoscopy was performed by an otolaryngologist (M.J.B.) with either a Bruening magnifying pneumatic otoscope, an operating microscope, or a Welch Allyn 3.5-V halogen-head pneumatic otoscope. The purpose of otoscopy was to examine the tympanic membrane and to test its mobility; ears were categorized as either normal, decreased [mobility], increased [mobility], or immobile. Results were recorded for each ear, and most were confirmed by the senior author (R.L.H.) or by another staff otolaryngologist (H.W.K.). Air/fluid levels, membrane retraction, and the presence or absence of OME were also noted. Cerumen was removed when it occluded the external auditory canal or obscured the view of the tympanic membrane.

A commercially available acoustic reflectometer, the EarCheck PRO Otitis Media Detector (MDI Instruments, a division of Becton, Dickinson & Co.; Franklin Lakes, N.J.), was used to evaluate all patients. The device uses principles of acoustic reflectometry to classify patients into five categories of risk for middle ear effusion (table 1).

In order to obtain the most accurate readings, we performed multiple reflectometry tests on some patients and manipulated the external auditory canal of others.
The results of acoustic reflectometry were compared with the diagnoses rendered by tympanometry. When these findings were independently confirmed by pneumatic otoscopy, Jerger’s type B tympanograms were used as the criterion standard for a diagnosis of OME. If any discrepancy was noted between the results of tympanometry and the results of acoustic reflectometry, we used the pneumatic otoscopy diagnosis for data analysis.

The EarCheck PRO provides measures of reflectivity called spectral gradient levels and angle data. It also displays reflectivity in graph form. Spectral gradient levels and angle data are related to risk categories for OME, and they therefore require that breakpoints be established. Data obtained by the three diagnostic modalities were analyzed using spectral gradients of 3 or higher as breakpoints for indicating OME.

The results of acoustic reflectometry obtained from randomly selected ears (1 ear in each patient) were analyzed in multiple subsets using the Wilcoxon matched-pairs signed rank test. Because no significant differences were found between right and left ears \((p = 0.80)\), the data were combined for analysis as done previously.

### Results

The prevalence of OME was 11.7% (11 of 94 ears) in our adult population and 28.8% (19 of 66 ears) in the pediatric group (table 2).

#### Adults

On acoustic reflectometry, a spectral gradient level of 3 or higher correctly identified OME in 7 of 9 ears for a sensitivity of 77.8%. Acoustic reflectometry also correctly identified 76 of 81 ears as normal, for a specificity of 93.8%.

A spectral gradient level of 4 or 5 yielded a sensitivity of 66.7% (6 of 9 ears) and a specificity of 97.5% (79 of 81). The positive predictive value of a spectral gradient level of 3 or higher was 58.3%, and the negative predictive value was 97.4%.

In 4 of the 94 ears (4.3%), the reflectometer generated an “error report”—that is, the test was unsuccessful despite repeated attempts, primarily because of the small size of the external auditory canal.

#### Children

A spectral gradient level of 3 or higher correctly identified OME in 13 of 17 ears for a sensitivity of 76.5%; the specificity was 95.5% (42 of 44 ears).

A spectral gradient level of 4 or 5 yielded a sensitivity of 58.8% (10 of 17 ears) and a specificity of 100% (44 of 44 ears).

The positive predictive value of a spectral gradient level of 3 or higher was 86.7%, and the negative predictive value was 91.3%.

The reflectometer generated an error report for 5 of the 66 ears (7.6%). As was the case with the adults, the pediatric error reports were associated with small external auditory canals.

### Discussion

Despite the fact that OME is a common otolaryngologic condition, it can be difficult to diagnose. Diagnostic tests include pneumatic otoscopy, audiometry (including tympanometry), and acoustic reflectometry.

#### Pneumatic otoscopy

Pneumatic otoscopy has been the preferred method of diagnosing middle ear effusion, but interpretation is subjective and examiners must undergo substantial training and gain significant experience to attain reliable results. Otherwise, trained staff may be needed to validate the interpretive ability of individual otoscopists who are not expert in the procedure. This technique also requires visualization of the tympanic membrane.

#### Audiometry

Measurement of pure-tone threshold is both time-consuming and subjective, and it does not necessarily identify changes characteristic of ears with OME. The use of impedance audiometry became popular in 1970, when the A-B-C tympanogram configuration system was described. Since then, many other classification systems for tympanograms have been proposed, but none has become widely accepted. Studies have shown that tympanometry is an objective method of identifying OME, and its sensitivity and specificity are usually higher than those of otoscopy. However, different authors may not interpret data in the same way, which can lead to conflict-
ing results or conclusions. Nevertheless, preoperative tympanography is a valuable diagnostic tool for detecting OME in children who are scheduled to undergo bilateral myringotomy with tube placement. Even so, tympanography is time consuming, and it requires an airtight seal in the external auditory canal and a cooperative patient (tympanograms obtained from crying children can be unreliable). Finally, the use of tympanography without correlated otoscopic findings may lead to an overdiagnosis of middle ear effusion.

Acoustic otoscopy. The first acoustic otoscope (Endeco Medical; Marion, Mass.), an experimental device that led to the development of acoustic reflectometry, was introduced in the 1980s. However, the otoscope was plagued by numerous drawbacks:

- Results were not accurate in the presence of air/fluid levels.8
- It was unreliable in children younger than 6 months of age.9
- It was sensitive to operator technique.9
- It generated error reports when used in ear canals partially occluded by cerumen.9
- Its sensitivity and specificity were low at any given breakpoint in a population of children with chronic middle ear disease.7
- It yielded false-positive results when tympanic membranes were thickened, scarred, or retracted.8

Acoustic reflectometry. Acoustic reflectometry was introduced in 1984 as a method of improving the diagnosis of OME by measuring sound waves that bounce off tissue.1 We found that with the EarCheck PRO, which was introduced in 1997, the positive and negative predictive values, sensitivity, and specificity with regard to OME were high. The fact that the device does generate an error signal when used in small ear canals suggests that the problem is an inherent design limitation. Nonetheless, we found that EarCheck PRO was useful as a screening tool to rule out OME because it generates reports rapidly, does not require an airtight seal, is comfortable for patients, does not require a great deal of cooperation from the patient, and is highly sensitive for detecting middle ear fluid. The device is also portable and easy to use.

**Acknowledgments**
MDI Instruments, a Division of Becton, Dickinson & Co., provided the acoustic reflectometry devices used in this study. Lynn Ackerson, PhD, provided statistical assistance. The Medical Editing Department of the Kaiser Foundation Research Institute provided editorial assistance.

**References**

<table>
<thead>
<tr>
<th>Spectral gradient level</th>
<th>Adult ears (n = 94)*</th>
<th>Pediatric ears (n = 66)†</th>
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<tbody>
<tr>
<td></td>
<td>Normal middle ear</td>
<td>Otitis media with effusion</td>
</tr>
<tr>
<td></td>
<td>46</td>
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<tr>
<td>Error reports</td>
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</tbody>
</table>

* Includes 5 false-positive and 2 false-negative tests obtained at a spectral gradient level of ≥3.
† Includes 2 false-positive and 4 false-negative tests obtained at a spectral gradient level of ≥3.

Table 2. Middle ear status as determined by the EarCheck PRO acoustic reflectometer and confirmed by pneumatic otoscopy and tympanometry.