Historic Perspective of the Acoustic Otoscope

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Abstract
The acoustic otoscope, originally called the acoustic reflectometer, was developed and produced by John and David Teele in the early 1980s. Since initial production, two different instrument versions have been developed by two separate companies. During the period of time in which the acoustic otoscope has been in production, there have been numerous studies reported with the two instrument versions. We provide a historic summary of the acoustic otoscope, summarize the pertinent studies, and address the contrasting results found in the literature.

Key Words: Acoustic otoscope, middle ear effusion, tympanometry

Abbreviations: EAC = external auditory canal, MEE = middle ear effusion

The acoustic otoscope was developed for the purpose of screening children to identify the presence of middle ear effusion (MEE). According to Teele and Teele (1984), a diagnostic method was needed for the pediatric population to detect MEE that would meet the criteria of safety, accuracy, speed of diagnosis, and freedom from pain. Since the development of the original prototype, the acoustic otoscope has undergone upgrades in operation including changing from analog to digital microprocessor circuitry and the addition of two printer versions to assist with response interpretation.

Since the acoustic otoscope became commercially available, numerous studies have been carried out with varied results. We have endeavored to put these studies in perspective with regard to the diverse study variables, which may, in fact, be related to the different outcomes.

INSTRUMENT VERSIONS

Two instrument versions have been commercially available since the initial report of Teele and Teele (1984), including an analog version distributed by Endeco Medical and a digital model produced by ENT Medical. Variations include the input signal, instrument circuitry, and method for response interpretation. Table 1 summarizes the acoustic otoscope models used in clinical research.

The first commercially available instrument was a portable analog version manufactured by Endeco Medical. Response interpretation for the detection of MEE relied on the whole-number LED display of reflectivity located on the handle of the instrument. ENT Medical later assumed control of the patent rights and changed from an analog to a digital microprocessor. In addition, ENT Medical provided printers to assist with response interpretation, initially the 501 recorder and later the DPU-411 printer. The printed output display increases precision (reflectivity is rounded to the first decimal place). Also, a waveform is provided that illustrates the vector sum magnitudes of the input signals. Figure 1 illustrates examples of acoustic otoscope printed outputs.

The waveform of the output display provided by the ENT Medical 501 recorder indicates the extent of cancellation for each input frequency; however, the units and scales have been changed as compared to the prototype. Frequency decreases from left to right on the abscissa, and the scale is labeled in arbitrary “length” units increasing from left to right. The ordinate continues to represent vector sum amplitudes relative to a baseline, with increased amplitudes increasing in the vertical direction.
Table 1  Equipment Models Used in Clinical Research

<table>
<thead>
<tr>
<th>Model</th>
<th>Signal</th>
<th>Output</th>
<th>Circuitry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noncommercial prototype</td>
<td>65 dB SPL</td>
<td>Oscilloscope</td>
<td>Analog</td>
</tr>
<tr>
<td></td>
<td>1800-7000 Hz</td>
<td>XY plotter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20 msec or 20 sec</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endeco Medical</td>
<td>80 dB SPL</td>
<td>LED display</td>
<td>Analog</td>
</tr>
<tr>
<td></td>
<td>2000-4500 Hz</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 msec</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ENT Medical</td>
<td>80 dB SPL</td>
<td>501 recorder or</td>
<td>Digital</td>
</tr>
<tr>
<td></td>
<td>1800-4000 Hz</td>
<td>DPU-411 printer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>150 msec</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The units, however, have been changed as compared to the prototype, from decibels to arbitrary reflectivity units. For example, a decrease in vector sum amplitude compared to the baseline (plotted down) is referenced to a 0 to 9 scale, with 9 indicating the largest decrease in magnitude (Combs, 1989, 1991).

The ENT Medical DPU-411 printer, on the other hand, inverted the waveform's vertical scale. Decreased vector sum magnitudes relative to the baseline are plotted up. Also, frequencies with vector sum magnitudes that are greater than the baseline are ignored and are not displayed on the graph. The abscissa continues to illustrate length units with a scale increasing left to right (corresponding to frequencies decreasing left to right) (ENT Medical, 1993).

Figure 1  Examples of ENT Medical 501 and DPU-411 printer outputs, from normal ears (left) and ears with MEE (right).

**CLINICAL RESEARCH**

Considerable research has been conducted with the acoustic otoscope since the initial description in 1984. These studies, however, have produced variable results. Data have been reported that both support and question the validity of this instrument for MEE detection. Table 2 summarizes the results of some of the investigations. The published studies have used different study designs, methods, criteria for diagnosis of MEE, instrument version, printer type, parameters for interpretation of results, and sample size and selection. These various factors may account for the different results and conclusions reported in the literature.


Teele and Teele (1984) evaluated 290 ears of 160 children aged 7 days to 13 years. The subjects were inpatients and outpatients at Boston City Hospital, at risk for MEE. The acoustic otoscope was compared to acoustic immittance measures, with diagnosis being confirmed with pneumatic otoscopy. Some diagnoses were confirmed with myringotomy. Using a reflectivity cut-off criteria of 4.0, these authors derived values of 94 percent sensitivity and 79 percent specificity for the detection of MEE.

Buhrer et al (1985) studied 120 ears of 60 children referred for evaluation of hearing and otologic disorders. The acoustic otoscope was reportedly the least sensitive method for detecting middle ear disorders, when compared with
<table>
<thead>
<tr>
<th>Author</th>
<th>Subjects (Age)</th>
<th>N (Ears)</th>
<th>Prevalence of MEE (%)</th>
<th>Equipment Model</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teele and Teele (1984), Boston City Hospital Boston, MA</td>
<td>&gt;7 days to 13 years</td>
<td>290</td>
<td>37</td>
<td>Noncommercial prototype</td>
<td>94</td>
<td>79</td>
</tr>
<tr>
<td>Lampe et al (1985), Department of Pediatrics, Army Medical Center, El Paso, TX</td>
<td>&gt;6 months to 10 years</td>
<td>141</td>
<td>70</td>
<td>Endeco</td>
<td>87</td>
<td>70</td>
</tr>
<tr>
<td>Avery et al (1986), Pediatric clinic, San Antonio, TX</td>
<td>&gt;4 to 8 years</td>
<td>451</td>
<td>24</td>
<td>Endeco</td>
<td>80</td>
<td>54</td>
</tr>
<tr>
<td>Macknin et al (1987), Pediatric clinic, Cleveland, OH</td>
<td>&gt;1 to 11 years</td>
<td>R: 100</td>
<td>67</td>
<td>Endeco</td>
<td>R: 77</td>
<td>59</td>
</tr>
<tr>
<td>Lampe and Schwartz (1989), Department of Pediatrics, Army Medical Center, Washington, DC</td>
<td>&gt;5 months to 12 years</td>
<td>344</td>
<td>72</td>
<td>Endeco</td>
<td>94</td>
<td>90</td>
</tr>
<tr>
<td>Jehle and Cottington (1989), Emergency Medicine Division, Allegheny General Hospital, Pittsburgh, PA</td>
<td>&gt;Children: 7 weeks to 15 years</td>
<td>160</td>
<td>52</td>
<td>Endeco</td>
<td>82</td>
<td>100</td>
</tr>
<tr>
<td>Babonis et al (1991), Department of Pediatrics, Army Medical Center, Tacoma, WA</td>
<td>&gt;6 months to 10 years</td>
<td>220</td>
<td>54</td>
<td>ENT Medical (501 recorder)</td>
<td>58</td>
<td>88</td>
</tr>
<tr>
<td>Combs (1991), Pediatric office, Wallingford, CT</td>
<td>&gt;4 to 16 years</td>
<td>406</td>
<td>55</td>
<td>ENT Medical (501 recorder)</td>
<td>93</td>
<td>94</td>
</tr>
<tr>
<td>Pellett et al (1995), University and Boston City Hospitals Boston, MA</td>
<td>&gt;Children: 1-12 years</td>
<td>129</td>
<td>29</td>
<td>ENT Medical (DPU-411 printer)</td>
<td>Children: 85</td>
<td>Adults: 83</td>
</tr>
<tr>
<td></td>
<td>&gt;Adults: 13-69 years</td>
<td>446</td>
<td>3</td>
<td></td>
<td>93</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;Older Adults: 70-92 years</td>
<td>67</td>
<td>4</td>
<td></td>
<td>66</td>
<td>67</td>
</tr>
</tbody>
</table>
pure-tone screening, immittance testing, and otologic examination. Buhrer et al (1985) concluded that the acoustic otoscope was not adequate as a general screening tool. The test performance measures were derived using a relatively low criteria for a reflectivity cut-off (three or four).

Macknin et al (1987) also reported poor accuracy of the acoustic otoscope. This group of pediatricians compared the results of the acoustic otoscope on 198 ears of 100 children (aged 1 to 11 years) undergoing myringotomy with tube placement for recurrent otitis media (OM). The authors pointed out that the children were sitting upright for the examination, as recommended by the manufacturer. The accuracy for a range of reflectivity cut-off points for the acoustic otoscope was examined. For example, sensitivity and specificity measures were derived for cut-off points three to nine. Data for the right and left ears were analyzed separately, based on the reasoning that the results were not likely to be independent. The reflectivity readings were very different between ears; however, the authors could not explain why they found no significant differences between ears by myringotomy. The data analysis yielded a low sensitivity and specificity regardless of cut-off point (right ear 77% and 59%, respectively; left ear 54% and 62%, respectively). Macknin et al (1987) concluded that their data showed a lack of agreement between myringotomy and the acoustic otoscope.

In contrast, positive findings were reported by Schwartz and Schwartz (1987), who tested 511 ears of 256 children ranging in age from 2 months to 14 years (mean age 4 years). The subjects were from a private practice pediatric office. Sensitivity of the acoustic otoscope (88%) and tympanometry (87%) when compared with pneumatic otoscopy were similar. However, specificity was lower for tympanometry (78%) compared to 83 percent specificity for the acoustic otoscope. These data were obtained with a reflectivity cut-off point of five. Tympanograms were classified as either normal or abnormal with the abnormal classification including readings that were flat, shallow, or rounded and/or contained a pressure peak less than −200 mm H2O. Schwartz and Schwartz (1987) concluded that the acoustic otoscope was a reliable method to detect fluid in asymptomatic children that can be used to complement traditional methods for detection of MEE.

Oyiborhoro et al (1987) reported data that supported the accuracy of the acoustic otoscope in their evaluation of 200 children from an otolaryngology clinic. Comparisons were made from results of the acoustic otoscope, myringotomy, tympanometry, pure-tone audiometry, and visual otoscopy. Ninety-three percent sensitivity and 83 percent specificity measures were derived with an abnormality cut-off designation of four.

Gates and Avery (1988), however, responded to Oyiborhoro et al (1987) and stated that the conclusion made in this study regarding the clinical usefulness of the acoustic otoscope was not supported by the reported data. The areas of concern included the study population (no subjects with intermediate findings were included), validation procedures (inadequate sample for validating the pneumatic otoscopist), and data analysis (use of a single reflectivity cut-off point). Gates and Avery (1988) maintained that their criticisms of Oyiborhoro et al (1987) were based on their earlier work (Avery et al, 1986), which had found poor accuracy for this instrument. Avery et al (1986) compared the acoustic otoscope to pneumatic otoscopy, tympanometry, and pure-tone audiometry. Four thousand readings were taken from the acoustic otoscope over a 2-year period from 451 children with surgical confirmation of chronic MEE. Receiver operating characteristics curves were used to illustrate the effect of disease prevalence upon test performance. An acoustic otoscope cut-off point of four (i.e., reading of four and above to indicate MEE) yielded 80 percent sensitivity with 54 percent specificity when the acoustic otoscope measurements were compared to an algorithm derived from pneumatic otoscopy and tympanometry.

Lampe and Schwartz (1989) addressed some of the discrepancies that had been reported regarding accuracy of the acoustic otoscope. In this study, the acoustic otoscope was evaluated with 175 infants and young children who presented to the authors' pediatric practice with otalgia or acute OM as determined by pneumatic otoscopy. The authors reported a significant association of ears with acute OM and acoustic otoscope readings of six or higher and ears with no OM and low readings. No difference was noted between right and left ear data. Sensitivity was 94 percent and specificity was 90 percent. Factors were suggested that might account for the variation in results reported in earlier studies, such as different prevalence of middle ear disease in the various studies and different acoustic otoscope cut-off points (Lampe and Schwartz, 1989).
Babonis et al (1991) reported data on the ENT Medical acoustic otoscope with 501 recorder, which included myringotomy for confirmation of MEE. The results agreed with earlier studies that had suggested poor accuracy (Avery et al, 1986; Macknin et al, 1987). Subjects for the Babonis et al study ranged in age from 6 months to 10 years. The authors made a direct comparison of tympanometry and the acoustic otoscope. A printer provided the reflectivity data for response interpretation. (Babonis and Combs were the only identified investigators of the commercially available acoustic otoscope with printer.) Results were analyzed for 220 ears of patients scheduled for myringotomy and tube placement. Data analysis suggested higher sensitivity for tympanometry (90%) versus 58 percent sensitivity for the acoustic otoscope. In contrast, the acoustic otoscope had greater specificity (88%) versus 54 percent specificity for tympanometry.

Combs (1991) questioned data that had been reported regarding the acoustic otoscope when the results were only based on reflectivity and length measures (e.g., Buhrer et al, 1985; Lampe et al, 1985; Avery et al, 1986; Macknin et al, 1987; Oyiborhoro et al, 1987; Schwartz and Schwartz, 1987; Weir et al, 1987; Lampe and Schwartz, 1989). Combs reports greater accuracy when the recorder output is used in concert with reflectivity and length. In addition to the improved accuracy (printer measures to the 0.1 unit), the recorder permits shape analysis. For example, Combs (1989) performed tympanometry and reflectometry with ENT Medical 501 recorder for 1005 ears of 503 subjects aged 3 months to 12 years. Ears were judged as normal or abnormal based on the tympanometry results. One hundred eighty-five tracings were obtained with the acoustic otoscope that had two reflectivity peaks, 138 of which were associated with abnormal tympanometry. Combs contends that a recorder should be used with this device so that such tracings can be evaluated appropriately. Combs surmised that studies that did not use the recorder may have underestimated the accuracy of the acoustic otoscope (Combs, 1989).

In a later study, Combs (1991) evaluated 406 ears of 203 children (aged 4 to 16 years) with an acoustic otoscope with recorder. In addition to the absolute reflectivity measures, a shape analysis was included for response interpretation. The angle formed by the reflectivity dip was measured for each tracing. Tympanometry was used to document the presence or absence of MEE and to derive accuracy measures for the acoustic otoscope. Combs (1991) reported that the reflectivity variable with a cut-off point of 5.0 yielded 76 percent sensitivity and 90 percent specificity. Instrument performance with angle data (90-degree cut-off) reportedly improved sensitivity to 95 percent and specificity to 94 percent.

In a study conducted at Boston University Medical Center (Pellett et al, 1995), the acoustic otoscope with DPU-411 printer was evaluated for MEE detection using comparisons to a physician’s otoscopic examination. Best results for children (aged 1 through 12 years) were obtained with the angle variable alone (e.g., 81% sensitivity and 85% specificity). For adults (13 to 69 years), sensitivity (93%) was highest using both reflectivity and angle data, albeit with lower specificity (83%). The mediocre performance seen in the study questioned the use of this instrument version for MEE detection in children.

**DISCUSSION**

The reported sensitivity of the acoustic otoscope has varied widely for each of the two commercial instrument versions. Studies have been both positive and negative for each model. Comparing the investigations is difficult due to the numerous study variables. For example, subject sample size and selection criteria have varied. MEE prevalence in the study population, which affects instrument performance, has ranged in selected studies of children from 23 percent up to 72 percent. Another variation among the studies is the protocol for MEE diagnosis, which included myringotomy and/or pneumatic otoscopic examinations by physicians of differing specialties (i.e., pediatricians, emergency room physicians or residents, otolaryngologists, and neuro-otologists) and tympanometry.

Some of the studies have differed in the criteria for test subject selection. Teele and Teele (1984), for example, reported instrument sensitivity of 94 percent for their noncommercial prototype in which children with air-fluid levels or bubbles noted on otoscopy were excluded from the analysis. In an investigation of the latest commercial model (Pellett et al, 1995), the sensitivity for children (81%) was reported to be influenced by the ears with air-fluid levels. Most of the children with MEE who were missed by the acoustic otoscope had air-fluid levels in the middle ear. If we had removed the ears with air-fluid levels from the data analysis (as in Teele and Teele, 1984), the reported sensitivity for children would have been higher.
The diverse findings may be related to the variation in the criteria for response interpretation. For instance, several of the earlier studies analyzed the data with a single whole-number reflectivity cut-off, compared to the sensitivity reported in other investigations for a range of cut-offs.

The variation in the instrument models is another factor contributing to the different findings. ENT Medical, the manufacturer of the digital model, introduced some modifications that may have compromised instrument accuracy. For instance, a second, smaller tip size was offered for use with pediatric patients, which may have affected recording accuracy. According to the instrument patent (Teele, 1986), the relationship between the tip size and ear canal diameter is critical for the instrument's sensitivity for MEE detection. Furthermore, ENT Medical narrowed the spectrum of the input signal. The lower high-frequency cut-off would be a factor with smaller ear canals due to the inverse relationship between length and resonant frequency.

The difference in the two printer models may also have contributed to the contrasting results reported for the ENT Medical digital version. Pellett et al (1995) reported relatively poor performance for the ENT Medical version with DPU-411 printer with children, while Combs (1991) reported high sensitivity for children with the ENT Medical model and 501 recorder. As noted previously, the DPU-411 printer inverted the vertical scale of the output waveform and reduced the data on the graphic display.

CONCLUSION

Studies that have assessed the sensitivity of the acoustic otoscope in detecting MEE have yielded a wide variety of results. These varied outcomes may in fact be related to the different instrument versions, study design, printer type, population studied, sample size, criteria for diagnosing of MEE, etc. Furthermore, no studies have compared the different instrument versions to each other. To understand the true value of the acoustic otoscope in the detection of MEE, additional research is needed that addresses the issues raised above and controls for the variables listed. Presently, ENT Medical no longer has the patent rights. A third version is available from the company that has the patent rights, MDI Instruments Inc., of Woburn, Massachusetts. As a result, we must wait to see if there will be another chapter in the acoustic otoscope story.

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REFERENCES


