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LETTER

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Use of optical coherence tomography otoscopy to overcome cerumen and other view obstructions during ear examination and assessment

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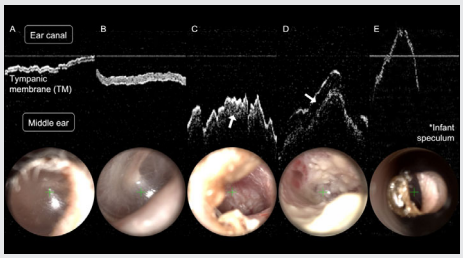
Abstract



Childhood ear infections are highly prevalent and diagnosed with the otoscope, a simple tool that illuminates and magnifies the eardrum to subjectively assess color, translucency and presence of any middle ear fluid. Frequently, however, this view is obstructed by cerumen, complicating clinician assessment and appropriate and effective management. An optical coherence tomography (OCT)-otoscope capable of capturing both depth-resolved OCT images and digital color surface images was used to compare OCT against otoscopy for imageability and readability despite cerumen obstruction. Image data were collected from 26 human subjects and read by 12 blinded clinicians and 5 blinded OCT experts. An average of 64.6% of otoscopy views were obstructed. For cases with >75% otoscopy view obstruction, OCT imageability was 84.6%, while otoscopy imageability was 37.5%, excluding complete obstruction cases. OCT-otoscopy is a promising technology to improve practical middle ear assessment despite the presence of obstructions that frequently render current diagnostic assessments ineffective.

KEYWORDS

cerumen, ear infection, optical coherence tomography, otitis media, otoscopy

1 | INTRODUCTION

Accurate ear examination is important in pediatric healthcare. Otitis media (OM; ear infection) is the most common diagnosis in preschool-age children, accounting for one-in-nine visits in US primary care practices annually [1]. Clinicians rely on otoscopy to view the tympanic membrane (TM; eardrum) and assess the middle ear to identify the presence and type of middle ear effusion (MEE) when diagnosing OM. Per American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) and American Academy of Pediatrics (AAP) guidelines, visualization of the TM is essential for assessing for OM via TM bulging/position, color, translucency and presence of

MEE [1, 2]. Factors like impacted cerumen (earwax), ear canal curvature and/or hair within the ear canal can obstruct the illumination and otoscopic view of the TM [3]. Excessive or impacted cerumen is present in 1 in 10 children, 1 in 20 adults, and more than one-third of geriatric and developmentally delayed patients [4, 5]. The average primary care physician's diagnostic accuracy for OM is ~50% using standard otoscopy [6]. Along with its high prevalence, OM is also the most frequent indication for US outpatient antimicrobial use [7]. Therefore, a reliable, noninvasive method for diagnosing OM, especially one that is not impacted by otoscopic view obstructions, is needed for improving OM diagnosis and management.

Optical coherence tomography (OCT), considered the optical analog of ultrasound imaging, uses a low-intensity light source to produce real-time, depth-resolved structural images with a micron-scale resolution and has been used and clinically demonstrated for imaging in the ear, including identifying MEE for diagnosing OM and identifying middle ear biofilms linked to chronic disease [8–10]. The images produced by the reflected light are analysed and can be used to objectively differentiate air from fluid with ~91% accuracy, largely because the MEE will contain some optically scattering particles, compared to air [11]. Additionally, OCT can be used to characterize the fluid properties due to the scattering of the imaging signal from particulates in the fluid [11, 12]. Coupling OCT with standard and/or pneumatic otoscopic examination may improve clinician assessment of the TM and middle ear space compared to otoscopy alone [13, 14].

2 | MATERIALS AND METHODS

In a single-site study under a protocol approved by the Carle Foundation Hospital Institutional Review Board, 26 human subjects were opportunistically recruited at Carle Health Departments of Pediatrics (14 subjects) and Otolaryngology (12 subjects). All subjects were imaged bilaterally with a commercial OCT-otoscope (OtoSight Middle Ear Scope, *PhotoniCare*) by their physician. This commercial OCT-otoscope simultaneously captures and displays real-time M-mode OCT images (depth vs time) along with co-registered digital CMOS camera color images of the surface of the imaged tissue, such as the TM. To assess the real-world practicality of this new technology compared to the standard otoscopy view of the TM, cerumen was not removed prior to imaging. During analysis, a percent-view obstruction was calculated for all

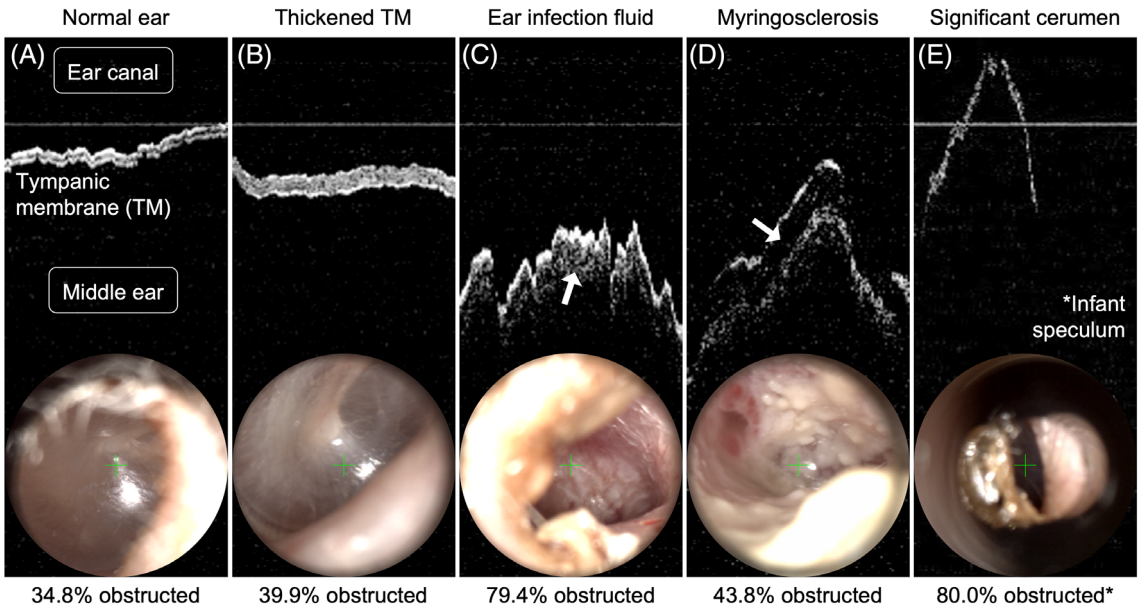


FIGURE 1 Representative correlated digital otoscopy and OCT images. (A) Normal ear, wherein the tympanic membrane (TM) can be seen in the M-mode OCT frame as a white ribbon, above which is the ear canal space and below which is the middle ear space. The horizontal axis is time, and the width of the M-mode OCT frame represents ~3 seconds of data. A lack of OCT signal in the middle ear space indicates the absence of middle ear fluid. The corresponding otoscopy image has a 34.8% obstruction of the total otoscopic view from the speculum tip. (B) Thickened TM with no middle ear fluid. (C) A case of acute otitis media wherein an OCT signal from middle ear fluid is indicated (arrow). (D) A case of myringosclerosis wherein separation of the layers of the TM is indicated (arrow). (E) A normal ear with significant otoscopic view obstruction due to cerumen and the ear canal, as well as using an infant speculum, yet the OCT image shows a clear TM with the absence of middle ear fluid.

TABLE 1 Imageability rates for OCT-otoscopy compared to standard otoscopy, and impact of otoscopic view obstruction due to cerumen, ear canal curvature and/or ear canal hair

	OCT			Otoscopy		
	Readable ear images	Total ear images	% imageability	Readable ear images	Total ear images	% imageability
Total	47	52	90.4	42	52	80.8
Cases >75% obstruction	11	16	68.8	6	16	37.5
Cases >75% obstruction (without 100% obstruction)[a]	11	13	84.6	6	13	46.2

Abbreviation: OCT, optical coherence tomography.

[a]Subject image data from three ears showed complete cerumen impaction and, therefore, 100% obstruction of the otoscopy view. The bottom row indicates analysis of all 13 ear study cases with >75% obstruction but <100% obstruction.

digital otoscopy images using an image segmentation algorithm (Matlab, *MathWorks*) to quantify the ratio of the area of any obstruction (eg, cerumen, ear canal wall and/or ear canal hair) to the total area visible inside the speculum tip.

To assess image readability, the OCT-otoscope's digital otoscopy images were analysed by 12 blinded clinician readers, with expertise across pediatrics (5), otolaryngology (6) and audiology (1). Readers determined whether the images were of sufficient quality to (1) identify the TM and (2) determine whether enough of the TM was visible to attempt diagnosis. Similarly, to assess OCT-otoscopy image pair readability, and therefore imageability of this new technology, a group of five blinded readers with OCT expertise analysed these image pairs using the following:

Otoscopy image: Discern that the otoscopy crosshair (see Figure 1) is not on the cerumen or ear canal wall.

OCT image: Identify the TM signal and underlying middle ear space for evaluation.

Images were classified as readable if >50% of readers classified the image as readable, and imageability was classified as the ratio of readable images to the total number of images.

3 | RESULTS

Results from this study are summarized in the Table 1 and representative OCT-otoscopy images are shown in the Figure 1. The average percent of obstructed otoscopy views was 64.6% ± 20.2%, with no statistically significant differences by one-way Analysis of Variance (ANOVA) between subject age group (child [20] vs adult [6]) or clinical site (pediatrics [14] vs otolaryngology [12]).

The maximum and minimum obstructed views are 93.8% and 31.1%, respectively, excluding datasets with complete view obstruction (100%; $n = 3$) due to cerumen impaction, and datasets with complete lack of obstruction (0%; $n = 1$).

Per reader analysis, at least one readable OCT image was collected from each subject (90.4% imageability), while standard otoscopy had 80.8% imageability. However, for cases with >75% otoscopy view obstruction ($n = 16$ ears), OCT imageability was 68.8% (84.6%, if excluding complete view obstruction cases), while standard otoscopy imageability was 37.5% (46.2%, if excluding complete view obstruction cases).

4 | DISCUSSION

In this study, OCT-otoscopy imageability proved superior to standard otoscopy, especially for cases with significant cerumen (>75% otoscopy view obstruction). It is not surprising that standard otoscopy imageability of the TM was only 37%-46% for cases with significant cerumen, as otoscopy is reliant upon sufficient illumination of the TM and a large enough view of the TM to properly assess for OM. However, OCT-otoscopy can enable middle ear assessment for OM fluid by aiming the OCT beam between any view-obstructing features like cerumen (see Figure 1E crosshairs). Therefore, OCT-otoscopy is a promising new technology to improve the ease of practical middle ear assessment despite cerumen or other obstructions, which frequently render current diagnostic assessments ineffective.

Further studies on the clinical utility of OCT-otoscopy will expand on the limited number of subjects and the limited number of blinded image readers involved in this preliminary study, compare OCT-otoscopy performance to other commercially available clinical imaging tools (eg, standard and/or pneumatic otoscopy or tympanometry), and evaluate OCT-otoscopy ease and speed of use in pediatrics by a variety of clinicians who routinely perform ear examinations. Lastly, the development of assistive image interpretation algorithms [15] to supplement clinician OCT-otoscopy interpretation has the potential to further improve the adoption and clinical utility of this promising imaging tool.

AUTHOR CONTRIBUTIONS

Ryan G. Porter and Ryan M. Nolan conceptualized and designed the study, coordinated and supervised data collection, carried out data analysis and interpretation, drafted the initial manuscript, and reviewed and revised the manuscript. Ryan G. Porter, Michael Novak and Jon Paul Youakim collected all data and critically reviewed the manuscript. Ryan M. Nolan and Ryan L. Shelton designed the data collection instruments, coordinated and supervised data collection, carried out initial analyses, and critically reviewed the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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CONFLICTS OF INTEREST

Mr. Nolan and Dr. Shelton are co-founders and employed by PhotoniCare and thereby report a financial interest. Dr. Novak reports a financial interest in PhotoniCare as a clinical advisory board member and investor. All other authors have no conflicts of interest to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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REFERENCES

[1] R. M. Rosenfeld, J. J. Shin, S. R. Schwartz, R. Coggins, L. Gagnon, J. M. Hackell, D. Hoelting, L. L. Hunter, A. W. Kummer, S. C. Payne, D. S. Poe, M. Veling, P. M. Vila, S. A. Walsh, M. D. Corrigan, *Otolaryngol. Head Neck Surg.* **2016**, *154*(Suppl 1), S1.

[2] A. S. Lieberthal, A. E. Carroll, T. Chonmaitree, T. G. Ganiats, A. Hoberman, M. A. Jackson, M. D. Joffe, D. T. Miller, R. M. Rosenfeld, X. D. Sevilla, R. H. Schwartz, P. A. Thomas, D. E. Tunkel, *Pediatrics* **2013**, *131*(3), e964.

[3] C. Michaudet, J. Malaty, *Am. Fam. Physician* **2018**, *98*(8), 525.

[4] S. R. Schwartz, A. E. Magit, R. M. Rosenfeld, B. B. Ballachanda, J. M. Hackell, H. J. Krouse, C. M. Lawlor, K. Lin, K. Parham, D. R. Stutz, S. Walsh, E. A. Woodson, K. Yanagisawa, E. R. Cunningham Jr., *Otolaryngol. Head Neck Surg.* **2017**, *156*(Suppl 1), S1.

[5] G. A. Horton, M. T. W. Simpson, M. M. Beyea, J. A. Beyea, *J. Prim. Care Comm. Health* **2020**, *11*, 1.

[6] M. E. Pichichero, M. D. Poole, *Arch. Pediatr. Adolesc. Med.* **2001**, *155*, 1137.

[7] S. Ahmed, N. L. Shapiro, N. Bhattacharyya, *Laryngoscope* **2014**, *124*(1), 301.

[8] G. L. Monroy, R. L. Shelton, R. M. Nolan, C. T. Nguyen, M. A. Novak, M. C. Hill, D. T. McCormick, S. A. Boppart, *Laryngoscope* **2015**, *125*(8), E276.

[9] C. T. Nguyen, W. Jung, J. Kim, S. A. Boppart, *Proc. Natl. Acad. Sci.* **2012**, *109*, 9529.

[10] P. Pande, R. L. Shelton, G. L. Monroy, R. M. Nolan, S. A. Boppart, *J. Assoc. Res. Otolaryngol.* **2016**, *17*(5), 403.

[11] D. Preciado, R. M. Nolan, R. Joshi, G. M. Krakovsky, A. Zhang, N. A. Pudik, N. K. Kumar, R. L. Shelton, S. A. Boppart, N. M. Bauman, *Otolaryngol. Head Neck Surg.* **2020**, *162*(3), 367.

[12] G. L. Monroy, P. Pande, R. L. Shelton, R. M. Nolan, D. R. Spillman Jr., R. G. Porter, M. A. Novak, S. A. Boppart, *J Biophotonics* **2017**, *10*(3), 394.

[13] R. Shelton, W. Jung, S. I. Sayegh, D. T. McCormick, J. Kim, S. A. Boppart, *J. Biophotonics* **2014**, *7*(7), 525.

[14] J. Won, R. G. Porter, M. A. Novak, J. Youakim, A. Sum, R. Barkalifa, E. Aksamitiene, A. Zhang, R. Nolan, R. Shelton, S. A. Boppart, *J. Biophotonics* **2021**, *14*, e202000215.

[15] G. L. Monroy, J. Won, R. Dsouza, P. Pande, M. C. Hill, R. G. Porter, M. A. Novak, D. R. Spillman, S. A. Boppart, *Digit. Med.* **2019**, *2*, 22.

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