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Ultrasound Characterization of Middle Ear Effusion

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Abstract

Purpose—To further enhance and assess the ability to characterize middle ear effusion (MEE) using non-invasive ultrasound technology.

Materials and Methods—This is a prospective unblinded comparison study. Fifty-six children between the ages of 6 months and 17 years scheduled to undergo bilateral myringotomy with pressure equalization tube placement were enrolled. With the child anesthetized, the probe was placed into the external ear canal after sterile water was inserted. Ultrasound recordings of middle ear contents were analyzed by computer algorithm. Middle ear fluid was collected during myringotomy and analyzed for bacterial culture and viscosity.

Results—Ultrasound waveforms yielded a computer algorithm interpretation of middle ear contents in 66% of ears tested. When a result was obtained, the sensitivity and specificity for successfully characterizing middle ear fluid content as either void of fluid, thick fluid (mucoid), or thin fluid (serous or purulent) was at least 94%. Mucoid effusions had higher measured viscosity values (P=0.002). Viscosity measures were compared to culture result, and those with low viscosity (thin consistency) had a higher likelihood of having a positive culture (P=0.048).

Conclusion—The device sensitivity and specificity for fluid detection was 94% or greater among interpretable waveforms (66% of those tested). Although this technology provides important information of the middle ear effusion presence and characteristic, further technological improvements are needed.

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INTRODUCTION

Otitis media is an inflammatory process affecting the middle ear and mastoid spaces causing the development of a MEE. Persistence of middle ear fluid can result in hearing loss[1–2] and recurrent otitis media with effusion (OME).[3] With these important clinical implications, accurate interpretation of middle ear contents proves to be an important determination. The presence of middle ear fluid is commonly assessed by pneumotoscopy and tympanometry. However, these methods have been shown to be limited in accuracy and are dependent on the practitioner's experience, with correct interpretation in 76% and 83% or less of cases using pneumotoscopy and tympanometry, respectively.[4–6] Therefore, additional technologies that may assist in determining the presence of MEE are warranted.

Ultrasound waves are high-frequency sound waves that are commonly and safely used to image soft tissues. Images are created by the amount of energy that is reflected back to the ultrasound transducer and are dependent on the acoustic impedances of the tissues that the waves traverse. The acoustic impedance of a tissue is in turn dependent on the amount of sound pressure to which it is exposed and its ability to transverse these vibrations. Therefore, tissues of different impedances will produce different characteristic ultrasound images. In theory, the ultrasonic properties of the middle ear space will be dependent on the presence and consistency of fluid. In this manner we aim to utilize ultrasound to characterize the fluid content of the middle ear as either no effusion, thin effusion, or thick effusion.

Ultrasound data may be displayed in multiple forms, where B-mode is the most commonly utilized method clinically. A-mode (amplitude modulation) is a simple method of displaying the amount of reflected energy as a vertical amplitude spike of Volts along a horizontal axis of time. A-mode ultrasound was utilized in this technology. To demonstrate, in the case that effusion is not present in the middle ear, ultrasonic energy reflects back to the probe from the tympanic membrane (TM) producing one recorded peak (Figure 1). The wave does not travel beyond the TM if there is no middle ear fluid to propagate it. On the other hand, if middle ear effusion is present, a fraction of ultrasound energy is reflected by the TM, while the remaining energy propagates through the middle ear fluid and reflects back to the probe from the bony structures of the inner ear to produce a second recorded peak. Configuration and amplitude of these peaks are dependent on the material's acoustic impedance. Hence, the waveform may be used to interpret the presence and character of MEE as either thick (mucoid) or thin (serous or purulent).

Previous studies have demonstrated the use of ultrasonography to determine the presence of MEE.[7–8] Most recently Discolo et al.[9] from our institution used a single propagating wave A-mode ultrasound in a preliminary group of patients. The waveforms produced were interpreted by a single human interpreter. This method was difficult, clinically inefficient, and ill-suited for practical usage. To advance this technology to clinical use, three key design changes were made. In order to automate waveform interpretation, a computer algorithm was created to provide this assessment. Further, to increase accuracy, strength of the ultrasound probe was increased to 20MHz. In the prior study, the probe required adjustment and aiming of the ultrasound wave to different areas of the TM in order to achieve an adequate waveform. To reduce this adjustment, 9 separate ultrasound emitting elements were placed into the current study's designed probe and arranged in a 3x3 array on the convex surface of the probe tip. This unique design maximizes the likelihood that 1 of the 9 emitted ultrasound waves will be perpendicular to the reflective surface of the TM and reflect back to the probe for adequate interpretation.[10] An appropriately aligned ultrasound wave will produce a characteristic wave form revealing the middle ear fluid content, as demonstrated in Figure 2.

With improved probe design to eliminate the need for human waveform interpretation, increased ultrasound strength, and added accuracy by addition of a unique 9 element ultrasound emitter, we aimed to assess the clinical capability of this novel device. Ideally, these improvements to the device allow its utility and feasibility as a clinically relevant tool to determine MEE presence and characteristics.

METHODS

The institutional review board of the Cleveland Clinic, Cleveland, Ohio, approved this study which took place between October 2004 and July 2006. During this time, children between ages 6 months to 17 years with diagnosis of OME who were scheduled to undergo bilateral myringotomy with pressure equalization tube placement were invited to enroll. Children undergoing additional procedures on the same operative day, such as adenoidectomy or tonsillectomy, were included in enrollment. Ears with presence of a previously placed ear tube were excluded. Children were consecutively invited to enroll in the study and were not excluded on the basis of syndrome or other co-morbidities. The results of the ultrasonic probe analysis did not change the planned surgical procedure(s). Full parental informed consent and minor assent, when appropriate, was obtained for all subjects.

Children were anesthetized either by mask anesthetic or general anesthesia with endotracheal tube. All ears were then examined under microscopic visualization, and debris was appropriately removed from the external auditory canal (EAC). If testing was to be performed, 0.5 to 1.0 mL of sterile water at room temperature was placed into the EAC using a dropper. The ultrasound probe was placed into the EAC at about 0.5 to 1 cm from the TM. Minor adjustments of probe positioning were made in order to provide an adequate ultrasound signal. The ultrasound signal was displayed on a monitor screen. After appropriate signal acquisition, the water was suctioned from the EAC. The planned ear tube placement was performed on that side. If middle ear fluid was encountered, collection was attempted with a suction trap. If sufficient amounts of fluid were collected, it was sent for routine culture and analyzed for viscosity measurements. Viscosity measures were performed with a cone-and-plate viscometer (Brookfield Engineering, Middleboro, Massachusetts). The experimental procedure was repeated on the contralateral side. Duration of ultrasound probe assessment was on average less than one minute per ear, and the total delay in operation was less than five minutes for all cases. The patients were re-evaluated post-operatively in clinic or by phone call.

The scans obtained were stored on a secured hard drive in digital format and then analyzed by a laboratory-based computer system. Fourier analysis and a computer algorithm (designed by Biomec, Inc., Cleveland, Ohio and now licensed to ElectroSonics Medical, Inc, Cleveland, Ohio) were used to interpret the ultrasonic wave produced. The experimental setup further consisted of a custom nine-channel pulser/receiver (Biomec, now licensed to ElectroSonics Medical, Inc.) and digital acquisition system (Acquisition Logistic, Worthington, Ohio). These components were assembled on personal computer boards. The ultrasound probe was custom designed (Biomec, now licensed and under development by ElectroSonics Medical, Inc.) and is shown in Figure 3. In vitro testing has been performed and previously described.[10]

Continuous measures distributions are described using means, standard deviations, and percentiles of interest. Sensitivity and specificity measures along with 95% confidence intervals for the ultrasonic probe were calculated. Comparisons of viscosity by other study conditions were performed using nonparametric Wilcoxon rank sum tests, due to group imbalance and potential non-normality of the viscosity distribution. P-values less than 0.05 were considered statistically significant.

RESULTS

Ultrasonic Probe Characterization of Middle Ear Contents

A total of 56 consecutive patients (112 ears) were enrolled in the study and underwent testing with the 3x3 array ultrasonic probe. The average age was 3.4 years (standard deviation [SD] 3.1 years), with 36 boys (64%) and 20 girls (36%).

Of the 112 ears, 21 ears were not tested due to presence of a previously placed ear tube (10 ears), significant retraction of the tympanic membrane (5 ears), aborted myringotomy procedure (4 ears), and computer malfunction (2 ears). Of the 91 remaining ears that were tested, the computer algorithm was able to provide results describing the presence and consistency of middle ear effusion (thick, thin, or none) for 60 ears from 41 patients. Therefore, the ultrasonic probe produced a descriptive result of the middle ear contents in 66% of ears attempted for analysis. The remaining 31 ears (34%) could not be analyzed by the ultrasonic probe and computer algorithm.

Of the 41 patients with middle ear effusion analyzed by the system (N=60 ears), there were 26 boys (63%) and 15 girls (37%). The average age was 3.7 years (SD 2.7 years), with a range of 6 months to 13 years. Forty of the 60 ears had no middle ear effusion (67%). Of the 20 ears with effusion present, 16 (80%) had a thick (mucoid) effusion and 4 (20%) had a thin (serous or purulent) effusion, based on visual inspection of the fluid after myringotomy. Table 1 shows the post-myringotomy findings and the ultrasonic probe's interpretation of the middle ear contents prior to each myringotomy. The device mis-classified one thick effusion as an empty middle ear. The remainder of the pre-myringotomy scans were correct in middle ear diagnosis.

The sensitivity and specificity of the ultrasound probe's pre-myringotomy identification of middle ear contents per ear are shown in Table 2 for ears with interpretable results (N=60).

Viscosity of Middle Ear Effusion

Viscosity measurements of middle ear fluid were attempted in patients examined with the above described 3×3 ultrasound array and patients who had undergone testing with a previous version of the ultrasound probe (single ultrasound wave emitting probe). Viscosity measurements were attempted on a total of 126 patients. However, on a majority of these patients, measurements could not be made due to a lack of effusion or insufficient amounts of middle ear fluid collected. A total of 41 ears among 34 patients had successful viscosity measurements. The average age in this population was 3.8 years (SD 3.3 years, range 1–13 years). There were 18 boys (53%) and 16 girls (47%). Of the 41 ears, 21 had culture results of middle ear fluid in addition to viscosity measures.

Upon visual inspection, thirty-seven ears (90%) were found to have a thick (mucoid) middle ear effusion at the time of myringotomy, while 4 ears (10%) had a thin (serous or purulent) middle ear effusion. Mucoid effusions were found to have higher viscosity values (p=0.002, Table 3). A boxplot graph (Figure 4) represents viscosity measures for both effusion types. All viscosity measures for middle ears with thick effusion were higher than the viscosity measures for middle ears with thin effusion. Thick effusions correlated to viscosity values greater than 400 centipoise (cP). Four outlier values for ears with thick effusion were observed, as shown in the figure.

Twenty-one ears with viscosity determination also underwent routine bacterial culture (Table 3). Of these, two ears (9.5%) had thin effusion. Cultures from only five effusions (23.8%) displayed bacterial growth. Specific culture results were consistent with expected community pathogens. The mean viscosities of positive and negative cultures are 666 and

1423 cP, respectively (Table 4). Middle ear effusions with positive cultures had significantly lower viscosity values (p=0.048), implying a thinner fluid consistency of effusions bearing positive bacterial culture results.

Follow-Up

Post-operative follow-up showed that there were no canal injuries from the probe or any other post-operative complications secondary to non-invasive ultrasound evaluation of middle ear contents.

DISCUSSION

Determining presence of MEE is an important component of the pediatric otologic examination, as persistent effusion predisposes to significant morbidities of recurrent acute otitis media (AOM) and hearing loss. Currently AOM is the most common indication for pediatric outpatient antibiotic use, and MEEs are the most common cause of pediatric hearing loss.[11–12] Therefore, accurate non-invasive assessment of middle ear contents is paramount.

Existing technologies of otoscopy and tympanometry are widely used to assess middle ear contents. However, both have limitations warranting consideration of alternate technologies. A recent study showed that 74% of otolaryngologists, 51% of pediatricians, and 46% of general practitioners were able to correctly recognize either AOM or OME when present using otoscopic examination.[13] In a separate study by Jones et al, the addition of pneumotoscopy raised diagnostic ability among pediatricians from 61% to 76% (although not significant).[14] A metanalysis of diagnostic methods for middle ear effusion showed a sensitivity of 94% and specificity of 80% for pneumotoscopy, but this may be representative of more experienced providers.[15] Tympanometry studies have shown an 83% correlation to the presence of middle ear effusion.[5] Palmu et al. performed tympanometry studies on children when well and then during an episode of OME, and found sensitivity and specificity values of 67 and 98 percent, respectively.[16] Although tympanometry may play a role in assisting in determination of middle ear fluid, it is unable to qualify the consistency of the effusion.

Given a need for additional clinical technologies to assist in middle ear content determination, we present the effective and safe use of ultrasound technology to not only predict the presence of middle ear fluid but also to characterize it as thick (mucoid) or thin (purulent or serous). However and importantly, 34% of our attempts to use the ultrasonic probe were unsuccessful to produce an interpretation of the collected waveform by the computer algorithm. In the remaining 64%, an interpretation could be made by the algorithm and the sensitivity and specificity were 94% or higher to classify the middle ear space as either no effusion, thin effusion, or thick effusion.

We attribute not achieving a higher result rate largely to the lack of direct result feedback of the scan while performing the test in the operating room, since interpretation of the scan was done post-operatively in the laboratory using an automated computer algorithm. Other possibilities include poor placement of the probe with respect to the TM, insufficient amounts of middle ear fluid, and anatomic abnormality of the ear canal not allowing proper probe placement.

These results are in contrast to our previous study where Discolo et al. used a single-element ultrasound probe technology and achieved accurate middle ear interpretation in 71 of 74 ears (96%).[9] This difference is likely due to the post-operative waveform interpretation utilized in the present study, while the previous study used intra-operative human interpretation of

the waveform by an experienced ultrasound engineer. Intra-operative interpretation allowed changes in probe position until an adequate result could be obtained. Therefore, development of a mechanism for instantaneous result with greater accuracy from the computer algorithm may allow for a greater waveform interpretation. Future designs of the ultrasound probe do incorporate this capability.

We also showed that the surgeon's perception of the effusion consistency post-myringotomy was accurate and did correlate with viscosity measurements (P=0.002). Thick (mucoid) effusions were those with viscosity measures greater than 400 cP. Our study population was imbalanced with greater numbers of ears with thick effusions. A larger study population would be needed to seek greater numbers of patients with thin effusions.

It has been previously shown that the viscosity of middle ear effusion does not correlate to prognosis or hearing loss in OME.[2,17] However, in our population, effusions that had positive culture growth had a lower viscosity value (P=0.048), implying a thinner consistency among culture positive effusions versus culture negative effusions. Therefore, information of the effusion's consistency may assist in determining the presence of bacterial colonization in an effusion. Although the ultrasound device is able to accurately identify an effusion's consistency as thin, both serous and purulent effusions were found to comprise the thin effusions. Viscosity values of serous and purulent effusions were similar in our limited number of thin effusions (data not presented due to low number). Combined with visualization of the TM, the clinician may likely be able to differentiate between these.

Senturia et al. after examining 102 middle ear effusion, found 63% of serous effusion to be culture-positive while approximately half of mucoid effusions (36%) were culture-positive.[18] Similar results were obtained by Liu et al.[19] In this study, 59% of serous effusions were culture-positive compared to 37% of mucoid effusions. An accurate diagnosis of the middle ear via ultrasound assessment provides physicians further information of the middle ear effusion characteristic beyond conventional otoscopic examination. This may provide the practitioner with additional data to make an informed decision regarding antibiotic administration.

In continuation of our previous study,[9] this study aims to highlight the use of a computerized interpretation of the produced ultrasound waveform of the middle ear. This advances progress to create a non-invasive handheld ultrasound device that may assist the physician to interpret the middle ear contents with higher confidence and accuracy than tympanometry and pneumotoscopy. As tympanometry is a measure of the compliance of the TM as a function of air pressure within the ear canal, it is not a true measure of the middle ear space. This is reflected in the limited accuracy of the tympanogram with 83% correlation to the presence of MEE. When an interpretation is produced by the ultrasound probe and computerized algorithm, it appears to have higher rate of successful interpretation of the middle ear contents. It further provides information of fluid consistency. These abilities create a potential clinical utility for this technology. Knowledge of the continued presence of an effusion will facilitate the physician to closely monitor the effusion for non-resolution necessitating possible ear tube placement to prevent effusion related hearing loss and recurrent OME.[20]

Several challenges have been addressed in this ultrasound device prototype. In vitro work has demonstrated that optimal ultrasonic echoes are produced when the transducer is positioned perpendicular to the reflecting surface of the TM. To address this, the probe was designed with 9 small ultrasound transducers on a convex curved surface. This allows the waves to propagate at minimally different angles to increase ability of the waves to

perpendicularly reflect from the TM. Additionally, computerized interpretation of the waveform allows device use without human interpretation.

Despite these advances, several challenges remain. Water placed in the external auditory canal in some awake patients may be intolerable. Therefore, clinical applicability may not be possible in these scenarios. Also, water placed in the external auditory canal can act as a transducing medium to distort the appearance of the TM and make accurate probe placement difficult. Due to its small size, the probe within the EAC is sensitive to slight hand movements, which may lead to difficulty in adequate waveform collection. Finally, in the current study, the device was used under direct microscopic visualization. Use of the device in awake patients in the clinic warrants design adjustments such that direct microscopic visualization is not required. Recent device alterations after the conclusion of this study have addressed several of these mentioned concerns. However, further design modifications are necessary to address all concerns.

CONCLUSION

The high prevalence of middle ear disease in the pediatric population and the lack of a highly sensitive and specific non-invasive tool to assess the contents of the middle ear warrant need for such a technology. Accurate characterization of the middle ear contents will assist the practitioner beyond previous clinical otoscopic evaluation and tympanometry. We present a promising automated technology with ability to provide the practitioner with a more accurate means of assessing the middle ear space. The sensitivity and specificity of ultrasonic detection of middle ear effusion is 94% or greater when a result was obtained, exceeding the accuracy of tympanometry and pneumotoscopy. However, an interpretation of the middle ear was accomplished by the device in 66% of attempted ears. Future advances in the computer algorithm aim to increase this yield. Further, characterization of the effusion as either thick or thin may give additional insight to the presence of bacterial infection. Improvements in device design and waveform analysis are needed to improve waveform interpretation rate and clinical feasibility.

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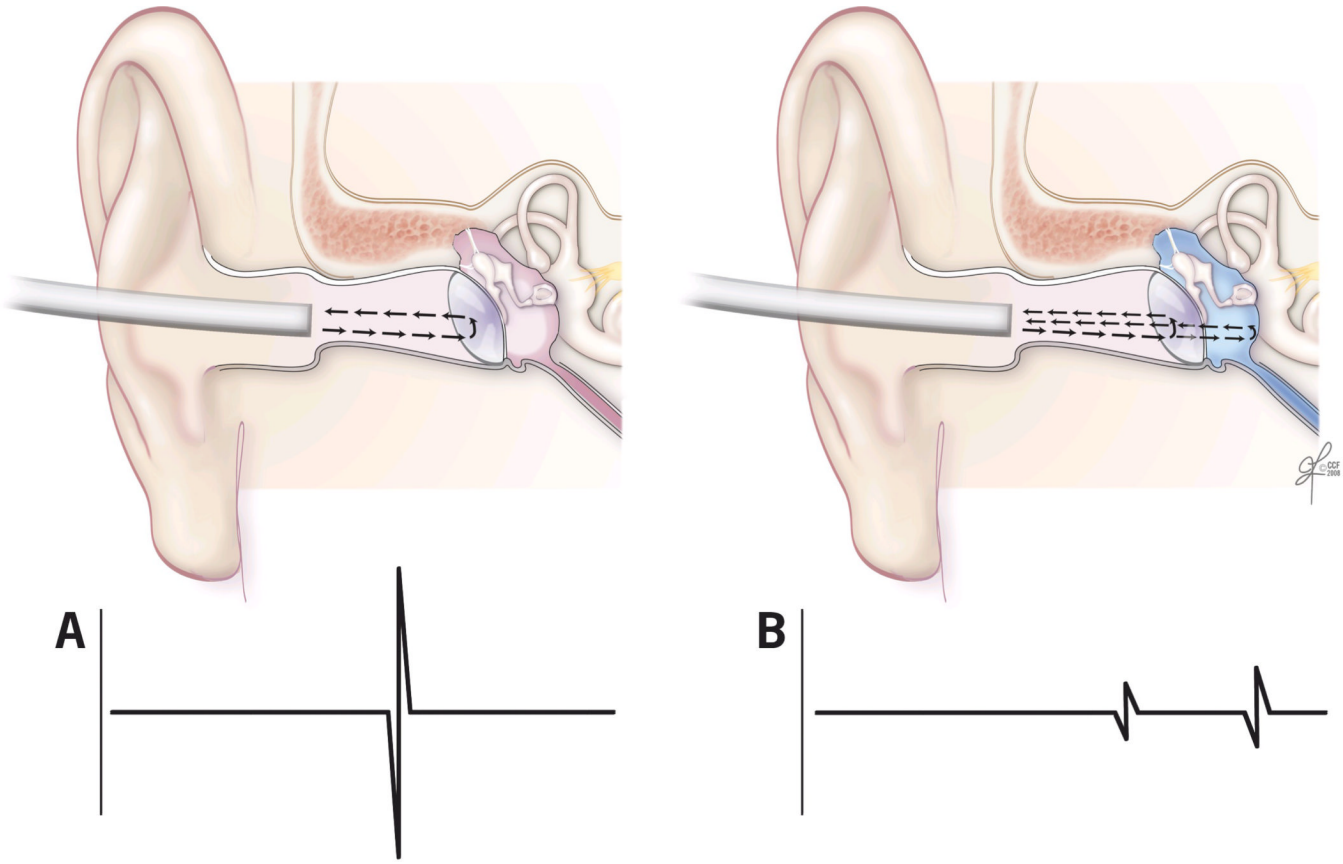

Figure 1.
The transducer probe tip is within a fluid medium of water to allow for ultrasound wave propagation to the TM and back to the probe if the middle ear contents is empty (A). If middle ear fluid is present (B), the ultrasound signal will be partially reflected by the TM but will continue traveling to the bony inner ear to produce a second reflection.

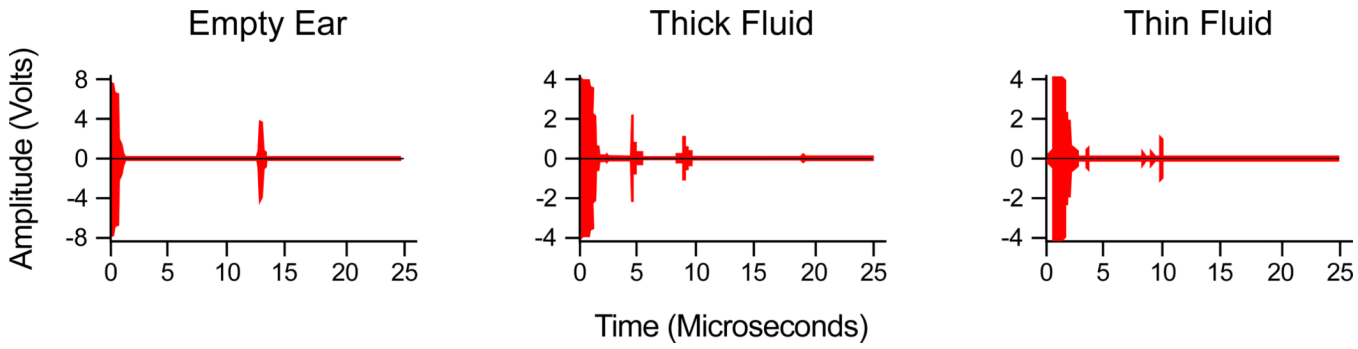

Figure 2.
Sample ultrasound recordings for different middle ear fluid consistencies. An empty ear has a single peak for the TM. If middle ear fluid is present, the amplitude of the second peak is dependent on the viscosity of that fluid. High viscosity (thick or mucoid fluid) has a higher attenuation of ultrasound, producing smaller second peak after a larger TM peak. Low viscosity (thin or serous/purulent fluid) attenuates ultrasound at a lesser degree, producing a characteristic higher amplitude signal after a smaller TM signal.

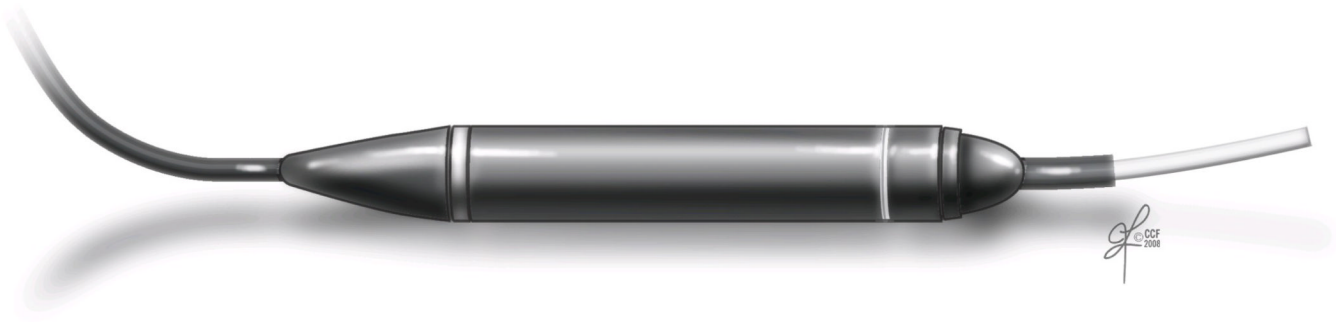

Figure 3.
The 3×3 curved array ultrasound probe used in this study. The size of the probe is approximately that of a No. 5 Frazier suction.

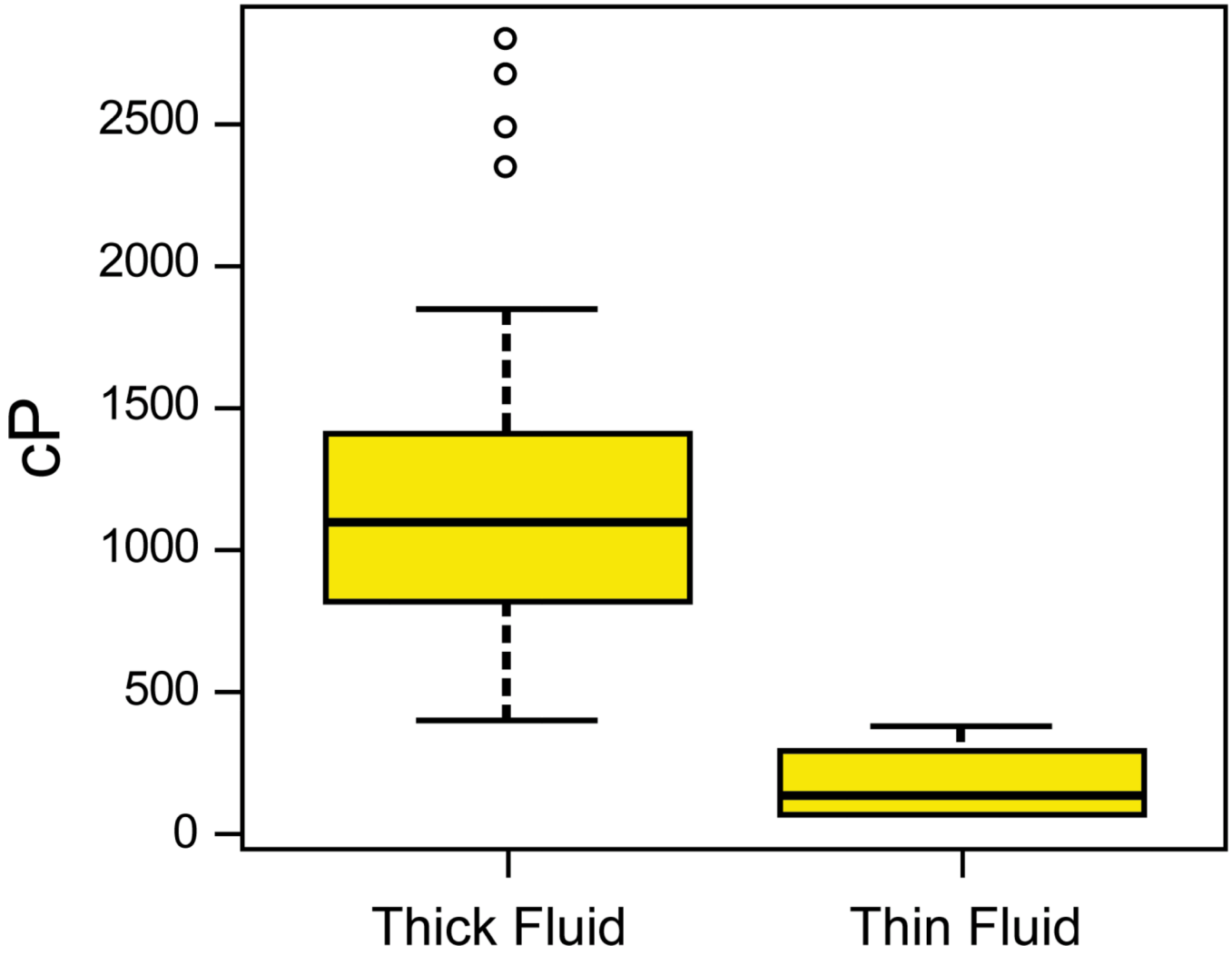

Figure 4.
By visual examination middle ear effusions were categorized as thick (mucoid, N=37) or thin (serous/purulent, N=4). Viscosity values (centipoise, cP) were determined, and are presented in this graph. Note that there is no overlap of the two categories at any data point. Effusions that were visually categorized as thick (mucoid) were found to have viscosity values greater than 400 cP.

Table 1

Middle ear effusion characteristics.

Middle Ear Contents	Pre-Myringotomy Ultrasonic Probe Analysis, N (%)	Post-Myringotomy Visual Inspection, N (%)	Percentage Correct, (%)
Empty	41 (68%)	40 (67%)	100%
Thick	15 (25%)	16 (27%)	94%
Thin	4 (7%)	4 (7%)	100%

Results of middle ear contents among ears that had interpretable results by the ultrasonic probe (N=60). The findings are displayed at pre-myringotomy with use of the ultrasonic probe and then at post-myringotomy using visual inspection of the middle ear fluid. The percentage correct is the ultrasound probe's ability to correctly identify the middle ear contents in the specific ear as determined by myringotomy result.

Table 2

Sensitivity and specificity of ultrasonic probe for middle ear characterization.

Middle Ear Contents	Sensitivity (95% CI)	Specificity (95% CI)
Empty	1.0 (0.94, 0.99)	0.95 (0.86, 0.98)
Thick	0.94 (0.85, 0.98)	1.0 (0.94, 1.0)
Thin	1.0 (0.94, 1.0)	1.0 (0.94, 1.0)

In the population that the ultrasonic probe provides a result (N=60), the sensitivity and specificity of the probe's determination of middle ears contents as empty, thick, and thin is shown.

Table 3

Viscosity by effusion type.

Observed Effusion Consistency	Effusion Viscosity, cP	
	Mean (SD)	**Median (IQR)**
Viscosity data (N=41), P=0.002		
Thin (N=4)	183 (150)	140 (69, 297)
Thick (N=37)	1214 (596)	1096 (823, 1409)
Culture and viscosity data (N=21), P=0.038		
Thin (N=2)	230 (221)	230 (73, 386)
Thick (N=19)	1349 (688)	1155 (87, 1690)

The visualized effusion consistency (thin, thick) is correlated to viscosity measured. Results are displayed for the group of ears that had viscosity data (N=41) and a subgroup within that group that additionally had culture data (N=21). P-values are shown for each group comparing the viscosities between thin and thick effusions. Centipoise (cP) is the unit of viscosity. SD is the standard deviation. IQR is the interquartile range (25^{th} percentile, 75^{th} percentile).

Table 4

Viscosity by culture result.

	Culture Result			
	Positive (N=5)		Negative (N=16)	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Effusion Viscosity, cP	666 (614)	495 (386, 686)	1214 (596)	1175 (921, 1754)

The mean effusion viscosity is shown for the positive and negative culture results. Positive cultures had statistically significant lower viscosity measures, P=0.048. Centipoise (cP) is the unit of viscosity. SD is the standard deviation. IQR is the interquartile range (25^{th} percentile, 75^{th} percentile).