Research Article

Aural Acoustic Stapedius-Muscle Reflex Threshold Procedures to Test Human Infants and Adults

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ABSTRACT

Power-based procedures are described to measure acoustic stapedius-muscle reflex threshold and supra-threshold responses in human adult and infant ears at frequencies from 0.2 to 8 kHz. The stimulus set included five clicks in which four pulsed activators were placed between each pair of clicks, with each stimulus set separated from the next by 0.79 s to allow for reflex decay. Each click response was used to detect the presence of reflex effects across frequency that were elicited by a pulsed broadband-noise or tonal activator in the ipsilateral or contralateral test ear. Acoustic reflex shifts were quantified in terms of the difference in absorbed sound power between the initial baseline click and the later four clicks in each set. Acoustic reflex shifts were measured over a 40-dB range of pulsed activators, and the acoustic reflex threshold was objectively calculated using a maximum 10 likelihood procedure. To illustrate the principles underlying these new reflex tests, reflex shifts in absorbed sound power and absorbance are presented for data acquired in an adult ear with normal hearing and in two infant ears in the initial and follow-up newborn hearing screening exams, one with normal hearing and the other with a conductive hearing loss. The use of absorbed sound power was helpful in classifying an acoustic reflex shift as present or absent. The

resulting reflex tests are in use in a large study of wideband clinical diagnosis and monitoring of middle-ear and cochlear function in infant and adult ears.

Keywords: acoustic stapedius reflex threshold, wideband, absorbed sound power, newborn hearing

INTRODUCTION

Aural acoustic stapedius-muscle reflex threshold (ASRT) and supra-threshold responses provide clinically relevant information on human peripheral auditory function in adults and infants. This report describes improvements and refinements to these tests that were developed during a multi-year study on wideband (WB) clinical diagnosis and monitoring of middle-ear and cochlear function with a measurement bandwidth from 0.2 to 8 kHz. These test improvements were of particular importance for objective reflex testing of infants in initial and follow-up newborn hearing screening exams. The ASR test provides clinically relevant assessments of auditory function (Margolis and Levine 1991). The ASR measured using a tonal or broadband activator is usually absent with the probe in the involved ear in patients with middle-ear disease (at the maximum sound level used to elicit the ASR) or elevated when stimulating the involved ear for the contralateral reflex threshold. The ASRT elicited by a tonal activator is only slightly affected by cochlear hearing loss up to about 50 dB HL, with more

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elevated ASRTs for more severe hearing loss (Gelfand et al. 1990). In contrast, the ASRT for broadband noise (BBN) is elevated monotonically with increasing hearing loss up to about 50 dB HL with only slight elevation for greater hearing loss (Popelka 1981; Margolis 1993). Thus, the difference between BBN and tonal reflex thresholds for ears with moderate degrees of sensorineural hearing loss are typically reduced compared to ears with normal hearing. Diseases affecting the neural arc of the ASR have complex effects on the ASR and are studied through combinations of ipsilateral and contralateral ASR tests to identify site of lesion, as further described in Margolis and Levine (1991). When used as a screening test in young infants, the absence of a detectable ASR elevates the risk of a conductive disorder in the middle ear, although the ASR is likely to be absent in infants with auditory neuropathy/dyssynchrony disorder based on subjects tested at ages from 2 months to 74 years (Berlin et al. 2005).

In contrast to adult ASR tests using a 226-Hz tone as the reference signal, many ASR studies on infants recommend the use of higher-frequency tones as a reference signal inasmuch as shifts are often absent at 226 Hz. This is mainly due to the much larger levels of internal noise in the infant ear at 226 Hz relative to higher frequencies at and above 0.8 kHz. For example, Weatherby and Bennett (1980) recommended frequencies between 0.8 and 1.8 kHz for ASR testing in neonates. ASR responses were measured using both BBN and 1-kHz activators in infants of age 1 to 6 days, and ASR shifts were observed in most infants (Sprague et al. 1985). ASRTs vary with the reference frequency used in newborns (McMillan et al. 1985), which suggests that a multi-frequency test may be more sensitive than a single-frequency test, unless one knows beforehand which reference frequency gives the largest ASR shift. Consistent with adult tests, infant ASRTs elicited by a noise activator are lower than those elicited by pure tones (Bennett and Weatherby 1982; Margolis 1993).

ASR measurements in neonatal ears are not currently recommended in NHS programs due to perceived difficulties in interpretation. Problems also exist in measuring ASR responses during follow-up testing in NHS programs. The reliability of ipsilateral ASRTs was measured in infants with a mean age of 2.5 days, who passed an initial newborn hearing screening exam based on transient-evoked (TE) otoacoustic emissions (OAEs), automated auditory brainstem response, and tympanometry using a 1-kHz reference tone (Kei 2012). ASRs were measured based on shifts in a 1-kHz reference tone. ASR shifts were elicited using BBN and pure-tone activators at 0.5, 2, and 4 kHz. The test-retest differences in ASRTs during the same test session were within 10 dB for 91 % of infants who had a detectable ASR shift in the

initial test, with the lowest mean ASRTs obtained using the BBN activator.

Using a reference signal at 0.8 kHz and the measured ASR shift in admittance magnitude, Hirsch et al. (1992) measured ASRTs in infants at high risk for hearing loss in groups that either passed or referred on a click-evoked auditory brainstem response (ABR) test. The ASRT was determined by the audiologist. The results showed promising sensitivity in the ability of the ASRT test to detect infants who referred on ABR tests, but the false-positive rates, i.e., the percentage of ears who passed the ABR test with no response on the ASRT test, ranged from 18 to 40 % for the combination of ASRT tests using both tonal and BBN activators.

An absent ASR response may help identify the presence of a transient middle-ear condition resolving within 12 h of birth (Geddes 1987). Using a reference signal at 1 kHz and the detection by an audiologist of a repeatable ASR shift in admittance magnitude in test ears of babies in a neonatal intensive care unit (NICU), a two-stage ASR and ABR exam to detect risk for hearing loss performed similarly to a two-stage OAE and ABR exam, in which both transient-evoked and distortion-product OAE tests were used (Rhodes et al. 1999). Contralateral ASR shifts were measured in 6-week-old infants and adults using a WB reference sound and BBN activator (Feeney and Sanford 2005). ASR shifts in energy reflectance were generally similar in infants and adults above 1 kHz, but infant measurements were noisier below 1 kHz, which made them less reliable than adult measurements. These studies demonstrate that ipsilateral ASR measurements in infants may yet contribute to NHS programs, and contralateral ASR measurements may be useful in older infants. One unresolved issue in previous studies is to construct an objective ASR test in infants, as audiologists may be unavailable to perform the ASR tests in a universal NHS program. This issue was addressed in the present study.

Studies have classified ASR shifts in adult ears in the complex pressure spectrum of pairs of stimuli. Using methodology adapted from OAE testing, Neumann et al. (1996) used a pressure response difference between two identical tone bursts to classify an ASR shift. Tone burst pairs were selected with frequencies of 0.5, 1, 2, and 4 kHz. The initial tone burst elicited an ASR so that its effect was recorded in the final tone burst. This signal-to-noise ratio (SNR)-based test was judged more sensitive than clinical ASR tests. Müller-Wehlau et al. (2005) refined this ASR technique to improve its reliability. They used a detection criterion based on the phase coherence between the pair of responses to evaluate their similarity, inasmuch as the SNR was sometimes contaminated by artifacts such as heartbeat. The

measured pressure difference between pairs of waveforms was assessed at frequencies near 1 kHz, at which the ASR results were judged to be more reliable.

A sensitive objective WB test of measuring ipsilateral and contralateral ASRTs was developed for use in adult and infant ears (Keefe et al. 2010). The resulting application to adult ears with a BBN activator showed lower ASRTs than in clinical tests. The ASR procedures for neonatal ears used a range of reference frequencies from 0.8 to 2.8 kHz, which overlapped and extended the 1-kHz reference frequency that Mazlan et al. (2009) used to detect ASR shifts in neonatal ears.

Most infant studies detected the ASR in terms of the shift in admittance magnitude at a single frequency, while Keefe et al. (2010) detected the ASR in terms of the shift in the complex pressure spectrum over a range of frequencies. ASR shifts have been compared in both infant and adult ears using measured shifts in compensated admittance magnitude at 226 Hz, admittance magnitude at 1 kHz, sound pressure level (SPL), and energy reflectance (or absorbance). In contrast, ASR shifts in absorbed power have been reported only for adults (Feeney and Keefe 1999). In results to be described, the presence of an ASR mainly, although not entirely, reduces the power absorbed by adult and infant ears when examined across a range of frequencies in the reference sound.

The present study is a first step in a larger multi-year study to evaluate the use of a WB ASRT test in a battery of multiple tests. This test battery also includes WB reflectance and OAE tests to diagnose and monitor middle-ear and cochlear function in infant and adult groups. Initial experience in the present study using the ASR procedures of Keefe et al. (2010) showed that the test was overly sensitive to detecting an ASR shift in ears expected to lack an ASR shift. This 2010 test was designed on the basis of preliminary results in ears with normal function who were likely to have an ASR present. In the absence of ears in the 2010 study that would be expected to have an absent ASR response, a risk was that the 2010 test was overly sensitive, and thus prone to the problem of false positives.

For this reason, the ASR test was newly formulated in the present study. Its subject group included adult and infant ears, in which some ears at each age had normal function and other ears did not. The latter ears were expected to lack a detectable ASRT or at least a substantially elevated ASRT compared to normal ears. Some of these ears had a moderate to profound hearing loss. Access to data from both normal and impaired ears allowed variation of the ASR test parameters to confirm the relative presence of ASR shifts in ears expected to have a reflex shift,

and the relative absence of ASR shifts in ears expected to lack a reflex shift. These subject groups are further described below in the “Methods” section.

As in previous WB ASRT studies (Feeney and Keefe 2001; Feeney et al. 2003, 2004; Keefe et al. 2010), the ASR is objectively classified as present or absent using both a test of the magnitude of the ASR shift and the similarity of the ASR shift to data at the same or different activator levels. The present procedures to calculate the ASRT differs from these past studies in that the ASR shift is characterized in terms of sound power measurements, and the similarity of the ASR shift is assessed both within the same activator level and across activator level. In this sense, the ASRT test procedures described below are an evolution of previous procedures.

The present report focuses on the theory underlying the ASR test based on absorbed power with illustrative test data presented for adult and infant ears. Group results using this new ASR test are described in Hunter et al. (2016) for infant ears and in Feeney et al. (2016) for adult ears with normal function.

METHODS

Subjects and Clinical Tests Performed

The research plan for the use of human subjects was approved by the Institutional Review Boards associated with each testing site. Adult test sites were at Boys Town National Research Hospital (Omaha, NE), the University of Washington (Seattle, WA), and Oregon Health & Science University (Portland, OR). Infant test sites were Cincinnati Children’s Hospital Medical Center (CCHMC) and Good Samaritan Hospital (Cincinnati, OH).

Adults

All adult subjects received air-conduction audiometry at octaves between 0.25 and 8 kHz, and bone-conduction audiometry between 0.25 and 4 kHz (GSI 61 audiometer). Subjects also received a clinical 226-Hz admittance tympanometry test (GSI Tymstar). A normal subject group was composed of those ears with normal audiometry and 226-Hz tympanometry within normal limits. Normal audiometry referred to air-condition thresholds ≤ 15 dB HL up to 8 kHz, and air-bone gaps ≤ 10 dB up to 4 kHz. Detailed reflex measurements are described for the right ear of a young female adult (age 21 years) from this normal group (subject A). Reflex data are also plotted for the right ear of a young female adult (age 29 years) from this normal group (subject B).

In preliminary testing while the ASR test procedures were being developed and refined, a subgroup of 98 adults with normal hearing and 226-Hz tympanograms within normal limits were tested. In further preliminary testing, a subgroup of eight test ears from five adults was defined as those ears unlikely to have a detectable ASR. These ears had a moderate or greater mixed hearing loss and were medically classified as having either otosclerosis or an ossicular discontinuity. These ears had absent reflexes when tested with a clinical reflex system using a 226-Hz probe tone. The preliminary ASR testing to finalize the form of the ASR procedures is described below.

Infants

This preliminary analysis was part of a multi-year study that included infants screened in normal nurseries (NNs) and NICUs. Research data were acquired just after completing an initial newborn hearing screening (NHS) exam at the hospital. NN infants were classified as pass or refer on this initial exam based on a TEOAE test (Natus Echoscreen). NN infants referring on the TEOAE exam received an automated ABR (Biologic) test. A NN infant passed the initial NHS exam by passing either of the TEOAE or automated ABR exams, and was otherwise classified as a refer on the initial exam. NICU infants received an initial NHS exam based on a pass or refer on an automated ABR test on their release date from the NICU.

Infants in the multi-year study participated in a follow-up NHS exam at CCHMC at an average age of 1 month, in which research data were also obtained. The clinical tests included distortion product (DP) OAEs (Vivosonic Integrity), otoscopy, and a tone-burst air and bone conduction ABR test (Vivosonic Integrity), with two to four test frequencies at octaves between 0.5 and 4 kHz. All infants were tested at 0.5 and 4 kHz, and data were additionally collected whenever possible at 1 and 2 kHz. Tone-burst ABR procedures are described in Elsayed et al. (2015). The inclusion criteria for the normal-hearing infants was also based on a pass on visual reinforcement audiometry (VRA) testing (Widen et al. 2000) at a typical age of 9 months.

In preliminary testing while the ASR test procedures were being developed and refined, subgroups of infants with normal hearing were tested for ASR at ages corresponding to the NHS screening and follow-up exams (116 ears at mean age 0 months and 121 ears at mean age 1 month, respectively) and the VRA exam (110 ears at 9 months). Infant subgroups were also tested for 93 ears at a mean age of 6 months and 83 ears at 12 months. The criterion for normal hearing was that each test ear passed the initial NHS exam, the follow-up NHS exam, and the VRA exam. The same test ear was tested at multiple ages

whenever possible. All ears in the normal subgroup were assumed likely to have an ASR in the normal range, as further explained below.

In additional preliminary testing, a subgroup of three additional infant test ears from two subjects was defined as those ears unlikely to have a detectable ASR (no other test ears were available at this relatively early stage of data collection at which the ASR test procedures were finalized). A challenge in accurate interpretation of infant recordings is to distinguish true physiologic acoustic reflex responses from artifactual responses. Two infant cases, one with mixed hearing loss and one with auditory neuropathy spectrum disorder (ANS), were examined early in the study to test the algorithm for reflex detection. The infant with ANSD had bilaterally absent ABR, with large cochlear microphonics and present DPOAEs. This infant was diagnosed with ANSD as a result of a genetic disorder that caused extremely high bilirubin levels at birth. This infant had reflex recordings that were abnormal and contained spurious noise. Thus, this case was informative with regard to improved algorithm development because the reflex should be absent as a result of the clear ANSD and absent ABR recordings. Another case of a moderate degree, mixed hearing loss was also examined since such a case would be reasonably expected to have absent acoustic reflexes. In this case, the right ear at age 1 month had tone-burst air-conduction ABR thresholds of 50–90 dB HL between 0.5 and 4 kHz, and bone-conduction ABR thresholds of 40 dB HL.

Detailed results on the ASR measurements are described in this report for the above infant subjects, with intermediate methodological results presented below for a third infant subject. Infant subject N was a male born prematurely at age 29 weeks and cared for in a NICU. Subject N received the initial NHS exam and other research tests on his release date from the NICU at age 36 weeks. Subject N passed both TEOAE and automated ABR tests in the initial NHS, passed diagnostic ABR and DPOAE tests in his follow-up NHS visit at age 1.3 months, and passed the VRA exam in both ears. Infant subject C was a male, full-term newborn, who referred on the initial NHS exam with refers on both the TEOAE and automated ABR tests. He was classified with a bilateral conductive hearing loss in a follow-up NHS performed at 0.9 months and was referred for otologic assessment. Detailed WB acoustic reflectance measurements in infant subjects N and C are described in Keefe et al. (2015), which complement the ASR results described in the present report.

Methodological data are also described for the left ear of a third infant subject I with elevated noise levels. This subject was a female infant in the NN born 0.8 months prematurely. Infant I referred on the TEOAE and passed the automated ABR in the initial NHS for the left ear, resulting in an overall two-stage

pass. Infant I was classified as having normal hearing in the left ear based on a diagnostic ABR test in a follow-up visit at 0.2 months corrected age.

General Methods

Measurements were performed using a computer with two-channel sound card (CardDeluxe) using custom software. An ear probe (Interacoustics) was used for all measurements that is the same probe used in the Interacoustics Titan device. This probe was the same used in Keefe et al. (2015). The outer diameter at its tip was 3.3 mm, to which various soft plastic eartips were pressed on to accommodate a range of ear-canal sizes from neonates to adults. This probe had two receiver ports to deliver sound stimuli and one microphone port to measure the acoustical pressure response. Each receiver generated sound stimuli under the control of a digital to analog converter (DAC) on the sound card. A microphone with preamplifier measured acoustic pressure, with its output voltage sent to an analog to digital converter (ADC) on the sound card. The sound card had 24-bit converters and acquired data at a 22.05-kHz sample rate. The manufacturer provided the sensitivity for the microphone, which was used to convert output voltage from the microphone preamplifier into sound pressure at each frequency.

An additional port exiting the probe tip coupled air pressure changes delivered by the pump in the tympanometer (AT235, Interacoustics, with modified firmware), and the probe from the cable to the tympanometer included a pressure sensor. For reflex measurements at a fixed air pressure in the ear canal, a pressure controller circuit on the tympanometer matched the actual pressure measured by the pressure sensor to the desired pressure.

One receiver delivered a click stimulus with a bandwidth from 0.2 to 8 kHz. The second receiver delivered a stimulus of variable level to elicit the ASR in ipsilateral testing. An insert earphone inserted into the opposite ear from the probe was used to deliver the elicitor stimulus in contralateral testing. A switch placed on the modified tympanometer allowed the operator to manually switch a DAC output signal for ipsilateral testing or contralateral testing with a contralateral earphone (ER3A).

Prior to any ASR test, WB tympanograms were recorded using downswept and upswept pressures ranging between +200 and -300 daPa (Keefe et al. 2015). The tympanometric peak pressure (TPP) was measured for each sweep condition, and these two TPPs were averaged to provide a TPP that was used as the ear-canal pressure during all pressurized reflex testing. This averaging substantially eliminated any bias in measuring TPP associated with the sweep polarity.

ASR Data Acquisition

ASR Stimulus Set

All data were acquired by the ADC with real-time filtering to exclude low frequency noise below 0.2 kHz. The ASR test used a pulsed-activator stimulus set, in which a BBN or tonal activator eliciting the ASR was pulsed on and off four times in alternation with five click stimuli presented at a reference level and at times in which no activator was presented. The BBN activator was lowpass filtered at 8 kHz. The stimulus set was the same as in Keefe et al. (2010), although the analysis procedures to be described were substantially different. Based on recordings with the probe inserted into a long anechoic tube, each click had a relatively constant incident sound pressure spectral density level over an analysis bandwidth from 0.2 to 8 kHz, i.e., the maximum change in level was 6.0 dB with a standard deviation of 1.2 dB.

The pressure waveform for an ipsilateral ASR test in a normal adult ear (subject B) is shown for the stimulus set with a BBN activator in Figure 1. Pulsing the reflex activator sound permitted analyses of individual click responses without contamination from any activator. Each click was analyzed in a buffer of duration 46.4 ms (1024 samples) that was well separated (by 11.2 ms) from the onset or 254 decay of adjacent clicks. Each BBN or tonal pulsed activator had a duration of 116 ms with onset and offset ramps, from which a 46.4-ms buffer was extracted from the middle of the steady-state waveform. The overall waveform duration in Figure 1 was 1.58 s, with the pulsed activator set present in half the buffer followed by silence in the latter half of the buffer. This silent duration of 0.79 s was usually sufficient to allow any reflex shift elicited by the activator to decay into the

FIG. 1. Stimulus pressure waveform (blue) for acoustic reflex measurement recorded in normal adult ear B. Pairs of adjacent black vertical lines show the click-present and click-absent time intervals.

noise floor (except at the highest supra-threshold activator levels in some ears). Data were acquired using two trials, or repetitions, of the stimulus set at each of 10 increasing activator levels in 5-dB steps for a total test duration of 31.6 s.

Contralateral reflex thresholds were measured in adults in which the five clicks were presented to one ear and the pulsed activators to the other via an insert earphone (Eartone ER-3). Activator levels were calibrated based on measurements in a 2-cm³ (HA-1) coupler following Keefe et al. (2010).

Each of the 10 activator conditions was specified by a DAC stimulus and level corresponding to the desired SPL in the reference 2 cm³ coupler. These ranged in 5-dB steps for BBN activators used for all ages from 35 to 80 dB SPL, and for tonal activators used for adults from 60 up to 105 dB SPL. This coupler is commonly used to calibrate acoustic levels in clinical research with adult subjects. The 2-cm³ volume is much larger than either the geometrical or equivalent ear-canal volume of an infant ear, which increases rapidly with age in the first year of life. As explained later, the ASRTs were calculated for both adult and infant ears in terms of this SPL in a 2-cm³ coupler, but also in terms of the in-the-ear SPL measured at the probe tip. The use of the same coupler for both age groups was advantageous because it provided a standard comparison of calibrated level across age, while the use of the in-the-ear SPL measurements at the ASRT revealed the maturation of the ASRT as influenced by the maturation of the ear canal and middle ear.

Real-Time Processing

An important issue in measuring ASR responses in infants is the problem of excessive noise, which has contributions from the immediate testing environment such as a hospital room in which other infants and medical staff are present, or from the physiological sources of noise within the infant. This noise has both quasi-stationary and intermittent components.

A real-time procedure is used during data collection to identify and exclude noisy responses. This procedure calculates the noise energy in the waveform responses at times at which the click response is not present relative to the signal energy in the first click of each stimulus set. These provided a measure of the SNR. A portion of the waveform starting 11.6 ms (256 samples) after each click is assumed to represent times at which no click response is present. A difference waveform is calculated while data are acquired by subtracting the 23.2-ms (512 sample) buffer starting 11.6 ms samples after the peak of the first click from the 23.2 ms buffer starting 11.6 ms samples after the peaks of the subsequent clicks (off

click region 2 minus off-click region 1, and off-click region 3 minus off-click region 1, etc.). Each buffer is multiplied by a Hanning filter and convolved with the impulse response of the microphone to convert from voltage to pressure. The spectra of these waveforms are calculated using a discrete Fourier transform (DFT). The squared spectral magnitudes in the first click buffer and the four off-click difference buffers are summed over the frequency range of 0.65 to 7.9 kHz and converted to a sound level in decibel.

Artifact rejection is accomplished by comparing the sound level in a 23.2-ms (512 sample) buffer centered on the peak of the first click waveform (baseline click) to the sound level in each of four click-difference waveforms. Each click-difference waveform is calculated as the difference in each of the four later clicks relative to the baseline click. If any of these level differences are less than a criterion value, the trial is marked as having artifact. The default value of the criterion was 40 dB for all subjects, but the operator had the option of adjusting this value during the recording session with a slider control. The option to adjust this criterion value was rarely used, although the test information was particularly useful in the infant-ear measurements. This default was based on preliminary testing in infant and adult subjects, including tests in which additional noise was introduced.

If a trial contains an artifact, it is repeated at the current activator level. The line color of the real-time waveform display changes from black to purple whenever an artifact is detected to provide immediate feedback of a possible probe-fit problem. If three consecutive presentations of a stimulus set contain artifact, the following trial is automatically accepted and the consecutive artifact count is reset to zero. This feature ensures that a noisy test is not caught in an endless loop.

The software provides the ability for the operator to manually pause data collection during a reflex test in situations with bad probe fits or when the infant (or adult) is too noisy. The operator has the option to restart the test at any of the 10 activator levels for which responses have already been acquired.

ASR Detection Procedures

The WB procedures to detect ASR shifts in Keefe et al. (2010) were developed through measurements in adult and newborn infant groups with normal function, so that the test ears might be assumed likely to have a detectable ASR response. The challenge in that study was to develop a sensitive WB test to detect the ASRT in ears expected to have shifts. That study also reported elevated mean ASRTs in a second infant group that referred on a NHS exam. This result demonstrated the

feasibility and potential utility of interpreting ASRTs in newborn infants. A limitation of that study was the absence of subject groups in whom the ASRT might be expected to be absent or elevated compared to normal ears, either due to a conductive loss, a sensorineural loss or a mixed loss. The ASRT would also be affected by some neural disorders, although there were no such disorders in the 2010 study.

The present study included 98 adult test ears and up to 121 infant test ears at various ages (0, 1, 6, 9, and 12 months) with normal function, in which each test ear was assumed likely to have a detectable ASRT. The study also included eight adult ears and three infant ears with a hearing loss of some kind, in which each test ear was assumed unlikely to have a detectable ASRT. No adult ears were recruited in the present study with any known neural disorders. Although not part of the aims of the present study, two infant ears were found to have an ANSD, and these ears were included in the infant sub-group unlikely to have an ASRT inasmuch as the ASR response is absent or elevated in ears with ANSD (Berlin et al. 2005). These sub-groups of subjects were analyzed to develop an ASRT test that might detect the ASRT in ears expected to have one and detect an absence of a ASR in ears expected to have no response. The resulting WB test to detect shifts in absorbed power is substantially different from that described by Keefe et al. (2010), which used shifts in sound pressure. This report describes the final form of the ASR test procedures after all preliminary data were analyzed.

Initial Processing

From the recorded average pressure waveform, each click-response buffer of length 1024 samples is partitioned into a click-present sub-buffer that contains the click response and any associated noise, and a click-absent sub-buffer that contains only noise. Both sub-buffers have a duration of 384 samples. The onset of the click-present sub-buffer is 75 samples before the time of the peak amplitude of the click, and the onset of the click-absent sub-buffer immediately follows the end of the click-present sub-buffer. These buffers differ somewhat from those described above for the real-time artifact rejection test, inasmuch as the ASR detection procedures are performed after all data are acquired and the real-time procedures were implemented prior to data collection. Each 384-sample sub-buffer is multiplied by a 384-sample Hanning window. The spectra $P_{cp}(f)$ and $P_{ca}(f)$ are calculated using a DFT for the windowed click-present and click-absent sub-buffers, respectively.

An ASR passband is defined over a range of lower frequencies to quantify the ASR and related noise

levels. The ASR passband is 0.2 to 2.4 kHz for adults and children aged 6 months or older, and 0.8 to 2.4 kHz for younger children. The ASR passband for younger children is reduced because of additional physiological noise present below 0.8 kHz, especially for younger infants (Bennett and Weatherby 1982; Keefe et al. 2010). A “signal” level over the ASR passband is calculated from the click-present spectrum and a “noise” level from the click-absent spectrum. Each is calculated as the level of the sum of the squared pressure magnitudes at all frequencies in the ASR passband, as further described below in the paragraph after Eq. (2).

For a given test ear, the distributions of ASR noise level are constructed for all 100 click-absent sub-buffers in the response. This total number is associated with the 5 clicks in each stimulus set, the 2 presentations of the stimulus set at each activator level, and the 10 activator levels. Two distributions of ASR signal level are also constructed with 20 signal levels for the baseline click, and 80 signal levels for all later clicks.

Artifact Rejection

A median absolute deviation (MAD) test (Hoaglin et al. 1983) is used to identify sub-buffers of ASR noise and signal levels that are outliers. For a given variable x_i that is measured N times with $1 \leq i \leq N$, the median X of x_i is calculated across the N measurements, and the absolute deviation $\Delta x_i = |x_i - X|$ of each value from the median is calculated. The median of these N absolute deviations is calculated as the MAD. The i th test value is classified as an outlier if its $\Delta x_i > \beta * \text{MAD}$ for a specified positive β . The value $\beta = 7.6081$ is used in the present study, which defined a “very far” outlier in comparison with typically recommended values. A larger β is used because the distributions of click-absent and click-present values are defined over a range of activator levels, so that fewer outliers are excluded in our implementation than would be the case if a smaller β were used.

The MAD test is applied to the distribution of all ASR noise levels, the distribution of all ASR signal levels for the sub-buffers containing the first click, and the distribution of all ASR signal levels for the sub-buffers containing the four clicks 2-5. For each set of adjacent five click responses (as in Fig. 1), a click set is an outlier if (1) the first ASR signal or noise level is an outlier, or (2) more than two of the four later clicks are outliers. Any click set that is not an outlier is termed a valid click set (in terms of the MAD test), although some later click-present or click-absent sub-buffers may still contain artifacts. The overall result is that the first click is not permitted to be an outlier, but one or two of the later clicks may be an outlier so that the analysis uses only the later clicks that are not outliers.

Each click response in a valid click set in terms of MAD is classified as valid in terms of noise if its noise level is not classified as an outlier. If the signal level of a baseline or later click response is valid in terms of noise, then the baseline or later click response is judged valid in terms of signal if the magnitude of the difference between its signal level and the median of the distribution of the baseline or later click signal levels, respectively, is less than 0.15 times this median. This parameter was selected based on preliminary testing. A set of four later click responses is a valid set if the responses are valid in terms of signal at three or four of the later clicks. Finally, a response at a given activator level and trial number (1 or 2) is valid overall if it is valid in terms of noise, the baseline click, and the set of four later clicks. If a baseline click-present or click-absent response is invalid, then all five click responses in the set are classified as invalid because each ASR shift is interpreted with respect to its baseline click response.

Examples of click signal and noise levels in ipsilateral ASR tests with a BBN activator are shown in Figure 2 for adult subjects A (solid lines) and B (dashed lines). The 100 click intervals along the abscissa are ordered such that activator level increased from 1 to 10 (low to high SPL), the trial number at the same activator level increased from 1 to 2, and the click number increased from 1 to 5 within a stimulus set. Thus, click responses 1–10 were for trial 1 and baseline click 1 over all 10 activators, click responses 11–20 were for trial 2 and click 1 over all 10 activators,

and so forth. The baseline clicks were numbers 1–20 in the top panel of Figure 2.

In adult subject A (top panel of Fig. 2), the click signal level generally decreased from lower to higher level activators within each set of 10 clicks after the first couple of clicks. The average signal level across all clicks in this ear was 43.4 dB (with a 1-dB range between 42.9 and 43.9 dB), which was much larger than the average noise level of about -3 dB (with a range from -6 to 5 dB).

The noise level fluctuated randomly about its mean value (bottom panel). Thus, the mean level in the click-present intervals was on the order of 40 dB larger than in the click-absent intervals, i.e., the SNR was about 40 dB.

In adult subject B (top panel of Fig. 2), the click signal level generally increased from lower to higher level activators within each set of 10 clicks until the last couple clicks (top panel). The range of click signal levels from 43.0 to 43.2 dB was smaller in subject B than in subject A, with a mean click signal level of 43.1 dB. The SNR in subject B was also about 40 dB.

While the click signal level increased for subject A in each set of 10 adjacent click responses in Figure 2 and decreased for subject B, the pattern for each subject was similar for each of the five clicks in the first and second presentations of the stimulus set at each of the 10 activator levels. This means that the click signal levels generally changed from the beginning to end of the 31.6-s measurements, but the level changes were small at each fixed activator level (i.e., within each 3.16 s of the

FIG. 2. Click signal and noise levels are plotted for the normal adult ears (solid line for subject A, dashed line for subject B) in the top and bottom panels, respectively, as a relative level in dB.

response). Such an overall variation might be due to variations in the air pressure within the middle-ear cavity over 31.6 s. If the change in click signal level were due to some hysteresis effect within the middle ear, it is unknown why it would have a different dependence on activator level in different adult ears.

The ASR procedure controls for any variation across individual presentations by calculating an ASR shift associated with each pulsed-activator stimulus set of duration 0.79 s (as shown in Fig. 1).

The duration of the supra-threshold ASR shift elicited by the ASR stimulus tended to increase with increasing activator level (not shown), so that the 0.79-s duration of silence was too short at the highest activator levels in some ears for the ASR shift to decay completely back to baseline (although not too short for adult subjects A and B).

Another example of click signal and noise levels is shown in Figure 3 for a normal-hearing infant test ear I tested at the time of the NHS exam at -0.2 months corrected age. The click signal level was based on the summed energy level of the click over all frequencies in the ASR passband (0.8 to 2.4 kHz). The median noise level was about 10 dB in the bottom panel with several narrow spikes present in the plot. The test was invalid for the increased noise level at click response 14, which corresponded to the baseline click at the fourth largest activator for trial 2. Consequently, the four later clicks at the fourth largest activator for trial 2 were reset to invalid for signal levels; this accounted for the invalid responses in the top panel at click numbers 34, 54, 74, and 94. The test was also invalid for increased noise level at click response 74 for one of the later clicks. This had no effect on the validity of any other click responses because it was not associated

with a baseline click, and click 74 was already classified as invalid because of noise response 14.

The click signal level in infant ear I generally decreased over a 1-dB range with increasing activator level in the neonatal response in Figure 3.

General Processing for a Single Activator Level

The in-the-ear activator SPL in an ipsilateral test is measured for each activator condition and each pulsed activator as the average over the two trials. The 1024-sample steady-state activator waveform is Hanning windowed, and the 1024-sample DFT is calculated. The in-the-ear band sound pressure spectrum level is also calculated for the BBN activator at each half-octave frequency within the ASR frequency passband. The acoustic admittance $Y(f)$ and pressure reflectance $R(f)$ of the ear at the probetip are calculated from each click response using procedures described in Keefe et al. (2015). The baseline click is assumed to measure the middle-ear response in the absence of the ASR, and later clicks reveal any ASR effects.

The admittance $Y(f)$ at the probe tip within the ear canal is parameterized in terms of the unit imaginary number j by its real part $G(f)$, the conductance, and its imaginary part $B(f)$, the susceptance, by $Y(f) = G(f) + jB(f)$. The power $W(f)$ absorbed by the middle ear is

$$W(f) = G(f)P_{rms}(f)^2 \quad (1)$$

in which the real, mean-squared (rms) spectral pressure $P_{rms}(f)^2$ is calculated using the DFT. The energy reflectance $ER(f)$ is calculated in terms of the pressure reflectance $R(f)$ of the ear by $ER(f) = |R(f)|^2$, and the absorbance $A(f)$ as $1 - ER(f)$. Averages are calculated over each half-octave bandwidth with center frequency f for the complex admittance $Y(f)$, and for the real absorbance $A(f)$ and absorbed power $W(f)$.

Detecting an ASR shift at a single activator level. For each pulsed-activator dataset, a procedure classifies the response as having an ASR present or absent based on the signal (click-present) and noise (click-absent) buffers defined above. A set of four variables are defined using the differences in the pressure, admittance, absorbance, and absorbed power for each of the four later clicks relative to the corresponding responses of the baseline click. The subsequent analyses are performed only for valid click responses.

As described above, the click-present spectrum $P_{cp}(f, m)$ and click-absent spectrum $P_{ca}(f, m)$ are calculated using the DFT of the Hanning-windowed waveforms for each of the four later clicks parameterized by $m = 1, 2, 3, 4$. The click-present and click-absent pressures for the baseline click ($m = 0$) are $P_{cp}(f, 0)$ and $P_{ca}(f, 0)$, respectively. The complex band sound pressure spectra $\Delta P_{cp}(f, m)$ for the click-present

FIG. 3. Click signal and noise levels are plotted for an infant ear I in the top and bottom panels, respectively, as a relative level in dB. The $\circ$ markers denote responses classified as invalid by the MAD outlier test.

sub-buffer, and $\Delta P_{ca}(f, m)$ for the click-absent sub-buffer, are defined in the ASR passband for the m -th later click by,

$$\begin{aligned}\Delta P_{cp}(f, m) &= P_{cp}(f, m) - P_{cp}(f, 0), \\ \Delta P_{ca}(f, m) &= P_{ca}(f, m) - P_{ca}(f, 0).\end{aligned}\quad (2)$$

For the click-present spectrum in the baseline click, the sound pressure level of the click-present signal $L_{cp}(0)$ is calculated as 10 times the common logarithm of the sum of $|P_{cp}(f, 0)|^2$ overall frequencies in the ASR passband. The sound pressure level of the click-absent signal $L_{ca}(0)$ for the baseline click is similarly calculated in terms of $|P_{ca}(f, 0)|^2$. For the click-present spectrum at each m , the sound pressure level $L_{cp}(m)$ of the click-present signal is calculated as 10 times the common logarithm of the sum of $|P_{cp}(f, m)|^2$ overall frequencies in the ASR passband. The sound pressure level of the click-absent signal $L_{ca}(m)$ at each m is similarly calculated in terms of $|P_{ca}(f, m)|^2$.

The corresponding level differences of the later click spectra relative to the initial click spectrum are calculated at each m as

$$\begin{aligned}\Delta L_{cp}(m) &= L_{cp}(m) - L_{cp}(0), \\ \Delta L_{ca}(m) &= L_{ca}(m) - L_{ca}(0).\end{aligned}\quad (3)$$

Two Boolean variables are defined in each trial for each difference variable. The first variable $B_1(m)$ assesses whether the click and noise levels are within normal limits, which is of particular importance for testing infants. This variable is set equal to 1 for each m if both of the following conditions are satisfied, and set to 0 otherwise:

$$\begin{aligned}L_{cp}(0) - \Delta L_{cp}(m) &> 4 \text{ dB}, \\ L_{cp}(0) - \Delta L_{ca}(m) &> 12 \text{ dB}.\end{aligned}\quad (4)$$

The first condition is that the level of the baseline click is at least 4 dB larger than the click-difference level $\Delta L_{cp}(m)$ of click m . The second condition is that the level of the baseline click is at least 12 dB larger than the click-absent difference level $\Delta L_{ca}(m)$, i.e., it is a SNR criterion. The $B_1(m)$ is 0 if the baseline click level associated with the stimulus is too small relative to either of the difference levels associated with the click-present and click-absent sub-buffers of the later click m . Such a condition of anomalously low click level would be a sign of a testing problem for which a retest might be recommended. In each trial, a retest is recommended if B_1 is 0 for two or more of the four later clicks.

The second Boolean variable $B_2(m)$ in each trial is set equal to 1 for each m if the following conditions are satisfied, and 0 otherwise:

$$\begin{aligned}\Delta L_{cp}(m) - \Delta L_{ca}(m) &> 3 \text{ dB}, \\ B_1(m) &= 1.\end{aligned}\quad (5)$$

For $B_1(m) = 1$, the Boolean variable $B_2(m)$ is a SNR test of whether the level associated with the m -th click-present condition is more than 3 dB larger than that associated with the click-absent condition. This tests whether the ASR is elicited in the m -th later click relative to the baseline click. The specific parameter values given in Eqs. (4–5) were selected based on preliminary analyses in the normal and impaired subgroups of adult and infant ears.

Correlations between the click-difference spectra $\Delta P_{cp}(f, m)$ are calculated between all six pairs of later clicks, with significance evaluated at the $\alpha = 0.05$ level using a Fisher Z transformed one-sided test (Feeney and Keefe 2001). For all pairs of clicks with each click having no stimulus artifact ($B_1 = 1$), the number of pairs with significant correlation are counted. If two or more pairs are significant, then the median of these significant correlations is stored as the inter-pair correlation for that trial. If fewer than two pairs are significant with no artifact, then the median of all six correlations is stored as the inter-pair correlation for that trial; this condition would lead to a trial with a much smaller correlation. The term significance in this context does not pertain to group analyses of ear tests but rather with respect to the procedural criteria used to classify an acoustic reflex shift as present or absent. The two tests based on SNR via B_2 for each later click, and on response similarity via the correlation test between pairs of later clicks, give complementary information on the presence of an ASR shift in a single trial.

The next step is to combine the information in the two trials at the same activator level, or use only one of the trials if the other trial is defective in some way.

Suppose that the stimulus-set conditions are satisfied on a given trial. The absorbed (sound) power level (in dB) for the m -th click from Eq. (1) is

$$L_W(f, m) = 10 \log_{10} (W(f, m)). \quad (6)$$

The difference in absorbed power level at the m -th later click relative to baseline is

$$\delta L_W(f, m) = L_W(f, m) - L_W(f, 0). \quad (7)$$

An absorbed power level difference $\Delta L_W(f)$ is defined as the average of $\delta L_W(f, m)$ over the later clicks (m) in that trial that have one or more significant inter-pair correlations. Difference quantities for absorbance and SPL are similarly averaged.

Measurements of changes in absorbed power level due to the action of the ASR elicited by contralateral tonal activators at 1 and 2 kHz were described by Feeney and Keefe (1999, 2001): the ASR reduced the absorbed power level by as much as 3 to 7 dB at frequencies below about 1.1 kHz and increased the

level by less than 1 dB at some higher frequencies. The present method incorporates their finding that the difference in absorbed power $\Delta L_W(f)$ produced by the ASR in a normal adult ear is typically a larger reduction at low frequencies, followed by a smaller enhancement at higher frequencies (examples of this pattern are shown in the “Results”).

The ASR shift is traditionally quantified to a scalar measure of reflex strength, whereas $\Delta L_W(f)$ varies across frequency. The first choice of scalar measure was the sum of $|\Delta L_W(f)|$ over a frequency bandwidth. This measure was analyzed using the preliminary test data in ears expected to have an ASR and ears expected to lack an ASR. A variety of frequency bandwidths were analyzed using various lower and upper frequencies. The results were unsatisfactory, as too many ears expected to lack an ASR (the absent-ASR group) were classified as having an ASR present.

An important factor is the assumption that the initial click of each set of five clicks is assumed to have an ASR absent. Some of the ears in the absent-ASR group had a complex shape that did not resemble that of a true baseline click, and thus each of the click-difference pairs classified the ASR as present. To obtain better test performance in the absent-ASR group, different frequency weightings of $\Delta L_W(f)$ were assessed, in which the polarity of $\Delta L_W(f)$ was retained. The ASR increases the stiffness-dominated impedance of the annular ligament to which the head of the stapes is attached (Pang and Peake 1985). This reduces the absorbed sound power and absorbance of energy transmitted into the cochlear at low frequencies, i.e., below any of the internal modal frequencies of the coupled ear canal and middle-ear system (i.e., at 0.5 kHz and below). The polarity of $\Delta L_W(f)$ is negative for a reduction in absorbed sound power, and any positive-polarity shift in $\Delta L_W(f)$ is assumed to provide evidence that the ASR is absent. The implementation of this test is next described.

The power difference $\Delta L_W(f)$ is parameterized in terms of two scalar parameters ΔL_{W1} and ΔL_{W2} . This is a pattern-extraction approach based on the frequency dependence of absorbed power observed in both adult and infant ears with normal function. A cumulative sum $S_W(f)$ of $\Delta L_W(f)$ is calculated from the minimum frequency of the ASR passband up to its maximum frequency. The minimum of this cumulative sum, denoted $\min(S_W(f))_{f \leq f_c}$ is identified along with the half-octave frequency f_c at which the minimum occurs.

If this minimum has a negative value as in a normal ear (as described above), then the procedure determines the subrange of higher frequencies $f > f_c$ over which $S_W(f) \geq 0$, and calculates a second cumulative sum $\tilde{S}_W > 0$ over that subrange of frequencies. If ΔL_W

(f) is not positive at any $f > f_c$ then $\tilde{S}_W$ is set to 0. A parameter ΔL_{W1} is defined by,

$$\Delta L_{W1} = \min(S_W(f)) - \tilde{S}_W. \quad (8)$$

The effects of any additional zero crossings in $S_W(f)$ at higher frequencies in the analysis band are ignored in the calculation of ΔL_{W1} , as the magnitudes of $S_W(f)$ are smaller at higher frequencies in a normal-ear response.

A parameter ΔL_{W2} is defined in this normal-ear case by,

$$\Delta L_{W2} = \min\left[0, \min(S_W(f))_{f \leq f_c}\right], \quad (9)$$

i.e., ΔL_{W2} is equal to the minimum cumulative sum of absorbed power for frequencies up to f_c if this sum is negative, and otherwise ΔL_{W2} is set to 0.

Suppose that the stimulus-set conditions are not satisfied on a given trial. Then, the absorbed power, absorbance, and SPL and their corresponding difference variables are stored for the final later click response ($m=4$). The difference in absorbed power between the final click and the baseline click is used in this case as the best single estimate of a shift due to the possible action of the ASR. The variable $\Delta L_W(f)$ is defined for this case as equal to $\delta L_W(f, 4)$ in Eq. (7), and the corresponding cumulative sum $S_W(f)$ is calculated over f . The scalar parameters ΔL_{W1} and ΔL_{W2} are calculated in the same manner as in Eqs. (8–9). The magnitude of $\Delta L_W(f)$ is typically smaller in ears that do not satisfy the stimulus-set conditions, which is consistent with an absent ASR.

An ASR shift in a normal ear would be expected to have negative ΔL_{W1} and ΔL_{W2} values with large magnitudes. An ASR status variable is defined for each trial that is equal to 1 when an ASR is present and 0 otherwise. The ASR is judged present only if the stimulus-set conditions are satisfied, and the following inequalities are satisfied:

$$\begin{aligned} \Delta L_{W1} &< -\delta_1, \\ \Delta L_{W2} &< -0.3 \times \delta_1. \end{aligned} \quad (10)$$

The value of δ_1 is 0.7 dB for testing ears of adults and children of age 6 months or older, and 0.35 dB for ears of younger children. These values along with the coefficient 0.3 in Eq. (10) were empirically determined based on preliminary analyses. The smaller value for younger children is related to the fact that ΔL_{W1} is based on cumulative sums over a more restricted ASR passband than for adults.

These inequalities assess whether the ASR shift is sufficiently large and has the expected reduction in absorbed power at lower frequencies combined with an enhancement at higher frequencies. The ΔL_{W1} combines information on the ASR shift in absorbed

power across the entire ASR passband, whereas ΔL_{W2} evaluates whether the reduction in absorbed power at any lower half-octave frequency is sufficiently large.

The final step at each activator level combines the information in both trials. If both trials have an ASR shift detected, then the medians across both trials of the pressure, admittance, absorbance and absorbed power variables, and their difference variables including ΔL_{W1} and ΔL_{W2} , are retained. If only one of the two trials has an ASR shift detected, then only the results of that trial are retained (the other trial may have been noisy, although not necessarily so in every case). If neither trial has an ASR shift detected, then the median of the results is retained for those trials in which no retest is recommended based on B_1 as described above. If a retest is recommended for both trials, then the responses for trial 1 are retained. This logic was adopted to cope with the problem of substantial intermittent noise in testing some infants.

ASRT Calculation Over Multiple Activator Levels

The analyses performed to this point classifies an ASR shift as present or absent for each activator level. The ASRT is determined based on these classifications and the underlying similarity and consistency of the ASR shift data across the range of activator levels.

In preliminary studies, the ASRT was calculated using responses measured either at all 10 activator levels or in which the response at the initial activator level was omitted. The rationale for dropping responses at the initial, lowest activator level was that attentional influences to the onset of the ASR stimuli might possibly have been present in some ears, perhaps due to an involvement of the medial olivocochlear reflex system (Backus and Guinan 2006) or some generalized behavioral response to the onset of a sound stimulus. The default procedure for determining the ASRT omits the response at the initial activator level.

The ASRT is classified as No Response (NR) if an ASR shift is absent at all activator levels (after omitting the response at the initial level). It is also possible to classify the ASRT as NR due to a noisy test or to an ASR detected at some lower level but not at the highest levels. The latter might also occur due to intermittent test noise or a probe seal that degraded over the test duration, especially when testing infants. The ASRT is classified as NR if a retest is recommended at six or more activator levels (due to excessive noise). Such a pattern is considered too noisy overall to accept as a threshold measurement. Irrespective of the pattern of ASR shifts present or absent at lower activator levels, the ASRT is also classified as NR if no ASR shift is present at each of the two highest activator levels. In this case, there is too little confidence in any estimate of an ASRT based on ASR shifts that are only present at lower activator levels.

The analysis continues for tests with an ASR shift present at one or more levels, which are not otherwise excluded by the tests described in the previous paragraph. Behavioral thresholds to pure tone sounds have been estimated using a yes-no task and an adaptive, maximum-likelihood procedure that is highly efficient (Green 1993; Gu and Green 1994), and extended to high-frequency audiometry (Goodman et al. 2009). Using a set of modified logistic functions to present the underlying psychometric function over a broad range of possible thresholds values, the procedure determines the most likely function to represent the set of yes-no responses, and thereby estimates the response threshold. This procedure was adapted to measure ASRTs in Keefe et al. (2010). The present procedure uses the 2010 procedure, except that the range of levels is limited to avoid inconsistent patterns of ASR-shift present at lower levels and absent responses at higher activator levels. A typical reflex pattern would have the ASR shift absent at lower activator levels and present at higher activator levels, which would be a monotonically increasing function of activator level with an absent ASR shift coded as zero and a present shift coded as one.

Some patterns were non-monotonic in Keefe et al. (2010), in which the reflex was judged present at lower activator levels, absent at intermediate levels, then present at higher activator levels. To handle such cases in the present procedure, when the ASR shift is absent at two or more consecutive intermediate activator levels that are not otherwise recommended for a retest based on excessive noise, the responses at all lower levels are not included in the inputs to the maximum-likelihood procedure. This has the effect of converting a non-monotonic pattern of ASR shift into a monotonic pattern over a reduced range of higher activator levels, and thereby constrains the calculated ASRT to reside in a range of higher activator levels.

In normal adult ears, the absorbed power shift between final and initial clicks is approximately similar in shape across frequency at activator levels above the ASRT, but its overall amplitude increases with increasing activator level (Feeney and Keefe 1999). This suggests that the absorbed power shift would be highly correlated in a normal ear across different supra-threshold activator levels. This observation is used to refine the estimate of ASRT for tests in which the ASR shift is present at two or more activator levels.

The calculated $\Delta L_W(f)$ is correlated between each pair of different activator levels with an ASR shift present, in which each term in the correlation is weighted by the average $|\Delta L_{W1}|$ across the pair of levels. The $|\Delta L_{W1}|$ in Eq. (8) is large for large supra-threshold ASR shifts, so this weighting emphasizes correlations between patterns with large-amplitude

responses. The weighted correlation is normalized to have values between -1 and 1 , and termed the across-level correlation to differentiate it from the inter-pair correlation described above, which is calculated for responses within the same activator level. If the median of the across-level correlations across all pairs of levels is significantly less than a criterion value, then the ASRT is recorded as NR based on Low Correlation. The criterion value was selected based on preliminary analyses as 0.4 for young children and 0.5 for older children and adults based on a Fisher Z transformed test of significance.

RESULTS

Results are described for ASR measurements in individual adult and infant ears to illustrate features of the responses and properties of the intermediate processing stages.

Adult-Ear Responses

WB reflex measurements are described for the young adult female subject A with normal hearing. The ASRT was measured at a TPP of 20 daPa. ASR tests were performed for tonal activators at 0.5 , 1 , and 2 kHz, and for a BBN activator. The activator SPLs were calculated for each activator type over the measurement bandwidth 0.2 – 8 kHz for the 2-cm^3 coupler, and ipsilateral activator SPLs were also measured in each test ear. For the BBN ipsilateral activator at the maximum level, the SPL was 80 dB in the coupler and 82.9 dB in the ear. For tonal ipsilateral activators at the maximum level, the SPL was 105 dB in the coupler at each frequency; the SPL in the ear was 99.5 dB at 0.5 kHz, 106.2 dB at 1 kHz, and 103.1 dB at 2 kHz. Higher sound levels than these were judged to be uncomfortable by some listeners in preliminary testing.

The ASR status functions in Figure 4 quantified the ASR as either present or absent at each of the nine activator SPLs at which the response was analyzed. The activator SPL on the abscissa is that measured in a 2-cm^3 coupler. The ASR status function had a monotonic shape for each of the eight ASRT tests, meaning the ASR was absent at lower activator levels and present at higher activator levels. For such a monotonic function, the ASRT was the lowest activator SPL at which an ASR shift was detected. The ASRTs ranged from 65 to 70 dB SPL for BBN activators and from 100 to 105 dB SPL for tonal activators.

Figure 5 illustrates the measured shift in absorbance ΔA relative to the baseline absorbance for each reflex

test condition over all 10 activator levels, including the lowest level 1 that was omitted in calculating the ASRT. These plots show a characteristic adult pattern (Feeney and Keefe 1999, 2001) of reduced absorbance (or increased energy reflectance) at frequencies below approximately 0.8 kHz, and increased absorbance at intermediate frequencies up to about 2 kHz followed by only small shifts at higher frequencies. The largest absorbance reduction in this ear was about 4 – 8% at frequencies close to 0.5 kHz. The shape of the absorbance shift was qualitatively similar across the eight test conditions, although some ASR tests produced larger absorbance shifts than others.

This absorbed power level shift $\Delta L_W(f)$ is shown in Figure 6 for the eight reflex tests for adult subject A. The maximum reduction in $\Delta L_W(f)$ was about 1 dB, which occurred at the lowest test frequencies up to 0.5 kHz. The fact that $\Delta L_W(f)$ was negative at all frequencies below about 1.2 kHz across all test conditions at the supra-threshold activator levels signified that the middle ear absorbed less power when the ASR was present than in the baseline condition in which the ASR was absent. These results for $\Delta L_W(f)$ were similar to published results in normal adult ears (Feeney and Keefe 1999). At frequencies above about 1.2 kHz, $\Delta L_W(f)$ was positive although with much smaller magnitude than at lower frequencies.

The contribution of higher frequencies to $\Delta L_W(f)$ with the opposite sign from its values at lower frequencies was relatively smaller than the corresponding contribution to $\Delta A(f)$ at higher frequencies in Figure 5. This property is the basis for calculating the ASRT using the shift in absorbed power level rather than the shift in absorbance. The ASRT was estimated based on the calculation at each activator level of the shift magnitude via ΔL_{W1} and ΔL_{W2} , and the shift similarity based on the interpair correlation. The shift magnitude is plotted using $|\Delta L_{W1}|$ as a ASR response growth function in Figure 7 for the eight test conditions. The horizontal dashed line represents the criterion value $\delta_1 = 0.7$ dB in Eq. (10) for the adult ear. For this ear measurement at low noise levels, the response satisfied $|\Delta W_1| > \delta_1$ at each supra-threshold activator level.

The inter-pair correlation, which was calculated as described in the paragraph following Eq. (5), is shown in Figure 8 as a function of activator level for this adult subject ear under all eight reflex test conditions. A circle marker on each correlation function indicates that the ASR shift passed the interpair correlation test. The horizontal dashed line represents the criterion value (close to 0.8) for a positive correlation to be classified as significant. The correlation was significant at higher activator levels that were at or above the ASRT (as indicated by the markers), but also at some

FIG. 4. ASR status function (i.e., present or absent ASR) in normal adult ear A is plotted over vs. activator level. Each panel displays the ASRT, the maximum likelihood value, and the across-level correlation.

lower activator levels in which an ASR shift was classified as absent.

For example, in the lower left panel for the contralateral ASR test using a 2-kHz activator, the correlation exceeded 0.9 at activator SPLs of 60–70 and 80–85 dB. That such conditions had no ASR shift present is confirmed by the results for the ASR response growth function ($|\Delta L_{WI}|$) in the lower left panel of Figure 7 at the same activator levels. Although not shown, other ears had a large-amplitude response in $|\Delta L_{WI}|$, but without a sufficiently large inter-pair correlation to validate that an ASR shift was present, as opposed to some intermittent glitch.

Infant-Ear Responses

Infant with normal hearing

WB reflex measurements are described for the infant subject N who was in the normal group at each test age. Data were acquired from the right test ear at ages 1 day and 1.3 months. The average TPPs used for

reflex testing in the infant subject were -58 daPa at age 1 day and -40 daPa at 1.3 months. ASR tests were performed for a BBN activator in the ipsilateral ear. The activator SPLs were calculated over the measurement bandwidth 0.2–8 kHz for the 2-cm³ coupler and in the ear. For the BBN activator at the maximum level, the coupler SPL was 80 dB. For the normal infant subject N, the corresponding in-the-ear SPL was 96.4 dB at age 1 day and 90.9 dB at age 1.3 months.

For each test age, the measured baseline click pressure waveforms are shown for infant ear N with normal hearing in the top row of Figure 9. The corresponding measurements of the click-difference waveforms between the final click in the pulsed-activator stimulus set and the baseline click are shown in the bottom for all 10 activator levels.

The morphologies of the baseline click waveforms in the top row were similar with age with only slight variation in pSPL from 101 dB down to 96 dB. The time $t = 0$ ms in each panel corresponded to the time at which the maximum amplitude occurred for the baseline click. Aside from effects of multiple reflections within the ear canal, the mainly unipolar shape

FIG. 5. Absorbance difference due to ASR in normal adult ear A at all activator levels 1–10. The legend specifies the line style and the rank order of the activator SPL (dB) from the lowest (rank order 1) to highest (rank order 10). The rank order in the legend applies to all

panels even though the range of activator SPLs varied across the panels. The range of activator SPLs for each ASR type in Figure 4 corresponds to rank order numbers 2–10 in the present figure.

of the waveform near time 0 was due to the fact that the incident click, defined as the acoustic click waveform in the absence of any reflected waves, was designed to approximate the impulse response of a linear-phase filter with bandpass frequencies of 0.25 to 8 kHz using a Kaiser window design.

The click-difference pressure waveforms in the bottom row of Figure 9 were more susceptible to low-frequency noise, especially in the initial NHS test at 1 day of age. The response at each age was qualitatively similar to the click-difference pressure waveforms measured in adult ears, which show a broad maximum between 0 and 1 ms (Keefe et al. 2010). The amplitude of this maximum tended to increase with increasing activator level, at least in the upper range of activator levels.

The ASR status functions in Figure 10 for each test age show whether the ASR was classified as present or absent at each activator level. At age 1 day, the ASR was present at all activator levels at

and above 60 dB SPL except that it was absent at 65 dB SPL. The maximum-likelihood procedure calculated the ASRT across all activator levels to be 65 dB SPL, at which the maximum likelihood attained a value of 0.047. The (median) across-level correlation was 0.84, which was sufficiently large for the response to be classified as having an ASR shift present.

At age 1.3 months, the ASR was present at all activator levels at and above 55 dB SPL, with an ASRT of 55 dB SPL. The maximum likelihood attained a value of 0.567 at this threshold level, which was more than an order of magnitude larger than the maximum likelihood at 1 day. This difference is due to the fact that the ASR status function was non-monotonic at 1 day, and monotonic at age 1.3 months. This illustrates the utility of the maximum likelihood value to assess the degree of non-monotonicity. The across-level correlation was equal to 1.00 at age 1.3 months.

FIG. 6. The ASR absorbed power level shift ΔL_W (f) in normal adult ear A at all activator levels 1–10. The legend specifies the line style and the rank order of the activator SPL (dB) from the lowest (rank order 1) to highest (rank order 10). The rank order in the legend

applies to all panels even though the range of activator SPLs varied across the panels. The range of activator SPLs for each ASR type in Figure 4 corresponds to rank order numbers 2–10 in the present figure.

The shifts in absorbance ΔA and in absorbed power level ΔL_W (see Eq. (7)) are plotted for each age in Figure 11. Each plotted shift is the difference in the response at the final, or fifth, click in the stimulus set relative to the response at the initial or first click.

At age 1 day (left panels), the absorbance shift ΔA for infant ear N was reduced at half-octave frequencies from 0.707 up to 1 kHz at higher activator levels, and had slightly positive values at 1.4 and 2 kHz at the highest activator levels. The absorbed power level ΔL_W was reduced at higher activator levels at all frequencies up to 4 kHz.

At age 1.3 months (right panels), ΔA was negative at the high activator levels at frequencies up to 1 kHz, with slightly positive values at 1.4 and 2 kHz that turned negative at higher frequencies. The ΔL_W was negative at the higher activator levels at and above the ASRT for frequencies of 1 and 1.4 kHz, and was positive with

much smaller amplitudes at 2 and 2.8 kHz. The ΔL_W was negative at frequencies from 4 to 8 kHz.

The supra-threshold infant-ear patterns of ΔA and ΔL_W in Figure 11 were qualitatively similar to the corresponding patterns for the normal-hearing adult ear in Figures 5 and 6, respectively. The general pattern is that ΔL_W was negative at low frequencies, and any positive value of ΔL_W at higher frequencies was closer to 0 dB. This spectral pattern was also reported by Feeney and Keefe (1999) in normal-hearing adult ears.

For infant subject N at age 1 day, the frequency range of negative values of ΔL_W in Figure 11 extended from 0.7 to 4 kHz at the largest activator level, and the range of positive values was the single frequency 5.6 kHz. At age 1.3 months, the frequency range of negative values extended from 0.7 to 1.4 kHz, and the range of positive values extended from 2 to 2.8 kHz. The values of ΔL_W at frequencies above 2.4 kHz were not used to classify an

FIG. 7. $|\Delta L_{W1}|$ due to ASR in normal adult ear A; dotted line showing criterion level for ASR present.

ASR shift as present or absent (at this largest activator level), even though an ASR shift appeared to be present from 4 to 8 kHz. The justification for not analyzing higher frequencies is that these responses were often noise dominated. Noise effects would complicate the calculation of the ASRT. Notwithstanding their exclusion in calculating the ASRT, the ASR shifts are plotted at frequencies above 2.4 kHz and are available for subsequent analyses.

The ASRT was estimated based on the calculation at each activator level of the shift magnitude response $|\Delta L_{W1}|$ (and L_{W2}) and the similarity across ASR shift measurements based on the inter-pair correlation. These are plotted for infant ear N in Figure 12. At age 1 day, $|\Delta L_{W1}|$ slightly exceeded the criterion level shift at an activator SPL of 45 dB (left top panel). Nevertheless, the ASR was classified as absent, inasmuch as the inter-pair correlation was not significant at 45 dB SPL (left bottom panel). Both $|\Delta L_{W1}|$ and the inter-pair correlation in Figure 12 were

significant at 60, 70, 75, and 80 dB SPL, which was the basis for the ASR-present classifications at these levels in Figure 10. The ASR was classified as absent at 65 dB SPL, inasmuch as the correlation was not significant at this level in Figure 12 even though $|\Delta L_{W1}|$ was significant.

At age 1.3 months, both $|\Delta L_{W1}|$ and the inter-pair correlation were significant for activator levels at and above the ASRT of 55 dB SPL, which was consistent with the monotonic pattern in Figure 10 at this age. The $|\Delta L_{W1}|$ increased monotonically with increasing activator level above the ASRT. This was in qualitative accord with the monotonic growth functions in adult ear A in Figure 7, although the slope of the infant growth function was more shallow. It is unknown whether this slope difference would be observed in groups of normal adult and infant ears. Such a slope difference might be related to neural maturation or result from using different ASR pass bands in adult and infant test ears.

FIG. 8. Inter-pair correlation due to ASR in normal adult ear A, with *dotted lines* showing criterion value for ASR present.

FIG. 9. Baseline click waveform (*top row*) and click-difference waveforms (*bottom row*) between final click and baseline click at all BBN activator levels in normal infant ear N. The activator levels in the legend are quantified by the SPL (dB) measured in a 2-cm³ coupler.

FIG. 10. ASR status function (i.e., present or absent ASR) in normal infant ear N for BBN activator SPLs measured in a 2-cm³ coupler.

Infant with Conductive Hearing Loss

WB reflex measurements are next described for the left ear of the infant subject C with a conductive hearing loss. The average TPPs used for reflex testing in the infant subject were 200 daPa at age 1 day and 175 daPa at 0.9 months. These positive TPPs at the young ages were consistent with large mobility in the ear-canal wall. The more elevated positive pressures tended to open up the ear canal in these cases. For infant ear C, the in-the-ear SPL of the BBN activator at the ASRT was 94.9 dB at age 1 day and 93.5 dB at age 0.9 months for the stimulus with the maximum coupler SPL of 80 dB.

The measured baseline click pressure waveforms are shown for this infant ear in the top row of Figure 13 at each test age. The corresponding measurements of the click-difference waveforms between the final click in the pulsed-activator stimulus set and the baseline click are shown in the bottom row for all BBN activator levels. The morphology of the baseline click waveform (top row) changed with age

with only slight variation in peSPL from 100 dB to 99 dB. The fast fluctuations resulted from multiple internal reflections within the infant ear canal.

The click-difference waveforms in infant ear C (bottom row of Figure 13) with a conductive hearing loss at age 1 day were noisier at some activator levels, e.g., at 50 and 60 dB SPL. At age 0.9 months, the waveforms showed narrow minima near 0 ms at the two highest activator levels (75 and 80 dB SPL) and a maximum near 0 ms at 70 dB SPL. Such extremal values straddling the time $t = 0$ ms of the peak of the reference click stimulus were either absent or much less prominent in the click difference waveforms of subject N (bottom row of Figure 9), for which extremal values were present at times slightly later than 0 ms. Both test ears C and N had noisier click-difference waveforms at 1 day compared to those at the older test age.

For infant subject C, the ASR at both ages was classified as absent at each activator level, and re-test was recommended at age 0.9 months at the two highest levels. Thus, the ASRT was classified as NR at

FIG. 11. Absorbance difference (top row) and absorbed power level difference (dB) due to ASR (bottom row) at all BBN activator SPLs in normal infant ear N. Legend shows activator SPL in dB.

FIG. 12. $|\Delta L_{W1}|$ (top row) and inter-pair correlation (bottom row) due to ASR in normal infant ear N. The horizontal dotted lines represent the minimum criterion values consistent with an ASR to be classified as present. A circle marker indicates an activator level that was at or above the ASRT.

both ages. The re-test recommendations were based on an outlier value of the baseline click signal level that was 6–7 dB higher in the MAD test relative to the median of the distribution of baseline click levels across all activator levels (not shown). This 6–7 dB change from the median level may be compared to the adult- and infant-ear data (see Figures 2 and 3), which showed a range of about 1 dB or less in signal level. The reason for such a relatively large change in click level in infant ear C is unknown, although a shift in the position of the probe within the ear canal

might explain such a change. This re-test outcome was calculated only during the post-hoc analysis and was unavailable to the test operator during the test.

For infant ear C at each test age, the shifts in absorbance ΔA and in absorbed power level ΔL_W are plotted in Figure 14 for each activator level. The absorbance shift ΔA (Fig. 14, top row) at both ages lacked the feature of reduced absorbance at low frequencies that was observed at the highest activator levels in the normal infant ear (see Fig. 11). Because the ASR test was classified as noisy at age 0.9 months at the

FIG. 13. Baseline click waveform (top row) and click-difference waveforms (bottom row) between final click and baseline click at all BBN activator levels in infant ear C with a conductive hearing loss. Legend shows activator SPL in dB.

two highest activator levels, these responses were not interpretable as regards the absorbance and absorbed power level differences. The absorbed power level ΔL_W generally lacked the features of negative values at low frequencies and positive values at intermediate frequencies that were observed for the normal infant subject N at the supra-threshold activator levels.

The ASRT was classified as absent in infant ear C based on the calculation at each activator level of the shift magnitude response $|\Delta L_{W1}|$ (and L_{W2}) and the similarity across ASR shift measurements based on the inter-pair correlation. These are plotted for infant ear C in Figure 15. At age 1 day across the 10 activator SPLs, $|\Delta L_{W1}|$ exceeded the criterion level shift at activator SPLs of 60 and at 70 dB and above, but the inter-pair correlation was below the criterion correlation value at all activator SPLs. Thus, the ASRT was a NR at age 1 day. At age 0.9 months, the data at the two highest activator SPLs (75 and 80 dB) were noisy on the basis of the MAD test for the baseline click signal level. Thus, the data in the right panel of Figure 15 were not considered for these two levels. Otherwise, $|\Delta L_{W1}|$ slightly exceeded the criterion level shift at an activator SPL of 65 dB, but the inter-pair correlation was not significant at this SPL. Thus, the ASRT was a NR at age 0.9 months.

DISCUSSION

The present ASR test procedures may differ from previous ASR test procedures in such areas as follows: the activator signal used to elicit a ASR, the response

used to quantify each ASR shift, the reference stimulus or stimuli used to detect the ASR, the process used to decide whether the ASR shift is present or absent, and the objective calculation of the ASRT. The clinical ASR test uses a tonal or BBN activator to elicit an ASR shift in either a substantially continuous or pulsed presentation mode. The clinical ASR test uses a change in the admittance magnitude at 226 Hz to quantify an ASR shift. The ASR shift may be objectively classified as present based on a sufficiently large reduction in the admittance magnitude with the activator present relative to the activator absent. The ASRT is usually determined based on manual adjustments of the activator level taking into account the classification of the ASR responses obtained at earlier presentation levels, although some clinical devices automate the process to measure the ASRT. Clinical ASR test procedures differ in infants compared to adults in the use of higher reference frequencies in infants, e.g., Weatherby and Bennett (1980) used reference tones in the range of 0.8–1.8 kHz to detect the ASR.

The present ASR test procedures used BBN and tonal activators in both ipsilateral and contralateral testing modes, a measured ASR shift in absorbed power at the probe tip, differences in multiple pairs of WB clicks as reference stimuli, an algorithm to classify the ASR shift as present or absent based on the similarity and magnitude of multiple ASR shifts, and an objective calculation of the ASRT using a maximum likelihood method that was adapted to control for any inconsistent responses at lower activator levels. These procedures were introduced to better control for noise artifacts and to detect excessively noisy tests, for which a re-test was

FIG. 14. Absorbance difference (*top row*) and absorbed power level difference (dB) due to ASR (*bottom row*) at all BBN activator SPLs infant ear C with a conductive hearing loss. Legend shows activator SPL in dB.

FIG. 15. $|\Delta L_{W1}|$ (top row) and inter-pair correlation (bottom row) due to ASR in infant ear C with a conductive hearing loss. The horizontal dotted lines represent the minimum criterion values consistent with an ASR to be classified as present.

recommended. The procedures were designed for use in universal newborn hearing screening protocols in which an ASR must be objectively classified without immediate input from an audiologist, although the procedures are also applicable for use in audiological testing in older children and adults.

The present study and Keefe et al. (2010) detected the ASR based on differences in the acoustic responses between the first and successive presentations of a reference click stimulus. In contrast to previous studies (Neumann et al. 1996; Müller-Wehlau et al. 2005), five rather than two presentations of an identical sound stimulus were used, and a tonal or BBN activator was placed between each pair of presentations (see Fig. 1). The additional presentations of the activator in the present study would evoke a larger-amplitude ASR shift that might be easier to detect than using only two presentations. The inclusion of four click-difference pairs relative to the initial baseline click in the present study rather than only one pair allowed analyses of the similarity of ASR shifts in multiple pairs within the same pulsed-activator stimulus set. Although detailed results are not described herein, a growth of ASR shift was evident in some test ears between the second and fifth clicks within the stimulus set. Another contrast with these previous studies is that the present study and Keefe et al. (2010) used an ASR detection criterion of any later click, such that the purported ASR shift needed to be both similar to other ASR shifts in the stimulus set and of sufficiently large amplitude. A key difference between the present study and Keefe et al. (2010) is that the present study analyzed ASR shifts in absorbed (sound) power level (see Figs. 6, 11, and 14), which varied less across frequency than the ASR shift in sound

pressure spectra used in the 2010 study. This led to a more uniform pattern of an ASR reduction in absorbed power at lower frequencies and a smaller increase in absorbed power at higher frequencies.

A concern in any ASR test is that its sound levels used be within safe limits (Hunter et al. 1999). One step in evaluating safety is to measure the actual in-the-ear SPL of the ipsilateral activator as contrasted with its SPL measured in a 2-cm³ coupler. These level differences were evaluated in the present results and compared to previous results in WB ASR testing. The level difference between the in-the-ear SPL relative to the coupler SPL for the BBN activator was 2.9 dB for adult subject A, whereas the mean level difference (± 1 standard error of the mean) in a group of young adults with normal hearing was 4.1 ± 1.7 dB (Keefe et al. 2010). The level difference for the tonal activators for adult subject A was similar to the group means at 1 and 2 kHz, although the level difference of -5.5 dB at 0.5 kHz in adult subject A was smaller than the group mean difference of 1.5 ± 1.4 dB reported in the 2010 study for the 0.5-kHz activator.

For infants N and C, the average in-the-ear SPL at the ASRT at age 1 day was about 95.6 dB, which exceeded the in-the-ear SPL at the ASRT in adult ear A by 12.7 dB. When accounting for the difference in the maximum SPL used for the BBN activator in adults versus newborns in Keefe et al. (2010), the mean in-the-ear SPL at the ASRT in newborns who passed the NHS exam on the first test date was effectively larger than that in adults by 13.9 dB (with a combined standard error of the mean of about 2.5 dB). Thus, the in-the-ear ASRTs in the two infant ears and the one adult ear were consistent with previous WB ASRT measurements.

The present report confined its scope to the full explication of a new ASRT test based on measured ear-canal shifts in absorbed power. The results presented in a small number of adult and infant ears were illustrations of the procedural steps and the type of data that are obtained from this test. Group results were obtained and analyzed in the multi-year study that included this ASRT test in combination with other tests for the clinical diagnosis and monitoring of middle-ear and cochlear function. These group results in adult ears with normal function are described in Feeney et al. (2016). Group results obtained in infant ears with normal function and with hearing loss are described in Hunter et al. (2016). Finally, the ASRT was classified as NR in all the adult and infant ears in the present study that were expected to have an ASR absent.

SUMMARY

New procedures to measure ASR threshold and supra-threshold effects were devised based on differences in absorbed power between responses to multiple pairs of identical click stimuli. The ASR tests are defined using both BBN and tonal activators in both ipsilateral and contralateral modes of operation. The ASR power shifts were analyzed over a bandwidth from 0.2 to 2.4 kHz in adult ears and over a more restricted bandwidth from 0.8 to 2.4 kHz in infant ears. The difference in the lower passband frequency between tests in adult and infant ears was because ASR shifts are more difficult to detect at frequencies below 0.8 kHz in infants. The upper passband frequency of 2.4 kHz was selected to include most of the integrated shift in absorbed power across frequency, although smaller ASR shifts were evident between 2.4 and 8 kHz. The results in the selected infant ears demonstrate the potential clinical use of this ASR test to measure differences in reflex function between normal infants and infants with hearing loss. Further study is needed to evaluate the performance of this ASRT test in groups of ears with normal function and ears with hearing loss or otologic disorders.

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