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Effects of ear canal static pressure on the dynamic behaviour of outer and middle ear in newborns

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Abstract:

Objective: The present study investigated the effect of ear canal pressure on the dynamic behaviour of the outer and middle ear in newborns with and without a conductive condition using the sweep frequency impedance (SFI) technology.

Methods: A test battery consisting of automated auditory brainstem response (AABR), transient evoked otoacoustic emission (TEOAE) and 1000-Hz tympanometry (HFT) was performed on 122 ears of 86 healthy newborns and 10 ears of 10 newborns with a conductive condition (failed TEOAE and HFT). The dynamic behaviour of the outer and middle ear, when the pressure applied to the ear canal was varied from 200 to -200 daPa, was evaluated in terms of the sound pressure level (SPL) in the ear canal, resonance frequency (RF) and displacement (∆SPL).

Results: Application of either a positive or negative static pressure to the ear canal of healthy newborns increased the resonance frequency of the outer (RF1) and middle ear (RF2), but decreased the displacements of the outer (∆SPL1) and middle ear (∆SPL2). Positive static pressures resulted in lower SPL while negative static pressures resulted in higher SPL than that at ambient pressure (0 daPa). At -200 daPa, more than 90% of ears showed signs of collapsed ear canal. The dynamic behaviour under various positive and negative static pressures for newborn ears with a conductive condition indicated similar pattern of SPL, RF1 and ∆SPL1 responses for the outer ear as per healthy ears, but abnormal responses for the middle ear.

Conclusions: While both positive and negative pressures applied to the ear canal have the same effect of stiffening the outer and middle ear, negative pressure of up to -200 daPa resulted in more than 90% of ears with a collapsed ear canal. The results of the present study do not only offer useful clinical information for differentiating
healthy ears from ears with a conductive condition, but also provide information on
the maturation aspects of the outer and middle ear in newborns.

**Key Words:** Sweep frequency impedance measure, dynamic behaviour, newborns,
resonance frequency, middle ear, ear canal.

**1. Introduction**

Technological advances have enabled the measurement of acoustical
characteristics of the outer and middle ear using multifrequency tympanometry (MFT)
[1]. MFT refers to the measurement of middle ear characteristics using tones of more
than one frequency. The MFT procedure may either use a sweep frequency technique
at multiple applied air pressures to the ear canal or a sweep pressure technique using
tone of multiple discreet frequencies [2, 3]. The MFT procedure may also utilise a
wideband technique using click stimuli at ambient or multiple applied air pressure to
the ear canal [4].

At present, new multi-frequency techniques that measure acoustic-mechanical
properties over a wide frequency range have been developed to assess the outer and
middle ear function. Two such techniques are sweep frequency impedance (SFI) [1, 5]
and wideband acoustic immittance (WAI) [5-8]. The SFI meter, developed by Wada
et al. [9], measures the sound pressure in the ear canal while a sweeping tone is
presented under various static pressure levels in the ear canal. From the SFI measures,
the dynamic behaviour of the outer and middle ear can be described in terms of the
sound pressure level (SPL) across frequencies at various static pressure applied to the
ear canal. From the SPL results, the resonance frequency (RF) and mobility of the
outer and middle ear system (Δ SPL) can be measured [9]. While the SFI is similar in
principle to MFT, it does not measure the admittance of the outer and middle ear.
Instead, it measures the SPL in the ear canal in dB SPL across the frequencies from
100 to 2200 Hz. The SFI has advantages over the traditional MFT. It is faster than the MFT and it also measures the RF accurately regardless of the direction and rate of change of ear canal pressure. The SFI test has also been reported to be better than the 226-Hz tympanometry in the differential diagnosis of middle ear dysfunction in adults [1, 5, 9-12].

The dynamic behaviour of the outer and middle ear system, as analysed using the SFI meter, of a normally hearing adult is different from that of a healthy newborn (Figure 1). The SFI results at ambient pressure (0 daPa) for the adult reveal one inflexion [Figure 1 (a)], while the results for the newborn reveal two inflexions [Figure 1 (b)]. The differences in dynamic behaviour may be attributed to differences in the anatomy and physiology of the outer/middle ear between the adult and the newborn.

Insert Figure 1 here

From an anatomical and physiological perspective, the outer and middle ear system of newborns is not mature at birth [13]. There is a thin layer of elastic cartilage surrounding the entire external auditory canal [14] which makes the ear canal relatively compliant, flaccid and prolapsed [15-17]. Newborns have a short ear canal with diameter increasing to 4.4 mm by the age of one month [18] and a short ear canal floor length of 17 to 22.5 mm and roof length of 11 to 22.5 mm by age of two month [14]. Orientation of the newborn eardrum is more horizontal relative to the ear canal axis [18-20]. The middle ear and mastoid cavities are small (452 mm\(^3\)) compared to adult tympanic cavity (640 mm\(^3\)) [14, 16, 21]. Newborns also have loose ossicular joints [14, 22] which become more stiff with age.

The anatomical and physiological properties of healthy newborns are altered when an external air pressure is applied to the ear canal. On pressurization, the
cartilaginous ear canal diameter increases by an average of 18.3% under positive pressure or decreases by an average of 28.2% of its original value under negative ear canal pressure [23]. Furthermore, ear canal volume changes from 27 to 75% over a range of ± 300 daPa in newborns [22]. In view of these characteristics, the dynamic behaviour of the outer and middle ear of newborns will undoubtedly change in response to pressurization of the ear canal [15, 16, 24]. These changes in dynamic behaviour of the outer and middle ear can easily be described using the SFI technique.

While the SFI has been successfully used with children and adults, its application to newborns is relatively new. To date, only two studies have investigated the dynamic behaviour of the outer and middle ear of newborns [25, 26]. In a pilot study, Murakoshi et al. [26] analysed SFI data obtained from 9 neonates under ambient ear canal pressure (0 daPa) condition and found two resonances corresponding to the two inflexions of the sound pressure level (SPL) curve (Figure 1b). By comparing their results with that obtained from a gel model which mimicked a newborn ear canal, they showed that the first resonance which occurred at 260 Hz ± 30 Hz, was related to the resonance of the ear canal wall. The second resonance, which occurred at 1130 Hz ± 120 Hz was related to the resonance of the middle ear. Aithal et al. [25] studied the dynamic behaviour of the outer and middle ear of healthy newborns under ambient pressure conditions using a larger sample (N = 100) and reported normative data for the resonance frequencies and Δ SPL (mobility of the system). Their findings were consistent with the results of Murakoshi et al. [26]. Furthermore, they affirmed the feasibility of assessing the function of the outer and middle ear in newborns using the SFI technique.

While the dynamic behaviour of the outer and middle ear in newborns under ambient pressure condition was described in detail by Murakoshi et al. [26] and Aithal
et al. [25], the dynamic behaviour under pressurized conditions has not been systematically investigated. Investigation of the effect of ear canal pressure on the dynamic behaviour in newborns is important since the ear canal and tympanic membrane of newborns are compliant and flaccid. The present study aimed to investigate the dynamic behaviour of outer and middle ear by inducing positive and negative ear canal pressures in newborn ears. In particular, the study was conducted to address the following questions (i) Is the dynamic behaviour under pressurised conditions significantly different to that under ambient pressure condition? (ii) Does the dynamic behaviour differ significantly between positive and negative ear canal pressures? (iii) Is the dynamic behaviour under pressurized conditions of a healthy newborn different from that of an ear with a conductive condition?

2. Materials and methods

2.1. Participants

This study was approved by the Human Research Ethical Committee of Townsville Hospital and Health Service, and the University of Queensland Behavioural and Social Science Ethical Review Committee. Parents provided written consent for newborns to be included in the study. The present study included 122 ears from 86 healthy newborns (45 males and 41 females) who passed in a test battery that included automated auditory brainstem response (AABR), transient evoked otoacoustic emission (TEOAE) and high frequency tympanometry (HFT) with a 1000-Hz probe tone. This study sample was a new cohort of newborn ears different from those included in previously published studies [25]. Additionally, 10 ears from 10 newborns who passed the AABR, but did not pass the HFT and TEOAE tests were included to investigate the dynamic behaviour of the outer and middle ear in newborns with a conductive condition.
Table 1 shows the mean, standard deviation (SD), and median for gestational age (in weeks), age of testing (in hours) and birth weight (in grams) for 86 healthy newborns. All newborns had uneventful birth history with no risk factors for hearing loss [27].

2.2. Procedure

All newborns were tested during their natural sleep or while awake, but quiet and settled. Testing was performed in a quiet room of the maternity ward where ambient noise levels were less than 40 dB A. Hearing screening was performed by trained maternity nursing staff using AABR, while the remaining assessments (HFT, TEOAE and SFI tests) were administered by a clinical audiologist. The entire test battery took an average of 30 minutes for both ears for a well settled newborn. Wherever possible, the HFT and TEOAE tests were completed for both ears of each newborn with no particular test order. The most accessible ear was tested first. SFI results were analysed independent of HFT and TEOAE results i.e., the audiologist who analysed SFI result was not involved in the classification of HFT and TEOAE results.

The present study used a test battery approach (pass in AABR, TEOAE and HFT) as the reference standard for normal middle ear function. Although a pass in TEOAE or HFT or AABR does not always rule out middle ear dysfunction [28-30], a pass in all three tests constituted a more stringent “reference” standard than a single test reference standard.

2.2.1. Automated Auditory Brainstem Response (AABR)

AABR screening was always performed first as part of the state mandated universal newborn hearing screening (UNHS) program using an ALGO3 newborn
hearing screener (Natus Medical Inc.). Clicks were presented at 35 dB nHL to both ears simultaneously during testing. A pass or refer result for each ear was automatically recorded by the equipment. Passing the AABR screen was necessary to ensure likelihood of grossly normal auditory function.

2.2.2. High frequency tympanometry (HFT)

HFT was performed using a Madsen Ototex 100 acoustic immittance device (GN Otometries) with a 1000-Hz probe tone. Admittance (Ya) was measured as the pressure was changed from +200 to -400 daPa at a rate of 400 daPa/sec. Pass criteria were a single positively peaked tympanogram with the middle ear pressure between 50 and -150 daPa and peak compensated static admittance (Ypc) (+200 daPa tail to peak) of at least 0.2 mmho [31].

2.2.3. Transient Evoked Otoacoustic Emissions (TEOAE)

TEOAE test was performed using a Scout sport system (Biologic Navigator Plus). The signal consisted of wideband clicks of 80 µs duration delivered at 80 dB pkSPL to the ear via a probe. Emissions were measured at 2000, 3000 and 4000 Hz. Pass criteria included a reproducibility of 70% and difference of at least 3 dB between the amplitude of the emissions and associated noise floor in one-third octave frequency bands from 2000 to 4000 Hz [30].

2.2.4. Sweep Frequency Impedance (SFI) test

SFI test was performed using a new SFI unit developed for testing newborns [26]. A full description of SFI unit used in testing infants is provided elsewhere [25, 26], however a brief description is provided here (Figure 2). The SFI device consists of a personal computer, an AD/DA converter, a probe system, a stepping motor, an air pump, a pressure sensor, and a pressure relief valve. The new probe used for testing newborns is small with a diameter of approximately 3 mm. The new probe consists of
three tubes: the first tube to apply static pressure (Ps) to the ear canal, the second tube to deliver sound to the external ear canal via an earphone, and the third tube to measure sound pressure in the external ear canal using a microphone. A specially designed cuff suitable for testing neonates is attached to the tip of the probe to obtain a hermetic seal during testing. This new SFI unit, controlled using LabView under MS WINDOWS, also performs HFT first as part of the automated test procedure. However, the HFT results were not included in the analyses because a commercially available Madsen Otoflex 100 device was used instead.

After performing the HFT, the SFI test began by presenting a probe tone with frequency sweeping from 100 to 2200 Hz while the external auditory canal static pressure (Ps) was held constant at 200 daPa. This measurement was repeated with Ps reduced in 50 daPa steps down to -200 daPa. The entire automated SFI procedure took less than two minutes to complete the test in each ear. The sweeping probe tone level was kept below 75 dB SPL to reduce the possibility of eliciting an acoustic stapedial reflex. The SFI results measured at multiple static pressures provide a comprehensive three-dimensional view (SPL-frequency-static ear canal pressure) of the dynamic behaviour of the outer and middle ear.

3. Results

Figure 3 shows typical SFI results obtained from the left ear of a healthy one-day-old newborn who passed AABR, HFT and TEOAE tests. For purpose of clarity, only traces obtained at 0, +200 and -200 daPa are shown. At ambient pressure, (Ps = 0 daPa), the graph (bold SPL curve) shows two resonances at frequencies between $F_{b1}$ (130 Hz) and $F_{a1}$ (350 Hz) and between $F_{b2}$ (900 Hz) and $F_{a2}$ (1560 Hz). Previous studies have shown that the greatest variation (volume displacement) of SPL (ΔSPL)
occurs at median frequencies RF1 and RF2, which are halfway between the frequencies F_a1 and F_b1, and between F_a2 and F_b2, respectively [9, 26]. The first resonance frequency (RF1) is defined as the frequency at which the SPL varies considerably between F_b1 to F_a1. Hence, RF1 and the corresponding change in SPL (ΔSPL1) are defined as shown in Equations (1) and (2) [9, 26].

First Resonance Frequency, RF1 = (F_a1 + F_b1) / 2
SPL change at RF1, ΔSPL1 = P_a1 - P_b1

Similarly, the second resonance frequency (RF2) and the corresponding change in SPL (ΔSPL2) are defined as shown in Equations (3) and (4).

Second Resonance Frequency, RF2 = (F_a2 + F_b2) / 2
SPL change at RF2, ΔSPL2 = P_a2 - P_b2

Insert Figure 3 here

As illustrated in the Figure 3, when the static pressure (Ps) = 0 daPa (ambient pressure), RF1 = 240 Hz, ΔSPL1 = 13 dB, RF2 = 1230 Hz and ΔSPL2 = 8 dB. These results indicate that there are two distinct resonance frequencies at which the SPL varies considerably. The ΔSPL variation reflects the mobility of the outer and middle ear system at these frequencies [25, 26]. According to Murakoshi et al. [26] and Aithal et al. [25], RF1 and ΔSPL1 are associated with resonance in the outer ear, while RF2 and ΔSPL2 are associated with resonance in the middle ear.

Figure 4 shows effect of static ear canal pressure (Ps) on SFI measure obtained from a newborn at different static pressure levels. Although SFI results were recorded at 50 daPa intervals starting from +200 daPa to -200 daPa, SFI data (RF and ΔSPL) were analysed only for static ear canal pressures at +200 daPa, +100 daPa, +50 daPa, 0 daPa, -50 daPa, -100 daPa and -200 daPa. The dynamic behaviour altered as the ear
canal pressure was increased from 0 to +200 daPa. In particular, when the static pressure was increased from 0 daPa to +50 daPa, the SPL decreased considerably between 1000 Hz and 2000 Hz, while the SPL at the lower frequencies increased slightly. When compared with the SFI data at 0 daPa, both RF1 and RF2 increased (i.e., shifted towards higher frequencies) while ΔSPL1 and ΔSPL2 decreased. Further increase in static pressure to +100 and +200 daPa led to reduced SPL level between 1000 Hz and 2000 Hz, as well as increased RF1 and RF2, and decreased ΔSPL1 and ΔSPL2 values. This change in dynamic behaviour with increased ear canal pressure is typical of healthy newborn ears.

Insert Figure 4 here

When the static pressure was decreased from 0 daPa to -50 daPa, the SPL between 500 Hz and 1500 Hz increased considerably while the SPL remained unchanged between 1500 Hz and 2200 Hz. RF1 increased considerably and RF2 decreased slightly, while ΔSPL1 decreased considerably and ΔSPL2 remained practically unchanged. This change in dynamic behaviour indicates that a mild negative pressure (-50 daPa) had greater influence on RF1 and ΔSPL1 than on RF2 and ΔSPL2. When a static negative pressure of -100 daPa was applied to the ear canal, the SPL between 200 Hz and 1500 Hz increased further with practically no change in SPL beyond 1500 Hz. The morphology of the SPL curve changed significantly without much variation of SPL with frequency (a relatively flat response across frequencies), suggesting that the ear canal had collapsed [25, 26]. Hence, no RF or ΔSPL could be measured. Further decrease of static pressure to -200 daPa showed similar flat responses with greater overall SPL than that obtained at -100 daPa. In the present study sample of 122 ears of healthy newborns, there were 110 ears collapsed at -200 daPa, 53 ears at -100 daPa, and 6 ears at -50 daPa.
Table 2 shows the number of ears, mean, SD, median for RF1, RF2, ΔSPL1, and ΔSPL2 at different static ear canal pressures in newborns with normal middle ear condition and newborns with conductive condition. At ambient pressure, mean RF2 (1243 Hz) was 4.3 times larger than mean RF1 (287 Hz), and overall mean ΔSPL1 (8.2 dB) was 1.7 times larger than mean ΔSPL2 (5 dB). These results are consistent with previous published studies [25, 26]. The SFI results at positive pressures showed a trend of increasing RF1 and RF2, and decreasing ΔSPL1 and ΔSPL2 with increasing pressure up to +200 daPa. The SFI results at negative pressures showed a clear trend of increasing RF1 and decreasing ΔSPL1 with decreasing (more negative) pressure. However, this trend is not evident for RF2 and ΔSPL2.

To investigate the effect of static ear canal pressure on RF and ΔSPL, a general linear model univariate analysis of variance (ANOVA) was applied separately to the RF1, RF2, ΔSPL1 and ΔSPL2 data with static pressure in the ear canal (-200 daPa, -100 daPa, -50 daPa, 0 daPa, 50 daPa, 100 daPa and 200 daPa) as independent (fixed) factors. The effect of static pressure in the ear canal was significant for RF1 [F (6, 678) = 118.3, p = 0.00], RF2 [F (6, 678) = 60, p = 0.00], ΔSPL1 [F(6, 678) = 37.6, p = 0.00] and ΔSPL2 [F(6, 678) = 8.1, p = 0.00], with RF values significantly increased. However, ΔSPL values significantly reduced with the introduction of both positive and negative static pressure in the ear canal. The magnitude of effect (partial eta squared) was large for RF1 (0.51), RF2 (0.35), and ΔSPL1 (0.25), and effect was medium for ΔSPL2 (0.07).

To further investigate the effect of static ear canal pressure on resonance frequency and mobility of ear drum, post hoc multiple pair-wise comparison tests with Bonferroni adjustment were performed on the SFI data. Table 3 shows results.
comparing the SFI measures at 0 daPa (ambient) with those at other ear canal pressures (50 daPa, 100 daPa, 200 daPa, -50 daPa, -100 daPa, and -200 daPa). RF1 was significantly different at all pressure levels whereas RF2 was significantly different only at positive ear canal pressure (0 daPa vs. 50 daPa, 0 daPa vs. 100 daPa, and 0 daPa vs 200 daPa). The ΔSPL1 was significantly different at all pressure levels, whereas ΔSPL2 was significantly different only extreme pressure levels (0 daPa vs +200 daPa and 0 daPa vs -200 daPa).

Insert Table 3 here

With the application of positive pressures to the ear canal, there was a shift in RF1 and RF2 towards higher frequencies. The shift was significant for all static ear canal pressure levels for RF1 relative to ambient pressure. However, RF2 showed a significant shift to higher frequencies only at positive pressure levels (50 daPa, 100 daPa, and 200 daPa) relative to ambient pressure. When the static ear canal pressure reached +200 daPa, mean RF1 doubled (2.1 times larger) relative to that at ambient pressure, and mean RF2 increased 1.4 times when compared to that at ambient pressure. With the introduction of –200 daPa negative static ear canal pressure, mean RF1 significantly increased with respect to ambient pressure (287 to 593 Hz), whereas RF2 did not show any significant change.

As a measure of inter-subject variability, SD for SFI measures was calculated. With the exception of 200 daPa for RF2, SDs generally remained constant across all static pressure levels. The increased SD for RF2 at 200 daPa could be due to small sample size as it included only 12 ears. As the ear canal pressure changed from positive to negative, ΔSPL1 showed greater changes than ΔSPL2. As the static pressure varied from 0 to -100 daPa, SD for ΔSPL2 decreased slightly, whereas SD for ΔSPL1 decreased considerably. As the ear canal pressure changed from ambient...
to positive pressure, $\Delta SPL_1$ showed a sharp decrease whereas $\Delta SPL_2$ remained steady. Overall, $\Delta SPL_1$ showed more variability than $\Delta SPL_2$.

Table 4 shows the number and percentage of ears collapsed at different static ear canal pressure levels. About 4.9%, 38.5% and 40.2% of the ear canals collapsed when static ear canal pressure reached -50 daPa, -100 daPa, and -150 daPa, respectively. Cumulatively, 83.6% and 90.2% of ear canals collapsed when static ear canal pressure reached -150 daPa and -200 daPa, respectively.

Figure 5 illustrates the SFI results obtained from a newborn who passed the AABR but did not pass the HFT and TEOAE tests. In the present study, this newborn was considered to have a conductive dysfunction. At ambient pressure, the first variation in sound pressure (RF1) was observed at around 400 Hz with $\Delta SPL_1$ of 8 dB. However, the second variation (RF2) was absent. With increasing positive ear canal pressures, SPL between 700 Hz and 2200 Hz decreased progressively from 70 to 66 dB at 2200 Hz. In contrast, SPL increased considerably between 500 and 1500 Hz as the static pressure changed from -50 to -200 daPa.

To investigate the effect of static ear canal pressure on SFI results in newborns with a conductive condition (did not pass the HFT and TEOAE tests), data from 10 ears were analysed. Table 2 shows mean RF1 and mean $\Delta SPL_1$ for ears with a conductive and normal condition. Results reveal that there is a trend of increasing RF1 and decreasing $\Delta SPL_1$ with changes in static pressure in the ear canal for healthy ears and ears with a conductive condition. However, RF2 and SPL2 was absent in ears with conductive condition.

4. Discussion
The present study investigated the effect of ear canal pressure on the dynamic behaviour of the outer and middle ear in newborns using the SFI technology. The results demonstrated that the dynamic behaviour of the outer and middle ear changed significantly between ambient pressure and pressurized conditions. There were also significant differences between effects of positive and negative ear canal pressures.

4.1. Effect of positive ear canal pressure on dynamic behaviour

As shown in Figure 4, SFI results obtained at ambient pressure show two regions of resonance, with the first resonance (of the outer ear) occurring at RF1 and second resonance (of the middle ear) occurring at RF2. The mean RF1 for this cohort of normal newborns was 287 ± 71 Hz, while the mean RF2 was 1243 ± 211 Hz (Table 2). These results are consistent with the results of previous studies [25, 26].

When the static pressure was increased from 0 to +50, +100 and +200 daPa, the corresponding SPL curves were progressively lower especially in the 1000 Hz to 2200 Hz region, indicating an overall decrease in SPL. This phenomenon occurred because the increase in static pressure would have distorted the ear canal and increased the ear canal volume in newborns [22], resulting in an overall decrease in SPL across the frequencies. Moreover, with increasing positive pressure, the SPL decreased progressively at frequencies between 1000 Hz and 2000 Hz, while the SPL at the lower frequencies increased slightly and steadily. Incidentally, Sanford and Feeney [24] found a similar pressure effect using wideband acoustic immittance measures. They applied positive pressure to the ear canal of 4-week-old infants and found that wideband reflectance increased in the low frequencies but decreased in the high frequencies relative to the reflectance results obtained at ambient pressure. They concluded that increased positive pressure increased the stiffness of the ear canal walls. They also found that the change in reflectance with increasing positive pressure
in older infants (≥ 12 months) was smaller than that in 4-month-old infants, indicating maturation of the outer and middle ear with age.

A close examination of the dynamic behaviour showed that when positive pressures up to +200 daPa were applied to the ear canal, RF1 and RF2 increased (Figure 4), while both ΔSPL1 and ΔSPL2 decreased. These changes may be attributed to the increased stiffness of ear canal wall due to increased strain on the inferior wall of the ear canal and the tympanic membrane by the static ear canal pressures [26].

4.2. Effect of negative ear canal pressure on dynamic behaviour

When the static pressure was decreased from 0 daPa to -50 daPa, the SPL between 500 Hz and 1500 Hz increased considerably while the SPL remained unchanged between 1500 Hz and 2200 Hz (Figure 4). There was an increase in overall SPL which may be caused by a smaller ear canal volume induced by the negative pressure. The SPL curve obtained at a pressure of -50 daPa showed two inflexions corresponding to two resonances. Surprisingly, RF1 increased considerably and RF2 decreased slightly, while ΔSPL1 decreased considerably and ΔSPL2 remained practically unchanged. This change in dynamic behaviour indicates that the negative pressure produced greater effect on the outer ear than on the middle ear.

When a static negative pressure of -100 daPa was applied to the ear canal, the SPL increased further in the low frequencies (200-1500 Hz) with practically no change in SPL beyond 1500 Hz (Figure 4). The SPL curve changed from a curve with two inflexions to a relatively flat curve, suggesting that the ear canal had collapsed [25, 26] and no RF or ΔSPL could be measured. This SPL pattern was observed in 53 out of 122 ears of healthy newborns. For the 69 ears that did not show this flat pattern,
RF1 continued to increase and ΔSPL1 decreased while RF2 decreased slightly and ΔSPL2 decreased slightly. In general, these results indicate that the stiffness of the outer and middle ear system continued to increase with further decrease in static pressure.

Further decrease of static pressure to -200 daPa resulted in flat SPL responses in 110 out of 122 ears, indicating collapsed ear canal in these ears (Figure 4 & Table 2). At this pressure, the overall SPL increased more than that at -100 daPa due to further decrease in ear canal volume and greater stiffness of the collapsed ear canal wall. For the 12 ears that showed non-flat SPL responses, RF1 and RF2 increased considerably while ΔSPL1 and ΔSPL2 continued to decrease.

4.3. Acoustic-mechanical properties of the outer and middle ear in healthy newborns

The dynamic behaviour is dependent on the acoustic-mechanical properties of the outer and middle ear system in response to sound stimulation under ambient or pressurized conditions. The SFI results showed that application of positive or negative static ear canal pressure resulted in significant increase in RF1 and decrease in ΔSPL1 (Tables 2 & Figure 4), indicating that the vibration of the ear canal walls was reduced as the compliant ear canal became stiffer. Wada et al. reported the relationship between the stress and strain of the cartilage of the inferior wall of the external ear canal [32]. They noted that the slope of stress-strain curve increased nonlinearly. Since the slope is equivalent to Young’s modulus, the increase in the slope leads to an increase in the stiffness of the ear canal wall. Hence, when the ear canal was pressurized, the strain of the inferior wall of the ear canal could have increased, leading to an increase in the stiffness of the ear canal wall and resulting in higher RF1 and smaller ΔSPL1 [26]. Such pressure-related effects have also been observed by Sanford and Feeney [24] who remarked that the compliant energy-absorbing ear
canal walls in young infants became stiffer with the introduction of an external static pressure.

The SFI results showed that application of positive or negative static ear canal pressure also resulted in an increase in RF2 and decrease in ΔSPL2. When compared to the results obtained at ambient pressure, the changes in RF2 and ΔSPL2 were small for static pressures up to ±100 daPa. However, these results suggest that pressurizing the ear canal produced less impact on the acoustic-mechanical properties of the middle ear than on the outer ear.

Further observation of the impact of static pressure on the volume displacements (ΔSPL1 and ΔSPL2) of the outer and middle ear revealed differential effects depending on the direction of the pressure change. For example, mean ΔSPL1 decreased progressively from 8.2 dB at ambient pressure to 2.8 dB at +200 daPa and 3.6 dB at -200 daPa (Table 2). This finding suggests that positive (+200 daPa) static pressure produced a greater impact than negative pressure (-200 daPa) on the mobility of the outer ear. This observation is supported by a three-dimensional nonlinear finite-element model study of a 22-day-old neonate [22]. In this study, Qi et al. [22], reported that displacements of ear canal wall are slightly larger under positive pressures than under negative pressures.

In contrast, mean ΔSPL2 decreased progressively from 5.0 dB at ambient pressure to 4.0 dB at +200 daPa and 1.8 dB at -200 daPa (Table 2). This finding suggests that positive (+200 daPa) static pressure produced a smaller effect than negative pressure (-200 daPa) on the mobility of the middle ear. This observation is consistent with the findings of Qi et al. study using a nonlinear finite element model of the newborn middle ear [33]. Qi and colleagues [33] reported larger displacement of the TM for negative pressures than positive pressures. From a clinical perspective,
the difference in the pattern of change between ∆SPL1 and ∆SPL2 revealed the differential effects of ear canal pressure on the outer ear and middle ear, respectively.

4.4. Effect of static ear canal pressure on newborn ears with a conductive condition

Figure 5 shows the SFI results obtained from the right ear of a one-day-old newborn who passed AABR, but did not pass HFT and TEOAE, indicating the possibility of a conductive condition [34]. The SPL curve at ambient pressure showed only one inflexion with RF1 at 375 Hz and ∆SPL1 of 8 dB. However, the second inflexion (RF2) in SPL curve was absent, indicating dysfunction in the middle ear. Further examination of the results showed that with increasing positive pressure to +200 daPa, the SPL varied between 66 to 70 dB. When negative pressures from -50 to -200 daPa were applied, the SPL increased significantly and progressively to 74 dB. The possibility of a collapsed ear canal at pressures from -100 to -200 daPa cannot be excluded in view of the high SPL level [26]. These SFI results represent the typical response pattern of an ear with a conductive condition.

In order to depict the dynamic behaviour of the outer and middle ear system for ears with and without conductive condition at the group level, the SFI results of the 10 ears that did not pass HFT and TEOAE were averaged and compared with normal group who passed AABR, HFT and TEOAE (Table 2). Overall, RF1 increased and ∆SPL1 decreased as static ear canal pressure was either increased or decreased for both groups. However, the results of static pressure on the dynamic behaviour of the middle ear in ears with a conductive condition showed a distinctive pattern from that in healthy ears (Figure 5). None of the SPL curves corresponding to static pressures of -100, -50, 0, +50, +100, and +200 daPa showed any inflexion (resonance) in the frequency region between 1000 and 2000 Hz, clearly showing
absence of RF2. This pattern is clinically significant as it can potentially identify ears with a conductive condition.

4.5. Collapse of ear canal at static negative pressures

As shown in Table 4, the number of ears with collapsed ear canal increased with increasing static ear canal pressure. About 4.9 percent of ears had this condition even at a mild negative pressure of -50 daPa, indicating that ears with very flaccid ear canal walls could collapse at this pressure. At ear canal pressures of -100 and -150 daPa, the proportion of ears with collapsing ear canal conditions increased to 38.5% and 40.2%, respectively, indicating that the flaccid ear canal walls in newborns are sensitive to negative ear canal pressures. Only 12 ears did not show any evidence of collapsed ear canal at a pressure of -200 daPa. These results provide further evidence that the ear canal walls of newborns are usually highly compliant and that the inferior wall elastic cartilage in the ear canal may be deformed when a negative pressure of about -200 daPa was applied [15, 16, 19, 22, 23, 35]. It can be predicted that older infants, who have less compliant ear canal walls, would have a smaller proportion of ears with a collapsed ear canal condition than newborns at -200 daPa. Hence, these results of collapsed ear canals at negative ear canal pressures may provide information on the maturation progress of the infant ears.

In a recent study using gel model, Murakoshi et al. [26] showed that infant ear canal started collapsing when a significant negative pressure was applied to the ear canal. At -200 daPa, the ear canal behaves like a 5 mm calibration cavity. They noted that a neonate’s ear canal probably collapsed at about 5 mm from the probe tip by application of negative pressure, resulting in a similar response obtained in the 5 mm calibration cavity. Clinically, these results imply that tympanometric procedures on newborns should not apply negative ear canal pressures beyond -200 daPa because of
the collapsed ear canal conditions. The collapsing ear canal in newborns due to negative static ear canal pressure beyond -200 daPa would render the measurement of peak compensated static admittance using the negative tail compensation method unreliable.

4.6. Limitations

Although the SFI test was automated to perform HFT and SFI smoothly, it required multiple pressurizations as a sweeping frequency tone was delivered to the ear. While the pressurization might be a source of discomfort for newborns, the SFI test required a tight probe seal for repeated sweeps. At times, it was difficult to maintain a hermetic seal for the entire test for some newborns. This difficulty was partially overcome by testing newborns when they were asleep.

Additionally, use of multiple probe tips for conducting HFT, TEOAE and SFI tests in the present study disturbed some newborns. Testing had to be discontinued for some newborns who became unsettled due to multiple probe insertion. Improvement in instrumentation to include a single probe assembly to perform multiple tests is desired. This improvement will reduce overall testing time and increased completion rate in testing newborns.

Another limitation of the present study is related to the lack of “gold standard” for confirmation of middle ear status in newborns. A pass in AABR does not rule out subtle middle ear dysfunction [28, 30]. Similarly, a pass in HFT or TEOAE test alone does not guarantee normal middle ear function, as infants and children with subtle middle ear dysfunction can pass this test [29, 36]. While the use of single test alone may not be accurate, use of battery of tests may provide greater assurance of an efficient conductive pathway in newborns. Hence, a test battery approach was used in the present study to evaluate the middle ear status [37]. However, it is acknowledged
that the test battery reference standard is not an ideal “gold standard” for detecting conductive conditions.

5. Conclusions

The present study found that applying positive or negative pressure to the ear canal of healthy newborns increased the RF1 and RF2, but decreased ΔSPL1 and ΔSPL2. The dynamic behaviour of the outer and middle ear under positive pressures was distinctively different to that under negative pressures. More than 83% of ears showed evidence of collapse when the static pressure was decreased to -150 daPa. Furthermore, the effect of ear canal pressure on the outer and middle ear of newborns with a conductive condition showed a different pattern of results from that of healthy newborns, suggesting that the dynamic behaviour observed under various static ear canal pressures can provide additional clinical information for differentiating healthy ears from ears with a conductive condition.

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References

Table 1. Mean, standard deviation (SD), and median of gestational age, age of testing and birth weight for 86 newborns (45 males; 41 females).

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| Conductive condition | Absent | Absent |

Table 2. Mean, standard deviation (SD) and median of RF1, RF2, ΔSPL1, ΔSPL2 at different static ear canal pressure levels for 86 newborns with normal middle ear condition (Note: At -50 daPa, n=116 as 6 ear canals collapsed; at -100 daPa, n=69 as 53 ear canals collapsed and at -200 daPa, n=12 as 110 ear canals collapsed) and 10 newborns with conductive condition (Note: n = 10 ears).
Table 3. Pair wise comparisons: Results of post hoc analysis with Bonferroni adjustment for SFI measures at different static ear canal pressures (daPa) relative to ambient pressure.

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<th>0 Vs 200</th>
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*significant with p<0.05
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<th>Number of ears (n)</th>
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Table 4. Total number (n) and percentage (%) of ear canals collapsed at different negative static ear canal pressures (daPa) relative to ambient pressure (0 daPa)
Figure 1. SFI results obtained (a) from a normal hearing adult who passed 226 Hz tympanometry. The SPL curve at ambient pressure shows a single variation at around 1220 Hz; (b) from a normal hearing newborn who passed HFT and TEOAE. The SPL curve at ambient pressure shows two variations in sound pressure, one (RF1) at around 260 Hz and the second (RF2) at around 1220 Hz. Note: RF = resonance frequency.
Figure 2. Block diagram of SFI meter used to test newborns in this study. The SFI meter consists of a personal computer, an AD/DA converter, a probe system, a stepping motor, a syringe pump, a pressure sensor and a relief valve. This new unit is controlled using LabView under WINDOWS. (From Murakoshi et al (2013). Int J Pediatr Otorhinolaryngol. Copyright © 2012 by Elsevier Ireland Ltd. Reprinted with permission of Elsevier Ireland Ltd.)
Figure 3. SFI results obtained from a healthy 2-day-old newborn who passed the test battery. The static ear canal pressure (daPa) applied were +200, 0 (ambient pressure), and -200 daPa. $P_a1$ and $P_b1$ are the maximum and minimum sound pressures, and $F_a1$ and $F_b1$ are the frequencies corresponding to these sound pressures (first variation). $P_a2$ and $P_b2$ are the maximum and minimum sound pressures, and $F_a2$ and $F_b2$ are the frequencies corresponding to these sound pressures (second variation). $RF1$ and $RF2$ are defined by $(F_a1+F_b1)/2$, and $(F_a2+F_b2)/2$, respectively. $\Delta SPL1$ and $\Delta SPL2$ are defined by $(P_a1- P_b1)$ and $(P_a2-P_b2)$, respectively. Figure also shows an increase in $RF1$ and $RF2$ when a pressure of +200 daPa was applied to the ear canal.
Figure 4. SFI measures at different static ear canal pressures (Ps). The static ear canal pressures (daPa) applied were +200, +100, +50, 0 (ambient), -50, -100, and -200 daPa. P_a1 and P_b1 are the maximum and minimum sound pressures, and F_a1 and F_b1 are the frequencies corresponding to these sound pressures (first variation) at 0 daPa. P_a2 and P_b2 are the maximum and minimum sound pressures, and F_a2 and F_b2 are the frequencies corresponding to these sound pressures (second variation) at 0 daPa.
Figure 5. SFI results obtained from the right ear of a one-day-old newborn who passed AABR but did not pass HFT and TEOAE. The static ear canal pressures (daPa) applied were +200, +100, +50, 0 (ambient pressure), -50, -100, and -200 daPa.