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Neonatal hearing screening using a smartphone-based otoacoustic emission device: A comparative study

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ABSTRACT

Objective: Increasing options are becoming available for clinicians and healthcare professionals who use smartphone-based applications (apps) to identify hearing loss. The use of smartphone-based apps for newborn hearing screening (NHS) has been proposed as an alternative screening method in NHS programs. This study aims to compare the screening outcomes of a smartphone-based otoacoustic emission (OAE) screening device to a commercially available OAE screening device.

Methods: NHS was conducted in the post-natal maternity ward and neonatal intensive care unit (NICU) of two tertiary public healthcare hospitals over a period of 8 months. Within participant DPOAE and TEOAE screening outcomes of a smartphone-based OAE device (hearOAE) were compared to that of the Otodynamics ILO V6.

Results: A total of 176 infants (n = 352 ears; 48.9 % female) underwent NHS (DPOAE n = 176; TEOAE n = 176). The mean age at was 4.5 days (SD 11.3). Signal-to-noise ratio (SNR) were higher with the hearOAE with TEOAE NHS, and equivalent or higher SNR at four out of six frequencies with DPOAEs. Mean and total noise levels were significantly lower for the hearOAE compared to the Otodynamics with DPOAEs noise levels of five out of six frequencies being equivalent to, or lower than the Otodynamics ($p < 0.001$). Lower noise levels are likely to be advantageous in less-than-ideal test conditions. Inter-device DPOAE comparison indicated no statistically significant difference in the refer rate between the devices ($p = 0.238$). DPOAE pass rates between devices differed in 6 ears ($p > 0.05$), and in 20 ears for TEOAEs, with the hearOAE demonstrating a higher TEOAE pass rate ($p = 0.009$). The hearOAE did, however, demonstrate lower noise levels at three out five frequencies, which may have impacted the pass rate. No statistically significant correlation was found between the independent variables and the screening outcome (pass/refer) for TEOAEs using either device ($p = 0.105$ to 0.810). A high concordance of NHS outcomes within-participants of 89.7 % and 85.0 % for DPOAE and TEOAE respectively, was measured.

Conclusions: The mHealth based OAE device demonstrated good agreement in NHS outcomes compared to a commercially available device. This verifies the performance of the novel smartphone based OAE device, and may facilitate increased accessibility of decentralised NHS service in resource constrained populations.

1. Introduction

Hearing loss is the most prevalent sensory disability globally and a condition that is of growing concern [1]. Recent estimates by the World Health Organisation (WHO) have shown an increase in the prevalence of children with disabling hearing loss [2]. It is estimated that at least thirty-four million children globally under the age of fifteen have disabling hearing loss [3]. Congenital/early-onset childhood hearing loss is associated with delayed speech and language development [4]. Cognitive, social, emotional, as well as academic development are subsequently also negatively affected [5,6]. Newborn hearing screening (NHS) protocols reportedly reduce adverse effects in the future [7]. The Early Hearing Detection and Intervention (EHDI) benchmark of the "1-3-6 principle" as proposed by the Joint Committee on Infant Hearing (JCIH), states that all infants' hearing should be screened by 1 month, hearing loss should be diagnosed by 3 months, and intervention should commence by six months of age [6]. Evidence suggests that children with hearing loss who were identified earlier and received early intervention, have better speech and language outcomes when compared to those whose hearing loss diagnosis and intervention were delayed [3,8]. Advocacy for universal NHS is based on two concepts. First, a critical period exists for optimal language skills to develop; and second, timely

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intervention of hearing loss has been shown to improve communication skills [8]. The positive long-term effects of early detection and intervention through NHS on children's language, cognition, and academic development are well documented [5,6]. NHS, subsequent diagnosis and intervention, offers children with congenital/early onset hearing loss the best chance for age-appropriate speech and language development.

The JCIH recommends objective measures as methods for NHS due to the poor sensitivity demonstrated by the results yielded by subjective measures in terms of outcomes [8]. NHS protocols vary globally, and this may be due to what is considered feasible for specific contexts [9]. Currently, otoacoustic emissions (OAE) and/or automated auditory brainstem response (AABR) screening for infants are recommended as screening tools in NHS programs [9]. The most commonly used model for NHS has been a hospital-based screening program employing a team of dedicated screeners measuring OAEs in infants prior to discharge [10]. Evoked OAEs, namely, transient evoked OAEs (TEOAEs) and distortion-product OAEs (DPOAEs), are commonly used techniques for testing the integrity of the outer hair cells of the cochlea due to their efficacy and test outcomes. Both TE- and DPOAEs are highly sensitive (85–100 %) and specific (91–95 %) [11,12].

A model of hospital-based NHS prior to discharge works well in hospital settings where the hospitals are served by single large maternity units [13]. Challenges that may occur with NHS within certain hospitals include, but are not limited to, poor infrastructure, demographics, accessibility, costs, and limited hearing screening programs, which thus affect the implementation of NHS across low-middle-income countries (LMICs) as well as upper-middle-income countries (UMICs) [14,15]. Challenges to NHS include insufficient resources, human resources, and high patient load [16,17]. Furthermore, the challenges in LMICs are exacerbated due to additional burdens such as poverty or life-threatening conditions, such as tuberculosis (TB) and human immunodeficiency virus and/or acquired immunodeficiency syndrome (HIV and/or AIDS) [17]. These are viewed as a priority, whilst hearing loss may be viewed as less urgent [17]. Moreover, the COVID-19 pandemic has put further strain on available resources [18].

Countries in sub-Saharan Africa still appear to be in the initial stages of implementing NHS programs for the early identification of hearing loss, especially due to limited access to healthcare services. Evidence suggests that in sub-Saharan Africa, where several types and levels of healthcare exist, NHS programs have not been standardized or uniformly implemented [19,20]. Regrettably, it is estimated that less than 10 % of the one million infants born annually in South Africa, for instance, will have the prospect to have their hearing screened [21]. Thus, many children in sub-Saharan Africa with congenital/early-onset hearing loss will most likely not receive NHS and consequently not receive critically required early auditory stimulation [21]. Increased efforts towards ensuring NHS are therefore required in resource-constrained contexts.

Increasing options are becoming available for consumers and clinicians who use mHealth-based smartphone applications to detect, diagnose, and treat hearing loss [22]. Advantages of smartphone-based digital hearing screening solutions, for both the consumer and clinician, include accessibility, affordability, and software-based quality control, alongside integrated cloud-based data management [23,24]. A study was conducted using a smartphone-based pure-tone audiometry application to subjectively screen for hearing loss in children and adults at primary healthcare clinics [25]. The application provided time-efficient identification of hearing loss, with adequate sensitivity and specificity for accurate testing in primary healthcare settings for a cooperative population [25–27]. In a systematic review, it was indicated that only a few applications that are currently available for screening and diagnostic hearing assessment have been validated in peer-reviewed studies [28]. Of these applications that have been validated, none of them have been appropriate for NHS, and further research is required to fully understand their accuracy in detecting ear and hearing pathology [26,28].

A smartphone-based OAE device, the hearOAE, was recently developed and the screening version of the OAE software offers automation of DPOAE and TEOAE test procedures and the interpretation of the results [25]. An mHealth device such as the hearOAE has the potential to offer NHS at a significantly reduced cost, thereby increasing accessibility to the equipment and NHS services in resource-constrained communities. The integration of low-cost mHealth technologies in hearing health care facilitates the decentralization of services to communities and health centres in LMICs and UMICs as the first point of access [27]. Several OAE systems are currently available commercially, but empirical evidence on their performance is limited for most devices. Also, to the authors' knowledge, there are no smartphone-based OAE devices available. Therefore, the current study aimed to compare the NHS outcomes of a smartphone-based OAE screener to an empirically validated, commercially available OAE device. More specifically, the within-participant outcomes of the OAEs, in terms of screening concordance, signal, noise, and SNRs, were compared.

2. Material and methods

2.1. Study design

A cross-sectional, within-participant comparative design was employed to compare the screening outcomes of a smartphone-based OAE screener (hearOAE) to a commercially available, established OAE screening device (Otodynamics ILO v6). To date, TEOAEs have been assessed in clinical practice mainly using the ILO system (Otodynamics Ltd., Hatfield, UK) [29]. This system is often considered as a reference OAE device and is frequently referred to in literature as it was created jointly with the pioneer of OAEs (Prof. David Kemp), in the late 1970s, which is why it was chosen for the purpose of the current study [29]. Both DPOAE and TEOAE NHS outcomes were evaluated. The study was approved by the Faculty of Humanities and the Faculty of Health Sciences at the University of Pretoria (HUM034/0820), as well as by the Free State Department of Health (FSDoH), on the National Health Research Database (FS_202102_006).

2.2. Research setting

An NHS program was initiated at two tertiary public healthcare hospitals in the Free State province in South Africa. The NHS program at both hospitals implemented a one-step TEOAE and DPOAE screening protocol at a tertiary healthcare level where only OAEs were performed as a screening measure on each infant [30,31]. The study was conducted in the post-natal maternity unit, and the baby-room of the two hospitals or in a quiet adjacent room. The post-natal maternity ward of a Tertiary Hospital encompassed twenty wards with four beds in each ward. The beds were not always fully occupied. The baby-room at an Academic Hospital consists of a single ward with sixteen beds, and the infant population that underwent NHS was made up of graduates of the neonatal intensive care units (NICU) who were ready to be discharged. The infants were classified into three categories based on their risk for presenting with congenital/early onset hearing loss, namely: 'no-risk' infants; 'at-risk' infants; and infants admitted to NICU. All infants born with risk factors for hearing loss according to the JCIH EHDI position statement (2019) but were not admitted to the NICU were classified under the 'at-risk' category [6].

2.3. Study population

The inclusion criteria for infants were specified as infants < three months of age, as well as the willingness of the caregiver to give consent for NHS and for participation in the study. Infants with active otorrhea and those with diagnosed neurological disorders that were verified according to the information indicated in their "Road-to-Health" booklets (a record of the infant's growth, development and immunization), were excluded as study participants. Informed consent was obtained from

each parent/caregiver before enrolment in the study. No parent/caregiver refused to consent to the NHS service and to participate in the study.

A total of 176 infants (352 ears; 48.9 % female) underwent hearing screening by a dedicated screener. Of the total sample, 50 % (n = 176 ears) of infants were screened with DPOAE and 50 % (n = 176 ears) were screened with TEOAE. The mean age at the time of screening was 4.5 days (SD 11.30), with the minimum age being a few hours after birth and the maximum age being approximately (13 weeks). For the total sample, the mean birth weight was 303.66 g (SD 0.46) (n = 176). The majority (72.2 %) of the infants were categorized as no-risk infants, whereas 13.0 % were considered 'at-risk.' Infants who were admitted to the NICU amounted to 14.8 % of the study sample.

2.4. Material and apparatus

DPOAE and TEOAE screenings were performed using both the commercially available OAE screening device, namely the Otodynamics ILO288 Echoport Plus OAE system, as well as the smartphone-based OAE screener device, the hearOAE. The Otodynamics ILO OAE device operated through a laptop and software (version 6) that stored test results on the laptop database [32,33]. The manufacturing of the hearOAE device complied with recommended manufacturing practices as dictated by ISO 13485 and 21 CFR part 820. The hearOAE consists of: 1) the Codec device that contains the hardware (version 0503) and software (version 2020–11) for signal generation and measurement; and 2) a probe connected to the Codec made up of two drivers/receivers and a microphone (version 1.0). The Codec device is powered by a rechargeable battery. The hearOAE was connected to and operated using hearOAE application (V1.3-dev) loaded on a smart device, Samsung Galaxy Tab A, viaBluetooth.

Prior to commencement of data collection, the hearOAE was calibrated according to EN 60645–6 'Electroacoustics – Audiometric equipment – Part 6: Instruments for measurement of OAEs'. Device validation was done in accordance with the requirements of EN 60645–6, §6 'Demonstration of conformity with specification'.

The hearOAE used a single-option operation and was solely dedicated to screening, while the Otodynamics ILO devices required a menu of steps because it has multiple clinical applications. Probe tips in various sizes were used to measure the OAEs, and alcohol swabs were used to disinfect reusable probe tips after each use. Probe cavity check for the Otodynamics was performed on a weekly basis using an optically transparent 1 cc probe cavity. Responses at 1, 2, and 4 KHz were observed where any variation in response greater than 3 dB SPL was accepted as significant. In the case where the probe was off-calibration, the sound tubes were checked, and the couplers were changed then calibration was repeated. The hearOAE probe cavity check followed a similar procedure. To check hearOAE volume calibration, "cavity check" tab on the start screen was selected, then the probe was inserted into the volume cavity of the Codec and a green tick was displayed on the screen once calibration was successfully complete. The researcher could not move onto the screening protocol screen in the case where the probe was off-calibration. Re-calibration had to therefore be repeated for researcher to continue with NHS.

The DPOAE screening protocol used included a 65/55 dB SPL stimulus intensity for the lower f1 frequency and higher f2 frequency. The frequencies tested were 1, 1.5, 2, 3, 4 and 6 kHz for DPOAE in both screening devices. The overall pass criterion for DPOAE screening was a DPOAE signal-to-noise ratio (SNR) of greater than or equal to 6 dB for four out of six test frequencies in both screening devices [34]. The frequencies tested for TEOAEs were 1, 1.5, 2, 3, and 4 kHz. TEOAE stimulus intensity level was presented at 80 dB SPL, and the overall pass criterion was an SNR of 3 dB or more in three out of five frequencies. Both devices required a probe fit check before the commencement of each OAEs screen. The hearOAEs integrated cloud-based data management system allowed for remote monitoring of testing, thus allowing for an audiologist or program coordinator to intervene when required. The data collected was stored on a secure AWS cloud server. AES256 encryption was used to encrypt the data at rest in the cloud. The cloud data management system was also fully POPIA compliant. Additionally, the integrated cloud-based data management system also allowed for advanced features such as location-based referrals and reporting.

2.5. Screening personnel

The first author (an audiologist with experience in NHS) was the designated screener at the two hospital sites. Two additional qualified audiologists assisted with NHS and administration tasks at the data collection sites.

2.6. Protocols and methods

A bilateral screening with either DPOAE or TEOAE was performed with both the Otodynamics ILO and hearOAE devices. Either screening device was used to perform the screening in a randomized, alternating method between the infants using a pre-compiled list. Each infant was screened with DPOAE in one ear and TEOAE in the other ear.

In instances where an infant became restless or irritable during the NHS, the parent/caregiver was asked to attempt to feed, swaddle, and/or calm the infant. If the screener was unable to test an infant due to high noise levels and restlessness, the caregiver was asked to return at a follow-up appointment. Infants with a unilateral or bilateral refer outcome were referred for a second screening, scheduled to coincide with their next post-natal follow-up visit. The follow-up screening was performed using the hospital's OAE screening device (Path Medical OAE screener). Only DPOAE was performed for the follow-up screening. The follow-up screening did not follow the protocol of the current study, and these results were not included in the data reported. If a second unilateral or bilateral refer result was obtained, the infant was referred directly to the respective tertiary hospital for tympanometry, diagnostic audiological and ear, nose, and throat (ENT) services where considered necessary. Parents/caregivers who consented to participate were counselled regarding normal speech, language, and hearing development, regardless of NHS outcome.

2.7. Data analysis

A total of 176 infants were included in the sample. DPOAE screening was completed in 175 infant ears while TEOAE screening was completed in 174 infant ears. A total of three ears were excluded from the infant group: two ears were within-participant comparison using TEOAEs with both hearOAE and Otodynamics ILO could not be recorded, and one ear where within-participant comparison using the DPOAE with both devices could not be completed.

All data from the Otodynamics ILO device was exported to Microsoft Excel. The data from the hearOAE device was stored remotely on a cloud-based database. The data from the two devices was then transferred to SPSS v28 software and analyzed using a 5 % level of significance. Only the data from the initial NHS was used. The absolute amplitude of the OAE was referred to as the 'signal,' and the difference between the absolute amplitude of the OAE and the noise floor was referred to as the SNR. These, together with the noise floor, were measured in decibel sound pressure level (dB SPL). Both mean and total (summed) OAE signal, SNR, and noise levels were calculated across frequencies to account for any frequencies with missing data with one or both devices. In order to achieve this, frequency-specific OAE measurements in dB were converted to Pascal, summed and averaged across frequencies, and then converted back to dB in order to determine the total and mean OAE signal, SNR, and noise. Frequency-specific, total, and mean OAE measurements were consequently described using mean and standard deviation (SD).

The normality of continuous variables was evaluated using the

Table 1
DPOAE mean and standard deviation for mean and total signal, noise, and SNR (n = 175 ears).

	Otodynamics ILO (dB SPL)		hearOAE (dB SPL)	
	Mean	SD	Mean	SD
TOTAL				
Signal**	14.57	10.51	10.98	9.60
Noise**	9.50	6.40	5.84	5.54
SNR*	18.36	12.19	17.40	9.40
MEAN				
Signal**	7.45	10.37	2.63	9.44
Noise**	2.37	6.34	−2.51	5.44
SNR**	11.24	11.85	9.05	9.26

dB: Decibels, SD: Standard deviation, SPL: Sound Pressure Level; *p < 0.05; **p < 0.001.

Shapiro-Wilk test. The parametric paired *t*-test (*t*) was used for variables that were normally distributed, whereas, for variables that were non-normal, the nonparametric Wilcoxon signed-rank (WSR) test was used to test for differences in cases where the same participants were involved. The WSR test (Z_{WSR}) was utilized for all frequencies except 1 kHz, where paired *t*-test was used to determine the significance of differences between SNR, overall noise, and overall signal of the two screening technologies. The Mann-Whitney *U* test (Z_U) was applied to evaluate if the device outcomes differed with respect to infant age at testing. The Pearson Chi-square test (X^2) was applied also applied to the categorical data to evaluate the differences between the two devices. Binary logistic regression analysis was performed to identify the associations of the categorical and continuous independent variables (age, status, and device) with the dependent variables (pass/refer). The percentage concordance in outcome (for both pass and refer outcomes) between the two devices for both DPOAEs and TEOAEs was calculated per ear specifically.

Table 2
Frequency-specific DPOAE screening variable outcomes for Otodynamics and hearOAE (n = 175 ears).

	Frequency	Otodynamics		hearOAE	
		Mean	SD	Mean	SD
Signal (dB SPL)	1 kHz*	4.57	8.94	4.49	10.84
	1.5 kHz**	4.56	11.97	1.04	11.74
	2 kHz**	6.64	12.65	2.29	12.45
	3 kHz**	2.36	13.01	−1.27	12.77
	4 kHz**	1.52	13.18	−2.97	11.51
	6 kHz**	4.77	15.00	−3.31	11.12
Noise (dB SPL)	1 kHz*	5.39	7.14	3.16	6.40
	1.5 kHz**	2.21	6.09	−2.55	6.21
	2 kHz**	−1.31	5.92	−6.31	5.63
	3 kHz**	−4.88	5.75	−9.75	5.30
	4 kHz**	−6.89	5.63	−11.66	4.35
	6 kHz**	−9.15	4.68	−12.68	4.90
SNR (dB SPL)	1 kHz*	−0.83	7.83	1.34	9.14
	1.5 kHz	2.35	10.93	3.59	9.29
	2 kHz	7.95	11.72	8.59	10.76
	3 kHz	7.24	12.02	8.48	11.29
	4 kHz	8.42	12.45	8.69	10.19
	6 kHz**	15.24	15.23	9.37	11.08

dB: Decibels, SD: Standard deviation, SPL: Sound Pressure Level * p < 0.05; **p < 0.001.

3. Results

3.1. DPOAE

Within-participant comparisons between the DPOAE measures across frequencies with the Otodynamics ILO and hearOAE screening devices are presented in Table 1. Both the mean and total (summed) signal, noise, and SNR values across frequencies are shown.

Mean and total OAE, signal, and noise levels in consecutive measurements for six frequencies (1, 1.5, 2, 3, 4, and 6 kHz) were recorded. A Wilcoxon signed rank test revealed statistically significant within-participant DPOAE differences between devices with reference to both total and mean signal, noise, and SNR values across frequencies (*t*=-7.90 to −3.00; p = 0.000 to 0.004). SNR was significantly higher for the Otodynamics ILO (total = 18.86 dB; mean = 11.24 dB) when compared to the hearOAE (total = 17.40 dB; mean = 9.05 dB). Noise levels were, however, significantly lower for the hearOAE (total = 5.84 dB; mean = −2.51 dB) than for the Otodynamics ILO (total = 9.50 dB; mean = 2.37 dB). There was no statistically significant difference in the refer rate between devices (X^2 (1, n = 176) = 2.000; p = 0.238). Within-participant diagnostic concordance between devices was 89.7 % for DPOAE screening.

Table 2 represents the SNR, signal, and noise levels per frequency for DPOAE in both the Otodynamics ILO and the hearOAE devices.

Statistically significant differences between signal (*t*=-6.535 to −3.942; all p < 0.001) and noise (*t* = −8.037 to −4.386; all p < 0.001) levels were measured at each frequency. No statistically significant differences in SNR levels were measured between devices at 1.5–4 kHz (*t* = −0.930 to −0.229; p = 0.117 to 0.482). Statically larger SNRs were measured with the Otodynamics ILO at 1 kHz (*t* = −2.632; p = 0.008). Noise levels were statistically lower for all frequencies with the hearOAE compared to the Otodynamics ILO (t = −4.374 to 0.369; p=<0.001 to 0.014).

3.2. TEOAE

Within-participant comparisons between the TEOAE measures across frequencies with the Otodynamics ILO and hearOAE screening devices are presented in Table 3.

Statistically higher SNR (Z_{WSR} = −6.664; p = 0.002), signal (Z_{WSR} = −6.199; p < 0.001), and noise levels (Z_{WSR} = −2.021; p = 0.043) were recorded for the hearOAE compared to the Otodynamics ILO. The total SNR for the Otodynamics ILO was overall 1.93 dB lower than the hearOAE (p < 0.001). Differences in 20 ears, with the HearOAE showing a greater TEOAE pass rate (X2 (2, n-176) = 7.54; p = 0.009). A within-participant percentage of concordance between devices of 85.0 % was calculated.

Table 4 displays the frequency-specific SNR, signal, and noise levels for TEOAE in both the Otodynamics ILO and the hearOAE devices.

SNR, signal, and noise levels were not significantly different between

Table 3
TEOAE mean and standard deviations for signal, noise, and SNR and mean signal, noise, and SNR (n = 174 ears).

	Otodynamics (dB SPL)		hearOAE (dB SPL)	
	Mean	SD	Mean	SD
TOTAL				
Signal**	10.94	6.33	13.40	6.39
Noise*	9.72	3.85	10.43	4.53
SNR**	9.25	5.25	11.18	5.01
MEAN				
Signal**	3.95	6.33	6.41	6.39
Noise*	2.73	3.85	3.44	4.53
SNR**	2.26	5.25	4.19	5.01

dB: Decibels, SD: Standard deviation, SPL: Sound Pressure Level; *p < 0.05; **p < 0.001.

Table 4
Frequency-specific TEOAE signals, SNR, and noise levels for Otodynamics and hearOAE (n = 174 ears).

	Frequency	Otodynamics		hearOAE	
		Mean	SD	Mean	SD
Signal (dB SPL)	1 kHz	2.25	7.98	3.40	6.91
	1.5 kHz**	1.57	7.54	6.67	7.74
	2 kHz**	4.39	8.07	7.99	7.55
	3 kHz**	0.83	6.46	4.94	5.79
	4 kHz	2.82	7.02	2.97	5.77
Noise (dB SPL)	1 kHz	3.33	5.15	2.56	6.02
	1.5 kHz	1.54	4.96	2.26	5.29
	2 kHz**	1.87	4.63	2.45	5.18
	3 kHz**	1.16	4.03	3.11	4.81
	4 kHz	1.68	4.96	1.52	4.96
SNR (dB SPL)	1 kHz*	−1.09	7.8	0.84	5.20
	1.5 kHz**	0.03	6.48	4.41	6.24
	2 kHz**	2.51	7.14	5.55	6.44
	3 kHz**	−0.29	4.03	1.82	4.81
	4 kHz	1.13	6.11	1.45	4.27

dB: Decibels, SD: Standard deviation, SPL: Sound Pressure Level * $p < 0.05$; **$p < 0.001$.

devices at 4 kHz ($Z_{WSR} = 0.369$ to 0.764; $p = 0.166$ to 0.724). Noise levels were lower than, but not significantly so, for the hearOAE compared to the Otodynamics at 1, 1.5 kHz, and 4 kHz ($t = -1.358$ to -1.579; $p = 0.114$ to 0.764), as was the signal at 1 kHz ($t = -1.384$; $p = 0.166$). Statistically larger SNRs were measured with the hearOAE than with the Otodynamics ILO at 1, 1.5, 2, and 3 kHz ($Z_{WSR} = -5.933$ to -1.936; all p=<0.001).

3.3. Relationship between overall outcomes and infant variables

Binary regression models assessed whether age and status (no risk, at risk, or NICU) were significant predictors of passing or referring the DPOAE and TEOAE screening. Table 5 presents the relationship between the dependent infant variables on the DPOAE screening outcomes (viz. pass or refer) for both devices. The independent variables considered in the regression analyses were age (days), and risk category (at risk, no risk, and NICU).

Age was a statistically significant predictor of outcome ($p = 0.013$; *B*: 0.004; 95 % C.I. lower: 1.013, 95 % C.I. upper: 1.312). For every day increase in age, the infants were 1.15 times more likely to refer DPOAE hearing screening with the Otodynamics ILO device. Status (NICU) also indicated statistically significant effect on the pass or refer outcome ($p = 0.029$; *B*: 1.129; 95 % C.I. lower: 1.125, 95 % C.I. upper: 8.491). Binary regression analysis showed that when using the hearOAE, infants who spent time in the NICU were 3.09 times more likely to refer DPOAE screening using the hearOAE device.

Table 6 presents the relationship between infant age and risk status on the TEOAE screening outcomes (pass or refer) for both devices.

There was no statistically significant association between the independent variables and the screening outcome (pass and refer) for TEOAE with either device ($p = 0.105$ to 0.810).

Table 5
Binary regression analysis results for the significance of DPOAE variables on overall screening outcome for Otodynamics and hearOAE (n = 175).

Independent variables	(EXP) β	SD	p-Value	95 % C.I. for β	95 % C.I. for β
				Lower	Upper
hearOAE					
Age (days)	0.984	0.021	0.425	0.945	1.024
Status			0.089		
At risk	1.287	0.556	0.650	0.432	3.829
NICU	3.091	0.516	0.029*	1.125	8.491
Otodynamics ILO					
Age (days)	1.153	0.066	0.031*	1.013	1.312
Status			0.445		
At risk	1.199	0.526	0.746	0.399	3.610
NICU	1.941	0.248	0.207	0.693	5.442

C.I.: Confidence Interval, SD: Standard Deviation, *$p < 0.05$.

Table 6
Binary regression analysis results for the significance of TEOAE variables on overall screening outcome for Otodynamics and hearOAE (n = 174).

Independent variables	(EXP) β	SD	p-Value	95 % C.I. for β	95 % C.I. for β
				Lower	Upper
hearOAE					
Age (days)	0.557	0.024	0.557	0.968	1.063
Status			0.572		
At risk	0.501	0.440	0.501	0.568	3.182
NICU	0.496	0.444	0.496	0.310	1.764
Otodynamics ILO					
Age (days)	0.015	0.024	0.528	0.969	1.064
Status			0.269		
At risk	0.879	0.450	0.810	0.371	2.168
NICU	0.443	0.502	0.105	0.166	1.186

C.I.: Confidence Interval, SD: Standard Deviation, *$p < 0.05$.

4. Discussion

The current study compared the NHS outcomes of a smartphone-based OAE device (hearOAE) with that of a commercially available device (Otodynamics ILO v6). Inter-device differences were noted within participants in the OAE SNR, signal (OAE response amplitude), and noise. Significant differences in the effect of independent variables (age and status) on the overall screening outcomes were also noted for DPOAEs between the two devices. Infants who spent time in the NICU were 3.09 times more likely to refer DPOAE screening using the hearOAE device. For every day increase in age, the infants were also 1.15 times more likely to refer DPOAE hearing screening with the Otodynamics ILO device. Fundamentally however, the percentage of concordance of NHS outcomes between the novel smartphone-based OAE and the conventional, commercially available Otodynamics device was high, namely 89.7 % and 85.0 % for DPOAE and TEOAE, respectively.

Mean and total DPOAE SNR was significantly higher for Otodynamics when compared to the hearOAE ($p < 0.001$). However, when looking at frequency-specific information, a significantly lower SNR for the hearOAE was only evident at 6 kHz ($p = 0.002$), while higher, albeit non-significant SNRs were recorded for the hearOAE compared to the Otodynamics ILO at 1.5, 2, 3, and 4 kHz. The SNR at 1 kHz was significantly higher for hearOAE compared to the Otodynamics ILO ($p = 0.008$). Stronger SNRs were therefore evident at five out of the six DPOAE frequencies with the hearOAE than with the Otodynamics ILO. Previous research has reported that with DPOAE NHS, SNR is commonly measured at frequencies of 2, 3, and 4 kHz, with the exclusion of 6 kHz [35,36]. Consequently, SNR differences noted at 6 kHz in the current study may have minimal implications in clinical settings depending on the screening protocol selected by the user.

With regards to TEOAEs, both SNR and signal, totalled and averaged across frequencies, was statistically higher for the hearOAE device compared to the Otodynamics ILO ($p < 0.001$). Frequency-specifically, results again demonstrated higher SNR and signals measured using the hearOAE versus the Otodynamics ILO at each frequency ($p < 0.001$). Screening outcomes are typically based on SNR, rather than signal. It is therefore noteworthy that the hearOAE demonstrated higher TEOAE SNR across all frequencies tested, and higher DPOAE SNR at 1–4 kHz.

The noise levels in large maternity units and NICUs frequently exceed the maximum acceptable level of 65 dBA (adjusted decibels) recommended by the American Academy of Pediatrics [5,37]. Noise is a critical parameter in NHS results especially if testing takes place in

suboptimal contexts such as noisy hospital wards or post-natal clinics. The current study revealed that total and mean noise levels for DPOAE were significantly lower for the hearOAE device in comparison to the Otodynamics ($p < 0.001$). Significant differences for TEOAE noise levels were only noted at 2 and 3 kHz where noise levels were lower for the Otodynamics compared to the hearOAE, but equivalent or lower for hearOAE at three out of five TEOAE frequencies (viz. at 1, 1.5, and 4 kHz; $p = 0.114$ to 0.764). The differences in noise levels recorded between devices were unsurprising given the dynamic nature of both physical noise from changing states of infants, and ambient noise in hospital wards where the screening took place. Nevertheless, the significantly lower total and mean noise levels measured with the hearOAE DPOAE compared to the Otodynamics ILO, with equivalent or lower noise levels at the majority of the TEOAE frequencies, suggests an advantage of the hearOAE device in noisy test conditions, as may be encountered with decentralised NHS service provision.

No significant within participant inter-device differences were noted in the DPOAE refer rates ($p = 0.238$). Conversely, there were notable differences with the hearOAE exhibiting a higher TEOAE pass rate with 20 ears demonstrating different outcomes of the 174 ears screened ($p = 0.009$). The higher noise levels measured with the Otodynamics at 3 out of 5 frequencies (viz. 1, 1.5, and 4 kHz) may have contributed to the higher HearOAE pass rate. It is not clear whether this increased pass rate indicates a higher risk of false-negatives, or if and how it relates to the sensitivity and specificity of the HearOAE device in terms of identification of hearing loss in infants as the outcomes of the diagnostic assessments the infants were not followed in the current study.

The mean age of infants at NHS was 4.5 days, but ranged from the day of birth to 13 weeks chronological age. As infants develop over the first days and months of life, their physical activity and alertness increase [19,38]. The increased noise levels may therefore explain why, with the Otodynamics ILO, for every day increase in age, the infants were 1.15 times more likely to refer to DPOAE hearing screening. Critically, as NHS was performed prior to discharge from the maternity unity, older infants reflect a longer stay in the maternity unit, and likely an associated increase in the number of risk factors for congenital and/or early onset hearing loss [39,40]. Although the majority of the infants in the current study presented with no risk factors for congenital or early onset hearing loss (72.2 %), 14.8 % of infants were NICU graduates.

In the current study, infants who spent time in the NICU were 3.09 times more likely to refer DPOAE screening using the HearOAE device. The reason for this is unclear [6,41–43]. Further investigation within this population would be needed to shed light on the results of the HearOAE screening for this infant demographic.

Hearing health care is currently moving toward equipment that is more compact, and intuitive [44]. Hearing screening has seen increasing use of mHealth approaches to improve access, quality, and convenience of hearing health care services [45]. A review revealed more than 80.0 % of available smartphone-based audiometric applications have been designed to perform audiometry, with less than 15.0 % performing otoscopy [46]. To the author's knowledge, the hearOAE is the first smartphone-based OAE device [46]. Innovations, such as the hearOAE can offer alternative models of NHS service provision that have the potential to increase and decentralise access to ear and hearing health care to underserved and resource-constrained populations by virtue of the reduced cost, increased mobility, leading to increased accessibility [47].

The hearOAE's usability in terms of overall user experience and ease of use was not assessed for the purpose of the current study. This qualitative metric is essential for assessing clinical utility and simplicity of application, particularly for various user types and differences in learning curves for each, if any. As stated by Oosthuizen et al. high usability would increase user acceptance of non-traditional screening techniques while also directly lowering training costs and time [48].

The NHS results in terms of sensitivity and specificity of identifying hearing loss were not compared in the current investigation. To address this limitation, a longitudinal study that incorporates the results of diagnostic testing for infants who passed and failed hearing screening would be necessary. It is recommended, however, that more research be done on the actual sensitivity and specificity of the hearOAE device. When a single technology methodology is employed for NHS, as was the case in the present study, there is a chance of false-positive results because OAE screening may overlook auditory neuropathy spectrum disorder (ANSD) and is more sensitivity to conductive pathology [49].

The current study was able to demonstrate equivalence of NHS outcomes of a novel smartphone based OAE device as compared to a well-known, commercially available device. Usability of the device in both hospital-based and decentralised settings by screening personnel with a variety of levels of health care training must still be explored. This may also lead to optimization of a NHS protocol, considering aspects such as choice of frequencies tested and pass criteria. Considering the affordability of available subjective smartphone-based hearing screeners, audiologists could similarly be motivated to train increased number of personnel to facilitate and expand on NHS.

5. Conclusion

Within-participant comparison of the NHS for the hearOAE device using both TEOAEs and DPOAEs compared to a commercially available OAE screener demonstrated equivalence in outcomes of $\geq$85 %. Crucially, for screening protocols, SNR were higher with the hearOAE with TEOAE NHS, and equivalent or higher SNR at four out of six frequencies for DPOAEs. Mean and total noise levels were significantly lower for the hearOAE compared to the Otodynamics with DPOAEs, with noise levels at three out of six frequencies with the hearOAE being equivalent to or lower, for TEOAEs. Lower noise levels are likely to be advantageous in less-than-ideal test conditions. This, and the equivalence of NHS outcomes, verifies the performance of the novel smartphone based OAE device, and may facilitate decentralised NHS service in resource constrained populations.

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Disclosure of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Andani Gluggy Madzivhandila: Data curation, Formal analysis, Investigation, Project administration, Writing – original draft, Writing – review & editing. **Talita le Roux:** Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing, Validation. **Leigh Biagio de Jager:** Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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