SMARTPHONE THRESHOLD AUDIOMETRY IN UNDERSERVED PRIMARY HEALTH CARE CONTEXTS

Josefin Sandström¹,²
De Wet Swanepoel³,⁴,⁵
Hermanus Carel Myburgh⁶
Claude Laurent²,³

1. Department of Public Health and Clinical Medicine, Family medicine, Umeå University, Umeå, Sweden
2. Department of Clinical Science, Otorhinolaryngology, Umeå University, Umeå, Sweden
3. Department of Speech-Language Pathology and Audiology, University of Pretoria, Pretoria, South Africa
4. Ear Science Institute Australia, Subiaco, Australia
5. Ear Sciences Centre, School of Surgery, The University of Western Australia, Nedlands, Australia
6. Department of Electrical, Electronic and Computer Engineering, University of Pretoria, Pretoria, South Africa

Address for correspondence:

Prof De Wet Swanepoel
Dept of Speech-Language Pathology and Audiology, University of Pretoria, South Africa
Tel: +27 12 4204280
Email: dewet.swanepoel@up.ac.za
ABSTRACT

Objective: To validate a calibrated smartphone-based hearing test in a sound booth environment and in primary health care clinics.

Design: A repeated-measure within-subject study design was employed whereby air conduction hearing thresholds determined by smartphone-based audiometry was compared to conventional audiometry in a sound booth and primary health care clinic environment.

Study sample: 94 subjects (mean age 41 years ± 17.6 SD and range 18-88; 64% female) were assessed of whom 64 were tested in the sound booth and 30 within primary health care clinics without a booth.

Results: In the sound booth 63.4% of conventional and smartphone thresholds indicated normal hearing (≤15 dBHL). Conventional thresholds exceeding 15 dB HL corresponded to smartphone thresholds within ≤10 dB in 80.6% of cases with an average threshold difference of -1.6dB ± 9.9SD. In primary health care clinics 13.7% of conventional and smartphone thresholds indicated normal hearing (≤15 dBHL). Conventional thresholds exceeding 15 dBHL corresponded to smartphone thresholds within ≤10 dB in 92.9% of cases with an average threshold difference of -1.0 dB ± 7.1SD.

Conclusions: Accurate air conduction audiometry can be conducted in a sound booth and without a sound booth in an underserved community health care clinic using a smartphone.

Keywords: Audiometry, air conduction, mHealth, smartphone, automated audiometer, ambient noise
INTRODUCTION

Hearing loss is an increasingly common disabling condition, largely due to rising global life expectancy leading to more age-related hearing loss (WHO, 2013a; Global Burden of Disease Study 2013 Collaborators, 2015). Disabling hearing loss, defined as a loss of sensitivity greater than 40dB in the better hearing ear for adults (≥15 years) and 30 dB for children (WHO, 2013a), is estimated to affect 360 million people globally (WHO, 2013a). Including milder degrees of loss increases the estimated number of the affected persons to more than a billion, making it a leading contributor to the global burden of disease (Global Burden of Disease Study 2013 Collaborators, 2015). The prevalence of disabling hearing loss is highest in sub-Saharan Africa, South-east Asia and Asia Pacific (6.5 to 8.3% among adults), but even in developed countries the prevalence can be as high as 4.4% (WHO, 2013a).

Early access to timely diagnosis, counseling, and commencement of intervention can minimize the detrimental impact of hearing loss and ultimately also the societal burden of disease (WHO, 2013a). Unfortunately access to hearing health care, particularly in developing countries, is severely limited (Goulios & Patuzzi, 2008; Fagan & Jacobs, 2009; WHO, 2013b). Typical ratios of audiologists to the general population reported for developing countries are one to every half a million to 6.25 million people (Goulios & Patuzzi, 2008; Fagan & Jacobs, 2009; WHO, 2013b). High-income countries also face a shortage of hearing health care workers as indicated by projections of need (Margolis & Morgan, 2008) and audiology training shortfalls (Windmill & Freeman, 2013) in the US.

To increase access to care there has been a growing interest to capitalise on mobile innovations, automation, and information and communication technologies (Swanepoel
et al, 2010a; Clark & Swanepoel, 2014). Automation refers to automated hearing health procedures with typical characteristics like ease of use, standardized settings and limited time consumption (Mahomed et al, 2013). Access to hearing health professionals can be improved for those who reside in underserved areas where facilities for hearing assessments are scarce and also for persons who are bedridden or unable to travel (Swanepoel et al, 2010a). With mobile, simple and user-friendly procedures health- and community workers without formal audiological training could perform initial assessments utilizing integrated data capturing systems for asynchronous interpretation by specialists (Clark & Swanepoel, 2014; Swanepoel et al. 2010a).

The widespread penetration of smartphones and cellular connectivity are opening up new opportunities for innovative hearing health care solutions especially in underserved areas (Kelly & Minges, 2012; Clark & Swanepoel, 2014). A number of smartphone apps for hearing tests have become available for end-users to download for a self-administered hearing assessment (Khoza-Shangase & Kassner, 2013 ; Szudek et al, 2012; Foulad et al, 2013). Reported validation results have varied and limitations have included reported apps only available on costly iOS smartphones using earphones that cannot be objectively calibrated according to international standards.

A recently developed smartphone application, however, was validated for accurate pure tone calibration using a low-cost smartphone (<$80) and headphone (<$40) with real-time environmental noise monitoring and data capturing that allows for centralised management (Swanepoel et al., 2014). In a follow-up clinical validation the hearScreen application demonstrated equivalent sensitivity and specificity performance for school-
based hearing screening at pre-specified screening intensities and frequencies compared to conventional audiometry (Mahomed et al. Submitted). As opposed to previous applications this application is not an end-user app but intended to be operated by a facilitator (e.g. community health worker, school-health nurse etc) to screen hearing abilities with a calibrated headphone operated through a user-friendly interface with automated screening protocols (Swanepoel et al, 2014).

In light of the promising validation study results the hearScreen application was adapted to allow for air conduction pure tone threshold audiometry employing either an investigator-controlled or a user-controlled method of threshold determination, similar to what was described by Van Tasell & Folkeard (2013). This prototype smartphone threshold test application may allow for a cost-effective method to determine hearing sensitivity in primary health care settings. Potentially the same equipment could be used for screenings and threshold testing, which may reduce false-positive screens with additional information provided for directed referrals to medical/audiological assessments and intervention. Furthermore, cost-effective mobile devices for air conduction audiometry could serve as tools for community-based hearing conservation and monitoring programmes for conditions such as multi-drug resistant tuberculosis that typically requires monthly audiometric assessments (Bardien et al, 2009).

This study therefore aimed to validate this smartphone hearing test in a controlled sound booth environment and in primary health care clinics in regard to accuracy, reliability and time duration.
METHOD

The institutional review board approved this study before any data collection commenced. A repeated-measure within-subject study design was employed whereby air conduction hearing thresholds determined by smartphone-based audiometry were compared to conventional audiometry.

Participants and test setting

Two groups of participants were included according to the site of assessment. The sound booth condition was conducted in conventional audiology clinics and the primary health care clinic tests were done without a sound booth.

Inclusion criterion was age >18 years irrespective of ear and hearing status. Exclusion criterion was a unilateral hearing loss >40dB HL to avoid any inter-aural effects since contralateral masking was not available in the smartphone hearing test prototype. In addition, subjects with poor concentration or poor cooperation were excluded and this group consisted of two mothers that brought their babies into the examination room and therefore weren’t alert during the instruction and examination. If a subject could not hear at the loudest level that the phone could test (90 dB HL) that specific frequency was excluded, which means that a subject could contribute to some frequencies but not always to the entire series. Across both test conditions the study enrolled 94 subjects (mean age 41 years ± 17.6 SD and range 18-88; 64% female) with 186 ears adhering to the inclusion criteria.
**Sound booth**

Sound booth assessments were done at the Department of Speech-Language Pathology and Audiology, University of Pretoria, South Africa and at the Steve Biko Academic Hospital, Department of Speech Therapy and Audiology, Pretoria, South Africa. All testing was conducted in a sound booth certified for diagnostic audiometry. Subjects included patients attending the clinics and included first time consultations and patients with known hearing loss who came for follow-up appointments. Enrolment also included persons interested to have a hearing assessment including personnel and students. A total of 64 subjects (mean age 40 years ± 18.4 SD and range 19-88; 70% female) were enrolled in this environment.

**Primary health care clinic**

Testing at the primary health care clinics was primarily performed on patients (27/30) from a primary health care clinic in Mamelodi, an underserved township in north-east Tshwane. Three other subjects were recruited from another primary health care clinic in west Tshwane (Daspoort clinic). Testing was conducted in an examination room without sound isolation and due to the busy nature of the clinics at times several subjects were examined at the same time in a room. These clinics offer hearing screening services and patients who failed the screen were enrolled for the smartphone hearing test. A total of 30 subjects (mean age 41 years ± 16.2 SD and range 18-78; 67% female) were enrolled from the primary health care clinics.

**Equipment**

The mobile phone used for the smartphone examinations was a Samsung Galaxy S3 (GT-19300), Android OS (v4.3). The software is a threshold prototype developed from
the recently validated hearScreen™ application (Swanepoel et al. 2014). Supra-aural Sennheiser HD 202 II headphones were used with equivalent threshold sound pressure levels (ETSPPLs) determined according to ISO 389-9:2009. Calibration was performed using the hearScreen™ calibration function according to prescribed standards (ISO 389-1, 1998) using an IEC 60318-1 G.R.A.S Ear stimulator connected to a Type 1 SLM (Rion NL-52). The smartphone was able to deliver pure tones (adhering to IEC 60645-1) up to 90 dB HL across frequencies assessed (0.5, 1, 2, 4 and 8 kHz). Lowest stimulus levels were 5, 10, 10, 0 and 5 dB HL for 0.5, 1, 2, 4 and 8 kHz respectively.

Conventional air conduction thresholds in the sound booth environments were conducted using a clinical audiometer (GSI 61) with supra-aural earphones (TDH49) calibrated according to ISO 389-1:1998.

In the primary health care environment conventional thresholds were measured with the KUDUwave diagnostic audiometer (eMoyoDotNet, Pretoria, South Africa), which has been validated for testing outside of a sound booth. The KUDUwave utilizes insert earphones covered by circumaural earcups and incorporates microphones that monitor ambient noise during testing. It has demonstrated accurate threshold audiometry in environments without sound treatment (Maclennan-Smith et al, 2013; Swanepoel, Maclennan-Smith et al, 2013; Storey et al, 2014; Visagie et al, 2015; Swanepoel et al. 2015). The KUDUwave audiometer was operated via an Acer Notebook running Windows XP. This audiometer was calibrated prior to the study according to ISO 389-5:2006. Average noise levels measured (3 separate occasions) in the test environment with a Type 1 SLM (Rion NL-52) varied between 67.3 and 68.7 dBA.
Procedures

Conventional audiometry in the sound booth was conducted by a registered audiologist using a modified Hughson-Westlake threshold-seeking method. Testing commenced at 1 kHz before proceeding to lower frequencies followed by higher frequencies. Testing with the KUDUwave audiometer at the primary health care clinic was performed using automated audiometry utilizing the same modified Hughson-Westlake threshold-seeking method (Swanepoel, Mngemane et al. 2010). Normal hearing was considered as a threshold at 15 dB HL.

For the smartphone testing an investigator-controlled method of adjustment was used on the smartphone user-interface. A medical student, with limited experience in basic audiometry, performed all assessments after a few hours of practice. All subjects were provided with the same oral instructions before the test in either English, Afrikaans or through an interpreter in an African language. To familiarize subjects to test signals, tones were played at elevated intensities without headphones as part of the instructions. During the test procedure, the test was paused and instructions repeated, if it was evident that a subject was not entirely sure about test expectations.

Subjects were required to sit on a chair with headphones on whilst the investigator stood behind them adjusting the volume with a slider in the right margin of the phone screen (figure 1). Test operation is by the use of an intensity slider on the smartphone touchscreen allowing patient or clinician operation (figure 1) in two stages. Subjects were required to raise their hand as long as they heard the sound and to lower it once the sound was inaudible.
Figure 1. Smartphone hearing test interface. 1) Test commences at 40 dB HL with 10 dB intensity increments; 2) When proceed is pressed increments change to 5 dB steps; 3) When proceed is pressed again threshold is accepted and 4) next frequency threshold test commences.

The first slider changes intensity in 10 dB steps starting at 40 dB once a threshold estimate is achieved by pressing the “proceed” button. The second slider changes intensity in 5 dB steps commencing 5 dB above the threshold estimate level achieved with the first slider. A repeated tone was played with a duration of 750 ms with a 500 ms pause in between, constituting a combined cycle of 1250 ms. The level determined to be the hearing threshold (i.e. 50% audibility) on the 2nd slider was selected by pressing the “proceed” button again where after the next frequency test commenced. The software automated some test features, e.g. the order of frequencies and initial dB level was preselected, but the investigator had to adjust the volume and estimate the hearing threshold according to the subject’s response. Test order was 1 kHz, followed by 0.5, 2,
4 and 8 kHz. A retest at 1 kHz was included and commenced after all thresholds for the other frequencies for that ear was obtained. Left was the default starting ear except if a subject indicated that the right ear was the better hearing ear.

The smartphone hearing test and conventional audiometry was conducted in succession. Due to the possible impact of a learning effect, fatigue, attention or motivation as suggested earlier (Mahomed et al, 2013) the order of testing was counterbalanced (53% commencing with conventional audiometry). Conventional audiometry was determined thresholds down to 0 dB HL as part of the clinical protocol whilst smartphone thresholds could only be tested down to 10 dB HL.

**Data analysis**

Data were recorded in an Excel worksheet together with demographic information. Data analyses were conducted with SPSS (v22) and MS Excel. Accuracy was calculated by a comparison of the means from the smartphone and conventional methods using the paired samples t-test. For all statistical analyses the probability value p<0.05 was considered statistically significant. Across frequencies the percentage of thresholds that did not differ more than ±5 and ±10 dB from each other was computed. To calculate the reliability of the smartphone hearing test a paired samples t-test was performed for the two measurements recorded at 1 kHz. For all smartphone hearing tests the mean test duration and standard deviations were described and compared between the booth and primary health care clinic (no booth) conditions with an independent samples t-test.
RESULTS

From the 94 subjects a total of 924 thresholds were included in the study for comparison between techniques. Table 1 provides a distribution of the hearing thresholds across different categories of hearing sensitivity recorded in the sound booth and primary health care clinic (no booth environment). Since smartphone testing could not determine thresholds down to 0 dB HL across all frequencies, as in the case of conventional audiometry, categories of threshold comparisons (table 1) were used to allow for comparisons that exclude the possible influence of a floor effect (≥15 dB HL).

Normal hearing thresholds were grouped as those ≤15 dB HL. In the sound booth 63.4% of thresholds were 15 dB HL or less (normal thresholds) for conventional and smartphone testing compared to 13.7% in the primary health care clinic environment. Smartphone thresholds (45/630) exceeded 15 dB HL in 7% of instances when

<table>
<thead>
<tr>
<th>Thresholds</th>
<th>0.5 kHz</th>
<th>1 kHz</th>
<th>2 kHz</th>
<th>4 kHz</th>
<th>8 kHz</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sound booth (n=630)</strong></td>
<td></td>
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</tr>
<tr>
<td>≤15 dB for C &amp; P</td>
<td>73.2</td>
<td>70.1</td>
<td>70.1</td>
<td>56.8</td>
<td>46.8</td>
<td>63.4</td>
</tr>
<tr>
<td>&gt;15 dB for C</td>
<td>25.9</td>
<td>25.2</td>
<td>24.4</td>
<td>31.2</td>
<td>40.5</td>
<td>29.5</td>
</tr>
<tr>
<td>≤15 dB for C &gt;15 dB for P</td>
<td>0.8</td>
<td>4.7</td>
<td>5.5</td>
<td>12.0</td>
<td>12.7</td>
<td>7.1</td>
</tr>
<tr>
<td><strong>No booth (n=294)</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>≤15 dB for C &amp; P</td>
<td>6.8</td>
<td>3.4</td>
<td>20.3</td>
<td>25.4</td>
<td>12.3</td>
<td>13.7</td>
</tr>
<tr>
<td>&gt;15 dB for C</td>
<td>64.4</td>
<td>69.5</td>
<td>66.1</td>
<td>59.3</td>
<td>77.2</td>
<td>77.2</td>
</tr>
<tr>
<td>≤15 dB for C &gt;15 dB for P</td>
<td>28.8</td>
<td>27.1</td>
<td>13.6</td>
<td>15.3</td>
<td>10.5</td>
<td>19.1</td>
</tr>
</tbody>
</table>
conventional thresholds were ≤15 dB HL, of which 81.3% were within 5 to 10 dB (table 1).

In the sound booth environment 29.5% of conventional thresholds were higher than 15 dB HL (table 1) and defined as having hearing loss. These cases had a mean difference of 1.6 dB (9.9 SD) between conventional and smartphone threshold differences in the booth environment (Table 2). Only 4 kHz did not show a statistically significant difference (p>0.05; paired samples t-test) for threshold comparisons in the sound booth environment with a mean difference of 1.0 dB (10.1 SD). In the sound booth environment 80.6% of smartphone and conventional thresholds corresponded within 10 dB of each other when conventional thresholds were >15 dB HL.

In the primary health care clinic environment (without a sound booth) 77.2% of conventional thresholds were higher than 15 dB (table 1) and defined as having hearing loss. These cases had a mean difference of -1.0 dB (7.1 SD) between conventional and smartphone thresholds (smartphone subtracted from conventional) in the primary health care clinic environment (Table 2). Across the frequencies only 4 kHz showed a statistically significant difference (p<0.05; paired samples t-test) for threshold comparisons in the primary health care clinic with a mean difference of -3.6 dB (6.3 SD). In the primary health care clinic 92.9% of smartphone and conventional thresholds corresponded within 10 dB of each other when conventional thresholds were >15 dB HL.
Table 2. Comparison of smartphone (P) thresholds to conventional (C) thresholds >15 dB HL
(Mean threshold difference = smartphone subtracted from conventional)

<table>
<thead>
<tr>
<th></th>
<th>0.5 kHz</th>
<th>1 kHz</th>
<th>2 kHz</th>
<th>4 kHz</th>
<th>8 kHz</th>
<th>ALL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sound booth</strong></td>
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<tr>
<td>Mean – C (SD)</td>
<td>32.0 (14.5)</td>
<td>35.8 (16.4)</td>
<td>45.0 (20.6)</td>
<td>49.0 (25.3)</td>
<td>44.1 (23.3)</td>
<td>41.7 (21.6)</td>
</tr>
<tr>
<td>Mean – P (SD)</td>
<td>26.8 (15.7)</td>
<td>31.9 (17.7)</td>
<td>40.8 (19.2)</td>
<td>48.0 (25.1)</td>
<td>47.3 (21.7)</td>
<td>40.0 (20.3)</td>
</tr>
<tr>
<td>Mean diff (C – P)</td>
<td>5.2 (9.0)</td>
<td>3.9 (8.8)</td>
<td>4.2 (8.7)</td>
<td>1.0 (10.1)</td>
<td>-3.1 (9.9)</td>
<td>1.6 (9.9)</td>
</tr>
<tr>
<td>(SD)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>33</td>
<td>32</td>
<td>31</td>
<td>39</td>
<td>51</td>
<td>186</td>
</tr>
<tr>
<td>± 5dB %</td>
<td>54.5</td>
<td>56.2</td>
<td>42.0</td>
<td>59.0</td>
<td>47.1</td>
<td>51.6</td>
</tr>
<tr>
<td>± 10dB %</td>
<td>72.7</td>
<td>84.4</td>
<td>87.2</td>
<td>79.5</td>
<td>80.4</td>
<td>80.6</td>
</tr>
<tr>
<td><strong>No booth</strong></td>
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<td></td>
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<tr>
<td>Mean – C (SD)</td>
<td>31.1 (13.4)</td>
<td>31.0 (11.7)</td>
<td>33.7 (12.3)</td>
<td>37.3 (14.9)</td>
<td>41.7 (18.9)</td>
<td>35.1 (15.0)</td>
</tr>
<tr>
<td>Mean – P (SD)</td>
<td>32.6 (10.8)</td>
<td>31.3 (10.9)</td>
<td>32.6 (11.6)</td>
<td>40.9 (15.3)</td>
<td>42.7 (18.2)</td>
<td>36.1 (14.5)</td>
</tr>
<tr>
<td>Mean diff (C – P)</td>
<td>-1.6 (6.4)</td>
<td>-0.4 (7.5)</td>
<td>1.2 (6.6)</td>
<td>-3.6 (6.3)</td>
<td>-1.0 (7.7)</td>
<td>-1.0 (7.1)</td>
</tr>
<tr>
<td>(SD)</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>n</td>
<td>38</td>
<td>41</td>
<td>39</td>
<td>35</td>
<td>44</td>
<td>197</td>
</tr>
<tr>
<td>± 5dB %</td>
<td>78.9</td>
<td>75.7</td>
<td>79.5</td>
<td>71.4</td>
<td>68.1</td>
<td>74.6</td>
</tr>
<tr>
<td>± 10dB %</td>
<td>92</td>
<td>97.7</td>
<td>94.9</td>
<td>91.4</td>
<td>88.6</td>
<td>92.9</td>
</tr>
</tbody>
</table>

$SD = \text{Standard Deviation}$

For the primary health care environment, where conventional thresholds were ≤15 dB HL and smartphone thresholds were >15 dB HL, smartphone thresholds were within 10 dB of 15 dB HL in 75.7% of comparisons compared to 81.3% in the booth environment (table 3).
Table 3. Distribution (%) of threshold correspondence in cases where smartphone thresholds exceeded 15 dB HL and conventional thresholds ≤15 dB

<table>
<thead>
<tr>
<th>Threshold correspondence (dB)</th>
<th>0.5 kHz</th>
<th>1 kHz</th>
<th>2 kHz</th>
<th>4 kHz</th>
<th>8 kHz</th>
<th>ALL</th>
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<td><strong>Sound booth (n=59)</strong></td>
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<tr>
<td>5</td>
<td>37.5</td>
<td>66.7</td>
<td>81.8</td>
<td>60</td>
<td>50</td>
<td>59.3</td>
</tr>
<tr>
<td>10</td>
<td>62.5</td>
<td>77.8</td>
<td>90.9</td>
<td>93.3</td>
<td>75</td>
<td>81.3</td>
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<tr>
<td>15</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>87.5</td>
<td>96.6</td>
</tr>
<tr>
<td>&gt;15</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td><strong>No booth (n=40)</strong></td>
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</tr>
<tr>
<td>5</td>
<td>12.5</td>
<td>58.3</td>
<td>40</td>
<td>75</td>
<td>75</td>
<td>51.4</td>
</tr>
<tr>
<td>10</td>
<td>62.5</td>
<td>75</td>
<td>60</td>
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<td>75.7</td>
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<td>15</td>
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<td>80</td>
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<td>94.6</td>
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<tr>
<td>&gt;15</td>
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<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
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</tbody>
</table>

Reliability of smartphone thresholds was determined as the mean difference of within-subject repeated measurements at 1 kHz in each ear for all subjects. In the sound booth reliability was -0.4 dB HL (SD 3.2) and outside the sound booth it was -0.9 dB HL (SD 3.7). There was no statistically significant difference (p=0.209 and p=0.055, respectively) in either condition.

Average test duration (excluding instructions) for smartphone hearing testing in the sound booth was 296 sec (SD 59) and outside the booth it was 355 sec (SD 48). There was a statistically significant difference between test times for the booth and no booth conditions averaging 59 sec (p<0.01).
DISCUSSION

The gold standard for air conduction pure tone audiometry remain thresholds determined in a certified sound booth with a conventional audiometer. The new smartphone-based hearing test, based on a recently reported screening version (Swanepoel et al. 2014), investigated in this study employed an investigator-controlled method to determine hearing thresholds for comparison in the same sound booth environment as the gold standard of conventional audiometry. This study provides the first evidence of accurate air conduction hearing thresholds determined by an inexpensive smartphone (Android OS) and off-the-shelf supra-aural headphones calibrated according to international standards. Previously published smartphone hearing threshold studies utilised end-user apps employing premium iOS products using intraconchal headphones supplied with the devices for which there is no standardized calibration procedure as yet (Handzel et al, 2013; Khoza-Shangase & Kassner, 2013; Szudek et al, 2012; Foulad et al, 2013).

Study findings demonstrate comparable hearing thresholds with smartphone-based audiometry compared to manual testing in the sound booth for adults. Smartphone and conventional hearing thresholds both indicated normal hearing (≤15 dB HL) in 63.4% of thresholds recorded in the sound booth. Smartphone thresholds exceeded 15 dB HL (45/630) in 7% of instances when conventional thresholds were ≤15 dB HL, of which 81.3% were within 5 to 10 dB.

In cases (183/630) where conventional audiometry thresholds exceeded 15 dB HL in the booth environment, correspondence between smartphone and conventional
thresholds was ≤10 dB in 80.6% of cases. This threshold correspondence is slightly poorer than reported (94% within 10 dB) by Foulad et al (2013) for an iOS application evaluated in a quiet environment. The variability in average threshold difference (-1.6 dB ± 9.9 SD) in the sound booth environment was slightly higher than typical test-retest variability for manual and automated audiometry (Mahomed et al, 2013). Interestingly smartphone thresholds in the lower frequencies (0.5 – 2 kHz) were slightly lower, on average, compared to the conventional thresholds in cases where conventional thresholds exceeded 15 dB HL. This may partly be due to the sampling of thresholds in this comparison, which is based only on conventional thresholds higher than 15 dB HL whilst smartphone thresholds could still have been 15 dB HL or less.

Smartphone thresholds recorded in the primary health care clinics outside a sound booth were compared to thresholds recorded with a mobile diagnostic audiometer (KUDUwave, eMoyoDotNet, Pretoria, South Africa) previously validated for testing outside a sound booth as conventional method (Maclennan-Smith et al, 2013; Storey et al, 2014; Visagie et al, 2015; Swanepoel et al. 2015). This audiometer allows for threshold testing outside a booth by incorporating double attenuation (insert earphones covered by circumaural earcups) and active noise monitoring (Maclennan-Smith et al, 2013; Storey et al, 2014; Visagie et al, 2015). In this no booth environment smartphone and conventional hearing thresholds both indicated normal hearing (≤15 dB HL) in 13.7% of threshold instances. In cases where conventional thresholds exceeded 15 dB HL the correspondence was within ≤10 dB in 92.9% of cases, similar to Foulad et al. (2013). The only significant difference between threshold comparisons in the no booth environment was at 4 kHz, with average thresholds slightly higher (3.6 dB) for smartphone compared to conventional audiometry. Clinically, however, threshold
correspondence at 4 kHz was similar to other frequencies with 91.4% within 10 dB or less of each other in comparisons where the gold standard of conventional thresholds exceeded 15 dB HL. The average threshold difference (-1.0 dB ± 7.1 SD) was similar to typical test-retest variability for manual (1.3 dB ± 6.1 SD) and automated (0.3 dB ± 6.9 SD) audiometry reported in a recent meta-analysis (Mahomed et al, 2013). Clinically therefore, smartphone audiometry was accurate for establishing normal hearing thresholds in the primary health care environment.

Test-retest reliability for repeated measurements (first and last threshold for each ear) at 1 kHz was similar for the booth and no booth environments with averaged threshold differences approximating zero with standard deviations less than 4 dB. This means in both environments test-retest reliability for smartphone thresholds was well within the typical 5 dB test-retest limits for thresholds measured in a booth (Stuart et al, 1991; Smith-Olinde et al, 2006; Margolis et al, 2010; Swanepoel, Mngemane et al, 2010; Swanepoel & Biagio, 2011).

Smartphone test duration for testing outside the booth was significantly longer, on average by 59 seconds, compared to inside the booth. This is likely because the test operator could pause the test if transient ambient noise incidences occurred or if subjects needed further test instructions. Despite the slightly longer test duration outside the booth, average test time for threshold determination across 5 octave frequencies (0.5 – 8 kHz) in both ears was still less than 6 minutes. This means that at a primary health care clinic a reliable air conduction audiogram could be determined bilaterally with a cost-effective, calibrated smartphone solution for patients suspected of
having a hearing loss. This could ensure early and affordable access to hearing health care at a primary care level (Clark & Swanepoel, 2014).

A limitation of the study included the thresholds determination method that required a test-operator to actively determine hearing thresholds. Initially this test method was intended as a self-test operated by patients. A pilot study at the primary health care clinic however, demonstrated patient difficulties operating the touchscreen slider in the underserved communities (figure 1). As a result the researcher used this test operation method to manually determine hearing thresholds. In future studies an automated test protocol utilising only a response button on the touchscreen should be investigated. Another limitation could be in the comparison of smartphone thresholds to audiometry conducted outside a sound booth in the primary health care clinic. The Kuduwave audiometer has however been validated extensively for testing in environments outside sound booths (MacLennan-Smith et al, 2013; Storey et al, 2014; Visagie et al, 2015; Swanepoel et al. 2015).

**CONCLUSION**

Smartphone hearing tests, employing calibrated headphones operated from inexpensive phones can increase hearing health care access in the future and offer the possibility of quality control and data capturing features (Swanepoel et al, 2014). This study is a step in that direction, demonstrating that accurate and time-efficient air conduction hearing thresholds could be determined in a underserved primary health care clinic using a smartphone application. This report is the first to provide validation for an application employing inexpensive smartphones (Android OS) that allows for headphone calibration according to international standards. This approach could
provide a cost-effective and accurate means to conduct community-based hearing assessments within a preventative approach through early access to care.

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**Declaration of interest**

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The hearScreen application is intellectual property owned, patented and trademarked by the University of Pretoria. The second and third authors are listed as co-inventors of the hearScreen software application.

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