

The effect of 40 kHz ultrasonic noise exposure on human hearing

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ABSTRACT

Purpose: High-Intensity ultrasound is being used for various applications in the latest consumer technology, including mid-air haptic feedback. International guidelines concerning maximum permissible levels (MPLs) for 40 kHz noise are contentious. This pilot audiometry study aimed to determine the immediate effects noise exposure at 40 kHz has on human hearing and to help inform concerns about noise exposure levels in future investigations. This study was conducted with cooperation from the NHS Occupational Health Service (UK) and was ethically approved by the Health Research Authority (HRA). **Methods:** 16 people (10 experiment, 6 control) (ages 24-67 years) were exposed to high-intensity ultrasound emitted from a haptic device (40 kHz, SPL values ranging from 100-120 dB SPL) for 5 minutes. Pure Tone Audiometry (PTA) was conducted prior to and immediately after exposure. **Results:** PTA test indicate no significant change in hearing sensitivity at any of the tested frequencies (statistical power >80% in all cases, with 5 dB threshold shift set as a clinically significant risk factor). **Conclusion:** Further studies are required to consider different age groups and to consolidate appropriate sensitivity levels to high frequency sound. Initial results suggest levels as high as 120 dB SPL could be used in future investigations.

Keywords: Ultrasound, Audiometry, Hearing

1. INTRODUCTION

Exposure to loud *audible* noise can cause temporary threshold shifts (TTS), a recoverable loss in hearing sensitivity. Repeated occurrences of TTS can ultimately lead to permanent hearing loss (1). For ultrasonic noise, these audiological effects are normally only attributed to SPLs in excess of 145 dB (2). To date, there has been no demonstration that 40 kHz ultrasound below 120 dB SPL has any effects on hearing (3). Nonetheless, ultrasound SPL in excess of 110 dB has been known to cause subjective effects in humans, and it is for this reason that many international guidelines have adopted this as their maximum permissible level (MPL) for ultrasound exposure. Currently, there is debate over the standing of these guidelines, having been based on limited and outmoded data (4). Therefore, there is a strong scientific motivation for updating current knowledge about the effects of ultrasonic noise.

Ultrahaptics is a technology that uses high-intensity 40 kHz ultrasound to produce mid-air haptic feedback (Figure 1). In order to achieve this, an array of transducers is focused at a point to produce an SPL in excess of 145 dB; a requirement for perceptible tactile sensation on the skin (5). This SPL drops significantly when away from the focus.

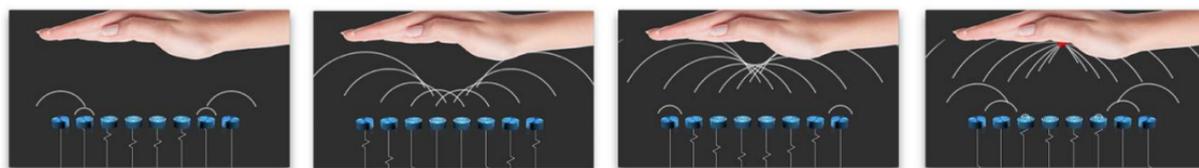


Figure 1 – Visualization of mid-air haptics using an array of ultrasonic transducers

What is of particular interest in terms of safety, is whether the incidental ambient noise (away from the focal point and reaching the ear) produced from the array is of a level that might produce TTS. With regards to quantifying and defining hearing loss, a standard threshold shift (STS) has been defined by

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OSHA as a 10 dB loss in hearing sensitivity (6,7). In contrast, threshold shifts greater than 5 dB can be considered of clinical relevance (8). Thus, this paper will need to demonstrate that the experiment had sufficient statistical power to detect a change as small as 5 dB.

Collecting accurate and meaningful SPL measurements of ultrasonic noise is challenging; ultrasonic acoustic fields are highly variable in terms of spatial and temporal distribution. Moreover, complex interference patterns can be generated by multiple coherent sources (e.g. an Ultrahaptics array). In terms of occupational health and safety for workplace monitoring, there currently exists no international standard for performing ultrasonic noise measurements (9). Since a single stationary measurement is not appropriate, it has been recommended to use a statistical approach, reporting also on the measurement uncertainty. An AU frequency weighting has also been adopted (10) but only for *audible* noise measurements in the *presence* of ultrasound.

This paper first describes measurements that were carried out to estimate the ambient SPL levels of mid-air haptics technology. It then describes a clinical trial that was conducted to determine if these noise levels would produce significant TTS within a general user-case scenario.

2. METHODS

2.1 SPL Estimates

In order to estimate ultrasound exposure levels, measurements were made using a B&K head and torso simulator (HATS) equipped with a single TYPE 4191 microphone (in the left ear). A data acquisition system comprising of a Picoscope (DrDAQ, Pico Technology) was used to collect real-time SPL measurements with digital implementations of a microphone equalization filter and a 1/3-octave band-pass filter centered at 40 kHz. SPL values were exponentially time weighted using a 1s time constant; equivalent to the ‘SLOW’ setting on a standard sound level meter.

As array output, a focal point was generated from the array at a height of 20 cm, centered over the array and tracing a 3 cm radius circle rotating at 100 rps. This is a typical output to create a circle haptic sensation. The HATS was kept approximately within ‘arms-length’ (~60cm) and was pseudo-randomly translated and rotated manually in the transverse plane. Results shown in Figure 2 are illustrative of a typical SPL exposure ($L_{eq} = 118$ dB SPL). Also shown are statistical measures $L_{10,50}$ and L_{90} that describe levels as percentile thresholds.

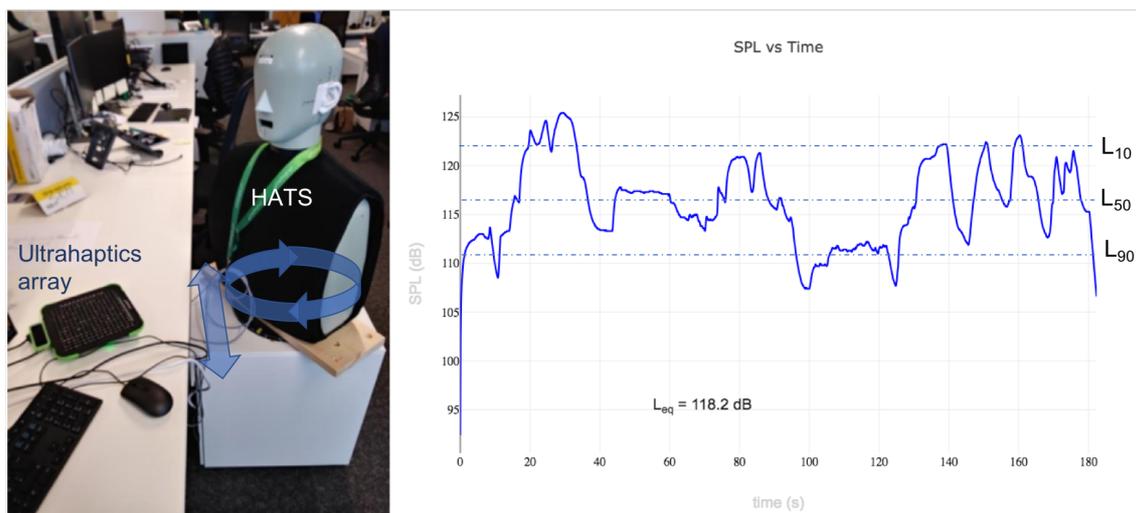


Figure 2 – (left) HATS setup with permissible motion paths. (right) SPL measurements (1/3-octave band , $f_c=40$ kHz) over time. $L_{eq}=118$ dB, $L_{max}=125$ dB, $L_{10}=122$ dB, $L_{50}=116$ dB, $L_{90}=111$ dB.

2.2 Audiometry

Pure Tone Audiometry (PTA) was carried out at an NHS clinic (Avon Partnership Occupational Health Service). Prior to this experiment, ethical approval was obtained through the UK Health

Research Authority (HRA) by the Southwest Research Ethics Committee. The experimental design consisted of a simple before-and-after noise exposure comparison of PTA results. A total of 16 participants (1 female, 15 males), ages [24-67], recruited from Ultrahaptics employees, were randomly split into experimental ($n_e=10$) and control ($n_c=6$) groups. All recruits were self-reported to be free of any underlying otological health issues and underwent a standard otoscopy examination to check for any blockages.

For each participant, a baseline audiogram was produced from a PTA test (BILSOM CA850 Series 3 Automatic Audiometer) which covered a standard test frequency range (500, 1k,2k,3k,4k,6k,8k) Hz in both left and right ears, separately.

Baseline tests were followed immediately by 5 minutes exposure to an actively emitting Ultrahaptics array. For the control group, nothing was emitted but a LED indicator light continued to flash on the array, as in normal operation.

Participants were instructed to sit at a table, arm's length from the array, and to avoid leaning over/placing hands over the array (Figure 3). The setup aimed to mimic that of the HATS experiments for SPL estimates. All participants were supervised during this phase of the experiment to ensure conformity with safety aspects of the protocol.



Figure 3 – (Left) anechoic chamber for PTA. (right) participant setup.

After the noise exposure phase, an immediate second PTA was conducted. Additionally, participants were also given a private consultation from the audiologist about their general audiological health. All research data was assigned to an anonymous participant study ID number for subsequent analysis.

2.3 Exclusions

Data from one individual complaining of moderate tinnitus after the baseline test was excluded from this study ($n_e=9$). In some cases, participants did not produce consistent responses to the PTA test at particular frequencies, despite a repeated attempt. This occurred in both baseline and second audiograms, across both experimental and control groups. Due to testing constraints, these data points were dropped; in total 6 data points were omitted from the analysis. These were accounted for in subsequent statistical calculations with the appropriate value for sample number.

3. RESULTS

The box-plot in Figure 4 amalgamates all baseline audiograms of both experiment and control group, in both left and right ears. Figure 5 and 6 depict the threshold shift (pre exposure audiogram subtracted from the post exposure audiogram) for control and experimental group respectively. Note that hearing loss is associated with positive values of threshold shift in these figures.

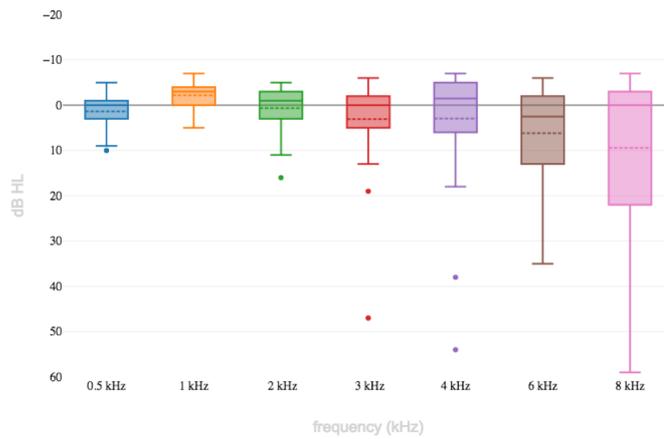


Figure 4- Box-plot of all baseline audiograms (experimental and control groups, left and right ears)

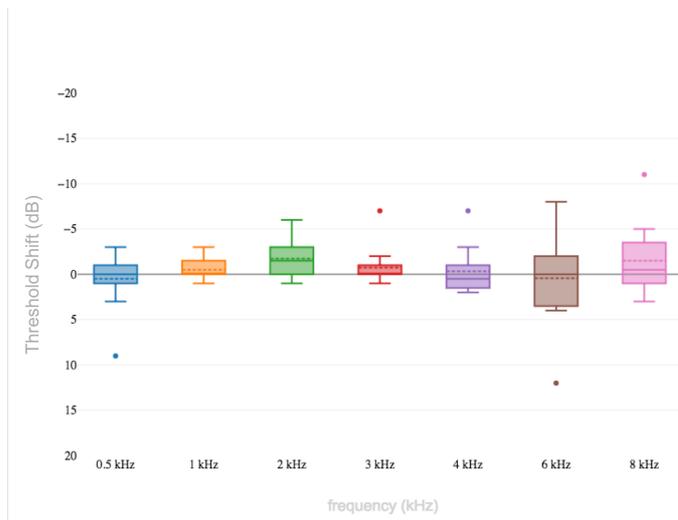


Figure 5 – Shift in hearing threshold (second audiogram – baseline) for the control group

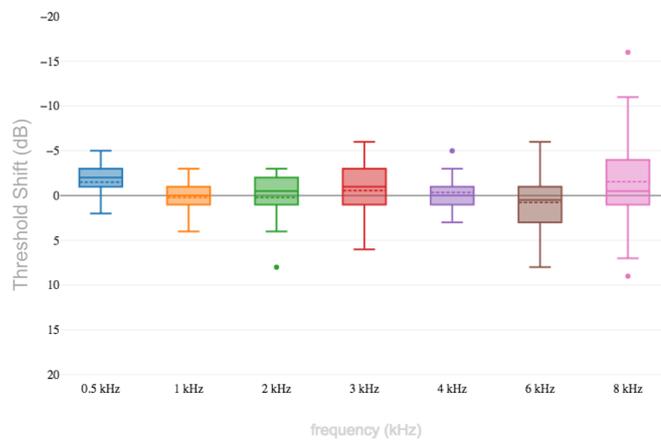


Figure 6 – Shift in hearing threshold (post exposure – pre exposure) for the experimental group

3.1 Statistical Analysis

A one-sided paired t-Test ($\alpha=0.05$) was used to test the significance of the threshold shifts observed within the experimental group. The main hypothesis underlying this experiment can be stated as follows:

H_0 : Ultrasound Exposure has no effect on PTA results ($\mu_o = 0$)

H_a : Ultrasound Exposure causes a threshold shift ($\mu_a \geq 5$ dB)

Each PTA frequency was analyzed independently. Moreover, each ear (right and left) was accounted for individually, resulting in a total of 30 ears (18 experimental, 12 control). The t-statistic was calculated at each frequency using the pooled variance from both groups. In all cases, the P-value far exceeded 0.05, indicating that H_0 could not be rejected (Table 1). However, this result alone does not rule out the possibility of some undetectable TTS having occurred due to the limitations of the experiment's sensitivity. It is important to demonstrate that a significant TTS *could be detected* with a reliably high probability (i.e. statistical power) in the event it *did occur*. Conventionally, the minimum requirement for statistical power is 80%. Subsequent retrospective analysis indicated the ability of the experiment to detect a shift as low as 4 dB at all frequencies (for an STS of 10 dB, statistical power increased to 99.9%).

Table 1 – P-value and mean threshold shift (experimental group) at each PTA frequency

f (kHz)	0.5	1	2	3	4	6	8
\overline{TTS}	-1.5	0.24	0.22	-0.56	-0.33	0.78	-1.56
P	0.99	0.29	0.35	0.8	0.72	0.23	0.88

4. DISCUSSION

4.1 SPL Estimates

It has been identified that the pinna/head related transfer function played an important role in ultrasound noise exposure as SPL levels varied greatly with head orientation (Figure 2). The HATS used in this experiment possessed only one variant of a realistic human pinna model. Moreover, the simulated workstation experiment was restricted to a single plane of motion. It was also not practical to conduct exhaustive testing on all possible haptic focal point outputs from the array.

It is important to note that in a real mid-air haptics user-case scenario, the ultrasound phased array output would be intermittent, switching on only to the presence of a hand. The hand itself would scatter the acoustic energy back towards the array. This would likely greatly reduce the overall L_{eq} that would reach the ear. However, removing hand gesture interference from this scenario provided more consistency throughout the experiment. It is not yet clear if other statistical measures (L_{max} , L_{90} , L_{10} , etc.) should also play a role in assessing risk factors to ultrasonic noise exposure.

4.2 Audiometry

Initial results suggest that high-intensity 40 kHz ultrasound of approximately 120 dB SPL does not contribute to TTS in standard PTA testing. However, there are several limitations to what can be concluded from this pilot study:

It was not practicable to refine recruitment for different age groups and/or demographics. Only one woman participated in the study, and no one under the age of twenty years old was tested; thus, potential vulnerable groups to ultrasonic noise were not adequately represented.

Intergroup comparison was not readily applicable due to the size and uneven distribution of age across the experimental and control groups. Moreover, the large age range is evident in the rapid increase in hearing thresholds above 4 kHz (Figure 4). Extended high-frequency PTA was not available at the audiometry clinic; however, it is clear that several participants would not have been able to complete a PTA test for frequencies above ~10 kHz, in any event.

PTA is heavily dependent on the test subject's ability to maintain focus throughout testing. For this reason, repeated data acquisition attempts on the same person would likely reduce reaction time and test-retest reliability, rather than actually improve the statistical certainty of results. It was for this reason that missing data points were not exhaustively chased-up.

Nevertheless, this study demonstrated the sensitivity to detect shifts as low as 4 dB using a relatively small sample size. An STS of 10 dB would have been detected with near statistical certainty. These results will help inform designs of future studies; it is likely that 5 dB TTS will be used as the benchmark for indications of hearing loss.

5. FINAL REMARKS

This experiment was conducted to ascertain what if any immediate effects high-intensity 40 kHz ultrasound has on hearing sensitivity. Results suggest that SPL levels of approximately 120 dB SPL does not contribute to TTS. It is hoped that these results can serve as a useful baseline in conducting future work that will include more controlled participation, with emphasis on potential vulnerable groups and testing using extended high-frequency PTA.

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