

Noise Exposure on Human Cochlea during Cochleostomy Formation Using Conventional and A Hand Guided Robotic Drill

Abstract:

Objective: To investigate the disturbance induced in the cochlea during cochleostomy using conventional drill and a hand guided robotic drill.

Study Design: The study is based on experimental measurements using the Laser Doppler Vibrometer during the drilling processes converted to Sound Pressure Levels (SPL) for comparison.

Setting: The study is based on experimental results of three sets of cochleostomies on human cadaver heads.

Main Outcome Measure(s): Robotic drilling, in comparison to the conventional drilling method, creates a consistently lower level of disturbance in cochlea across the hearing frequency range.

Results: Robotic drilling, in comparison to the conventional drilling method, creates a consistently lower level of disturbance in cochlea across the hearing frequency range.

Conclusions: It is reasonable to conclude that robotic drilling has a lower possibility of creating acoustic trauma in cochlea that endangers the residual hearing of patients.

Key words—Hand guided robotic drill, cochleostomy, drill disturbances, hearing preservation

I. INTRODUCTION

Preserving residual hearing for patients with hearing impairments is a critical objective in ear surgery. This cautionary approach applies to cochlear implant (CI) surgery, especially for patients who still have substantial hearing at low frequencies where acoustic signals can be perceived authentically by hair cells at the apical part of the cochlea. The enhanced hearing performance following cochlear implantation indicates potential expansion of the patient group able to benefit people who have residual hearing [1].

Apart from efforts to refine electrode characteristics [1], attention has been focused on the surgical procedure, more specifically exposure to acoustic and mechanical trauma during CI surgery. Among the steps of cochlear implantation, drilling is a significant contributor to trauma caused by both the potential high level of disturbance induced and the relatively long period of surgery. A normal CI surgery takes approximately 2 hours [2]. The average period of drilling directly on the cochlea to prepare the cochleostomy is 8 minutes [3]. Cochlea can be exposed to an average sound pressure level of 89.9 dB SPL, maximal 118 dB SPL during the approximately 8-minute continuous drilling period [3]. According to information provided by The American Hearing Research Foundation, persistent sound vibration louder than 85 dB SPL can cause permanent hearing loss [4]. The hearing mechanism of the ear cannot tolerate sound levels greater than 140dB SPL and the maximum duration the ear can be exposed to a 115dB sound without permanent hearing loss is 15 minutes. When measured on temporal bones, the noise level during cochleostomy was found to be from 116 to 131dB SPL, and exceeded 130dB SPL when the endosteal membrane was touched by the burr [5, 6].

A hand-guided robotic drill has been developed by the authors for cochlear implantation focusing on the formation of cochleostomies. Although there is an ongoing debate about the optimal procedure for opening cochlea through cochleostomy or round window (RW), sometimes cochleostomies cannot be avoided, particularly if the RW is difficult to access. Cochleostomy is considered crucial to hearing preservation, not only because it exposes the cochlea to perilymph and the risk of drill bit entering scalar vestibule, but also because the action of drilling can cause inner ear trauma. Drill induced mechanical trauma is proven to be severe in middle ear surgery, especially if the ossicular chain is drilled unintentionally. Using a robotic device to perform cochleostomy can help to improve the consistency and accuracy. An innovative tactile method to automatically discriminate mediums and structures ahead on a cutting tool trajectory has been demonstrated successfully in surgery to produce precise cochleostomies [7]. The method enables preservation of fine tissue structures by simultaneously determining the state of the process and automatically stopping the drilling if undesired drilling medium is detected. Most important, this is used to achieve high tissue preservation and low tissue trauma in surgery [8-10].

In this paper, the hand-guided robotic drill is compared with a conventional drill on mechanical trauma introduced during cochleostomy formation. The tests were performed on two human cadaver heads. Three sets of cochleostomies were created. The Middle Ear Transfer Function (METF) was measured on each of the tested ear

47 specimen. Drilling disturbances measured by the Laser Doppler Vibrometer (LDV) during the drilling process
48 were converted to Sound Pressure Level (SPL) to enable comparison.

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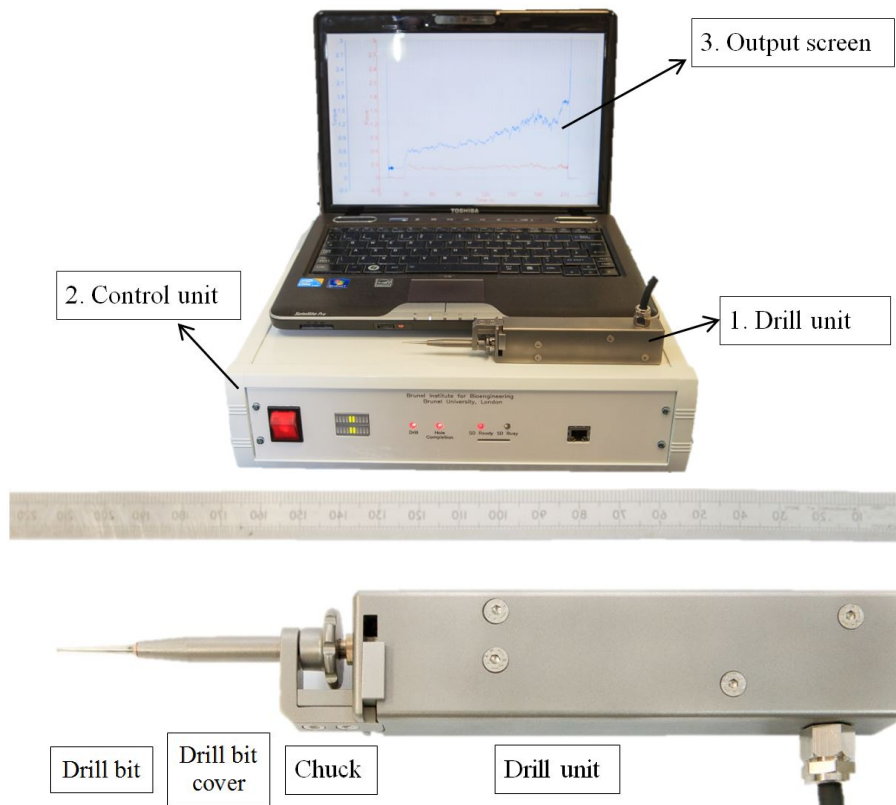
II. METHOD AND MATERIAL

50 A. Hand guided robotic drill

51 Robotic approach for surgery has made its mark as a precise means of tool deployment in surgical procedures
52 [11]. It has demonstrated consistently positive results [12-14] for certain procedures, such as laparoscopic surgery,
53 with reduced length of stay and blood loss [15,16]. Several robotic devices have been developed for minimally
54 invasive cochlear implantation [17-19]. Such robotic devices require high resolution CT images for the operator
55 to pre-plan the drilling path [17,18] or calibrate the robot [19]. During the surgery, an image navigation system is
56 used to track the movement of the robotic arm relative to the patient. Primarily for such robotic device
57 development is focused on creating an access tunnel to cochlea, avoiding the facial nerve during the drilling
58 process. Similar to many other procedures, the upfront cost, surgeon training overhead, consumable and
59 maintenance costs of an extensive system cannot be justified [20]. Meanwhile, a number of hand-guided robotic
60 systems which are smaller and intuitive to use have been developed. For example, to assist gripping tissues
61 (Laparoscopy), guiding hand-held instruments and in cutting applications (knee joint replacement surgery) [20-
62 24]. Hand-held robots have the advantage of being compact and easily integrated into routine surgical practice.
63 These devices have a physically smaller footprint and make use of the available surgeon dexterity. They are
64 typically lower in cost, require minimal setup time, and lower training overhead [25].

65 The concept of a hand guided robotic drill has been inspired by an automated, mechanical arm supported, robotic
66 drill recently applied in clinical practice to produce cochleostomies [10]. The smart sensing algorithm uses
67 information derived from coupled force and torque transient discriminating tissue boundaries/ structures ahead on
68 the drilling path. A hand-held drill is more convenient to use than a device constrained by a mechanical support
69 arm. From the perspective of surgeons, who are used to deploying tools by hand, it is likely to appear more
70 intuitive to use. Previous research has proved that the flexibility in the drilling trajectory will help the control of
71 drilling into the basal turn of the cochlea. Initial cutting without slip is achieved more readily when the drilling
72 trajectory is perpendicular to the surface [26-27].

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Figure 1 The experimental hand guided surgical robot drill system [27]

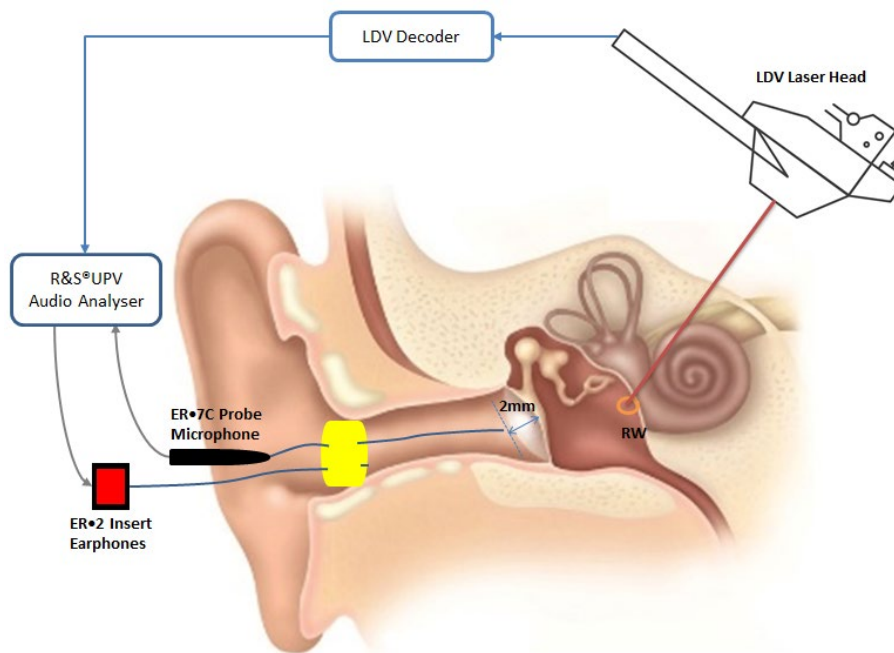
77 The hand-guided drilling system contains three units, a drill unit, a hard-wired control unit, and an output screen.
 78 Figure 1 shows the system containing all the three units. The drill unit uses standard drill bit driven by a servo
 79 motor. The design of the chuck helps to change the drill bit easily and transfer the pushing force to the sensor
 80 inside the unit. The hard-wired control unit contains two micro-controllers. One is to provide servo control of the
 81 drill unit, and the other is to control the information communication to the output screen through ethernet. There
 82 are also LED bars on the control unit showing the pushing force during drilling. It is important to maintain the
 83 pushing force in the range between 0.5N to 1.5N shown as green area on the LED bars. If pushing too hard or too
 84 light, the LED bar will display red. On the output screen, a user interface is displayed to show information such
 85 as pushing force, rotation torque, and rotation speed. The system has been tested on a variety of phantoms such
 86 as raw eggs and porcine cochlear [27]. The feasibility results demonstrated the consistency and robustness when
 87 drilling on variety phantoms.

88

89 *B. Measurement of Round Window Velocity during Drilling Procedure*

90 In the context of inner ear noise measurement, there are two general approaches: the laser approach [28-29] and
 91 the microphone approach [5, 30]. Due to the limited surface area on the cochlea - about the size of a pea with
 92 approximately 2.5 mm^2 membranous exposure at round window, it has been particularly challenging to
 93 accurately observe and quantify the vibration on or within the cochlea before immense advances in
 94 microelectronics and applications of laser became ubiquitous. The laser approach measures the vibrating velocity
 95 in mm/s at RW. The value measured is then calibrated against a reference measurement. The reference
 96 measurement is conducted by measuring the vibration amplitude in mm/s at the RW when the specimen is exposed
 97 to a stimulus of a known acoustic noise level in dB SPL. This method enables highly accurate and non-intrusive
 98 vibrational measurement and it provides a straightforward quantification of the drilling-evoked noise levels
 99 purveyed inside the cochlea.

100 An illustration of the calibration experimental setup is provided below in Figure 2. A probe microphone ER-7C
 101 (Etymotic Research, Elk Grove Village, IL 60007, USA) and a wide band earphone ER-2 (Etymotic Research),
 102 both coupled to an ER1-14A disposable foam eartip (Etymotic Research), were inserted into the external ear canal.
 103 The end of the probe tube of the microphone was placed at 2mm lateral to the tympanic membrane. The earphone
 104 was driven by a frequency logarithmic sweep signal from 0.1 to 10 kHz at 1 Vrms from R&S UPV Audio Analyser
 105 (Rohde & Schwarz, 6821 Benjamin Franklin Drive, Columbia, MD 21046, USA). According to sensitivity of the
 106 ER-2 earphone, tones delivered were at 100 dB SPL. A standard calibration process of the probe microphone was
 107 implemented before measurement and a sensitivity value was checked against the range of 40-60 mV/Pa.



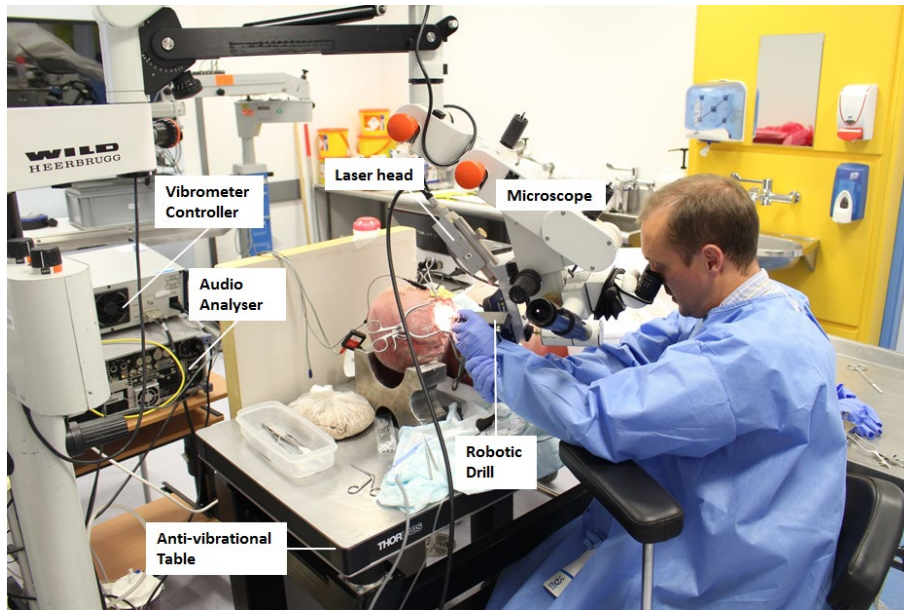
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Figure 2 Schematic illustration of the calibration setup

110 An LDV system was used to measure both stapes and RW velocity. The laser head part of the compact sensor
111 head system OFV-534 (Polytec, D-76337 Waldbronn, Germany) and micro-manipulator A-HLV-MM30 (Polytec)
112 was mounted over the lens of a surgical microscope (Wild Heerbrugg, CH - 9056 Gais, Switzerland). Self-
113 adhesive retroreflective tape (<1mm²) was placed on the posterior crus of the stapes, and later at the centre of
114 RW, to achieve a reasonably strong reflected signal and a signal to noise ratio within the acceptable range (>10dB).
115 The reflected signal was captured and decoded by the OFV-5000 vibrometer controller (Polytec) to produce an
116 output voltage proportional to the velocity detected. The voltage signal is fed into R&S UPV Audio Analyser for
117 real-time monitoring and recording. The angle of the laser to vibration axis in both cases was kept less than 45°
118 and compensated for in data analysis. After the calibration process, the hand-guided robotic drill was used to
119 create a cochleostomy, followed by another cochleostomy on the same ear (<1mm apart) with a conventional
120 surgical drill. After each cochleostomy was made, METF was measured and checked to make sure that no
121 significant change has incurred in the dynamics of the cochlea and the wider hearing conducting system.

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Figure 3 RW vibration measurement using LDV while the surgeon was performing cochleostomy drilling

125 Figure 3 is a comprehensive view of the laboratory setup of the measurement of RW response to cochleostomy
126 drilling on human cadaver heads. The robotic drill was in use here. As illustrated in the figure, the surgeon's
127 drilling arm was supported by the armrest of a surgery stool, which was ensured to bear no contact with the anti-
128 vibrational table. This removes the direct transmission of the energy from hand and arm movement to the
129 workbench, i.e. the anti-vibrational table where the cadaver head was laid. The surgeon's drilling hand was aided
130 by his other hand to ease the maintenance of a consistent posture throughout the whole drilling session. The
131 supporting arm was retained from touching the workbench for the same reason. All drilling processes were
132 performed under the microscope, with the laser focused through the microscope on the retroreflective tape at the
133 centre of RW. Care was made to ensure the laser beam remained on the retroreflective tape and that the beam was
134 not interrupted by the surgeon's hand or instruments. Axial force exerted throughout the robotic drilling process
135 was monitored and kept constant at approximately 1N – the surgeon was able to correct the force applied according
136 to a real-time indication signal. During the conventional drilling measurements, standard cochleostomy drilling
137 surgical procedure and approach was followed and no attempt was especially made to apply constant pressure or
138 remain contact. No irrigation was used in either drilling case, as this would interrupt the vibrometry signal.

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III. RESULTS

140 A. Cochleostomies and data processing

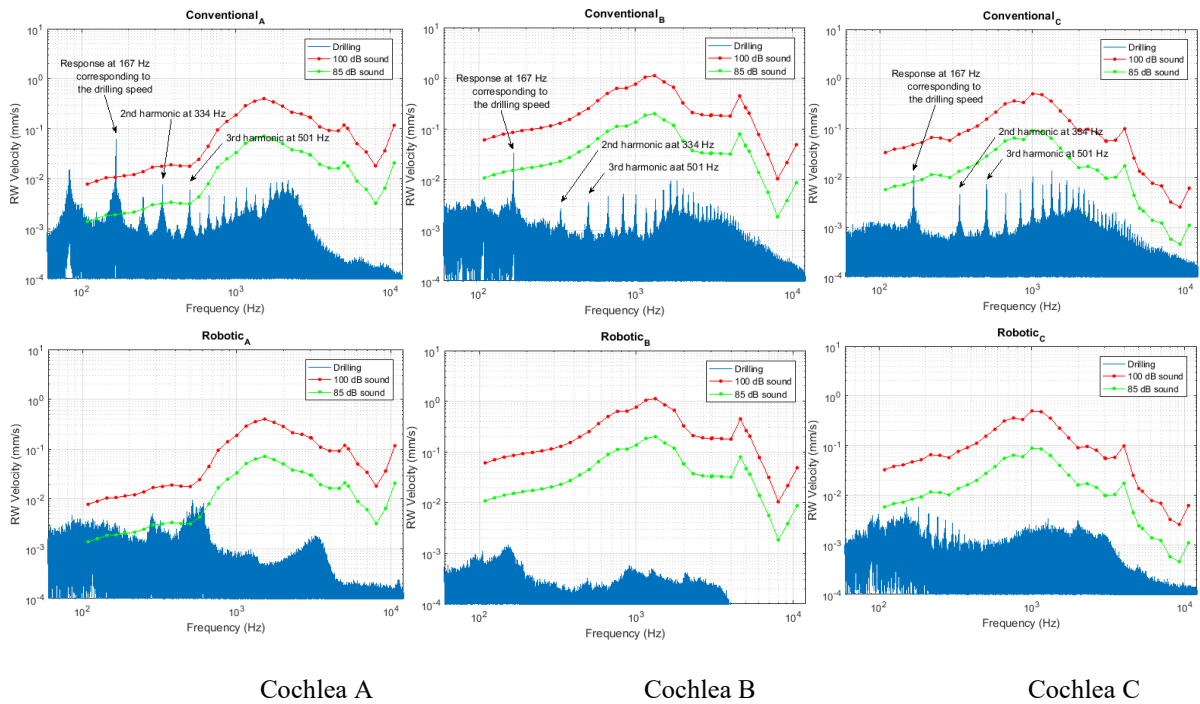
141 Two complete cochleostomies were created. 1 was performed using robotic drill, while 2 with standard otologic
142 drill. The milling, lifting and pushing motion during the conventional drilling procedure can make the opening
143 slightly enlarged and not perfectly circular as manifested in Cochleostomy 2.

144 The round window velocity during drilling was measured by the laser vibrometer. A retroreflective tape was
145 applied at the visually-estimated centre of the round window to aid the reflection of laser light. Sampling rate was
146 set to 48 kHz to cover the whole hearing frequency range of interest. Due to limited on-chip memory of the

147 analyser, only a period of 10s of data is achievable at every saving. To obtain a recording of the whole
 148 cochleostomy session, multiple continuously-taken 10-second recordings were attached in sequence in MATLAB.
 149 This recording of the full drilling session in the time domain was then processed through a set of algorithms to
 150 remove the unwanted off-target oscillation signals due to the unstable focus of the laser light. The ‘off-target’
 151 events are typical to laser vibrometer measurement on a non-rigid moist biological membrane surface, and are
 152 artefacts introduced by the measurement procedure rather than the medical procedure under investigation. The
 153 limited size of the retroreflective tape ($<1\text{mm}^2$), in consideration of minimising mass load on the membrane,
 154 makes it more difficult to maintain laser reflection. The multiple 10-second recordings are attached in a sequence
 155 to form a raw data trace. The signal-to-noise ratio (SNR) is calculated by comparing signal power to the power of
 156 the ambient noise captured before drilling.

157 *B. Frequency Spectrum of Round Window Velocity*

158 The frequency spectrum of the drilling signal is obtained from the post-processing time series data, via fast Fourier
 159 transform (FFT). The frequency spectra for Cochlea A, B, C are plotted in Figure 4. Also plotted are the traces
 160 indicating the equivalent round window velocity if 100 dB and 85 dB sound is introduced into the ear, calculated
 161 from the METF described in Section 2B. The two traces are introduced because they denote critical thresholds for
 162 hearing protection. According to the National Institute for Occupational Safety and Health, long or repeated
 163 exposure to sounds at or above 85 dB can cause hearing loss. As a guide, the maximum time recommended that
 164 a healthy individual can be exposed to 100 dB sound is limited to 15 min. Threshold time is halved for every 3dB
 165 increase. Above all, the reference traces provide a snapshot of the level of disturbance in the context of hearing.



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 167 Cochlea A Cochlea B Cochlea C

168 Figure 4. Frequency spectrum of the drilling disturbance signal during the whole cochleostomy procedure.
 169 Top: conventional. Bottom: robotic.

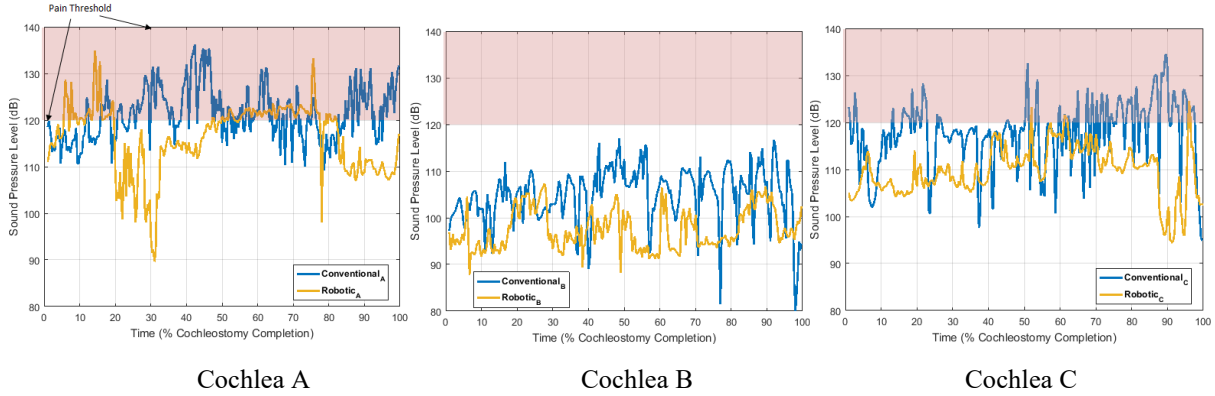
170 *C. Formation Instantaneous Total Sound Pressure Level*

171 It is also possible to obtain the instantaneous equivalent sound pressure level from the data collected on cadaver
 172 heads, by accounting energy of all frequency components within the frequency range of interest. According to
 173 IEC standard [31], the sound pressure level is defined as:

174
$$SPL = 20 \cdot \log_{10} \frac{p}{p_0} \quad (1)$$

175 For any particular time, the total sound pressure level can be calculated by substituting p in the equation with the
 176 summation of the squares of the equivalent sound pressure at all frequencies [32]. Since the sound energy is
 177 proportional to the square of the sound pressure [33], this is equivalent to taking each frequency component as an
 178 independent source of energy and calculated the total impact of energy in units of dB SPL.

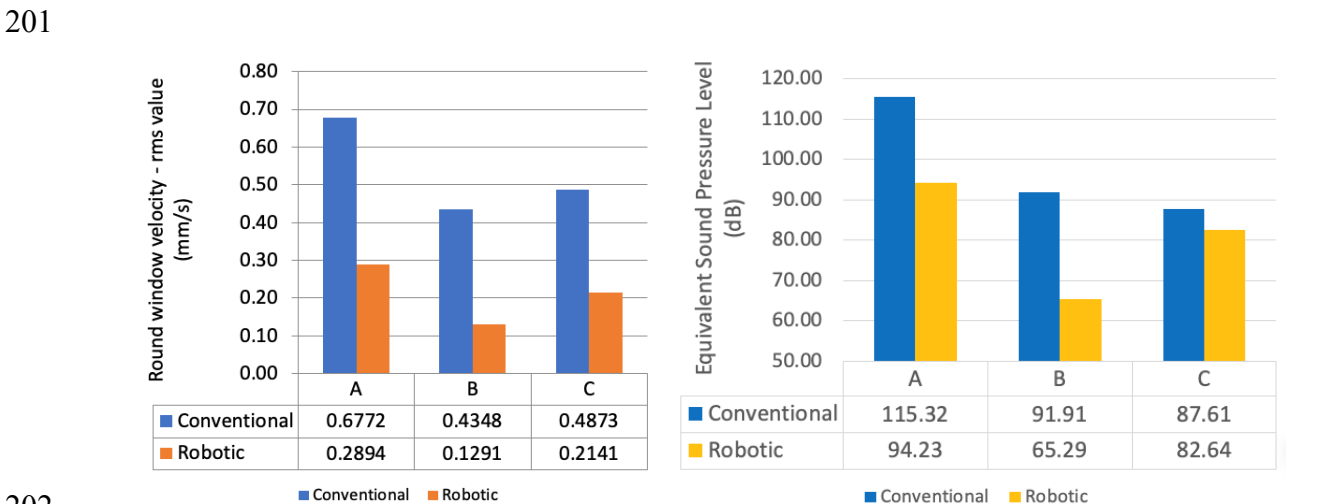
179 Using the short-time Fourier transform and the METF-RW curve after interpolation, the time-resolved equivalent
 180 sound pressure levels can be determined. Instead of peak amplitude obtained straight from Fourier transform,
 181 root-mean-square amplitude of the sinusoidal component at each specific frequency is used here, to properly
 182 reflect the corresponding energy content [34, 35]. The equivalent total sound pressure level is plotted against time
 183 in Figure 5. To facilitate the direct comparison between results that are of different recording lengths, the time is
 184 normalised by total cochleostomy time of each particular measurement. Accordingly, the calculation of sound
 185 pressure level is done in sliding sections of 1% of drilling time. The pain threshold of 120-140 dB SPL [36] is
 186 denoted by the red-shaded area in the figure. Frequency weighting is considered however not reported here since
 187 the threshold referred to (120-140 dB SPL) is an unweighted value.



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 190 Figure 5. Sound Pressure Level plotted against time which is normalised by total recorded cochleostomy drilling
 191 time. Shaded in red is the pain threshold of 120-140 dB SPL.

192 IV. DISCUSSION

193 A direct comparison between conventional and robotic drilling on Cochlea A, B and C, is presented in Figure 6(a).
 194 Each bar value is the Root Mean Square (RMS) velocity of round window vibration over the whole procedure of
 195 cochleostomy drilling. In all three cases, robotic drilling delivers an RMS velocity that is approximately 1/3 of
 196 that of conventional drilling. The peak amplitudes of equivalent sound pressure level are summarised in the Figure
 197 6(b). A comparison between conventional and robotic, in respect of the peak amplitude of the frequency-specific
 198 equivalent sound pressure level is presented on top of the table. On all three cochlea specimen robotic drilling
 199 delivers a decrease in peak equivalent sound pressure level compared to conventional, ranging from 6% on
 200 Cochlea C to 29% on Cochlea B.



202
 203 Figure 6. (a) Root mean square for round window velocity averaged over the whole cochleostomy procedure
 204 (b) The peak amplitude of the induced mechanical disturbance in equivalent sound pressure level

205
 206 From the results shown in Figure 5, the level of disturbance induced by robotic drilling is consistently lower, and
 207 below the pain threshold for much longer, compared to that of conventional drilling. The peak disturbance

208 amplitude during conventional drilling can be 20 dB SPL larger than that during robotic drilling, as per the trace
209 of drilling-evoked equivalent sound pressure level over time. There is no obvious surge of disturbance level at the
210 end of cochleostomy drilling which has been reported by other groups [5, 28]. This can be most likely attributed
211 to the discontinuing of both drilling and recording immediately upon completion of the fenestration. When drilling
212 by robot, the running drill burr would have negligible or no direct contact with the exposed endosteum. Minimising
213 trauma produced by physical disturbances is often the expressed goal in improving ear surgery as, in contrast, the
214 resulting trauma is not readily understood or quantified. It is reasonably assumed that a reduction in disturbance
215 in duration and amplitude will lead to reduced trauma. In cochleostomy drilling, the tissue guided robotic
216 approach offers clear advantage.

217 V. CONCLUSION

218 Tissue guided robotic drilling offers advantage in minimising induced intracochlear disturbances over
219 conventional surgical practice using conventional drills. The results have shown a consistently lower level of
220 disturbance in cochlea both in the time domain and across the hearing frequency range. It is therefore reasonable
221 to conclude that robotic drilling offers the possibility of reducing acoustic trauma in cochlea that currently places
222 the residual hearing of patients at risk.

223 A hand-held robotic drill able to discriminate and respond to varying tissue types and conditions was compared
224 with a conventional surgical drilling technique by an experienced otologist in cochlear implantation. In all three
225 cases- there was a typical reduction of 20dB when robotic drilling that is reflected by a reduction in RMS velocity
226 at the round window to approximately 1/3 of that of conventional drilling. The improvements are reinforced
227 through the robotic approach by avoiding both intermittent removal and reconducting of the cutter, and by
228 avoiding interaction with the endosteum with a running burr. These critical effects are unavoidable when
229 controlled by a human operator seeking feedback on the state of the process, unable to stop the process on reaching
230 the endosteum, and while compensating for induced tissue response to applied drilling force.

231 Although based on three cadaver specimens, the early results presented are promising. This indicates that the
232 robotic approach has clear advantage in lowering disturbance to hearing organ. To consolidate and further
233 establish the trend observed in this study, data from additional specimen is needed. This will diminish the likely
234 effects imposed by variance in specimen condition, such as specimen freshness, anatomy, age, and gender.

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