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Noise exposure of the inner ear during robotic drilling

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Abstract

Introduction Preserving the cochlear structures and thus hearing preservation, has become a prominent topic of discussion in cochlear implant (CI) surgery. Various approaches and soft surgical techniques have been described when approaching the inner ear. Robot-assisted cochlear implant surgery (RACIS) reaches the round window in a minimally invasive manner by following a trajectory of minimal trauma. This involves the drilling of a keyhole trajectory to the round window, through the facial recess, with no need for a complete mastoidectomy. It involves less drilling, less drilling time and less structural damage. A lot of attention has been paid to the structural traumatic causes of hearing loss but acoustic trauma during the exposure of the inner ear appears to be neglected topic.

Aim The aim was to measure the noise exposure of the inner ear during the robotic drilling of the mastoid and bony overhang of the round window. The results were compared with the milling in conventional cochlear implantation surgery.

Intervention RACIS on fresh frozen human cadavers.

Outcome measurements The equivalent frequency-weighted and time-averaged sound pressure level L_{AF} in dB and the noise dose in % derived from a noise damage model, both obtained during RACIS.

Materials and methods The robotic drilling of 6 trajectories towards the inner ear were performed, including 4 trajectories through round window access and 2 trajectories through cochleostomy. The results were compared with the data of 7 cases of conventional CI surgery that have been described in literature. The induced equivalent sound pressure level L_{AF} was determined via an accelleration sensor at the zygomatic arch and a calibration according to bone conduction audiometry. A noise dose for the whole procedure was calculated from the equivalent sound pressure level L_{AF} and the exposure time using a noise damage model. A noise dose of 100% is considered a critical exposure limit and values above are considered potentially harmful, with the risk of hearing impairment.

Results The maximum L_{AF} was 82 dB during fiducial screw placement; 87 dB during middle ear access; 95 dB for the accesses through the round window and 88 dB for the accesses through cochleostomy. The noise dose due to the HEARO®-procedure was always far below the critical value of 100%. There was no acoustic trauma of the inner ear in all cases with the noise dose being smaller than 0.1% in five out of the six cases. The maximum L_{AF} in the seven cases of conventional CI surgery was 118 dB with a maximum cumulative noise dose of 172.6%. The critical exposure limit of 100% was exceeded in three cases of conventional CI surgery.

Conclusion RACIS provokes significantly less acoustic trauma than conventional mastoid surgery in our findings. There were no observable differences in noise exposure levels between a cochleostomy or a round window approach where the bony overhang needed to be drilled.

Keywords HEARO®-procedure · Sensorineural hearing loss · Cochlear implantation · Robot-assisted cochlear implant surgery · Image-guided surgery · Structure preservation · Hearing preservation · Noise exposure

Extended author information available on the last page of the article

Introduction

Cochlear implant (CI) surgery is regarded as the most effective treatment for patients with severe to profound sensorineural hearing loss [1]. The emphasis on preserving the cochlear structures and thus hearing preservation, has become a prominent topic of discussion. This is particularly pertinent for patients with residual hearing, as electro-acoustic stimulation has demonstrated superior outcomes [2, 3]. More importantly, for younger patients who have a higher probability of undergoing revision cochlear implant surgery in the future, or potential new emerging therapies like gene therapy [4, 5].

Various approaches and soft surgical techniques have been described when approaching the inner ear. The facial recess approach, involving mastoidectomy followed by a posterior tympanotomy has been considered the golden standard and remains the most commonly used technique today [6, 7]. Several alternative techniques with their reported advantages such as achieving an enhanced exposure of the cochlea, minimizing trauma during drilling, reducing the risk of facial nerve injury and decreasing surgical time have been proposed. Among these approaches, the transcanal/Veria approach first described by Kiratzidis [8], the suprameatal approach first described by Kronenberger et al. [9] and the pericanal approach first described by Häusler [10] have all been the topics of past discussions. All these approaches involve inner ear access through cochleostomy. Schart-Morén et al. described more intra-cochlear damage of the soft tissues for accesses through cochleostomy compared to round window accesses using synchrotron radiation phase-contrast imaging [11]. Additionally, Topsakal et al. described for the facial recess approach, trajectory angles more parallel to the basal turn of the cochlea, potentially facilitating smoother insertions compared to alternative approaches [12].

Robot-assisted cochlear implant surgery (RACIS) or the HEARO®-procedure (CAScination, Bern, Switzerland) reaches the round window in a minimally invasive manner by following a trajectory of minimal trauma. This involves the drilling of a keyhole trajectory to the round window, through the facial recess, with no need for a complete mastoidectomy [13], and recently without the requirement of a tympanomeatal flap for electrode visualisation during electrode insertion [14]. Compared to the conventional approach, the HEARO®-procedure involves less drilling, less drilling time and less structural damage. The drilling speeds in the HEARO®-procedure are also smaller compared to conventional mastoidectomy, where milling speeds of up to 75.000 rpm can be achieved.

CI surgery-related hearing losses are categorized into traumatic/immediate and delayed types of hearing loss. Immediate types of hearing loss encompass damage to middle ear structures, damage during round window access, damage during electrode insertion and post-insertion-related hearing loss. All have been well described with immediate types of hearing loss caused by a vibratory injury to the inner ear because of the drill hitting the ossicles also being reported [15]. Pau et al. described noise exposure levels of up to 139 dB Sound Pressure Level (SPL) upon the contact of the ossicles with a running burr, which as a result may cause significant damage to the inner ear [16]. A lot of attention has been paid to the structural traumatic causes of hearing loss but acoustic trauma during the exposure of the inner ear appears to be neglected topic. Cases of sensorineural hearing loss that were attributed to acoustic trauma during drilling have been described in several studies [17–19]. Drilling induced noise can exceed the recommended daily noise exposure limits according to the criteria set up by the National Institute for Occupational Safety and Health (NIOSH) [20]. The recommended exposure limit is 85 dB as an eight-hour time-weighted average. For every 3 dB increase of the noise exposure level, the time limit decreases by half. Pau et al. described SPL's of more than 100 dB when drilling the bone near the cochlea, up to 122 dB when the endosteal layer was exposed and increasing up to 134 dB when the membrane was touched directly [16]. Fleischer et al. described equivalent noise exposure levels of up to 134 dB. The highest values were observed during mastoidectomy and the preparation of the implant bed [21]. Bone conduction noise levels are measured instead of air conduction noise levels because of these being 10 dB higher during drilling [22].

The aim of this study is to measure the noise exposure levels of the inner ear during the HEARO®-procedure and to compare these results with the milling in conventional CI surgery. Lower noise exposure levels are expected for the HEARO®-procedure.

Materials and methods

Study design and ethical considerations

An experimental cadaver study was performed to analyze the noise exposure levels during the HEARO®-procedure and compare to conventional CI surgery and determine if critical noise exposure levels are reached. Noise exposure data were collected during the HEARO®-procedure and compared with the data during conventional CI surgery from another study [21]. Additionally, one conventional mastoidectomy was performed to evaluate comparability between studies.

The experiment was carried out on four fresh frozen human cadaver heads, retrieved from the Anatomical Research and Clinical Studies (ARCS) lab of the Vrije Universiteit Brussel. The approval of the UZ Brussel ethics committee was granted with number BUN: 1,432,023,000,004.

Statistical considerations

The noise exposure levels, expressed as the noise dose during the HEARO®-procedure is expected to be below the critical value of 100% for all cases. Based on another study [21] and the fact that less bone is removed, significantly lower values of noise dose are expected for the HEARO®-procedure with a mean of 30% and a range of 10–50% compared to conventional CI surgery. With these initial data and assumptions, at least 5 samples/measurements are necessary to show that the upper limit of the tolerance interval of the noise dose is 82% and thus below the critical value of 100%. The tolerance interval was estimated for a coverage of 99% and with a confidence level of 95%. Details on the statistics are provided in the appendix.

Noise exposure data of the current study were compared with data obtained during conventional CI surgery [21] using unpaired t-tests.

Noise exposure measurements

In addition to airborne sound, bone vibrations in the skull also lead to a sensation of hearing. This is clinically used in e.g. bone conduction audiometry. Bone conducted sound is transmitted in the skull via wave propagation in the skull bone. The component of this wave propagation in the normal direction of the skull surface can be measured very well with an acceleration sensor. This is the basis of the set-up used in this study to measure noise exposure via bone conduction [21].

The acceleration sensor (352C33, PCB Piezotronics Inc., Depew, USA; sensitivity 3.05176E-5 m/s2) is placed at the zygomatic arch (near the site of drilling) with an elastic headband. The sensor is calibrated before starting the measurement. For this purpose, bone vibrations are induced on the mastoid using a piezoelectric shaker (P-842, Physik Instrumente (PI) GmbH & Co. KG, Karlsruhe, Germany) and measured with the acceleration sensor. The applied dynamic force is measured with a load cell (1022 V IEPE, Dytran Instruments, Inc., Chatsworth, USA) between the shaker and the mastoid. The reference threshold force level defined in bone conduction audiometry can be used to assign a perceived sound pressure level to the measured force (standard ISO 389-3 2016). The calibration thus provides a perceived or equivalent sound pressure level L_A for a measured acceleration sensor value.

During milling or the HEARO®-procedure, only the signal from the acceleration sensor is measured and converted into an instantaneous perceived sound pressure level using the calibration. The instantaneous levels are averaged over a period of 128 ms, corresponding to the temporal resolution of the human ear for continuous sound levels. This finally gives an equivalent sound pressure level L_{AF} at every 128 milliseconds.

Equivalent sound pressure levels above 85 dB are considered potentially harmful. The standard for "occupational noise exposure" [20] provides recommended daily exposure limits and calculation instructions to determine a noise dose from sound pressure level and exposure time. A noise dose (D) of 100% is considered a critical exposure limit and values above are considered potentially harmful, with the risk of hearing impairment.

$\mathrm{D} = 100\% * \sum \mathrm{C_i}/\mathrm{T_i}$ with

$\mathrm{C_i}$ is the exposure time (in min.) at a specific sound pressure level, and

$\mathrm{T_i} = 480/2\hat{}\left(\left(\mathrm{L}_{AF} - 85\right)/3\right)$ is the exposure time (in min.) for which this sound pressure level L_{AF} becomes hazardous.

The equivalent sound pressure levels were measured during all steps of the HEARO®-procedure that involve drilling, i.e. fiducial screw placement, middle ear approach and inner ear access [13]. The same measurements were also made during one conventional mastoidectomy to evaluate comparability between studies.

Cochlear implantation according to the HEARO®-procedure

As previously described [13], the usual steps of the HEARO®-procedure were performed.

I. Retro-auricular incision and skin flap
II. Fiducial screw placement
III. Pre-operative imaging

   The cadaveric heads were scanned on a 64 slice CT (Revolution Apex, GE Healthcare) at 140 kVp, pitch 0.5, and 470 mAs.

IV. Trajectory planning

   The trajectories were planned using a dedicated planning software programme. A 3D reconstruction of the patients anatomy was made and trajectories through round window access or through cochleostomy were calculated for comparison. Safe distances from critical structures such as the facial nerve and the chorda tympani were accounted for where possible. If not possible because of the size of the facial recess being too small (< 2.5 mm) than drilling would be performed through the chorda tympani. The plan was exported to the HEARO®-system to commence drilling.

V. Registration

Patient to image registration is performed with the use of fiducials that serve as artificial landmarks.

VI. Middle ear approach.

The middle ear approach involves robotically drilling from the mastoid cortex to the middle ear utilizing a 1.8 mm custom tungsten carbide drill bit [23]. The drilling is performed at a speed of a 1000 rpm in 2 mm intervals, adjusted to 0.5 mm intervals when nearing the facial recess with a feedforward rate of 0.5 mm/s [24, 25].

VII. Inner ear access.

Inner ear access was achieved through round window access (robotically drilling through the bony overhang of the round window leaving the round window intact) through cochleostomy for comparison. It is performed with a 1.0 mm diamond burr at a speed of 2000 rpm. The feedforward rate automatically adjusts upon reaching a force threshold of 2.0 N to reduce the drilling force [13].

A conventional mastoidectomy at drilling speeds of 30.000, 60.000 and 75.000 rpm was performed with a 6 mm cutting burr after the HEARO®-procedure by an experienced otologist. This case was validated for comparability with the reference data described in literature of 7 other monitored conventional CI procedures [21].

Results

Results were obtained for 3 out of the 4 cadaver heads; so 6 measurements/samples in total. The use of one cadaver head was cancelled because of a problem with the processing of the CT-images. The fiducials were not completely visible on the CT-images. Therefore, Step IV, trajectory planning and step V registration were not possible on this cadaver head. In total, using both the right and left side of each cadaver head, 6 trajectories towards the inner ear were planned and performed. This included four trajectories through round window access and two trajectories through cochleostomy. Two additional trajectories through cochleostomy could not be performed because of the processing issue of the CT-images.

The L_{AF} during fiducial screw placement was only measured for cadaver 1 right and for cadaver 3 right. The maximum L_{AF} during fiducial screw placement was 81.63 dB as seen in Fig. 1, with a daily noise dose of 0%. The maximum L_{AF} during middle ear access was 87.4 dB. There were also no great observable differences in maximum L_{AF} between the inner ear accesses through the round window (94.5 dB) and through cochleostomy (88.1 dB). There was no acoustic trauma of the inner ear in all cases with the noise dose being smaller than 0.1% in five out of the six cases, as seen in Table 1. The duration of drilling is seen to vary greatly across samples. As seen in Fig. 2, the L_{AF} over time during the HEARO®-procedure, rarely reached levels more than 85 dB. The L_{AF} in Fig. 2 are from cadaver 2 right which are the highest of the entire experiment. Only when drilling at or

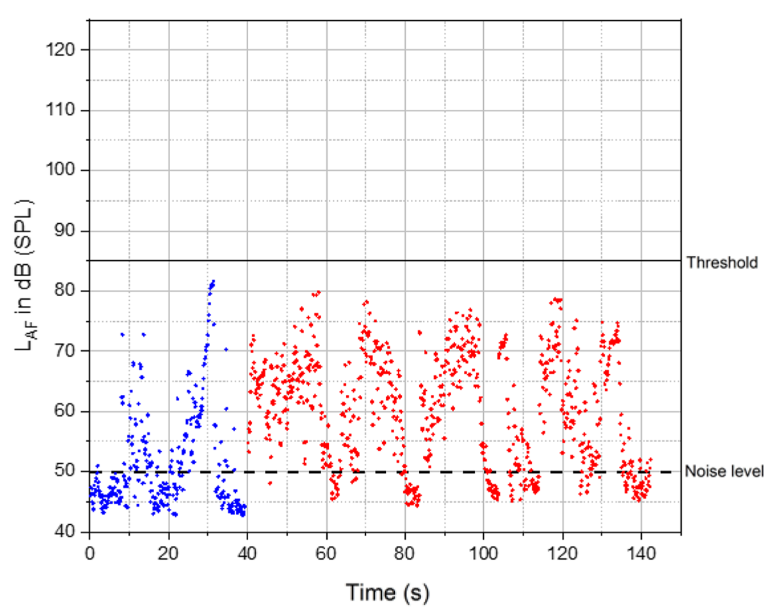

Fig. 1 Equivalent frequency-weighted and time-averaged sound pressure level L_{AF} over time for fiducial screw placement in cadaver 1 right (blue) and cadaver 3 right (red). The ambient noise level and recommended exposure threshold are marked at 50 dB and 85 dB, respectively

Table 1 A total of 6 trajectories were performed

Specimen nr./side	Surgical step	Max. L_{AF} (dB)	% of daily noise dose	Time (seconds)
Cadaver 1 left	Middle ear access	87	< 0.1	562
	Inner-ear access[1]	72	0	238
Cadaver 1 right	Middle ear access	87	< 0.1	831
	Inner-ear access[2]	88	< 0.1	539
Cadaver 2 left	Middle ear access	82	0	686
	Inner-ear access[1]	86	< 0.1	324
Cadaver 2 right	Middle ear access	86	< 0.1	1112
	Inner-ear access[1]	95	3.5	648
Cadaver 3 left	Middle ear access	87	< 0.1	940
	Inner-ear access[1]	83	0	860
Cadaver 3 right	Middle ear access	81	0	645
	Inner-ear access[2]	83	0	375
Cadaver 2 right	Mastoidectomy 30.000 rpm	121	89	133
	Mastoidectomy 60.000 rpm	115	7,5	140
	Mastoidectomy 75.000 rpm	112	6,5	86

[1]Cadaver 1 left, cadaver 2 and cadaver 3 left included inner ear access through the round window

[2]Cadaver 1 right and cadaver 3 right included inner ear access through cochleostomy

One conventional mastoidectomy was performed for comparison. A 6 mm cutting burr was used at three different speeds

near the level of the cochlea were a prolonged L_{AF} measured above 85 dB.

The L_{AF} regularly exceeded the threshold value of 85 dB during conventional mastoidectomy as seen in Fig. 3. The maximum L_{AF} was 121 dB (at a drilling speed of 30.000 /min) which lowered to 112 dB at a higher drilling speed (75.000 /min). In intermediate phases, when the burr was not in contact to bone, the L_{AF} was at the noise floor around 50 dB. The standard procedure caused a cumulative noise dose of 103%, which is just above the limit.

A comparison of the results between the HEARO®-procedure compared with standard CI surgery [21] can be seen in Fig. 4A-B. The values of our single standard procedure (max L_{AF} = 121 dB, noise dose = 103% and procedure time = 360 s) are all within the range of the respective values of the 7 other monitored conventional CI procedures described in literature [21]. The results of the 6 cases of the HEARO®-procedure can thus be compared with the 7 cases of conventional CI surgery as seen in Table 2.

The maximum L_{AF} of the HEARO®-procedure are significantly lower ($p < 0.05$) than those of the standard procedure, as seen in Fig. 4A. The L_{AF} during the HEARO®-procedure hardly exceeded 85 dB and the noise dose was always far below the critical value of 100%, as seen in Fig. 4B. These results are far below of what was assumed when planning the study. Due to the small sample size and because almost all values are near zero, no statistically reliable value can be given for the 99% interval of the noise dose. Based on the present values however, it is expected that a critical noise dose will never be reached during the HEARO®-procedure.

Discussion

RACIS involves robotically drilling towards the round window in a minimally invasive manner by following a preplanned trajectory of minimal trauma. The maximum SPL's in RACIS are lower compared to conventional mastoidectomy. The difference in maximum L_{AF} ranges from 17 to 33. This depends on which drilling speed was used during conventional mastoidectomy and if inner ear access was

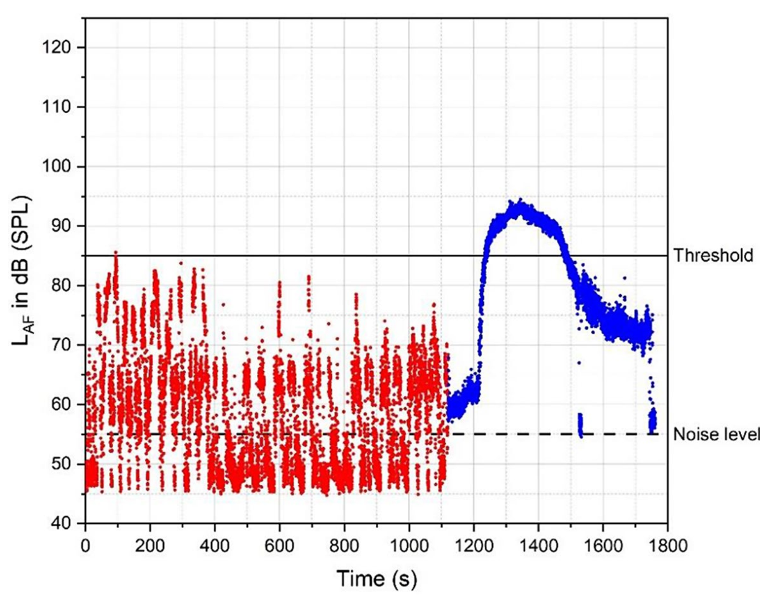

Fig. 2 Equivalent frequency-weighted and time-averaged sound pressure level L_{AF} over time during the HEARO®-procedure in cadaver 2 right. Both the robotic middle ear access (red) and inner ear access (blue) can be visualised. The ambient noise level and recommended exposure threshold are marked at 50 dB and 85 dB, respectively

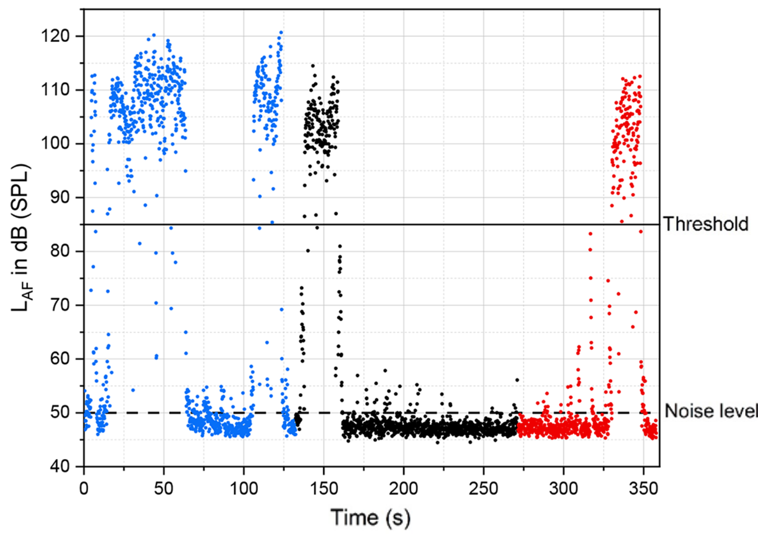

Fig. 3 Equivalent frequency-weighted and time-averaged sound pressure level L_{AF} over time during the conventional mastoidectomy in cadaver 2 right. Drilling was performed with a 6 mm cutting burr at a drilling speed of 30.000 rpm (blue), 60.000 rpm (black) and 75.000 rpm (red). The ambient noise level and recommended exposure threshold are marked at 50 dB and 85 dB, respectively

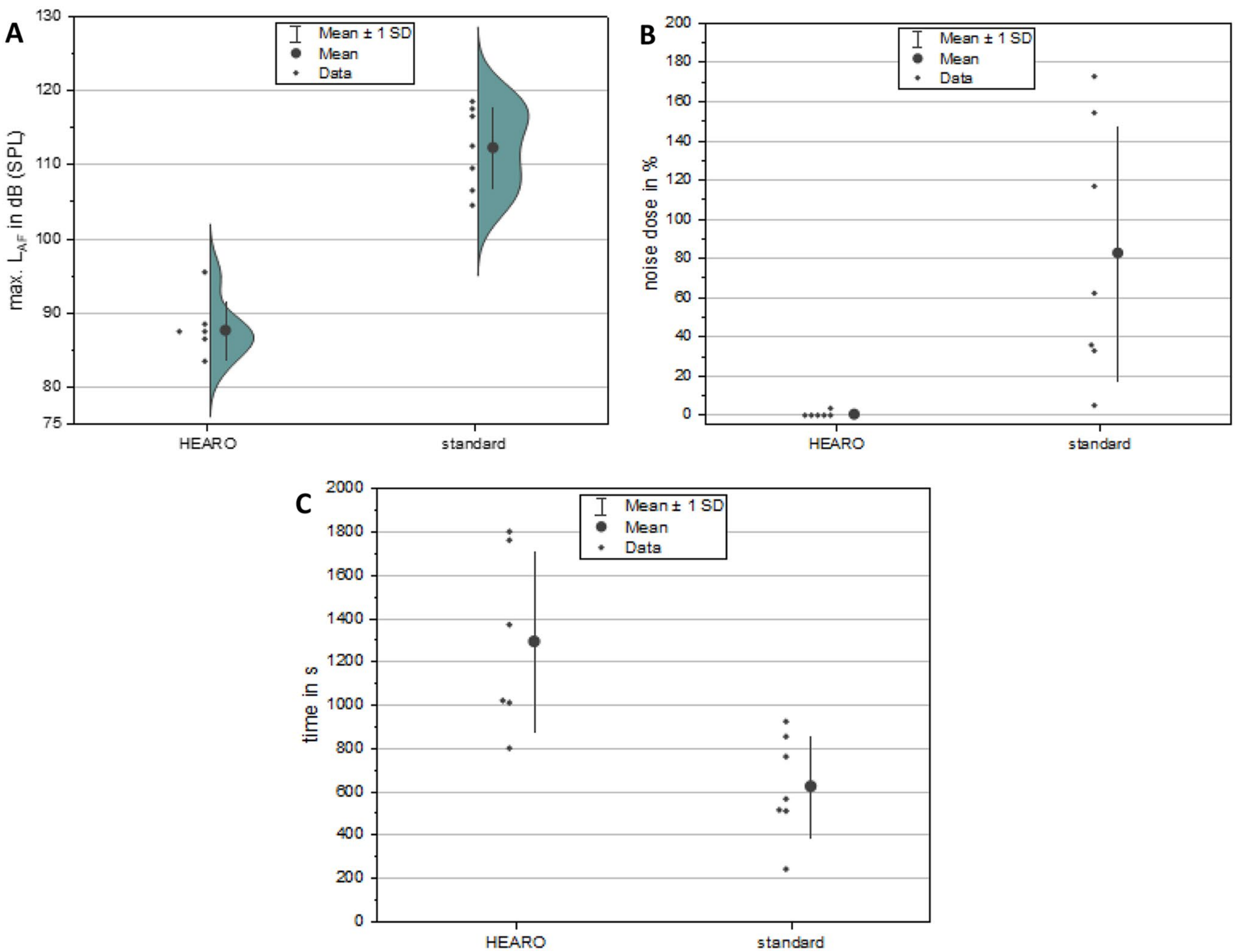

Fig. 4 **(A-B)**: A comparison of the results between the HEARO®-procedure (this study) compared to standard CI surgery [21] **(A)** Maximum equivalent frequency-weighted and time-averaged sound pressure level L_{AF}, **(B)** percentage of daily noise dose and **(C)** drilling and milling time

Table 2 The results are compared with the data of 7 cases of conventional CI surgery that have been described in literature

Case nr.	Max. L_{AF} (dB)	% of daily noise dose	Time (seconds)
1	105	35.8	566
2	107	32.9	761
3	118	5	242
4	117	62.2	515
5	113	116.7	510
6	109	154.1	854
7	118	172.6	923

achieved through the round window or through cochleostomy. Although the drilling time is higher in RACIS in this study as seen in Fig. 4C, the SPL's are almost continuously under 85 dB as seen in Fig. 2 which is lower than the critical exposure limit. This is not considered harmful. There is thus no risk of hearing impairment because of noise induced trauma compared to conventional CI surgery. The use of a smaller diamond drill of 1.0 mm and the automated feedback between the feedforward rate and the drilling force are factors that are expected to have contributed to lower noise exposure levels during inner ear access.

Although RACIS can claim to cause less acoustic trauma compared to conventional cochlear implantation surgery, the audiological results cannot be claimed to be superior. There was no significant difference in pure-tone audiometry, speech perception in quiet and noise between robotically implanted and conventionally implanted patients after 2-years of follow up [26]. Perhaps the improvement in audiological results will be seen when achieving fully autonomous cochlear implant surgery including autonomous electrode insertion which is now still performed manually through the keyhole trajectory [13]. In order to better evaluate the effect of acoustic trauma, specific studies must be carried out in which patients with single-sided deafness are provided with a CI and the effect of the procedure is evaluated on the healthy contralateral side.

Autonomous inner ear access involves the drilling of the bony overhang of the round window, also referred to as the canonus fossulae fenestrae cochlea which covers the round window for a part [27]. The process of autonomous inner access is divided into four phases, as seen in Fig. 5. A force-torque sensor measures the forces in Newton (N) during robotic drilling. Phase 1 is the moment the drill comes into contact with the lateral wall of the bony overhang, a sudden increase in force is measured. Phase 2 or the plateau phase is when the drill is fully positioned inside the bony overhang, the forces stay the same during this time. Phase 3 or the breakthrough phase starts when the drill has reached the medial wall of the bony overhang. This is also illustrated by a decrease in force. In phase 4 or the enlarging phase, the drill must still drill 0.3 mm beyond the edge of the medial wall. Forces decrease to 0 during this phase. Interestingly, the L_{AF} (as seen in Fig. 2 blue) and the measured forces during inner ear access seem to be following the same course. An increase in the forces during the robotic drilling of the bony overhang is correlated with an increase of the SPL and vice versa. A lot of variability is seen in the duration of drilling across samples. This is influenced by both the drilling depth and the adjustable feedforward rate during inner ear access. The feedforward rate decreases when the

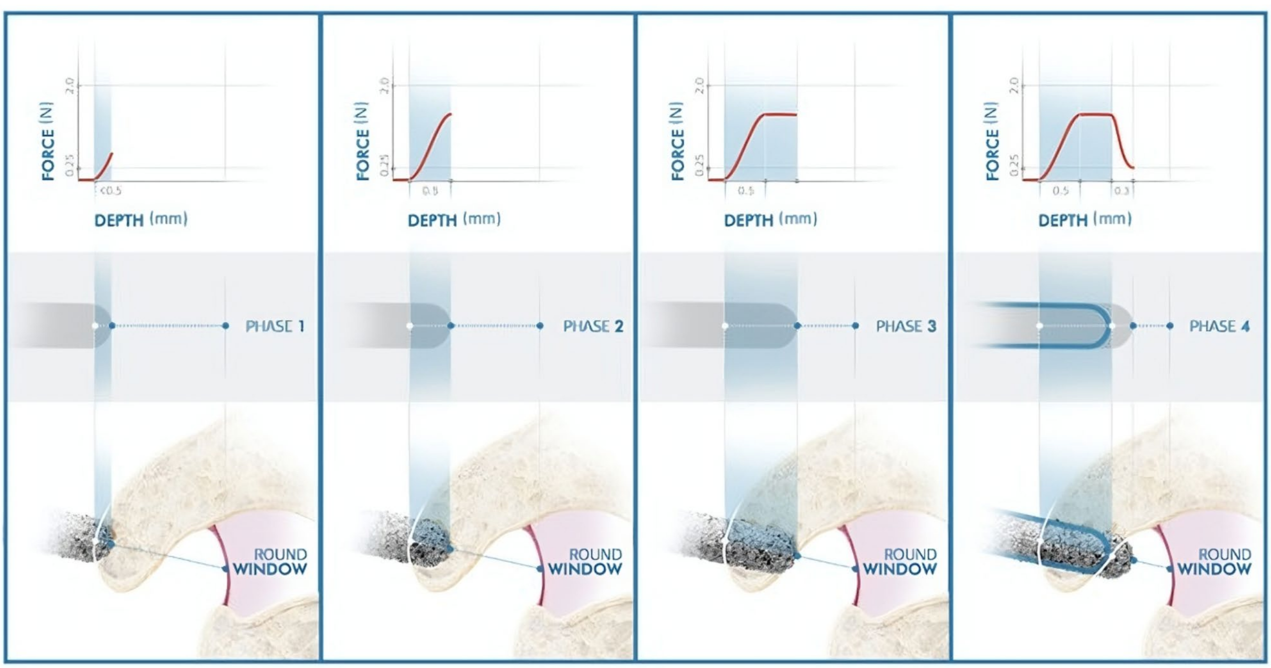

Fig. 5 Inner ear access algorithm

force-torque sensor measures increased forces which results in a prolonged duration of the drilling time. But although the drilling time is prolonged, the noise dose does not increase because of the L_{AF} not exceeding 85 dB.

Conclusions

RACIS provokes significantly less acoustic trauma than conventional mastoid surgery in our findings. There were no observable differences in noise exposure levels between a cochleostomy or a round window approach where the bony overhang needed to be drilled.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00405-024-08925-1.

Data availability Data used for this study are available from the corresponding author on request.

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