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# AUDIOLOGICAL OUTCOMES OF ROBOT-ASSISTED COCHLEAR IMPLANT SURGERY

Heuninck Emilie[1,*]
Van de Heyning Paul[2,3]
Van Rompaey Vincent[2,3]
Mertens Griet[2,3]
Topsakal Vedat[1]

[1]*Department of Otorhinolaryngology Head and Neck surgery, University Hospital Brussels, Vrije Universiteit Brussel, Brussels Health Campus, Brussels, Belgium*
[2] *Department of Otorhinolaryngology, Head and Neck Surgery, Antwerp University Hospital, Belgium.*
[3]*Experimental Laboratory of Translational Neurosciences and Dento-Otolaryngology, Faculty of Medicine and Health Sciences, University of Antwerp, Belgium.*

***All correspondence should be addressed to:**
Mrs. Emilie Heuninck, University Hospital Brussels, Department of Otorhinolaryngology Head and Neck Surgery, Laarbeeklaan 101, 1090 Brussels, Belgium. E-mail: emilie.heuninck@uzbrussel.be. Telephone number: +32 2/474 97 72.

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## DECLARATIONS

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**Competing interests**
The authors declare that there is no conflict of interest.

**Ethics approval and consent to participate**
The EAR2OS study was registered at clinical trials.gov under identifier NCT03746613 and HEARO device exemption number 80M0763 from the Federal Agency for Medicines and Health Products (FAMHP). The approval of the Antwerp University Hospital ethics committee was granted with number B300201837507. A follow-up study (ARCI25) was registered at clinicaltrails.gov under identifier NCT04102215. The approval of the Antwerp University Hospital ethics committee was granted with number B300201941457 and HEARO device exemption 80M0793. All participants gave written informed consent prior to participation in accordance with the Declaration of Helsinki.

**Author contribution**
VT and PH contributed to the conception and design of the study. VV and GM were involved in inclusion and postoperative evaluation of participants. EH analyzed data and wrote the first draft of the manuscript. VT, PH, VV and GM critically revised the manuscript. All authors read and approved the submitted version of the manuscript.

**Data availability**

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

# ABSTRACT

## Purpose

The main objective of this study is to evaluate the short-term and long-term audiological outcomes in patients who underwent cochlear implantation with a robot-assisted system to enable access to the cochlea, and to compare outcomes with a matched control group of patients who underwent cochlear implantation with conventional access to the cochlea.

## Methods

In total, 23 patients were implanted by robot-assisted cochlear implant surgery (RACIS). In order to evaluate the effectiveness of robotic surgery in terms of audiological outcomes, a statistically balanced control group of conventionally implanted bilaterally deaf patients was created. Minimal Outcome Measures (MOM), consisting of pure-tone audiometry, speech understanding in quiet and speech understanding in noise were performed pre-operatively and at 3 months, 6 months, 12 months and 2 years post-activation of the audioprocessor.

## Results

There was no statistically significant difference in pure-tone audiometry, speech perception in quiet and speech perception in noise between robotically implanted and conventionally implanted patients pre-operatively, 3 months, 6 months, 12 months and 2 years post-activation. A significant improvement in pure-tone hearing thresholds, speech understanding in quiet and speech understanding in noise with the cochlear implant has been quantified as of the first measurements at 3 months and this significant improvement remained stable over a time period of 2 years for HEARO implanted patients.

## Conclusion

Clinical outcomes in robot-assisted cochlear implant surgery are comparable to conventional cochlear implantation.



**Clinicaltrails.gov trail registration numbers:** NCT03746613 (date of registration: 19/11/2018), NCT04102215 (date of registration: 25/09/2019)

# INTRODUCTION

The World Health Organization estimates that 163.5 million people suffer from severe-to-profound sensorineural hearing loss (SNHL) worldwide [1]. Cochlear implantation is an established treatment that bypasses the middle ear and inner ear structures to stimulate the auditory nerve directly in order to restore hearing in severe-to-profoundly deaf patients [2]. Cochlear implants (CI) have a proven beneficial impact on speech perception and health-related quality of life [3]. Since the first cochlear implantation more than 60 years ago [4], significant technological innovations have been implemented as a result of close collaborations between engineers and surgeons. Recently, image-guided robot-assisted techniques have been introduced in otology which facilitates minimally invasive keyhole access from the lateral surface of the mastoid through the facial recess to the middle and inner ear for cochlear implantation. Labadie et al. [5] succeeded stereotactic drilling of the facial recess in a clinical study for the first time. Although they have shown that minimally-invasive image-guided cochlear implantation is clinically achievable, they acknowledged that improvements in drilling technology are necessary to minimize risk of injury of the facial nerve (FN) and allow atraumatic cochlear access. Quantitative research showed a navigation accuracy requirement of less than 0.5 mm is necessary to safely preserve critical anatomical structures, including the FN, chorda tympani (ChT) and ossicles [6]. To comply with the need for a high navigation accuracy, the Image Guided Therapy group at the ARTORG Center for Biomedical Engineering, University of Bern developed an image-guided robotic system and a dedicated surgical planning tool. Sufficient end-to-end drilling accuracy was proven in vitro with an error of 0.15 ± 0.08 mm at the target of the round window (RW) [7]. Williamson et al. [8] combined the image-guided robotic system to drill a direct cochlear access (DCA) tunnel to the middle ear space (promontory) and a drilling system for cochleostomy using integrated force-torque sensing technology and successfully achieved inner ear access in vitro. After optimization of

the drilling trajectory for a minimally invasive round window approach [9], robotic middle ear access was successfully achieved in seven patients and followed by a manual access to the cochlea via an extended round window approach for subsequent electrode insertion [10-12]. This image-guided robotic system was commercialized as the HEARO procedure (CAScination AG, Bern, Switzerland) and the surgical planning tool as OTOPLAN (CAScination AG, in collaboration with MED-EL, Innsbruck, Austria). The HEARO procedure for CI surgery consists of pre-operative scanning and planning, performing middle ear access with a 1.8 mm cutting burr, performing inner ear access with a 1.0 mm diamond burr, the manual insertion of the electrode array through a removable cannula and post-operative scanning. The surgical planning software OTOPLAN allows to configure all relevant anatomical structures three-dimensionally before surgery in order to screen for eligibility and for a personalized drill trajectory to the RW. The optimal angle of cochlear approach (ACA) can be calculated for an electrode insertion with the lowest risk for intracochlear damage [9, 13]. Furthermore, the cochlear duct lengths (CDL) are estimated pre-operatively in order to choose the electrode array to obtain complete cochlear coverage for optimal audiological outcome [14, 15]. The implementation of the robotic inner ear access required even more accuracy as a 1.0 mm diamond burr needs to be perfectly aligned with the RW membrane with a diameter of 1.31 ±0.31 mm [16]. Topsakal et al. [17] and Caversaccio et al. [18] proved the clinical feasibility of the HEARO robotic system. In 22 out of 25 patients, the HEARO procedure was successfully completed with full insertion in all cases, except for 1 case with the last electrode positioned at RW level [17]. The final aim of CI surgery is not only the correct placement of the electrode array, but also the hearing outcomes and the subjective benefit of patients.

This study aims to evaluate short-term and long-term audiological outcomes (including aided pure-tone thresholds, speech understanding in quiet and noise, binaural effects and sound

localization) in patients who underwent cochlear implantation by means of the HEARO robotic system, and to compare outcomes with a matched control group of patients who underwent conventional cochlear implantation.

## METHODS

### Study design

For the intervention group, a prospective interventional clinical trial was performed in 2 stages. A pilot study to evaluate the feasibility of robot-assisted cochlear implant surgery (RACIS) including access to the inner ear was completed in 3 patients between December 2018 and April 2019. This study (EAR2OS) was registered with HEARO device exemption number 80M0763 from the Federal Agency for Medicines and Health Products (FAMHP). The approval of the local ethics committee was granted with number B300201837507. A follow-up study (ARCI25) was performed in 23 patients between September 2019 and September 2020 also involving the effectiveness of RACIS. The approval of the local ethics committee was granted with number B300201941457 and HEARO device exemption 80M0793. The HEARO procedure has been described in detail by Topsakal et al. [17]. To evaluate the effectiveness of robotic surgery in terms of audiological outcomes, long-term data were matched to long-term data of conventionally implanted patients.

### Subjects

- Intervention group

Adult (18 years or older) patients scheduled for cochlear implantation were screened for eligibility, both clinically and radiologically. The inclusion criteria comprised adult CI candidates with an acquired SNHL and a normal temporal bone anatomy; patients for instance with previous temporal bone surgery e.g., radical cavities were excluded. Exclusion criteria consisted of pregnancy, the vulnerability of the patient (not able to consent), withdrawn or

invalid informed consent. Radiological exclusion criteria were defined by a planned trajectory on the routine clinical high-resolution computed tomography (HRCT) scan using 0.3 mm slice thickness: patients with a distance to the FN < 0.4mm and < 0.3 mm to the ChT were excluded from the study.

In total, the HRCT images of 32 patients were screened for eligibility between December 2018 and July 2020 by using OTOPLAN. A safe trajectory for RACIS was identified in 26 patients. All participants gave written informed consent prior to participation in accordance with the Declaration of Helsinki. In 3 patients, the trajectory planning did not allow a safe trajectory because the distance to FN was smaller than 0.4 mm, in 2 cases the surgeon decided that the distance to the ear canal was too small and in 1 case the ChT was not visible due to low soft tissue contrast in the image. In 23 out of 26 cases the HEARO procedure was completed. The HEARO procedure had to be converted to conventional surgery (mastoidectomy and facial recess approach) due to an intra-operative software failure in 2 cases and due to an unsafe intra-operative report in 1 case. In total, 21 patients with bilateral severe-to-profound SNHL were implanted and 2 single-sided deaf (SSD) patients. In 1 case a 20-mm FLEX electrode array was used and in all other cases a 28-mm FLEX electrode array of MED-EL (Innsbruck, Austria) was inserted. All electrodes were inserted following the soft surgery technique for intracochlear placement of electrodes as described by Lehnhardt et al. [19]. All patients had a full electrode insertion, except for 1 patient where the last electrode C12 was situated at RW level (Fig. 1). The average insertion depth was 571 degrees (SD: 65 degrees). The audioprocessor was activated approximately 2-4 weeks after implantation and was fitted according to standard clinical practice. Patients were fitted with a RONDO2, SONNET (EAS) or SONNET2 sound processor (MED-EL GmbH, Innsbruck, Austria).

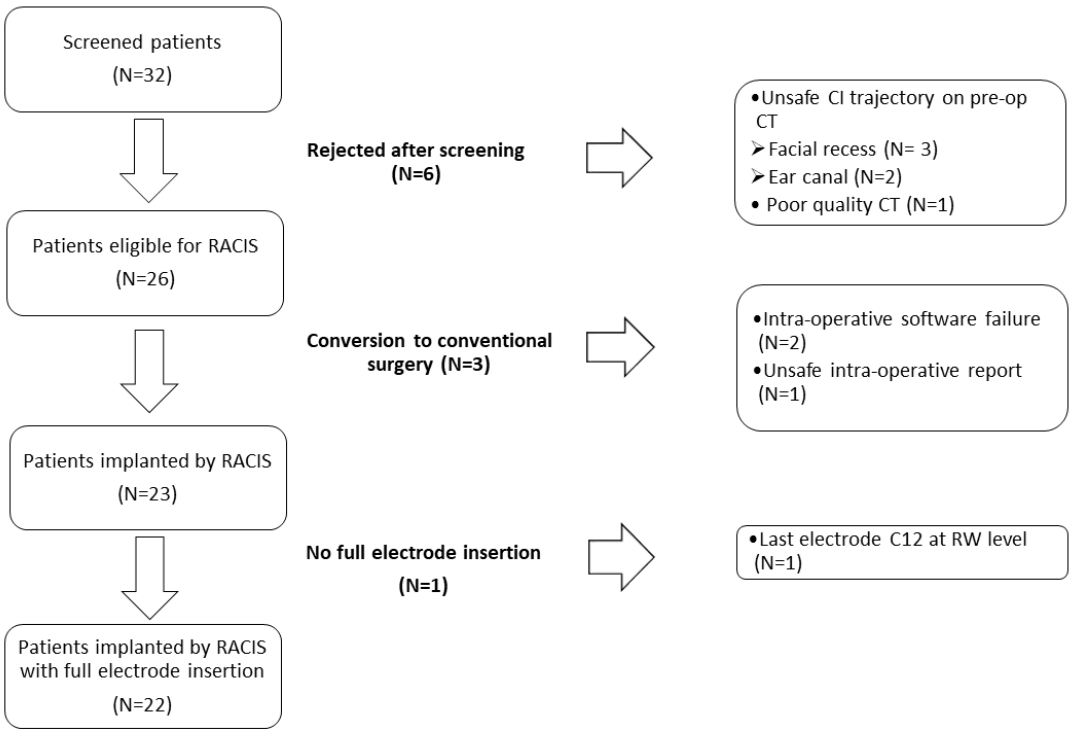


**Fig. 1** Patient selection for the intervention group

- Control group

As results of bilaterally deaf patients and SSD patients are analysed and reported separately, a control group of conventionally implanted patients was created to match each group of patients. For this study, a conventional surgery is defined as a mastoidectomy in combination with a posterior tympanotomy [13]. Electrode arrays were inserted following the soft surgery technique for intracochlear placement of electrodes as described by Lehnhardt et al. [19].

To create a balanced control group for the bilaterally deaf patients, nearest neighbor matching was used in statistical package R (R Foundation for Statistical Computing, Vienna, Austria). Propensity score difference (estimated using multivariate logistic regression) was used as distance measure to define a group of control patients which is closest to the group of treated patients. The following covariates were used based on literature [20, 21]: (1) age at onset of the SNHL (2) age at onset of bilateral severe-to-profound SNHL (3) duration of bilateral severe-to-profound SNHL (4) etiology of hearing loss (5) hearing aid use pre-

implantation (6) age at implantation (7) pre-operative residual hearing and (8) pre-operative aided speech perception in quiet of the implanted ear. In total, 21 patients with a bilateral severe-to-profound SNHL that were conventionally implanted between 2012-2019 with a MED-EL (Innsbruck, Austria) cochlear implant were included. One patient was implanted with a FORM24 electrode array and 20 patients were implanted with a FLEX28 electrode array. All patients had a full electrode insertion and were fitted with an OPUS2, SONNET, RONDO or RONDO2 sound processor (MED-EL GmbH, Innsbruck, Austria).

Due to small number of included SSD patients (because of local reimbursement and candidacy criteria), it was not possible to perform a reliable statistical matching. Therefore, an SSD cohort group of 8 patients implanted with conventional surgery was created in order to interpret the results of the 2 SSD patients of our study. Patients in the SSD cohort were implanted with a FLEX24 or FLEX28 electrode array with full electrode insertion and fitted with a RONDO, RONDO2, SONNET or SONNET2 sound processor (MED-EL GmbH, Innsbruck, Austria).

Similar to the intervention group, the audioprocessor of all control patients was activated approximately 2-4 weeks after implantation and was fitted routinely.

## Audiological Assessments

All subjects performed audiological testing, called the Minimal Outcome Measurements (MOM)[22], pre-operatively and at 3 months, 6 months, 12 months and 2 years after the activation of the audioprocessor. The MOM consists of pure tone audiometry, speech audiometry in quiet and speech audiometry in noise for bilaterally deaf subjects and of localization and speech audiometry in noise in 3 different spatial configurations to quantify binaural effects for SSD subjects.

- Pure tone audiometry

Unaided pure tone audiometry was performed pre-operatively with a standard clinical audiometer and 5A10 insert earphones. The aided thresholds with CI were measured post-operatively with warble tones in free field with a loudspeaker at a distance of 1 meter in front of the listener. Both unaided and aided pure tone audiometry were performed at 125, 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz with the 10-down 5-up Hughson-Westlake method in a soundproof booth [23]. Pure-tone average thresholds were calculated as the mean of the thresholds at 500, 1000, 2000 and 4000 Hz.

- Speech audiometry in quiet

Speech perception in quiet was measured using the Dutch open-set NVA lists, developed by the Nederlandse Vereniging voor Audiologie (NVA) [24]. Each word list consists of 12 monosyllabic words (consonant-vowel-consonant) of which the first one is a trail item. One list was presented at 65 dB SPL in free field with a loudspeaker at 0° azimuth at 1 meter of the subject. Speech recognition in quiet was performed pre-operatively in the CI ear in the best aided condition and post-operatively with the CI. The speech recognition score was determined as the percentage of correctly identified phonemes.

- Speech audiometry in noise

The speech perception in noise was tested with the Leuven Intelligibility Sentences Test (LIST) [25]. An adaptive procedure was used to determine the speech reception threshold (SRT). The level of the speech-weighted noise was held constant at 65 dB SPL and the intensity level of the speech signal was varied in steps of 2 dB adaptively in a one-down, one-up procedure according to the response of the subject. If the subject repeated the keywords of the sentence correctly, the level of the speech signal is decreased by 2 dB SPL. If the subject failed to repeat the keywords, the level was increased by 2 dB SPL. Each list consists of 10 sentences and the SRT was determined based on the level of the last 5 sentences of a list together with the level of an imaginary 11$^{th}$ sentence. If a subject was not able to complete the test, the worst score

was registered (>20 dB SNR). Tests were conducted pre-operatively in the CI ear in the best aided condition and post-operatively with the CI in free field in a soundproof booth with the loudspeaker positioned at 1 meter in front of the listener.

- Binaural effects

Speech audiometry in noise, as described above, was executed in 3 spatial configurations for SSD subjects: both speech and noise presented from the front ($S_0N_0$) for the measurement of the binaural summation effect (SRT $S_0N_0$ unaided - SRT $S_0N_0$ aided), speech from the front and noise from the SSD side ($S_0N_{SSD}$) for the measurement of the binaural squelch effect (SRT $S_0N_{SSD}$ unaided - SRT $S_0N_{SSD}$ aided) and speech presented from the SSD side and noise from the normal hearing (NH) side ($S_{SSD}N_{NH}$) for the measurement of the head shadow effect (SRT $S_{SSD}N_{NH}$ unaided - SRT $S_{SSD}N_{NH}$ aided).

- Localization

Seven broadband Fostex 6301 loudspeakers located in a frontal semicircle in a horizontal plane at subject head level were used. The loudspeakers were positioned at intervals of 30° in azimuth from -90° (left) to +90° (right). The CCITT (Comité Consultatif International Téléphonique et Télégraphique) noise bursts of 1 sec duration were presented. The stimuli were roved by +/-5 dB (sound levels between 70–80 dB SPL). In each trial 6 stimuli were offered from each loudspeaker in a random sequence. For each of the 42 stimulus presentations (7 loudspeakers × 3 levels × 2 signals), the judged azimuth in response to a loudspeaker k was recorded ($\psi_k$). Participants' accuracy of sound localization was analyzed as the root-mean-square localization error (RMSE) in degrees, calculated as the root-mean-square of the magnitudes of the differences between the azimuth angle of the sound presenting speaker ($\varphi_K$) and the azimuth angle of the judged speaker ($\psi_k$) across all 42 stimulus presentations. The smaller the RMSE, the better the localization accuracy.

## Statistics

IBM SPSS Statistics version 28 (IBM Corp., New York, NY) was used to perform the statistical analysis. Pure-tone audiometry (PTA), speech audiometry in quiet (SPIQ) and speech audiometry in noise (SPIN) results of the HEARO patients were compared to the results of the conventionally implanted patients, both pre-operatively and post-operatively. The Mann–Whitney U test was used to carry out the unpaired comparisons between CI users of the HEARO group and the control group in order to test whether the audiological outcomes of HEARO patients are equal to the outcomes of conventionally implanted patients (null hypothesis). Furthermore, the PTA, SPIQ and SPIN results before implantation were compared to the postoperative results for the HEARO group. Both one- and two-sided Wilcoxon signed-rank test was used for the pairwise comparisons of the pre- and post-operative results of the HEARO patients. These non-parametric tests were used due to the small sample size of each group (n = 21). In addition, Bonferroni- Holm correction was applied to correct for multiple pairwise comparisons for PTA, SPIQ and SPIN results. A significance level of $\alpha=0.05$ was used.

# RESULTS

## Bilaterally deaf patients

The age of the patients in the intervention group ranged from 31 to 83 years old. The study population consisted of 7 women (33%) and 14 men (67%) and the left-right ratio was 9:12. Patients in the matched control group were between 18 and 78 years old (9 men, 12 women). Ten patients were implanted on the right side and 11 were implanted on the left side. Table 1 shows a complete overview of the patients' demographics.

Figure 2 shows the PTA results of the HEARO group and the control group. The Mann-Whitney U test showed no significant difference ($p>0.05$) between the HEARO and the control group pre-operatively ($p=1.000$), at 3 months ($p=1.000$) , at 6 months ($p=1.000$), at 12 months ($p=1.000$) post-activation and at 2 years post-activation ($p=0.110$). For the HEARO patients,

Wilcoxon signed-rank test revealed a significant improvement of the hearing thresholds 3 months (p<0.001), 6 months (p<0.001), 12 months (p<0.001) and 2 years (p<0.001) post-activation of the audioprocessor in comparison to pre-operative hearing thresholds. There were no significant differences between the post-operative hearing thresholds in the HEARO group (p>0.05).

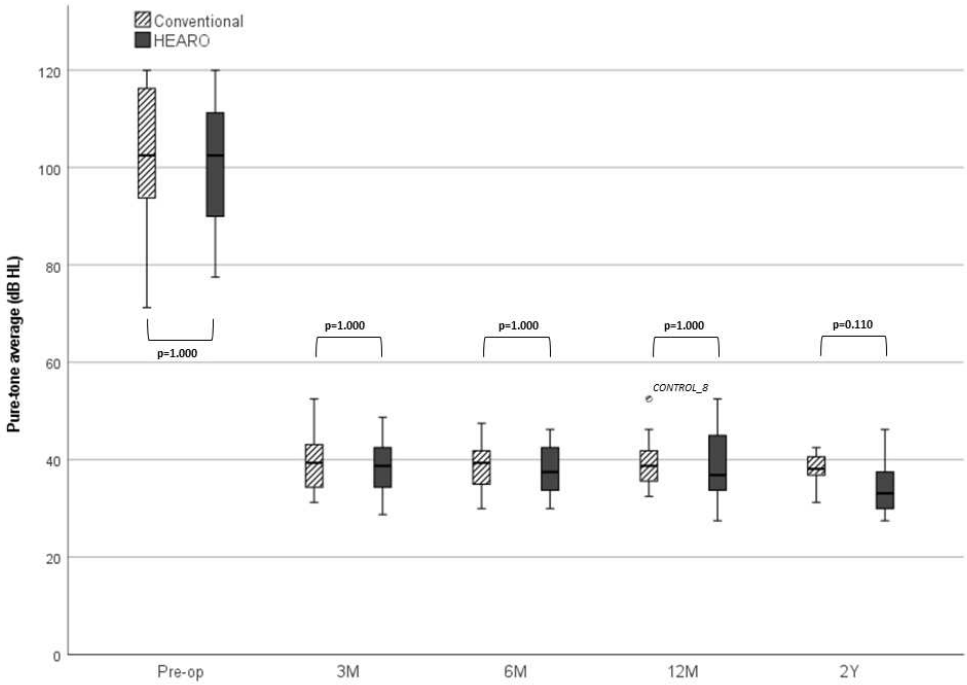


**Fig. 2** Pure-tone average pre-operatively (CI ear in the unaided condition), 3 months post-activation (3M), 6 months post-activation (6M), 12 months post-activation (12M) and 2 years post-activation (2Y) for conventionally implanted and HEARO implanted bilaterally deaf patients. The boxes of the box-and-whiskers plots represent the 1st quartile, median and the 3rd quartile. The whiskers connect the values within 1.5 times the interquartile range (IQR) of the 1st and the 3rd quartile. All values outside this range are considered as outliers and are indicated by circles

SPIQ was not significantly different (p>0.05) between the HEARO group and the control group pre-operatively in the best-aided condition (p=1.000) and 3 months (p=1.000), 6 months (p=1.000), 12 months (p=1.000) and 2 years (p=1.000) post-activation of the audioprocessor (Fig. 3 ). Wilcoxon signed-rank test showed a significant improvement of the percentage correctly repeated phonemes for the HEARO patients at 3 months (p<0.001), 6 months (p=0.002), 12 months (p<0.001) and 2 years (p=0.030) post-activation in comparison to pre-operative best aided SPIQ results. Post-operative SPIQ results showed no significant

difference between different moments in time (3 months, 6 months, 12 months and 2 years) for the HEARO group (p>0.05).

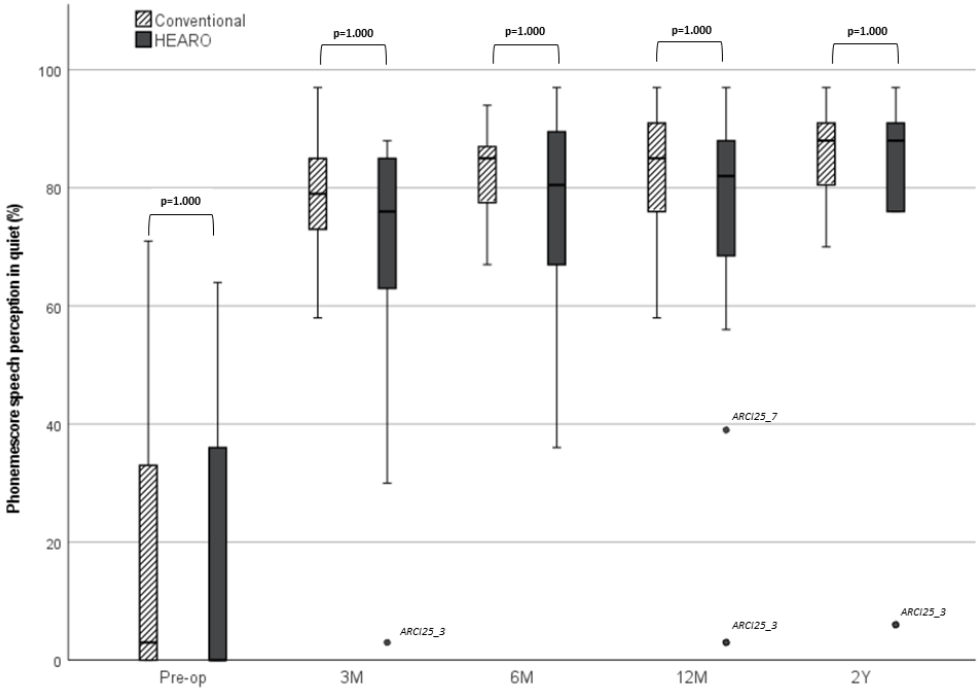


**Fig. 3** Speech audiometry in quiet (SPIQ) pre-operatively (CI ear in the best aided condition), 3 months post-activation (3M), 6 months post-activation (6M), 12 months post-activation (12M) and 2 years post-activation (2Y) for conventionally implanted and HEARO implanted bilaterally deaf patients. The boxes of the box-and-whiskers plots represent the 1st quartile, median and the 3rd quartile. The whiskers connect the values within 1.5 times the interquartile range (IQR) of the 1st and the 3rd quartile. All values outside this range are considered as outliers and are indicated by circles

Figure 4 shows the results of SPIN of the HEARO and the control group. The Mann-Whitney U test revealed no significant difference (p>0.05) in SRT between the HEARO and the control group pre-operatively in the best aided condition (p=1.000) and at 3 months (p=1.000), 6 months (p=1.000), 12 months (p=1.000) and 2 years (p=1.000) post-activation. Wilcoxon signed-rank test showed a significant improvement (p<0.05) in SRT 3 months (p=0.010), 6 months (p=0.032), 12 months (p=0.018) and 2 years (p=0.046) post-activation in comparison to the best-aided pre-operative SPIN results for the patients in the HEARO group. Post-operative SPIN results showed no significant differences between different moments in time for the HEARO patients (p>0.05).

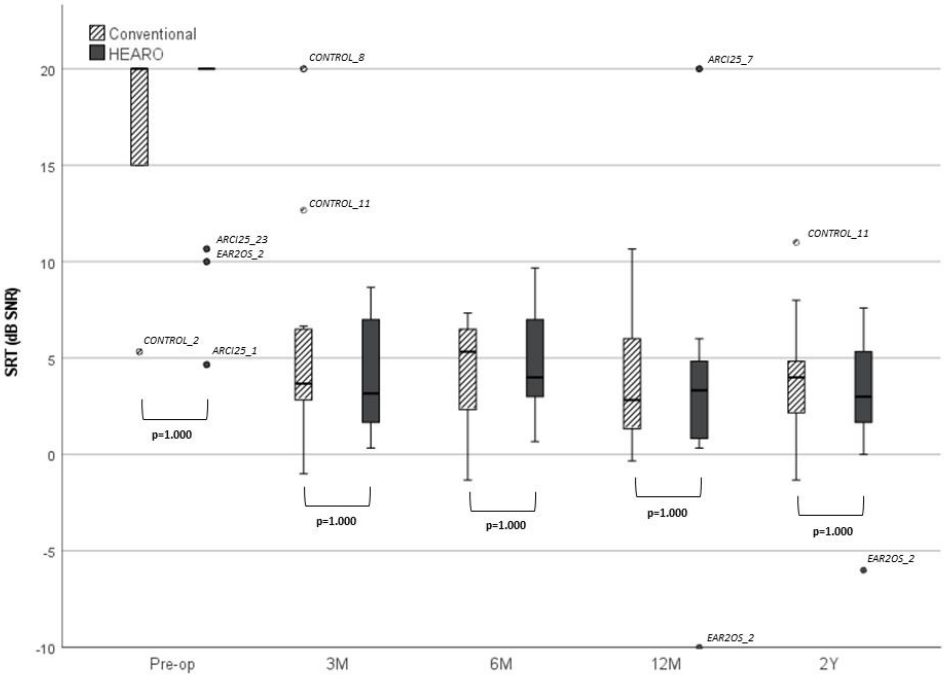


**Fig. 4** Speech reception threshold (SRT) pre-operatively (CI ear in the best aided condition), 3 months post-activation (3M), 6 months post-activation (6M), 12 months post-activation (12M) and 2 years post-activation (2Y) for conventionally implanted and HEARO implanted bilaterally deaf patients. The boxes of the box-and-whiskers plots represent the 1st quartile, median and the 3rd quartile. The whiskers connect the values within 1.5 times the interquartile range (IQR) of the 1st and the 3rd quartile. All values outside this range are considered as outliers and are indicated by circles

## SSD patients

For the SSD cases in our study, the mean age at implantation was 51 years old and consisted of 2 men that were implanted on the left side. The age of the SSD study cohort ranged from 36 to 82 years old, consisted of 3 men and 5 women and the left right ratio was 4:4. Table 2 presents more details on the demographics of the SSD patients.

Figure 5A-C shows the summation effect, squelch effect and head shadow effect respectively of the conventionally implanted SSD cohort and the HEARO implanted SSD cases at 3 months, 6 months, 12 months and 2 years post-activation. The summation effect of both HEARO cases are between the first and second quartile at 3 months and above the maximum value of the SSD cohort at 6 months and 12 months post-activation. At 2 years post-activation, the summation effect is beneath the minimum of the SSD cohort for one HEARO patient and at the third quartile of the SSD cohort for the other HEARO implanted SSD patient (Fig. 5A).

The squelch effect of both HEARO cases lies above the 50th percentile of the SSD cohort at 3 months, 6 months, 12 months and 2 years post-activation (Fig. 5B). The head shadow effect of both HEARO SSD cases lies between the first and third quantile of the SSD cohort at 3 months post-activation. At 6 months and 12 months post-activation, the head shadow effect lies above the second quartile of the SSD cohort. The head shadow effect lies beneath the minimum of the SSD cohort for one HEARO patient and above the maximum value of the SSD cohort for the other HEARO implanted SSD patient at 2 years post-activation (Fig. 5C).

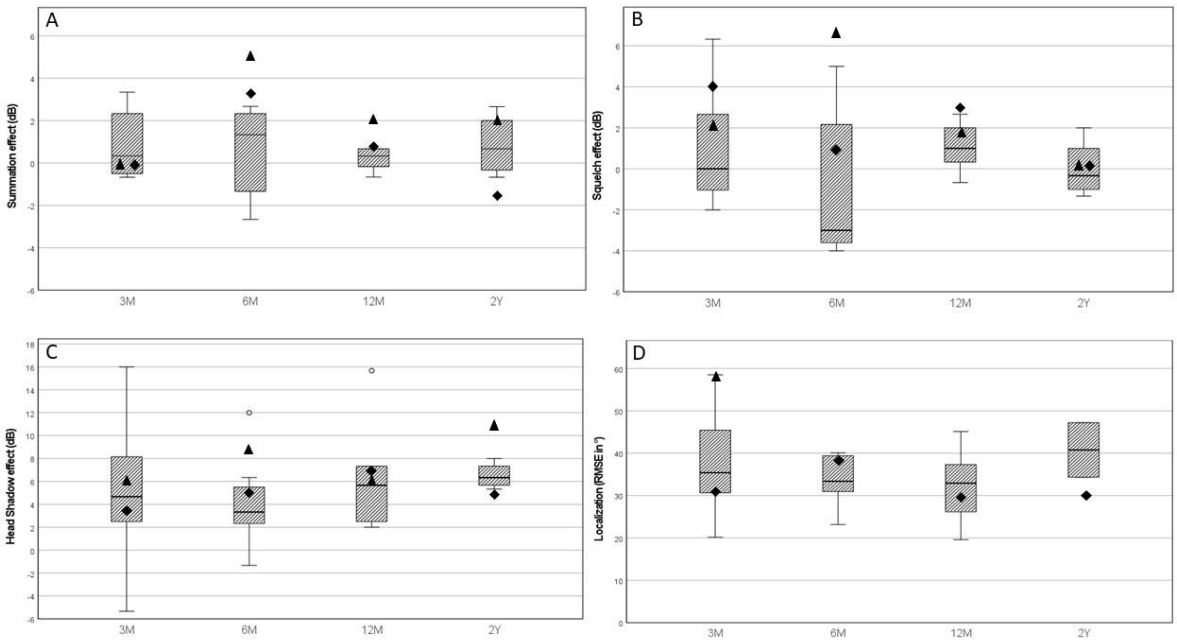


**Fig. 5** A) Summation effect ($S_0N_0$), B) Squelch effect ($S_0N_{SSD}$), C) Head Shadow effect ($S_{SSD}N_{NH}$) and D) Localization of conventionally implanted single-sided deafness (SSD) cohort and HEARO implanted SSD cases at 3 months (3M), 6 months (6M), 12 months (12M) and 2 years (2Y) after activation of the audioprocessor. The boxes of the box-and-whiskers plots represent the 1st quartile, median and the 3rd quartile. The whiskers represent the minimum and the maximum of the summation effect, squelch effect and localization. For the head shadow effect, the whiskers connect the values within 1.5 times the interquartile range (IQR) of the 1st and the 3rd quartile. All values outside this range are considered as outliers and are indicated by circles.

The result of the localization performance of the conventionally implanted SSD cohort and the 2 HEARO SSD cases is displayed in Figure 5D in RMSE in degrees. Note that the results of one SSD patient are missing at 6 months, 12 months and 2 years post-activation. The lower the RMSE, the better the result. The localization performance of the SSD cases lies between the minimum and the 75th percentile of the SSD cohort at 3 months post-activation,

between the 25th and 50th percentile at 6 months post-activation, between the 50th and 75th percentile at 12 months post-activation and above the 75th percentile at 2 years post-activation.

## DISCUSSION

The ultimate goal of cochlear implant surgery is the improvement of speech understanding in patients with severe-to-profound SNHL, regardless of a manually or robotically performed surgery. Most studies involving robot-assisted cochlear implant surgery already claim success when immediate radiological results mimic those of manual surgery. Although a full and correct positioning of the electrode array in the inner ear is crucial, the audiological outcomes of implanted patients are as important. Audiological results of implanted patients involving robotic middle and inner ear access have not been published to date in the short-term, nor in the long-term.

Here we report long-term audiological outcomes of patients that underwent the HEARO procedure for cochlear implant surgery. This study shows that there is no evidence that HEARO implanted patients perform different than conventionally implanted patients in terms of pure-tone audiometry, speech understanding in quiet and speech understanding in noise in bilaterally deaf patients. A significant improvement in pure-tone hearing thresholds, speech understanding in quiet and speech understanding in noise with the cochlear implant has been observed as of the first measurements at 3 months and this significant improvement remained stable over a time period of 2 years for HEARO implanted patients. Furthermore, HEARO implanted SSD patients perform similar to a conventionally implanted SSD cohort in terms of binaural effects and sound localization performance. During this long-term follow-up period no medical complications occurred.

This study focuses on audiological outcomes after cochlear implantation. In order to quantify the subjective experience and vestibular outcomes of HEARO implanted patients, it would be useful to implement questionnaires in future studies to measure health-related quality of life, subjective auditory performance and benefit, and to evaluate vestibular function.

In this study, only 2 SSD patients were included due to local reimbursement and candidacy criteria. Therefore, statistical matching with a conventionally implanted control group was not possible. Audiological outcomes of these patients were compared to the cohort of conventionally implanted SSD patients at our hospital. In a future study, it would be necessary to include more SSD patients in order to confirm the equality of the HEARO procedure and conventional implantation in terms of binaural effects and localization performance.

Despite a successful application of the HEARO procedure in a patient with postmeningitis cochlear ossification (ARCI25_3), the audiological outcomes were limited for this patient (Fig. 3). As reported in literature, patients with cochlear ossification have difficulties to achieve open-set speech recognition in comparison to patients with no cochlear ossification, but performance depends strongly on duration of deafness prior to cochlear implantation [26] . Patient ARCI25_3 had a duration of deafness of 50 years and cochlear implantation resulted in basic sound detection and speech recognition in presence of visual support (lip reading). On the contrary, one patient (EAR2OS_2) outperformed all other patients in terms of speech perception in noise at 12 months and 2 years post-activation (Fig. 4). This patient was fitted using electro-acoustic stimulation (EAS). As stated in literature, EAS patients show a better performance in noise in comparison to patients without acoustically amplified residual hearing [27].

Although all conventionally and HEARO implanted patients had a pre-operative CT scan, surgical planning with OTOPLAN to determine the CDL and the electrode length pre-

operatively was only performed for HEARO implanted patients. All HEARO patients were implanted with a FLEX28 electrode, except for one patient that was implanted with a FLEX20 electrode due to a congenital inner ear malformation (POU3F4 mutation). However, it needs to be mentioned that 20 HEARO patients were eligible for a FLEXSOFT electrode, but were implanted with a shorter FLEX28 electrode due to the constriction of the keyhole tunnel diameter of 1.0 mm. The conventionally implanted patients had their implantation between 2012 and 2019, before individualized surgical planning with OTOPLAN was available and implemented as a standard procedure at the hospital. For those patients, the CDL and the electrode length was estimated using the pre-operative CT scan. All patients who underwent conventional surgery received a FLEX28 electrode, except for one patient who received a FORM24 electrode because of a congenital inner ear malformation (POU3F4 mutation). Furthermore, electrode insertion depth could not be determined for the group of conventionally implanted patients as a post-operative CT scan was not a standard procedure at the time of implantation. The electrode insertion depth is known to influence hearing outcomes in CI recipients [14], but could not be taken into account in the present study.

A robotic approach may lead to a higher preservation of residual hearing, as it aims to reduce the mechanical and noise-induced trauma in the inner ear and the abrupt rupture of the round window membrane. The robotic workflow had to overcome some challenges to be able to provide stable and consistent reliability to first access the middle ear [10-12] and thereafter provide reliable and safe access to inner ear [17]. In a next phase, an algorithm can be designed to robotically insert the array in order to minimize the mechanical trauma to preserve residual hearing. Studies so far have not focused on hearing preservation, since the current robotic protocol involves manual insertion by the surgeon. Furthermore, residual hearing after cochlear implant surgery is affected by multiple factors, such as electrode design (length, flexibility, thickness), surgical technique, insertion technique, use of dexamethasone, cause of deafness

and pre-operative hearing thresholds [28]. In order to investigate correctly the degree of hearing preservation, above mentioned predictors should be precisely monitored in a group of conventionally and HEARO implanted patients. Although robotic insertion will be the next step in robotic CI surgery, these factors will still remain. Therefore, not only hearing preservation, but also tissue preservation should be the focus of further research.

The development of the surgical planning software OTOPLAN® for the HEARO procedure described here has led to a new focus on cochlear implant signal processing, i.e. anatomy-based fitting. The surgical planning software allows to import the post-operative computed tomography (CT) images to estimate the location of each electrode contact. An individualized frequency band for each electrode can be calculated based on the electrode locations in order to reduce the frequency-to-place mismatch (i.e. mismatch between the tonotopic frequency and the fitted center frequency of the electrode contact). Previous research has shown that this mismatch has an impact on initial hearing outcomes: the smaller the mismatch, the better the speech perception [29]. Further research is necessary to investigate the audiological outcomes of patients fitted with anatomy-based fitting.

The robotic cochlear implantation procedure is probably more standardized than conventional surgery, but in our series of implanted patients it has not outperformed it yet. The current benefit can therefore be found in its robustness and reliability rather than in its surgical or audiological outcomes. The direct inner ear access, requiring even more accuracy than middle ear access, has been proven safe [17] and now has paved the way to the next robotic step: robotic insertion. As stated before, a fully robotic CI placement may have better audiological outcomes in terms of hearing preservation. As residual hearing would be better preserved, this could widen the indication field for cochlear implantation. Whether surgery is manual or robotic, the ultimate goal of cochlear implantation is hearing rehabilitation of patients with severe-to-profound SNHL.

## CONCLUSIONS

Clinical outcomes in robot-assisted cochlear implant surgery are comparable to conventional cochlear implantation with respect to pure-tone audiometry, speech understanding in quiet and in noise.

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1 *Table 1. Demographics of bilaterally deaf patients in HEARO and matched control group.*

| | HEARO group | Control group |
|---|---|---|
| **Number of bilaterally deaf patients** | 21 | 21 |
| **Mean age at implantation (y) (SD)** | 59 (14) | 59 (14) |
| **Mean age at onset sensorineural hearing loss (SNHL) (y) (SD)** | 40 (22) | 44 (18) |
| **Mean age at onset bilateral severe-to-profound SNHL (y) (SD)** | 54 (18) | 59 (14) |
| **Mean duration of bilateral severe-to-profound SNHL (y) (SD)** | 3 (11) | 0 (0) |
| **Mean pre-operative residual hearing (dB HL) (SD)** | 100 (16) | 103 (13) |
| **Mean pre-operative aided speech perception in quiet (SPIQ) of the implanted ear (%) (SD)** | 16 (24) | 18 (22) |
| **Hearing aid use before implantation** | | |
| **Yes** | 57% | 67% |
| **No** | 43% | 33% |
| **Etiology** | | |
| **Unknown** | 38.1% | 19% |
| **Sudden unknown SNHL** | 9.5% | 14.3% |
| **Genetic** | 23.8% | 28.6% |
| ***DFNA9*** | *9.5%* | *23.8%* |
| ***POU3F4*** | *4.8%* | *4.8%* |
| ***OPA1*** | *4.8%* | *0%* |
| ***MELAS*** | *4.8%* | *0%* |
| **Far advanced otosclerosis** | 4.8% | 9.5% |
| **Menière** | 0% | 4.8% |
| **Usher** | 4.8% | 0% |
| **Meningitis** | 4.8% | 4.8% |
| **Auto-immune** | 9.5% | 4.8% |
| **Chronic middle ear infections** | 4.8% | 4.8% |
| **Cholesteatoma** | 0% | 4.8% |
| **Noise exposure** | 0% | 4.8% |
| **Implanted ear** | | |
| **Right** | 57% | 48% |
| **Left** | 43% | 52% |
| **Gender** | | |
| **Female** | 33% | 57% |
| **Male** | 67% | 43% |

*Table 2. Demographics of single-sided deafness (SSD) patients in HEARO and control SSD cohort.*

| | HEARO group | Control SSD cohort |
|---|---|---|
| **Number of SSD patients** | 2 | 8 |
| **Mean age at implantation (y) (SD)** | 56 (12) | 51 (15) |
| **Mean age at onset sensorineural hearing loss (SNHL) (y) (SD)** | 49 (6) | 47 (15) |
| **Mean age at onset severe-to-profound SNHL (y) (SD)** | 49 (6) | 49 (14) |
| **Mean duration of severe-to-profound SNHL (y) (SD** | 7 (6) | 2 (2) |
| **Mean pre-operative residual hearing (dB HL) (SD)** | 114 (9) | 96 (17) |
| **Hearing aid use before implantation** | | |
| **Yes** | 0 | 0 |
| **No** | 2 | 8 |
| **Etiology** | | |
| **Sudden unknown SNHL** | 2 | 3 |
| **Menière** | 0 | 2 |
| **Trauma** | 0 | 1 |
| **Intracochlear schwannoma** | 0 | 2 |
| **Implanted ear** | | |
| **Right** | 0 | 4 |
| **Left** | 2 | 4 |
| **Gender** | | |
| **Female** | 0 | 3 |
| **Male** | 2 | 5 |