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Impedance and Functional Outcomes in Robotic-Assisted or Manual Cochlear Implantation: A Comparative Study

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Keywords

Cochlear implants · Robot-assisted surgery · Impedance · Hearing preservation

Abstract

Introduction: Preservation of residual hearing, mainly the low frequencies, is the current main objective of cochlear implantation. New electrode arrays and the development of minimally invasive surgery have allowed electroacoustic stimulation. Over the past several years, robotic-assisted cochlear implant surgery aimed to improve the insertion process while respecting inner ear structures. However, the introduction of a foreign body inside the cochlea can lead to the development of fibrous tissue around the electrode array, or even induce osteogenesis. These histological changes disrupt the parameters of the cochlear implant, resulting in elevated impedance. In addition, long-term auditory performance can be affected, with a deterioration in word comprehension. We evaluated the potential impact of RobOtol® on impedance changes over time, leading to potentially positive functional outcomes. ***Methods:*** Cochlear implant surgery with a round window approach was performed under general anesthesia. Fifteen Med-El Flex24 electrode arrays were inserted manually and 24 using RobOtol®. All subjects underwent pure-tone audiometry tests before the surgery and at regular intervals up to 1 year after the surgery. Based on the pure-tone average at the low frequencies from 250 to 1,000 Hz, we divided the patients according to the degree of auditory preservation (full preservation ≤15 dB, partial preservation 15 dB–30 dB, significant loss >30 dB). These different groups were compared in terms of impedance changes and auditory performance, specifically word recognition score. ***Results:*** We found proportionally fewer patients who experienced significant low-frequency hearing loss after robotic insertion (53.33% in the manual group compared to 41.67% in the robot-assisted insertion group). Impedance changes at the apex of the electrode array, especially at the first electrode ($p = 0.04$), after robotic surgery, with less overall variability, a continuous decreasing trend without secondary elevation, and lower values in cases of complete residual hearing preservation (for the three first electrodes: $p = 0.017$, $p = 0.04$, $p = 0.045$). The speech intelligibility amelioration over time showed favorable evolution in patients with complete residual hearing preservation regardless of the insertion method. However, in the absence of auditory preservation, the positive evolution continued more than 6 months after robotic surgery but stagnated after manual insertion (difference at 1 year, $p = 0.038$; median auditory capacity index 83% vs. 57%). ***Conclusion:*** Atraumatic electrode array insertion with consistent, slow speed and the assistance of

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RobOtol® minimizes disturbances in the delicate neurosensory structures of the inner ear and leads to better auditory performance.

Introduction

Cochlear implants (CIs) have revolutionized the treatment of severe to profound sensorineural hearing loss. Since the first electrode array implantation performed by Djoo and Eyries in 1957, their evolution has continued to progress to the minimally invasive technique it is today.

The current main objective was protection of delicate intracochlear structures with preservation of residual hearing, mainly at low frequencies. Therefore, the criteria for hearing implant placement have been broadened to allow for electroacoustic stimulation. This significantly improves CI performance, including speech understanding in noise, music appreciation, and sound localization [1].

For more than a decade, several otological robots have been developed in the field of cochlear implantation. RobOtol® was the first to obtain European certification for clinical use. Robotic-assisted cochlear implant surgery (RACIS) aims to optimize the insertion process and could lead to less intracochlear trauma, potentially improving long-term audiological outcomes [2]. An electrode array (EA) placed completely inside the scala tympani (ST) with no scalar deviation is associated with better outcomes for patients by creating an optimal electrode-neural interface [3]. The clinical feasibility of robotic cochlear implantation has already been demonstrated in both adults and children. Robot-optimized insertion reduces inner ear trauma and allows a greater number of well-positioned electrodes into the ST [4, 5].

Our preliminary results were comparable to Torres data, with greater hearing preservation and no radiological inner ear trauma when the EA is inserted at a slow and constant speed in the inner ear using RobOtol® [6]. The robotic insertion allows insertion forces to be reduced, as well as pressure changes within the cochlea, increasing the likelihood of insertion in the ST axis. Nevertheless, its association with speech perception was not analyzed. The speed of electrode insertion has a significant positive impact on the preservation of hearing and vestibular function [3, 7–9].

EAs have constantly evolved to be as adapted to the cochlea as possible. According to a meta-analysis [10], no electrode design has shown a clear advantage in hearing preservation. However, Med-El Flex24 has been reported to have the best median hearing preservation score at low frequencies due to its highly flexible electrode array and ideal insertion depth. This was confirmed by a review of the literature supporting the use of straight electrodes for RACIS [3, 11].

However, EA insertion can still induce changes in the cochlea, and residual hearing loss remains possible. Intracochlear neuronal damage may by early onset (mechanical) or late onset. The hypothesis of delayed changes has been put forth on the basis of a chronic inflammatory reaction, fibrosis, or neo-osteogenesis induced by trauma, as well as on the basis of an immunological reaction to a foreign body [9, 12]. Subsequently, the normal physiology of the inner ear could be disrupted by these reactions, leading to a deterioration of the residual level of hearing and a limitation in good results [13]. Furthermore, postoperative word recognition scores have been reported to negatively correlate with the percentage volume of new bone within the cochlea [14]. In addition, fibrosis has been described as being associated with increased electrical impedance leading to lower hearing thresholds, less comfortable listening levels, less compliance level, and reduced sound quality [2, 15–17].

Overall, combining RACIS with atraumatic electrodes appears to improve the preservation of residual hearing. The aim of this study was to determine whether these changes improve postoperative impedance over time and lead to positive functional outcomes.

Materials and Methods

Study Design

We performed a retrospective single-center study to evaluate impedance measurements and audiometric outcomes in a population of patients who underwent manual or robot-assisted cochlear implantation.

Study Participants

Individuals, who met the general eligibility criteria for CI surgery, were ≥18 years old, and fluent in French were included in this study. The exclusion criteria were pregnancy or anatomical malformations of the middle or inner ear. We also excluded patients with low-frequency pure-tone average (PTA; 250 to 1,000 Hz) ≥100 dB to evaluate the potential residual hearing level. A total of 24 subjects in the robotic-assisted insertion group and 14 subjects in the manual insertion group gave written informed consent and were subsequently enrolled in the study. One patient in the manual insertion group had bilateral CIs.

Type of Electrode Arrays

All subjects had Med-El CIs and the same type of EA (Flex24) that was 24 mm long with an active length of 20.9 mm. To enable more flexibility at the tip, the five most apical electrode contacts were single, whereas the basal seven electrodes were paired. This reduced the diameter of the tip to 70% of the standard Med-El Combi40+ electrode.

Surgical and Robotic Procedure

CI surgery via the conventional surgical approach was performed under general anesthesia. The same senior surgeon performed all surgeries. A posterior tympanotomy was created with respect to the facial nerve and chorda tympani. The bony overhand of the round window niche was carefully drilled to expose the round window membrane. The RobOtol® (Collin, Bagneux, France) robot was used to introduce the EA into the cochlea. The RobOtol® arm with the insertion tool mounted on it was placed in the surgical field in the view of the posterior tympanotomy and the round window membrane. We descended the inserter's tip into the posterior tympanotomy using the robot. The robotic insertion tool was retracted 30 mm with respect to the trajectory of the insertion through the round window. The EA was clipped on the instrument 10 mm from the full insertion marker ring. The round window membrane was gently opened with the tip of a Rosen needle toward the perilymph. The axes of freedom of the robot were blocked, so the robot could only move linearly toward the round window. The insertion tool was moved gently toward the tip of the EA and inserted into the cochlea under guidance of a fork. The manual speed insertion of the EA was calculated by reviewing the videos of the procedures and the time needed to insert 5 of the 12 electrodes. The robotic speed insertion was fixed from 0.1 to 0.2 mm/s. After it was inserted completely, the EA was gently unclipped from the insertion instrument. We did not use any IV or local steroids during the surgery. Round window sealing and array fixation in the mastoid were performed using fibrin glue (Tisseel®). For the manual insertion group, CIs were inserted within the round window manually and as slowly as possible.

Outcome Measures

Audiological fitting was performed according to our standard routine, which comprises activation and initial fitting 10 days postoperatively and at regular intervals for 12 months after the surgery (1 month, 3 months, 6 months, and 12 months). An audiological evaluation was performed using the PTA, the average of hearing threshold levels (in dB HL) at a set of specified frequencies. For this study, we assessed the PTA at the range of frequencies including 250, 500, 1,000, 2,000, and 4,000 Hz. Then, we focused on the low frequencies: 250, 500, and 1,000 Hz. Postoperatively, patients were divided into three groups with regard to preservation of the low-frequency PTA (250–500–1,000 Hz): those who considered having complete preservation or no residual hearing trauma (≤15 dB HL), partial preservation or minor residual hearing trauma (15–30 dB HL), and a significant loss or major residual hearing trauma (>30 dB). This classification was selected from the consensus on hearing preservation proposed by Skarzynski et al. [18].

Electrode impedance (kOhms) was calculated according to Ohm's law (voltage = current × impedance). Impedance measurements were performed using a MED-EL Cochlear Implant System. Impedance of the 12 electrodes was measured postoperatively from CI activation onwards and at the same regular intervals.

Postoperatively, speech intelligibility performance was measured by the articulation function using the auditory capacity index (ACI). The ACI was defined as the average speech discrimination score obtained at 40, 55, and 70 dB SPL. We used words from Fournier's dissyllabic list in French, which were pronounced to the patient through a loudspeaker. Measurements were recorded at 40, 55, and 70 dB SPL and at regular intervals for 12 months after the surgery (1 month, 3 months, 6 months, and 12 months).

Imaging Analysis

All patients underwent a preoperative or postoperative, high-resolution cone beam CT of the temporal bone, which was analyzed using OTOPLAN® (CE-certification number: G1 17 10 95657 003). The software allows the analysis of the electrode array insertion angle in the cochlea.

Statistical Analysis

The data were analyzed using standard statistical software R version 3.6.1. Impedance value comparisons were made between each group using the Welch non-parametric test which is an adaptation of the *t* test, for comparing two independent samples. Variance comparisons were performed using the Levene test. The interaction effect of two independent factors was analyzed by a two-way ANOVA test, type two. The results were considered significant when $p \leq 0.05$.

Table 1. Audiological data

	Manual			Robot-assisted		*p* value
	N	mean±SD		*N*	mean±SD	
Preoperative PTA	15	84.27±9.93			82.58±13.79	0.34
Low-frequency preoperative PTA	15	76.67±13.79			73.26±13.16	0.21
Loss at low frequencies	*N*	%		*N*	%	
Preservation group						
Full (≤15 dB)	6	40	46.67	8	33.33	58.33
Partial (15–30 dB)	1	6.67		6	25	
Loss >30 dB	8	53.33		10	41.67	

Results

Participants

Thirty-eight participants took part in this study and were divided into two main groups depending on whether they were implanted manually (14 patients, 1 had bilateral CIs) or robot-assisted (24 patients). The mean age at implantation was 60 years (SD = 10) and 55 years (SD = 19), respectively. The etiologies of hearing loss for the two groups were: unknown (26.7–46%), genetic hearing loss (33.3–21%), sudden sensorineural hearing loss (20–21%), meningitis (6.7–4%), ototoxicity (none–8%), Meniere's disease (6.7%–none), multi-operated cholesteatoma (6.7%–none). All of the patients were implanted with a MED-EL Flex 24 EA by the same senior surgeon. Surgical videos of 5 randomly selected patients in the manual insertion group were reviewed to measure the speed of insertion of five electrodes of the Flex 24 EA. The mean speed was 2.48 ± 0.52 mm/s. In contrast, for robotic insertion, the speed was fixed at 0.1–0.2 mm/s. The electrode arrays insertion depth was measured using the Otoplan program after a cone beam CT of the temporal bone. When the postoperative images were not available, the preoperative were used and the putative insertion angle for the flex 24 electrode array was calculated. The insertion depth was not significantly different between the manual (419.89 ± 49.19°) and the robot-assisted (428.6 ± 37.6°) insertion in the cochlea (Mann-Whitney Z score = 0.707, p value = 0.477).

Audiological Analysis

In the manual insertion group, the preoperative PTA for five frequencies (250, 500, 1,000, 2,000, and 4,000 Hz) was 84.27 ± 9.93 dB and the preoperative low-frequency PTA (250, 500, and 1,000 Hz) was 76.67 ± 11.25 dB. In the robot-assisted insertion group, the preoperative PTA for the same five frequencies was 82.58 ± 13.79 dB and the preoperative low-frequency PTA was 73.26 ± 13.16 dB. These two groups were comparable; there was no significant difference between them ($p = 0.34$ and $p = 0.21$; Table 1). We divided each group into three subgroups based on the severity of hearing loss at the low frequencies and, thus, the degree of preservation or, conversely, the degree of residual hearing trauma. Eight patients had a loss of this PTA >30 dB in the manual insertion group and 10 in the robot-assisted group, which represents a proportion of 53.33% and 41.67%, respectively. Therefore, we found that, proportionally, 27.98% more patients had a loss >30 dB at low frequencies after manual insertion. This means that 1 out of 4 patients experience a significant loss in their residual hearing when the EA is inserted manually. However, with respect to the loss of hearing greater than 30 dB, there is no significant difference in the PTA between the two modes of insertion. Since the insertion depth can have an influence on hearing preservation [19], an analysis of the effect the insertion angle of electrode 1 on hearing preservation was performed and no significant correlation was found.

Impedance Analysis

First, we compared between the two main groups the impedance of the different electrodes at each timepoint with particular focus on the most distal electrodes, those that can reach the low-frequency region depending on the insertion and cochlear morphology. Before 12 months, we did not find any significant differences between manual and a robot-assisted insertion. The impedance data for the first five electrodes at 12 months are provided in Table 2. At this time, a difference appeared when we compare the two subgroups with a >15 dB decrease in residual hearing. This regroups the patients with minor and major residual hearing trauma who had significantly higher impedance values for the first electrode 1 year after the surgery when the EA was manually inserted ($p = 0.04$). The impact of the insertion method and degree of hearing loss (cutoff 15 dB), two independent factors, on the impedance values analyzed by two-way ANOVA demonstrates a significant combined effect for

Table 2. Impedance (in kOhms) at 12 months for the first five electrodes

	≤15 dB				>15 dB				>30 dB			
	mean	median	SD	N	mean	median	SD	N	mean	median	SD	N
Manual												
E1	4.73	4.61	1.22	6	6.86	6.49	1.80	9	7.06	6.58	1.81	8
E2	3.70	3.52	0.96	6	5.18	5.04	1.56	9	5.44	5.10	1.45	8
E3	3.47	3.81	1.14	6	5.07	5.28	1.66	9	5.31	5.34	1.60	8
E4	3.66	3.68	0.84	6	4.83	5.18	1.64	9	5.14	5.18	1.45	8
E5	3.60	3.49	0.76	6	4.99	5.00	1.43	9	5.20	5.11	1.38	8
Robot-assisted												
E1	5.91	6.17	1.75	4	5.22	4.63	1.11	8	5.56	4.66	1.29	5
E2	5.25	4.98	2.00	4	4.97	4.73	1.22	8	5.37	4.92	1.18	5
E3	4.44	4.29	1.39	4	4.01	4.08	0.85	8	4.42	4.60	0.82	5
E4	3.81	3.38	1.06	4	3.84	3.82	0.64	8	4.03	3.73	0.54	5
E5	4.89	3.55	3.17	4	3.95	3.69	0.87	8	4.27	3.72	0.96	5

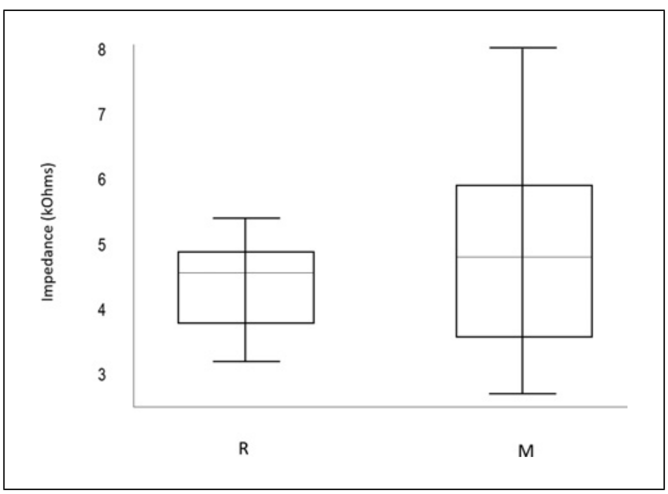

Fig. 1. Impedance disparity for the robot-assisted and manual insertion groups. The data are from electrode 1–5, the more representative electrode. The bold line represents the median; the box includes all patients from P25 to P75, with the error bar equivalent to 1 SD. One patient in the manual insertion group had an extreme impedance value.

the first, third, and fifth electrode ($p = 0.03$, $p = 0.05$, and $p = 0.05$, respectively). One other major difference between the two main groups is the consistency of values, without significant differences across the three subgroups, in the robot-assisted insertion group. In contrast, there is a clear disparity in values among these same subgroups in the manual insertion group. At 12 months, this disparity is marked by a significant difference for the first three electrodes when comparing the ≤15 dB and >15 dB subgroups ($p = 0.017$, $p = 0.04$, $p = 0.045$) and for the first five electrodes when comparing the ≤15 dB and >30 dB subgroups ($p = 0.014$, $p = 0.02$, $p = 0.03$, $p = 0.018$, $p = 0.03$). This difference in impedance disparity is illustrated in Figure 1. Finally, we observed a different evolution over time, with a continued decrease beyond 6 months for the robot-assisted insertion group (all patients included), whereas, after manual insertion, this decrease slowed and even tended to reverse, with values that slightly increased at 1 year (Fig. 2). In addition, the evaluation of the insertion angle on the electrode impedances was assessed and no correlation could be found for the first 5 electrodes (E1: $p = 0.837$, E2: $p = 0.379$, E3: $p = 0.919$, E4: $p = 0.813$ and E5: $p = 0.123$) demonstrating that the insertion depth has no influence on the impedances variations. The same analysis was performed for the manual and the robotic insertion cohorts and no correlation could be demonstrated. These covariance analysis allow to exclude the influence of the insertion depth on the impedance difference between the manual and the motorized insertion procedures.

Speech Intelligibility

The speech intelligibility performance based on the ACI is provided in Table 3. Overall, it appears that speech intelligibility improved up to 6 months in both groups, but this improvement ceased to progress in the manual insertion group. In contrast, in the robot-assisted group, the

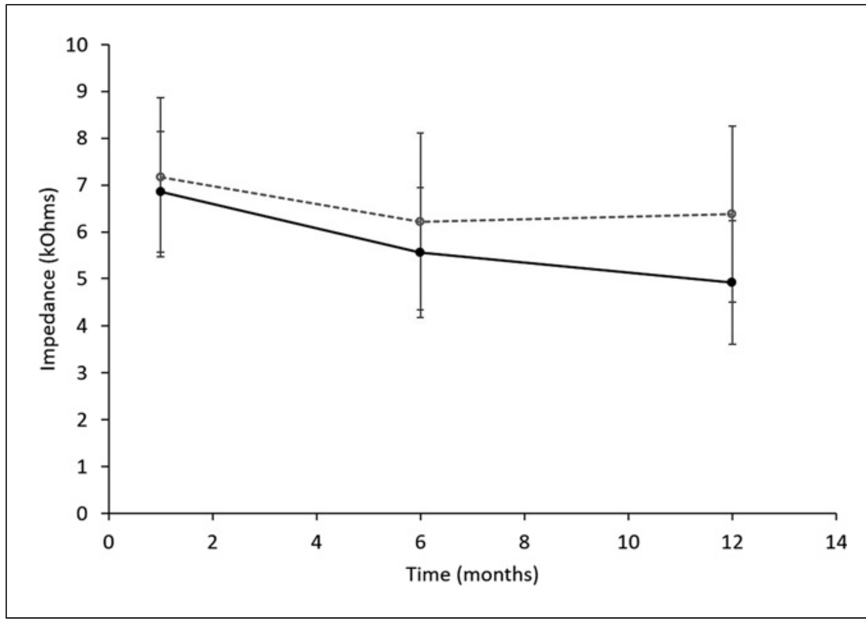

Fig. 2. Impedance evolution in electrode 1 from 1 to 12 months based on the insertion group. The solid line represents the impedance evolution for the robot group, whereas the dotted line represents the evolution for the manual group.

improvement continued over a longer time period. In fact, the overall median score for manual insertion patients decreased from 6 to 12 months due to the patients who experienced a loss >15 dB. However, patients in the same group who retained complete hearing preservation still showed a positive trend in their speech intelligibility scores. All of the patients who experienced complete hearing preservation had a generally comparable evolution regardless of the insertion method. The difference became evident when comparing patients with residual hearing loss (>15 dB), with a significant difference between the two groups that experienced significant loss (>30 dB) at 1 year ($p = 0.038$). This evolution over time in these two subgroups is illustrated in Figure 3. It appears that, even in cases of significant residual hearing loss with robotic insertion, auditory performance is not affected and patients show very good speech perception scores at 1 year (median 83%).

Discussion

CI surgery is constantly evolving, with a particular focus on making EA insertion as minimally traumatic as possible in order to preserve the structures of the inner ear. The main objective of this effort was to preserve the low-frequency range as much as possible in order to enable electroacoustic stimulation and improve CI performance, including speech understanding in noise, music appreciation, and sound localization [1]. Furthermore, significant residual postoperative hearing improves speech perception scores in patients who receive electric-only stimulation compared to those without residual postoperative hearing [20]. Conversely, patients who do not have preoperative residual hearing may benefit from atraumatic CI insertion, as this has been found to be a favorable factor for hearing performance [21, 22]. To achieve less traumatic surgery, the round window approach is preferred over cochleostomy because it allows greater preservation of the residual hearing level [23]. In addition, the design and properties of the EA may impact results. Manufacturers are paying more and more attention to the shape, the size, the diameter, and the flexibility. Therefore, to promote atraumatic surgery, the trend is to favor shorter, more flexible, and thinner EAs. The Med-El Flex24 results in fewer, if any, signs of inner ear trauma, such as scalar dislocation, than the longer arrays and has the best median low-frequency hearing preservation score [11, 24]. All of the subjects in the present study were implanted with the Med-El Flex24 EA using a round window approach.

The philosophy of RACIS is a lower insertion speed, which is associated with lower insertion forces and mainly allows more consistent CI insertion than manual insertion [7, 25]. High insertion speeds cause a significant increase in the forces that induce inner ear trauma and, therefore, are responsible for the deterioration of residual hearing. Robotic insertion results in significantly less inner ear trauma, such as a reduced translocation rate, than manual insertion [4]. A slower EA insertion speed appears to facilitate full electrode insertion with less resistance and, thus, to promote preservation of inner ear function [8].

Table 3. ACI values over time

Months	Overall			≤15 dB			>15 dB			>30 dB		
	mean	median	SD	mean	median	SD	mean	median	SD	mean	median	SD
Manual												
1	35.40	30.00	25.27	36.75	33.50	33.30	34.50	30.00	21.94	35.40	30.00	24.41
3	43.53	47.00	31.68	51.17	50.00	32.31	38.44	37.00	32.11	36.63	30.00	33.83
6	60.93	58.50	21.21	65.50	61.50	20.62	57.50	58.50	22.37	57.57	60.00	24.17
12	63.67	57.00	16.77	68.50	70.00	21.50	60.44	57.00	13.18	58.88	57.00	13.16
Robot-assisted												
1	41.90	40.00	24.30	39.86	50.00	21.55	42.93	38.50	26.29	44.25	35.00	29.55
3	42.73	41.50	25.26	37.86	33.00	15.98	45.00	47.00	28.81	47.56	60.00	26.74
6	62.27	61.50	27.43	63.86	60.00	14.74	61.53	70.00	32.15	66.70	73.50	32.24
12	73.05	73.00	18.48	73.71	73.00	14.94	72.21	76.50	20.54	78.00	83.00	20.72

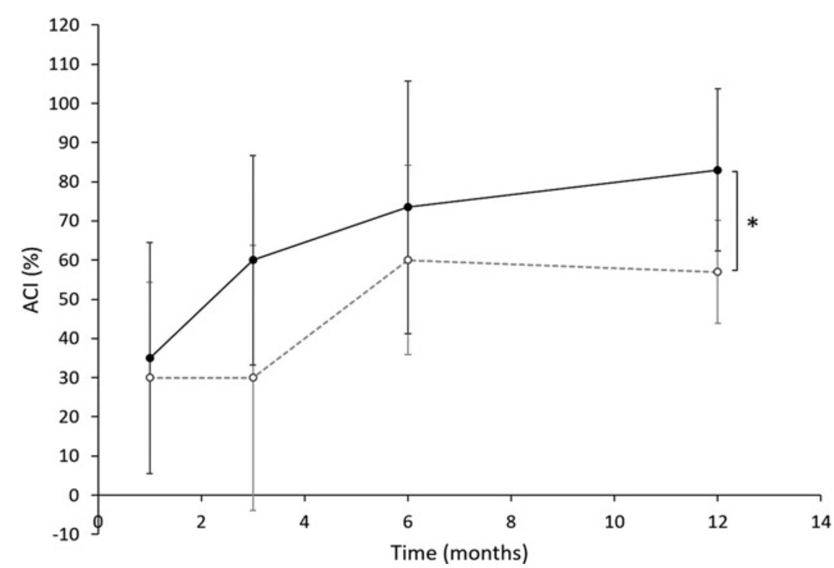

Fig. 3. ACI over time for the two subgroups that experienced residual hearing loss >30 dB. The solid line represents the robot group. The dotted line represents the manual group. The significant difference at 1 year is marked by the asterisk.

Our hearing outcomes in the low-frequency range follow the same trend as our preliminary study, with a higher rate of residual hearing preservation observed in robotic-assisted insertion cases [6]. Jia et al. [5] did not observe any difference in residual hearing outcomes after robotic-assisted insertion, but the patients' preoperative hearing was poor, generally >95 dB. An animal model study showed that we can expect a hearing loss limitation of up to 15 dB after a slow, controlled speed insertion with a robotic arm and using a flexible EA [26].

Hearing loss after cochlear implantation is related to EA position in the cochlea, but also to fibrosis in the ST. The presence of fibrous tissue surrounding the EA is associated with elevated electrical impedance and reflects the electrode-to-tissue status [27]. In the present study, the impedance values of the most apical electrode 1 year after the surgery were significantly less elevated when a patient seemed to have had initial inner ear trauma with a robotic insertion compared to a manual insertion. This suggests that, even in cases categorized as initially traumatic, the development of fibrous tissue could be less important over time. This is also supported by the evolution over time, in which a consistent decrease was observed after robotic surgery, whereas, after manual surgery, a break and upward trend in the impedances at the apex of the EA were observed from the sixth month onwards.

Scar tissue formation around the EA caused by the insertion of the CI changes the mechanical properties of the basilar membrane and can decrease residual hearing [13]. The degree of tissue encapsulation around the EA varies among subjects but is usually most pronounced in the basal turn of the cochlea, modifying the vibration of the basilar membrane apically, which may impact native low-frequency hearing [13]. This fibrous tissue can extend apically beyond the distal end of the electrode in the low-frequency range and cause a delayed residual hearing loss from 3 months to 3 years after implant surgery [12]. Unfortunately, one limitation of our study is the lack of audiological follow-up in some patients, which prevented us from accurately measuring the time interval between surgery and hearing loss.

The impedance measurements in the manual insertion group varied greatly, whereas the values in the robotic insertion group were much more homogeneous. We think that this reflects more random insertion by the human hand and much more consistent insertion with robotic assistance. Significant variations in insertion depth significantly impact impedance fluctuations. Therefore, the insertion angle of electrode 1 was measured and no difference was found between the manual and the robot-assisted procedure allowing to rule out a potential effect the insertion depth on the impedances of the electrodes. In addition, no correlation could be found between the insertion depth and the impedances for the first 5 electrodes reinforcing the hypothesis of the influence of the motorized insertion on the fibrosis due to the insertion trauma.

Finally, we investigated the clinical aspect of hearing performance after cochlear implantation. The two groups, i.e., manual or robot-assisted insertion procedures, can be compared because the assessment of the insertion depth showed no significant difference between the 2 cohorts of patients. This was important to rule out since insertion depth of the electrodes exerts an influence on speech intelligibility. In addition, no correlation was found between the insertion angle and the hearing preservation. Evolution of the word recognition score was comparable regardless of the insertion method when there was full residual hearing preservation but, as soon as there was partial residual hearing loss, a certain slowing down became apparent in the manual insertion group. This is significant in patients with residual hearing loss >30 dB. Even if fibrous tissue extends the length of the EA and beyond the tip in most cases, the degree of fibrous tissue alone does not significantly correlate with the word recognition score or intracochlear insertional trauma [14]. In contrast, these authors found that auditory performance correlated with residual spiral ganglion cell counts and the degree of intracochlear new bone formation associated with the trauma to the inner ear. Our results suggest that, in the major residual hearing loss group, the consequences of CI insertion result in deeper damage to the structures of the inner ear and in a poor electrode-neural interface.

Conclusion

The RobOtol® surgical robot allows for safe and slow CI electrode array insertion in the cochlea. This results in a reduced risk of deterioration of residual hearing at low frequencies. This gentle insertion seems to impact the degree of fibrous tissue formation around the EA tip, resulting in stable impedance. Even in the presence of residual hearing loss, the auditory performance is not affected, suggesting better preservation of the delicate neurosensory structures of the inner ear.

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Statement of Ethics

This study was performed according to the regulation of the University Faculty Hospital Ethics Committee of CHU Liège (Liège, Belgium) and the principles outlined in the World Medical Association Declaration of Helsinki. The study was approved by the Local Ethics Committee of CHU Liège (Ethics Committee number 707; ref: 2023-23). Written informed consent was obtained from participants before enrollment in the study.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

P.P.L. performed the surgeries. Clinical evaluation was assessed by G.G. and P.P.L., U.D. performed clinical assessment based on CT-scan images. G.G. and N.P. reviewed the electronic medical records. S.C. performed the statistical analyses, draft review, and editing for final manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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