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ORIGINAL RESEARCH ARTICLE

Hearing preservation and cochlear implants based on inner ear approach: Multicentric evaluation

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ABSTRACT

Introduction: Electroacoustic stimulation is an excellent option for people with residual hearing in low frequencies, who obtain insufficient benefit from hearing aids. For be effective, residual hearing must be preserved during cochlear implant surgery. **Objectives:** To evaluate hearing preservation in implanted patients and compare the results according to the inner ear approach. **Method:** 19 individuals were implanted with a surgical technique for hearing preservation, MED-EL FLEX^{TM} EAS electrode, designed to be atraumatic, was used. We evaluated tonal audiometric tests preoperatively at an average of 18.4 months after implantation n to measure the rate of residual hearing preservation. **Results:** 17 patients had complete or partial preservation of residual hearing five achieved preservation of total hearing, and two individuals had no hearing preservation. Electrode insertion occurred via cochleostomy in 3 patients. In 2 of these patients there was no hearing was not preserved. The other 16 patients were submitted to the round window approach. All patients benefited from cochlear implantation, even those patients who used only electrical stimulation. **Conclusion:** Hearing preservation occurred in 89.4% of cases. There was no significant difference between the approaches to the inner ear.

Keywords: cochlear implants; inner ear; correction of hearing impairment; bilateral hearing loss

1. Introduction

Electroacoustic stimulation is an excellent option for people with residual hearing in the low frequencies, but not in the high frequencies, and who have insufficient benefit from hearing aids. For electroacoustic stimulation to be effective, the patient's residual hearing must be preserved during

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cochlear implant (CI) surgery.

In the last decades, several electrodes have been developed and improved with the goal of causing as little damage as possible to cochlear the cochlear structures as little as possible, in order to preserve the residual preserving the auditory residue[1–4]. However, for preservation to be successful, the surgical technique is crucial. Since the first surgeries in which a conventional cochlear conventional cochlear implant lead has been partially inserted into the cochlea[5], in order to make the surgery less traumatic, "soft surgery" has been studied, which aimed at hearing preservation, and many advances have since then[6,7].

A widely studied and discussed aspect in relation to the surgical technique is the route of electrode insertion into the cochlea.

Initially, insertion through the round window was considered the standard for hearing preservation surgery, as it consists of a minimal consists of a minimal incision in the membrane and does not pierce the cochlea, thus reducing acoustic trauma and the possibility of bone of bone fragments in the tympanic ramp[8].

However, a recent study has shown that the angle of introduction of the electrode is similar between the round window and window or cochleostomy technique, and in both, tissue damage is minimal when is minimal when using an electrode designed for hearing preservation[9]. In a 2013 systematic review comparing the two approaches, no study was found specifically comparing the insertion techniques, and the levels of hearing preservation were similar between the two approaches, being slightly higher in patients undergoing to insertion through the round window[8].

These data currently comprise the largest series of patients of patients undergoing hearing preservation in cochlear implantation in Latin America. This group of patients is also the one with the longest post-operative follow-up.

Considering the importance of better understanding the factors that contribute to a higher rate of hearing preservation in preservation rate in implanted patients, this study aimed to evaluate the rate of hearing preservation in implanted patients and compare the results and hearing performance of patients according to the type of inner ear approach.

2. Method

This is a multicenter, retrospective study of patients implanted in the last four years in two institutions in Latin America, who underwent the same were submitted to the same surgical technique for hearing preservation technique, using an electrode designed to be atraumatic (MED-EL FLEX™ EAS)[10].

It is worth mentioning that the surgical technique used was similar in all patients, having been described in a previous publication previous publication[10].

General patient characteristics were analyzed were analyzed (age, gender, clinical history), audiological data (etiology of deafness, duration of deafness, audiometric and speech tests, pre- and postoperative sequential).

3. Inclusion and exclusion criteria

The inclusion criteria were: Bilateral sensorineural discuses with little or no benefit with hearing aids, tonal thresholds better than 65 dB at frequencies of 125,250 and 500 Hz, and worse than 80 dB at frequencies above 1,000 Hz (**Figure 1**), auditory discrimination with monosyllables below 40% in the best possible sound amplification condition, stable hearing loss for at least the last two years.

All patients outside these criteria were excluded from the from the study.

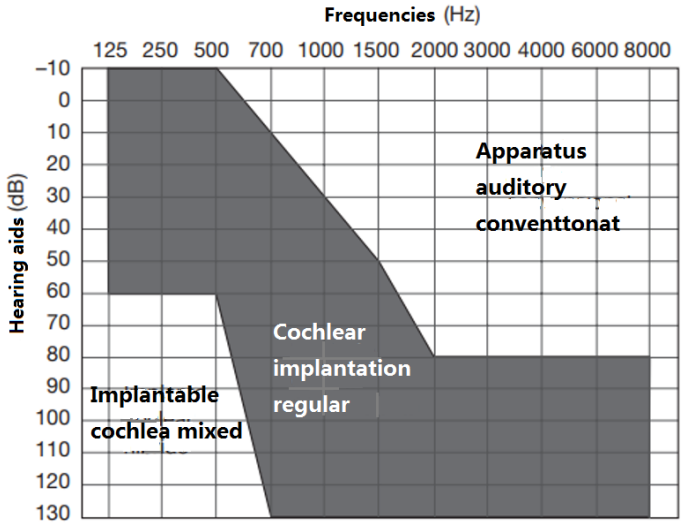

Figure 1. Graph showing the audiometric pattern expected in hybrid implant candidates.

4. Implant used

The implant used in all cases was the MED-EL FLEX™ EAS, with complete insertion of the electrode array in all cases.

The MED-EL FLEX™ EAS electrode is 24 mm in total length diameter at the base of 0.8 mm and 0.3 mm at the apex, a 0.5 mm extended tip, and a cochlear coverage of approximately of approximately 1.5 turns (**Figure 2**), configuring around 21 mm of intracochlear stimulation area.

All patients used the internal component model Sonata™ internal component and were fitted using the Maestro System™ software. Patients who had postoperative electroacoustic stimulation used a Duet 2™ speech processor. The group that had purely electrical stimulation differed only in the speech processor, and in these cases the OPUS 2™ was used.

5. Surgical approach of the inner ear

In all patients, initially the introduction of the electrode through the round the electrode through the round window, but in those who did not have good exposure of the round window niche, a cochleostomy was performed for electrode insertion. In all the steps proposed for hearing preservation were followed[10].

It is worth remembering that when exposure of the round window niche was not adequate through posterior tympanotomy, cochleostomy was chosen, without any manipulation of the cochlear manipulation of the cochlear or round window region.

6. Hearing preservation

To determine residual hearing, audiometric tests without electrical stimulation were repeated as follows: on the date of activation/1 month postoperatively, 3 months post activation, 6 months post-activation, and then every six months at follow-up. The preoperative examinations were considered all up to two years prior to treatment. The exams were also repeated on the date of surgery, before the procedure. For statistical evaluation, the most recent preoperative exams (on the date of surgery) were used for statistical evaluation, as well as the latest postoperative evaluation, recorded in the medical records of these patients, were used for statistical evaluation.

The protocol included tone audiometry in the field with the implant and speech tests, standardized according to the rules of the rules of the institutions.

We defined “residual hearing preservation” in three ways.

Total hearing preservation is that the postoperative hearing loss of 0–10.

Partial hearing preservation is that postoperative hearing loss greater than 10 decibels, but maintaining less than or equal to 80 decibels, in at least one frequency at least one frequency between 250 and 1,000 Hz;

Without hearing preservation is that patient who will not benefit from EAS because their postoperative thresholds without electrical stimulation are electrical stimulation are greater than 80 dB.

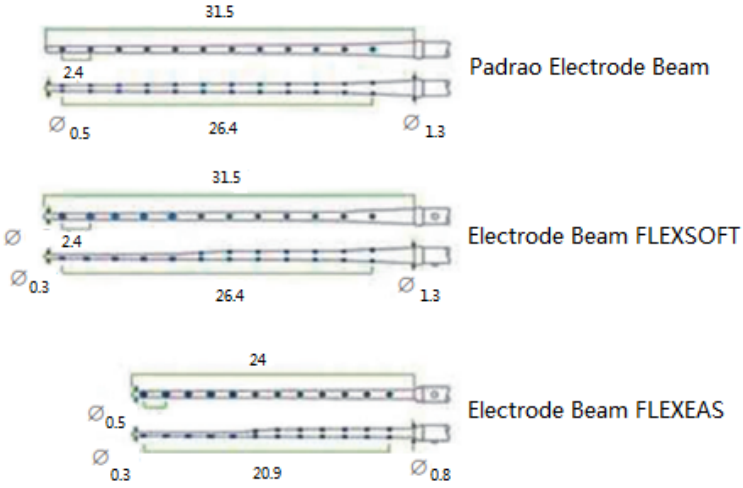

Figure 2. Schematic diagram of the MED-EL FLEX^{TM} EAS electrode (21 mm).字太大

7. Ethical Aspects

This study was approved by the local Research Ethics Committee site.

8. Results

Nineteen patients were included in the study, nine of them operated at institution 1 and 10 at institution 2. Nine patients were female and 10 patients were male. The age of the patients ranged from 19 to 70 years, with a mean age of 48 years old. All surgeries were uneventful or complications.

Regarding the etiology of deafness in these patients, it was distributed as follows: idiopathic in 11 cases (57.8%), genetic in three cases (15.7%; GJB2 homogigoze); two cases by otosclerosis (10.5%), and others (trauma, neonatal hypoxia and chronic otitis media).

The average time of the last postoperative audiometry measurement was 23.6 months after cochlear implant surgery, varying cochlear implant surgery, ranging from 4.5 to 81 months.

Of the 19 implanted patients, in 16 cases the insertion of the electrode insertion occurred through the round window, and in three it occurred through cochleostomy, due to the lack of good exposure of the round niche of the round window. It is noteworthy that in the three cases in which the insertion occurred through cochleostomy, the genetic etiology occurred in two of them, and in another it was idiopathic.

Hearing preservation was total in five patients, partial in 12, and in two of them there was no hearing preservation (**Figure 3**). Of the three patients submitted to cochleostomy, in there was no hearing preservation, and in one case there was partial preservation was partial (**Figure 4**).

In all patients, the results of the tone average of 500 Hz, 1 kHz, 2 kHz, 3 kHz with the implant activated were superior than preoperative audiometry results ($p < 0.001$) (**Figure 5**). The Kolmogorov-Smirnov test was used before the

analyses to check the distribution of the data. As the distribution of the data was approximately normal, paired t-test was used to evaluate the difference between the individual test intervals for the whole group.

Regarding the speech perception test in silence, the patients also benefited from cochlear implantation (**Figure 6 and Figure 7**). As the distribution of the speech perception tests was not normal, the Wilcoxon Signed Rank test was used to test the difference between the individual test intervals. The results showed a significant improvement in speech test performance for the entire group between the preoperative and postoperative tests ($p < 0.001$).

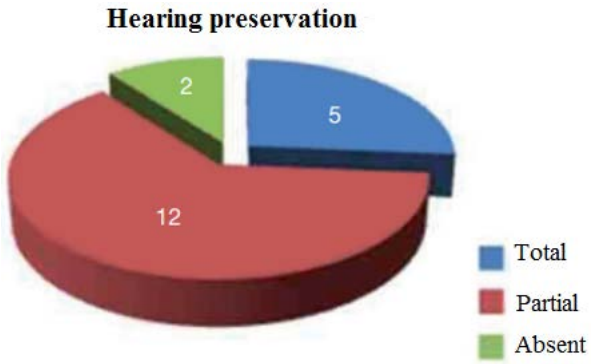

Figure 3. Distribution of patients according to residual hearing preservation after surgery.

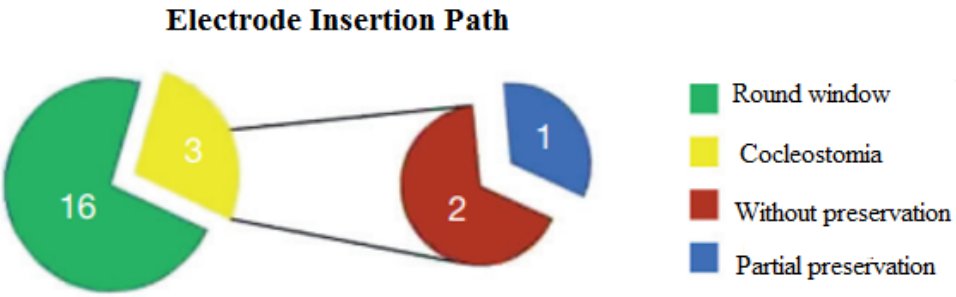

Figure 4. Distribution of patients according to the route of lead insertion electrode insertion route and the hearing preservation rate of patients submitted to cochleostomy.

9. Stratified analyses according to the inner ear

For the stratified analyses the Wilcoxon test was used. Individuals with the round approach achieved a significant improvement in postoperative tone thresholds with activated EAS implantation ($p < 0.001$).

The improvement of postoperative tone thresholds in subjects with the cochleostomy inner ear approach was not significant ($p = 0.109$) with activated EAS implantation. We have that this group has a small n ($n = 3$), which may be a bias (**Figure 8**).

10. Is there a significant difference in the intervals of the individual tests between the groups?

To see if there is a difference between the two approaches inner ear (round window vs. cochleostomy) in the individual test intervals, the Mann-Whitney U test was performed. Thus, between the two inner ear approaches, no significant difference was found in the preoperative test ($p = 0.866$), but in the postoperative (EAS) ($p = 0.823$) there was a trend towards a difference in the one with the activated implant ($p = 0.073$) (**Table 1**).

Table 1. Comparative table between the score of speech perception tests in the round window approach by cochleostomy

	Round window		Cocleostomia	
	Pre-op	**Post-op**	**Pre-op**	**Post-op**
Average	25.38	83.19	20.00	62.67
Median	30.00	90.00	25.00	82.00
Standard	16.395	26.945	18.028	40.612

Regarding speech tests, in the comparison between the approach to the inner ear, the subjects with the round approach reached a significant improvement in speech test performance in speech test performance between the preoperative and preoperative and postoperative tests (p = 0.001). The improvement for patients with the cochleostomy approach between preoperative and the preoperative and postoperative tests was not significant (p = 0.109).

To see if there is a difference in test performance speech between the approaches in the intervals of the individual tests, the Mann-Whitney U test was performed. Individuals with the round-window approach achieved higher speech performance scores on preoperative and postoperative tests, but the difference was not difference was not significant (preoperative tests: p = 0.499; postoperative post-operative: p = 0.206).

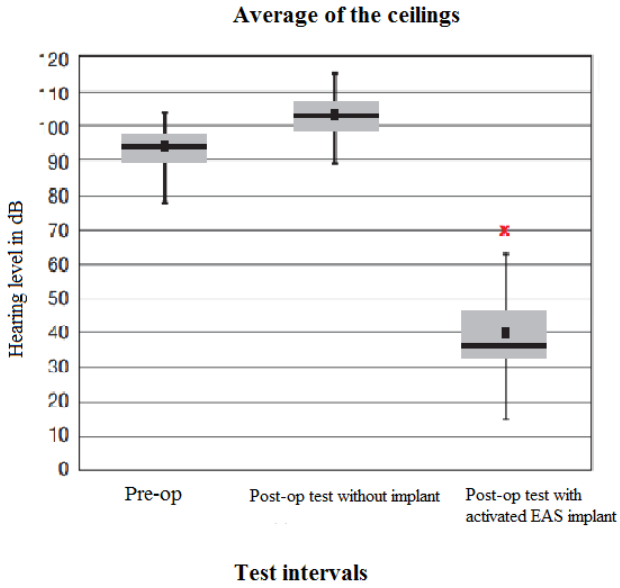

Figure 5. Mean tonal audiometric thresholds (500 Hz, 1 kHz, 2 kHz, 3 kHz): comparison between preoperative tests, the last postoperative last post-operative test without hearing aid and the last test with the implant (EAS) (hearing level in dB) (n = 19). Mean values are presented as vertical black dashes vertical dashes, and median values as horizontal lines. Asterisk red represents the discrepancies.

11. Discussions

Electroacoustic stimulation of hearing aims to combine the amplification of the patient's residual hearing by conventional hearing aids with electrical stimulation of the cochlea by cochlear implantation. Although there are still controversies about the real advantages of combined stimulation, several benefits of combined stimulation are described for patients with hearing loss who have preserved hearing, such as good speech discrimination[11,12], better speech perception in noisy environments[1,12], better musical appreciation ability[13,14] and better discrimination of sounds of different frequencies[15].

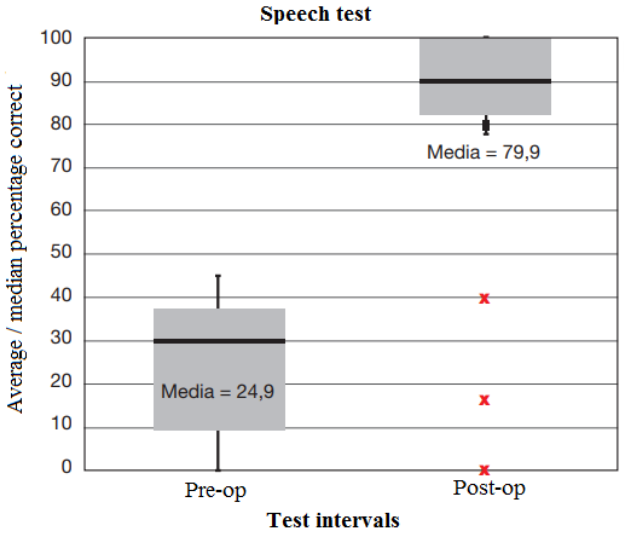

Figure 6. Speech test results: comparison of preoperative and postoperative tests (in percentages). Mean values are presented as black plots, and median values as horizontal lines. Red asterisks represent the discrepancies.

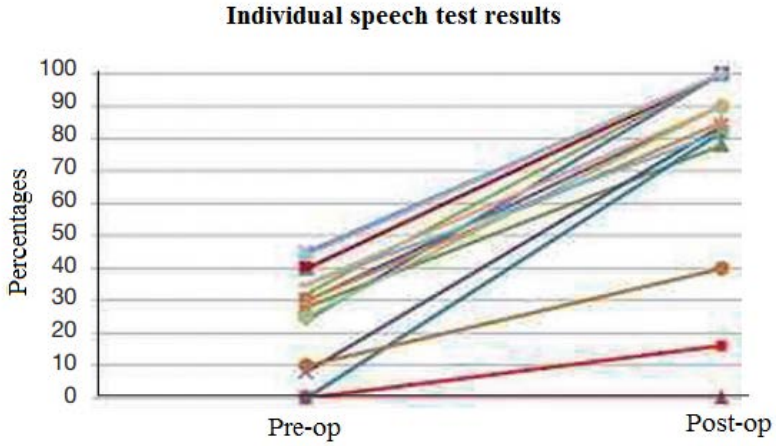

Figure 7. Individual speech test results: comparison of the preoperative tests with the postoperative tests (in percentage).

There are some classifications of hearing preservation to evaluate the degree of preservation of the auditory residue, the most widely used is that proposed by Skarzynski[16], which was used in the present study. Many factors are related to hearing with hearing preservation, such as the surgeon's experience the electrode used[17], the insertion velocity of the electrode[18], the use of preoperative corticosteroids[19] and the technique used. However, some steps in the surgical technique seem to make no difference in the rate of hearing preservation[20], whereas, in relation to the different routes of electrode insertion of the electrode in the cochlea, there is still controversy regarding their importance[8,21].

In general, hearing preservation occurs in 70%–100% of implanted patients[22]. In only two of them we did not we obtained hearing preservation, with an overall preservation rate of 89.4%. Despite the fact that only three patients in us were implanted through cochleostomy because of round window exposure difficulty, in 66.7% of them there was of these patients did not have hearing preservation, while in all cases inserted through the round window had total or partial hearing total or partial hearing preservation.

This was the first study to assess hearing preservation of patients implanted by the authors' institutions, and we believe that, with more experience with this surgical technique, we will be

able to report increased rates of residual hearing rates of residual hearing preservation. A more detailed more detailed follow-up and other modalities of are essential for a better evaluation of the results.

The improvement of postoperative tonal thresholds in individuals with an inner ear approach by cochleostomy was not significant (p = 0.109) with activated EAS implantation. We conclude that this group has a small n (n = 3), which may be a bias (**Figure 8**).

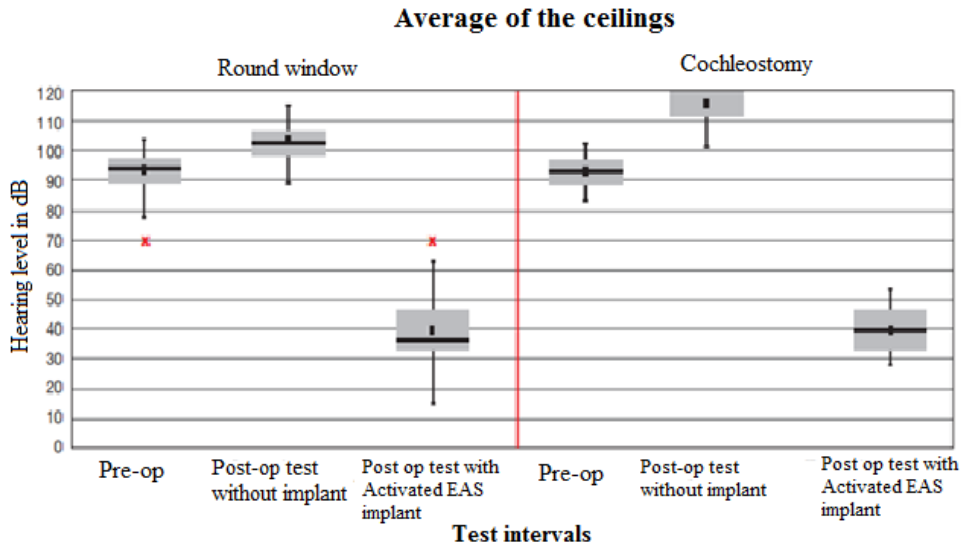

Figure 8. Mean tonal audiometric thresholds (500 Hz, 1 kHz, 2 kHz, 3 kHz): graph shows the comparison between preoperative and postoperative tests without the use of a cochlear implant (in dB hearing level). The analysis was stratified by inner ear approach (round window, n = 16; cochleostomy, n = 3). Mean values are presented as vertical black dashes, and median values as horizontal lines. Red asterisks represent the discrepancies.

In all 19 operated patients, regardless of hearing preservation, implant-activated tone thresholds increased significantly. Therefore, all patients benefited from cochlear implantation. A recent study involving implanted patients with hearing loss also showed that they had better hearing outcomes and a better quality of life[23,24].

This study has some biases, mainly because of its methodological design (retrospective). We can also evidence selection bias, as the cochleostomy group and the cochleostomy group was the result of the impossibility of approaching the inner ear inner ear through the round window. This results in an asymmetry between the groups, which could compromise the analysis.

Despite the limitations described, the n of the study is considerable, being the largest casuistic in Latin America, with the longest follow-up time of these patients. The dissemination of these results helps in a better understanding of cochlear implantation.

12. Conclusions

The hearing preservation rate of patients with hearing loss cochlear implanted with MED-EL FLEX^{TM} EAS cochlear implants was 89.4%, (27% total preservation and 63% partial preservation), with a trend towards greater preservation by inserting the electrode insertion through the round window.

Regardless of hearing preservation, tone thresholds and speech tone thresholds and speech tests improved in implanted patients, with either electroacoustic or purely electrical stimulation.

Conflict of interest

The authors declare no conflict of interest.

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