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Performance and Results of Hifocus 1j ® Cochlear Implants

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Abstract

Background: Cochlear Implant (CI) is the standard treatment for auditory rehabilitation of postlingual patients with severe to profound deafness who do not benefit from conventional hearing aids. Brazilian census (2010) showed that nearly 9.7 million people report having hearing impairment (5.1%). Severe hearing loss was reported by more than 2.1 million, the vast majority being composed of people over 15 years.

Objective: The aim of this study is to describe the performance and results of HiFocus1j ® cochlear implant, besides to perform a medical literature review of this topic.

Methods: A retrospective study of medical records of patients who underwent surgery treatment for severe/profound hearing loss with cochlear implants. The medical literature review was performed using the MeshTerms "hearing loss; cochlear implants; rehabilitation of hearing impaired" at Pubmed and Scopus database.

Results: The sample was composed of seven postlingual patients who underwent HiFocus 1J CI. The average age at surgery was 36.07 years, ranging between 12.08 and 66.25 years. Most of the cases (4/7) had idiopathic auditory deficit. The comparison between the levels of hearing before and after the CI revealed improvement in all patients. All of them also reported an increased overall satisfaction 1 year after procedure.

Conclusion: Postlingual patients have demonstrated significant gain in hearing levels using HiFocus 1J CI.

Keywords: Hearing loss; Cochlear implant; Post lingual deafness; Hearing rehabilitation.

Introduction

According to World Health Organization, over 5% of the world's population –360 million people – has disabling hearing loss (328 million adults and 32 million children) [1]. The same scenario was observed in Brazil. Brazilian census showed that nearly 9.7 million people report having hearing impairment (5.1%) [2]. Severe hearing loss was reported by more than 2.1 million, the vast majority being composed of people over 15 years [2].

Before the development of cochlear implants (CI), people with profound deafness had the lowest median education achievement level and the lowest median annual family income when compared with other disabled populations [3]. The benefits of CI in prelingual patients (children and adults) are well documented, including not only better speech perception, language and reading performance but also a higher quality of life [4-6].

For a better audiological outcome, the correct position of CI electrode seems to be critical. Research revealed a probable association between electrode position and discrimination of frequencies and speech perception [7-8]. HiFocus 1j could be an advantage, since it is designed for easy and highly effective placement inside the cochlea [9].

Despite the already described benefits brought by CI as improvement in tinnitus and psychological status [10], patients often report difficulty in understanding speech when exposed to noise [11]. Worst results also can be found in patients with symptoms of depression or denial [11].

The aim of this study is to describe the audiological performance and satisfaction of HiFocus 1j ® cochlear implant.

Materials and Methods

Retrospective study of medical records of patients who underwent surgical treatment for severe/profound hearing loss with advanced bionics cochlear implants.

The medical literature review was performed using the MeshTerms "hearing loss; cochlear implants; rehabilitation of hearing impaired" at Pubmed and Scopus database.

Device

For this study, we used the Advanced Bionics® devices (the HiFocus®1j electrode and the HiRes 90K® implant). The HiFocus® 1j electrode consists of a fantail, electrode lead, and HiFocus 1j electrode array. The electrodes, composed of platinumiridium alloy, are housed in a silicone carrier and extend from the titanium case.

The HiFocus® 1j intra cochlear electrode array is designed to be inserted approximately 25 mm into a normally patent cochlea. It consists of 16 planer contacts arranged along the medial (or inside) surface of the electrode array for stimulation of discrete segments of the cochlea. The electrode contacts are numbered 1 through 16 from apex to base.

The neck refers to the jog at the proximal end of the array that transitions the array to the lead. The fantail is directly connected to the electronic implant. The lead, which extends from the fantail, refers to the silicone carrier in which the electrode wires are enclosed [9].

The HiRes 90K® implant has 16 independent output circuits with bi-directional communication link of telemetry, the information update rate is 90kHz, a stimulation rate up to 83,000 pulses per second, weights 12 grams and has an impact resistance value of 6 joules [9].

Patient Selection

The sample was composed by patients who underwent cochlear implant HiRes 90K with HiFocus 1J electrode, followed in hearing care service university hospital in the last three years.

Only patients who underwent audiological and electrophysiological testing with the same staff and equipment and also had complete data in the medical records were included in the sample.

Inclusion Criteria

Inclusion criteria were: sensorineural hearing loss (severe/profound), normal otoscopy, absence of middle ear disease, absence of acoustic reflex, absence in ABR waves and imaging (MRI / CT) showing the presence of the cochlear nerve and excluding retrocochlear disturbances.

Hearing aids were used in all subjects before treatment and when no benefits were showed it was indicated the cochlear implants (have sensorineural bilateral hearing loss with little or no benefit from HA (less than 40% of auditory discrimination in monosyllables), have pure-tone thresholds ≥ 80 dB hearing loss, have had stable hearing loss for at least the past two years, and lastly pass a psychological examination ensuring they had realistic expectations about the potential benefits of receiving a cochlear implant . All subjects underwent Pure Tone Audiometry (PTA) and speech tests, pre- and postoperatively.

Audiological Evaluation

Audiological tests were performed including timpanogram, speech and pure tone audiometry. The tests were performed using an audiometer AC30-SD25, calibrated according to ISO 389 standards / 64.

For ABR, which were repeated at least two times, we used the device AT-235 (Interacoustics).

The hearing impairment was stratified in mild, moderate, severe or profound hearing loss, according to Goodman [12].

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All subjects underwent Pure Tone Audiometry (PTA) and speech tests, pre- and postoperatively.

Speech Perception Tests

Preoperatively, all subjects took a speech perception test at the same day of their implantation. We used a speech perception sentence test based on Bevilacqua et al [13]. Subjects did the test with their hearing aids on, in a quiet place.

Postoperatively, all subjects repeated the speech perception test at least one year after CI. Tests were done in subject's best-aided condition: CI-only. The same audiologist conducted all the pre and postoperative tests.

All patients who did not complete these criteria were excluded from the study.

Subjective Ratings

When the subjects did their postoperative speech tests they were asked to rate the quality of their experience with CI over the past year on a Likert scale scored 0 to 10. A score of 0 indicated the user regretted the intervention, would not recommend it to others, and felt he/she had been better off in the past with their hearing aids. A score of 10 indicated the user was completely satisfied with the intervention and would strongly recommend it.

Statistical Analysis

The data were analyzed using descriptive analysis, with production of means, medians, standard deviation tabs.

T-student test was used to compare the pre-operative and postoperative speech perception scores. The confidence Interval was of 95 %, and p-value < 0.05 was considered significant.

Ethical Considerations

This study was previously approved by the Research Ethics Committee of the Faculty of Medical Sciences of the University of Campinas.

Results

All of the patients were females and the mean age at surgery was 36.07 years old. The most frequent cause of deafness was idiopathic. The mean time of deafness was 20.5 years. Profile of these patients is summarized in (Table 1).

Preoperative audiometric thresholds are demonstrated in (Figure 1). Each patient is represented by a colored line in the same order presented in (Table 1). All subjects had hearing loss from severe to profound. Only three patients had residual hearing in low tones (patients 4, 5 and 6). There were improvements in

all preoperative audiometric thresholds after cochlear implant surgery. The value of each patient is shown on. (Figure 1 and Figure 2).

Speech Perception Test (SPT) evaluates the sentence recognition ability and displays a result in percentage of correct answers. SPT results were favorable in all cases (Table 2). The mean SPT before surgery was 5.7% and 70.6% after surgery. Best result showed an increase of 94% (from 0% to 94%) and the lower increase was 18% (from 26% to 44%). Statistical analysis using t-student test revealed an undeniable benefit of speech perception after CI (Table 3). It is worth noting that the preoperative SPT was collected with adequate bilateral hearing aids. SPT tends to progressively increase with adaptation to CI, especially during the first 6 months of use [14]. Then, postoperative values were collected with a minimum time span of one year after surgery (Table 1 and Table 2).

The overall satisfaction increased. Before surgery the mean score of Likert scale was 2,0. After one year of experiencing CI, the satisfaction score increased to 7, 3. The lower scores (patients 2 and 6) are associated with worse speech perception.

None patient showed up unsatisfied with the procedure, but subject 6 reported sporadic local pain (Figure 3).

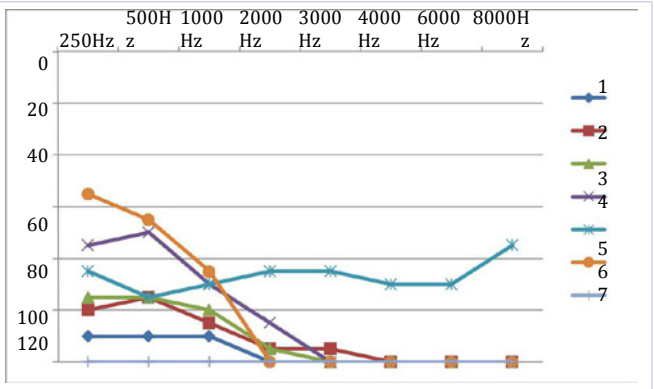

Figure 1: Pure tone preoperative audiometric thresholds.

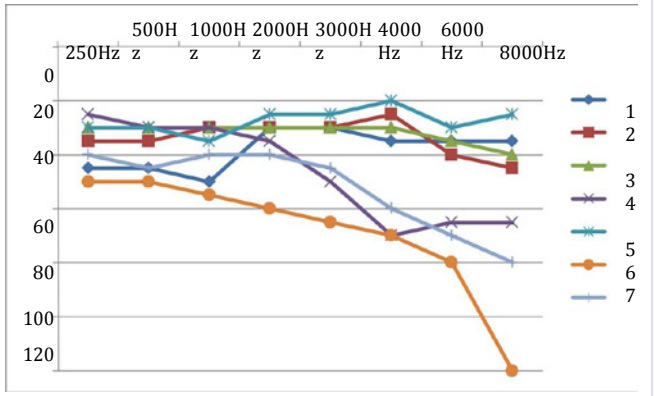

Figure 2: Pure tone postoperative audiometric thresholds (cochlear implant on).

Discussion

The sample was composed by young women with hearing loss predominantly idiopathic. Data from literature present a large number of patients with non-syndromic genetic hearing loss, corresponding to up to 60% of early onset hearing loss [15]. It has become increasingly clear that genetic factors have a central role in disease etiology; mutations in more than 100 genetic loci have already been linked to non syndromic deafness [16]. Perhaps a large number of patients classified here as idiopathic have a genetic hearing loss unidentified.

The mean time of deafness (20.5 years) found is elevated and results even better could be found with early intervention. Long periods of hearing deprivation can jeopardize integrity of auditory peripheral nervous system, such as spiral ganglion cells. Neuroplasticity is also responsible for loss in speech and non-

Table 1: Subjects clinical data.

PATIENTS	SEX	AGE	ETIOLOGY	TIME of DEAFNESS
1	F	66	IDIOPATHIC	48Y
2	F	12	IDIOPATHIC	20Y
3	F	18	IDIOPATHIC	10Y
4	F	50	TRAUMA	15Y
5	F	60	MENIERE	30Y
6	F	24	MONDINI	19Y
7	F	21	IDIOPATHIC	2Y

Table 2: Preoperative Vs postoperative speech perception test (open set).

PATIENTS	PREOP	POSTOP
1	0%	64%
2	0%	20%
3	0%	94%
4	0%	82%
5	14%	96%
6	26%	44%
7	0%	94%

Table 3: T-student test data comparing preop Vs post op regarding speech test (open set).

	PREOP	POSTOP
Count	7	7
Mean	0,057142857	0,705714
St Dev	0,103555828	0,293874
SE Mean	0,039140424	0,111073917
t	-586,17	-200,72
p-value (2-sided)	0,0000	0,0000
UC (2-sided, 95, 0%)	0,152916	0,977502
LC (2-sided, 95, 0%)	-0,03863031	0,705714

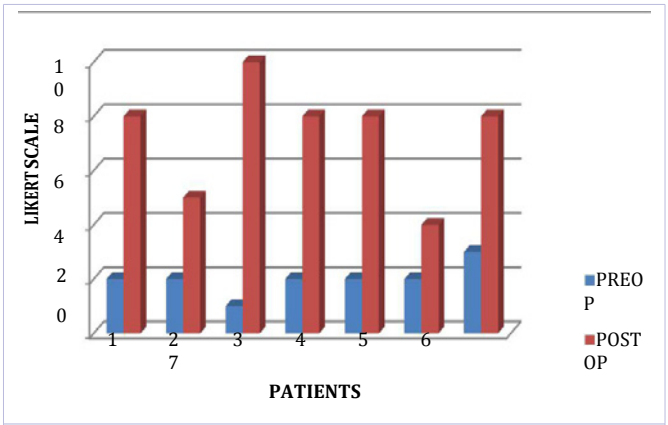

Figure 3: Preoperative x postoperative Likert scale.

speech sound memory. Brain regions associated with sound can be irreversibly modified over time. A good CI outcome is based on proper functioning of not only peripheral, but also central nervous system [17-18].

Literature review also showed favorable results of postlingual CI. A cross-sectional Brazilian study observed the outcome of CI in postlingual children after 10 years of CI. There was no device failure and functional results in relation to auditory perception and speech intelligibility were achieved [19].

Considering the experience of using CI, other study had shown high or very high degree of satisfaction between postlingual patients. This study found that CI satisfaction was not related to speech perception scores, duration of deafness, length of CI use, or other sociodemographic factors. Positive self-esteem, having less severe symptoms of depression, and the use of humor or self-distraction were conducive to CI satisfaction [11]. Psychosocial aspect can be directly related to CI outcome. Depressed subjects were associated with worst engagement in postsurgical rehabilitation [20]. That is why the application of psychological questionnaires becomes essential for planning an effective individual approach.

Other benefit brought by Advanced Bionics CI can be the music perception. Subjects that were frequently listeners and enjoyed music before deafness and also singers tend to have a higher performance after CI [21]. This fact could be a contributor to the high notes in Likert scale.

A multi professional team is also very important to assure satisfaction. The involvement of trained otolaryngologist, nurse, speech therapist and psychologist is a protocol in our hospital, which is applied to all candidates to CI. The adequacy of expectations is a crucial part of the decision to undergo surgery and can be an important factor to determine postoperative overall satisfaction [22].

It must be considered that although this study included only seven patients, there is no previous research published about the outcomes of HiFocus 1J electrode and this is first study about this topic performed in Brazilian population.

Conclusion

Improvements in preoperative diagnosis, surgical techniques and model of the electrodes have broadened the spectrum of CI applications, especially for post lingual patients. There is a remarkable auditory gain in post-lingual patients who underwent IC HiFocus 1J.

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