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ORIGINAL RESEARCH ARTICLE

Digisonic® SP cochlear implant evaluation: Patient evolution and titanium screw fixation system

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ABSTRACT

The cochlear implant for patients with severe/profound dysacusia has revolutionized the way they interact with their environment. Neurelec has developed a system that allows fixation using two simple titanium screws, without the need to drill into the patient's skull bone. The purpose of this paper was to describe a series of patients submitted to cochlear implantation with the Digisonic® SP, to show the surgical results and details of the procedure. **Method**: This was a retrospective study that evaluated patients who underwent cochlear implantation with the Digisonic® SP over a period of 18 months. All patients were post-lingual. Data collection performed by analyzing the patients' medical records, in addition to a standardized questionnaire applied to the surgeons who performed the procedure. **Results**: The six cases implanted with Digisonic® SP were performed by experienced surgeons and the surgical time ranged from 95 to 203 minutes (mean 135 minutes), which is shorter than that described with other forms of fixation. There were no complications and the hearing gain was satisfactory. **Conclusion**: The Digisonic® SP implant developed by Neurelec showed good audiological results in adults, shorter surgery time and no surgical or postoperative complications.

Keywords: cochlear implantation; deafness; electrodes; implanted; hearing loss sensorineural; prostheses and implants

1. Introduction

The cochlear implant, since its introduction as a tool for auditory rehabilitation for patients with deafness or severe and/or profound dysacusia, has revolutionized the way these patients interact with other individuals and the environment. They have shown good results with improved speech perception in all age groups[1–3]. Cochlear implant surgery results in improved quality of life for all patients, being more significant for those under 65 years of age[4].

The surgery is safe and reliable. However, surgical complications occur in about 16% of the patients, with the biggest and most frequent ones being related to the insertion of the electrodes into the cochlea, occurring in about 4% of the cases[5].

Migration of the internal component is a problem described by many authors, and it may favor a malfunction of the implanted device and facilitate in-

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fections[6–8]. Several cochlear implant surgery techniques are found in the literature, mainly with less invasive situations[9–11].

The surgical time for making the bed to position the internal component is an important and expensive step, and the focus of much investment by the cochlear implant industry[12,13]. Because of this, there is increased spending on the development of surgical instruments and new materials, such as titanium plates, polypropylene mesh, GORE-TEX, resorbable materials, among others[14–16]. Regarding the fixation of the internal component, Neurelec Inc (Sophia-Antipolis, France) developed a system that allows fixation using only two simple titanium screws, without any need to drill the patient's skull bone[17] (**Figure 1**).

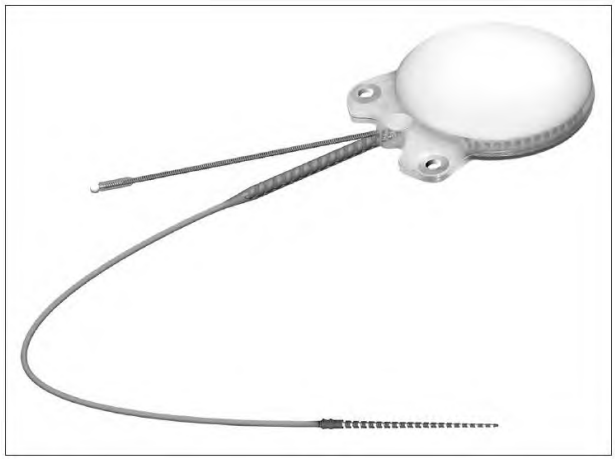

Figure 1. Illustration shows the internal component where the receiver, stimulator and magnetic region are located, in a small ceramic structure sealed in a titanium base. Note the lateral recess of the two Digisonic® SP fixation screws developed by Neurelec.

Therefore, the purpose of this study is to describe the case series of patients from a specialized tertiary hospital who underwent cochlear implant surgery with the Digisonic® SP, in order to show the post-surgical clinical and audiological results and details of the procedure, in the last 18 months.

2. Method

This is a retrospective study, carried out at a specialized tertiary hospital, which evaluated patients who underwent cochlear implant surgery with the Digisonic® SP over a period of 18 months.

For the accomplishment, a protocol was prepared for data collection with digital storage. The data analyzed were: age, gender, etiology of deafness, time of hypoacusis, implanted side, postoperative audiometric data (audiometry and speech perception test), time of surgery, time to fix the internal component, complications of the procedure, follow-up time in months. All patients in this series are post-lingual (hearing loss after speech and language development and having had previous hearing).

The data was collected by analyzing the patients' medical records, and by means of a standardized questionnaire applied to the surgeons who performed the procedure.

The ethical precepts of the institution were respected and the data were kept anonymous.

2.1. Patients

Patients who underwent cochlear implant surgery with the Digisonic® SP within 18 months were selected. All patients underwent a preoperative protocol with etiological investigation (laboratory and genetic tests), radiological (CT and MRI scans of the ears and mastoids), psychological evaluation, and a complete speech and hearing evaluation.

2.2. Device

The Digisonic® SP cochlear implant system, consisting of the Digisonic SP implant and the Digi SP or Digi SP'K speech processors, was launched on the market by the French company Neurelec S.A. in 2004. This device corresponds to the latest available version of the implantable component developed by the company, and presents several advances in relation to previous generations. The increase in the number of electrodes in the beam, allowing a greater number of active channels for stimulation and better spectral representation within the cochlea, the receiver-stimulator fixation system with the use of two titanium screws, and the increase in stimulation rate with the inclusion of the Mean Peak Interleaved Sampling (MPIS) sound processing strategy, are its main features.

Internal device component

The internal component developed by Neurelec, the Digisonic® SP, is shown in **Figure 1**.

The receiver-stimulator (RS) is composed of a convex-shaped ceramic capsule, a flat and uniform titanium base, both hermetically wrapped in a biocompatible silicone coating. The Digisonic® SP is extremely compact, and both the electronic components related to signal decoding and the internal magnet are contained in a single structure, called a "monoblock" structure, which is about 30 millimeters in diameter.

The characteristics of Digisonic® SP are described in **Table 1**.

The device features a fixation system composed of two titanium screws, approximately 3.4 mm in length to be fixed into two small titanium holes of approximately 5 millimeters in diameter, coated by silicone and positioned at the ends of the receptor-stimulator, as shown in **Figure 2** and **Figure 3**. The screws have a bone penetration of 1.91 mm[17].

The compact structure and screw fixation system of the Digisonic® SP allows for a faster and less invasive surgical procedure, without the need for bone drilling or suturing for implant positioning and/or fixation[17].

Digisonic® SP features atraumatic, flexible electrodes that quickly adjust to the site where they are placed and are connected to the RE by a reinforced connection. The beam is composed of 20 platinum-iridium electrodes that enable the stimulation of up to 20 channels along the cochlea, with an active length of 25 mm and a stimulation rate of up to 1,000 pulses per second for each stimulation channel, using the MPIS processing strategy. It also has silicone rings for easy insertion[18].

Table 1. Technical characteristics of Digisonic® SP

Features	Remarks
Indications	**Normal or ossified cochlea**
Mechanical Properties	
Receiver dimensions	4.9 mm edge–5.75 mm center–30.2 mm diameter
Weight	10.5 g
Receiver materials	Titanium Base–Ceramic Capsule A1203–Silicone Envelope
Stimulation	
Stimulation mode	Monopolar or "Common Ground" Biphasic pulses
Stimulation frequency	Up to 2,400 pulses per second
Pulse duration	From 1 to 120 μs (resolution = 0.5 μs)
Pulse amplitude	Adjustable
Electrode impedance	Less than 2 kΩ
Coupling capacity of the electrodes	Average residual current less than 100 nA
Security	
Surgery	Fixation with two titanium screws with bone adhesion
Electrode insertion depth	25 mm
Cochleostomy	1 mm
MRI Compatibility	Compatible (1.5 Tesla)
Reference electrodes (ground)	2
Electrode Beam	
Materials	Platinum–iridium, silicon
Active electrodes	20
Active electrode beam length	25 mm
Base diameter (silicone ring)	1.07 mm
Diameter of apex (distal end)	0.5 mm
Surface of the electrodes	0.63 mm^2 to 1.1 mm^2
Electrode beam type	Straight with memory
Objective Measures	
It allows the performance of electrically evoked brainstem potentials, stapedial reflexes and psychoacoustic tests (such as the gap test, etc.). Digistim® SP USB Diagnostic System (Compatible with Windows 98SE, ME, 2000, XP and VISTA®).	

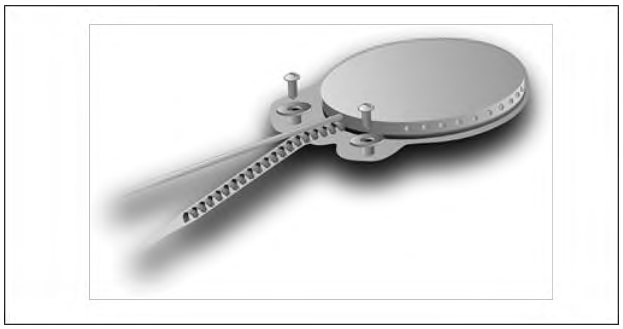

Figure 2. Digisonic® SP fixation system.

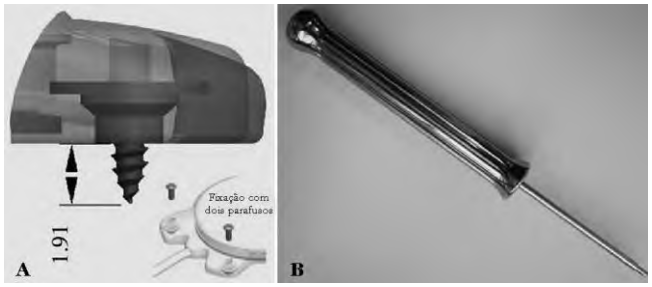

Figure 3. Illustration of the Digisonic® SP fixation system using two titanium screws, which need to penetrate the temporal bone 1.91 mm. There is no need for any drilling or preparation of the region. Developed by Neurelec S.A.

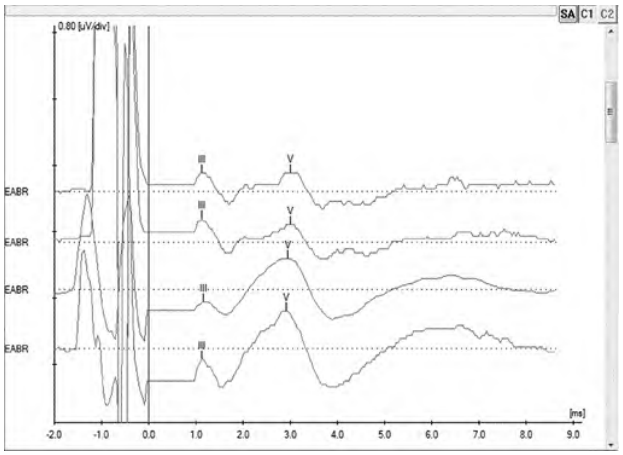

Figure 4. Record of brainstem evoked potentials measured intraoperatively in subject 5 for electrodes 19, 14 and 9 and 6 using Navigator Pro Interface and AEP Software version 7.0.0, Biologic. The presence of waves III and V is observed, demonstrating effective stimulation of neural fibers.

The internal device is composed of a bidirectional telemetry system that allows recording the impedance of the electrodes. This recording is possible through the use of the Digistim SP diagnostic interface and Digistim for Windows SP® software, current version 1.9.15, which also allows other objective measurements, such as the investigation of electrically evoked brainstem potentials and electrically evoked stapedial reflex thresholds (ESRT)[18].

The EABR is routinely performed in the intraoperative stage in order to verify the functioning of the device and whether the peripheral auditory neural fibers are being effectively stimulated[19]. Furthermore, it is possible, by means of its results, to predict the psychophysical levels for the subsequent programming of the speech processor[20], which is especially important in children. The same is done at the end of the surgical procedure, with the patient still under general anesthesia.

The procedure comprises the electrical stimulation of neural fibers, performed from electrodes inserted into the cochlea, and the capture of responses via conventional equipment for recording brainstem auditory evoked potentials (BAEP) and synchronization cable. It is possible to visualize waves II, III and V, the last two being the most commonly observed, and the presence of wave V indicating effective stimulation of the auditory nerve. The absolute latencies of these waves are reduced when compared to conventional BAEP, since the stimulation in EABR is performed directly on the auditory nerve, by means of the electrodes in the implant beam[20] (**Figure 4**).

Digisonic® SP is compatible with Magnetic Resonance Imaging (MRI) scans up to 1.5 Tesla, following appropriate recommendations[18].

3. Results

Table 1 illustrates the characteristics and technical details of the device used in the surgeries described.

Table 2 and **Table 3** show the general and specific data of patients implanted with Digisonic® SP.

In **Table 4**, we have the data about the occurrences during the surgical procedure and the duration of the procedure.

No patient had radiological changes on either MRI or CT scan.

In all procedures, the research of brainstem-evoked potentials and electrically evoked stapedial reflex thresholds (ESRT) was performed at the end of the surgery, with the patient still anesthetized. In all cases, the results of this examination were satisfactory and showed the effectiveness of the device.

The graphs below show the pre- and postoperative audiometric tests of the operated patients (**Figure 5**).

Table 2. General data of the implanted cases

Subject	Sex	Age*	AD Time*	AD Etiology	Date IC	Activation Date	IC Side
1	M	50	25**	Infectious	12/04/11	31/05/11	Left
2	F	33	21	Idiopathic (Progressive)	23/10/10	01/12/10	Right
3	F	30	10	Ototoxicity	28/09/11	25/10/11	Left
4	F	52	15	Idiopathic	30/08/11	25/10/11	Left
5	M	20	9	Idiopathic (Progressive)	20/03/12	26/14/12	Right
6	F	26	20	Rubella	14/12/11	02/02/12	Left

***** Time in years. ****** Had dysacusia in the DO when he was 1 year old, and with 25 years after meningitis had worsening in the EW. At 49 years had TBI as which lost the remnants in the left ear. M: Male; F: Female; AD: Auditory Dysacusis; CI: Cochlear Implant.

Table 3. Specific data of the implanted patients

Subject	Electrode Insertion Site	Electrode Type	Active Channels	External Processor	Follow Up*
1	Cochleostomy	Digisonic® SP	All	Digi SP	15
2	Cochleostomy	Digisonic® SP	All	Digi SP	33
3	Cochleostomy	Digisonic® SP	All	Digi SP	10
4	Cochleostomy	Digisonic® SP	All	Digi SP	11
5	Cochleostomy	Digisonic® SP	All	Digi SP	4
6	Cochleostomy	Digisonic® SP	All	Digi SP	8

* in months.

Table 4. Surgical data of the implanted patients

Subject	Total time*	Fixing time*	Time Saving*, **	Intercurrences (intra-op/postop) ***
1	158	3.58	30	Absent
2	203	5.60	30	Absent
3	144	4.12	30	Absent
4	100	4.68	30	Absent
5	109	3.44	30	Absent
6	95	6.01	30	Absent

* in minutes. ** reported by the surgeon the economy of time in making the fixation of the internal component. The mean time of this surgical step (making of the internal component niche) was calculated by analyzing 10 random cases performed in the same period of the study group, by the same surgeons, but with prostheses with different fixation systems (drilling of the temporal bone to make the niche). *** fixation errors, bleeding, injury to noble structures, infections, dehiscence, migration of the internal component, migration of the electrodes, need for explantation, cholesteatomas, otitis media.

4. Discussions

The Digisonic® SP cochlear implant, developed by Neurelec, has a fixation system with the use of two titanium screws, saving the need to make a site for the internal component of the cochlear implant, without the need to drill the patient's skull bone. In addition to reducing the risks and complications that may be associated with making the cochlear implant niche, this fixation system aims to reduce surgical time.

In our study, the six Digisonic® SP implantation cases were performed by experienced surgeons, and the surgical time ranged from 95 to 203 minutes, with an average of 135 minutes. The mean time for conventional cochlear implant surgery performed by an experienced surgeon was 255 minutes when the S-shaped retro auricular incision and implant niche were used, and 200 minutes when a small retro auricular incision and subperiosteal pocket were used[21]. Therefore, the surgical time in our series was shorter than that described with other forms of fixation.

Studies evaluating cochlear implant costs have varied greatly in methodology, and therefore, according to what is considered as part of the costs involved,

it may vary significantly[22]. However, according to existing studies, the cost for unilateral implantation in post-lingual deaf patients ranges from € 30,026 (US$ 21,018) to € 45,770 (US$ 32,039), with the device accounting for most of this cost[23]. In Brazil, the cost of the Digisonic® SP implant is similar to that of similar implants with conventional fixation system, i.e., which require making a niche for the internal component.

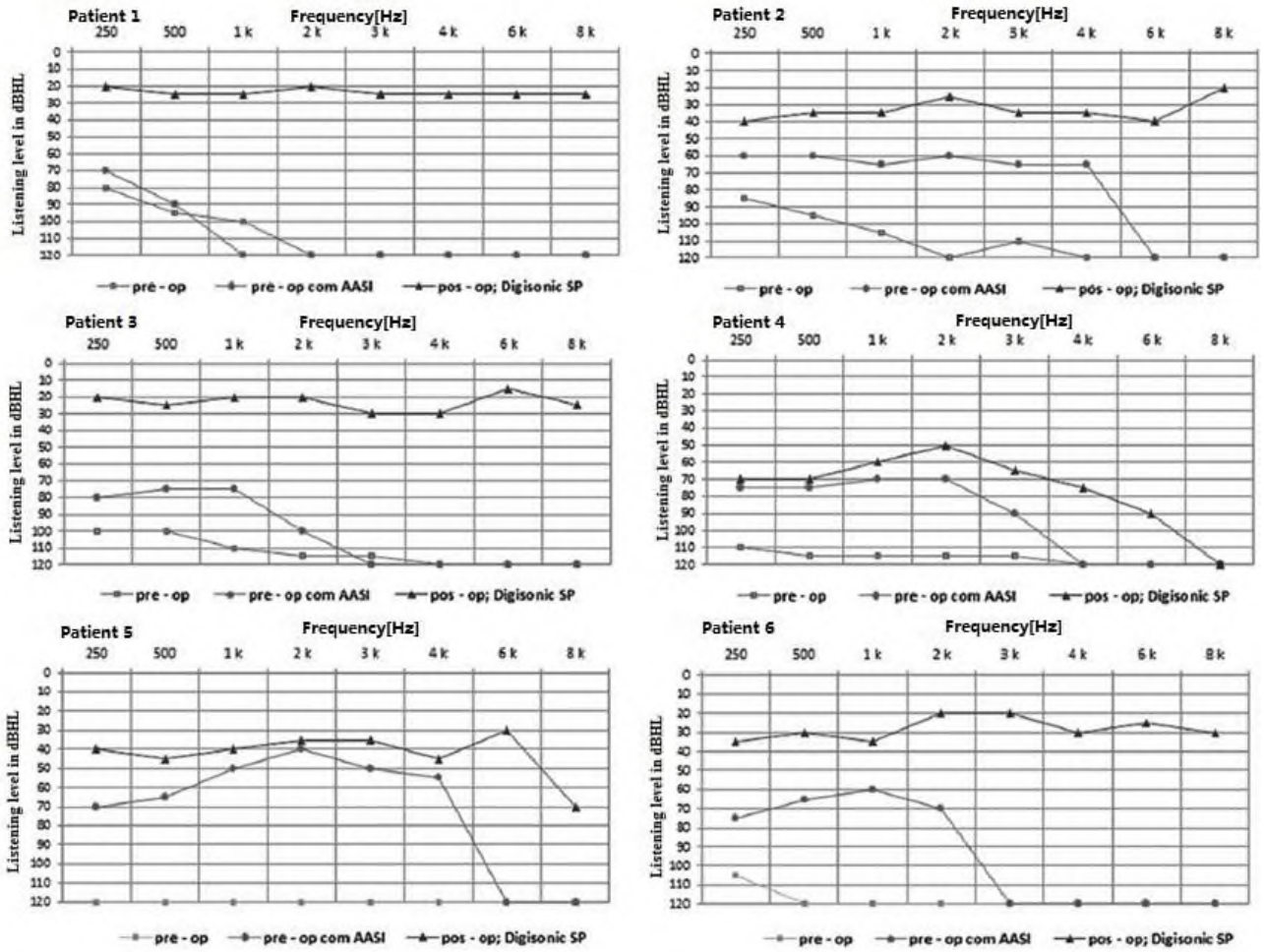

Figure 5. Image represents audiometric thresholds pre- and post-surgery for cochlear implantation of the six cases with Digisonic® SP. Note the threshold improvement in the cases.

Despite the high cost, the benefits of cochlear implantation outweigh the costs, by enabling auditory rehabilitation and improving communication and quality of life for deaf patients, and this relationship is more evident for younger patients[23–25].

In our series, there were no complications and the hearing gain was satisfactory in all cases. Since complications in general are described in about 16% of cochlear implant surgeries[5], although our sample was small, the results were better than average.

5. Conclusions

The Digisonic® SP cochlear implant developed by Neurelec in our series showed good audiological results in adults, shorter surgery time, and no intra- or postoperative surgical complications.

Conflict of interest

The authors declare no conflict of interest.

References

1. Yang W, Moon IS, Kim HN, et al. Delayed cochlear implantation in adults with prelingual severe-to-profound hearing loss. Otology & Neurotology 2011; 32(2): 223–228.

2. Budenz CL, Cosetti MK, Coelho DH, et al. The effects of cochlear implantation on speech perception in older adults. Journal of the American Geriatrics Society 2011; 59(3): 446–453.
3. Klop WM, Briaire JJ, Stiggelbout AM, et al. Cochlear implant outcomes and quality of life in adults with prelingual deafness. Laryngoscope 2007; 117(11): 1982–1987.
4. Chung J, Chueng K, Shipp D, et al. Unilateral multichannel cochlear implantation results in significant improvement in quality of life. Otology & Neurotology 2012; 33(4): 566–571.
5. Brito R, Monteiro TA, Leal AF, et al. Surgical complications in 550 consecutive cochlear implantations. Brazilian Journal of Otorhinolaryngology 2012; 78(3): 80–85.
6. Yun J, Colburn MW, Antonelli PJ. Cochlear implant magnet displacement with minor head trauma. Otolaryngology-Head and Neck Surgery 2005; 133(2): 275–277.
7. Hoffman RA, Cohen NL. Complications of cochlear implant surgery. Annals of Otology Rhinology and Laryngology 1995; 166: 420–422.
8. Migirov L, Muchnik C, Kaplan-Neeman R, et al. Surgical and medical complications in pediatric cochlear implantation: A review of 300 cases. Cochlear Implants International 2006; 7(4): 194–201.
9. Mann WJ, Gosepath J. Technical note: Minimal access surgery for cochlear implantation with MED-EL devices. ORL J Otorhinolaryngology Relat Spec. 2006; 68(5): 270–272.
10. Loh C, Jiang D, Dezso A, et al. Non-sutured fixation of cochlear implants using a minimally-invasive approach. Clinical Otolaryngology 2008; 33(3): 259–261.
11. Carvalho GM, Valente JPP, Duarte ASM, et al. Electro acoustic stimulation of the auditory system: Unicamp's surgical approach. Brazilian Journal of Otorhinolaryngology 2012; 78(1): 43–50.
12. James AL, Papsin BC. Device fixation and small incision access for pediatric cochlear implants. International Journal of Pediatric Otorhinolaryngology 2004; 68(8): 1017–1022.
13. Dalchow CV, Werner JA. A new instrument for minimal access surgery in cochlear implantation. Otology & Neurotology 2005; 26(4): 678–679.
14. Lee DJ, Driver M. Cochlear implant fixation using titanium screws. Laryngoscope 2005; 115(5): 910–911.
15. Davis BM, Labadie RF, McMenomey SO, et al. Cochlear implant fixation using polypropylene mesh and titanium screws. Laryngoscope 2004; 114(12): 2116–2118.
16. Otto RA, Lane AP, Carrasco VN. A new technique for securing cochlear implants. Otolaryngology-Head and Neck Surgery 1999; 120(6): 897–898.
17. Guevara N, Sterkers O, Bébéar JP, et al. Multicenter evaluation of the Digisonic SP cochlear implant fixation system with titanium screws in 156 patients. Annals of Otology Rhinology and Laryngology 2010; 119(8): 501–505.
18. Vincent C, Ruzza I, Vaneecloo FM, et al. Magnetic resonance imaging with the Digisonic SP Neurelec cochlear implant. Eur Arch Otorhinolaryngology 2008; 265(9): 1043–1046.
19. McCormick B, Archbold S (editors). Cochlear implants for young children: The Nottingham approach to assessment and rehabilitation. 2nd ed. London: Whurr; 2003. p. 162–215.
20. Truy E, Gallego S, Chanal JM, et al. Correlation between electrical auditory brainstem response and perceptual thresholds in Digisonic cochlear implant users. Laryngoscope1998; 108(4 Pt 1): 554–559.
21. Prager JD, Neidich MJ, Perkins JN, et al. Minimal access and standard cochlear implantation: A comparative study. International Journal of Pediatric Otorhinolaryngology 2012; 76(8): 1102–1106.
22. Nadège C, Valérie G, Laura F, et al. The cost of cochlear implantation: A review of methodological considerations. International Journal of Otolaryngology 2011; 2011: 210838.
23. Turchetti G, Bellelli S, Palla I, et al. Systematic review of the scientific literature on the economic evaluation of cochlear implants in adult patients. Acta Otorhinolaryngologica Italica 2011; 31(5): 319–327.
24. Turchetti G, Bellelli S, Palla I, et al. Systematic review of the scientific literature on the economic evaluation of cochlear implants in paediatric patients. Acta Otorhinolaryngologica Italica 2011; 31(5): 311–318.
25. Peñaranda A, Mendieta JC, Perdomo JA, et al. Economic benefits of the cochlear implant for treating profound sensorineural hearing loss. Revista Panamericana de Salud Publica-Pan American Journal of Public Health 2012; 31(4): 325–331.