

## A Report of Surgical Complications in a Series of 262 Consecutive Pediatric Cochlear Implantations in Iran

Mohammad Ajallouyeen<sup>1</sup>, MD; Susan Amirsalari<sup>\*2</sup>, MD; Jaleh Yousefi<sup>1</sup>, MD; Mohammad-Ali Raeesi<sup>1</sup>, MD; Shokofeh Radfar<sup>3</sup>, MD, and Mahdieh Hassanalifard<sup>4</sup>, MS

1. Department of ENT; Cochlear Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran
2. Department of Pediatrics; Cochlear Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran
3. Department of Psychiatry; Cochlear Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran
4. Department of Audiology, Cochlear Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran

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### Abstract

**Objective:** Cochlear implantations have become a routinely performed and successful surgical intervention in both adults and children. The current article reports the complications encountered in various age groups of consecutive children who underwent implantation in our center.

**Methods:** We performed a prospective analysis of all profoundly deaf children who underwent cochlear implantation from March 2006 to July 2009 at Baqiyatallah Cochlear Implantation Center. All patients were younger than 5 years old at the time of implantation.

**Findings:** The minor complications occurred in 49 (18.7%) cases, The most common postoperative complications were temporary facial weakness detected in 15 cases (5.7%) all of which were reversible. Magnet wound was observed in 14 (5.3%) patients, keloid formation in 10 (3.8%), wound infection in 2 (0.8%), otitis media in 5 (2%), and electrode movement, meningitis, vertigo, Laryngospasm each in 1 (0.4%) case was detected among our patients.

**Conclusion:** Cochlear implantation in children continues to be reliable and safe in experienced hands, with a low percentage of severe complications as long as the patient is monitored closely.

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**Key Words:** Cochlear Impantation; Deafness; Operative Complication; Surgery

### Introduction

Cochlear implantations have become a routinely performed and successful surgical intervention in both adults and children. Cochlear implantation is associated with rather low complication rates,

regardless of the individually chosen cochlear implant device [1-3].

Pediatric cochlear implants provide children with severe and profound hearing loss in greater access to sound and improvement in their auditory skills, speech understanding, and oral

\* Corresponding Author;

Address: Cochlear Implantation Center, Floor 3rd, Baqiyatallah Hospital, Molla sadra Ave, Tehran, Iran

E-mail: bcic\_bcic@yahoo.com

linguistic development [3,4]. In fact, several researchers have confirmed the effects of cochlear implantation on speech perception of profoundly deaf children [4,5]. However, studies about cochlear implant surgery in children present several additional risks that are not present in adult patients [6,7].

Children younger than 6 months of age have an increased risk of respiratory failure and bradycardia from anesthesia. In children with other medical co-morbidities, there is an increased risk from anesthesia in infants up to 1 year old.

Up to now different reports have detailed possible medical, surgical or audiologic complications of cochlear implantation [7-9] but there are few studies that demonstrate the different complication rates in children of various age groups [10-13].

This article reports the complications encountered in various age groups of consecutive children undergoing implantation in our center.

## ***Subjects and Methods***

We performed a prospective analysis of all profoundly deaf children who underwent cochlear implantation from March 2006 to July 2009 at Baqiyatallah Cochlear Implantation Center. All patients were younger than 5 years old at the time of implantation. The patients were evaluated for demographic information, etiology of the hearing loss, specific kind of cochlear implant device.

The consecutive and unselected series of 262 children in the current study have all undergone implantation in this center. The inclusion criteria for these patients were; 1) permanent hearing loss, 2) onset of hearing loss before six months of age, 3) use of amplification and/or intervention program emphasizing spoken language. The exclusion criteria were 1) family opposition to having an implant and 2) the presence of cognitive disorders.

The study was approved by the Ethics Committee of Baqiyatallah University of Medical Sciences. The operation was carried out by one

surgeon using standard techniques. Almost all of the children undergoing implantation received the Nucleus device (Cochlear, Lane Cove, NSW, Australia).

The soft-tissue approach has changed over years, beginning with the extended endaural approach of Lehnhardt to the minimal access approach which is now used on the program.

Routine antibiotic prophylaxis, currently ceftriaxon, was administered intravenously, with one dose at induction and two further doses within 24 hours. Hospital stay has been reduced from 24 hours to days after surgery, which reflects the rapid recovery of these children. A postoperative radiograph was obtained to confirm the position of the electrode array.

We divided the children into five age groups: less than 1 year, 1- <2 years, 2-<3 years, 3-<4 years, and 4 years and more than 4 years. The complications included implant failure, meningitis, hematoma (intracranial and extra cranial), implant extrusion, cerebrospinal fluid leak, facial palsy, wound infection, otitis media, cellulites, electrode movement, vertigo, skin flap failure, colesteatoma, atlanto axial subluxation. anesthetic complications included bradycardia and laryngeal spasm.

We used SPSS soft ware for analyzing the data (V 16 SPSS Inc © Chicago IL) and the tests used in the analysis included paired t-test and chi-squared test. A major surgical complication was defined as an adverse event occurring during or after surgery that necessitated a major surgical intervention or a permanent disability such as persistent facial weakness.

Minor complications were defined as those managed by medical measures or by a minor surgical procedure (e.g., aspiration of a hematoma).

## ***Findings***

A total of 262 patients with prelingually profound hearing loss were enrolled in this study. 129 of cases were male (49.2%) and 133 were female

**Table 1:** Risk factors in children with hearing loss

Risk factor	Number of patients (%)
Hereditary	103 (39.3)
Unknown	62 (23.6)
Prematurity	32 (12.2)
Syndromic	15 (5.7)
Sever hyperbilirubinemia	9 (3.4)
Asphyxia	6 (2.4)
Meningitis	8 (3)
Maternal TORCH infection	12 (4.6)
Eruptive infections	9 (3.4)
Oto-toxic drugs	6 (2.4)
<b>Total</b>	<b>262 (100)</b>

(50.8%). The present study consists of 262 consecutive children who underwent implantation.

262 patients with prelingually profound hearing loss with a mean age of  $4.09 \pm 1.86$  years were evaluated in this study. Of these cases 28(10.7%) had developmental deprivation, 96 (36.6%) were over active and 58 (22.1%) had both developmental deprivation and over activity. The hearing loss risk factors among our patients are shown in Table 1.

17 Patients were in group1 (implanted under 12 m/o), 62 patients in group 2 (implanted 1- <2 y/o), 60 patients in group3 (implanted 2-<3 y/o), 66 patients in group4 (implanted 3-<4 y/o) and 57 patients in 5+ groups (implanted 4 y/o and more).

Major preoperative complications that lead to explanation have been detected in one case. A summary of the complications based on patients'

age is given in Table 2. Minor complications occurred in 49 (18.7%) cases, The most common postoperative complications were temporary facial weakness detected in 15 (5.7%) cases all of which were reversible. Magnet wound was observed in 14 (5.3%) patients, keloid formation in 10 (3.8%), wound infection in 2 (0.8%), otitis media in 5 (2%), electrode movement, meningitis, vertigo, and laryngeal spasm each in 1 (0.4%) case.

Skin flap failure was the major complication after cochlear implantation. Implant failure was seen in one case. The patient was a known case of acrodermatitis enteropathica which led to explanation. No intracranial or extracranial hematoma, no cellulites, no cerebrospinal fluid leak, no colesteatoma, no atlanto axial subluxation and no anesthesia complication including bradycardia was seen in our cases.

**Table 2:** Complications rate in different age groups

Complication	< 1 year	1-2year	2-3 year	3-4 year	>4 year	Total
Temporary facial weakness	1(5.7%)	2(3.2%)	5(8.3%)	4(6%)	3(5%)	15(5.7%)
Keloid	1(5.7%)	4(6.4%)	2(3.3%)	1(1.5%)	2(3.5%)	10(3.8%)
Magnet Wound	1(5.7%)	4(6.4%)	4(6.7%)	4(6%)	1(1.8%)	14(5.3%)
Otitis media	1(5.7%)	2(3.2%)	1(1.7%)	1(1.5%)	-	5(1.9%)
Electrode movement	-	-	1(1.7%)	-	-	1(0.4%)
Imbalance	-	1(1.6%)	-	-	-	1(0.4%)
Skin flap failure	-	-	1(1.7%)	-	-	1(0.4%)
Wound infection	-	-	1(1.7%)	1(1.5%)	-	2(0.8%)
Meningitis	-	1(1.6%)	-	-	-	-
Laryngo Spasm	1(5.7%)	-	-	-	-	-
<b>Total</b>	<b>5(29.4%)</b>	<b>13(20.9%)</b>	<b>15(25%)</b>	<b>11(16.7%)</b>	<b>6(10.5%)</b>	<b>49(18.7%)</b>

## Discussion

Several areas of potential risks are specific to the pediatric population. Not only some studies demonstrated higher anesthetic problems in pediatric patients especially in group less than one year old but also the skull and scalp are thinner in children, particularly in very young ones. The thin nature of the skull may prevent full recession of the receiver intraoperatively. The thin scalp flap can increase the risk of wound dehiscence [4,6,7,8,13]. For this reason, some surgeons advocate waiting until the child is 12 to 18 months old before proceeding with implantation. However, waiting is not infallible due to the fact that the lower age is a predictor of outcome in pediatric cochlear implantation [13,15-17].

The present study showed a surgical complication rate of 1 of 262 (less than 0.4 %) major and 49 of 262 (18.7%) minor complications. Our results confirm that pediatric cochlear implantation can be a safe procedure in skilled hands [13,14].

Among our patients apart from the loss of potential hearing benefit for the child known as a case of Dermatitis entrophepatica who underwent explantation, no child suffered a permanent physical disability after cochlear implantation.

Prevalent serious complications included flap necrosis, otitis media, cholesteatoma formation, nonauditory stimulation of the facial nerve, and electrode extrusion; each of these complications occurs at a rate of about 1%. The overall rates of major complications requiring surgical intervention range from 2% to 5% in large series [13-19].

Based on our findings major complication rate was 1 of 262 (0.4%) patients. This result compares favorably with reports from other major centers. In a multicenter analysis of implantation in the United States, Cohen and Hoffmann [2] reported a major complication rate of 3.9% for 309 children, though it seems that device failure was included in their criteria as a major complication. We had no case of device failure. Webb et al [20] who not making distinction between adults and children, recorded a major complication rate of 21 of 153 (13%) of their cases. Kempf et al study reported the major complications rate of 3% among their 100 cases [21].

Gibson et al [8] reported a major complication rate of 6% in the first 100 adults who underwent implantation in Sydney but included an obliterated cochlea that could not be implanted, as a surgical complication. De Jong et al [21] reported major complications in 2 of 52 (3.8%) children undergoing implantation in Toronto, one of which was a device failure [8]. In the largest single center pediatric series to date, Kempf et al [19] reported on 366 children who underwent implantation, in whom 12 complications (3%) had the criteria as major complication.

Studies of the largest multicenter pediatric series reported by Hoffmann and Cohen [2] showed 39 (2%) postoperative complications that needed mandatory revision surgery from the Cochlear corporation database for 1,905 pediatric implants using the CI22 device, in that study they excluded device failures from their report.

As our data show, the most prevalent problem of our patients was temporary facial weakness which in comparison with other studies was more prevalent. Hoffmann and Cohen [2] reported on data from the Cochlear Corporation database for 1,905 pediatric implants 18 facial nerve injuries, although details were not provided as to whether any of these facial palsies were permanent or not. Hoffmann and Cohen [2] reported on data from the Cochlear Corporation database for 1,905 pediatric implants using the CI22 device they also demonstrated 18 facial nerve injuries, although details were not provided as to whether any of these facial palsies were permanent. These complication rates less than 10% were also reported by Gysin et al [10] and Cervera-Paz et al [14].

One prevalent complication among our patients was related to flap and magnet problems: 14 (5.3%) cases had magnet wound, 2 (0.8%) cases had wound infection, all of which were cured with local wound care because the problems were identified early. Wound care was initiated or magnet strength reduced, the problems were resolved without need for any surgical intervention. Use of a smaller incision, minimal hair shaving, and close observation of the skin overlying the magnet, and reduced magnet strength when indicated, can reduce the rate of flap infections [14-16].

In our patients there were two wound infections that developed early in the

postoperative period and one case of meningitis that was a recurrent case of meningitis before surgery; after antibiotic therapy and vaccination the meningitis was cured and did not recur. Actually, infection makes an important contribution to surgical complications, being directly or indirectly associated with a large number of complications. Fortunately, the majority of infections can be treated with no further adverse effect on device uses, provided that infections are detected early and treated aggressively<sup>[17-21]</sup>.

Subsequent investigation of the issue by the FDA, the Centers for Disease Control and Prevention and several health departments identified 41 cases of bacterial meningitis, the majority due to *Streptococcus pneumoniae*, among 4264 children with cochlear implants, or an incidence of 189 cases per 100,000 person-years that is a less rate compare with our result (0.8%). The development of meningitis was strongly associated with the use of a positioner, a small silicone rubber wedge inserted next to the implanted electrode to improve transmission. As a consequence, positioners are no longer used in cochlear implantation<sup>[21-24]</sup>.

Our results indicate that different age groups have significant difference complication rates; up to now there are little studies that show the association between complication rate of implantation and age of children. In contrast to our results Bhatia et al<sup>[18]</sup> reported that there was a clear trend for older children who had undergone implantation to have lower complication rates which was 29% in children undergoing implantation under 2.5 years, 19% in children undergoing implantation between 2.5 and 5 years, and 13% in children undergoing implantation when they were older than 5 years. However, that trend had not reached statistical significance and concerned mainly minor complications as the number of major complications was too small to allow valid statistical comparisons.

As in our center all operation was carried out by one surgeon. The surgical experience of surgeon along with the age of implantation may affect the complication rate.

## Conclusion

Cochlear implantation in children continues to be reliable and safe in experienced hands with a low percentage of severe complications as long as the patient is monitored closely. Previous complications related to device failure and flap problems seem to be decreasing in incidence compared with older data reported in other studies. The decrease in complications may be due to improvement in technology, smaller incision size, and improved follow-up on implanted patients. Implantation in children even if under one year old provides early and effective access to auditory stimulation and can enable them a safer environment and complete aural rehabilitation with decreasing complications, as technology and expertise improves.

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## Conflict of Interest:

Non declared

## References

1. Hou JH, Zhao SP, Ning F, et al, Postoperative complications in patients with cochlear implants and impacts of nursing intervention. *Acta Otolaryngol* 2010;130(6):687-95.
2. Cohen NL, Hoffman RA, Stroschein M. Medical or surgical complications related to the Nucleus multichannel cochlear implant. *Ann Otol Rhinol Laryngol* 1988;97(Suppl 135):8-13.
3. Hampton SM, Toner JG. Belfast Cochlear Implant Center; the surgical results of the first 100 implants. *Rev Laryngol Otol Rhinol (Bord)* 2000; 121(1):9-11.
4. Deneuve S, Loundon N, Leboulanger N, et al. Cochlear implant magnet displacement during magnetic resonance imaging. *Otol Neurotol* 2008;29(6):789-90.

5. Papsin BC, Bailey CM, Albert DM, Bellman SC. Surgical aspects of paediatric cochlear implantation. *J Laryngol Otol* 1997;111(3):240-4.
6. Arnold W, Brockmeier SJ. Medical, surgical, and technical complications with the Combi-40. *Am J Otol* 1997;18(6 Suppl):S67-8.
7. Archbold SM, Nikolopoulos TP. Multi-disciplinary working practice: examples of research into outcomes from paediatric cochlear implantation. In Gallaway C, Young A, eds. *Deafness and Education in the UK: Research Perspectives*. London: Whurr. 2003; Pp: 153-73.
8. Reefhuis J, Honein MA, Whitney CG, et al. Risk of bacterial meningitis in children with cochlear implants. *N Engl J Med* 2003;349(5):435-45.
9. Colletti V, Shannon RV, Carner M, Veronese et al. Complications in auditory brainstem implant surgery in adults and children. *Otol Neurotol* 2010;31(4):558-64.
10. Odabasi O, Mobley SR, Bolanos RA, et al. Cochlear implantation in patients with compromised wound healing. *Otolaryngol Head Neck Surg* 2000;123(6):738-41.
11. Gysin C, Papsin BC, Daya H, Nedzelski J. Surgical outcome after paediatric cochlear implantation: diminution of complications with the evolution of new surgical techniques. *J Otolaryngol* 2000;29(5):285-9.
12. Gibbin KP, O'Donoghue GM, Nikolopoulos TP. Medical and surgical aspects of pediatric cochlear implantation. In McCormick B, Archbold S, eds. *Cochlear Implants for Young Children*. London: Whurr. 2003; Pp: 13-14.
13. Arnoldner C, Baumgartner WD, Gstoettner W, Hamzavi J. Surgical considerations in cochlear implantation in children and adults: a review of 342 cases in Vienna. *Acta Otolaryngol* 2005;125(3):228-34.
14. Loundon N, Blanchard M, Roger G, et al. Medical and surgical complications in pediatric cochlear implantation. *Arch Otolaryngol Head Neck Surg* 2010;136(1):12-5.
15. Ramos A, Charlone R, de Miguel I, et al. Complications in cochlear implantation. *Acta Otorrinolaringol Esp* 2006;57(3):122-5. [In Spanish].
16. Postelmans JT, Cleffken B, Stokroos RJ. Post-operative complications of cochlear implantation in adults and children: five years' experience in Maastricht. *J Laryngol Otol* 2007;121(4):318-23.
17. Gibson WP, Harrison HC. Further experience with a straight, vertical incision for placement of cochlear implants. *J Laryngol Otol* 1997;111(10):924-7.
18. Bhatia K, Gibbin KP, Nikolopoulos TP, O'Donoghue GM. Surgical complications and their management in a series of 300 consecutive pediatric cochlear implantations. *Otol Neurotol* 2004;25(5):730-9.
19. Kempf HG, Johann K, Lenarz T. Complications in pediatric cochlear implant surgery. *Eur Arch Otorhinolaryngol* 1999;256(3):128-32.
20. Webb RL, Clark GM, Shepherd RK, Franz BK, Pyman BC. The biologic safety of the **Cochlear** Corporation multiple-electrode intracochlear implant.
21. De Jong AL, Nedzelski J, Papsin BC. Surgical outcomes of paediatric cochlear implantation: the Hospital for Sick Children's experience. *J Otolaryngol* 1998;27(1):26-30.
22. McJunkin J, Jeyakumar A. Complications in pediatric cochlear implants. *Am J Otolaryngol Head Neck Med Surg* 2010;31(2):110-3.
23. Cullen RD, Fayad JN, Luxford WM, et al. Revision cochlear implant surgery in children. *Otol Neurotol* 2008;29(2):214-20.
24. O'Donoghue GM, Nikolopoulos TP. Minimal access surgery for pediatric cochlear implantation. *Otol Neurotol* 2002;23(6):891-4.
25. Ovesen T, Johansen LV. Post-operative problems and complications in 313 consecutive cochlear implantations. *J Laryngol Otol* 2009;123(5):492-6.