Fourteen-Years Experience with Cochlear Implantation in Ramathibodi Hospital

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Objective: *To review the cochlear implant program in Ramathibodi Hospital and share experience of cochlear implantation emphasized on clinical and surgical outcomes.*
Material and Method: *Retrospective review of 143 ears (140 patients) operated with cochlear implant between 1995 and 2009. The demographic data including etiology of deafness and findings from temporal bone CT scans were reviewed. The authors' experience with cochlear implant surgery in terms of patient selection, patient advisory clinic, necessary equipment, pre- and postoperative evaluations, surgical techniques and complications were discussed.*
Results: *Most congenital origin was unknown etiology and congenital rubella was the most common known cause. From the CT scans of congenital deafness, vestibular aqueduct dilatation was the most common and found in 29.31% while Mondini malformation was shown to be 16.37%. The authors' surgical technique of using the pocket method and designed bony ridge at cortical mastoid rim had helped stabilizing the implant and electrode fancoil. During the last two years, no complication or revision surgery was detected.*
Conclusion: *Cochlear implant surgery in both children and adults can result in good surgical outcome and fewer complications under experienced surgeons and a good team.*

Keywords: *Cochlear implant, CT scans of temporal bone, Cochleostomy, Hearing loss*

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Cochlear implantation is accepted as an effective treatment for profound hearing loss and deafness. It bypasses damaged parts of the inner ear cochlea and delivers sound signals directly to stimulate the auditory nerve and send sound information to the brain. The young deaf children with cochlear implants had significantly greater rates of language growth than the non-implanted ones. Actually, these rates of language growth in children with cochlear implant were similar to those rates expected in normal hearing children. Most studies had provided strong evidence that cochlear implants resulted in an improved spoken language[1,2].

About 500 cases had been operated in Thailand by the end of 2009[3]. Ramathibodi Hospital started the cochlear implantation program in 1995[4,5]. Between December 1995 and December 2009, 143 ears were operated on with three different kinds of devices (Table 1). The first case was done with a Nucleus devices (Cochlear Corporation, Melbourne, Australia) in 1995, three years later a second case was done. By 2002, 11 cases were operated with Nucleus device. In 2003, the MED-EL device (MED-EL, Innsbruck, Austria) was used during the operation. In 2006, the HiRes 90K Auria and Harmony devices (Advanced Bionics Corporation, Valencia, CA, USA) were introduced. The objective of the presented paper was to review the fourteen-year experience with cochlear

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Table 1. Number of ears operated with different cochlear implant devices

Year	Devices							Total
	Nucleus		MED-EL			Advanced bionics		
	22 channels	24 channels	Combi 40+	Pulsar CI 100	Sonata	HiRes 90K Auria	HiRes 90K Harmony	
1995	1 **							1
1999	2 * **							2
2000	1 * **	1 **						2
2001	1 **	3 * **						4
2002		2 * **						2
2003			2 * **					2
2004			11 **					11
2005			10 **(9)					10
2006			10			3		13
2007			4	12		3	8	27
2008			3	8		11	20	42
2009			1	10	1 + ***(1)	3	12	27
Total	5	6	41	30	1 + ***(1)	20	40	143

* Cases reported in ref. 4
** Cases reported in ref. 5
*** Case operated in 2004 had revision surgery from Combi 40 to Sonata because of device failure

implant in Ramathibodi Hospital, emphasizing on the surgical outcomes.

Material and Method

Clinical and CT scan of temporal bone findings from cochlear implant patients were retrospectively reviewed.

Patient selection

Patients who met the general criteria for cochlear implantation were selected. The candidacy was defined as 1) patient with bilateral, severe to profound hearing loss (pure tone average of $\geq$ 90 dB in both ears) who received little or no benefit from hearing aids and speech discrimination scores less than 50% in adults with post-lingual deafness. The exclusion criteria were 1) patient with cochlear aplasia or total calcification, 2) patient with neurological deficits or mental retardation, 3) patient with bilateral eight-nerve aplasia or tumor, 4) patient with severe medical conditions and would not be able to tolerate the surgery.

Cochlear implant advisory clinic

Prior to surgery, all candidates and relatives who were interested in the cochlear implant program were invited to attend the cochlear implant advisory clinic. This 2-hour clinic would explain the general knowledge about the devices, the eligible candidates, the surgical methods, the risks and complications and finally the intensive rehabilitation program. They were allowed to make their own decision in selections of device. The eligible candidates who had decided to have cochlear implants were further evaluated by an audiologist, speech pathologist, psychologist and otologist. For those with congenital deafness, genetic analysis was also consulted.

Investigation

High resolution CT scan of the temporal bone is one of the prime investigations for cochlear implant eligibility. From this scan, the evaluation reveals mastoid status, middle ear cavity, the ossicles, the inner ear abnormality especially the patency of the cochlear duct, and the internal acoustic canal (IAC). MRI scan is selectively indicated only for those who were post meningitis with possibility of intracochlear obliteration and those with small IAC suggestive of cochlear nerve abnormality. Other basic preoperative evaluations are applied.

Method of surgery

The surgery is performed under general anesthesia. Facial nerve monitoring (NIMS, Metronics, Minneapolis, USA) is generally applied. A postauricular incision and standard transmastoid facial recess approach is used to approach the middle ear. All patients receive intraoperative intravenous antibiotics and continue for at least 24 hour before changing to oral form and discharge. All reviewed data were summarized in term of frequency and percentage for presenting demographic characteristics causes of deafness CT scan findings and complications.

Results

Demographic data

During the 14-year study period between December 1995 and December 2009, 143 ears (140 patients) underwent cochlear implantation in Ramathibodi Hospital. One hundred and thirty seven patients had unilateral implantation while three patients had bilateral implantation. As mentioned before, the first 11 cases received the nucleus devices, which had 22 channels in five cases and 24 channels in six cases. Three of the 11 cases needed revision surgery due to incorrect position of cochleostomy and the electrode arrays were inserted into the hypotympanic cells instead of scala tympani. They finally had successful revision cochleostomy and electrode insertion.

Seventy-two ears (71 patients) received MED-EL devices. One patient had bilateral implantation. Four patients needed revision surgery performed on the opposite side from the inability to find the cochleostomy lumen due to basal turn ossifican in three patients and dislodging electrode out of the cochlea in one. The device models for 72 ears included Combi 40+ in 40 ears, Pulsar CI 100 in 30 ears, and Sonata in two ears. (One who had dislodged electrode had changed from Combi 40+ to Sonata).

For the 60 ears receiving Advanced Bionics devices, eighteen ears received the HiRes 90K Auria and 42 ears received the HiRes 90K Harmony systems. Two cases had the second ear implanted with HiRes 90K Harmony while the first sides were previously implanted with Combi 40+ of MED-EL devices. Of these 60 cases, only one case had revision surgery due to incorrect position of the electrode.

Among the 140 patients who received cochlear implant, there were 82 male and 58 female. The youngest candidate was 1.5 years while the oldest was 68 years old. There were 111 children (age 1-17), this comprised of 79.28% and adults clarified as aged 18 years up comprised of 29 patients (20.71%).

Among the children age group, 31 cases were between 1-2 years, 31 cases were between 3-6 years (55.85%) and 49 cases were between 7 -17 years (44.14%).

Children were mostly pre-lingual deaf except two were post-lingual deaf. They were 5 and 17 years old, both had suffered from meningitis one year earlier. Although most adults (68.96%) were post-lingual deaf, nine of 29 adults (31%) aged between 18 and 46 were pre-lingual deaf.

Overall, among 140 patients, 118 patients (84.58%) including 109 children and 9 adults were pre-lingual deaf while 22 patients (15.71%) including 20 adults and two children were post-lingual deafness.

All but two pre-lingual deaf patients were congenital in origin, two children had acquired deafness from ototoxic drugs, one at the age of two years old suffered from chemotherapy and the other at the age of three years from treatment of infection at 3-months old. Therefore, deafness from congenital origin was found in 116 cases (82.86%) and acquired in 24 cases (17.14%). The etiology of deafness both congenital and acquired is shown in Table 2. Most congenital origin was unknown etiology in which genetic evaluation had been under carrying out and the report would be published later. Of all the known congenital origin, congenital rubella was the most common cause. From CT scan of congenital origin, Mondini malformation (incomplete turn of cochlea) was found in 19 of 116 patients (16.37%). Vestibular aqueduct dilatation either unilateral or bilateral was more common and found in 34 patients

Table 2. Causes of deafness

Cause	Number	%
Congenital rubella	10	7.14
CHARGE syndrome	1	0.71
Usher's syndrome	2	1.42
Waardenburg syndrome	2	1.42
Noonan syndrome	1	0.71
Congenital meningocele	1	0.71
Ototoxic hearing loss	2	1.42
Chronic otitis media	1	0.71
Bacterial meningitis	5	3.57
Progressive hearing loss	11	7.86
Traumatic hearing loss	3	2.14
Unknown	101	72.14
Total	140	100

Table 3. Findings from CT scan of temporal bone in 116 cases with congenital deafness

CT temporal bone findings	Number of ears
Cochlear abnormality (Mondini malformation)	19
Vestibular aqueduct syndrome	34
Vestibular abnormality	15
Cochlear and vestibular abnormalities	13
Cochlear abnormality and vestibular aqueduct syndrome	3
Vestibular abnormality and vestibular aqueduct syndrome	9
Cochlear and vestibular abnormalities and vestibular aqueduct syndrome	7
Normal inner ear	48

(29.31%). Mondini malformation was not found to be associated with any other congenital origin except two cases were congenital rubella. Abnormal vestibular apparatus, mostly dilated, was less common, and found in 15 patients (12.93%). Thirteen cases (11.20%) had coincidence of both cochlear and vestibular abnormalities (Table 3).

Among three cases with bilateral implantation, they had sequential implantations. The first case was performed at 17 and 19 years, the second case at 2 and 7 years. Both had different systematic devices on each side by using Combi 40+ (MED-EL) on the first sides and later had Hires 90K Harmony (Advanced Bionics) on the other sides. For the third case, she had an interval of a year between both sides with Combi 40+ and Pulsar CI 100, which were from the same systematic devices (MED-EL) but different models.

Review the surgical technique and outcome

The surgical technique

Both extended and minimally extended postauricular incisions were performed with step incision at periosteum. A standard transmastoid facial recess approach is used to approach the middle ear. Cochleostomy was performed through the promontory at the antero-inferior to round window membrane.

Creation of a bone bed for the implant, the lateral skull was drilled at supero-posterior to the mastoid cavity and approximately 3.5 cm from the posterior part of external auditory canal. This will allow the magnet to be in a proper distance from the ear-anchored processor in order to avoid the unwanted interactions from the magnet to the processor. An extended bony recessed channel was created for placing the electric fancoil from the implant case to the cortical mastoid (Fig. 1). The authors designed a bony ridge created at the mastoid rim to help prevent the fancoil dislodging (Fig. 2). Previously using tie-down suture holes at the tegmen mastoideum or later using the pocket method without suture fixation were performed to stabilize the implant. The landmark for cochleostomy into the scala tympani was just anterior and slightly inferior to the round window, this was performed by using a 1 mm burr (Skeeter, Metronics, Minneapolis, USA) (Fig. 3). The cochlear implant procedure is completed by positioning the internal device at the bone bed and intimate insertion of the electrode arrays into the cochleostomy lumen manually or by using the insertion tool stylet depended on the model device (Fig. 4). Finally packing the cochleostomy and posterior tympanostomy with tissue muscle graft will prevent the leakage of perilymph and help to prevent the dislodging of the electrode arrays. Tight suture especially the periosteum was performed for stabilizing the implant in the pocket under the periosteal layer. Intraoperative telemetry of electrode impedance and nerve response (NRI) were routinely measured but this procedure was not performed in the earlier cases due to recent development of the program.

The surgical complication outcomes

Revision surgery was totally carried out in eight pediatric patients (5.71%). Three cases were due

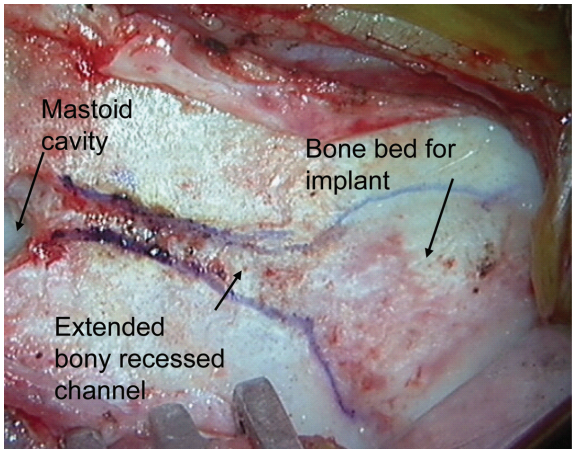

Fig. 1 Bone bed for the implant case was drilled at lateral skull, supero-posterior to mastoid cavity. Extended bony recessed channel was created for placing the electric fancoil connecting the implant to the cortical mastoid

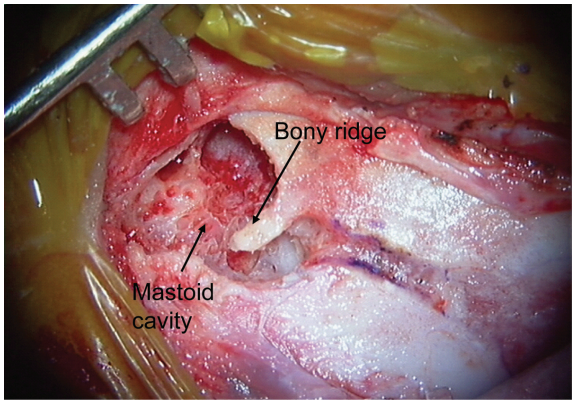

Fig. 2 Bony ridge created at the cortical mastoid at the end of bony recessed channel help prevent the implant fancoil dislodging

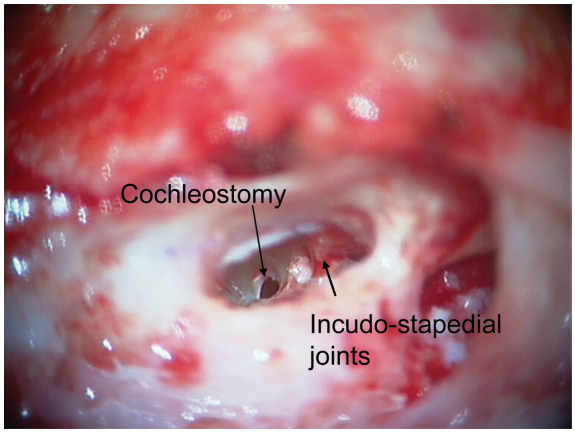

Fig. 3 Cochleostomy into the scala tympani was performed just anterior and slightly inferior to the round window membrane

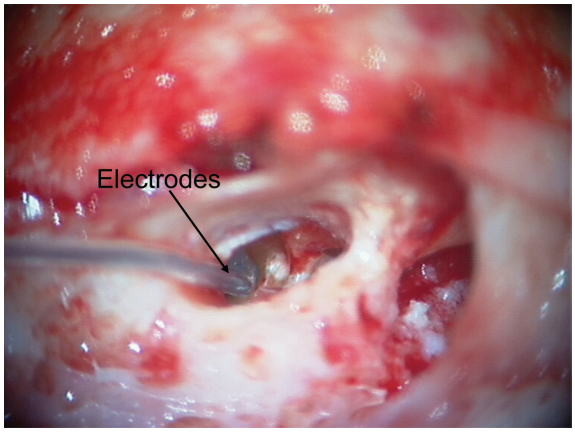

Fig. 4 Electrode was fully inserted into the cochleostomy

to inability to find the cochleostomy lumen, another three cases were due to wrong position of the electrode into the hypotympanic cells, one case had misplaced electrode into the superior semicircular canal, and the last case had dislodging of electrode arrays from the cochleostomy lumen of unknown reason. Five cases had successful revisions on the same ears and three cases had to change to the other ears due to obliteration of the cochlear duct.

Other intra-operative complications included two cases who suffered from facial nerve paralysis and included one with transient mild weakness and the other had total paralysis with partial recovery after 2 years. These complications occurred before using the facial nerve monitoring (NIMS) as the standard equipment to every case, thereafter no such complication happened. Mild perilymph gusher was detected in six cases whereas no subsequent complication such as infection was detected. Transient immediate post-operative dizziness or vertigo was detected in mostly adult and elderly pediatric age groups. There was no immediate wound infection or massive bleeding however one patient had late postoperative wound infection and recovered after incision and drainage. Table 4 shows the complications according to years of surgery. Most patients generally had good post-operative recovery and were discharged two days after the operation.

Discussion

The candidates for cochlear implantation include all patients who have profound sensorineural hearing loss of more than 90 decibels. It is important to confirm the hearing loss in the younger pediatric group by selectively using OAE, ASSR and ABR[6].

In the earlier cases with extended post-auricular incision, method of implant fixation was using the tie-down suture. However, after changing to minimal extended incision, no fixation was done but using the pocket technique to stabilize the implant in the bone bed of temporal bone.

Care is seriously taken not to injure the facial nerve. The fully equipped facial nerve monitoring is necessary since it helps preventing this unwanted serious complication of nerve injury. To provide more accuracy of nerve monitoring, the effect of muscle relaxant, if used during intubation, should have been fully declined. The maximal approach of posterior tympanotomy could be applied at the inferior aspect of the facial recess for allowing the better identification of the round window and the basal turn of the cochlea at

Table 4. Number of complications categorized into period of years and total number of ears operated during each period

Number of ears operated according to years		Revision surgery	Facial weakness	Late wound infection	Total
1995-1998	1	0	0	0	0
1999-2001	8	2	1	0	3
2002-2004	15	3	1	1	5
2005-2007	50	3	0	0	3
2008-2009	69	0	0	0	0
Total	143	8	2	1	11

the promontory. All the landmark structures in the mastoid and middle ear, which included short process of incus, incudo-stapedial (IS) joints, stapes, stapedius tendon, and round window should be clearly identified. To locate accurately the cochleostomy lumen and ensure of the scala tympani approach is critical in some cases. Several anatomic studies have shown that opening adjacent to the antero-inferior of the round window membrane is the most favorable site for scala tympani cochleostomy. Insertions more superior or anterior to the round window are more likely to enter into the scala vestibule[7]. Fig. 5 shows the alternate way to locate the area for cochleostomy. This is performed by measuring the width of the incudo-stapedial joint as A then measure the same length as B and as C subsequently in the inferiorly direction. At this third part (C), by estimation will roughly be at the anterior to the round window niche. By using both methods to locate the area for cochleostomy, the authors felt more confident in performing the precise cochleostomy. To insert the electrode arrays is sometimes difficult, the authors found that this procedure is more convenient when using the insertion tool stylet.

The perioperative and 24-hour postoperative intravenous antibiotics was helpful in preventing bacterial infection in which no serious complication such as meningitis or immediate wound infection occurred. One case was found to have late wound infection with cellulitis. It recovered after incision and drainage. Another one case suffered from urinary tract infection in which intraoperative catheterization could be the cause.

Experience plays a siginificant role in the success of the operation. Although 7.69% of the ears operated had complications, including 5.59% that needed revision surgery from misposition of electrode and unability to find cochleostomy and 1.39% that had facial weakness, the occurrence mostly happened in the earlier cases. There was no complication detected in the last two years in which 48.5% of ears were operated (Table 4). With careful preoperative evaluation of the images and intraoperative telemetry had helped lessen the improper position of the electrode and ensuring the surgical outcome. Most surgical time in normal cases is generally two to three hours, which was lessened markedly from the earlier cases. This should result from gaining more experience in intraoperative care and surgical procedure.

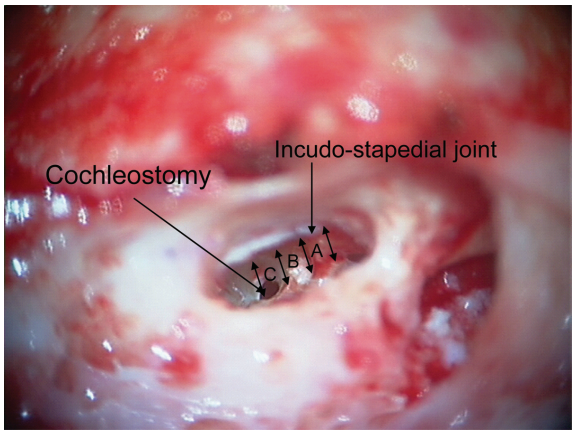

Fig. 5 The alternate way to locate for cochleostomy. It can be located at C on the promontory by measuring the width of the incudo-stapedial joint as A, then measure the same length as B and C in the inferior direction. At C will roughly be just anterior to the round window niche

Conclusion

The authors found that cochlear implant surgery is safe under an experienced surgeon. The surgery would be smooth and with fewer complications under well prepared preoperative evaluation, intra-operative antibiotics, intraoperative facial nerve monitoring, and a good team and instruments.

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ประสบการณ์ 14 ปีในการผ่าตัด ใส่อุปกรณ์รับเสียงฝังหูชั้นใน (cochlear implant) ในโรงพยาบาลรามาธิบดี

ลลิดา เกษมสุวรรณ, วิชิต ชีวเรืองโรจน์, จำรูญ ตั้งกีรติชัย, ธงชัย พงศ์มฆพัฒน์, เจียมจิต ถวิล, กฤษณา เลิศสุขประเสริฐ, รัตตินันท์ ฏิระวนิชย์กุล, รดา ดารา, จิรพร เหล่าธรรมทัศน์

วัตถุประสงค์: *เพื่อศึกษาผลการผ่าตัดผู้ป่วยในโครงการผ่าตัดใส่อุปกรณ์รับเสียงฝังหูชั้นใน (cochlear implant) ในโรงพยาบาลรามาธิบดี*

วัสดุและวิธีการ: *เป็นการศึกษาย้อนหลังในผู้ป่วย 143 หู (140 ราย) ที่ได้รับการผ่าตัดตั้งแต่ เดือน ธันวาคม พ.ศ. 2538 ถึงเดือน ธันวาคม พ.ศ. 2552 ศึกษาผู้ป่วยในด้านคลินิก ถึงสาเหตุการสูญเสียการได้ยิน และผลการดำเนินงานของโครงการนี้ซึ่งประกอบด้วย การเลือกผู้ป่วย การให้ความรู้ผู้ป่วย การดูแลทั้งก่อนและหลังการผ่าตัด และท้ายสุดวิธีการผ่าตัดและปัญหาแทรกซ้อน*

ผลการศึกษา: *การสูญเสียการได้ยินแต่กำเนิดส่วนใหญ่ไม่ทราบสาเหตุ ในกลุ่มที่ทราบสาเหตุพบว่า มารดาติดเชื้อหัดเยอรมันเป็นสาเหตุที่พบมากที่สุด สำหรับความผิดปกติจากภาพถ่ายทางรังสีเอกซเรย์คอมพิวเตอร์ พบความผิดปกติของ Vestibular aqueduct dilatation มากที่สุด (ร้อยละ 29.31) รองลงมาเป็น Mondini malformation (ร้อยละ 16.37) วิธีการผ่าตัดด้วยการเซาะเยื่อ periosteum ให้เป็นช่องกระเป๋า และออกแบบ การกรอกระดูกให้เป็นแง่งบริเวณส่วนที่ติดโพรงกระดูกมาสตอยด์ช่วยทำให้อุปกรณ์ยึดอยู่กับที่*

สรุป: *การผ่าตัดใส่อุปกรณ์รับเสียงฝังหูชั้นในสามารถทำผ่าตัดได้ผลดีทั้งในเด็ก และผู้ใหญ่ พบปัญหาแทรกซ้อนน้อยในทีมงานที่มีความชำนาญ*
