Effectiveness and safety of non-fixation method in cochlear implantation

Azzam M.A.Alsalami M.B.Ch.B , F.I.B.M.SI*, *Ahmed M, Rasheed* M.B.Ch.B , F.I.B.M.S**Ragheed T, Miteab* M.B.Ch.B F.I.B.M.S**

ABSTRACT

Background: cochlear implants are electronic devices that convert sound energy into electrical signals to stimulate ganglion cells and cochlear nerve fibers. These devices are indicated for patients with severe to profound sensorineural hearing losses who receive little or no benefit from hearing aids. The implant basically takes over the function of the cochlear hair cells. The implant consists of external components (microphone, speech processor and transmitting coil) and internal components (receiver stimulator and electrode array). The implant is inserted via a trans mastoid facial recess approach to the round window and scala tympani.

Objectives: to determine the effectiveness and safety of non fixation method in cochlear implantation.

Methods: a prospective study carried out from September 2009 to September 2012 in Gazi Hariri Hospital. Eighty patients with congenital severe -profound sensorineural hearing loss prepared for cochlear implantation involved in the study and divided into 2 groups. Group A includes 40 patients in whom the internal device was fixed to the skull by nylon suture materials through small burr holes on both sides of the well. Group B includes 40 patients in whom the internal device placed in a tight sub pericranial pocket without nylon fixation to the skull. All patients followed postoperatively for 6 months observing wound healing and local complications (hematoma, infection, wound dehiscence, device extrusion and migration).

Results: mean age 4.2 years and male-female ratio was 1.3:1.

Group A: 1 patient (2.5%) developed minor wound infection treated conservatively. Three patients (7.5%) developed severe wound infection with wound breakdown and device extrusion despite the use of antibiotics and local rotational flaps, the device was explanted in those 3 patients. Two patients (5%) developed hematoma without history of trauma and treated conservatively. One patient (2.5%) had device migration without affection of its function.

Group B: 2 patients developed minor wound infection treated conservatively. One patient (2.5%) had severe wound infection ends up with wound dehiscence and device extrusion despite the use of antibiotics and local rotational flaps. Explantation of the device was done for this patient. Hematoma occurred in one patient (2.5%) without history of trauma and treated conservatively. Another one patient (2.5%) developed device migration without impairment of its function.

Conclusion: creation of sub pericranial pocket without internal device fixation by nylon materials is an effective and reliable method in cochlear implantation without compromising the patient safety or device performance.

Key words: cochlear implantation, non- fixation, sub pericranial pocket.

Al-Kindy College Medical Journal 2014: Vol.10 No. 2
Pages: 32-35

**Department of surgery, College of Medicine, Baghdad University, ** Medical city, Al-Shaheed Gazi Al-Hariri Hospital, Baghdad Medical City*
Received 16th Dec 2013, accepted in final 16th Mar 2014
Corresponding to Dr Azzam M.A.Alsalami email: azzamsalami@gmail.com

Cochlear implants are implantable electrical prosthesis designed to convert mechanical sound energy into electrical signals that directly stimulate the auditory nerve in severely to profoundly deaf individuals [1]. Cochlear implants delivering coded pulses of electrical energy to the inner ear can transmit recognizable samples of speech sounds across a range of frequencies [2]. They are currently indicated for patients at least 12 months of age who have bilateral sever to profound sensorineural hearing loss and show little or no benefit from hearing aids for at least 6 months[3]. The electrical stimulation provided by the implant is perceived as auditory sensation that varies in pitch and loudness. Many patients are able to understand speech without visual cues and some are able to use the telephone [4].

A normal human cochlea has 30,000 spiral ganglion cells (the cell bodies of auditory nerve fibers) arranged in spiral around the modiolus of the cochlea. In patients with severe to profound hearing loss due to hair cell damage, many of the spiral ganglion cells survive and can be stimulated directly by the cochlear implant[5]. There are currently 3 cochlear implant systems in widespread use at present time: 1. Cochlear system, produced by cochlear Ltd of Sidney, Australia. 2. Med-El system, produced by Med-El of Innsbruck, Austria. 3. Clarion system produced Advanced Bionics of California, USA.

All cochlear implant systems include external and internal hardware. The external equipment include a microphone, a speech processor and a transmission system. The internal device includes a receiver stimulator and an electrode array.

The external microphone picks sound and speech in the environment and sends the information to the speech processor. The speech processor converts the sound into electric signals which are then sent across the skin viaradiofrequency transmission to the internal receiver stimulator.

The receiver stimulator decodes the signals and delivers them to the electrodes that are positioned within the cochlea [6]. The implant is inserted via a trans mastoid facial recess approach to the round window and scala tympani [7].

Operative technique: the operation is performed under general anesthesia with endotracheal intubation. Broad spectrum antibiotics are given at the induction of anesthesia and continue for 5-7 days postoperatively. The surgical field is prepared by shaving two thirds of the scalp on the side to be operated on. The scalp and ear are cleaned with suitable antiseptic and the area is draped with sterile towels. Several incisions can be used. These include an inverted-u incision, a c-shaped or an extended endaural incision. It is important that there should be a margin of at least 2 centimeters between the intended position of the implant and the edge of the wound so that

the implant will not lie under the suture line. A scalp flap is raised to expose the squamous and mastoid portions of the temporal bone.

A cortical mastoidectomy is done without saucerisation the edges of the cavity. A well is fashioned posterior to the cavity for the implant receiver stimulator. A groove is then drilled to connect the well with the mastoid cavity. Four anchoring sites are drilled, two on either side of the well to accommodate the nylon securing suture.

A posterior tympanotomy is then performed in the triangle bounded by the short process of incus superiorly, the chorda tympani anteriorly and the mastoid segment of the facial nerve posteriorly. The posterior tympanotomy is then enlarged to expose the round window niche. Facial nerve monitoring may reduce the chance of facial nerve injury. A cochleostomy is then performed. Two approaches are available, either directly through the round window or through a fenestration anteroinferior to the round window. The electrode array is then inserted into the scala tympani through the posterior tympanotomy and cochleostomy openings. This can be facilitated by using a claw to gently advance the electrode array. Wound closure should be in layers after meticulous hemostasis. Once the device is in place the electrical cautery must not be used. Drains should be avoided. A mastoid pressure dressing is applied and electrophysiological testing carried out during wound closure to check for the device integrity and electrical dynamic range [8]. The implant is programmed about four weeks postoperatively to allow subsidence of the edema at the operative field [9].

Training has been determined as an important factor in determining complication rates [10]. The risks of cochlear implantation are similar to the risks for chronic otitis media surgery and include wound infection, facial paralysis, cerebrospinal fluid (CSF) leakage, meningitis and complications of anesthesia [11]. Failure of wound to heal and associated wound infections are the most common problems associated with cochlear implantation. In few patients in whom the internal receiver has been placed too close to the wound edge or in patients in whom the flap over the internal device is too thin, the internal receiver has extruded [12]. Problems with facial nerve can occur as the result of the surgery or the postoperative stimulation [13]. CSF gusher is more common in patients with congenital malformation of the inner ear. Children with cochlear implants are at an elevated risk for meningitis as compared with the general population. Streptococcus pneumonia is the commonest micro-organism isolated, that is why it is advised that all patients undergoing cochlear implant surgery be vaccinated against streptococcus pneumonia [14, 15].

Methods. A prospective study has been done in the Otolaryngology Department in Gazi Hariri Hospital from September 2009 to September 2012. Total number of patients was 80; all underwent cochlear implantation using the device manufactured by the Cochlear Corporation. In all the cases a consent for the surgery has been taken from the parents of the patients after discussion about the cochlear implant as a device, possible benefits and postoperative complications, as well as the importance of follow up and rehabilitation following surgery.

Before the operation all patients were subjected to the followings: Thorough history taking including age of onset, events during pregnancy, birth trauma, early neonatal infections or hyperbilirubinemia, pastmedical and pastsurgical history, similar conditions in the family, use of hearing aids and the method of communication used with the patient, Also Complete systematic examination, Also Audiological, Pediatric, Neurological and Psychological counseling. Free Field Audiometry, Tympanometry and Auditory Brainstem Response Audiometry were done to all patients , also CT scan of the temporal bone and routine blood investigations and virology screen.Each patient followed postoperatively for a minimum period of six months looking for hematoma, wound healing, wound infection, flap necrosis, device extrusion and device migration. Patients who sustain head trauma in the postoperative period or those with any medical, neurological or psychological illnesses were excluded from the study. The patients divided into two groups:

Group A: 40 patients in whom the internal receiver stimulator was fixed to the bone using nylon suture material through small anchoring burr holes drilled on either sides of the well, two on each side. The skin incision was lazy s-shaped postero-superior to the auricle which is necessary to give enough space for fashioning the burr holes.

Group B: 40 patients in whom the internal receiver stimulator was placed in a tight sub pericranial pocket without the use of anchoring holes and nylon suture material. The skin incision was small postauricular and c-shaped.

Apart from the skin incision and device fixation, the same surgical steps were performed and the same antiseptic precautions were undertaken before, during and after the operation for all patients in both groups.

Statistical analysis data were introduced to PC computer and Fisher Exact test was used in statistical analysis, P value less than 0.05 was considered as significant difference.

Results. The age of the patients ranges between 2 to 6 years, mean age was 4.2± 1.21 SD years and male to female ratio was 1.3:1.In the early postoperative period up to one month following surgery, some patients in both groups developed complications.

Group A: One patient (2.5%) developed minor skin flap infection treated successfully with local and systemic antibiotics. 3 patients (7.5%) developed more severe infection with wound dehiscence and device extrusion despite of the use of antibiotics and local rotational flaps. The device was explanted in those 3 patients. Hematoma occurred in 2 patients (5%) without history of head trauma managed successfully by watchful waiting and prophylactic antibiotics. Device migration happened in one patient (2.5%) posteriorly near the occipit but still functioning for the 6 months period of follow up.

Group B: Two patient (5%) developed minor skin flap infection managed successfully by systemic and local antibiotics without compromising the device function. Severe wound infection with wound dehiscence and device extrusion occurred in one patient (2.5%) despite of antibiotics therapy and local rotational flap. The device was explanted in this patient. One patient (2.5%) developed hematoma treated conservatively (observation with antibiotics) without surgical intervention. In one patient (2.5%) there was device migration anterosuperiorly slightly above the pinna and remained functioning for the 6 months period of follow up. Number of implants explanted was 3 (7.5%) in group A and 1 (2.5%) in group B. Fisher exact test shows no statistically significant difference between the postoperative complications of the 2 groups. P value above 0.05.

Discussion. The fashioning of small burr holes on both sides of the device well for fixation of the internal receiver stimulator with nylon suture material is more invasive, takes time and needs long skin incision to give space

Table 1: Postoperative complications in fixation and non fixation groups.

Complication	Group A (40 patients) fixation method	Group B (40 patients) non fixation method
Minor skin flap infection without wound dehiscence	1 (2.5%)	2 (5%)
Sever skin flap infection with wound dehiscence and device extrusion	3 (7.5%)	1 (2.5%)
Hematoma	2 (5%)	1 (2.5%)
Device migration	1 (2.5%)	1 (2.5%)

during instrumentation and fixation of the receiver stimulator. While the non fixation method is less invasive, saves more time and more importantly allows for smaller skin incision with its better healing and less risks for wound dehiscence and flap necrosis.

This prospective study shows that fixation of the internal receiver stimulator adds no extra advantages. The steps of small burr holes fashioning and device nylon fixation take time and unhelpful. This goes with Jethanamest D. In his retrospective study who found that non fixation to be feasible without compromising the patient safety or device performance [16].It also agrees with the study of Vanlommel M who showed that non fixation is superior to fixation regarding operation safety with less postoperative minor and major complications [17].

Shelton C. in his retrospective study showed a similar rate (1 %) of major complications (wound infection, flap necrosis with dehiscence, device migration or extrusion) in patients undergoing device fixation using nylon suture materials as compared with patients without nylon fixation [18].

Balkany TJ. Found that the incidence of internal device migration is zero in his retrospective study, in patients who underwent sub pericranial T-pocket without nylon or miniplates fixation of the receiver stimulator [19].

De Varebeck SP. underwent an extensive literature review about cochlear implantation and he noticed an increasing number of otologists who no longer fix the internal device by any method [20]. Black B. reviewed a series of 547 patients who underwent cochlear implant surgery using a mini c-shaped postauricular incision without the creation of a bony retention well and no internal device fixation neither by suture materials nor did miniplates and he found that the rate of device migration in those patients was zero [21].

In conclusion, placement of the internal device in a tight sub pericranial pocket without the use of burr holes and nylon suture materials is a reliable and safe method. It is technically easier, requires less operative time and smaller skin incision than the fixation method without significant difference in the postoperative complications and without compromising the device performance.

References:

1. Eugene N. Myers. Operative Otolaryngology, ***Head and Neck Surgery*** 2008. Volume 2; 1377-1384.
2. Roger F. Gray. Maurice Hawthorne. ***Synopsis of Otolaryngology***.1992; 136-140.
3. Bruce W. Jafek, Bruce W. Murrow. ***E.N.T Secrets*** 3rd edition.2005; 56-59.
4. Rubinstein J.T, Miller CA: How do cochlear prosthesis work? 1999. ***Curr Opin Neurobiol*** 9: 399-404.
5. K. J. Lee. Essential Otolayngology, ***Head and Neck Surgery*** 2003; 132-139.
6. Cummings Otolaryngology **Head and Neck Surgery** 4th edition. Volume 4. 2005. 3603-3635.
7. Brackmann. Shelton. ***Arragia.Otologic Surgery*** 3rd edition. 2010. 373-381.
8. Operative Otolaryngology, Nigel Bleach. Chris Milford. Andrew Van Hassell. 1997. 85-89.
9. ***Synopsis of Operative E.N.T Surgery***. Brian J.G. Bingham. Maurice R. Hawthorne. 1992. 131-138.
10. Cohen NL. Hoffman RA. Strochein M. Medical or Surgical complications related to nucleus multichannel cochlear implant. ***Annals of Otology Rhinology Laryngology***.1988; 135: 8-13.
11. Webb RL. Lehnhardt E. Clark GM. Surgical Complications with cochlear multiple-channel intracochlear implant. Experience at Hannover and Melbourne. ***Ann OtolRhinolLaryngol*** 1991, 100: 131-136.
12. Haberkamp TJ. Schwaber MK: Management of flap necrosis in cochlear implantation. ***Ann OtolRhinolLaryngol*** 1992, 101: 38-41.
13. Niparko JK, Oriatt DL, Coker NJ, et al: Facial nerve stimulation with cochlear implantation. ***Ann OtolRhinolLaryngol*** 1992, 101: 38-41.
14. Reefhuis J, Honein MA, Whitney CG, et al: Risk of bacterial meningitis in children with cochlear implantation. ***N Engl J Med*** 2003, 349: 435-445.
15. Biernath KR, Reefhuis J, Whitney CG, et al: Bacterial meningitis among children with cochlear implantation beyond 24 months after implantation. ***Pediatrics*** 2006, 117: 284-289.
16. Jethanamest D, Channer GA, Moss WJ, Lustig LR, Telischi FF. Cochlear implant fixation using a subperiosteal tight pocket without either suture or bone recess technique. ***Laryngoscope*** 2013 Oct 1. doi: 10.1002.
17. VanlommelM ,Lipski S , Dolen P. Minimally invasive technique for cochlear implantation of Neurelec Digisonic SP cochlear implant. ***Eur Arch Otorhinolaryngol*** 2013 April 11.
18. Shelton C, Warrea FM. Minimal access cochlear implant fixation: temporalis pocket with a plate. ***OtolNeurotol.*** 2012 Dec; 33(9): 1530-4.
19. Balkany TJ, Whitley M, Shapira Y, Angeli SI, Brown K, Eter E, Van De Water T, Telischi FF, Eshraghl AA, Treaba C. The temporalis pocket technique for cochlear implantation: anatomic and clinical study. ***OtolNeurotol***: 2009 Oct; 30(7): 903-7.
20. De Varebeke SP, Goveaerts P, Cox T, Debenk, Ketelslagers K, Waelkens B. Fixation of cochlear implants: an evidence-based review of literature. **B-ENT** 2012; 8(2): 85-94.
21. Black B. Keyhole cochlear implantation: current status. ***OtolNeurotol***. 2011 Dec; 32(9): 145-63.