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Revision Cochlear Implantation in Baghdad Medical City: A Retrospective Study

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Abstract:

- ***Background***: Revision cochlear implant surgeries are uncommon but they represent a challenging issue for surgeons. Thoughtful preparation and evaluation of patients with proper counseling are mandatory.
- ***Objectives:*** To identify the rate of revision surgeries and re-implantations, evaluate the causes, and analysis of clinical and operative findings.
- ***Patients & Methods:*** A retrospective study including 46 cases underwent revision surgeries out of 1144 patients had cochlear implantation in the department of otolaryngology/Baghdad Medical City in the period from March 2009 to November 2019. The data were collected from 3 statistical record sources (the otolaryngology department records, operative theatre records, and hospital's main statistic department).
- ***Results:*** Revision cochlear implantation ratio was 4%. It was found that most of the cases were from pediatric age group (98% of cases with mean age of 6.77 years) with no difference between males and females (male to female ratio was 1.1:1). The most common causes for revision surgeries were non-device related (63%) while device related causes counted (37%). Re-implantation rate was (24%).
- ***Conclusion:*** Revision cochlear implant surgeries in our center were within lower limits of the universal revision rates. Most commonly encountered cause for revision was wound infection with/without dehiscence followed by hard device failure. No significant complications recorded per and post operatively.

Keywords: Revision cochlear implantation, Re-implantation , Device failure.

INTRODUCTION

Cochlear implantation is a well-tolerated and effective surgery for hearing rehabilitation in the severe and profoundly hearing-impaired population. However, revision cochlear implant (RCI) may become necessary for a variety of reasons. Although the need for RCI is uncommon, special consideration towards indications, proper surgical techniques, and patient counseling about expected outcomes is needed. The rate of revision surgery reported in the literature has ranged from 3.8 to 7.2%. [1–3] Overall, improvements in cochlear implant device technology and manufacturing techniques, as well as improved surgical technique, have decreased the incidence of RCI surgery. However, one can expect that, as the currently implanted devices age and new technologies emerge, one or more revision surgeries may be indicated in a patient's lifetime. [1] The external part of the cochlear implant detects the sound signal and converts it to an electrical signal which is transmitted to the internal processor. The way in which the signal is passed into the electrode array depends on the speech processing strategy utilized by that device. Each implant manufacturer has developed strategies that they believe have advantages over the others. In normal young adults, there are approximately 35 000 auditory nerve fibres; it is estimated that at least 10 000 are required for speech recognition using a cochlear implant.[4] Performance with a cochlear implant is optimized postoperatively through a process of programming known as 'mapping', combined with intensive rehabilitation. The cochlear implant team is therefore multidisciplinary and includes teachers of the deaf, speech and language therapists, psychologists, audiologists, audiological scientists, radiologists and surgeons. [4] In the earliest years of cochlear implants, the technology was considered to be experimental and was offered only to the most profoundly deaf adults. In modern practice, the reliability and outcomes of CI have improved and criteria for candidacy have evolved to include both adults and children with some residual hearing as well as congenitally deaf infants.[4] Criteria differ according to the healthcare systems and

funding arrangements of individual countries. In England and Wales, the National Institute for Health and Care Excellence (NICE) have stipulated the following criteria for CI, based on clinical and cost-effectiveness assessments:[4,10]

- A cochlear implant should be considered for any person with a severe to profound hearing loss who does not gain adequate benefit from acoustic hearing aids.
- Severe to profound deafness is defined as the ability to hear only sounds louder than 90 dB HL at 2 kHz and 4 kHz without hearing aids.
- Hearing aids should be used for at least 3 months unless inappropriate or contraindicated.
- Adequate benefit with hearing aids is defined as:
    - For adults, a score of 50% or greater on Bamford– Kowal–Bench sentence testing at a sound level of 70 dB SPL.
    - For children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.

Complications of cochlear implant surgery can be classified into major and minor complications, and also can be classified according to the timing into early and late. In our thesis we are conscerned about the major and minor complications as possible causes for revision surgery.[14]

Device failures:

Failure modes are most commonly related to trauma, electronic dysfunction, or CSF leakage. After device failure, explantation and re-implantation is a safe and acceptable treatment option.[14] By definition: the device exhibits characteristics outside the manufacturer's specification, resulting in a loss of clinical benefit or failure to attain benefit. Other definitions concerning device function are:[14,15] Functioning device: The device has no evidence of any

device-related malfunction or no deficiency can be observed from the available test results. Characteristics decrement: A device has measured characteristics outside the manufacturer's specification, but still of benefit to the patient. Performance decrement: Unexplained but documented decrement in performance or a device that causes non-auditory sensations necessitating explantation. Loss to follow-up: Those implanted patients who have been lost to clinical surveillance.

- Hard Device Failure: is the absence of auditory input or electronic lock between external and internal components. In a short: a proven malfunctioning device.[14]
- Soft Device Failure: is considered a malfunction of the implant but without any proof with available in vivo methods of testing. In short: a suspected device failure without any proof.(14)

DEVICES

- ***The external part: the microphone, sound processor and transmitter coil:*** this part of the cochlear implant detects the acoustic signal and converts it to an electrical signal with both temporal and spatial components. The encoded signal is transmitted to the internal device using radiofrequency via the external coil.
- ***The internal receiver–stimulator package:*** This contains the internal magnet, telemetry coil and hermetically sealed electronics system. There is also a ground electrode for current return, either incorporated within the package or as a separate electrode placed under the temporalis muscle.
- ***The intracochlear electrode:*** The electrode that is placed into the cochlea is in fact a group of individual wires, each ending at a contact point along the silicone casing. The number of individual wires varies depending on the manufacturer and type of electrode. [4]

- ***Manufacturers:*** At present, there are three major cochlear implant manufacturers including Advanced Bionics Corporation, USA (www.advancedbionics.com), Med-El Corporation, Austria (www.medel.com), and Cochlear Corporation, Australia (www.cochlear.com). Several other companies are also developing advanced and low-cost multi-electrode cochlear implants, including Oticon Medical (www.oticonmedical.com), Nurobiosys Corporation in Seoul, Korea, and Nurotron Biotechnology Inc. based in both Irvine, CA and Hangzhou, China (www.nurotron.com).[16]

Revision cochlear implantation

Reoperation on a patient with an indwelling cochlear implant is uncommon. When necessary, surgery is performed for explantation of an existing device with immediate or delayed reimplantation, or for scalp flap revision and receiver-stimulator repositioning in the case of infection or device migration. Rarely, revision surgery is performed to reintroduce intracochlear electrodes that may have partly or entirely extruded from the cochlea or were placed inappropriately. Successful revision cochlear implant surgery requires attention to certain surgical principles. Good outcomes, as measured by speech perception tests, are common, but are not guaranteed.[22] There are two main categories for indications for revisions: non-device related indications and device related indications. Device related indications include those patients where there is confirmed or suspected device failure, facial nerve stimulation, and the need for device upgrading. Non-device related indications include patients who require revision surgery because of scalp flap infections, allergic reactions, misplacement of the electrode array and electrode extrusions.[23,24] Revision cochlear implant surgery, although uncommon, presents the clinician with several challenges. Thoughtful preparation and patient counseling, combined with appropriate procedures, will lead to

successful outcomes in most cases. The patient should be aware that a reimplantation, even with a newer generation of device, will not always lead to improved outcomes.[22]

- ***History:*** In 1985, Hochmair-Desoyer and Burian did first successful cochlear re-implantation. Revision surgery was successfully performed on two Vienna cochlear implant patients. Twenty months and 40 months, respectively, after initial insertion into the cochleas of two bilaterally deaf patients, electrodes were removed from the scala tympanis and replaced by electrodes of the same design. Psychophysical and speech data gathered before and after the revision surgery were compared. These were thresholds, loudness scalings, amplitude difference limens, pitch scalings, frequency difference limens, and speech tests in the "stimulation only" modality. No negative changes were found. The data available demonstrate a continuous improvement in performance over many months of practice with the sound processor. This development was not impeded by the revision surgery. Thus, it was demonstrated that the removal and replacement of a molded scala tympani electrode is feasible.[22,25]
- ***Types of revision surgeries:*** Revision surgery was classified into reimplantation, minor revision surgery, explantation without reimplantation, and electrode array reinsertion. Reimplantation was defined as explantation of an existing device followed by the replacement with a new implant. Minor revision surgeries were procedures performed on the wound or the existing implant, including receiver stimulator reposition, skin flap revision, change of magnet, magnet reinsertion, and aeroseal operation. Explantation without reimplantation referred to the removal of an existing implant with no subsequent replacement. Electrode array reinsertion involved repositioning of the existing intracochlear electrode array.[26]

- ***Surgical considerations:*** Reoperation for a failed or failing cochlear implant requires thoughtful planning and consideration of several issues. Most of the time, the same incision used for the first operation is opened and similar flaps are developed. It is important to avoid monopolar cautery to prevent current spread through the device to the delicate neural elements of the cochlea. [22] The explanted device is returned routinely to the manufacturer for analysis and the information obtained is used in designing future devices. During reoperation, mechanical damage to the explanted device should be avoided. The electrode lead wire might be encased in new bone and additional drilling and excavation is usually required. The intracochlear electrode is left in place until reimplantation is performed, either during the same surgical procedure or at a future date in the case of infection, and is accomplished by cutting the electrode at the facial recess or in the mastoid cavity. The electrode acts as a stent, keeping the intracochlear pseudocapsule open and preventing scalar occlusion by new bone growth in the case of delayed reimplantation.[22] In situations where the receiver-stimulator has migrated, or where a serious infection has occurred, usually the bed or well is also revised or relocated and new subcortical suture holes are made to secure the device. Care is taken not to dislodge the intra-cochlear electrodes. An intraoperative radiograph is recommended to confirm success.[22] If the device has been exposed by scalp flap breakdown, the area is irrigated copiously with antibiotic-containing solution and the tissues around the device are debrided aggressively. On occasion, when device salvage is attempted, a larger scalp flap may have to be designed to rotate healthy vascularized tissue over the device. When surgical salvage is unsuccessful, usually because of persistent or recurrent infection after 6 weeks of intravenous antibiotic therapy, the receiver-stimulator is removed, with the electrode array remaining in the cochlea. Three months of flap healing permits reimplantation

in a sterile environment. Electrode choice for revision surgery requires consideration.[22] If many years have passed since the initial surgery, new device options will have become available. The new electrode should not be larger in diameter than the explanted electrode. Also, a reimplantation case may develop an obstructed cochlea situation requiring obstructed cochlea techniques. A split or double array device may be required, especially if there is significant luminal obstruction by ossification of the scala tympani, and should be available in the operating room; however, this situation is rare. Scala vestibuli insertions are considered if full insertion is not accomplished in the lower scala.[22,27] In patients with labyrinthitis ossificans, reimplantation can be even more challenging. The same device can be used for electrode extrusion, or a new device might be necessary.[22]

Aim of the study

1. Identification the revision rate in department of otolaryngology in Baghdad Medical City Complex.
2. Identification of the re-implantation rate.
3. Evaluation of the causes for revision surgeries, generally and specifically for device types.
4. Analysis of the clinical and operative findings in revision cases.

Methodology

- ***Study design:*** Retrospective cross-sectional record based study
- ***Setting:*** Department of otorhinolaryngology, Martyr Ghazi Al-Hariri teaching hospital for surgical subspecialties, Medical city, Baghdad, Iraq
- ***Inclusion criteria:*** All patients who underwent the primary implantation and revision surgeries in our department were included.

- ***Exclusion criteria:***
    - All patients who underwent the primary implantation surgery outside the center were excluded.
    - Cases with lost or incomplete data in records.
    - Patients with revision surgeries without intervening with implanted device (for example: surgical site infection debridement and rotational flap operations)
- ***Subjects:*** This study was done retrospectively for all patients who underwent revision cochlear implantation surgery in the department of otolaryngology at Martyr Ghazi Al-Hariri teaching hospital for a period of 10.5 years (from March 2009 till November 2019). The study included 46 patients who met the inclusion criteria and had revision surgeries from the total number of 1144 cochlear implantation done for 1144 patients (all cases underwent unilateral cochlear implantation). The study involved all device types that were used in cochlear implantation during the research period. These devices were mainly from two manufacturing companies (652 devices from Cochlear corporation and 490 devices from MED-EL) with only two devices from Oticon Medical. All cases of primary implantations and revision surgeries were done by 8 surgeons who are well trained in cochlear implantation with the exception of two devices from Oticon which were implanted by a foreign (French) surgeon. After appropriate approvals had been obtained from Institutional Review Board, data were collected from our department's statistics department, operative room records, and main statistics department of the hospital. Some data were collected from the personal records of the operating surgeons. Data collected include the name, age, gender, residence, record number, name of the surgeon, date of primary implantation, time interval from implantation to revision surgery, side of implantation, type of

implanted device, operative notes, surgical findings, enquiry about re-implantation, side of re-implantation (if done), type of device used in re-implantation (if done), electrophysiological tests in form of ART or NRT (according to the manufacturing companies) and Impedance test results, and outcomes of the revision surgery. A questionnaire prepared for each case data to be recorded and results were collected at the end and statistical analysis done for them. Causes of revision surgeries were divided into two main classes: device related, and non-device related causes. Device related causes included hard device failure, soft device failure, device upgrading, and facial nerve stimulation. Non-device related causes included scalp flap necrosis/device exposure, wound infection/dehiscence, electrode extrusion, biofilms, cholesteatoma, and subperiosteal abscess. All cases with scalp flap complications and wound infections received appropriate systemic medications and local debridement and wound care and underwent explantation of the device after failure of all management trials including rotational flap procedures in corporation with plastic surgeons. All explanted devices were sent to the manufacturing companies for assessment and evaluation. Classification of device failure into hard and soft done according to the standard criteria described by Cochlear Implant Soft Failures Consensus Development Conference Statement in 2005. Cochlear implantation surgery done in our department by the classical technique with mastoidectomy and posterior tympanotomy. During the first two years of starting cochlear implantation in our department (2009-2010), the incision used in almost all cases was post auricular lazy S incision. After 2011, almost all cases underwent cochlear implantation had classical retroauricular incision. Re-implantation. whenever planned, were tried to be done on the same side if there was no contraindication.

- ***Surgical steps in revision surgeries:*** These steps have been done in most of the cases but it was not the standard for all of them.

1. All cases underwent surgery under general anesthesia with supine position and tilting the head to the other side, sterilization and drapping.
2. Prophylactic antibiotic (ceftriaxone 50 mg/kg and/or amikacin 15 mg/kg) given at time of induction.
3. Post-auricular skin incision (regardless the site of previous incision) with hemostasis by bipolar cautery.
4. Subperiosteal flaps elevated (anteriorly based or posteriorly based according to the surgeons' preference).
5. Electrode identified at entrance to the mastoid cavity and cut.
6. Receiver/stimulator of the implant removed with removal of any granulation tissue, fibrosed tissue, or bony regrowth.
7. Irrigation of the new cavity and hemostasis done.
8. In cases where no immediate re-implantation planned, the electrode cut at facial recess and kept inside the cochleostomy or round window to maintain lumen patency for future re-implantation.
9. In cases where re-implantation planned, new device inserted in the well and secured, and the old electrode removed and replaced with new electrode immediately.
10. Electrophysiological tests in form of ART or NRT and Impedance test performed to confirm functioning.
11. Hemostasis secured and wound closed in layers.
12. Dressing done after application of povidone iodine ointment on the scar area and patients kept as inpatients in the ward at least for 24 hours.

RESULTS

Forty-six patients underwent revision cochlear implantation surgeries out of a total number of 1144 cases (4.02% of total implantations) met the inclusion criteria of our study.

- ***Age distribution:*** Patients age ranged from 2.5 years to 27 years with a mean age of 6.772

± 4.628 SD. The cases were divided into two age groups: children (<18 years) and adults (at or >18 years). According to this classification, only two of our cases were adults (4.35%) and the

remaining 44 patients were children (95.65%).

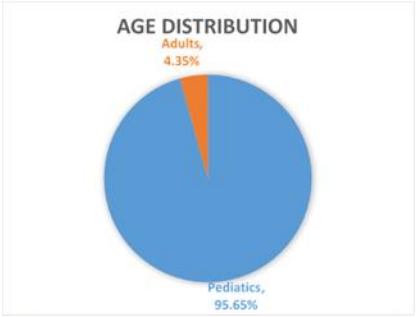

Figure 3-1: age distribution

- ***Gender distribution:*** In this study, 24 patients (52.2%) were males while 22 patients (47.8%) were females. The male to female ratio is (1.1:1).

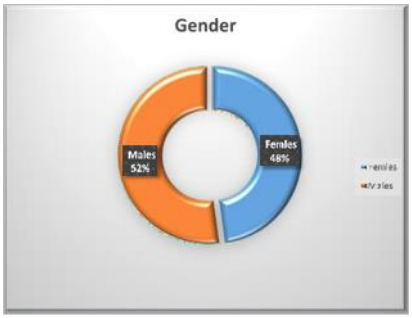

Figure 3-2: gender distribution

- ***Date of revision surgery:*** Cases in this study were distributed into 5 periods, first period included years 2009 and 2010, second period included 2011 and 2012, third period included 2013 and 2014, fourth period included 2015 and 2016, and the fifth period included 2017, 2018, and 2019. Most of the revision cases were done during the first period (28 cases, 60.9%), the remaining cases distributed through remaining period groups as follows: second period (2 cases, 4.3%), third period (1 cases, 2.2%), fourth period (2 cases, 4.3%) and the last period (13 cases, 28.3%).

Figure 3-3: date of revision surgery

- ***Time interval from implantation to revision surgery:*** The time interval from the primary implantation surgery to the last revision surgery was ranging from 1 to 106 months (the mean time was 19.7 months ± 27.69 SD).

- ***Side of primary implantation surgery:*** Almost all cases who had revision surgeries were primarily implanted on the right ear (45 cases, 97.8%) except a single case who had left sided implantation (2.2%).
- ***Device types:*** First cochlear implantation done in our department was in the 4th of March 2009 and the device used was Nucleus® Freedom™ [CI24RE (CA)] from Cochlear® corporation which was the same device model used during the first 5-years (from 2009 till 2014). The first implantation surgery from MED-EL company

was done in the 7th of April 2014 and the device model used was CONCERTO for the last 5-years (from 2014 till 2019) in cochlear implantation surgeries in our department.

- Cochlear® corporation devices: the total number of patients who were primarily implanted by cochlear® was 652 cases (56.99% of total number of implanted devices in our center); 36 cases underwent revision surgery which forms 78.3% of the total revision cases, 5.52% from the cochlear® implanted devices, and 3.14% of overall total implantation cases.
- MED-EL devices: the total number of patients who were primarily implanted by MED-EL devices were 490 cases (42.83% of total number of implanted devices in our center); 8 cases underwent revision surgery which forms 17.4% of the total revision cases, 1.63% from the MED-EL implanted devices, and 0.7% of overall total implantation cases.
- Oticon Medical devices: only 2 cases were implanted primarily by Oticon Medical device and both devices underwent revision surgery forming 4.3% of the revision cases, 0.17% of overall total implantation cases.

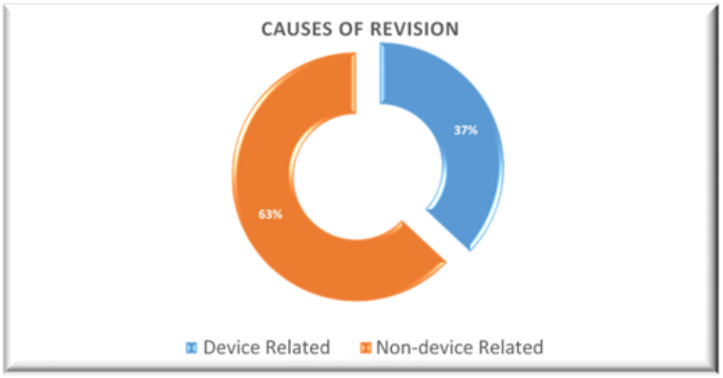

Figure 3-5: device related VS non-device related causes of Revision

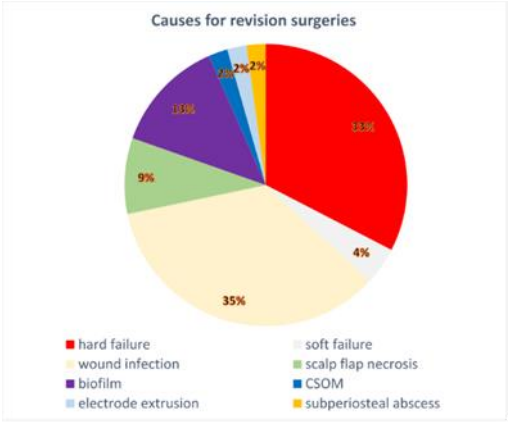

Figure 3-6: causes for revision surgeries

- ***Causes of revision surgeries:*** Twenty-nine cases of revision surgeries were due to non- device related causes (63%) while the remaining 17 cases were due to device

related causes (37%). Regarding device related causes, the most common cause was hard failure in 15 cases (32.6%) while soft failure documented to be the cause in 2 cases (4.3%). In non-device related causes, the most common cause was wound infection and dehiscence in 16 cases (34.8%) while the remaining causes distributed on biofilm in 6 cases (13%), scalp flap necrosis with device exposure in 4 cases (8.7%), CSOM in one case (2.2%), electrode extrusion in one case (2.2%), and subperiosteal abscess in one case (2.2%). Most of cases with hard device failure were due to trauma. Only two cases were defined as soft device failure in this thesis after receiving the feedback of explanted device reports from manufacturing company. No one of the cases underwent revision surgery solely for upgrading technology.

- ***Causes of revision surgeries according to device type:***
    - Cochlear® corporation devices: the most frequent cause of revision surgeries was wound infection with/without dehiscence which counted in 16 cases (34.8%), followed by hard device failure in 6 cases (13%) and biofilm in other 6 cases (13%).
    - MED-EL devices: the most frequent cause of revision surgery was hard device failure which counted in 7 cases (15.2%) and a single case had revision surgery due to CSOM and electrode extrusion (2.2%).
    - Oticon Medical devices: only 2 cases (4.3%) underwent revision surgeries with hard device failure being the cause for both cases.

Table 3-2: causes for revision surgery according to device type

Devices / Causes	Cochlear		MED-EL		Oticon	
	N	%	N	%	N	%
Hard failure	6	16.7%	7	87.5%	2	100%
Soft failure	2	5.6%				
Wound infection/dehiscence	16	44.4%				
Scalp flap necrosis/device exposure	4	11.2%				
Biofilm	6	16.7%				
Subperiosteal abscess	1	2.8%				
Electrode extrusion	1	2.8%				
CSOM			1	12.5%		
TOTAL	36	100%	8	100%	2	100%

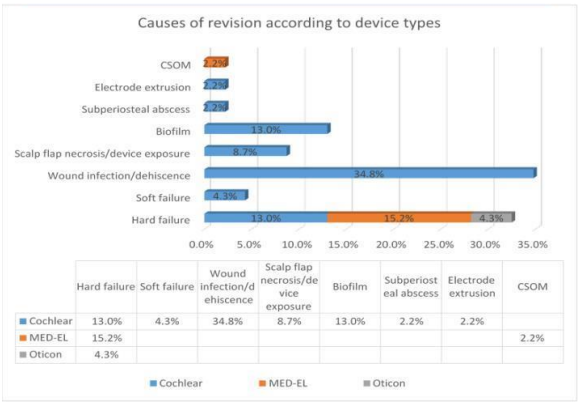

Figure 3-7: causes for revision surgery according to device types

 Re-implantation ratios: As mentioned above, revision surgeries were classified into four types: explantation without re-implantation, explantation with re-implantation, minor revision surgery, and electrode array reinsertion. During the period of the study, 34 cases (73.9%) underwent explantation of their devices without re-implantation, 11 cases (23.9%) had explantation with re-implantation, and only one case (2.2%) underwent revision surgery without explantation for electrode array reinsertion. All re-implantation cases have been implanted on the same ear except two cases who had implantation on the other side. All cases of re-implantation have been implanted by a device from the same manufacturer of the primary implantation except one case who was implanted by a device from Oticon and had re-implantation by a device from Cochlear®. Almost all cases implanted primarily by Cochlear devices had explantation without re-implantation apart from two cases who had re-implantation, the first one was during the same surgery of explantation while the other one re-implanted after two years of explantation. All

cases underwent explantation from MED-EL devices had re-implantation on the same surgery and on the same side which primarily implanted. A single cases underwent revision surgery

due to electrode extrusion and didn't necessitate explantation of the device as the re-insertion of the electrode resulted in functioning device intraoperatively.

DISCUSSION

As the number of cochlear implant surgeries increasing annually worldwide, it is suspected that this increment will be associated with an increase in the number of revision surgeries. However, in spite of increasing in implanted devices, the incidence of revision surgeries remained the same.

- *Revision rates:* Forty-six patients underwent revision cochlear implantation surgeries out of a total number of 1144 cases (4.02% of total implantations) met the inclusion criteria. The rate of revision surgeries in our center was in concurrence with the results of most literatures from tertiary cochlear implant centers including the works of Sorrentino et al. (4.1%)(28), Amaral MSAd et al. (4.23%)(29), Lassig et al. (5.10%)(30), Trozzi et al. (5.14%)(31), Brown et al. (5.50%)(3), Kumari et al. (3.53%)(32), Battmer et al. (3.79%)(33) and Manrique-Huarte et al. (3.90%)(34). Other studies showed higher rates of revision surgeries such as study done by Wang et al.(26) (who had revision rate 8.30% after recording data of 235 revision surgeries out of 2827 cases underwent cochlear implantation in their center during 30 years period), Cullen et al.(35) (with 11.2% revision rate from 107 revision surgeries out of more than 1000 cochlear implantation), and Marlowe et al.(36) (who had the higher revision rates of 12.90% by recording 64 cases out of 482 primary implantation surgeries).
- *Age at revision surgery:* Patients age in this study ranged from 2.5 years to 27 years with a mean age of 6.772 ± 4.628 SD. The cases were divided into two age groups: children (<18 years) and adults (at or >18 years). The pediatric age group was

predominant in our study with 44 cases (95.65%) compared to only two adult cases (4.35%). These results disagree with most of literatures like works done by Sorrentino et al. (55% pediatric versus 45% adults)(28), Wang et al. (41.4% pediatric versus 58.6% adults)(26), Lassig et al. (51% pediatrics versus 49% adults)(30), Brown et al. (63.6% pediatric versus 36.4% adults)(3), Balkany et al. (69% pediatric versus 31% adults)(37), and Cote´ et al. (55.6% pediatric versus 44.4% adults)(38). The smaller percentage of adults in our results is a logical outcome *M.W.Ibrahim Revision Cochlear Implantation in Baghdad Medical City; A Retrospective study* as most of the primarily implanted patients were less than 6 years as part of cochlear implantation program in our center.

- *Date of revision surgery:* Cases in this study were distributed into 5 periods, first period included years 2009 and 2010, second period included 2011 and 2012, third period included 2013 and 2014, fourth period included 2015 and 2016, and the fifth period included 2017, 2018, and 2019. These periods correspond to the rations of devices received during these years. The highest rate of revision surgeries was done during the first period (28 cases, 60.9%). The most common cause for revision during this period was surgical site infection and wound dehiscence.
- *Time interval from implantation to revision surgery:* The time interval from the primary implantation surgery to the last revision surgery was ranging from 1 to 106 months (the mean time was 19.7 months ± 27.69 SD). These results were close with the mean time interval from the work of Kumari et al.(32) (mean time interval of 18 months) and Cunningham et al.(39) (mean time interval of 11.3 months). Other studies disagree with our results including the work of Marlowe et al.(36) (mean time interval of 40 months), Trozzi et al.(31) (mean time interval of 41 months), Cullen et al.(35) (mean time interval of 31.5 months), and Yeung et al.(40) (mean time interval

of 54 months). The relatively shorter mean interval between our results and the above results is due to the short interval of the revision surgeries in the first period of our study which compromise most of the cases due to surgical site infection which prompt revision surgery.

- *Device type and model:* The type and the model of the devices implanted were mainly from cochlear® corporation (652 cases, 56.99%) and MED-EL (490 cases 42.83%) with only two cases implanted by devices from Oticon Medical. As the method for choosing the device type and model differs from one center to another, it was difficult to compare the rates of revision surgeries from our study results with other series. The device type implanted during the first 5-year period was solely from cochlear® corporation (Nucleus® Freedom™) and most of the devices implanted during the last 5-year period was from MED-EL (CONCERTO). The revision rate for devices from cochlear® corporation was 78.3% of the overall revision cases (5.52% of cochlear® device revisions) while the revision rate from MED-EL devices was 17.4% of the total revision cases (1.63% of MED-EL device revisions). The higher rate of revision cases from cochlear® devices was due to the high rate of revision surgeries during the first period of our study (years 2009 and 2010) which was caused mainly by wound infection and dehiscence were implanted primarily by Cochlear® devices.
- *Causes for revision surgery:* The causes of revision surgeries in our study were classified into device-related and non-device related causes. The non-device related causes were more common etiology for revision surgeries (29 cases, 63%) compared with device- related related causes (17 cases, 37%). These results disagree with most of relevant literatures in which the device-related causes (specifically hard failure) were the most common cause for revision as shown in the table (4-1) below. The commonest cause of non- device related causes in our study was due to the relatively

higher number of wound infection/dehiscence and flap necrosis during the first period of this study and this may be explained by larger incision size (Lazy-S shaped) compared with the smaller post-auricular incisions (4-5 cm) used from the year 2011 onward which was associated with significant reduction in infection rate and subsequent revision rate. This was supported by Sorrentino et al.(28) who reached to the same conclusion. In addition, the usage of same instrument sets that are used in other ear surgeries other than cochlear implantation such as mastoid operations, and the recency of cochlear implantation program during the first two years with not optimum operative room preparations and trained staffs may be other causes blamed for higher rates of revision cases due to infection and its complications.

Table 4-1: rates of revision cochlear implantation surgeries in literatures

Series	Device-related	Non-device related	Total revision rate
Sorrentino et al.[28]	55%	45%	4.10%
Trozzi et al.[31]	55%	45%	5.14%
Brown et al.[3]	78%	22%	5.50%
Kumari et al.[32]	73.6%	26.4%	3.53%
Manrique-Huarte et al.[34]	57.9%	42.1%	3.90%
Lassig et al.[30]	72.5%	27.5%	5.10%
Cullen et al.[35]	63%	37%	11.20%
Marlowe et al.[36]	71%	29%	12.90%
Cote´ et al.[38]	76.2%	23.8%	6.30%
Yeung et al.[40]	80%	20%	5.90%
Migirov et al.[41]	73%	27%	8.10%
Wang et al.[26]	57.9%	42.1%	8.30%
This study	37%	63%	4.02%

- *Causes for revision in relevant to device type:* The most common causes for revision in patients implanted with cochlear® devices was non-device related comprising 77.8% of total cochlear® revision cases, compared with 22.2% of device related causes for the same device type. the most common cause blamed in these cases was

wound infection/dehiscence (44.4%) which was the main cause during the first period of our study and these devices was the only implanted models during these years. On the other hand, the most common cause for revision in MED-EL devices were device-related, counting 87.5% of total MED-EL revision cases, compared with 12.5% of non-device related causes. The most common cause blamed in these devices was hard failure in 7 cases (87.5%) and the main causes for failure was trauma as documented in the history papers in medical records and supported by the reports from manufacturers.

- *Re-implantation rate:* We classified the types of revision surgeries into four categories: explantation without re-implantation, explantation with re-implantation, minor revision surgery, and electrode array reinsertion. The overall explantation without re-implantation rate in this study was 73.9% (34 cases) while the explantation with re-implantation rate was 23.9% (11 cases) with only one case underwent revision surgery for electrode array re- insertion (2.2%). The higher rate of re-implantation surgeries was with cases implanted by MED-EL devices comprising 72.2% of all re-implanted cases (100% of revision cases for same device type), while the re-implantation rates for cochlear® devices were 18.2% of all re-implanted devices (5.6% of revision cases for the same device type) It was difficult to compare the re-implantation rate with the results from other series due to difference in the policies and guidelines in each center. The rate of re-implantation in our study (23.9%) was much lower when compared with the rates reported in many literatures like the work of Wang et al.(26) (re-implantation rate of 85.5%), Yeung et al.(40) (re-implantation rate of 95.2%), and Trozzi et al.(31) (re-implantation rate of 85%). The reason for this low rate in re- implantation in our center was due the higher rate of revision cases from cochlear® devices in which re-implantation was not part of their

policy in management of revision cases in contrast to cases from MED-EL in which all cases implanted by their devices had re- implantation on the same session (which forms 72.2% of all re-implantation cases in our study)

CONCLUSION

With the obvious increment in cochlear implantation ratio, revision surgeries became a fundamental and essential part in the cochlear implant programs worldwide. Revision ratio in our center was found to be within the lower limits of universal revision rates. Increment of surgical experience and training resulted in obvious decrement in the non-device related causes for revision surgeries. Re-implantation rates were determined by the contracts and financial limitations which resulted in lower rates compared with other centers. Precise recording system leads to more informative data about the surgical steps, difficulties of the primary and revision operations and audiological outcomes which facilitate future surgical planning and researches. Revision cochlear implant surgery can be regarded as a safe procedure with a low rate of surgical complications

RECOMMENDATIONS

1. Informing the parents and caregivers about the probability of revision surgeries both for device-related and non-device related causes.
2. Arrangement of well-organized database record system for all cochlear implant surgeries for facilitation of future research.
3. Emphasis on manufacturing companies to inform the implantation center and the surgeons with documented feed-back for all explanted devices.
4. Further study regarding audiological outcomes in future researches is recommended.

5. Sending the junior surgeons for training on cochlear implantation surgery as part of the development in the project in the country.

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