



International Journal of Surgery Science

E-ISSN: 2616-3470

P-ISSN: 2616-3462

© Surgery Science

www.surgeryscience.com

2020; 4(2): 571-575

Received: 25-02-2020

Accepted: 29-03-2020

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Causes and frequency of cochlear explantation

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DOI: <https://doi.org/10.33545/surgery.2020.v4.i2f.446>

Abstract

Background: The cochlear implant (CI) is unique among medical devices in that it serves as a neurosensory prosthesis capable of restoring or providing de novo the sense of hearing to its users. Causes of cochlear device explantation are divided primarily into device failures and medical failures.

Study design: Retrospective and prospective analysis.

Objective: determine the causes and the frequency of device and medical failure.

Patients and Methods: The study involve 17 patients who had cochlear explantation from total implantation 766 patients in the department of otolaryngology in AL-Yarmouk teaching hospital during period from April 2008 to March 2018, and the data was collected from operative notes that is documented in patients files.

Results: A total of 766 implants were performed from April 2008 to March 2018, with 17 devices explanted, the implanted devices were 45.8% Cochlear nucleus devices, and 27.5% were MED-EL devices and 26.6%. Where Advance bionics. The overall failure rate was 17 of 766 (2.22%) of which 13 (76.47%) due to medical failures and 4 (23.5%) due to device failures. Patients with cochlear nucleus devices underwent 9 explants (2.56% failure rate) of which 8 (88.9%) was medical failures and 1(11.1%) was device failures. Patients with MED-EL underwent 3 explants (1.42% failure rate), which all of them was due to device failures Patients with advance bionics underwent 5 explants (2.45% failure rate) all of them was medical failure. Medical failures included wound infection with wound breakdown, wound infection with flap necrosis, hematoma, cholesteatoma and biofilm. Device failure include hard failure and soft failure. Over all the average time to explantation was 559days (range, 10-3468 days).

Conclusion: Overall, cochlear explantation rate is low. The medical causes was more common and more with cochlear nucleus device type. the device failure rate was more common with MED-EL device type.

Keywords: Cochlear explant, wound dehiscence, device failure

Introduction

The cochlear implant (CI) is unique among medical devices in that it serves as a neurosensory prosthesis capable of restoring or providing de novo the sense of hearing to its users ^[1].

The indications for explanting the cochlear implant device are divided primarily into device failures and medical failures. Device failures can further be divided into “hard” and “soft” failures

A hard failure is a lack of communication between the internal and external hardware, resulting in no sound perception. Testing can be done to diagnose a hard failure. Soft failures are more difficult to determine, as they often have vague presentations, such as tinnitus, facial nerve stimulation, pain, or vertigo. Soft failures cannot always be detected on routine testing of the hardware because both the internal and external hardware are functioning properly. A consensus statement was issued in 2005 to define a soft failure as the following: exclusion of hardware- or software related causes of performance deterioration, exclusion of medical problems that results in implant failure, radiographic evidence of proper implant and electrode placement, and return of function with subsequent reimplantation. Medical failures generally include infection and wound dehiscence. Implant failure rates in the past have been estimated as low as 1.5% to as high as 15% ^[2].

Candidacy criteria for cochlear implantation ^[3].

According to FAD-approved guidelines for cochlear implantation, Current adult Selection criteria in the most recent clinical trials include: 1) severe or profound hearing loss with a pure-tone average (PTA) of 70 dB or greater hearing level (HL), 2) use of appropriately fitted hearing aids or a trial with amplification for at least 1 to 3 months. 3) aided scores on open-set sentence

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tests of less than 50%, 4) no evidence of central auditory lesions or lack of an auditory nerve, and 5) no evidence of contraindications for surgery in general or cochlear implantation surgery in particular.

Current pediatric selection criteria in the most recent clinical trials include: 1) Age 12 months through 17 years; 2) profound SNHL (unaided PTA thresholds of ≥ 90 dB HL); 3) minimal benefit from hearing aids, defined as less than 20% to 30% on single-syllable word tests, or for younger children, lack of developmentally appropriate auditory milestones measured using parent-reported scales; for at least 3 to 6 months of hearing aid use. 4) no evidence of central auditory lesions or lack of an auditory nerve; and 5) no evidence of contraindications for surgery in general or CI surgery in particular the rates of revision surgery are higher in children, nearly twice that of adults. The exact reasons for the higher rates are unclear, but possible explanations include increased incidence of head trauma and increased likelihood of infection in the younger age group [4].

Device Failure

A device with characteristics outside the manufacturers specification resulting in a loss of clinical benefit [5].

Device failures are categorized as "hard" or "soft," among which the former are more common and account for most revision surgeries. A hard failure occurs when there is a complete interruption of auditory input and confirmed malfunction of a component of the cochlear implant device, preventing communication between the internal and external components.

Hard failures may be heralded by a sudden failure or an abnormal sound and no link to the processor. A soft failure is less well defined, but is often indicative of pending hardware failure and may be regarded as a "prefailure" condition. Soft failures may not always be evident from *in-vivo* integrity testing. Symptoms of soft failure may be subtle and include decreased performance and speech perception, poor performance relative to expectations based on preimplantation characteristics, aversive stimuli causing subjective discomfort or pain especially at low stimulation levels, and static and hearing while the device is off from an unclear but repeatedly observed mechanism. When deterioration in performance is observed, it is a significant risk factor for a soft failure.

Despite the absence of telltale signs from *in-vivo* integrity testing, a detectable hardware defect is revealed in 38 to 86% of ex-planted devices with suspected soft failure [4].

Medical-Surgical Reasons [4].

Other reasons for revision surgery include medical-surgical indications such as breakdown of the scalp flap, infection, middle ear pathology including cholesteatoma, silicone-mediated allergic reactions, device exposure, electrode migration, poor initial electrode placement, trauma, or receiver/stimulator migration

Patients and Methods

Study design: Retrospective and prospective studies

Setting: Department of otolaryngology in AL-YARMOUK Teaching Hospital.

Patient's selection: The study involve 17 patients who all had cochlear explantation from total implantation 766 patients in AL-YARMOUK Teaching Hospital during period from April 2008 to march 2018, and the data was collected from operative notes that is documented in patients files.

Inclusion Criteria

- All age groups who received unilateral cochlear implantations and explantation done in Al- Yarmouk hospital.
- All patients with successful cochlear implantation

Exclusion Criteria

- Implantation done outside Al Yarmouk hospital
- explantation done outside in Al- Yarmouk hospital

The patients were submitted to

1. Full history covering post auricular discharge, pain, extrusion of implant, deterioration of hearing, aversive sound, vertigo, tinnitus, facial twitching, ear discharge, meningitis and trauma.
2. General physical examination: including general health of the patient.
3. Otolaryngological examination: thorough examination of the wound site (redness, tenderness, implant extrusion, discharge, swelling and fluctuation over the implant) and otoscopic ear examination for tympanic membrane retraction, perforation, discharge, and cholesteatoma.
4. Radiological testing: CT scan of the temporal bone.
5. Audiological assessment: Free field audiometry, electrical Auditory brainstem response audiometry and electrical stapedial reflex audiometry
6. Company assessment
7. Other investigations: blood test, ECG and chest X-ray to prepare the patients for general anesthesia.

Four Patients with wound infection and dehiscence or flap necrosis with implant extrusion firstly admitted, then treated conservatively with wound care and IV antibiotic, ceftriaxone 50mg /kg/day for 10 days. The decision of explantation was done after failure of medical treatment.

The decision to do implant on ipsilateral side whenever it is possible, to preserve the opposite ear. The choice to reimplant on the contralateral side was justified by an active skin infection or suspicious of an extensive cochlear ossification.

patient presented with chronic offensive ear discharge in ipsilateral implanted ear, on examination and suction clearance we found electrode migrated into external auditory canal and obvious cholesteatoma, CT scan imaging done and the decision was explantation with radical mastoidectomy.

Another four patients presented with swelling, fluctuation over the implant site, frequent aspiration showing dark fluid collection (which send for culture and sensitivity and the result was negative) the patients were admitted to hospital, frequent aspiration of fluid was done with pressure dressing and antibiotic cover (IV ceftriaxon 50mg/kg /day), after complete audiological and medical assessment, the decision was to remove the cochlear implant

Family awareness of hearing deterioration or sudden loss of hearing, on examination the implanted site there is nothing significant, The audiologist checking the user's external equipment, troubleshooting with new pieces of the external components and also reprogramming was done but no improvement occurred. CT scan be done to check that the electrode array is in correct position. After all that approaches, we don't determine the causes of failure, the manufacturer's integrity testing assesses the functionality of the internal device done (impedance field telemetry and auditory nerve response telemetry) by device manufacturer's clinical application specialist and diagnosed its as device failure (hard or soft

failure).so the decision was explantation and re-implantation at same time

One patient who is known cases of haemophilia A. cochlear implantation was done for him after haematological consultation and management. On the day one postoperatively, haematoma developed at site of operation. frequent aspiration was done under an aseptic technique and antibiotic cover, but recollection occurred, so the decision of haematologist and surgeon was to remove the implant.

Results

1. Implantation and explantation rate for each C.I company

The higher implantation rate and explantation rate with cochlear device type.

Table 1: Total number of implantation and explantation according to device type

Device types	Total implantation No (%)	Explantation No (%)
Cochlear nucleus	351(45.8%)	9(2.56%)
MED-EL	211(27.5%)	3(1.42%)
Advance Bionics	204 (26.6%)	5 (2.45%)
	766 (100%)	17 (2.22%)

2. Causes of explantation

There are two major causes of explantation medical and device

failure.

Table 2: Causes of explantation in general

Causes of explantation	NO	%
Device failure	4	23.5
Medical failure	13	76.47
Total	17	100

In current study, the most common type of failure is medical failure. Specifically wound infection with wound breakdown and biofilm in equal frequency (23.5%)

Table 3: Causes of Failure

Failure	Causes	No	%
1. Medical failure	Wound infection & breakdown	4	23.5
	Wound infection & flap necrosis	3	17.6
	hematoma	1	5.9
	Cholesteatoma	1	5.9
	biofilm	4	23.5
2. Device failure	Hard failure	3	17.6
	Soft failure	1	5.9%

3. Causes of explantation for each company:

The higher percentage with cochlear type and most common causes wound infection and wound breakdown (44.5%)

Table 4: Causes of explantation according to device type.

Causes of explantation	Total		MED-EL		Cochlear nucleus		Advance Bionics	
	No	%	No	%	No	%	No	%
Wound Infection & break down	4	23.5	-	-	4	44.5	0	0
Wound infection & flap necrosis	3	17.6	-	-	2	22.2	1	20.0
Haematoma	1	5.9	-	-	-	-	1	20.0
Cholesteatoma	1	5.9	-	-	-	-	1	20.0
Biofilm	4	23.5	-	-	2	22.2	2	40.0
Device failure	4	23.5	3	100	1	11.1	-	-
Total	17	-	3	-	9	-	5	-

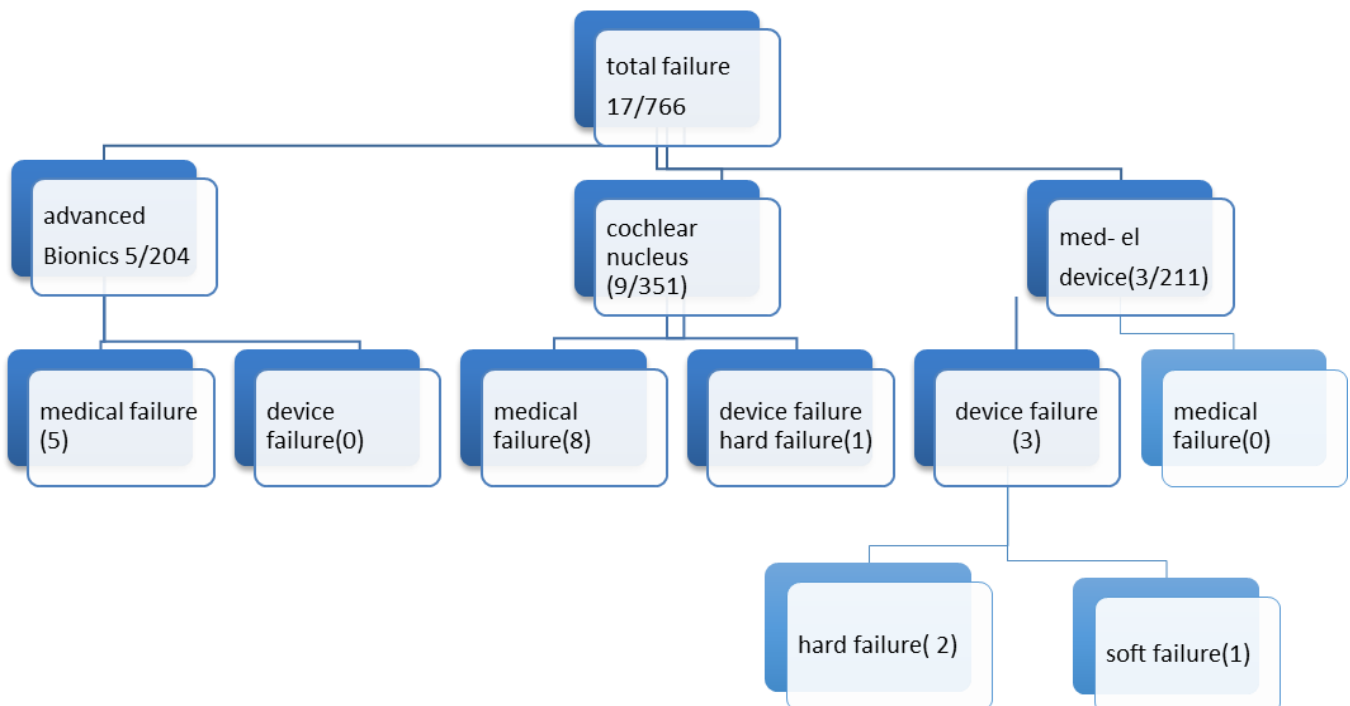


Fig 1: Causes of cochlear implant failures for each device type.

Discussion

Management of implant failures and performance of explantation surgery are becoming increasingly important in cochlear implant programs. When considering cochlear explantation, Diagnostic criteria for device failure and criteria for explantation must be ascertained. The current study found overall failure rate was (17/766) 2.22%. The failure rate in cochlear nucleus (9/351) 2.56%, which higher than the failure rate in advance bionics (5/204) 2.45, which is also higher than failure in MED-EL (3/211) 1.42%. In our study medical causes of failure were 76.47%, which is higher than device failure rate (23.5%). Although it is difficult to compare the failure rates between many studies because some consider any revision surgery is a failure, while other consider only implants that must be explanted are a failure and others consider only hard device failures as true failures. Roby BB. *et al.* (2012) [2] found over all failure rate was 15%, with medical failure rate 6%, device failure rate 9%, and The overall failure rate of Advanced Bionics (16.7%) was higher than the overall failure rate of Cochlear Nucleus devices (11%). That disagree with our study result. Wang J T *et al.* (2014) [6]: found over all revision rate 8.3%, from that reimplantation rate 85.5% and explantation without reimplantation rate 4.3%, that close to our study. But report device failure rate 57.8% and non device failure 42.1% That disagree with our study result. Sunde J *et al.* (2013) [7] report: cochlear explanation rate 6.21% (pediatric 4.95%, adult 1.26%) which is close to our study rate. Migirov *et al.* (2007) [8]: report: the cochlear explantation rate 8.1% (33/405) which is close to our study. The failure rate higher with advance bionics compared to that of cochlear nucleus and Med-EL that was different from the result of our study. Amaral MSAD *et al.* (2018) (9):4.3% revision surgical rate, that agree with our result

Medical causes of explanation

1- Wound infection & breakdown and flap necrosis: Four patients in this group experienced persisting infections without device exposure, despite of medical treatment and frequent wound debridement. The failure rate was 23.5%. the four cases was cochlear nucleus types which represent (44.5%) of Cochlear nucleus company failure. Three patients experience persistent infection with device exposure or extrusion. The failure rate was 17.6%. Two of them belong to cochlear nucleus with (22.2%) of cochlear failure rate and one of them belong to Advance bionics type (20.0%) of its company failure rate. Roby BB. *et al.* (2012) [2] reported infection with wound dehiscence rate was 35.0% of advance bionics failure rate and 58.0% of cochlear nucleus device failure rate. The result was different to our study. Kim c-s *et al.* (2008) [10] study reported: wound infection rate 6.5%. flap necrosis and/or device extrusion rate 6.5%. That disagree with what found in our study Wang J T *et al.* (2014) [6] report: infection and complication rate 17.0%. that disagree with our study

2-biofilm: Four patients explanted because of painless swelling and fluctuation without sign of infection, over implanted site with recurrent dark fluid collection not respond to antibiotic treatment and multiple aspiration. The failure rate 23.5%, two of them cochlear type (22.2% of this type) and another two was advance bionics type (40.0% of this type). Giorba *et al.* (2012) [11] disagree with our study who: reported one case of 438 (0.2%) of infection due to *Pseudomonas aeruginosa* biofilm which required partial explantation.

3-haematoma:- One patient who is a known cases of haemophilia A developed blood collection over implanted site in the first 24 hours post-surgical implantation, despite frequent

aspiration and medical treatment but didn't resolved and explantation was done. Failure rate (5.9%). The device type was advance bionics and haematoma represent 20.0% of advance bionics failure rate.

Kim c-s *et al.* (2008) [10]: report that haematoma represent 9.6% of revision surgical rate which is close to our study failure rate. 4-cholesteatoma: One patient diagnosed as intratemporal cholesteatoma (5.9%), and the device type was advance bionics Lassig AD *et al.* (2005) [12]: intratemporal pathology rate 3% (two cases cholesteatoma and one cases encephalocele). and Cote *et al.* [13]: intratemporal pathology 6.7%. Both result were close to our study.

Device failure: Four patient presented with over all device failure rate (23.5%), three of The devices was from MED-EL company with failure rate 1.42% and one device belong to Cochlear nucleus with failure rate 11.1% of its company failure rate. Four patients presented with sudden hearing deterioration. They assessed by the surgeon, audiologist and seen by device manufacture specialist, no improvement was found. After device removal, the device manufacture confirmed upon examination of explanted device that there is failure with the device (hard failure rate 17.6% and soft failure rate 5.9%). Roby BB. *et al.* (2012) [2] reported: device failure rate 9%. Advance bionics 65% (49% hard failure and 16% soft failure) and MED-EL 42% (31% hard failure and 11% soft failure). That disagree with our study. Sorrentino *et al.* (2009) [14] found total device failure rate 2.26% (hard failure 1.44% and soft failure 0.82%). MED-EL failure was 0%. Advance bionics (hard failure 11.8% and soft failure 0%), and cochlear type failure 7.76% (hard failure 4.07% and soft failure 3.69%). That disagree with our result. Wang JT. *et al.* (2014) [6] reported: device failure rate 57.8% (hard failure 47.2%, soft failure 10.6%) that higher than which we found in our study. Sunde j *et al.* (2013) [8]: over all hard failure 0.7% and soft failure 1.1%. Giobra *et al.* (2012) [11] reported over all device failure rate 2.1% which both were lower than our study. Kim c-s *et al.* (2008) [10] reported: over all device failure rate 38.7%, with advance bionics 2.6%. MED-EL failure rate 2.2%. Cochlear nuclear failure rate 1.4%. over all failure rate was close with our study, while failure rate for each device type was different Roby BB. *et al.* (2012) [2] reported average duration of explantation for hard failure 4.5 months and for soft failure 4.2 months while our study reported actual duration of explantation for device failure (6 months-1 years) in 11.76% of explanted patients. and between (1-2) years in an others 11.76% explanted patients.

Conclusion

1. Overall, cochlear explantation rates is low (2.22%)
2. The medical causes were more common and more with cochlear nucleus device type. Which includes wound infection with breakdown, wound infection with flap necrosis, hematoma, cholesteatoma and biofilm
3. the device failure rate was more common with MED-EL device type

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