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Original Article

Cochlear Implant Device Failure in the Postoperative Period: An Institutional Analysis

Simple Ravikumar Bhadania, Rajesh Vishwakarma[1], Amit Keshri

Department of Neurosurgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh, [1]Department of ENT and Head and Neck Surgery, BJ Medical College, Ahmedabad, Gujarat, India

Abstract

Introduction: As the cochlear implant (CI) surgeries are on rise, there is a compelling need to understand its long-term complications and revision surgery protocols. Our experience in the management of CI devices failure is shared in this paper. **Aim:** To review the experience in patients who underwent CI device manipulation/explanation in terms of failure rate, etiology, surgical considerations, and preoperative and postoperative auditory and speech outcome. **Study Design:** This was a retrospective study. **Materials and Methods:** A retrospective study of 250 patients (201 children and 49 adults) with normal cochlea at a tertiary care center from June 2004 to June 2014 was done. All cases were implanted multichannel devices via Veria technique of CI surgery. Preoperative assessment, surgical considerations, and postoperative auditory and speech outcomes were analyzed. Preoperative and postoperative auditory/speech outcomes were analyzed using Category of Auditory Perception (CAP) and Speech Intelligibility Rating (SIR) scores. **Results:** Reimplantation rate was 4%. The causes of revision CI surgery were hard device failure (n = 3), surgical site infection (n = 3), magnet displacement (n = 2), and electrode extrusion (n = 2). In one patient, recurrent cutaneous infection on the implanted site ultimately resulted in reimplantation in the opposite ear after multiple surgical interventions on the same side. The preoperative and postoperative CAP and SIR scores showed improvement in the postoperative period with $P < 0.05$ as compared with the paired t-test. **Conclusions:** Preoperative counseling for device failure should always be emphasized. The success rate is high in revision surgery with good performance in the postoperative audiological outcome. There is a compelling need for an agreed international definition of CI failure and the adoption of uniform reporting protocols.

Keywords: *Category of Auditory Perception score, cochlear implant device failure, reimplantation protocol, Speech Intelligibility Rating score, surgical considerations*

Introduction

Cochlear implant (CI) is one of the most successful implants in history. The cost-effectiveness of CI in a developing child is well established in the literature.[1] However, any implanted device is prone to a considerable risk of failure. Literature review suggests that the overall reimplantation rate ranges from 5% to 10%.[2] The first report of revision CI (RCI) surgery dates back to 1985 by Hochmair-Desoyer.[3]

Device failure in the postoperative period can either be a hard or be a soft device failure. Hard device failure means that there is a complete loss of connection between the external and internal device and the device has failed in its integrity testing. Soft device failure is more of a warning when there is deterioration in patient's auditory performance or any new associated symptom with the use of implant.

The main reasons for hard device failure are either related to electrode array or receiver-stimulator. Any trauma in the postoperative period can lead to cracks in the silicon casing, circuit failure, coil damage, and many more unknown causes.[4]

The other major reasons for the reimplantation surgery are wound infection, scalp necrosis, and device upgradation. With the recent improvement in technology, we can predict that device upgradation will be the most important reason in reimplantation surgery in the near future. The varied etiology of device failure, intraoperative surgical issues, pre and post-operative audiological outcomes, and complications are discussed in this study.

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Address for correspondence:
Dr. Simple Ravikumar Bhadania, MRA 85, Sanjay Gandhi Post Graduate Institute Campus, Sanjay Gandhi Post Graduate Institute, Rai-Bareilly Highway, Lucknow - 226 014, Uttar Pradesh, India.
E-mail: simplepatadia@gmail.com

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Materials and Methods

This is a retrospective study of 250 cases with normal cochlear anatomy that underwent CI surgery at our tertiary care center from June 2004 to June 2014. Of 250 cases, 201 cases were children and the rest 49 were adults. Informed consent was obtained before the surgery. The minimum follow-up was 9 months, and many cases are still in the follow-up period. All cases were implanted with multichannel implant devices (MedEl, Cochlear, Advanced Bionics) and underwent surgery via Veria technique. The pre- and post-operative audiological outcomes were compared using Category of Auditory Perception (CAP) and Speech Intelligibility Rating (SIR) scores. Both the pre- and post-operative audiological outcomes were assessed using paired *t*-test.

Only those cases which required any form of surgical intervention were included in this study. The reimplantation surgery protocol for assessing the patient as a candidate is as shown in Figure 1. The explanted device/device parts were sent to the manufacturer for detailed analysis.

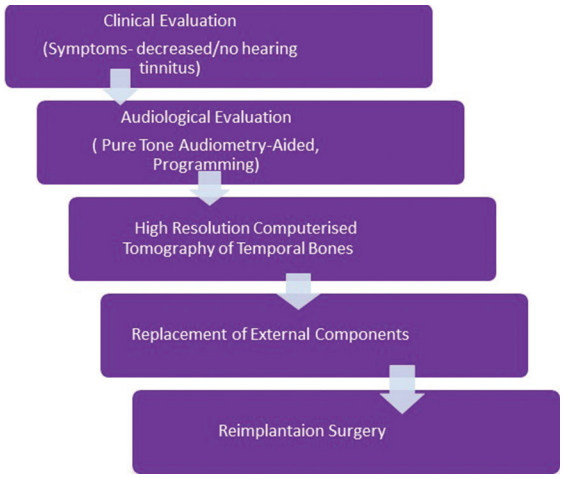

Figure 1: Reimplantation protocol

Results

The reimplantation rate at our center was 4% (10 out of 250 cases). Three patients had soft device failure in the postoperative period, for which they are kept under observation and the relatives were counseled for the same. The main symptoms of the patient who developed soft device failure were tinnitus (n = 1), decrease in hearing (n = 1), and facial twitching (n = 1). The main reasons for hard device failure were trauma while playing (n = 2) and sudden device failure in one case. The other reasons which lead to device failure were postoperative infection (n = 3), magnet displacement (n = 2), and electrode extrusion (n = 2) [Figure 2].

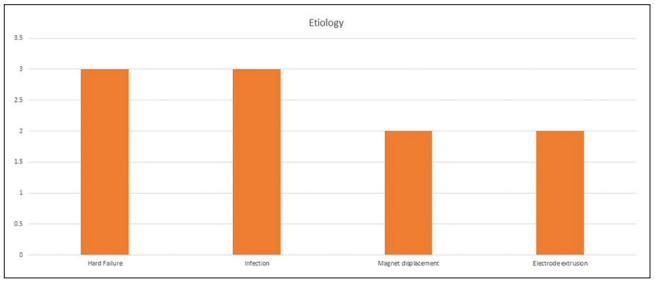

Figure 2: Bar chart showing the etiology of cochlear implant failure in our series

The intraoperative surgical concerns during a reimplantation surgery are as described below.

Incision site

Endaural incision extending till the squamous part of temporal bone [Figure 3] is the incision site (as used in previous surgery).

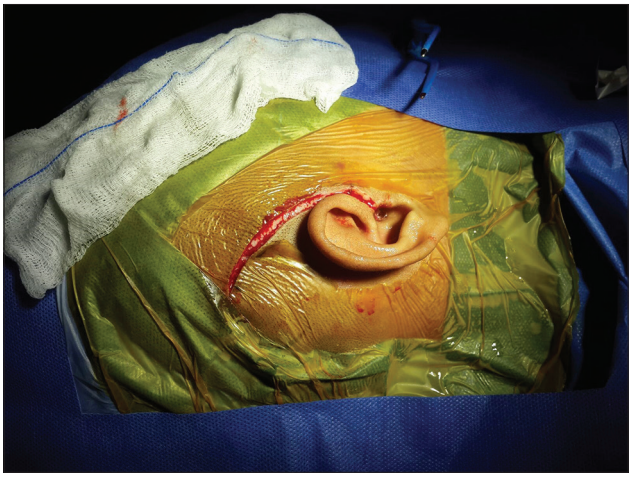

Figure 3: Incision site is same in reimplantation surgery as in Veria technique

Subcutaneous tissue and temporalis fascia elevation

There was a presence of fibrosis as in any revision surgery [Figure 4]. The flap was elevated in two layers as in primary surgery. Monopolar cautery was not used in the surgery.

Implant bed

The implant was secured in prolene sutures as in primary surgery. In 2 cases with post-operative infection at scar site, there was presence of granulation and biofilm formation surrounding the receiver stimulator and implant bed.

Ground electrode

The ground electrode – which was previously secured in the tunnel made under temporalis fascia – was intact in all cases. There was no evidence of electrode migration [Figure 5].

Tympanomeatal flap elevation

Some fibrosis was seen in tympanomeatal flap, more in the region of fibrous annulus. However, there was no perforation in the tympanic membrane in patient.

Mastoidectomy site

There was a neoosteogenesis at mastoidectomy site [Figure 4].

Electrode insertion

All electrodes were completely inserted in cochleostomy site except two. The extra electrode array in the mastoidectomy site was not stretched or displaced. All electrodes were surrounded by a thin film of mucosa, which was not touched. The removed implant was thoroughly washed in normal saline, sealed, and sent back to the company. There was a complete insertion of electrodes from the same cochleostomy site in all cases. Cochleostomy site was secured with the help of temporalis fascia as in primary surgery.

Magnet displacement

Two patients who had displacement of magnet in the postoperative period detected by X ray Skull [Figure 5] managed by magnet removal and new magnet insertion by a small incision posterior to receiver-stimulator site [Figure 6].

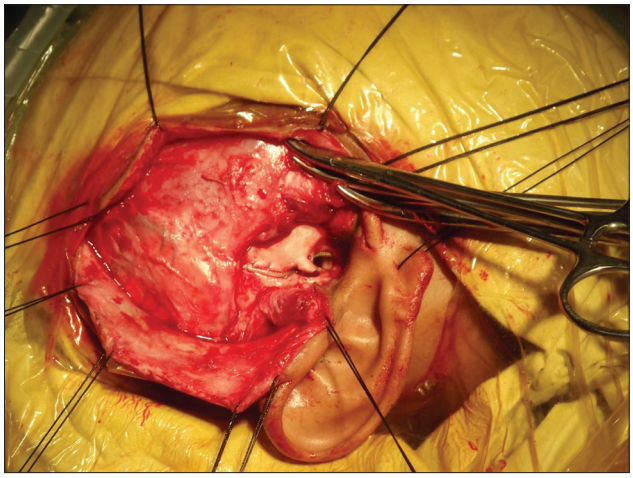

Figure 4: Fibrosis surrounding the previous implanted electrode along with neoosteogenesis

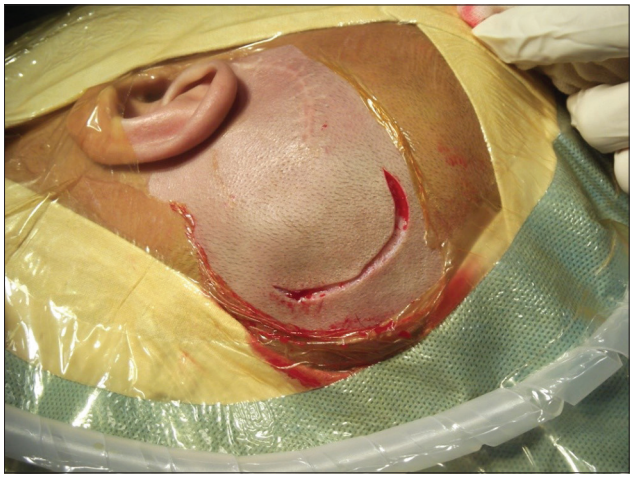

Figure 6: Incision for removal of magnet

The preoperative and postoperative audiological outcomes at 1 year were analyzed using Student's *t*-test [Figures 7 and 8].

Discussion

CI device needs to be revised either by its removal or repositioning, due to medical reasons or device failure. The factors leading to RCI surgery are described below:

Device failure

Hard device failure means that there is complete loss of connection between the external and internal device and the device has failed in its integrity testing. Hard failure is the most common reason for undertaking revision surgery, and this mode of failure is frequently associated with preceding head trauma.

Two of our patients had trauma in the postoperative period [Figures 9 and 10], which leads to sudden hard failure. Trauma can lead to circuit failure, case leaks, loss of hermeticity seals, coil damage, or even electrode array damage. Still, there are many unknown reasons reported in the literature.[2,4]

Postoperative infection

The major etiopathogenesis of any infection surrounding the implant is because of biofilm production.

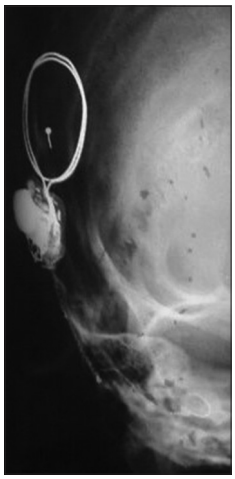

Figure 5: X-ray of the skull lateral view showing displacement of magnet from its silicon socket inferiorly

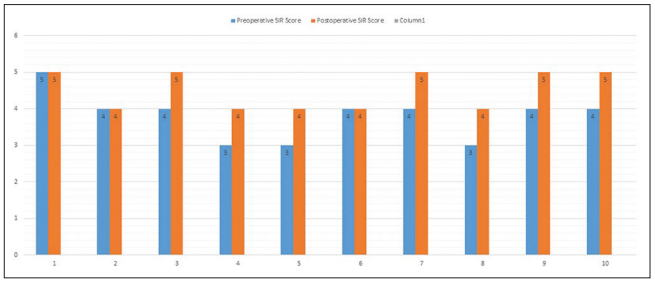

Figure 7: Preoperative and postoperative bar graph showing improvement in Category of Auditory Perception score at 1 year

Implant – being a foreign material the body – cannot develop microcirculation surrounding the implant; hence, antibiotics are unable to reach it. Any source of infection surrounding the foreign material will multiply, adhere to the implant surface, and later on produce exopolysaccharide (glycocalyx) which leads to biofilm production. The body also forms a foreign body granulation reaction surrounding this implant which hampers recovery from infection.[5,6]

One of our patients had late onset of infection [Figure 11] which presented as extrusion of receiver-stimulator at 6 months of the postoperative period. She was started on broad-spectrum antibiotics and local dressing, but there were no signs of improvement. With the aim of saving the implant, the implant bed was made superior in the parietal bone, previous to the present site, and the extrusion site was excised and closed with a rotation flap. This patient again developed an extrusion after 2 months, and finally, she underwent explantation. After proper counseling and consent, the patient was reimplanted on the opposite side which is working well till date.

Magnet displacement

The major reasons for magnet displacement were as follows.

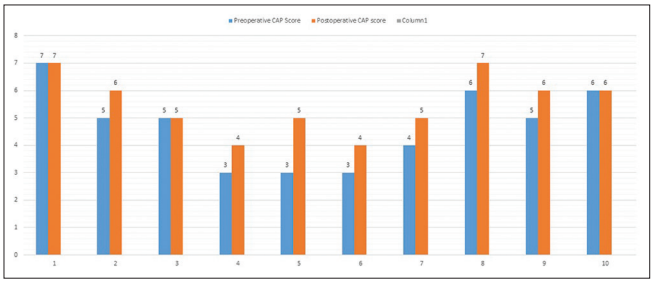

Figure 8: Preoperative and postoperative bar graph showing improvement in Speech Intelligibility Rating score at 1 year

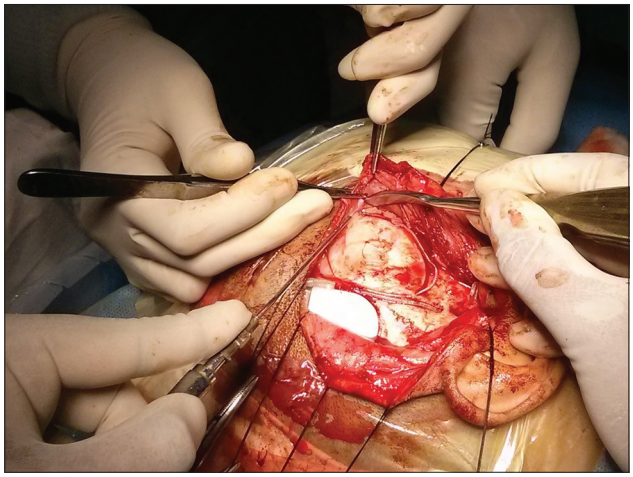

Figure 10: Removal of receiver stimulator in a case of posttraumatic cochlear implant device failure. Also note the ground electrode is still in position

Trauma

Because of their hyperactive behavior, children are more prone to trauma than adults. As the skull of a child develops, the magnet is placed at a greater angle which is more prone to even trivial trauma.[7] This was also the cause in our patients.

Improper placement of external magnets

The maximum torque of any magnet to induce a magnetic momentum occurs at its poles. Hence, if external magnet is not placed recurrently in its proper position, it might remove the internal magnet from its silicon cover and either flip or displace it.

Removable magnets

To felicitate magnetic resonance imaging in the postoperative period, magnet is kept in silicon casing which can be displaced due to trauma or either improper placement.[7]

Electrode extrusion

In literature, electrode has been found to be in eustachian tube, mastoid, middle ear, vestibular aqueduct, carotid

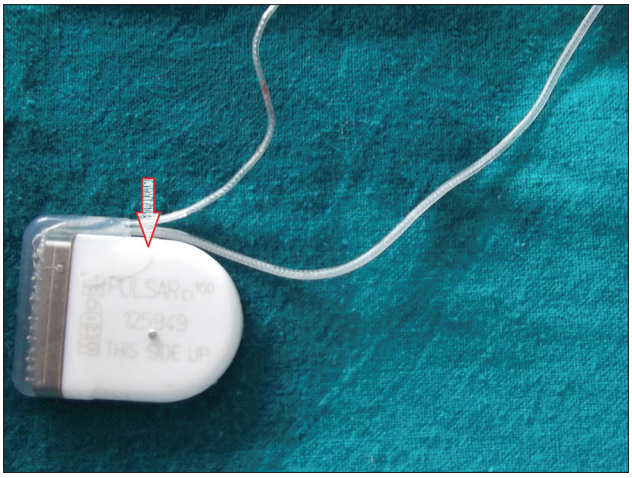

Figure 9: Fracture line on the receiver stimulator

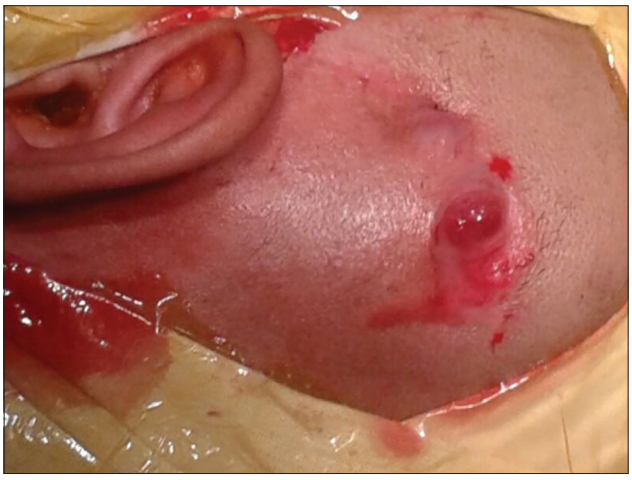

Figure 11: Extensive granulations and inflammated soft tissue surrounding implant in a case of infection

canal, and interscalar septa.[8] The cause of electrode extrusions is usually unknown, possibly occurring with skull growth or possibly from forces from the CI itself.[9] We had a referred case with the postoperative incomplete insertion and the presence of active electrodes in the middle ear and mastoid cavity. This patient was reexplored in the same manner, and the electrodes were completely inserted. The cochleostomy site was secured with the help of temporalis fascia. There was no evidence of device migration from its pocket in our series.

The most common reason for reimplantation surgery as documented in the literature is hard device failure as seen in our series too. In a developing nation such as India, reimplantation surgery does not only have a financial burden to parents but also have a deep social and mental health impact.

In 2005, the European Consensus Statement on CI Failures and Explantation[10] gave a very important landmark paper for diagnosis and treatment of a patient with suspected soft device failure. However, there is still no international surveillance team for CI failure which can guide in its management. We propose that all data of CI failure should be reported to an international surveillance team which will help improve technology and also guide surgeons about the real cost-effectiveness of CI in developing countries.

Conclusions

Implant failure is a major complication in the postoperative period, and all guardians/patients should be properly counseled for the same. There should be awareness among audiologist and guardians for immediate notification of any regression in the performance of the patient and should be dealt with an emergency. Electrodes have to be given special importance in revision surgery. There is a high success rate in revision surgery with good performance in postoperative audiological outcome. There is a compelling need for agreed international definitions of failure and for the adoption of uniform reporting protocols.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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