Skin Flap Complications in Patients Undergoing Cochlear Implantations

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ABSTRACT

Objective: To carry out a retrospective analysis of demographic information and complications related to the skin flap in patients who underwent cochlear implantation.

Patients and Methods: We performed a retrospective analysis of 840 patients who underwent cochlear implantation at King Hussein medical centre during the period between March 2010 and November 2020.The patients were reviewed for demographic information and complications related to the skin flap over the implanted device.

Results: In total, 380 (45.2%) patients were male and 460 (54.8%) were female. The age of patients at time of surgery ranged between 7 months and 68 years and the mean age was 4.64±2.91 years. The majority of patients underwent unilateral cochlear implantation (837 patients), with only three patients receiving a bilateral implant. There were a total of 19 implanted patients who developed complications related to the skin flap around the implanted device, with an incidence rate of 2.3%. Hematoma was the most commonly encountered complication and other complications were: seroma, wound infection, abscess formation and flap necrosis.

Conclusion: Cochlear implantation is considered to be a reliable and safe surgical procedure for rehabilitation of deaf patients. In the hands of an experienced surgeon the rate of complications is low and the majority of these complications can be conservatively managed.

Key words: cochlear implantation, skin flap, complications.

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INTRODUCTION

Cochlear implantation is considered to be one of the great achievements of modern medicine, restoring the function of hearing for both children and adults with severe to profound sensorineural hearing loss who receive limited benefit from conventional hearing aids [1].

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The cochlear implant is a small electronic device designed to directly stimulate the auditory nerve through an array of electrodes and to translate acoustic signal into electric stimulation [2].
It is important that the stimulation threshold is set accurately and the implant is set at comfortable levels to enable better functioning of the device to provide these patients with a greater access to sound and improvement in their auditory abilities, understanding of speech, and linguistic development [3].
The surgical technique used varies, but the classic procedure involves mastoidectomy with the creation of separate skin and soft tissue flaps over the mastoidectomy site and a soft tissue envelope surrounding the receiver of the implant, posterior tympanotomy, cochleostomy, or round window approach and insertion of an array of electrodes through the basal turn of the cochlea.
Since cochlear implantation is considered a life-time implanted device and is covered by the overlying skin and soft tissues, which are all tightly adherent to the underlying bone of the skull, the operation has a unique set of complications. These complications are associated with either the complexity of the operation or implantation of a deeply-placed foreign body on the scalp, or device failure [4].
The complications can be classified as an immediate or delayed according to their timing, or they can be considered minor or major according to their severity. Knowledge of the risks associated with this procedure is important [4].
Skin flap complications post-cochlear implantations are considered to be rare and treatable [5]. The management varies from conservative treatment to device explantation.
In this study, we focused on the complications that are related to the skin flap over the implanted device.

PATIENTS AND METHODS

We performed a retrospective analysis of 840 patients who underwent cochlear implantation at King Hussein medical centre during the period between March 2010 and November 2020.
All patients were diagnosed with bilateral severe to profound sensorineural hearing loss by detailed history taking in addition to complete Ear, Nose, Throat and neurological examination.
Audiological tests included pure tone audiometry with tone decay, aided audiometry, auditory brainstem response (ABR) test, otoacoustic emission and speech discrimination test. Pre-operative radiological evaluation by the mean of computed tomography scan (CT) and magnetic resonance imaging (MRI) of temporal bone and brain were performed in all patients.
Majority of implantations were performed on one side. All operative procedures were performed by one of the cochlear implant surgeons, who are well trained to perform such procedures using a standardised surgical technique.

Over the years, there have been some changes to the soft-tissue approach of the procedure, which has been influenced by technological advancements in implant receivers. Initially, when we started the cochlear implant program in 2002, we used an extended post-auricular S-shaped skin incision and we placed the receiver-stimulator of the implant in the bony bed, which is later appropriately fixed using sutures on both sides of the bony bed. Later, since 2008, a minimal C-shaped retroauricular skin incision and flap approach with a tight subperiosteal pocket was used; this approach is used to date. The wound was closed in three sutured layers followed by a compressive mastoid dressing, which was placed and maintained for one week.

All patients in this study underwent a minimal C-shaped retroauricular skin incision.
After surgery, patients were kept in the hospital for 48 hours. X-ray imaging was routinely performed to verify the position of the electrode array of the device. A prophylactic broad-spectrum antibiotic

that can cross the blood-brain barrier was provided intravenously during the hospital stay, the compressive mastoid dressing was changed, and the patient was discharged home with oral antibiotics. On the tenth postoperative day, the wound was assessed for any complications and the sutures were removed.
Patients were seen at the outpatient clinic 4 weeks after surgery for the first activation of the implanted device.
The patients were reviewed for demographic information and complications related to the skin flap over the implanted device.
Data analysis was performed using relative frequency distribution.

RESULTS

The records of 840 patients who were implanted at our centre during the period between March 2010 and November 2020 were reviewed. We followed up all patients for at least one year after cochlear implantation.
In total, 380 patients (45.2%) were male and 460 patients (54.8%) were female. The age of patients at the time of surgery ranged between 7 months and 68 years and the mean age of the patients was 4.64±2.91 years.
The youngest age at time of implantation was 7 months, with only four children being implanted when under one year old. Overall, 612 (72.8%) patients were below 6 years of age.
All patients had bilateral severe to profound sensorineural hearing loss; 720 patients had prelingual hearing loss (85.7%), while 120 patients had postlingual hearing loss (14.3%).
The majority of patients underwent unilateral cochlear implantation (837 patients), with only three patients receiving bilateral implants.

Overall, 805 cases received implantation on the right side (95.8%), while 32 cases had implantation on the left side (3.8%) and three cases on both sides (0.4%).
Regarding the type of device implanted in this study group, the vast majority of implanted devices were MED-EL devices (Med El Corporation, Innsbruck Austria), accounting for 833 (99.2%) of the implantations. Six cases (0.7%) were implanted with Nucleus devices (Cochlear Corp., Australia) and only one case (0.1%) was implanted with an AB device (Advanced Bionics Corporation, USA). (Table I).

Table I Demographic characteristics of patients

Characteristics	Number of Patients	Percentage
Gender		
- Male	380	45.2%
- Female	460	54.8%
Age at implantation		
- below 6 years of age	612	72.8%
- above 6 years of age	228	27.2%
Type of hearing loss		
- prelingual hearing loss	720	85.7%
- postlingual hearing loss	120	14.3%
Site of implantation		
-Right	805	95.8%
-Left	32	3.8%
-Bilateral	3	0.4%

Type of cochlear implant device		
- MED-EL	833	99.2%
- Cochlear	6	0.7%
- Advanced Bionics	1	0.1%

There was a total of 19 implanted patients who developed complications related to the skin flap around the implanted device, with an incidence rate of 2.3% (Table II). The onset of skin flap complications ranged from 2 weeks to 9 years after surgery, with a mean time of 23.4 months.

Table II Skin flap complications around the implanted device

Type of Complication	Number of Patients	Percentage
Wound Infection	3	0.4%
Hematoma	9	1.1%
Seroma	4	0.5%
Abscess formation	2	0.2%
Flap necrosis	1	0.1%

Skin flap complications around the implanted device Wound infection

Wound infection was reported in three cases. They were manifested by swelling and redness of the surgical incision 11 days postoperatively. Patients were admitted to the hospital and treated with intravenous (IV) antibiotics and daily dressing changes; all recovered without any further intervention.

Hematoma

Nine patients presented with postoperative hematoma above the area of the device, which was manifested by post-auricular tender fluctuant swelling. Five patients developed hematoma 2–3 days post-surgery, three patients had hematoma 2 weeks after surgery and one patient developed hematoma 6 months following the operation without any history of direct trauma to the site of the device.

Patients were admitted to the hospital and received IV antibiotics, aspiration of hematoma and local mastoid pressure dressings. Patients were discharged from the hospital when the hematoma was completely resolved; the duration of hospitalisation ranged between 3 and 7 days.

Wound seroma

Seroma was observed in four patients, who developed local painless swelling around the site of the implant years after operation; the swelling was soft and fluctuant without any tenderness. Aspiration revealed a yellowish fluid which was shown by laboratory analysis to be a serous fluid with negative pus cells. Culture of the fluid from all patients revealed no bacterial growth. Patients were treated as outpatients by mean of aspiration under aseptic conditions in addition to pressure dressing and antibiotics, which was effective in all cases.

Abscess formation

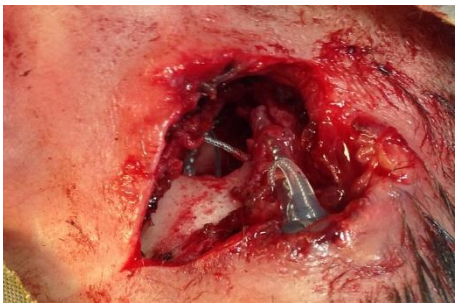
We reported two patients who presented with fever, swelling, redness and tenderness around the implanted device. The treatment protocol for those patients was hospitalisation, puncture and drainage

of purulent fluid and pressure dressing, in addition to systemic antibiotics and symptomatic treatments. The abscess resolved in all patients with this protocol.

Flap necrosis

Flap necrosis occurred in one patient. This patient developed delayed-onset flap necrosis 9 years after cochlear implantation, which required debridement and removal of the device in addition to systemic antibiotics and implantation of a new device 3months later (Figure 1).

Figure 1: Cochlear implant explanation for flap necrosis



DISCUSSION

Cochlear implantation is considered to be a safe and effective procedure for profoundly deaf patients. It has enabled this category of patients to continue communicating with others using speech by providing them with sufficient hearing [6, 7].

With the development of technology and evolution of surgical equipment and techniques, the possible complications of this procedure have progressively declined. Surgical complications are rare in the hands of experienced surgeons, but can still occur [8].

Skin flap complications after cochlear implantation are associated with infection and inflammation of the soft tissue around the internal receiver of the implant. The most frequently reported (non-device-related) complications are flap necrosis, infection, dehiscence and device explantation [9, 10]. In our study, the incidence of flap complications was 2.3%, while rates of complications reported in the literature range from 0.06% to 10% [11–13]. Although this incidence is not considered to be high, management of complications related to the skin flap around the implanted device remains challenging.

Hematoma over the area of the device was the most commonly encountered complication in our study, reported in nine cases (1.1%).This is comparable to the incidence of flap hematoma in the literature, which ranges from 0.4% to 3.7% [14–16]. This complication usually developed one to two days post-surgery. However, we reported a case that developed hematoma 6 months after surgery without any history of trauma. This delayed-onset hematoma was reported by previous studies [11, 17]. We managed this complication using IV antibiotics, aspiration of the hematoma and local mastoid pressure dressings, which is the same protocol advocated by other studies [11, 15–17].

Wound infection is one of the complications that is considered to be a major concern by the cochlear implant team. According to the literature, the rate of wound infection ranges from 1.7% to16.6% [11–13]. In our study, the overall rate of skin flap infection was 0.4%. All patients were managed successfully with IV antibiotics and daily wound dressing.

In our data, seroma was observed in four patients, who developed local painless swelling around the site of the implants years after operation, which was soft and fluctuant without any tenderness. The

mechanisms leading to seroma formation remain unclear. Some studies reported that the silicone rubber of the implanted device results in delayed allergy reactions, which leads to seroma formation [18]. All cases were treated as outpatients by mean of aspiration under aseptic conditions in addition to pressure dressing and antibiotics, which was effective in all cases. Several studies have reported a low incidence of delayed seroma in both children and adults, years after cochlear implantation [16, 19].
In two patients, abscesses around the implanted device developed, which manifested by fever, swelling, redness and tenderness. All abscesses were resolved by drainage in addition to pressure dressing and systemic antibiotics.
We reported one case that developed delayed-onset flap necrosis 9years after cochlear implantation, which required debridement and explantation of the device in addition to systemic antibiotics and later reimplantation. Several studies reported the treatment of skin flap necrosis by debridement of necrotic tissue and skin rotation flaps with device removal [20, 21].

CONCLUSION

Cochlear implantation is considered to be a reliable and safe surgical procedure for rehabilitation of deaf patients. In the hands of an experienced surgeon, the rate of complications is low and the majority of these complications can be conservatively managed.

RECOMMENDATIONS

Complications can be avoided by proper patient preparation, appropriate incision and flap design, rigorous surgical techniques, and periodic postoperative follow-up to detect and manage any complications early.

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