Case Report

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Biofilm in cochlear implantation: our experience

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ABSTRACT

Bacterial biofilm formation on cochlear implant leads to intractable infections. Though rare, it is one of the most dreaded complications which leads to explantation in most of the cases. 400 consecutive cases of cochlear implantation done at tertiary care center over a period of 7 years included. Treatment protocol followed in Biofilm and results are discussed in our case report. Two cases of biofilm where one implant could be successfully salvaged whereas other needed explantation of the implant. There is no universally accepted standardized treatment for this complication. Salvage surgery can be attempted before explantation.

Keywords: Biofilm, Cochlear implant, Complications

INTRODUCTION

The only sensory organ function that can be restored in human beings is hearing, through the gift of cochlear implantation (CI). Though CI is a safe surgical procedure, it also comes with its own set of potential complications. The reported occurrence of complications following CI ranges from 1.75% to 4.1%, with infections being one of the most concerning issues due to their ominous prognosis. Predicting the severity of these infections in their early stages poses a considerable challenge, and one of the hurdles lies in treating them when biofilm is present on the implant device.

Biofilm is a structured community of bacterial cells enclosed in a self-produced matrix known as extracellular polymeric substance (EPS) which is responsible for adhesion to surface and cohesion in the biofilm.⁴ It grows on biotic and abiotic surface with delayed onset of symptoms which are not resolved by host defense mechanism and antibiotic therapy. It has 100-1000-fold increased tolerance to antibiotics, when compared to normal bacteria. Bacterial cells communicate and exchange genetic material by Quorum sensing and acquire new traits and become more resistant to antibiotics.^{5,6}

Thus, understanding of potential complications is crucial for facilitating timely and optimal management.

The initial presentation may manifest subtly as a recurrent, non-tender swelling, eventually progressing to skin breakdown, granulation tissue formation, and implant extrusion. Handling such infections is a formidable challenge due to the persistence of biofilm caused by the presence of a foreign body in the infected area, which hinders wound healing. Achieving biofilm eradication from the implant surface is essential, as conservative management attempts are likely to fail. Recent literature endorses the efficacy of tea tree oil and hydrogen peroxide in eliminating biofilms, as well as the high efficacy of rifampicin in controlling such infections. We report our experience in two cases of biofilms in CI including treatment protocol followed and results achieved.

CASE REPORTS

400 consecutive cases of CI were done at tertiary care center over a period of 7 years included. Treatment protocol followed in two cases of biofilm among 400 consecutive cases of CI is discussed.

Case 1

A 2-year-old male, known case of developmental delay with bilateral profound hearing loss underwent left CI in April 2018 (CI24 REST). Immediate post-operative period, activation and mapping were uneventful. After 8 months of surgery, he was brought to ENT OPD with complaints of swelling, purulent discharge at the receiver stimulator (RS) region. On local examination, granulations over the RS region were present (Figure 1a) and no features or systemic infection was there.



Figure 1: (a) Granulations over the RS region, and (b) anteriorly based temporal muscle flap used to cover the relocated implant.

Regular cleaning with betadine and multiple local antibiotic dressings done unsuccessfully. Possibility of biofilm was diagnosed at this stage and was managed conservatively with MRSA antibiotics (linezolid, rifampicin and vancomycin) after culture and sensitivity. Later, patient underwent wound debridement and secondary suturing under general anesthesia which failed. Then a decision was made to salvage the implant by anterior relocation and layered closure. The surgical procedure included an extended post aural incision, and the granulation tissues in the RS region were debrided. The biofilm region thoroughly washed with betadine, hydrogen peroxide and vancomycin. The implant was carefully relocated anteriorly, ensuring precautions taken to protect the electrode area from displacement. As the disease was confined to the RS region, the mastoid was not explored. Granulation tissue was sent for histopathological examination (HPE). An anteriorly based temporal muscle flap used to cover the relocated implant (Figure 1b). Finally, the wound was closed using the temporoparietal fascia and skin.

Post operatively there were no complications on follow up over 5 years. Debridement, relocation and double layered closure using temporalis muscle flap was successful in salvaging the implant.

Case 2

A 2-year-old female, with bilateral profound hearing loss underwent bilateral CI in December 2021 (CI632). Immediate post-operative period, activation and mapping were uneventful. After 6 months of surgery, she presented with complaints of swelling, purulent discharge at the RS region (Figure 2a). Possibility of biofilm was diagnosed and managed conservatively similar to the case 1. Regular

dressing with betadine and prontosan was also used. The conservative management was unsuccessful, hence implant salvage attempted by anterior relocation and temporal muscle flap as in case 1 (Figure 2b).



Figure 2: (a) Swelling, purulent discharge at the RS region, (b) implant salvage attempted by anterior relocation and temporal muscle flap, (c) extensive granulation tissue around the implant region, and (d) implant was removed leaving the electrode array in cochlea.

The child presented back with recurrent granulation tissue at the RS region after 3 months. Despite intravenous antibiotic and conservative management efforts, the device was exposed and explantation decision was made. At the time of explantation, extensive granulation tissue around the implant region was noted (Figure 2c). Implant was removed leaving the electrode array in cochlea, so as to avoid intracochlear fibrosis (Figure 2d). On follow up over 1 year, no further complications noted and the child is doing well.

DISCUSSION

Infections at the site of the surgical wound in the presence of a prosthetic device are linked to the development of biofilm on its surface and it may lead to stubborn infection, serving as a continual reservoir of resistant microorganisms that are discharged into the surrounding tissue, leading to repeated wound breakdown.7 Frequently identified organisms include Staphylococcus aureus, Staphylococcus epidermidis, and Pseudomonas aeruginosa.8 Clinically, the characteristic feature of such infections is rubbery, inadequately vascularized granulation tissue.9

When a biofilm develops at the cochlear implant site, the majority of reports (Table 1) indicate explantation as the primary treatment approach, and early explantation is deemed necessary for wound healing. ^{2,9,10} However, Yu et al in 2001concluded that biofilm after CI can be effectively

managed with surgical intervention and extended medical care. 11

Studies show that erythromycin, rifampicin, tetracycline, and phosphomycin generally presented a higher killing effect than vancomycin, clindamycin, cephalothin, teicoplanin, and ofloxacin in biofilms. ¹⁵ Rifampicin, which targets RNA polymerase, stands out as one of the highly potent compounds combating infections associated with biofilm formation. ¹⁶ Combining rifampicin was identified as particularly efficacious in addressing *S. epidermidis* and methicillin – resistant *S. aureus*, making it an essential component of antimicrobial therapy for biofilms attributed to these organisms. ¹⁷

In our case series of 400 consecutive cochlear implantations, the incidence of biofilm is 0.5% and salvage rate is 50%. To date, there are no clear-cut guidelines for addressing biofilm infection, and there is no universally standardized treatment to preserve the implant. So, we decided to manage conservatively initially with rifampicin, vancomycin, linezolid antibiotics, along with regular dressing with betadine and prontosan. When this approach failed, both patients underwent anterior relocation and temporal muscle flap coverage. We successfully salvaged implant in one case, whereas the other had to be explanted due to recurrence of the disease (Figure 3).

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Study	Incidence of biofilm infection	Explantation rate (%)	Remarks				
Vaid et al ¹⁰	1.14% (2 out of 175)	100	Early explantation recommended				
Gawecki et al ¹²	1.76% (19 out of 1076)	78.9	Analyzed MSFC				
Sharma et al ¹³	Case report-1		Salvaged the implant (antibiotics and tea tree oil)				
Suri et al ¹⁴	5 cases	20	Polyhexanide and betaine for wound dressing				
Germiller et al ⁹	2 cases	100	Re implanted after 3 months				
Yu et al ¹¹	1.65% (4 out of 241)	0	Managed with surgical intervention and extended medical care				

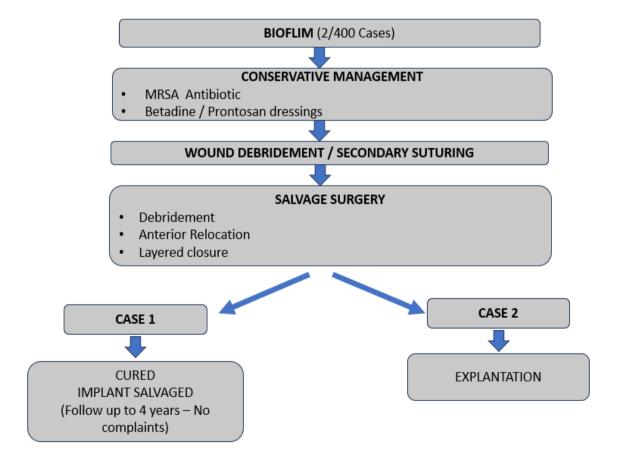


Figure 3: Flow chart - biofilm management algorithm.

CONCLUSION

Biofilm is one of the most dreaded complications of cochlear implant surgery. Most of the published reports suggest explantation as the treatment of choice once biofilm occurs. There is no universally accepted standardized treatment for this complication. We attempted to salvage the implant in both of our biofilm cases in a series of 400 consecutive implants. One of them could be salvaged, and the other implant was explanted. Salvage surgery can be attempted before explantation.

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