

## ABSTRACT

**Objective:** To report an unusual cochlear implant complication secondary to allergic reaction to silicone and to review the literature.

**Study Design:** Case report and literature review

**Setting:** A large hospital-based practice

**Results:** Silicone allergy can cause cochlear implant inflammation leading to a foreign body reaction. This has been shown to be a type 4 hypersensitivity reaction which may play a role in cochlear implant complications. There have only been 7 reported cases of cochlear implant explantation secondary to allergic reaction to cochlear implants. The reaction has primarily been to the silicone component used in Cochlear America's implants.

**Conclusion.** Although rare, it is important to be aware of delayed hypersensitivity reaction to the silicone component of a cochlear implant. Associated symptoms such as pruritis, urticaria and loss of hair are signs of possible allergic reaction to the implant. Steroids may help to alleviate symptoms however symptoms resume after steroids are stopped. Treatment requires removal of the device.

## INTRODUCTION

- Cochlear implant surgery has been increasing in numbers worldwide and has revolutionized the treatment of bilateral severe to profound sensorineural hearing loss.
- Recently there has been increasing number of cochlear implantations for single sided deafness.
- Cochlear implants have a very good track record with respect to safety in both adults and children.<sup>1,2</sup>
- Unfortunately, the increase in cochlear implantations worldwide has been associated with increase in complications and need for re-operations.<sup>2,3</sup>
- The most common complications are:
  - Wound infection
  - Skin flap breakdown. The incidence of skin necrosis has been reported to be up to 5.4%.<sup>2</sup>
  - In addition, there are hardware failure, soft failure, dizziness, meningitis, facial nerve injury or stimulation, and CSF leak.<sup>1,2,4</sup>
- A rare implant complication is a hypersensitivity reaction to the implant components.
- Kornenberg et al 2001 first reported a foreign body reaction as cause of device extrusion.<sup>5</sup>
- The first report of contact dermatitis caused by the silicone component of a cochlear implant was published by Puri et al 2005.<sup>6</sup>
- Overall, there has only been 7 reported cases of implant extrusion as a result of confirmed silicone allergy.
- We present a case of cochlear implant extrusion in an adult due to allergy to silicone found in the cochlear implant CI 632 manufactured by Cochlear Corporation.

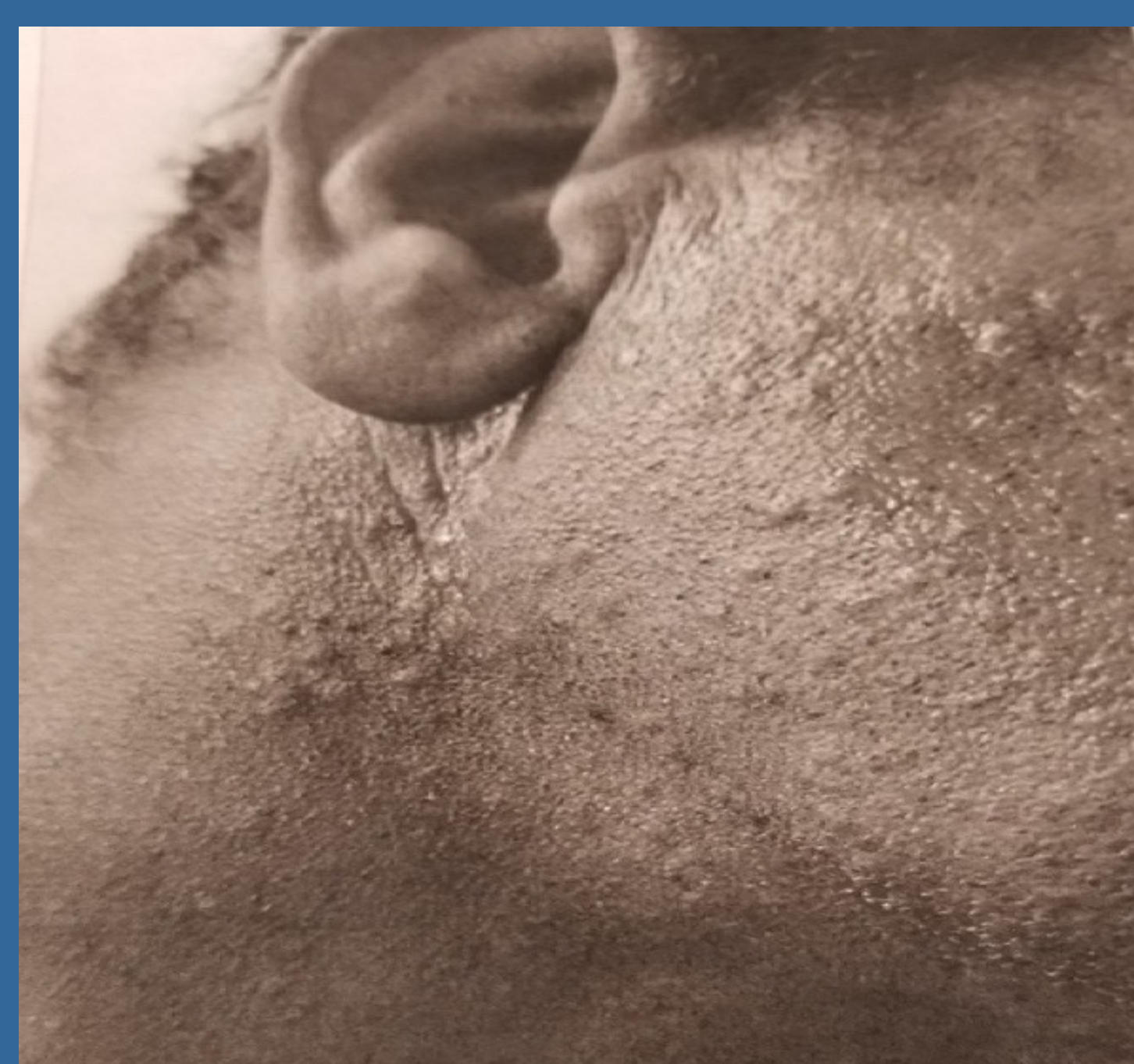


Figure 1. Urticarial reaction after cochlear implantation. One month after surgery, patient presented with itchy raised bumps all over scalp, face and neck.

## CASE REPORT

- A 62-year-old man presented with asymmetric L>R bilateral hearing loss
- Preoperative audiogram and CI candidacy testing revealed mild sloping to profound mixed hearing loss in the right ear and left ear with severe to profound mixed hearing loss
  - SRT: 45R/80L WRS: 100%R/0%L; Az Bio right aided 87%, Az Bio left 8% at 60dB SPL, 12% WRS at 60dB SPL).
  - Preoperative CT and MRI within normal limits
- Underwent uneventful left side cochlear implantation with a Nucleus 24 contour CI 632 (Cochlear Ltd., Sydney, Australia) on 1/13/2022.
  - Intraoperative NRT / impedances were normal
  - Xray indicated good placement.
- At 5 weeks postop (2/22/22), he reported urticaria and raised bumps over scalp and neck (Figure 1.)
- Cancelled his activation due to TMJ related pain and scalp sensitivity.
- 4/4/2022 – Activation. He reported scalp itching and hair loss around the surgical site and now recurring episodic brief vertigo.
- 6/14/22- He stopped using the processor due to increased itching. No edema, erythema or tenderness over the implant area.
- 6/28/23 – He requested removal of the implant. Scalp sensitivity and itching was more severe, and exam revealed edema and fluctuance over the implant. Serosanguinous fluid was aspirated. Started on Augmentin x 14 days for possible infection and CT ordered.
- 7/14/22 – CBC, and CRP were normal but ESR was elevated 32 (range 0-20mm/HR). CT revealed no obvious fluid collection but implant appeared to have shifted and off the skull (Figure 2).
  - Silicone allergy was considered. He was placed on high dose prednisone for symptom relieve and another course of Augmentin. The steroid helped considerably with itching, burning and beginning of resolution of urticaria on his face and scalp.
- 7/29/23 - Allergy referral and decision made for explantation
- 8/11/2022 – Explantation. Intraoperative findings revealed serous fluid in the implant pocket, thick capsule around the implant and fibrous tissue at the cochleostomy. The implant including the electrode array was removed. The device was sent for patch testing.
- Pathology - Giant cell reaction and inflammation, wound culture was positive for light growth of *S. aureus*. Anaerobic cultures showed no growth. ANA, DSDNA was normal and follow-up CRP and ESR had normalized. 10 days after removal of implant the itching and rash had improved.
- Patch testing 4 weeks after finishing prednisone revealed allergy to components of the CI (Figures 3,4). He had mild reaction to cochlear implant components indicative of a Type 4 hypersensitivity reaction.
- His symptoms had resolved at 2 month follow-up.

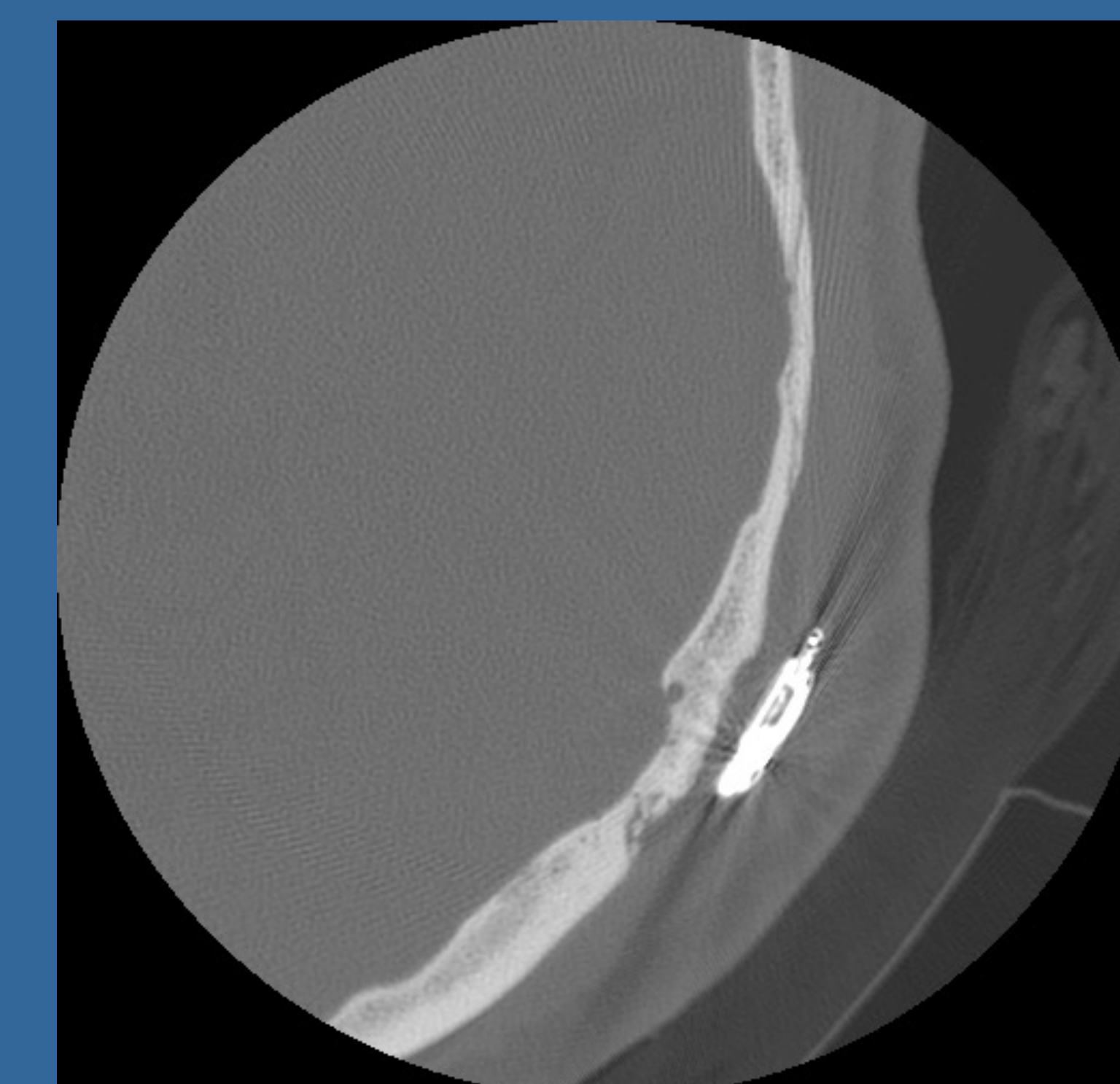


Figure 2. Postoperative CT temporal bone w/o contrast suggests shift and movement of implant away from skull

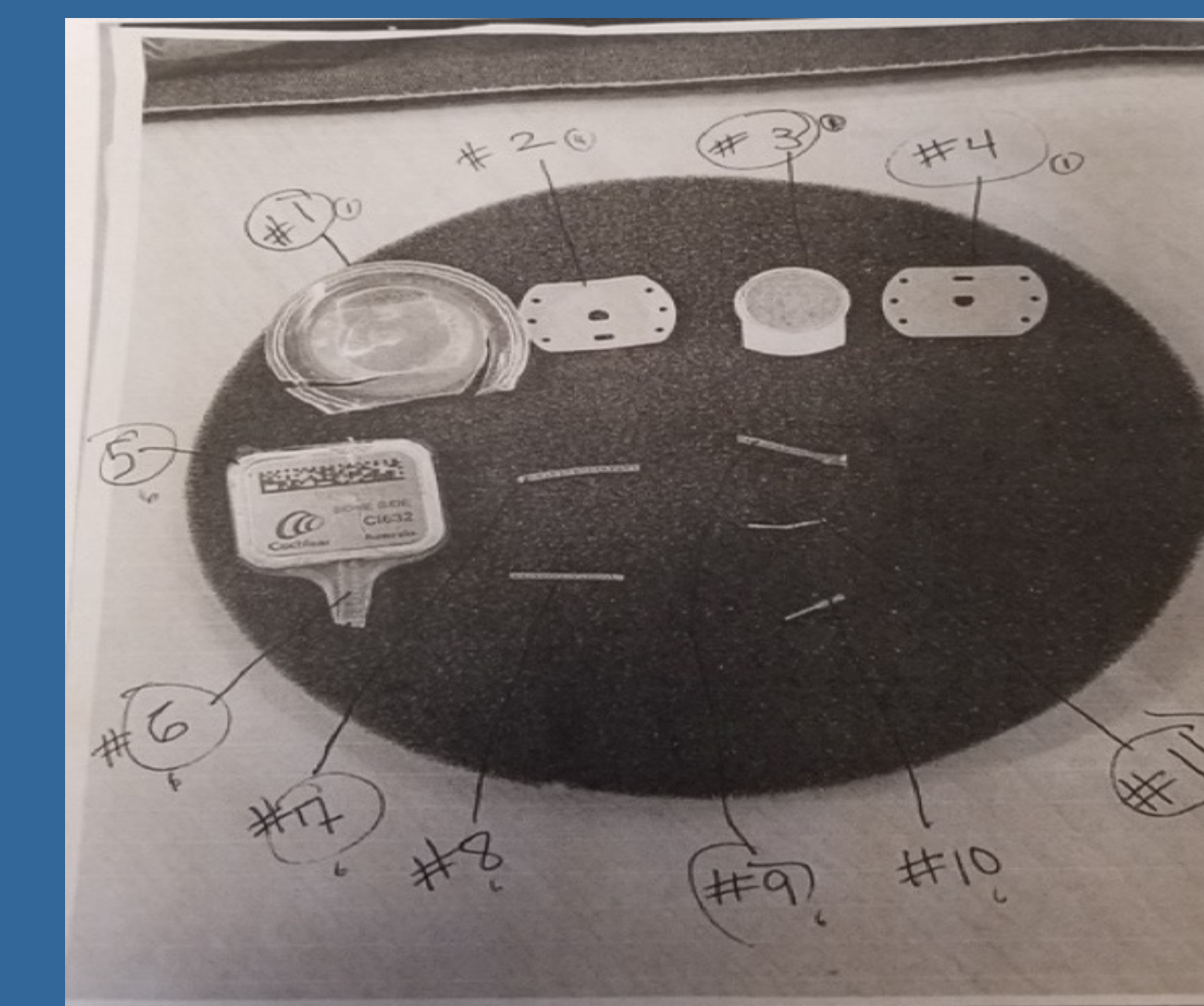


Figure 3. Cochlear Implant components used for patch testing. Patient had reaction to component #1, 3, and 4. 1- silicone, 3-middle piece, 4- plastic cover.



Figure 4. Patch testing method

## REFERENCES

1. Kempf HG, Johann K, Lenarz T. Complications in pediatric cochlear implant surgery. *Eur Arch Otorhinolaryngol.* 1999; 256: 128-132.
2. Hoffman R, Cohen N. Complications of cochlear implant surgery. *Ann Otol rhinol Laryngol Suppl.* 1995; 104: 416-418.
3. Vaas G, Torkos A, Altmayer A, et al. Epicutaneous patch test- A new diagnostic option to prevent the rejection of silicone-covered cochlear implants in children. *Int J Ped Otolaryngol.* 2013; 77: 1635-1638
4. Cunningham C, Slattery W, Luxford W. Postoperative infections in cochlear implant patients. *Otolaryngol Head Neck Surg.* 2004; 131: 109-114.
5. Kornenberg J, Wolf M, Magirov L, et al. Foreign body reaction to cochlear implant. *Otorhinolaryngol Nova.* 2001; 11: 207-208
6. Puri S, Dornhoffer J, North P. Contact Dermatitis to Silicone after Cochlear Implantation. *Laryngoscope.* 2005; 115: 1760-1762.
7. Kunda L, Stidham K, Inserra M, et al. Silicone Allergy: A New Cause for Cochlear Implant Extrusion and Its Management. *Otol Neurotol.* 2006; 27: 1078-1082
8. Lim H, Lee Eu, Park H, et al. Foreign body reaction after cochlear implantation. *Int J Ped Otorhinolaryngol.* 2011; 75: 1455-1458
9. O'Malley J, Burgess B, Galler D et al. Foreign body response to silicone in cochlear implants electrodes in the human. *Otol Neurotol.* 2017; 38: 970-977.
10. Seyyed M, Nadol J. Intracochlear inflammatory response to cochlear implant electrodes in the human. *Otol Neurotol.* 2014; 35: 1545-1551.
11. Nadol J, Eddington D, Burgess B. Foreign body or hypersensitivity granuloma of the inner ear after cochlear implantation: one possible cause of a soft failure? *Otol Neurotol.* 2008; 29: 1076-1084

## DISCUSSION/CONCLUSIONS

Cochlear implants consist of platinum or platinum/iridium electrodes imbedded in a silicone case. These substances are considered biocompatible, but are not inert. Foreign body reactions do often occur and are common with cochlear implantation.<sup>9</sup> It has been reported that many cases of cochlear implants are associated with a foreign body reaction. One report of a series of temporal bones from patients with cochlear implants, a foreign body reaction was noted in 96% of cases.<sup>10</sup> The degree or severity of the inflammatory response also varied from patient to patient with some noting mild fibrosis or neo-osteogenesis to more severe cases with foreign body granulomas with necrosis.<sup>11</sup> Our patient showed a type 4 hypersensitivity reaction. Steroids helped to alleviate his symptoms but those symptoms returned after stopping the steroid.

Silicone hypersensitivity reactions are rare events, however, its important to understand how it may present and there maybe cases of "soft failure" which may be a minor form of this reaction. Past reports of silicone reaction noted that all the cases were associated with the silicone (LSR30) used in Cochlear Corp and certain Med El devices and not silicone LSR-70 used in Advanced Bionics implants.<sup>5-7</sup> One study reported re-implantation with CI from Advanced bionics with no subsequently allergic response. In addition custom made nucleus devices using a different silicone were implanted in couple of patients and were tolerated.<sup>7</sup>

Signs and Symptoms which suggests an allergic response to CI are: delayed onset of itching, swelling over the implant and/or sterile fluid collection, urticaria in head and neck regions, pain and discomfort which is not supported by the physical exam, and responsiveness to steroids. Patch testing, as apposed to prick or intradermal testing, in experienced hands has sensitivity and specificity of 70%.<sup>7</sup> The only definitive treatment is removal of the device and placement with a custom CI or AB/ Med EL CI if the patient is in agreement.

## CONTACT

Syed F. Ahsan, MD  
[Syed.f.ahsan@kp.org](mailto:Syed.f.ahsan@kp.org)  
Otology/Neurotology  
Department of Head and Neck  
Surgery  
Kaiser Permanente,  
Orange County, California  
3460 East La Palma Ave.  
Anaheim, CA 92806