

## Silicone Allergy: A New Cause for Cochlear Implant Extrusion and Its Management

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**Objective:** We introduce silicone allergy as a rare cause for cochlear implant extrusion and discuss its management.

**Study Design:** Retrospective case series and literature review.

**Setting:** Tertiary referral centers.

**Patients:** Primary eligibility criteria included patients who experienced a delayed extrusion of their cochlear implants with negative wound cultures and had a suspected or a test-proven allergy to silicone components of an implant.

**Interventions:** Silicone allergy testing, explantation of a cochlear implant containing allergenic silicone materials, reimplantation with a custom-made cochlear implant excluding an allergenic silicone component.

**Outcome Measures:** Uneventful wound healing and extrusion-free long-term follow-up after the reimplantation with a custom-made cochlear implant excluding an allergenic silicone component.

**Results:** Three known cases of cochlear implant extrusion as a result of silicone allergy have been noted from 1991

through 2004 in three cochlear implant programs in the United States. All three devices extruded, resulting in explantation of the old device and reimplantation with a new custom-made device eliminating the allergenic silicone component. Wound cultures were negative in all cases. All three patients experienced a delayed extrusion of their devices. Two of these patients had a test-proven allergy to the implant's silicone components, whereas the third patient was presumed to have a hypersensitivity solely on the basis of a clinical presentation.

**Conclusion:** We propose that silicone allergy is a rare cause of cochlear implant extrusion. Patients experiencing cochlear implant extrusion, particularly with a delayed onset and negative wound culture results, should be tested for silicone allergy. **Key Words:** Allergy testing kits—Cochlear implant—Delayed extrusion—Silicone allergy.

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The established etiologies for cochlear implant extrusion include poor surgical technique, flap necrosis, and infection. However, some cases of device extrusion reported in the literature seem to be delayed in onset and associated with negative wound culture results, which challenges the established etiologies and suggests a possible alternative causality (1–5). One of the most puzzling case reports of recurrent extrusion of Nucleus 22 device is presented by Harada et al. (3), where the patient experienced two episodes of delayed extrusion at 1 year and then 5 years postimplantation, without clear cause.

We report three cases of cochlear implant extrusion as a result of silicone allergy and propose that silicone allergy is a rare cause of cochlear implant extrusion. To the best of our knowledge, no cases of the allergic reaction to the silicone components of the cochlear implants have been reported in the English-language medical literature until a recent case report by Puri et al. (6) documented

hypersensitivity to the silicone LSR-30 component of a Nucleus 24 Contour device. Earlier reports of allergy to implanted silicone in the English-language otolaryngology literature include the article by Pulec (7), where a presumed silastic allergy caused endolymphatic shunt failure. In the neurosurgical literature, there are case reports of silicone allergy to ventriculoperitoneal shunt tubing (8–10). A number of publications have also indicated an allergic reaction to silicone mammary implants (11,12).

We propose that silicone allergy is one of the rare etiologies of cochlear implant extrusion. Patients experiencing cochlear implant extrusion, particularly with a delayed onset and negative wound culture results, should be tested for silicone allergy.

### RESULTS

We encountered a case of delayed extrusion of a Nucleus 24 Contour device caused by a test-proven allergic reaction to the implant's RTV silicone adhesive. On the basis of an informal survey of physicians in the United

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States and a review of the Manufacturer and User Facility Device Experience (MAUDE) database (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>), two similar cases were noted in the United States between 1991 and 2004. All three identified treating physicians completed a questionnaire (Table 1). Of the three cases, only two patients had allergy testing and were found to be allergic to the RTV silicone adhesive. The remaining patient was thought to have an allergy to an older version of silicone (MDX-4-4515; Dow Corning Corporation, Midland, MI).

### CASE 1

A 20-month-old boy with bilateral profound sensorineural hearing loss underwent an uneventful right cochlear implantation with Nucleus 24 Contour device. Before cochlear implantation, the patient had bilateral tympanostomy tubes placed for recurrent otitis media. The intubated right ear was dry on the day of cochlear implantation.

The patient did well until 6 months postimplantation, when edema and purple discoloration of the skin were



FIG. 1. Postauricular wound before explantation.

TABLE 1. *Silicone allergy and cochlear implant questionnaire*

|                                                                        |
|------------------------------------------------------------------------|
| 1. Patient's demographics                                              |
| a. Age                                                                 |
| b. Sex                                                                 |
| c. Type of hearing loss                                                |
| d. Allergies (drug, food, etc.)                                        |
| 2. Initial cochlear implant data                                       |
| a. Date of implant                                                     |
| b. Type of device                                                      |
| c. Laterality                                                          |
| d. Patient's performance with cochlear implant                         |
| 3. Information on suspected allergic reaction                          |
| a. Date                                                                |
| b. Symptoms                                                            |
| c. Signs                                                               |
| d. Photographs (please attach if available)                            |
| e. Medical treatment and outcome                                       |
| 4. Allergy testing information (please attach the report if available) |
| a. Date                                                                |
| b. Type of allergy testing                                             |
| i. Skin surface testing                                                |
| ii. Intradermal testing                                                |
| iii. Other                                                             |
| c. Materials tested and outcome                                        |
| i. Silicone elastomer HCRP-50                                          |
| ii. Silicone LSR-30                                                    |
| iii. RTV silicone adhesive                                             |
| iv. Silicone Nussil 4515 tubing                                        |
| v. PET mesh                                                            |
| vi. Titanium                                                           |
| vii. Platinum                                                          |
| 5. Data on replacement device                                          |
| a. Date                                                                |
| b. Type                                                                |
| c. Patient's performance with replacement device                       |
| d. Follow-up information                                               |
| 6. Additional comments                                                 |

detected just below the receiver-stimulator during a scheduled follow-up visit. Aside from reported pruritis over the site, the patient was asymptomatic. The patient began receiving Keflex for a presumed infection and was requested not to wear the coil. Six days later, a small area of the wound dehiscence and a mucoid discharge was collected for culture (Figure 1). Final wound culture results revealed no growth. The dehiscence area subsequently healed, and all swelling and discoloration resolved within the next month.

The patient subsequently began to scratch vigorously over the wound, causing the previously tied down receiver-stimulator to migrate inferiorly. He was taken back to surgery for repositioning of the device. At surgery, the normal fibrous capsule around the implant was noted to be absent; and instead, a gelatinous matrix surrounded the device (Figure 2). Cultures were obtained and again were negative. Pathology was consistent with both acute and chronic inflammatory tissue. The area of purpura and edema subsequently recurred after surgery.

At this point, an allergic reaction to the cochlear implant was suspected. It is worth mentioning that the patient had no known allergies. At the recommendation of an allergist, the patient was treated with antibiotics, antihistamines, and a short course of corticosteroids, and then referred for an allergy testing. None of the attempted treatments completely resolved the pruritis or clinical findings.

Subsequently, the patient underwent allergy testing using the Material Sample Kit, Nucleus Cochlear Implant System from Cochlear Corporation (Table 2). Patch testing was completed first, and the result was negative. Prick (scratch or puncture) testing was then performed by an

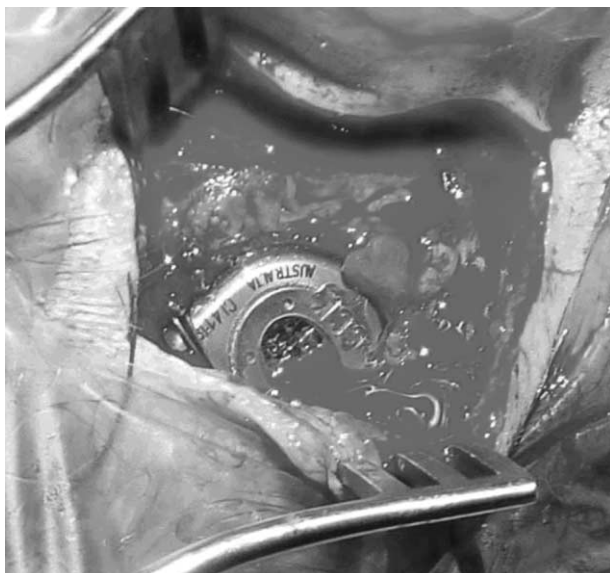


**FIG. 2.** Immediate intraoperative findings.

allergist to test for the silicone components that could be solubilized: elastomer HCRP-50, silicone LSR-30, and the RTV silicone adhesive. The patient tested positive for the RTV silicone adhesive at both 1:100 and 1:10 concentrations with glycerine-negative and histamine-positive controls (Table 3). Confirmatory intradermal testing was then performed for the RTV silicone adhesive at 1:1,000 dilution, with positive results.

Thus, 2 years after the original cochlear implantation, the cochlear implant was explanted; and a custom-made Nucleus 24 Contour device excluding the RTV silicone adhesive was implanted on the contralateral side. The intraoperative findings included soft gelatinous tissue around the device without any evidence of purulence. A fragment of the explanted device was analyzed for the presence of a bacterial biofilm, but the result was found to be inconclusive (M Murray, M.D., personal communication). The final pathology report revealed evidence of acute and chronic inflammation. The patient

subsequently healed without difficulty and currently is doing well 16 months after the reimplantation.

## CASE 2

A 2-year-old girl with bilateral profound sensorineural hearing loss and no history of otitis media underwent uneventful right cochlear implantation with a Nucleus 22 device. Two months later, she extruded the implant and required reimplantation in the same ear. Three months later, the wound breakdown over the receiver-stimulator led to a second explantation of the device. An allergic reaction was suspected, but the parents declined formal allergy testing. Otherwise, the patient had no known allergies.

Seven years later, the patient desired a subsequent attempt at implantation. Allergy testing to the silicone components of the cochlear implant was performed using a skin patch technique. Sensitivity to the RTV silicone adhesive was identified after 72 hours. The patient tested negative to the other silicone components of the implant. The patient was then successfully reimplanted with a custom-made Nucleus 24 Contour device excluding the RTV silicone adhesive. She healed without difficulty and remains an active cochlear implant user 2.5 years after implantation.

## CASE 3

A 4-year-old girl with bilateral profound sensorineural hearing loss was implanted with a Nucleus 22 device on the right. Initial wound breakdown over the receiver-stimulator occurred approximately 6 weeks after surgery. The patient underwent four subsequent surgical procedures by plastic surgeons in an attempt to cover the device. After each procedure, the patient experienced initial uneventful wound healing, and then gradual skin breakdown over the receiver-stimulator site within 4 to 6 weeks postoperatively. All final wound culture results were negative.

Skin patch testing to the silicone components of the implant was performed, and the result was found to be negative. The child's parents were unwilling to proceed

**TABLE 2.** Material sample kit contents from Advanced Bionics, Cochlear, and Med-El Corporations

| Advanced Bionics                         | Cochlear                   | Med-El              |
|------------------------------------------|----------------------------|---------------------|
| LSR70                                    | Silicone elastomer HCRP-50 | LSR40               |
| MED-1137                                 | Silicone LSR-30            | MED 4244            |
| Titanium                                 | RTV silicone adhesive      | Dispersion silicone |
| Platinum                                 | Silicone Nusil 4515 Tubing |                     |
| Titanium with a titanium-nitride coating | PET mesh                   |                     |
|                                          | Titanium                   |                     |
|                                          | Platinum                   |                     |

**TABLE 3.** Results of prick and intradermal tests for the RTV silicone adhesive

| Type of skin testing | Material tested       | Dilution         | Erythema (mm) | Wheal (mm) |
|----------------------|-----------------------|------------------|---------------|------------|
| Prick testing        | RTV silicone adhesive | 1:10             | 17            | 8          |
|                      | RTV silicone adhesive | 1:100            | 14            | 6          |
|                      | Histamine             | Positive control | 18            | 8          |
| Intradermal testing  | RTV silicone adhesive | 1:1,000          |               | 12         |

with intradermal allergy testing and desired reimplantation with a different device under the assumption that the patient was indeed allergic.

The device was subsequently explanted 1 year after the initial implantation and replaced with a custom-made Nucleus 22 device constructed of alternative silicone, MDX-4-4210 (Dow Corning Corporation) instead of MDX-4-4515 (Dow Corning Corporation). The patient had no further problems and remains problem-free for the past 12 years.

## DISCUSSION

Silicones are used as encapsulants, adhesives, or coatings in medical devices. They are commonly used in cerebrospinal fluid shunts, intravenous tubing, drug delivery systems, cardiac valves, arthroplasty prostheses, and intraocular lens implants (13). The uses of silicones in otology include, but are not limited to, silicone sheeting, silicone-containing pressure-equalizing tubes, silicone ossiculoplasty prostheses, and cochlear implants.

Silicone is a group of synthetic polymers called *organopolysiloxanes*, with a molecular structure consisting of alternating silicon and oxygen atoms. Silicones can be fluids, gels, or solids (elastomers), depending on the length of the polymeric chain and the degree of cross-linking (13).

In 2001, Kronenberg et al. (14) published a case report of a foreign body reaction to the silicone material of the Nucleus 22 device. More recently, Puri et al. (6) reported a case of contact dermatitis to the silicone component of a cochlear implant. In the latter report, the patient tested positive for silicone LSR-30 of the Nucleus 24 Contour device, but tested negative to silicone LSR-70 used in the Advanced Bionics device. Thus, the Cochlear device was explanted and replaced with the Advanced Bionics device.

There are reports in the Food and Drug Administration database under MAUDE (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>) that record any adverse events involving medical devices, including cochlear implants. When MAUDE is searched for "allergy and cochlear implant", "allergic reaction and cochlear implant", or "silicone and allergic reaction and cochlear implant", two cases of questionable allergy to cochlear implants from Cochlear Corporation and two cases from Advanced Bionics were found, with one case of a confirmed allergic reaction to the silicone components of Med-El Combi 40+ device.

In most cases, silicone allergy seems to be a type IV or delayed-type hypersensitivity reaction (15,16). This reaction is mediated by T lymphocytes and typically initiates 2 to 7 days after the exposure. Other more common examples of type IV reaction include the Mantoux test (purified protein derivative) and allergic contact dermatitis. In our case series, the cochlear implants extrusions occurred several months postimplantation.

The same is true of other silicone hypersensitivity cases reported in the literature (6–10). The reason for such significant delay in cases of silicone allergy is not clear. One theory is that the type IV reaction in silicone allergy cases may be initiated at a low level, but only becomes symptomatic after time, with a variable severity of clinical presentation depending on the patient's own cellular and humoral response (10). There is also a possibility that another exposure such as chronic infection may change the presentation of the silicone to the immune system and subsequently lead to a delayed allergic reaction.

A type I or immediate hypersensitivity reaction associated with silicone has been described in the German literature in a case report by Stuck et al. (17), where the patient was found to have type I hypersensitivity to a silicone tube for swimming after laryngectomy. Contact urticaria, as an example of type I hypersensitivity, has also been reported to the silicone rubber with the use of the MCU-2A/P gas mask (18). Type I and type IV hypersensitivity reactions may coexist. Type I reaction occurs within 1 hour of exposure and is mediated by immunoglobulin E antibodies in response to specific antigens, causing mast cells to release histamine (19). In our small case series, we did not find any correlation with patient's history of allergies and allergy to silicone components of cochlear implant. Nevertheless, a thorough allergy history should be obtained to potentially find any cross-reactivity patterns that can exist between latex and certain plants and foods (20).

The silicone components in cochlear implants differ for three major cochlear implant manufacturers (Advanced Bionics, Cochlear, and Med-El). In Advanced Bionics devices, LSR-70 is used in the receiver-stimulator (S Kapoor, Advanced Bionics, personal communication). In Cochlear devices, the receiver-stimulator is carried in liquid silicone rubber LSR-30 and contains RTV silicone adhesive, whereas the electrode array has three parts: LSR-30, a silicone that is cured with hydrogen peroxide, and RTV silicone adhesive (P Segel, Cochlear Corporation, personal communication). In Med-El devices, high-strength RTV silicone adhesive is used for the coating of the stimulator, and liquid silicone rubber LSR-40 is used in the overmold and active electrode lead, whereas silicone tube HCRA 50 is used in the reference electrode lead (<http://www.fda.gov/cdrh/pdf/p000025b.pdf> Summary of Safety and Effectiveness Data).

In Cochlear custom-made devices, the RTV adhesive that is normally used to hold parts of the implant assembly together during fabrication is substituted by a platinum-catalyzed silicone (P Gibson and F Risi, Cochlear Corporation, personal communication). This modification of the assembly process enables the manufacturer to fabricate an equivalent device without the use of the RTV silicone adhesive. The appearance of such custom-made devices is largely the same as the standard devices. There may be minor differences in the flexibility and feel of the device, with a slightly stiffer array and a slightly higher opacity of the material.

Cochlear Corporation verified that the reliability and mechanical performance of custom-made Nucleus devices made excluding RTV silicone adhesive are equivalent to that of a standard device (P Gibson and F Risi, Cochlear Corporation, personal communication).

All three above-mentioned cochlear implant manufacturers carry an allergy kit (Table 2). These kits provide the samples of materials contained in the specific type of cochlear implant, but lack recommendations on their application. In our experience, the testing process had been performed by dermatologists or allergists. The consensus for the allergy testing protocol for the silicone components of cochlear implant has not been reached, and we attempt to outline our experience with allergy testing in patients found to have allergies to silicone components of cochlear implants.

The specific tests that have been used in allergy testing to cochlear implant components include the patch test, prick (puncture or scratch) test, and intradermal test. Patch testing is recommended when allergy is thought to be responsible for contact dermatitis and is appropriate for nonsoluble materials. This test involves placement of a small amount of the material on the skin, which is then covered with a watertight bandage for 48 to 96 hours (19). A positive result manifests as areas of erythema with edema covering at least half of the test area, and in more severe cases associated with papules or vesicles (20). Patch testing in experienced hands has sensitivity and specificity of 70% (20). The prick (also known as puncture or scratch) test is a viable option for soluble allergens or crushed diluted nonsoluble material. With this test, a drop of dilute allergenic substance is placed on the skin, and the skin is scratched or pricked with a needle (21). If prick or patch tests yield negative or equivocal results, more sensitive intradermal testing can be used to test the suspected allergens. Each set of intradermal skin testing includes a dilute sterile extract with diluting agent alone as a negative control and histamine as a positive control. A skin test is read as positive if a wheal reaction is produced in 15 minutes, with a wheal diameter at least 5 mm larger than the control (21).

## CONCLUSION

Silicone allergy is a rare but real cause for cochlear implant extrusion. We recommend that patients experiencing cochlear implant extrusion, particularly with a delayed onset and negative wound culture results, be tested for silicone allergy.

A uniform testing protocol for suspected silicone allergy in cochlear implant recipients should be established. If the cochlear implant recipient tests positive

for one of the silicone components of the cochlear implant, a silicone-free device technology is a viable alternative.

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