

Case Report

Providing Re-Essure-ance to the Nickel-Allergic Patient Considering Hysteroscopic Sterilization

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ABSTRACT Essure is a popular method of permanent sterilization that offers a minimally invasive approach that avoids the risks of traditional sterilization procedures in the operating room. Despite the rarity of complications, there has been concern in the popular media over the safety of Essure. We describe the third reported case of systemic contact dermatitis due to the nickel component of the device, with a resolution of symptoms following surgical removal of the inserts. Despite these cases, we believe that extremely rare complications such as this should not dissuade patients from choosing this safe, effective method of sterilization. *Journal of Minimally Invasive Gynecology* (2016) 23, 126–129 © 2016 AAGL. All rights reserved.

Keywords: Complication; Essure; Nickel allergy; Sterilization

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Essure (Bayer AG, Leverkusen, Germany) is the only Food and Drug Administration (FDA)–approved method of hysteroscopic sterilization. Dynamically expanding microinserts are placed in the proximal portion of the fallopian tubes. The inserts consist of nitinol, a nickel and titanium alloy outer coil, a stainless steel inner coil, and polyethylene terephthalate (PET) fibers wound in and around the inner coil. The outer coil holds the device in place, while the PET fibers elicit an inflammatory response that results in tissue ingrowth and tubal occlusion by 12 weeks. The manufacturer estimates that 750,000 units have been sold worldwide, although the number of units placed is unknown [1,2].

Nickel allergy was initially a contraindication to placement when the device was released in 2002. However, in 2011, the FDA approved the manufacturer's request to remove nickel allergy as a contraindication because there had been no proven reported allergic reactions to the nickel component of the inserts [3]. Since that time, there have been 2 reported cases of systemic allergic reactions that necessitated surgical removal of the devices [4,5].

We report the third case of systemic contact dermatitis due to the nickel component of the Essure device, review previously published cases, and describe a surgical approach to device removal. This case report was approved by the Greenville Health System institutional review board (File # Pro00042313).

Case Presentation

A 27-year-old gravida 3 para 3 with an uncomplicated medical history and no known allergies presented to our clinic with a request for permanent sterilization. She denied a history of nickel allergy, pelvic infections, previous tubal ligation, or other tubal surgeries. She underwent uncomplicated Essure placement in our office.

Within days of placement, she developed a pleomorphic, pruritic, urticarial, maculopapular rash over the pelvis and returned to our office 10 weeks after placement for evaluation (Fig. 1). Over the ensuing weeks, the rash cleared and then reappeared multiple times over the pelvis, as well as at distant sites (including the neck and axilla). She also experienced several episodes of facial edema. Pruritus was continuous and only minimally relieved with diphenhydramine.

Further directed questioning elicited a history of multiple reactions to jewelry, metal buttons on clothing, and piercings. An allergist confirmed a nickel allergy with patch

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Fig. 1

Pruritic maculopapular dermatitis consistent with systemic contact dermatitis.



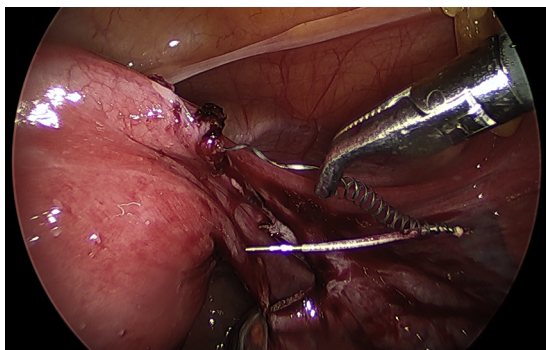
testing. She completed a trial of oral prednisone (40 mg for 5 days, then 20 mg for 5 days), which provided only transient relief. The patient requested surgical removal and repeat sterilization.

Eighteen weeks after placement, diagnostic laparoscopy confirmed that both inserts were properly placed in the fallopian tubes without perforation or migration. The left insert was identified within the tube using an atraumatic grasper, which was advanced distally until the insert was no longer present. At this location, the tube was coagulated and divided with a Ligasure 5-mm blunt tip instrument (Covidien, Minneapolis, MN). Next, a Maryland dissector and a monopolar scissors were used to tease apart the tube until the distal end of the insert was visualized. The inner coil was grasped and easily removed from the tube. The outer coil was grasped where it was attached to the inner coil and was slowly extracted in a hand-over-hand technique until the device was completely removed. After insert removal, a salpingectomy was performed. The same process was completed on the right (Figs. 2 and 3).

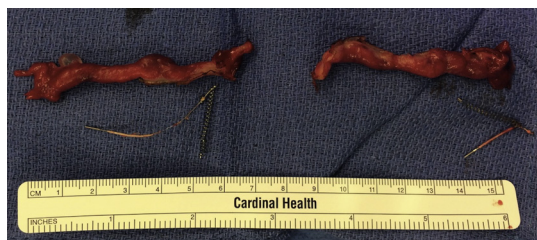
The patient was discharged on the day of surgery with an oral steroid taper (oral prednisone 40 mg for 5 days, then 20 mg for 5 days). At both 2- and 6-week postoperative follow-up appointments, the patient was free of symptoms.

Fig. 2

Removal of Essure insert from right fallopian tube.

**Fig. 3**

Bilateral fallopian tubes and Essure inserts at completion of the procedure.



Discussion

Essure is a popular method of minimally invasive sterilization with a 5-year efficacy of 99.8% and 96% to 99% patient satisfaction. Placement is well-tolerated in the office and offers a cost savings over laparoscopic sterilization, while also avoiding the risks of general anesthesia [6]. Despite recent concerns in the popular media, complications remain rare and include malpositioning, unintended pregnancy, chronic pain, and pelvic infection [7,8].

Nickel allergy is the most common metal allergy, with a prevalence of 18.8% of females in the United States [9]. Self-reported nickel allergy is a poor indicator of true allergy as less than 60% of those reporting will have a patch-confirmed test for nickel allergy [10]. Patch testing is the gold standard for diagnosing a nickel allergy, but it is not a reliable predictor of clinically significant reactions [11].

Essure inserts consist of 55.8% nickel, 44% titanium, and 0.25% chromium by weight. The inserts are processed in such a way that the surface is covered in a layer of titanium oxide that is believed to minimize leaching of the constituent metals. A corrosion study of the inserts detected a daily nickel leaching rate of approximately 2143 times less than the average daily dietary nickel intake [10].

Nickel alloys are common in many medical implants. Although rare, there have been reports of hypersensitivity reactions to nickel-containing orthopedic implants, dental prostheses, orthodontic wires, and endovascular devices [12–14]. Despite direct exposure to the bloodstream, the risk of a clinically significant reaction to nickel-containing endovascular devices is only 1 in 17,000 [10].

Systemic contact dermatitis (SCD) results when a previously sensitized individual is exposed to the allergen systemically. Baboon syndrome, a form of SCD, includes a characteristic pattern of diffuse, well-demarcated erythema of the buttocks, upper thigh, and axilla, as seen in our patient [15].

Al-Safi et al [4] published the first case report of a suspected allergic reaction to Essure, describing a patient without a history of nickel allergy, who for 3 days after placement experienced generalized pruritus and intermittent nausea. Patch testing diagnosed a nickel allergy. The device was removed 8 days after placement, and the symptoms resolved.

Bibas et al [5] published the only other case report found by our search. A patient presented 3 months after placement with 3 weeks of severe anogenital pruritus and a generalized erythematous maculopapular eruption, predominantly distributed in the genital and flexural areas. Her symptoms were resistant to treatment with topical and oral corticosteroids and antihistamines. History and patch test were consistent with a nickel allergy, and her symptoms resolved within 3 months of device removal [5]. Table 1 summarizes these cases.

Reports of Essure surgical removal are limited to case series. Berral et al [16] recently reported 2 cases of Essure devices that were removed hysteroscopically at 12 and 55 months. Before this report, there had been no hysteroscopic removals reported after the 12-week period in which tubal occlusion is known to occur. Our resection occurred before the publication of this report, 18 weeks after insertion, so we performed laparoscopic removal. Laparoscopic removal is generally described as salpingosotomy with electrocautery, followed by traditional salpingectomy once the devices have been freed from the cornua [17–19]. The patient's desire for sterilization and the experience of the surgeon will individualize the approach.

A review of the FDA Manufacturer And User Facility Device Experience database identified 63 reports of suspected nickel hypersensitivity to Essure from 2001 to 2010 [10]. Assuming that all patients with a nickel allergy would have a clinically significant reaction, these authors estimated there should have been 72,000 to 96,000 cases. Only 2 of these patients had symptoms that could be potentially attributable to a nickel allergy, underwent confirmatory patch testing to confirm the allergy, and had improvement with removal of the device. In comparison, the review also identified 2 patients whose symptoms did not improve after removal and 3 patients who improved without removal.

We offer the following suggestions to assist providers in counseling concerned patients. We agree with the 2011 FDA statement that nickel allergy is not a contraindication to Essure placement [3]. We do not believe nickel allergy should be discussed unless the patient requests this information. The principles of informed consent set by the American College of Obstetricians and Gynecologists state that the provider should focus on the reasonable needs and expectations of the ordinary individual, which would not include such rare complications [20].

Instead, counseling should focus on known contraindications to placement: uncertainty about permanent sterilization, previous tubal ligation, suspected pregnancy, pregnancy termination or delivery within 6 weeks, active or recent pelvic infection, or known allergy to contrast media [2]. We do not believe referring all patients with a self-reported nickel allergy to a dermatologist for patch testing would be beneficial because of the inability of patch testing to predict clinically significant outcomes and the high prevalence of nickel allergies.

If a patient with the device in situ begins to experience symptoms concerning for SCD, we believe referral for patch testing may be warranted if no other cause of the symptoms can be found. A negative test is reassuring, whereas the interpretation of a positive test is less clear. We recommend an initial trial of noninvasive treatments, such as topical or oral corticosteroids and antihistamines. If the symptoms do not resolve and the patient requests removal, we suggest a low threshold for device removal. The patient should be counseled that her symptoms might not be due to Essure and may persist or even worsen despite removal. Continued desire for sterility and surgeon experience should guide surgical approach. However, an initial attempt at hysteroscopic removal seems reasonable.

Table 1

Reports of confirmed allergic reactions to Essure

Study	Symptoms	Patch test confirmed nickel allergy?	Time from placement to removal	Attempted noninvasive therapies	Technique for removal	Resolution of symptoms?
Present study	Intermittent pleomorphic, pruritic, urticarial, maculopapular rash over the pelvis, neck and axilla, facial edema, onset <2 wks after placement	Yes	18 wks	Diphenhydramine, prednisone	Laparoscopic	Yes
Al-Safi et al [4]	Generalized pruritis, intermittent nausea, onset 3 days after placement	No	8 days	No	Hysteroscopic	Yes
Bibas et al [5]	Anogenital pruritis, generalized erythematous maculopapular eruptions in the genital flexural areas, onset 3 mo after placement	Yes	15 wks	Topical and systemic corticosteroids, oral antihistamines	Laparoscopic	Yes

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