Nickel release from surgical instruments and operating room equipment

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Abstract

Background

There has been no systematic study assessing nickel release from surgical instruments and equipment used within the operating suite. This equipment represents important potential sources of exposure for nickel-sensitive patients and hospital staff

Objective

To investigate nickel release from commonly used surgical instruments and operating room equipment.

Methods and Materials

Using the dimethylglyoxime nickel spot test, a variety of surgical instruments and operating room equipment were tested for nickel release at our institution.

Results

Of the 128 surgical instruments tested, only 1 was positive for nickel release. Of the 43 operating room items tested, 19 were positive for nickel release, 7 of which have the potential for direct contact with patients and/or hospital staff.

Conclusion

Hospital systems should be aware of surgical instruments and operating room equipment as potential sources of nickel exposure.

Keywords: nickel, surgical instrument, operating room equipment, allergic contact dermatitis

Introduction

Nickel is the most common allergen documented in patch testing with up to 20% of North American patients testing positive to it [1]. Owing to the high prevalence of nickel allergy, the European Union enacted legislation in 1994 that limited the allowable release of nickel from various materials to 0.5 $\mu g/cm^2$ weekly [2]. A similar restriction has not yet been legislated in the United States. Nickel is favored in the manufacturing of consumer and medical products as it is relatively inexpensive, has a high tensile strength, and is resistant to heat and corrosion [3]. Clinically relevant nickel release from coronary stents, pacemakers, implantable cardioverter defibrillators, percutaneous patent foramen ovale occluders, Nuss bar implants, skin clips, gynecological intrauterine devices and implants, hypodermic needles, and hyfercator tips have been documented in the literature [4-13].

Less is known, however, regarding the nickel-releasing potential of surgical instruments themselves or the other metals found within the operating suite. These could be important sources of nickel exposure for patients and hospital staff. Although nickel-plated metals, especially polished nickel, are common causes of allergic contact dermatitis [14], approximately 85% of surgical instruments are made of stainless steel [15], and the potential for nickel release from this is less well understood.

To our knowledge, there are no studies systematically assessing surgical instruments and other operating room (OR) equipment for the release of nickel. Thus, we sought to perform this study to better characterize the potential for nickel release from surgical instruments as well as the operating equipment within a typical operating room (OR) using the dimethylglyoxime test, the clinical

standard for nickel testing. This test can detect nickel in as low a concentration as 10 parts per million (ppm).

Methods

This study was conducted at Hennepin County Medical Center (HCMC) in Minneapolis, MN. It was IRB exempt as no human subjects were a part of the investigation. There were three parts to this study: First, the investigator (AB) entered into two of the main ORs and also into a few of the OR storage units within HCMC to test for nickel release from commonly used OR equipment. Any item that appeared to contain metal was tested, including operating equipment used in surgical cases, along with items simply found in the OR such as light switch panels and office supplies. Second, the investigator entered the Central Processing Department, located those instruments that had been properly cleaned, and tested a sample of commonly used surgical instruments for nickel release. In the Central Processing Department, various groups of instruments were kept on separate and labeled racks for organization and easy identification. There were high grade stainless steel instruments approved for use within the ORs (referred to going forward as "high grade instruments"), low grade stainless steel instruments used for procedures within the hospital but outside of the ORs (referred to going forward as "low grade instruments"), and other instruments for use in the fclinics, which were a mix of both high and low grade stainless steel (referred to going forward as "clinic instruments"). Third, the investigator entered the dermatology clinic area of HCMC and tested the more commonly used instruments specifically within this clinic. These items from the dermatology clinic were also a mix of both high and low grade stainless steel (referred to going forward as "clinic instruments" as well).

Figure 1. *Photos of the nickel spot test used to test for nickel release. Delasco Dermatologic Lab & Supply, Inc. Spot Test For Nickel. Contains 1% dimethylglyoximiguree and 10% ammonium hydroxide.*

Nickel release was detected using the dimethylglyoxime nickel spot test (**Figure 1**), [16] in the following fashion: 2-3 drops of the solution were applied to a cotton tipped applicator, which was then rubbed on the item of interest for 5 seconds. If the cotton tipped applicator turned a bright pink in color, nickel release was considered positive. If there was no color change, nickel release was considered negative. If there was any question about nickel release with the first test, a new cotton swab with fresh solution was used to re-test the item of interest. A positive control of a known nickel-containing metal was used for comparison during the testing. Results of positive or negative nickel release for each item were recorded and photos were taken of each piece of OR equipment and each surgical instrument that tested positive for nickel release.

Results

The results of items tested were separated into four categories: OR equipment and items, high grade instruments, low grade instruments, and clinic instruments. Regarding the OR equipment, 43 total items were tested and 19 were positive for nickel release (**Table 1** lists these OR items and testing results; **Figures 2** and **3** are photos of some the positive results). Seven of the OR items that tested positive had the potential for direct contact with patients and hospital staff: intravenous (IV) line poles, operating table clamps, machine handles, stethoscope chest pieces, sink metal, oxygen and other air tanks, and laryngoscope handles.

Regarding surgical instruments, 128 were tested: 41 high grade instruments (**Table 2**), 33 low grade

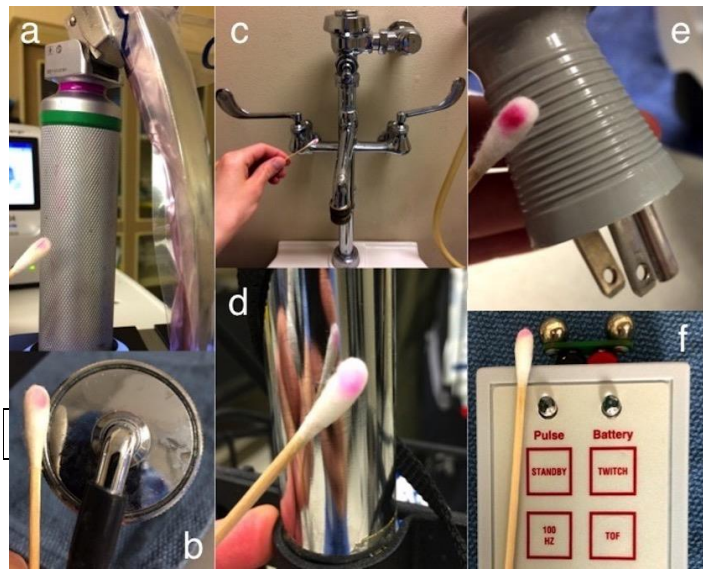

Figure 2. *Photos **a)** laryngoscope handle, **b)** stethoscope chest piece, **c)** metal of OR sink, **d)** intravenous line pole, **e)** prongs of one of the plug-ins tested, **f)** nerve stimulator electrodes. All tested positive for nickel release.*

instruments (**Table 3**), and 54 clinic instruments (**Table 4**). All instruments used within the hospital itself, i.e. the high and low grade instruments, were negative for nickel release. One (1) clinic instrument, the handle of a blunt curette, tested positive for nickel release. Safety pins used in the clinical setting also tested positive for nickel release (**Figure 4**).

Figure 3. *Photos of a variety of the operating table clamps that tested positive for nickel release.*

Discussion

The dimethylglyoxime test

The sensitivity of the dimethylglyoxime test for nickel release is approximately 60%, as the test detects <10 ppm of nickel. Although metals may certainly release nickel below this detectable level, the generally held threshold for a cutaneous reaction in a nickel sensitive patient is 11 ppm [17], which roughly equates to the limit set by the European Union for nickel release from metals at 0.5 μg/cm^2/week [18]. In support of this generally held threshold, a study conducted in 1987 of nickel-containing metal alloys by Menné et al. demonstrated that among nickel sensitive individuals, alloys with nickel releasing more than 1 μg/cm^2/week can cause strong patch test reactivity, whereas alloys releasing less than 0.5 μg/cm^2/week had low reactivity on patch testing [19]. Stainless steel with a 9% nickel content was included in this Menné et al. study and induced weak patch test reactions in some nickel-sensitive patients [19]. Although there have been reports of patients reacting to internally implanted nickel-containing metals (e.g. surgical clips and wires [12]) that tested negative on the dimethylglyoxime test, but whose reactions ceased upon removal of the metal agent, the dimethylglyoxime test is generally a reliable test for clinically relevant nickel release from metal materials. This is especially the case for non-implanted metal materials such as those within this study.

Surgical Instruments

Stainless steel is a mixture of carbon, iron, and chromium. Carbon is alloyed with iron (steel) to

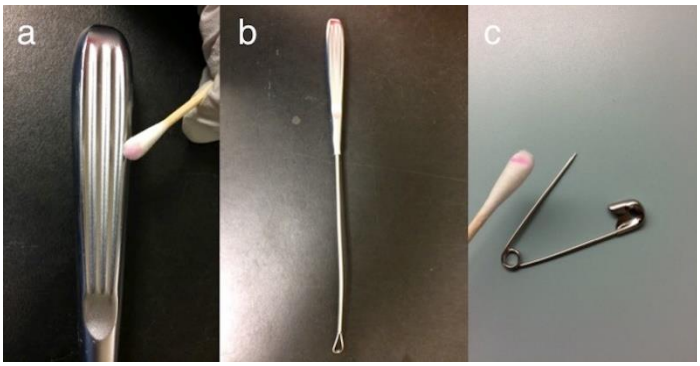

Figure 4. *Photos **a)** and **b)** of a blunt curette and **c)** of a safety pin, each of which tested positive for nickel release.*

increase the hardness and strength of the iron and chromium is added to increase resistance to oxidation (stainless steel). Nickel is additionally added to further increase tensile strength and resistance to heat and corrosion [3]. Manufacturers can also employ other techniques to increase the resistance of their steel to corrosion by polishing its surface and/or adding an external layer of ferrochromate-oxide. As long as this external layer remains intact, release of internal nickel or other ions is diminished [20].

The nickel content in the most common grades of stainless steel used to make surgical instruments can vary between 0 and 28% (**Table 5**), [15, 21]. In

Table 1: *List of the 43 pieces of OR equipment and other OR items tested for nickel release.*

OR Equipment and Other OR Items Tested	
Positive for Nickel Release	**Negative for Nickel Release**
Some surgeon stool legs[1]	Some surgeon stool legs[1]
Some intravenous (IV) line poles[2]	Some intravenous (IV) line poles[2]
A few of the bolts and screws of the cardiopulmonary bypass machine[3]	Remainder of the cardiopulmonary bypass machine[3]
Drill and screw driver heads[4]	Drill equipment other than drill and screw driver heads[4]
Variety of operating table clamps[5]	Operating table equipment metal other than the clamps[5]
Fast Flow Fluid Warmer® machine handle[6]	Fast Flow Fluid Warmer® machine other than handle[6]
Metal of Klein Infiltration Pump machine[7]	Remainder of Klein Infiltration Pump machine[7]
Some of the prongs of different plugs[8]	Some of the prongs of different plugs[8]
Stethoscope chest piece	Switch panels on OR walls
Metal of computer stand	Medical hamper
Metal of three-ring binder	Surgical kick bucket
Metal of sharps container	Telephone in OR
Metal of OR sink	Suturing and other surgical needles
Electrical outlet	Anesthesia machine
Staple remover	Anesthesia workstation
Magnetic paper clip	High vacuum suction machine
Portions of metal on nitrous oxide, compressed air, and oxygen tanks	Blood pressure monitoring machine
Nerve stimulator electrodes	Sequential compression device machine
Laryngoscope handles	Surgical energy platform machine
	Generator cart
	Smoke evacuation machine
	Medical instrument stand
	Cautery tips
	Surgical step stools
	Bair Hugger™ machine
	Patient monitoring machine
	Surgical equipment tables
	Defibrillator machine
	Medistim VeriQ™ machine
	Intra-aortic balloon pump automated counterpulsation machine
	ROTAFLOW Centrifugal Pump® machine
	Cell Saver® intraoperative blood salvage machine

[1] Only some of the surgeon stools had legs that tested positive, all others were negative.
[2] Only some of the intravenous (IV) line poles tested positive, all others tested negative.
[3] The entire cardiopulmonary bypass machine was negative for nickel release except for a few of the bolts and screws incorporated into the system.
[4] The drill head and screw driver heads were both positive for nickel release, the rest of the drill equipment was negative.
[5] The operating table had several pieces of metal, and only a few of the table clamps were positive. The remainder of the metal was negative.
[6] The Fast Flow Fluid Warmer® machine was negative except for the handle on the machine.
[7] All of the metal found on the Klein Infiltration Pump machine was positive.
[8] Several of the cords from different equipment had prongs to the plug in end that tested positive for nickel release. Some of the plug in ends also tested negative for nickel release.

Table 2: *List of the 41 high grade instruments tested for nickel release.*

High Grade Instruments Tested	
Instrument	**Nickel Release? (Y = yes, - = no)**
Regular Rochester-Carmalt forceps	-
Long Rochester-Carmalt forceps	-
Allis forceps	-
Kocher forceps	-
Small Kocher forceps	-
Straight Kelly forceps	-
Curved Kelly forceps	-
Tonsil forceps	-
Rankin forceps	-
Straight mosquito forceps	-
Curved mosquito forceps	-
Suture scissors	-
Short suture scissors	-
Mayo scissors	-
Short Mayo scissors	-
Metzenbaum scissors	-
Small Metzenbaum scissors	-
Tenotomy scissors	-
Iris scissors	-
Bandage scissors	-
Wire cutter	-
5" needle holder	-
6" needle holder	-
6" fine needle holder	-
7" needle holder	-
7" fine needle holder	-
7" Ryder needle holder	-
7" Sarot needle holder	-
8" needle holder	-
Towel clamp	-
Small towel clamp	-
Israel retractor	-
4-pronge rake retractor	-
Murphy rake retractor	-
Weitlander retractor	-
Adson rongeur	-
Lempert rongeur	-
Leksell rongeur	-
Graves vaginal speculum	-
Pederson vaginal speculum	-
Variety of surgical beakers and bowls	-

general, 300 and 400 series grade stainless steels are used to make a variety of medical instruments; the 300 series grades are typically used for non-cutting instruments that require strength, whereas the 400 series grades are used in both cutting and non-cutting instruments. It is important to note that stainless steels 420 and 440 are the most commonly used for surgical instruments and are completely free of nickel. Medical instruments can also be separated into high grade or low grade based on the quality of the stainless steel used in manufacturing [15]. High grade instruments are made from what is considered higher quality stainless steel (the 300 and 400 series grades) and low grade from lower quality stainless steel, which are sometimes further plated with metals such as gold, silver, copper, tin, and nickel [15, 22]. Nickel-plated instruments may release up to 100 μg/cm^2/week of nickel, far above the threshold that elicits dermatitis for some individuals [20]. Additionally, if low grade stainless steel instruments are sterilized in an ultrasonic cleanser with high grade instruments, changes in the metals of the higher quality instruments can occur owing to ion transfer [15]. Whether the amount of nickel release could change from an instrument after sterilization and how sterilization impacts corrosion is unclear.

Our findings are overall reassuring as almost all surgical instruments tested were negative for nickel release. For the blunt curette that did test positive, manufacturing details were not available, so it is unclear if this was a nickel plated instrument, a stainless steel instrument releasing nickel from the alloy, or an instrument which had obtained nickel ions through transfer during sterilization or another process. Our study supports that in general, surgical instruments are not expected to release nickel in an amount above the clinical threshold to cause allergic contact dermatitis.

Operating Suite Equipment

Numerous pieces of OR equipment and other OR items tested positive for nickel release, some of which could have direct contact with patients or hospital staff. We should seek to make our surgical, anesthesia, and nursing colleagues aware of these potential sources of nickel exposure. Individual hospitals may investigate their own operating suites for such sources of nickel release in order to replace nickel-containing equipment with non-nickel releasing options to prevent occupational or iatrogenic allergic contact dermatitis.

Table 3: *List of the 33 low grade instruments tested for nickel release.*

Low Grade Instruments Tested	
Instrument	**Nickel Release? (Y = yes, - = no)**
Sharp operating scissors	-
Blunt operating scissors	-
Bandage scissors	-
Straight Iris scissors	-
Curved Iris scissors	-
Strabismus scissors	-
Wire cutter	-
Episiotomy scissors	-
Long straight Mayo scissors	-
Short straight Mayo scissors	-
Long curved Mayo scissors	-
Short curved Mayo scissors	-
Straight mosquito forceps	-
Curved mosquito forceps	-
Straight Kelly forceps	-
Curved Kelly forceps	-
Babcock forceps	-
Rankin forceps	-
Kocher forceps	-
Allis forceps	-
Straight Rochester-Carmalt forceps	-
Curved Rochester-Carmalt forceps	-
Long curved Rochester-Carmalt forceps	-
Small towel clamp	-
Small needle holder	-
Medium needle holder	-
Long needle holder	-
Adult Magill catheter forceps	-
Pediatric Magill catheter forceps	-
Randall stone forceps	-
Tenaculum	-
Large sponge forceps	-
Small sponge forceps	-

Strengths and Limitations

The primary strength of this study is that, to our knowledge, this is the first study to systematically assess nickel release from surgical instruments and OR equipment. The results show that occupational and iatrogenic exposures are possible in the healthcare setting. There are a few notable limitations to this study, however. Firstly, we did not test every single piece of OR equipment in every operating or surgical suite, but rather a representative number within the main operating suites. Thus, there may be items in other operating rooms, specialty centers, and clinics, which may release nickel that were not identified in our study. Secondly, the list of surgical instruments tested was expansive but not exhaustive, as it was meant to be a representation of the more commonly used instruments. We also did not test every single surgical instrument within the hospital and clinic system. Thus the impacts of corrosion or wear and tear on nickel release for the same instrument over time cannot be elucidated by this study. Lastly, the surgical instruments and OR equipment used at our hospital likely differ from other hospitals throughout the country, so the results may not be generalizable.

Conclusion

This study aimed to analyze nickel release from a variety of surgical instruments and OR equipment, which are important sources of nickel exposure for nickel sensitive patients and hospital staff. Using the dimethylglyoxime nickel spot test, we tested OR equipment, high and low grade surgical instruments, and clinic instruments for nickel release. Several OR items and only one clinic instrument tested positive for nickel release. Thus, this study demonstrated that nickel release from surgical instruments is rare but not zero, and the operating suite contains potential sources of nickel exposure. Although our specific results may not be generalizable to other institutions, these findings are overall reassuring for patients and hospital staff. However, testing OR equipment and surgical instruments for nickel release could be considered, especially if patients and/or hospital personnel suffer from allergic contact dermatitis to nickel and another nickel source has not been identified.

Table 4: *List of the 54 clinic instruments tested for nickel release.*

Clinic Instruments Tested			
Instrument	**Nickel Release? (Y = yes, - = no)**	**Instrument**	**Nickel Release? (Y = yes, - = no)**
Blunt curette	Y (some handles)	Tracheal dilator	-
Safety pin	Y	Blunt tracheal hook	-
Nail splitter	-	News tracheal hook	-
Nail elevator	-	Jackson tracheostomy tube #0 through #11	-
Nail clipper	-	Anoscope	-
Nail nipper	-	Bone curette	-
Comedone extractor	-	Nasal speculum	-
Jaeger lid plate	-	Bayonet forceps	-
Chalazion clamp	-	Gomco circumcision clamps 1.1, 1.3, 1.45, and 1.6	-
Electrodesicator tip	-	Mogen circumcision clamp	-
Disposable skin stapler, the staples	-	Circumcision probe	-
Disposable skin staple remover	-	Blunt ear curettes #1-#3	-
18G needle (1 ½ inch)	-	Sharp ear curettes #00-#2	-
25G needles (both 1 and 1 ½ inch)	-	Splinter forceps	-
27G needle (½ inch)	-	Uterine Sound	-
30G needles (both ½ and 1 inch)	-	Short Russian tissue forceps	-
#11 stainless steel protected disposable scalpel blade	-	Sharp rake retractor	-
#15 stainless steel protected disposable scalpel blade	-	Farabeuf retractor	-
6 mm biopsy punch	-	Amy-navy retractor	-
Skin hook	-	Straight Iris scissors	-
Earspoon	-	Curved Iris scissors	-
Grooved director	-	Thumb forceps	-
6" debakey forceps	-	Green goiter retractor	-
Scalpel handle	-	Adson tissue forceps	-
Bone rongeur	-	Sharp curettes #2 and #6	-
Skin punch	-	Pratt dilators	-
Laryngeal mirror	-	Bohler traction bow	-

Table 5: *Common medical-grade stainless steel composition and properties. Stainless steels 420 and 440 are the most commonly used steels for surgical instruments. Adapted from Atlas Steels web site and from Kneedler et al. on the Pfiedler web site [15, 21].*

Stainless Steels Used in the Medical Industry		
Stainless Steel Grade	**General Composition**	**Notes**
304	Iron + carbon, 18-20% chromium, 8-12% nickel	Good resistance to corrosion. Malleable. Cannot be hardened by heat treatment. Commonly used in a variety of medical devices.
316	Iron + carbon, 16-18% chromium, 10-14% nickel, 2-3% molybdenum	High resistance to salt corrosion. Commonly used in implantable devices.
409	Iron + carbon, 10.5-11.75% chromium, 0.5% nickel	Resistant to atmospheric and automotive gas corrosion.
410	Iron + carbon, 11.5-13.5% chromium, 0.75% nickel	Less corrosion resistance than 430. Can be hardened by heat treatment.
420	Iron + carbon, 12-14% chromium, no nickel	When hardened, good resistance to corrosion. Commonly used for surgical instruments.
430	Iron + carbon, 16-18% chromium, 0-0.75% nickel	Less corrosion resistance than 300. Cannot be hardened by heat treatment.
440	Iron + carbon, 16-18% chromium, no nickel	Commonly used for surgical instruments.

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