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Nickel release from metallic earrings
ORIGINAL ARTICLE

Nickel release from metallic earrings: a survey of the Danish market and validation of the nickel spot test

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ABSTRACT

Background: Exposure to nickel releasing ear piercing jewelry may explain the persistently high prevalence of nickel allergy in Europe. While nickel release from earrings is regulated, field studies show that the regulation is not always respected. More knowledge is needed regarding the risk of piercing exposure including suitable screening methods.

Objective: To examine the proportion of earrings on the Danish market that release more nickel than allowed, and to validate the use of the dimethylglyoxime (DMG) test as a screening tool.

Methods: 304 earrings were purchased and tested with the DMG test and X-ray fluorescent (XRF) spectrometry. The level of nickel release was quantified in a selected subsample of 100 earrings by the European reference test EN 1811. The DMG spot test was validated against EN 1811 at different thresholds.

Results: Excessive nickel release according to the European regulation was found in 45 (14.8%) of tested earrings. The sensitivity of the DMG test decreased with reduced levels of nickel release (sensitivity of 45.2% at $\geq 0.2 \mu\text{g}/\text{cm}^2/\text{week}$ vs. 61.1% at $> 0.5 \mu\text{g}/\text{cm}^2/\text{week}$).

Conclusion: Excessive nickel release is common in earrings on the Danish market. Due to low sensitivity, the DMG test has limited use in screening of earrings for research but may be still be used clinically.

1. INTRODUCTION

Nickel is the most prevalent cause of contact allergy worldwide despite regulatory efforts to reduce the incidence.^{1–3} Around 14.5% of the European adult general population is sensitized to nickel.⁴ Women are more commonly affected than men: 22.2% compared with 5.2%. This gender difference is associated with women's greater propensity to have ear and body piercings.^{5–9}

Earrings and piercing jewelry are largely composed of metal. The exposure differs from that on intact skin, as the skin barrier initially is bypassed after the piercing procedure, where nickel and other metals may be released directly into the blood plasma.¹⁰ Furthermore, after epithelialization of the pierced canal, the skin contact may be regarded as occluded, often during a prolonged time. This distinctive exposure has been recognized by the European Commission, which is why nickel release from piercing post assemblies is restricted to 0.2 µg/cm²/week, lower than from items with contact with intact skin (0.5 µg/cm²/week).^{11–13} The lower limit only applies to the post assembly of the earring, meaning the parts inserted in, and coming in direct contact with the pierced skin canal. The European standard reference test EN 1811 yields a quantitative measurement of nickel released from an object under standardized conditions and is used to control for compliance with the regulatory limits.¹⁴

It has been discussed whether the continued high prevalence of nickel allergy in women could be due to the regulation not being respected or whether the limits in the regulation are too high.^{8,15–17} Several European studies of consumer items have shown nickel release exceeding the regulatory limits.^{18–27} Only a few studies have focused on exposure from earrings and there is no recent survey of the Danish market. Most market surveys have used the dimethylglyoxime (DMG) spot test to rapidly screen for nickel release,²⁸ although the sensitivity is known to be modest. In some market studies, X-ray fluorescent (XRF) spectrometry has been used to rapidly determine the elemental composition of a metallic object.^{29–31}

This study evaluated the elemental composition and nickel release from a random sample of earrings available on the Danish market. Additionally, the DMG spot test was validated against EN 1811.

2. METHOD

2.1. MATERIALS

From March to May 2020, a total of 304 earrings were bought from 35 different stores. Only unique earrings with a metal perforating post were bought. Earrings marked “nickel-free” were not included. Of the 35 different stores 15 were fashion stores (n = 86), 7 accessory stores (n = 40), 4 variety stores (n = 44), 2 supermarkets (n = 52), 2 beauty retailers (n = 8), 1 jeweler (n = 5) and 4 online accessory retailers (n = 69). All stores including the online retailers were situated in Denmark.

Approximately 3300 EUR were spent, ranging from 2.5 to 50 (mean = 12.9) EUR per earring.

The posts from all 304 samples were analyzed with the XRF spectrometer and the DMG spot test. Many samples lacked a lock and/or decorative part, or the part consisted of non-metallic materials, usually plastic or glass. Hence XRF analysis and DMG spot testing were only done when the lock (n = 37), the decorative part with skin contact (n = 18) and/or decorative part without skin contact (dangle charm) (n = 33) visibly consisted of metal.

2.2. XRF SPECTROSCOPY

A handheld XRF device (X-MET8000 Series, Udem, Germany) was used to measure the elemental composition of the earrings on up to three different components.

The XRF spectrometer determines the elemental composition by capturing the characteristic fluorescent radiation emitted when excited with high-energy X-ray beams.^{29–31}

Each measurement was taken on the factory default settings for alloy measurements with 10 seconds exposure time recommended by the manufacturer. Every sample measurement was done in triplets where the mean is presented as the result.

2.3. DMG SPOT TEST

The DMG spot test was prepared by the hospital pharmacy in the Capital Region of Copenhagen. The test solutions were 1% DMG in ethanol and 10% ammonium hydroxide in water. DMG spot testing was done in the laboratory at the Department of Dermatology and Allergy, Gentofte Hospital.

Two drops of each solution were added to a cotton swap that was rubbed on the test area for 20 seconds. A positive result was indicated by a pink/red coloration of the swap, and a negative result was indicated by no change in color of the swap. A doubtful test reaction, defined by a discoloration other than a reddish hue, was retested. If the reaction remained doubtful, the result was registered as negative.^{18,28}

2.4. EN 1811: NICKEL RELEASE IN ARTIFICIAL SWEAT

A subsample of 100 earrings was tested for metal release in artificial sweat, by the current European standard reference test EN 1811:2011.¹⁴ Earrings with a positive DMG spot test and/or nickel content in the post measured by XRF were selected. Due to limited number of test sample (n = 100), we excluded 36 samples with low nickel content (<10%) in the post.

Nickel release was measured by ILAC, UKAS, and CPSC accredited institution Eurofins | BLC Leather Technology Centre Ltd. (Kings Park Road, Moulton Park, Northampton, NN3 6JD, UK) according to BS EN 1811:2011 +A1: 2015.¹⁴ Prior to the test, samples were disassembled in up to five components and/or masked if necessary. Components were tested regardless of visible metallic constituents, with a more detailed subcategorization. The components were tested individually and later categorized into post, lock, decorative part, and dangle charm for data analysis. A total of 273 individual components were tested.

Each component was submerged in artificial sweat consisting of de-ionized water containing sodium chloride 0.5%, lactic acid 0.1%, and urea 0.1% with adjusted pH 6.5. The test volume was ~1ml of artificial sweat per cm² sample area. The samples were left at 30° for 168h. The resulting nickel released in the artificial sweat was measured by inductively coupled plasma mass spectrometry (ICP-MS) for nickel, chromium, and cobalt. Results from chromium and cobalt release will be reported separately. The lower limit of detection (LOD) was 0.02 µg/ml. The measured release was compared with the surface area of the component, measured with digital calipers, and reported as µg/cm²/week.

3. RESULTS

3.1. XRF SPECTROMETRY

Nickel was found in 39.8% (121/304) of the earrings; mainly in posts (n = 118). Nineteen percent of tested locks (7/37) contained nickel and 51% of decorative parts (26/51). Among the samples containing nickel, the mean constitutional percentage of nickel was 10.9% in the post, 6% in the lock, and 11.2% in the decorative part.

An overview of the elemental composition of the earring parts is found in figure 1. Many components consisted ~100% of a single metal (copper, silver, titanium, iron, nickel, or aluminum) resulting in a large elemental variance between the samples in all three categories.

The most common element was copper, found in 92% of posts (281/304), 100% of tested locks (37/37), and 98% of the tested decorative parts (50/51).

3.2. DMG SPOT TEST

Of all samples, 9.2% (28/304) were DMG positive in one or more components. Of post components, 6.6% were found positive (20/304), 5.4% (2/37) of locks, and 25.5% (13/51) of the decorative parts. The positive decorative parts were divided into 7 parts with apparent skin contact and 6 without (Table 1).

3.3. EN 1811

Of the 100 tested samples, 86 released nickel. Notably, the post showed most frequent release among the tested components with 74 positive posts (Figure 2). In general, results were skewed towards LOD ($0.02 \mu\text{g}/\text{cm}^2/\text{week}$) with a median of $0.22 \mu\text{g}/\text{cm}^2/\text{week}$ and some high outliers with a maximum of $180 \mu\text{g}/\text{cm}^2/\text{week}$ (Supplementary table 1).

Results were stratified for each component according to the limits set by the European regulation^{12,13} (Table 2). Excessive nickel release, defined as $\geq 0.2 \mu\text{g}/\text{cm}^2/\text{week}$ in the post and/or lock component and/or $> 0.5 \mu\text{g}/\text{cm}^2/\text{week}$ in the decorative part with skin contact, was found in 45 earrings. The cause for excessive nickel release was largely from the post component ($n = 38$) (Table 2, Figure 2). Eleven locks and 9 decorative parts showed excessive nickel release. The component category 'dangle charms' did not have any apparent prolonged skin contact during normal wear and are thus not covered by the European regulatory limits.

3.4. SENSITIVITY AND SPECIFICITY OF DMG SPOT TEST

To test the validity of the DMG spot test, the results were compared with the amount of nickel release found by the EN 1811 for each component examined with both tests ($n = 179$).

Sensitivity was calculated as $\frac{\text{true positives}}{\text{true positives} + \text{false negatives}}$ and specificity were calculated as $\frac{\text{true negatives}}{\text{true negatives} + \text{false positives}}$ in accordance with published methods.^{28,32,33}

The DMG spot test had a sensitivity of 29% when all components with nickel release were regarded as true positives. If true positives were defined as more than $0.5 \mu\text{g}/\text{cm}^2/\text{week}$, the sensitivity is calculated to 61.1%. At a threshold of $\geq 0.2 \mu\text{g}/\text{cm}^2/\text{week}$, the sensitivity declined to 45.2% (Table 3).

The specificity for the DMG-test was 97.8%, as nickel could not be quantified in two DMG spot test positive components.

3.5. SENSITIVITY AND SPECIFICITY OF XRF ANALYSIS FOR NICKEL RELEASE

The XRF analysis measures elemental content and not the release of metal-ions. However, a bivariate Spearman's correlation analysis showed a moderate linear correlation between the nickel content and the nickel release ($r = 0.592$, $n = 179$, $P < .001$).

The sensitivity of the XRF analysis as a predictor for nickel release was calculated to 85.1% (95% CI: 77.2 - 91.1%) with a specificity of 36.9% (95% CI: 25.3 - 49.8%) of the total 179 components tested with both tests (Table 4).

4. DISCUSSION

4.1. NICKEL RELEASE FROM EARRINGS

In this study of 304 earrings on the Danish market, nickel release was found from at least 28.3% (n = 86), and nickel release exceeding the limits of the regulation in at least 14.8% (n = 45).

Previous market studies have shown that excessive nickel release from earrings is common throughout European countries. Studies using either EN 1811 or the DMG test have reported excessive nickel release from 10%-18.4% of sampled earrings^{19,21,22} except for one Swedish study from 2010, using the DMG spot test reported as little as 3.7% (n = 107).³⁴ The most recent Danish survey from 2009 reported 14.7% positive DMG spot test in a sample of 170 earrings.¹⁸ In this study we report 9.2% (n = 304) with the DMG spot test, demonstrating a decrease with similar method.

In countries not covered by the European regulation, the percentage is much higher; ranging 29.2%-42.5%.^{30,35,36}

The post component was the most common source of nickel release (24.3%, 74/304) and had additionally, by far, the highest levels of nickel release. A similar finding has previously been reported.¹⁹ High release from the posts may be more critical than from other components of the earring, as the post is in direct contact with the blood plasma after piercing, bypassing the skin barrier. Further, metal-ions in earrings may more easily be released to plasma than water.³⁷ Of the total 86 earrings positive for nickel release, in EN 1811, 20 earrings (6.5%) had concurrent nickel release from the post, the lock, and the decorative part with apparent skin contact, resulting in an aggregated exposure. Due to the relatively small size of the earlobe, this aggregated exposure might be substantial, contributing to the risk of nickel allergy.

From a clinical point of view, the elicitation threshold for nickel exposure has been difficult to establish as it varies largely between individuals.² In a meta-analysis, Fischer et al. found that 10% of the sensitized population reacted to 1.04 µg Ni/cm² after occluded exposure on intact skin.¹⁰ Additionally, the elicitation threshold for a penetrating exposure, such as the body piercing, may be lower than a single occluded exposure. Räsänen et al. found allergic reactions in sensitized individuals from the use of earrings releasing as little as 0.15 and 0.17 µg Ni/cm²/week.³⁷ In 2011, and later clarified in 2015, the EN 1811 reference test was amended to introduce a measurement of uncertainty to make it easier to assess products for compliance. This amendment effectively increased the allowed level of nickel release to 0.35 µg/cm²/week for post assemblies and 0.88 µg/cm²/week for items intended for prolonged skin contact.^{11,14} Together with the critical characteristics of a piercing exposure, this may question whether the European regulatory limits are sufficient in protecting the population from nickel allergy.

The XRF analysis on metal alloys is useful as a preliminary analysis to an EN 1811 as it positively identified 85.1% of nickel releasing components and has some predictive value regarding the level of nickel release (Spearman's $r = 0.592$, $n = 179$, $P < .001$). However, the low specificity (36.1%)

does not make it suitable as a determining analysis for nickel release. The surprisingly high rate of false negatives ($n = 17/41$, Table 4) is likely because the XRF analyzes a small delimited area, where the EN 1811 analyzes the complete surface area of the tested component, including joints, surface irregularities or smaller parts. Our XRF results also demonstrated content of other allergenic metals, which theoretically could promote sensitization.

In this study, the EN 1811 results and the interpretation of the DMG spot test results, should be considered conservative. Our subsampling for EN 1811 analysis did not include all nickel-containing piercing posts. In our interpretation of the DMG spot test results, excessive nickel release from the decorative part was expressed by the limit for prolonged skin contact ($>0.5 \mu\text{g}/\text{cm}^2/\text{week}$). We did not specifically test the area of the decorative part in contact with the pierced canal, where excessive nickel release should be defined as $\geq 0.2 \mu\text{g}/\text{cm}^2/\text{week}$.

4.2. DMG SPOT TEST VALIDATION FOR SCREENING PIERCING POST ASSEMBLIES

In our testing, the DMG spot test identified 28 earrings that released nickel, as opposed to 86 identified by the EN 1811.

We found that the DMG spot test had a sensitivity of 61.1% and specificity of 90.9%, on objects that released $>0.5 \mu\text{g}$ nickel/ cm^2/week , close to previously reported.²⁸ The sensitivity declined with decreasing levels of available nickel; noticeably below $0.5 \mu\text{g}/\text{cm}^2/\text{week}$.

The DMG spot test has previously been used to assess nickel release from earrings,^{21,22,30,34,35} which has a lower regulatory limit ($0.2 \mu\text{g}/\text{cm}^2/\text{week}$) than the *estimated* detection limit ($0.5 \mu\text{g}/\text{cm}^2$).²⁸ At a threshold of $\geq 0.2 \mu\text{g}/\text{cm}^2/\text{week}$, the sensitivity of the DMG spot was 45.2%, making it less useful to correctly assess piercing post assemblies for excessive nickel release and the EN 1811 reference test should be preferred.

Due to the small test area of earring components, the volume of DMG test solution used in this study, is arguably large. It could prove beneficial for the sensitivity of the DMG test to only use one drop of each solution when testing earrings, and even mix the solutions beforehand to ensure correct proportions of test solutions.

It should be emphasized that the DMG spot test is a qualitative screening tool for nickel release, with an estimated detection limit, and is not designed to screen for excessive nickel release. Thus, the false positives that emerge when setting a quantitative defined threshold (Table 3) cannot truly be regarded as false positive as these are still positive for nickel release. The decline in specificity is hence a construct and for the purpose of the DMG spot test as a screening tool, the specificity is reported to 97.8%.

The two true false-positive results, with no nickel release, could be explained by the small test area of earring-components, making it difficult to accurately and isolated test a single component without touching other parts of the earring. In the EN 1811 test, this is avoided by dismantling and/or masking irrelevant components, which could also be applied for the DMG spot test of earrings to improve testing accuracy.

5. CONCLUSION

We found that at least 14.8% of a random sample of 304 earrings released nickel in levels that may elicit allergic nickel dermatitis. The sensitivity of the DMG spot test declined at levels of nickel release less than 0.5 µg/cm²/week. The quantitative EN 1811 reference test should therefore be used to correctly assess nickel release from piercing post assemblies where the limit is only 0.2 µg/cm²/week. The DMG spot tests may still be used to detect higher levels of nickel in clinical settings due to its rapidness and high specificity. A safe level of nickel release in earrings should be identified to better protect consumers from nickel allergy.

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7. TABLES

TABLE 1 Earrings and earring components with nickel content (measured by XRF), positive DMG spot test and nickel release (measured by EN1811). For DMG and XRF testing we broke the earring down to a total of 392 components and for EN1811 the subsample of 100 were broken down to 273 components.

		XRF Ni- positive	Tested	DMG positive	Tested	EN1811 positive	Tested (subsample)
Complete earring		121	304	28	304	86	100
		(39.8%)		(9.2%)		(86%)[†]	
<i>Lock</i>		7	37	2	37	37	50
		(18.9%)		(5.4%)		(74%) [†]	
<i>Decorative part</i>	With skin contact	9	18	7	18	27	63
		(50%)		(13.7%)		(42.9%) [†]	
	Dangle charm	17	33	6	33	33	60
		(51.5%)		(11.8%)		(55%) [†]	
Total components		151	392	35	392	171	273
		(38.5%)		(8.9%)		(62.6%)[†]	

[†]Percentage of selected subsample; not representative for the market survey.

TABLE 2 Nickel release from earrings tested with EN 1811 (n = 100) presented in tested components (n = 273) stratified according to the European regulatory limits.^{12,13}

	Post	Lock	Decorative part	Dangle charm	Total
<LOD	26	13	36	27	102
0.02-0.2 µg/cm ² /week	36	26	14	13	89
0.2-0.5 µg/cm ² /week	13	2	4	5	24
Above 0.5 µg/cm ² /week	25	9	9	15	58
Total tested	100	50	63	60	273
Total positive	74 (38)	37 (11)	27 (9)	33	171

Components with excessive nickel release are presented in bold font. LOD = 0.02 µg/cm²/week.

TABLE 3 Sensitivity and specificity of DMG spot test at different thresholds for positive EN 1811 value.

Nickel release from metallic earrings

Threshold (µg/cm ² /week)	EN 1811											
	>0.5				≥0.2				≥LOD			
		+	-	Total		+	-	Total		+	-	Total
DMG	+	22	13	35	+	26	9	35	+	33	2	35
	-	14	130	144	-	31	113	144	-	81	63	144
Total		36	143	179		57	122	179		114	65	179
Sensitivity (95% CI)			61.1% (43.5–76.9%)				45.2% (32.4 - 59.3%)				29% (20.9 - 38.2%)	
Specificity (95% CI)			90.9% (85 - 95.1%)				92.6% (86.5 - 96.6%)				97.8% (89.3 - 99.6%)	

Only components tested with DMG spot test and EN 1811 were included (n = 179). Presented with "exact" Clopper-Pearson 95% confidence intervals.³³ LOD = 0.02µg/cm²/week.

TABLE 4 Sensitivity and specificity of XRF analysis as a predictor for nickel release verified by EN 1811.

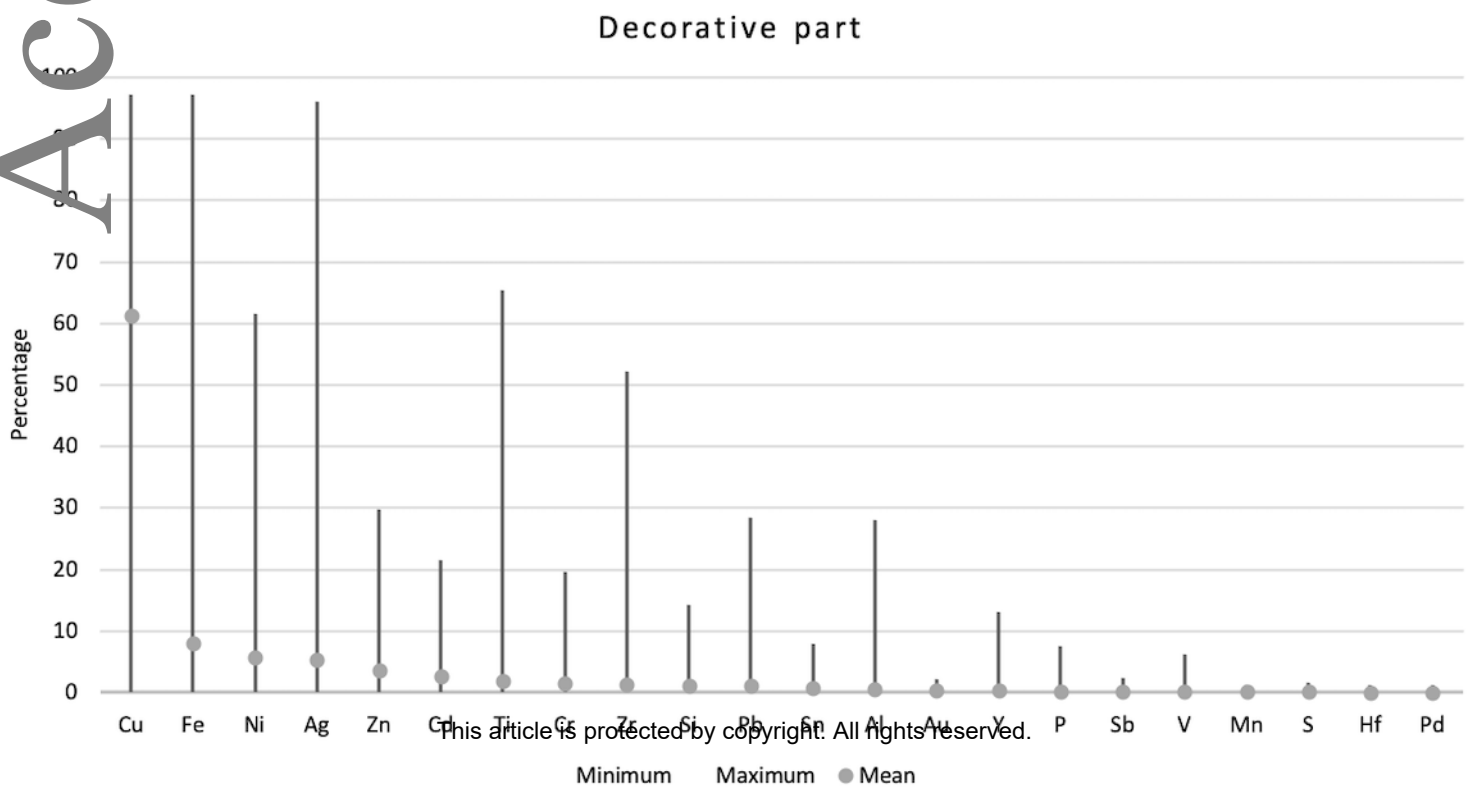
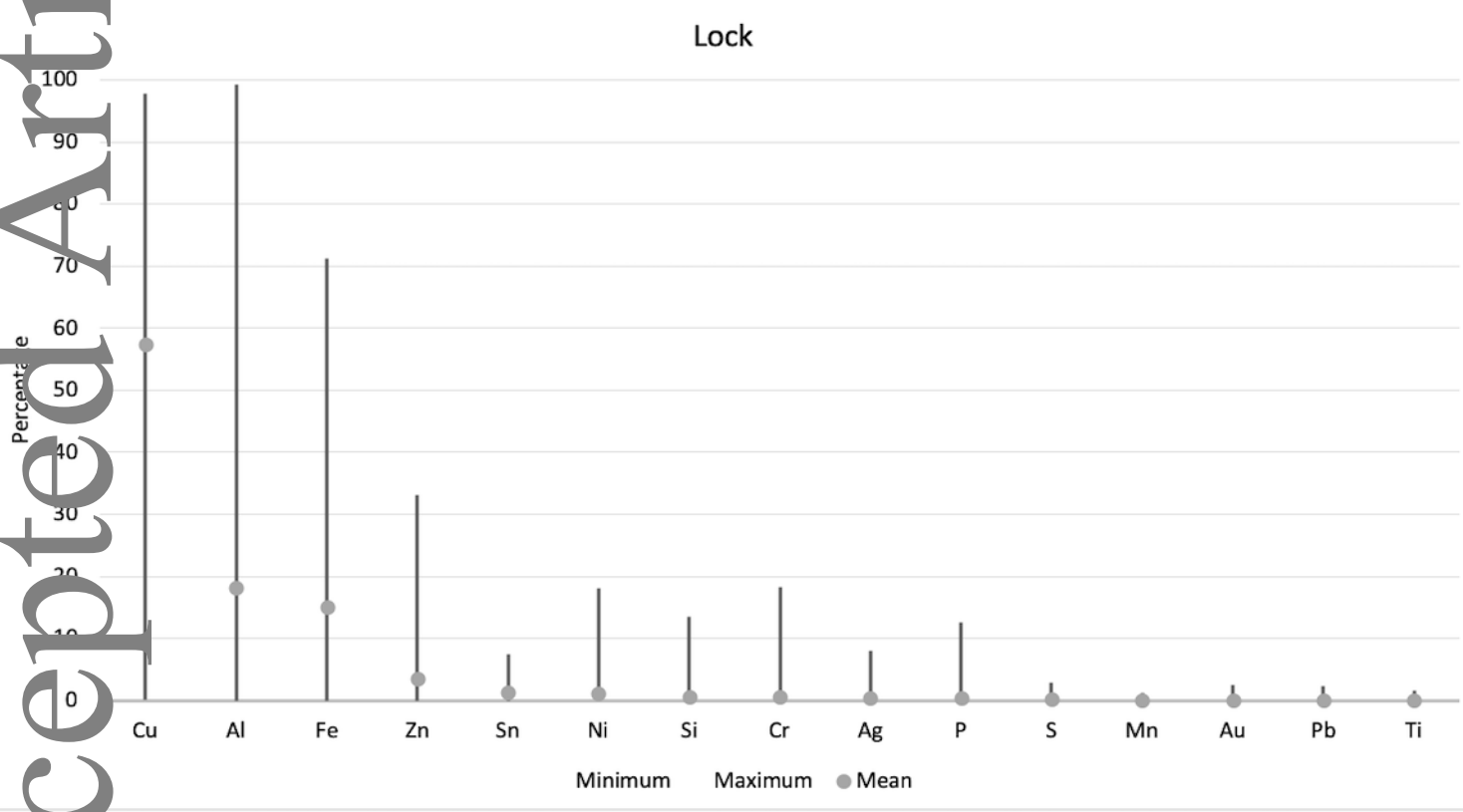
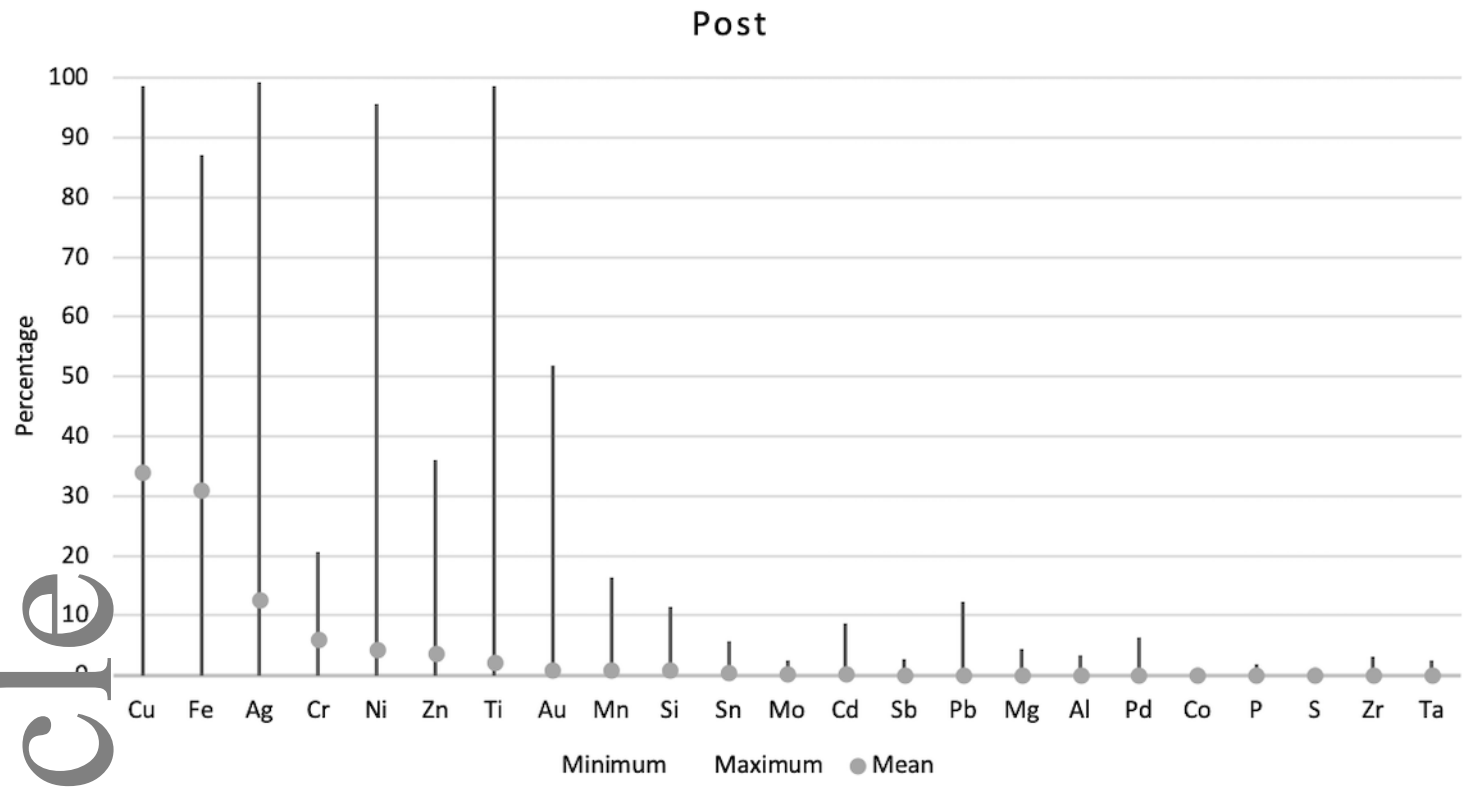
	EN 1811			
		+	-	Total
XRF	+	97	41	138
	-	17	24	41
Total		114	65	179
Sensitivity (95% CI)			85.1% (77.2–91.1%)	
Specificity (95% CI)			36.9% (25.3–49.8%)	

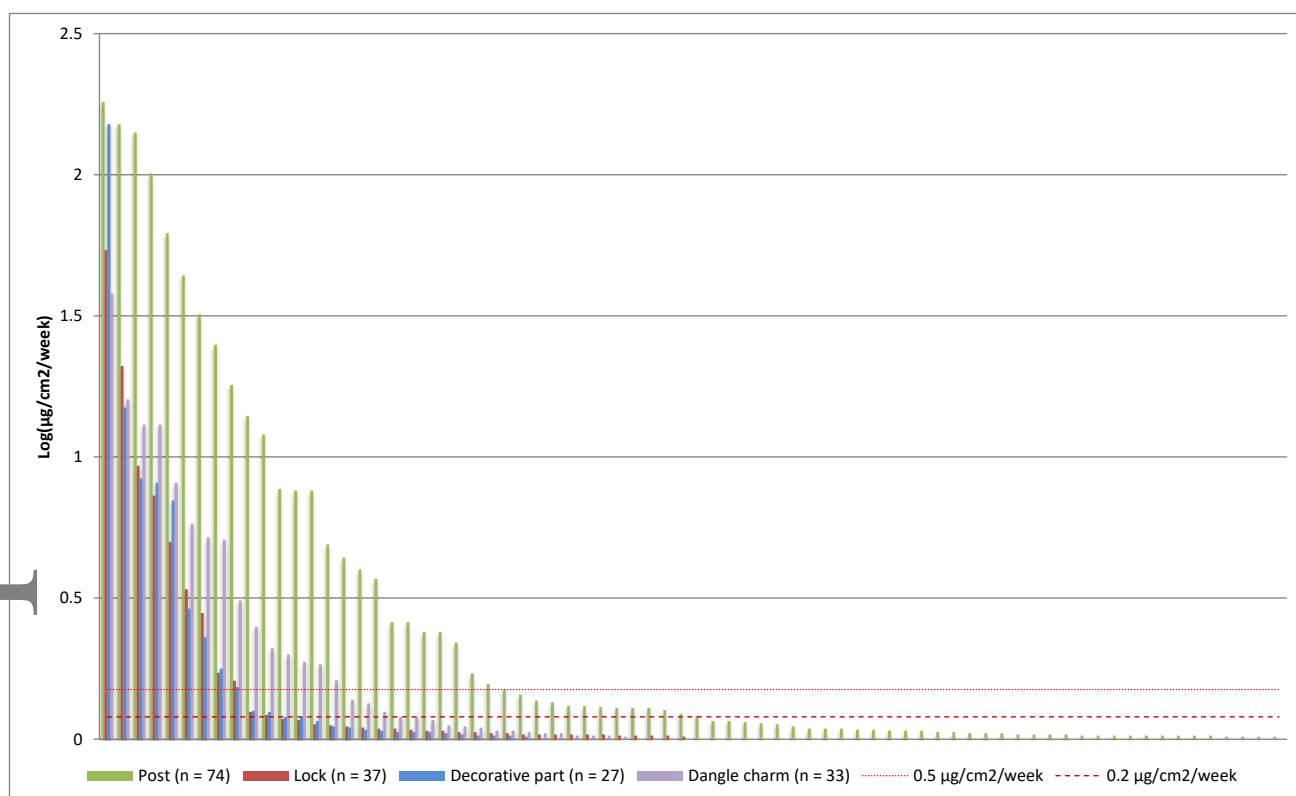
Only components tested with XRF analysis and EN 1811 were included (n = 179). Presented with "exact" Clopper-Pearson 95% confidence intervals.³³

8. FIGURE LEGENDS

FIGURE1 Mean, minimum and maximum elemental compositions of post (n = 304), lock (n = 37) and decorative part (n = 51) of sampled earrings.

FIGURE2 Nickel release from sample earring components measured by EN 1811 on a base-10 logarithmic scale.





1. SUPPLEMENTARY

SUPPLEMENTARY TABLE 1 Excerpt of the maximum nickel release values measured by EN 1811 in µg/cm²/week among the different components.

Post	Lock	Decorative part	Dangle charm
180.00	53.00	150.00	37.00
150.00	20.00	14.00	15.00
140.00	8.30	7.40	12.00
100.00	6.30	7.10	12.00
61.00	4.00	6.00	7.10
43.00	2.40	1.90	4.80
31.00	1.80	1.30	4.20
24.00	0.72	0.78	4.10
17.00	0.61	0.53	2.10
13.00	0.25	0.26	1.50