# A Patch Test Study to Evaluate the Allergenicity of a Metallic Jewelry Alloy in Patients Allergic to Cobalt

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Cobalt is a common inducer of allergic contact dermatitis. A new jewelry alloy containing cobalt was developed and tested on 30 individuals with documented allergy to cobalt. Of these subjects, 5 (18%) were found to be allergic to the new alloy after 7 or 8 days of exposure. In all cases, the reaction was much less severe than allergy to the 1% cobalt chloride patch test material. This new alloy should be better tolerated by individuals allergic to cobalt, perhaps because the cobalt is tightly bound in the alloy by the other main component, platinum.

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obalt is a common metal allergen, with sensitivity documented at 7.6% by the North American Contact Dermatitis Group in individuals patch tested from 1998 to 2000.<sup>1</sup> Individuals may come in contact with cobalt through various products, such as jewelry, coins, other metal items, and cosmetics. Cobalt also is used in glass, ceramic, enamel, and pigment industries, to name a few.<sup>2</sup> Allergy to jewelry is a common cause of allergic contact dermatitis. Most jewelry allergy is to metals in costume jewelry, such as nickel and cobalt, but allergies to gold and, less commonly, palladium do occur.

A new metal alloy containing cobalt and platinum was developed. In theory, this alloy would cause less reaction in individuals known to be

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allergic to cobalt because the cobalt in the alloy is bound by the platinum, thus having decreased bioavailability for skin absorption. Platinum itself is a rare cause of contact dermatitis.<sup>2</sup> This novel metal alloy of cobalt and platinum is intended for use in jewelry. If this new jewelry alloy is found to be less allergenic, individuals allergic to cobalt should be able to wear the new alloy without developing allergic contact dermatitis.

#### Methods

To test the allergenicity of the new metal alloy, 30 subjects 18 years or older who previously were documented by diagnostic patch testing to be allergic to cobalt were enrolled. Exclusion criteria included subjects who were pregnant or breast-feeding; subjects with high noncompliance potential; subjects with active severe dermatitis; or subjects who had used a corticosteroid, immunosuppressive, or immunomodulator systemically within the previous 30 days or topically at the patch sites within the previous 7 days. Of these 30 subjects, 22 (73%) had either a 2+ or 3+ reaction on the standard scale (range, 0 to 3+) developed by the North American Contact Dermatitis Group.<sup>2</sup> The other 8 subjects (27%) had a 1+ or 1 to 2+ reaction. Each subject was patch tested with a disc of a commercially available cobalt salt, the study alloy, and a blank control chamber. The 3 patches were applied on day 0. On day 2, the patches were removed, the patch sites were scored, and the jewelry alloy was reapplied if no reaction was present. Finally, on day 7 or 8, the jewelry alloy patch was removed, and the patch site was scored. To increase the sensitivity of the test, a scale ranging from 0 to 7+ was used (Table 1). Responses at the test sites were compared with responses at the positive and negative control sites. The investigators were not blinded.

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### Results

Thirty subjects were enrolled in the study, and all completed the study. Two of the subjects had no reaction at the positive control site and therefore were excluded from further evaluation. Eight subjects had a borderline reaction (1+) at the alloy test site during the first reading (48 hours after application). At the final reading, after 7 or 8 days of continuous contact with the disc, 3 of the 28 subjects (11%) had a 1+ reaction, 2 of the 28 (7%) had a 2+ reaction, 2 of the 28 (7%) had a 3+ reaction, and 1 of the 28 (4%) had a 4+ reaction. Based on the 0 to 7 scale used, the 3 subjects (11%) with a 1+ reaction were labeled as having a borderline reaction. The 5 subjects (18%) with either a 2+, 3+, or 4+ reaction were labeled as having a mild to moderate allergic reaction. In all cases, the reaction at the disc site was less than the reaction at the positive control site. One patient had a slight transient redness at the negative control site. The sum of reaction scores in all subjects at the positive control sites was 122; at the alloy disc sites, the sum was 17 (Table 2).

## Comment

The number of people allergic to cobalt is increasing. These individuals are limited in the jewelry they are able to tolerate wearing. To offer another choice to those allergic to cobalt, a new jewelry alloy was designed.

The original patch testing of the subjects in our study was performed with common methods used

by the North American Contact Dermatitis Group and others for decades. Diagnostic patch testing is, by necessity, different from the predictive testing that we performed in this study. When testing for cobalt and other metal allergies, metal salts are used. These salts allow for more rapid skin penetration and antigen presentation to sensitized T lymphocytes compared with testing with solid metal. This is necessary because diagnostic testing is performed over a shorter time and on different skin locations than occurs with routine exposure to the metal. In addition to increased sensitivity, diagnostic testing with metal salts may lead to false-positive reactions. Particularly in the case of cobalt, a nonallergic "poral" reaction may be seen, presumably because of the toxic effects of the cobalt on the acrosyringium. Potential subjects with these and other irritant reactions were not included in this study. Testing with a solid metal object reduces the likelihood of these nonallergic reactions. The purpose of our study was not to diagnose cobalt allergy but rather to see if individuals already known to be cobalt allergic would react to this novel alloy. Thus, it was necessary to simulate longterm metal exposure, which we did under the confines of this controlled study. Nonetheless, we realize that more skin reactions may develop in actual jewelry use.

Studies of contact allergy using solid metals for testing have been successful in identifying metal allergy. An example of this is the recent euro coin

#### Table 1.

Score	Description	Definition
0	No change	No reaction
1+	Faint erythema only	No reaction, may be irritant or pressure phenomenon
2+	Erythema, infiltration	Weak allergic reaction
3+	Erythema, infiltration, possibly papules	Weak allergic reaction
4+	Erythema, infiltration, papules	Moderate allergic reaction
5+	Erythema, infiltration, papules, small vesicles	Moderate allergic reaction
6+	Intense erythema and infiltration, papules, vesicles	Strong allergic reaction
7+	Intense erythema and infiltration, coalescing vesicles	Strong allergic reaction

# Definitions of Scoring

# Table 2.

# Subject Results

		Visit 2 (Day 2)			Visit 3 (Day 7 or 8)		
Subject No.	Cobalt Allergy History	Cobalt	Alloy	Control	Cobalt	Alloy	Control
1	2+	2+	0	0	2+	0	0
2	2+	5+	1+	0	7+	0	0
3	2+	7+	1+	0	7+	1+	0
4	2+	3+	0	0	7+	0	0
5	3+	1+	0	0	7+	2+	0
6	2+	5+	0	0	5+	4+	0
7	2+	0	0	0	2+	3+	0
8	1–2+	1+	0	0	3+	0	0
9	2+	4+	1+	0	6+	0	0
10	1+	1+	0	0	2+	0	0
11	3+	6+	0	0	6+	3+	0
12	3+	3+	0	0	2+	0	0
13	2+	2+	0	0	3+	0	0
14	1+	3+	0	0	5+	0	0
15	2+	1+	0	0	6+	0	0
16	2+	5+	1+	0	6+	1+	1+
17	2+	3+	1+	0	5+	0	0
18	2+	1+	1+	0	2+	0	0
19	3+	5+	0	0	6+	0	0
20	1+	2+	1+	0	6+	0	0
21	1–2+	1+	0	0	1+	0	0
22	3+	1+	0	0	4+	0	0
23	3+	4+	0	0	6+	2+	0
24	2+	1+	0	0	6+	0	0
25*	2+	2+	0	0	0	0	0
26	1+	2+	1+	0	2+	1+	0
27	2+	3+	0	0	2+	0	0
28	1+	0	0	0	2+	0	0
29	2+	0	0	0	4+	0	0
30*	1+	0	0	0	0	0	0

\*Excluded from the final calculations because of nonreactivity at the positive control site.

study that, similar to our study design, used the method of taping the metal directly to each subject's skin.<sup>3</sup> It is intuitive that testing with solid metal on intact skin is a good predictor of allergy because most patients who develop metal allergy do so from direct contact of the solid metal with intact skin.

Our study demonstrates that the majority of individuals known to be allergic to cobalt can tolerate continuous exposure to the new metal alloy disc for 7 or 8 days. Only 5 (18%) of the subjects had a mild to moderate allergic reaction to the new metal alloy disc after this intense exposure. No subject had an allergic reaction after 48 hours of continuous exposure. Because many jewelry items are worn in contact with the skin for shorter periods, this alloy rarely should cause an allergic reaction. Because the cobalt in this alloy is tightly bound to the platinum component, we believe it is unlikely that allergic reactions will occur as frequently as with costume jewelry made from base metals.

# REFERENCES

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