

Cobalt release and complications resulting from the use of dental prostheses

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Summary

Background. Cobalt release from dental prostheses has been shown to elicit allergic reactions in cobalt-allergic patients. It is therefore important to investigate whether these prostheses are possible sources of sensitization.

Objectives. To assess (i) cobalt release from dental prostheses and (ii) allergic reactions to components of dental prostheses, and (iii) to investigate the oral mucosa for inflammation 1–5 years after insertion of the prostheses.

Method. Clinical oral examination was conducted in 66 patients with 84 dental prostheses. Cobalt release from 84 functional (used) and 32 non-functional (new) prostheses was investigated with the cobalt spot test. Contact allergy was assessed by patch testing. Smear tests for *Candida* spp. were performed in patients showing signs of inflammation of the oral mucosa. The prostheses were assessed for biological and technical complications.

Results. None of the functional prostheses released cobalt, whereas this was observed in 24 of 32 non-functional prostheses. None of the patients had contact allergy to cobalt. Of the 66 patients, 11 showed signs of inflammation of the oral mucosa, 2 had oral candidiasis, 16 had ill-fitting prostheses, and all had insufficient oral hygiene.

Conclusions. Dental prostheses released cobalt during the fabrication stages, but not 1–5 years after insertion. No allergic reactions were observed. Signs of inflammation were related to candidiasis, insufficient oral hygiene, and ill-fitting prostheses.

Key words: cobalt–chromium–molybdenum alloys; contact allergy; dental prosthesis; hypersensitivity; inflammation; oral mucosa; patch test.

Treatment with partially removable dental prostheses enhances the masticatory function and the social and

oral wellbeing of patients who have lost some teeth (1–3). These prostheses replace the missing natural teeth with artificial teeth fixed on acrylic resin supported by a metal frame. Among the materials available for construction of the metal frame, cobalt–chromium (Co–Cr) alloys offer both good strength and stiffness and relatively low cost, and are therefore frequently the materials of choice (4). Studies have also shown satisfactory longevity of prostheses fabricated with Co–Cr alloys (5, 6). Despite the mechanical advantages of Co–Cr alloys, their biocompatibility has recently drawn attention (7). It is known that the biological response to dental alloys is influenced by susceptibility to corrosion and the consequent release of metal ions (8, 9). Metal ions released in the oral cavity

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may be washed away by saliva (10). However, in partially removable prostheses, particularly in the upper jaw, where a large part of the palate is in close contact with the metal frame for a long period of time, the metal ions released are not in contact with the saliva. Thus, metal ions released from these dental prostheses can be found in high concentrations underneath the metal frame, and may act as local irritants (8).

Previous studies have shown cobalt release from dental prostheses (11–15), but allergic reactions in patients wearing such prostheses have rarely been reported (15).

The prevalence of cobalt allergy in the population is low, namely ~1% (16). However, cobalt is a well-known contact allergen, and has previously been associated with the development of metal sensitization in patients with orthopaedic implants (17). Furthermore, a higher prevalence (6–10%) of cobalt allergy has been found in individuals with dermatitis (18). This is surprising, as cobalt is rarely used in everyday consumer materials, such as jewellery, hair clasps, telephones, and tools (19). A possible hypothesis is that these individuals have been sensitized by exposure to cobalt from other sources, including dental reconstructions. As the development of sensitization can take from months to years for weak sensitizers (20), it is relevant to investigate whether Co–Cr alloys continue to release cobalt after prolonged periods of contact with the oral soft tissues.

A case report from 2010 showed a link between cobalt release from dental reconstructions and oral hypersensitivity reaction in a cobalt-allergic patient (21). In this case, the patient experienced a constant and severe burning sensation in the oral mucosa, tongue and lips 2 months after the insertion of new implants in the upper and lower jaw, but the symptoms disappeared after replacement of the implants. In another report, the patient suffered for a year from pustules, vesicles and scaly erythema on the hands and feet after treatment with Co–Cr crowns, despite the lack of symptoms in the oral cavity. These symptoms disappeared 3 weeks after removal of the crowns (22). Furthermore, a clinical trial assessing whether metal release from cobalt–chromium–molybdenum (Co–Cr–Mo) alloys was sufficient to elicit an allergic skin reaction in cobalt-allergic patients found a positive response in 5 of 16 patients who had direct contact with the alloy. In this latter study, metal release from this alloy was evaluated with atomic absorption spectrometry (23), which is more scientific than a routine clinical method. A simple test providing fast results would therefore be useful for clinicians to easily assess metal release from dental reconstructions.

The cobalt spot test (Co test) used in the present study allows determination of cobalt release from metal items (21, 24). Initially, this test was described as detecting cobalt release at concentrations above 8 ppm, which is close to the reported elicitation threshold in cobalt-allergic patients (24). However, the sensitivity of this test is higher than previously assumed, as it can identify cobalt concentrations as low as 1–1.5 ppm (25). A weak colour change is visible when low amounts of cobalt are released (25, 26), whereas a strong colour change is visible at higher concentrations (24, 26).

The Co test has been used to investigate cobalt release from several materials, including dental alloys (19, 26). From six of eight Co–Cr alloys used in dental laboratories, cobalt was released in concentrations above 8 ppm, thus suggesting that these alloys may cause sensitization (19). On the other hand, studies using atomic absorption spectrometry and inductively coupled plasma–mass spectrometry have reported low elution of elements from Co–Cr alloys (9, 23). Hence, further research is needed to clarify whether cobalt release from dental prostheses reaches a clinically relevant threshold that is capable of sensitizing patients. Thus, the objectives of the present study were (i) to assess cobalt release from Co–Cr-framed removable dental prostheses by use of the Co test, (ii) to evaluate possible allergic reactions to cobalt, chromium, molybdenum and methylmethacrylate (MMA) by the use of patch tests, and (iii) to investigate the oral mucosa adjacent to the metal frame for clinical signs of inflammation 1–5 years after insertion of the dental prostheses.

Materials and Methods

The local Danish Ethical Committee approved the study protocol (no. H-4-2013-090), and all patients included in the study completed an informed consent form according to the Declaration of Helsinki. A total of 128 patients who had been treated with partially removable dental prostheses at the Department of Odontology, Faculty of Health and Medical Sciences, University of Copenhagen, from 2008 to 2013, were invited by telephone or letter to a follow-up examination 1–5 years after insertion of their prostheses. These prostheses were produced at Esbjerg Dental Laboratory, Denmark, and comprised a metal frame fabricated with Vitallium® 2000 Plus (Dentsply, Woodbridge, Ontario, Canada), which is an alloy composed of cobalt (63.4%), chromium (29%), molybdenum (5.2%), silicon (1%), magnesium, carbon, and nitrogen (<1%). Patients who had knee and/or hip replacements or other prosthetic objects consisting of Co–Cr alloys in direct contact with the tissues, and patients who had received a new prosthesis from a private dentist or who

did not use prostheses produced by the aforementioned laboratory, were excluded from the study. Sixty-six of the invited patients treated with a total of 84 functional dental prostheses (49 in the upper jaw; 35 in the lower jaw) agreed to participate in the study. Of the 62 patients not included in the study, 35 did not wish to participate, 13 did not wear the prosthesis or had received a new one, 13 failed to show up for examination, and 1 had died.

Cobalt release from the 84 metal-framed dental prostheses in use (herein referred to as functional) was examined with the Co test. The Co test was prepared by mixing 0.1% (wt/wt) oxalic acid, 0.02% (wt/wt) disodium-1-nitroso-2-naphthol-3,6-disulfonate (nitroso R salt) and 5.0% (wt/wt) sodium acetate in deionized water (24). A cotton swab was moistened with the test reagent, and was then rubbed against the metal frame for 20–30 seconds. A strong colour change from light yellow to orange–red indicated release of cobalt ions at a concentration of >8 ppm (no release of cobalt, –; release of cobalt, +) (24). Doubtful discolouration in this study was defined as a colour change other than yellow, orange, or red. As the colour change resulting from low cobalt concentrations is weak, discolouration other than that expected from the spot test may mask a positive reaction. Hence, a doubtful reaction was considered to be a positive reaction (25, 26). Furthermore, cobalt release was tested on 32 prostheses under fabrication and not yet inserted in the oral cavity (herein referred to as non-functional). Three fabrication stages were examined: casted metal frame only, metal frame with mounted teeth for try-in, and finished prostheses.

History taking and clinical oral examination were performed by the same clinician (H.A.I.). The patient's history included questions regarding general and oral health, medication intake, smoking habits, alcohol consumption, and issues regarding any oral or systemic reactions arising after insertion of the dental prostheses. Additionally, the patients were asked about potential exposure to other sources of cobalt, chromium, molybdenum, and MMA, and about known sensitization to metals and acrylic materials. The clinical examination included documentation of general oral hygiene and hygiene of the dental prostheses (no biofilm, sufficient hygiene; presence of biofilm, insufficient hygiene). Any signs of mucosal inflammation in close proximity to the prostheses and symptoms of oral itching or burning were recorded. The intensity of the inflammatory reaction was scored as mild or severe. If there were no clinical signs of inflammation, an absent response was registered. Photographs of the mucosa and of the dental prostheses were taken to document the clinical findings. Furthermore, an objective assessment was performed to search for

technical complications regarding the fit of the denture and eventual fractures of the acrylic resin and clasps. An ill-fit was defined as gaps between the prosthesis and the oral mucosa or instability of the prosthesis when it was pressed on different sites. Patients who needed repair of their prostheses or other dental treatments were referred to the Clinic of Oral Rehabilitation, Department of Odontology, University of Copenhagen.

As the dental prostheses also contain chromium, molybdenum, and MMA, it was highly relevant to investigate whether previous sensitization to these components had occurred. Patients were therefore patch tested at the Department of Dermato-Allergology, Gentofte Hospital with the following allergens: cobalt chloride 1% pet., potassium dichromate 0.5% pet., molybdenum chloride 0.5% pet., and MMA 2% pet. The test substances were supplied by Trolab®, Hermal, Reinbek, Germany. Twenty milligrams of each solution was applied in an 8-mm Finn Chamber®, and affixed with Scanpor® tape to the upper back of the patient. The patches were left in place for 2 days, and then removed by the patient. The reactions were read on day 3 by the staff of Gentofte Hospital, according to the guidelines of the European Society of Contact Dermatitis (27). A minimum requirement for an allergic reaction was the presence of redness and homogeneous infiltration covering the whole test area in contact with the test substance. A negative response was registered if there was a doubtful reaction, an irritant reaction, or no reaction (28).

An oral *Candida* smear test was performed in patients showing signs of inflammation in the mucosa underlying the dental prostheses, including signs and symptoms of *Candida* infection. A sterile wooden spatula was rubbed against the inflamed oral mucosa. The smear was stained with periodic acid–Schiff, and examined histologically. The numbers of *Candida* spores and hyphae were determined semi-quantitatively (29). The presence of oral candidiasis was defined as a clinical lesion harbouring *Candida* hyphae.

Results

Cobalt release from the metal frame was not detected for any of the 84 functional prostheses after they had rested for 1–5 years in the oral cavity. Interestingly, however, cobalt was released from 24 (75%) of the 32 non-functional prostheses, that is, during the fabrication stages (Table 1). The Co test showed the strongest colour change when the metal frame was tested at the initial stages of fabrication (Fig. 1).

Of the 66 patients, 44 underwent patch testing (13 did not wish to continue participating in the study, 6

Table 1. Results of the cobalt spot test on the functional and non-functional dental prostheses at different stages

Prosthesis	Number	Stage	Spot test	
			–	+
Non-functional	32	Metal frame only	1	12
		Metal frame with teeth	0	6
		Finished prosthesis	7	6
Functional	84	1–5 years after insertion	84	0

could not be contacted, and 3 were found to have other prosthetic objects in the body consisting of Co–Cr alloys). None of the tested patients was found to be sensitized to cobalt, chromium, molybdenum, or MMA.

During clinical oral examination, 16 patients were found to have ill-fitting dental prostheses, 1 had fractured acrylic resin, and 3 had fractured clasps on their prostheses. Inflammation of the underlying mucosa was found in 11 of 66 (16.7%) patients: in 7 patients it was mild, and in 4 patients it was severe (Fig. 2). *Candida* infection was found in 2 of these 11 patients. In 7 of the 9 remaining patients, ill-fitting prostheses were found. All 66 patients had biofilm on the surface of their prostheses, owing to insufficient hygiene.

Discussion

Co-release from dental alloys has been found in a number of previous studies (12–15, 19), but the clinical relevance of the findings has been difficult to interpret, and most studies did not follow up the metal release after prolonged periods of wear. In the current study, the Co–Cr alloy used to fabricate dental prostheses released cobalt in quantities

of >8 ppm. This amount has previously been shown to cause allergic reactions in cobalt-allergic patients (17, 18). However, the cobalt release was only observed during the initial phases of fabrication of the dental prostheses, and not in functional dental prostheses. A possible explanation for these findings is the high corrosion resistance of the used Co–Cr alloy combined with passivation of the alloy (14, 30–32). Earlier studies have shown that the presence of chromium increases surface stability, owing to the formation of chromium oxides, and that both chromium and molybdenum improve the surface passivation on these alloys by impeding the release of cobalt and chromium ions (14, 15). Some studies have examined the release of cobalt and chromium by using chemical analysis of saliva and tongue scrapings (12, 14). One of these studies showed the release of small concentrations of cobalt in the saliva of patients during the first few days after insertion of the dental prostheses, with a subsequent decrease in an evaluation period up to 30 days (12). In the same study, a higher concentration of cobalt was detected in tongue scrapings, also during the first few days after insertion of the prostheses, than in saliva. Besides electrochemical corrosion, mechanical wear could explain the cobalt release in the previously mentioned study (12). Other factors, such as the phase structure of the alloy, the surface structure, crevices, thermal treatment, and time in service, may also affect the amount of corrosion (8), and consequently the release of metal ions.

The released metal ions may cause sensitization and subsequent allergy. Earlier studies have shown that a high level of nickel release may induce oral tolerance rather than sensitization (10, 33). However, this mainly applies to orthodontic devices, and not to dental cast

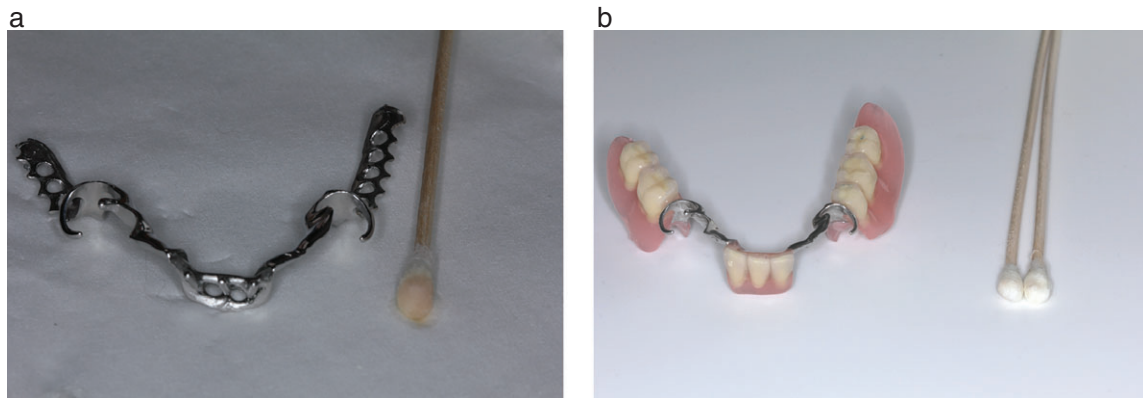


Fig. 1. A cobalt spot test performed on the metal frame of a non-functional removable dental prosthesis showing a positive reaction, indicated by a strong colour change (a), and a cobalt spot test performed on the same finished prosthesis showing a negative reaction, indicated by no colour change (b).

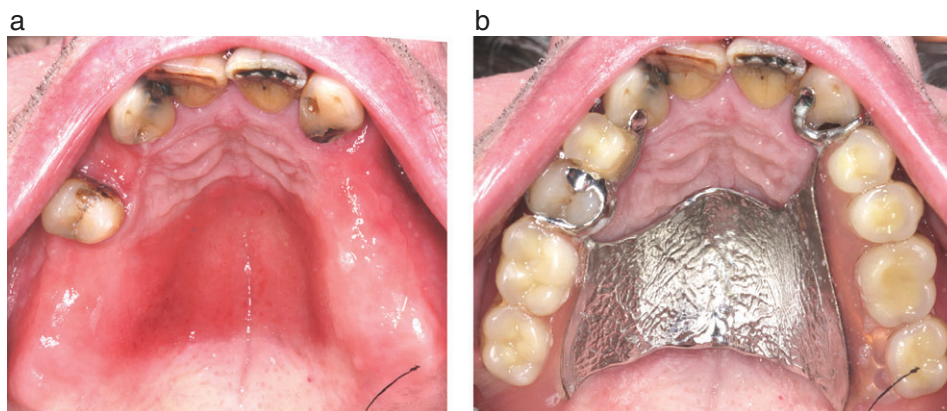


Fig. 2. Examination for changes of the oral mucosa underneath the metal frame of the removable dental prostheses (a, b). Note the inflammation of the mucosa underneath the metal frame (a).

alloys (34). Whether these findings are transferable to cobalt is unknown, as composition, corrosion resistance and other factors influencing metal release differ between the two metals. Thus, further research assessing dental alloys is needed.

In the present study, no signs of previous sensitization or allergic reactions in the examined patients were found with the patch test. In an earlier report from the Adverse Reaction Unit in Bergen, only 37 of 196 patients who were referred because of adverse reactions to dental biomaterials reacted positively to cobalt and chromium (15). Owing to the low frequency of cobalt allergy in the population (16) and the small number of patients included in this study, it was unlikely that we would find any positive reactions to cobalt.

The most common clinical sign of an allergic reaction is inflammation of the oral mucosa, which can also result from insufficient oral hygiene, *Candida* infection, or ill-fitting prostheses. In this study, inflammation of the oral mucosa in direct contact with the dental prostheses was found in 16.7% of the patients. Only in 2 cases was this inflammation related to *Candida* infection; in the remaining patients, it was associated with ill-fitting prostheses. Likewise, ill-fitting prostheses were reported as a source of inflammation of the underlying mucosa in a previous study (35). It is important to emphasize that the fit of a prosthetic reconstruction has been defined as the ability to adapt one structure to another (36), which is a quite broad definition, and very dependent on the examiner. In this study, the professional judgement of fit was not always confirmed by the patients, and most patients with ill-fitting prostheses did not complain.

Additionally, this study focused on the clinical assessment of the dental prostheses. In this context, the Co

test was considered to be simple and useful for screening for the release of cobalt. This test has been previously proven to be clinically relevant and efficient for screening purposes (24). Furthermore, it has shown high specificity and sensitivity (24, 25).

However, as there is no established reference threshold concentration for cobalt, it is possible that the cobalt release below the detection limit of the Co test is still relevant under certain conditions. Local factors, such as higher permeability of the oral mucosa than of the skin, the constant presence of inflammation and bacteria, the use of oral products containing fluoride, and the corrosive potential of the saliva, may lead to increased metal release as compared with other environments (10). Thus, further research assessing the diagnostic properties (sensitivity, specificity, and predictive values) of the Co test against reference methods in different settings is needed.

It should also be noted that the sensitivity of a spot test in general is lower than that of other methods (37). In spite of the accuracy of spectrometric techniques, the required laboratory assistance can result in increased costs and delay in obtaining the results. The spot test, in contrast, provides quick, accessible results at the chair-side. Within the limitations of the present study, particularly regarding the small number of enrolled patients, it seems that the dental prostheses are not among the main sources of cobalt exposure and sensitization, as previously suspected (21). Further studies including a larger number of patients are necessary to better understand the underlying aetiology of cobalt allergy. It could also be of particular relevance to include dermatitis patients, who have an increased prevalence of cobalt allergy as compared with the general population (21).

Conclusions

The Co spot test was useful in screening cobalt release from dental prostheses. The metal-based frameworks from dental prostheses released cobalt during the fabrication stages, but not 1–5 years after insertion in the mouth. No clinical signs of allergic reactions or previous sensitization to cobalt, chromium, molybdenum or MMA were found. The clinical signs of inflammation on the

underlying mucosa were mainly caused by insufficient oral hygiene and/or technical complications of the dental prostheses.

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