Rev. Port. de Est. e Cir. Maxilofac.
29 (4): 285-296, 1988

BIOCOMPATIBILITY OF COBALT-CHROMIUM ALLOYS. "IN VITRO" AND "IN VIVO" STUDIES

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ABSTRACT

Several papers report sensitivity to partial denture Co-Cr alloys; both generalized skin reactions and local reactions related to the framework constituents of nickel, chromium and cobalt have been described. The present paper reports the results of a study planned to evaluate "in vitro" the effects of brushing or tooth contacts on the corrosion of two dental Co-Cr alloys, and also "in vivo" to establish wheter Co-Cr dentures consistently release measurable amounts of cobalt and chromium to the saliva of patients. It was demonstrated that the corrosion behaviour of Co-Cr alloys was affected by abrasion normally encountered during clinical services. It was also assessed that amounts of cobalt and chromium sufficient to induce reactions were released to the saliva in individuals wearing Co-Cr partial dentures.

KEY WORDS

Biocompatibility; corrosion; Dental alloys.

RESUMÉE

Plusieurs publications scientifiques ont mis l'accent sur les réactions provoquées par des prothèses adjointes métalliques sur les muqueuses buccales. Des réactions dermatologiques généralisées ou localisées, provoquées par le nickel, de chrome et par le cobalt ont fait l'object de raport cliniques. Ce travail a pour but de présenter les résultats qui ont étés obtenus "in vitro" suite à l'étude de l'effet de

Association Stomatologique Internationale
Journees Internationales, Lausanne, 29-30-31 May 1986

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l'abrasion sur la corrosion de deux alliages de Co-Cr. Nous avons aussi vérifié chez les patients porteurs de prothèses partielles en Co--Cr le phénomène de corrosion de ces alliages en milieu buccal. Nous avons démontré que la corrosion des alliages Co-Cr était directement accélerée par l'abrasion fonctionelle en bouche. Une quantité importante d'ions Cr et Co a pu être mesurer dans la salive des patients porteurs de prothèses adjointes fabriquées à partir de ces alliages. Ce travail tend à démontrer que la quantité d'ions libérées est suffisante pour provoquer les reactions pathologiques décrites dans cet ouvrage.

MOTS CLÉS

Biocompatibilité; corrosion; alliages dentaires.

INTRODUCTION

Precious alloys containing gold, platinum and palladium as major components have been used successfuly in prosthetic dentistry for many years. Non-precious alloys where metals like Ni, Cr, Co Ag replace in different ratios the traditional noble elements, became popular once they seemed to exhibit good mechanical properties such as stiffness and hardness, comparable resistance to tarnish, and overall a considerably lower cost. The increasing use of such alloys is generally correlated to the rapidly rising gold prices. As the price began to climb steeply in 1972, dentists began to experiment with lower cost alloys (19, 22).

In 1978, a survey of 1,000 dental laboratories in USA, showed that only 29% were using nickel-chromium or cobalt-chromium alloys, while in 1980 and 1981 the percentages of laboratories using these alloys incresed to 66% and 70% respectively; however it is interesting to notice that the general acceptance of these alloys did not show any decline following the recent decrease in price of noble metals (22).

Cobalt-chromium base alloys were introduced to dentistry as early as th 1930's and are used for casting dental appliances, such as bases and other structures for removable partial dentures, certain types of bridges and ocasionally complete denture bases; they are also used for dental implants and in orthopedic surgery.

Because of the relatively large size of partial dentures, lower cost and accuracy requirements, the use of alloys of this type in removable prothodontic procedure has virtually replaced that of gold alloys since 1949 (22).

These alloys must, by the composition requirement of American Dental Association Specification N.º 14, contain a total of not less than 85% by weight chromium, cobalt and nickel. Cobalt (around 60%) and chromium (25 to 30%) are the major constituents of most available products (1).

Molybdenum, carbon and tungsten are principal strengthening elements. The alloys may also contain minor additions of iron, manganese, silicon, copper, tantalum, niobium and gallium (1-2%). Within limits, cobalt can be replaced by nickel thus increasing the ductility; while strenght, hardness, modulus of elasticity and melting point decreases. Corrosion resistance is also affected. Recently new alloys having 1% of precious metal (Pt) in order to increase freedom from tarnish have become available.

One alloy acceptable for use in partial dentures is formulated on an nickel (about 70%) chromium (about 16%) system, containing relatively little cobalt; important minor components such as aluminium (about 2,5%) and beryllium (about 0,5%) are also present.

Cobalt-chromium alloys seemed to be ideal in all respects. At least none of the following clinical surveys of its use made evident unsatisfactory mechanical properties nor any adverse reaction in the underlying oral mucosa caused by the material itself:

Anderson, J.N. et al	1959 — (2)
Tomlin, A.R. et al	1961 — (25)
Bissada, N.F. et al	1974 — (6)
Nyquist, G.	1975 — (18)

According to the considerably high number of patients examined in the above mentioned studies, it could be predicted that adverse reactions to the use of cobalt-chromium alloys are rare, or at least very few in comparision to the great number of dentures in which these alloys have been used (3).

However, an attentive survey of the literature made evident some reports on sensitivity to one or more of the components of the cobalt-chromium dentures:

Deissler, K.J.	1942	— "Contact stomatitis"	Ni Co	(7)
Jacobs, F.	1953	— "Dermatitis: face and neck"	Ni Co	(13)
Sidi, E.	1961	— "Generalized eczema"	Ni Cr	(23)
Brendlinger, D.L.	1970	— "Eczematous dermatitis"	Ni Cr	(7)
Glendennings, W.E.	1971	— "Eczema"	Co	(11)
Fisher, A.A.	1973	— "Allergy"	Ni	(10)
Levantine, A.V.	1974	— "Eczema"	Ni Cr	(15)
Wood, J.F.L.	1974	— "Oral mucosa + Skin rash"	Co Cr Ni	(26)
Ovrutsky, G.D.	1976	— "Allergy"	Steel	(21)
Dooms-Goosens, A.	1980	— "Contact dermatitis"	Co Cr Ni	(9)
Merrit, K., Brown, S.	1980	— "Sensitivity to orthopedic implants"		(18)

In these papers both generalised skin reactions and local reactions related to the dentures have been described (7, 8, 9, 21, 26). It most instances skin patch testing of the patients revealed positive reactions to the constituents of the alloys, especially nickel and chromium (7, 9, 21). Sensitivity to cobalt and reactions to the alloy itself have been also found (8, 9, 15, 26). Removal of the dentures resulted in complete regression of the symptoms in most pacients.

Orthopedic implants containing nickel, chromium or cobalt may give rise to clinical symptoms and positive reactions in blood tests for metal sensitivity (18).

In the literature no report appears to have been published in which a denture of cobalt-chromium has caused tumor formation. The carcinogenic effect mentioned in rats in experiments is questionable when extended to humans (12).

The number of similar cases reported incresed so that the concept of metal safety become controversial, although involving dental materials with long histories of good clinical application.

Dentists became especially concerned about the possibility of having misunderstood some clinically observable signs in their patients, related to the use of a metal base denture, attributing the reason for those lesions to other factors, such as incorrect design or poor fit. Moreover, reactions at remote sites unrelated to the primary site of eruption may result in underestimation of the incidence of allergic responses induced by intra-oral aplliances. For instance "nickel dermatitis" can spread symetrically to secondary sites such as the arms, eyelids, neck and face, so that associated areas of dermatitis appear to be unrelated to the primary site of eruption. "Chromium dermatitis" is not as frequent but in some cases results in a serious cosmetic problem which may remain for a number of years (27).

On the other hand, subjective symptoms are much more pronounced when the physical and mental conditions are weakened or less resistant, when hormone changes occur (menopause), when the oral hygiene is neglected or when acidic foods or certain drugs are consumed. Therefore it is often difficult to reveal the correct diagnosis of the pacient's complaint (24).

In January 1977, the National Institute of Health, USA, sponsered a symposium on "Alternatives to gold alloys in dentistry" (12). During the discussion of one of the papers it was questioned the risk that dental profession could be overgeneralising the relative safety of nickel alloys, because of lack of allergy-induced intraoral lesions observed in their private practices. It was mentioned that the iatrogenic incidence of nickel-induced cancer from the new dental alloys may not be evident for at leat 25 years, because the clinical detection of cancer in humans occurs 25 to 33 years after the start of chronic exposure to nickel. The need of the direct involvement of the Council on Dental Materials and Devices on this subject was recognised.

Reference was also made to the example of Sweden, where the National Board of Health and Welfare recognized this potential risk in 1974, and definitely forbade the use of dental cast alloys with a nickel content exceeding 1% by weight, and also cadmium in dental alloys (3).

So the concept that there is always a potential risk that patients fitted with cobalt-chromium dentures may develope a hypersensitivity to any of the constituents gradually arose.

However the consensus established in different countries about biocompatibility of cobalt-chromium in dentistry varied quite a lot, from one extreme of underestimation of the problem, to the opposite of establishing as considerable alarm about this new potential health hazard. Such attitudes could be related to a certain extent to the publication of case reports involving metals like cadmium and beryllium where more severe side effects occurred.

The recent workshop on "Biocompatibility of metals in dentistry" (27) hosted by the American Dental Association in July 1984, seems to be relevant in defining the "state of the art" and some concluding remarks should be now pointed out:

NICKEL

* There is a need by dentists and physicians to recognize nickel as a common allergen.
* Nickel is a common sensitizer, ranking third among the five most common causes of allergic contact dermatitis. The prevalence is estimated to be 10% in women and less than 1% in men.
* Allergic reactions to nickel can be manifested both localy and systemically. Occasionally, associated areas of dermatitis appear to be unrelated to the primary site of eruption.
* Nickel has been implicated as a toxic material in several nondental apllications.
* The systemic response to nickel as a result of the use of oral nickel-based restorations over extended periods has not been studied adequately.
* Airborne exposure to nickel in dusts has been related to its potential to induce carcinogenesis in nasal lung tissues. Industrial workers exposed to nickel have a much

higher incidence of nasal and lung cancer up to 900 times the average rate.

COBALT

* Cobalt is also capable of inducing sensitization.
* The prevalence of individuals allergic to cobalt is estimated to be less than 1% and appears to be isolated to females.
* Cobalt exhibits reduced potential to systemic effects.

CHROMIUM

* Chromium can sensitize individuals and produce a "chronic dermatitis".
* Carcinogenesis related to dental and medical apllications has not been reported.
* Professional exposure to chromium dusts should also be controlled.

Workshop conclusions and recommendations:

At the present time, the toxicity or carcinogenic potentials of cobalt-chromium alloys seems to be of minor concern in comparison with the sensitivity reactions; however further research should be conducted.

* Manufacturers, laboratories, and dentists should be encouraged to identify alloys used in the fabrication of prosthetic devices in terms of elements that may affect the pacient's health (Ni, Cr, Co, etc.).
* Practitioners are encouraged to document in the records of patients the content of alloys used in restorative materials.
* Professional exposure (dentists, laboratory technicians, dental hygienists and dental assistants) to excessively high concentration Ni, Cr dusts should be controlled and submitted to standard levels defined by Occupational Safety and Health Institutes.

Finally, it is time to mention the valuable contribution of the Scandivanian researchers to this subject during the last two decades.

Several comprehensive reports of biocompatibility to metal alloys were published by Soremark, (24), Bo Bergman, (5), Maud Bergman (4), reinforcing the interest in its biological testing.

After a long period of time where most efforts in specification of dental materials were mainly developed towards mechanical, physical and chemical properties, the interest was extended to biological properties as well.

According to Soremark and Bergman (3, 21) it seems reasonable to regard and classify dental materials as substances used for a "medicinal purpose" like drugs and pharmaceuticals, and so, before being used in humans, they must subjected to biological tests which take into consideration both local effects on adjacent tissues and any systemic effect that may occur due to release of an ingredient and its subsequent absorption into and distribution by the circulatory system.

The key of the problem seems to be fundamentally related to the fact that the oral cavity often presents exceptional conditions for electrochemical corrosion.

There are constant fluctuations in the oral cavity:

1. In temperature
2. In quantity and quality of saliva
3. In the amount of bacterial plaque
4. In ph
5. In the physical and chemical properties of foods and liquids
6. In the intake of drugs
7. In the general and local health conditions

All dental alloys corrode in the dental environment, more or less; however elements like gold, paladium and platinum seem to be nealy inert and corrode less than others (24). Cast metals such as cobalt-chromium are passive but the components of any alloy in contact with tissue fluids can ionize in time (24), so one important requirement of dental alloys in prosthetic dentistry is that they should be corrosion resistant.

Corrosion products can sooner or later, in one way or another, be harmful to the tissues in the oral cavity and/or in the other parts of the body. The corrosion products can be taken up by saliva, the gengiva, and the dental pulp; and be transported throughout the body and specific organs where they are accumulated, as demonstrated by Bergman and Soremark with nickel, on experiments in mice (4, 5).

The severity of the ensuing reactions depends on the cytotoxic potentials of the ions made available through the dissolution of the products by wear and corrosion of the alloy surfaces. Only minor amounts are needed to bring about reactions in sensitive subjects, so it can be suspected that partial denture alloys may release sufficient amounts of metals to cause reactions.

Certain factors which include the rate of ion release from the base metal denture which is in service, as well the number and types of ions absorbed by the target tissues of the human host, have yet to be determined.

Undoubtedly, the key factor is that this phenomena seems fundamentably to be corrosion.

This statement is greatly supported by Kuhn (14) in a recent publication about "Corrosion of cobalt-chromium alloys in aqueous environments", from which I extract the last statement:

"Thus we see that though it is over 80 years since cobalt-chromium alloys were first investigated, neither is their corrosion behavior understood nor is there any suggestion that one has yet achieved the optimum in performance that they can provide".

From those authors we got the aim of this experimental project. By the use of appropriate laboratory techniques we proceeded to evaluate the effects of conditions that can accelerate corrosion of cobalt-chromium dental alloys "in vitro".

We also measured "in vivo" the release of metal ions from cobalt-chromium dental alloys in patients wearing removable partial dentures.

1. THE EFFECT OF ABRASION ON CORROSION OF DENTAL COBALT--CHROMIUM ALLOYS

In this first experiment we tried to reproduce " in vitro" the agressive effects onto a cobalt-chromium denture when submitted to mechanical forces similar to tooth brushing or contact with opposing teeth. When in use in the mouth the corrosion resistance of cobalt--chromium alloys depends on the passivating film covering the alloys that may be affected by different factors, as previously mentioned.

The present experiment reports the results of a study planned to evaluate the effect of brushing or tooth contacts on the corrosion behaviour of two cobalt-chromium alloys used in prosthetic dentristry.

Materials and methods

Speciments of two commercial cobalt-chromium alloys* were used in the investigations , one intended for partial dentures and the other for crown and bridge wrok, as presented in Table 1.

Table 1. Composition of the alloys tested (in weight %). Analyses by electron microprobe, 10 spots analyzed per alloy*

	Wironium		Wirobond	
	Mean	SD	Mean	SD
Co	63.2	2.1	65.0	2.2
Cr	30.8	0.9	28.7	1.3
Mo	5.3	0.8	4.7	0.8
Mn	0.3	0.0	0.3	0.0
Fe	0.5	0.0	1.0	0.0
Si	0.9	0.1	0.9	0.0

* SD = standard deviation.

The chemical composition of the alloys testeded was determined by an electron microprobe (ARL — Scanning Electron Microprobe Quantometer). For each alloy 10 separate spots on the metal surface were analysed (16).

Three specimens of each alloy, with a rectangular surface (35 mm × 13 mm approx.), were cast by the induction method. Then embedded in epoxy resin and polished. The interface metal/resin was covered with plastic lacquer. The specimens were mounted in an apparatus as shown in Fig. 1.

The abrasion of the surface specimen was carried out with a rider which included either

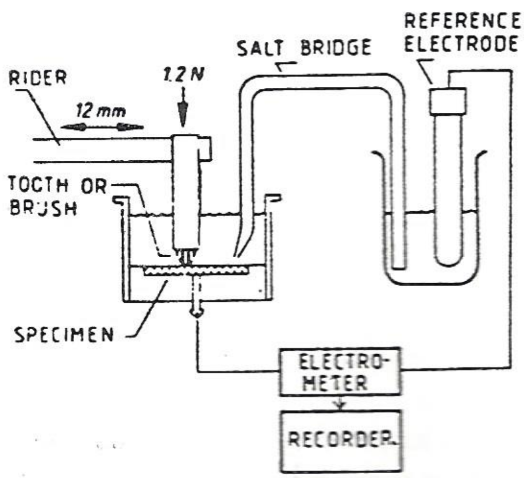

Fig. 1. The experimental set-up used for measuring the effect of abrasion on the corrosion of Co-Cr alloys. The brush or the tooth enamel was glued to the rider, which was moved by an electrical motor.

a toothbrush or the buccal portion of a human premolar. The brushor the tooth enamel was glued to the rider which was moved by an electrical motor with an amplitude of 12 mm, a frequency of 36 strokes/min., under an apllied load of 1.2N (the toothbrush had a contact area of 1.7 cm^2, whereas the tooth made a contact less than 1 mm wide). Electrical contac to the specimen was obtained by a screw through the resin.

The open-cell potentials were measured relative to Ag/Ag Cl reference electrode. The potentials were continously recorded during the test. The electrolyte was Fusyama artificial saliva and was open to the atmosphere at a temperature 23 ± 2° C and ph 5.0-5.5. The testing was devided into an initial period, during whith the metal was allowed to stabilize, and a test period (Fig. 2).

In the first 30 minutes of the test period the rider was moved close to, but not in contact with, the metal surface. During the next 30 minutes the rider was lowered in to contact with the metal. At the end of each period the electrolyte was drawn off and kept for analysis. Fresh electrolyte was then added. The amount of Co and Cr released were determined by electrothermal atomic absorption spectrophotometry (Perkin Elmer HGA 76 B). The potentials were read at the end of each period. To assess the effect of abrasion the potentials were compared for the non contact and the contact period.

Results:

During the initial period the potentials moved towards more positive values but stabilizes after 1 hour aproximatly. During the non--contact-period of the test the potentials vary very little. When the rider was lowered into contact with the metal there was a sharp drop in the potential (Fig. 3). With the brush values recovered rapidly but never reaching the starting values. The potential drop during tooth enamel contact was 2.3 - 4 times higher

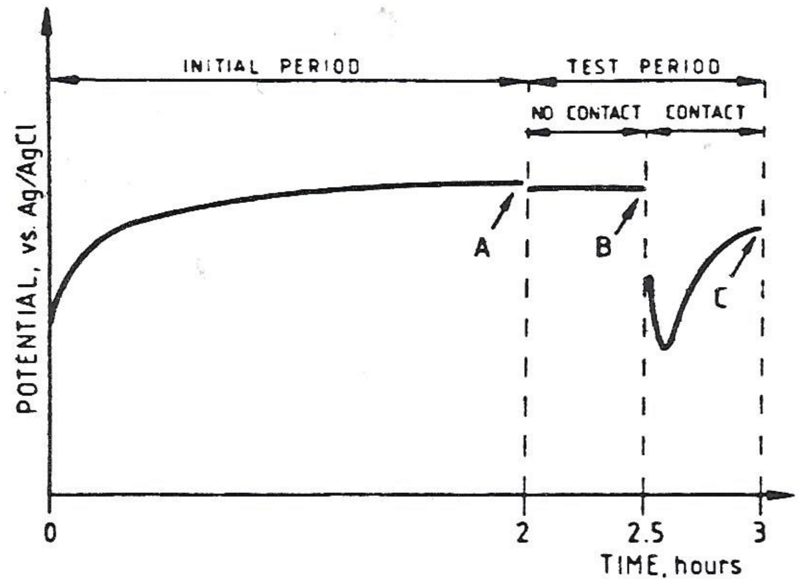

Fig. 2. Schematic representation of the potentials recorded during a test. In the initial period the alloy was allowed to stabilize. During the non-contact period the rider was moved close to the metal surface, whereas during the contact period the rider was in contact with the alloy. Potentials were read at A, B, and C. The electrolyte was changed between each period.

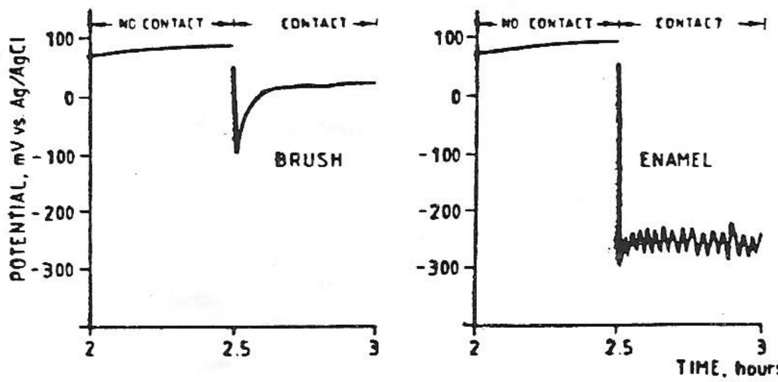

Fig. 3. Examples of potentials obtained during the test period. The material is Wironium. *Left:* brushing. *Right:* tooth (enamel) contact.

than during brushing. The potential drop during brushing indicates that even light abrasion increases the corrosion susceptility for a period due to the interfearence with passivating film covering the alloys. The increase in potentials after a few minutes suggests that repassivation takes place. The abrasion caused by tooth enamel, did not enable the metal to repassivate during the test.

Fig. 4 presents the changes in potentials and the amount of released Co and Cr due to abrasion with a brush or tooth enamel for the two alloys tested. The values represent the difference betwen the measurements during the contact and the non-contact periods. Abrasion with dental enamel caused a pronounced release of cobalt, which was 13 to 14 times higher than the values encountered during the brushing. The chromium values were much lower than the cobalt (factor of approximately 3). The potential changes and metal release during the tests indicate a behaviour similar to that which could be antecipated from the minor differences in chemical composition.

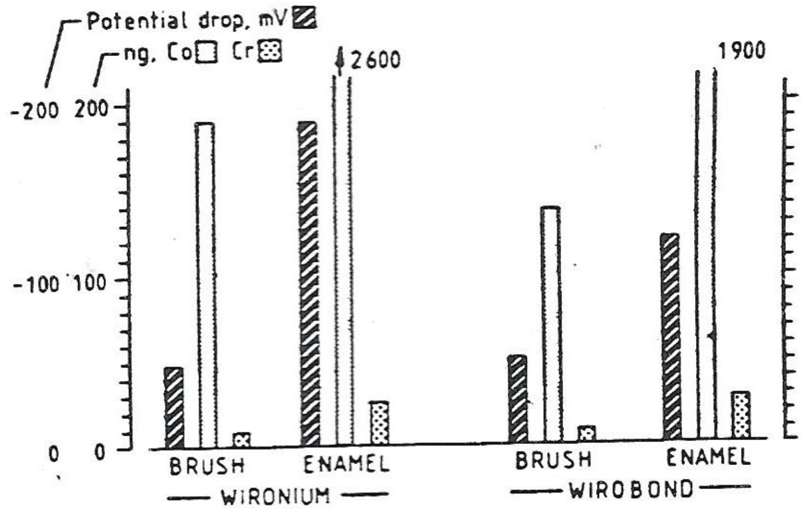

Fig. 4. The change in potentials and the amounts of released Co and Cr due to abrasion with a brush or tooth enamel for the two alloys tested. The values represent the difference between the measurements during the contact and the non-contact period.

Discussion

The present results do not enable a distinction to be made between the two alloys tested; however they may have distinct ranges of passivity, when submitted to potentiodynamic polarization curves.

The large amounts of cobalt detected as a result of the enamel-alloy contacts may be explained by the corrosion susceptibility of cobalt in the present ph range. Although chromium shows spontaneous passivation in this environment, cobalt ions may be released during the period of passivity breakdown due to abrasion. The release of cobalt in contrast with chromium is highly dependent on the type of abrasion.

This study demonstrates that the corrosion behaviour of presumably passive cobalt-chromium alloys is sensitive to even light abrasion. Transpassivation and repassivation are well illustrated and seem to occur rapidly and constantly when the metal surface is submitted to minimal mechanical agression.

Since restorations in the mouth are continuously subjected to abrasion and wear, protocols for corrosion assays of dental alloys should be take this aspect into consideration.

2. METAL RELEASE FROM COBALT-CHROMIUM PARTIAL DENTURES IN THE MOUTH

The aim of this second investigation was to establish whether cobalt-chromium dentures consistently release mesurable amounts of cobalt and chromium to the saliva of patients.

Materials and methods

Thirty patiens with cobalt-chromium partial dentures seen as pacients at the Prosthodontic Department at the School of Dentistry in Lisbon (Portugal) and Bergen (Norway) were asked to participate in the study (17).

Most patients included in the investigation wore dentures that had been in service for 3 days to several years. Some patients with new dentures, inserted some minutes before the saliva sampling, were also included.

The dental laboratories in which the dentures were made stated that they used cobalt--chromium alloys containing less that 0.5% nickel.

Saliva was sampled during five minutes with the mouth closed. Two samples were taken from each patient, one with the denture inserted and another without.

The saliva samples were treated as described in Fig. 5. The chemical analyses were done by electrothermal atomic absorption spectrophotometry (Model 372, Perkin Elmer+Graphite furnace).

A test of the accuracy of the testing method was performed by carrying saliva samples with known amounts of cobalt and chromium added through the complete analysing procedures.

Between 70% and 80% of the metals were retrieved with chromium showing the highest percentage of retrieval.

Results

The saliva concentrations of cobalt and chromium showed large variations between patients. Large variations in saliva secretion rates were also found (Table 2).

Laboratory procedure	*Patient procedure*
Acid-clean and weigh test tubes SALIVA SAMPLING ⟶ Find total mass of saliva Add water if mass is less than 0.5 g Take out 0.5 ml for analyzing Add 0.15 ml of concentrated HCl* Heat at 80°C for 8 h Atomic absorption analyzing procedure Calculate the concentrations of metals in saliva Calculate the differences in masses of metals between the A and B sample	Remove denture Wash the mouth with distilled water for 1 min Collect saliva for 5 min (A sample) Insert denture Collect saliva for 5 min (B sample)

* Suprapur, Merck, W. Germany

Fig. 5. Procedures for sampling and analyzing saliva samples.

The differences in total masses of metal in the saliva samples taken with and without the dentures inserted revealed that in more than 80% of the patients, amounts of cobalt and chromium incresed when the dentures were present. Chromium showed the highest median increase, approximately twice that of

Table 2 Saliva concentrations of cobalt and chromium, as well as saliva masses obtained with and without cobalt-chromium dentures present in the mouth. Patients with both old and new dentures are included

	Without denture		With denture		No. of patients
	Median	Range	Median	Range	
Cobalt (ng/g)	3	0–569	6	0–225 000	29
Chromium (ng/g)	6	1–196	10	3–1710	30
Saliva mass (g)	1.4	0.2–3.4	1.7	0.1–4.5	30

Table 3. Increase in absolute amounts of metals in the presence of cobalt-chromium dentures. 'Old dentures' are plates which have been in use for more than 3 days

	Median	Maximum	Minimum	No. of patients
Cobalt increase (ng)				
Old dentures	3‡	493	−8	22
New dentures	103*	740 000	2	6
Chromium increase (ng)				
Old dentures	6‡	198	−7	23
New dentures	37†	534	−9	7

Levels of statistical significance: *$p \leq 0.05$, †$p \leq 0.01$, ‡$p \leq 0.005$.

cobalt (Table 3). New dentures gave 3-6 times higher median values than older ones, which indicates that the alloys appear to become more strongly passivated with time and/or covered by deposits which reduce the corrosion.

It is interesting to mention that no patients reported any metallic taste related to their partial dentures. For dentures which have been in service for some time, the increase in cobalt and chromium was correlated with both age and size of the metal parts of the dentures (Table 4).

Older and smaller dentures released less than did newer and larger ones.

Discussion

This investigation demonstrates that release of metals from cobalt-chromium dentures is readily detected in a short time in an "in vivo" experiment.

From the results it is not possible to ascertain at what rate the corrosion continues, beyond the 5 minute test period. However abrasion during mastication may tend to increase the release of metals compared to the static experimental situation of this test.

Since it is established that only minor amounts of metal are needed to bring about reactions in sensitive subjects, it can be suspected that partial denture alloys may release sufficent amounts of metals to cause reactions.

Therefore we may conclude that there is always a potential risk that patients fitted with cobalt-chromium dentures may develop a hypersensitivity to any of the metal constituents.

The present results demonstrate that metal release is a consistent feature of cobalt-chromium dental alloys.

Table 4. Correlation coefficients related to the increase in absolute amounts of saliva metals in the presence of cobalt-chromium dentures. Only dentures which had been in use for more than 3 days are included

	Age of denture	Area of exposed metal	Cobalt, increase
Cobalt, increase	−0.55*	0.26	—
Chromium, increase	−0.33	0.54*	0.55*

* Values which are statistically discernible from zero at $p < 0.01$ level of significance.

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