

Heraeus

# bio- compatibility

Biological effects of dental  
alloy components – an overview

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## Components of dental alloys

As a result of greater health awareness in the population, dentists and dental technicians are increasingly being confronted with questions on the composition of dental materials.

This brochure aims to provide you with generally comprehensible information, so that you can quickly answer specific patient questions concerning dental alloys.

Even though the following text presents the specific properties of the individual alloy components, please note that the properties of an alloy cannot be explained by the properties of the individual components alone. An alloy features characteristics that are not shared by any of the individual elements contained in the alloy.

This is most easily explained using an example from daily life. Let us briefly examine common table salt.

It is not poisonous; it is even essential to human health. Chemically, table salt is NaCl, a compound consisting of sodium and chlorine. Sodium is a soft, silvery metal that easily ignites on contact with water. Chlorine is a very poisonous, green gas. Clearly, the properties of sodium and chlorine have nothing to do with the properties of table salt, since salt is neither ignitable using water nor poisonous.

Precious metal alloys are similar in this respect. In particular, the non-precious components are protected by the unreactive characteristics of the precious metals. Metals that, when alone, are easily soluble and subject to corrosion in the mouth are tightly bound in the alloys and only soluble in tiny amounts at the surface of the materials, if at all. Naturally, this optimised behaviour requires alloys that were developed and tested for the special demands in the biological environment. In addition, the processing and especially the casting process must be performed in consideration of the alloys' characteristics.

The effects of a medically used material on the patient largely depend on the release of its components to the patient. If no components are released, no biochemical reactions can take place. Therefore, knowledge of the corrosion values is the basis of all biocompatibility assessments. If these values are known, the risk associated with the corresponding material can be estimated using general knowledge of immunology and toxicology. Poor processing, especially regarding casting and surface processing, can significantly reduce the corrosion resistance of alloys.

Individual assessments of the alloy components that are most commonly used in dental technology are found below.

The biological assessment is preceded by a short summary of each element's area of use in dental technology.

Naturally, a comprehensive discussion is beyond the scope of this brochure.



Sodium (Na) and chlorine (Cl) combine to form table salt (NaCl)

## Chromium – Cr

Chromium is an indispensable additive to Cobalt and Nickel alloys, which only become corrosion-resistant with the addition of Chromium. The alloys are protected through a thin layer of Chromium oxides, which are characterised by high chemical stability.

Metallic Chromium and compounds of trivalent Chromium are relatively nontoxic to humans.

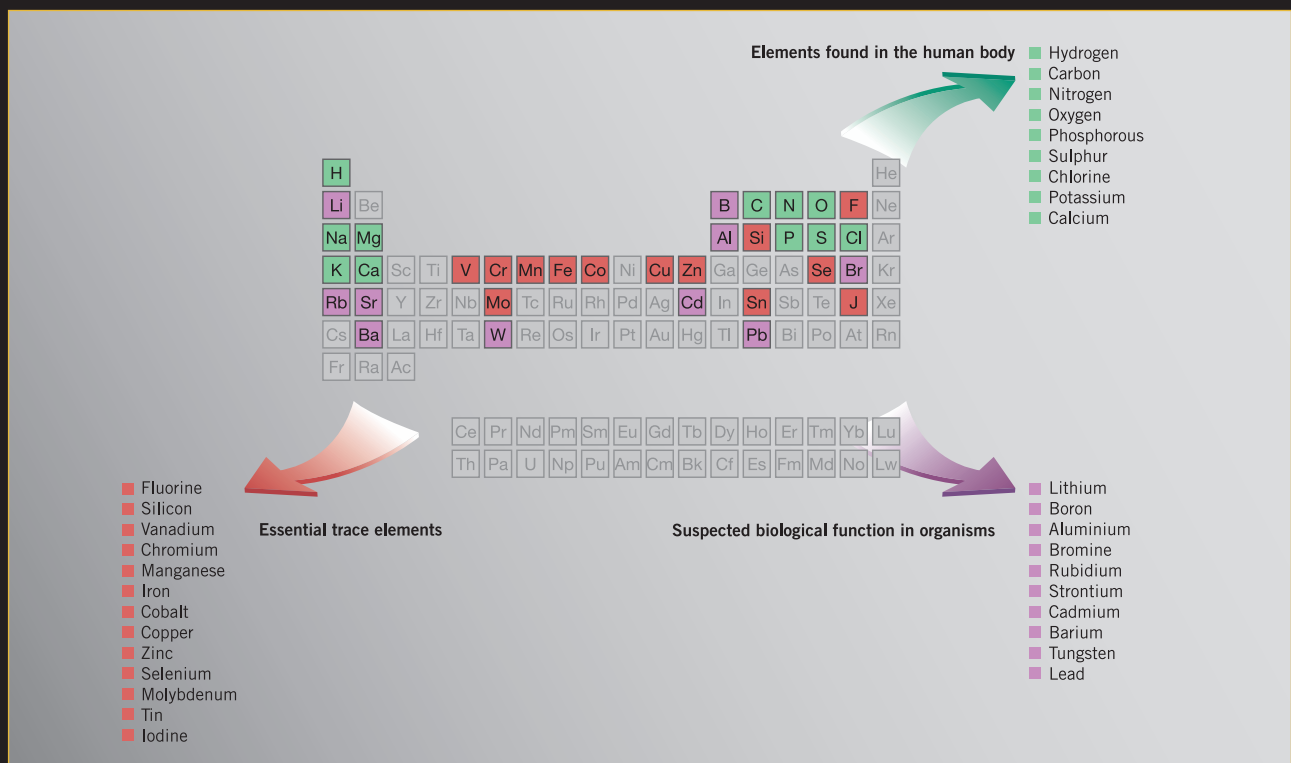
In contrast, hexavalent Chromium is highly toxic, allergenic and carcinogenic. However, hexavalent Chromium compounds cannot form from alloys in the oral environment. It is difficult to estimate the prevalence of Chromium metal allergies, since most tests are performed using hexavalent Chromium, with mostly positive results.

## Iron – Fe

Precious metal alloys only contain very small amounts of Iron.

Non-precious metal alloys contain Iron as an alloy component. In both types of alloys, it serves to fine tune some properties, such as hardness, strength, oxidation behaviour and structural constitution. We do not need to devote much space to the discussion of its biologically relevant properties, since the importance of Iron to human health is generally known. Humans need about 18 mg of Iron every day. Poisoning would require the consumption of large amounts of Iron compounds.

Likewise, allergies against an element of which we must consume such large amounts every day are only conceivable under extreme conditions.



Elements in the periodic table and their biological classification

## Components of dental alloys

### Germanium – Ge

This element more frequently encountered in microelectronics is rarely used as an additive in palladium-based alloys. It affects hardness and flowability.

The percentage of Germanium present in alloys is generally too small to cause toxic reactions. The allergological behaviour of Germanium alone is not well known at this time. However, no negative effects have been described to date in the context of dental alloys.

### Iridium, Rhodium, Ruthenium – Ir, Rh, Ru

These three metals are Platinum group metals.

Their properties, particularly their stability, are very similar to those of Platinum. In dental alloys, Iridium and Ruthenium are primarily used as grain refiners. They ensure a uniformly fine grain structure of the cast objects. Rhodium also controls the structural constitution, especially of alloys with high gold content, and it contributes to optimal strength.

No negative toxic or allergological effects of Iridium, Ruthenium or Rhodium are known to date, since these metals are insoluble and only found in small amounts in dental alloys.

### Gold – Au

Gold is the basis of the majority of dental alloys.

Its extremely high stability predestines Gold for use in patients' mouths.

The warm colour of Gold allows the dental technician to more easily achieve a natural colour in metal-ceramic restorations. Varying the alloy components permits the development of adequate gold-based materials for almost all indications and technical demands.

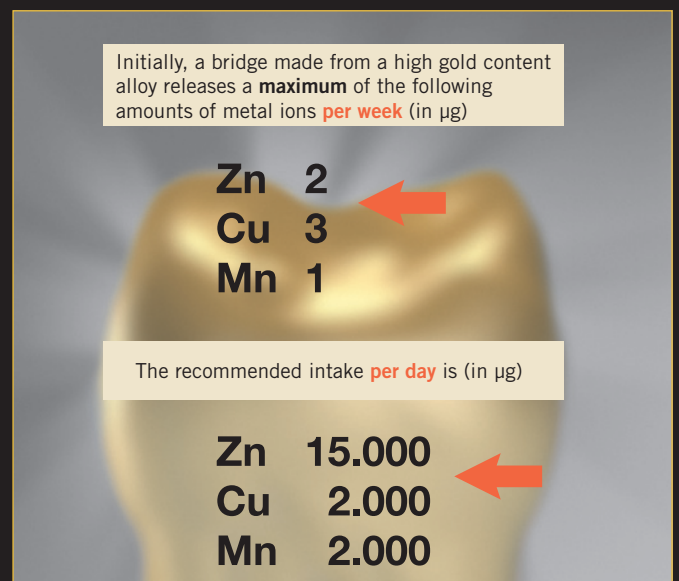
Metallic Gold features very good biocompatibility because of its great stability. Synthetic Gold compounds (such as Gold cyanide) irritate the skin, and some sensitise skin, since aggressive chemicals have to be used to dissolve Gold.

Toxic reactions to metallic Gold are impossible, and alleged immunological phenomena are very rare. Please also refer to the "Allergy test" chapter in this regard.

### Indium – In

Pure Indium is a silvery-white metal that is very similar to Tin. Indium is a hardening component of classic high gold content alloys for use with ceramic veneers. Reduced gold and palladium-based alloys are also primarily "hardened" using Indium.

Indium also lowers the casting temperature, which is particularly important in materials with high palladium content. Indium's oxidation behaviour in oxidation firing significantly contributes to metal-ceramic adhesion. For most organisms, including humans, Indium is not necessary for survival. The toxicological and allergological characteristics of Indium are not very well known. However, systemic toxic effects are only to be expected with the ingestion of greater amounts than those that can be present in dental alloys. Local toxic effects, such as at the gums, are conceivable in case of inadequate cleaning of oxidised alloy surfaces. Therefore, all oxides and impurities arising during manufacturing must be removed by polishing or pickling of the surface after a dental restoration is completed (see current Instructions for use for dental alloys).



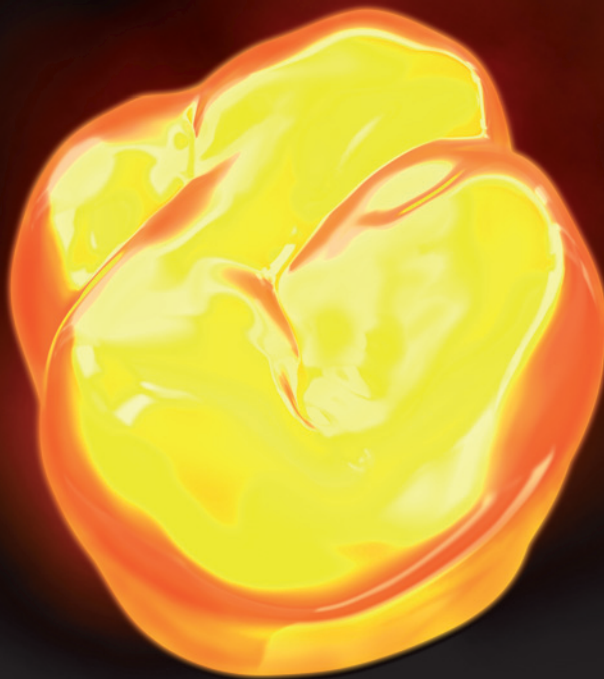
Metal ions released to the body

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### Gallium – Ga

In palladium-based alloys with low or no silver content, elements that lower the melting point of Palladium must be added for common laboratory casting machines to be used. Gallium is the most effective element for this purpose. At 29.8°C, the melting point of pure Gallium is insignificantly higher than room temperature. Even a few percent of Gallium therefore very effectively lower the melting range of palladium based alloys. At the same time, adding Gallium “hardens” the material.

Not very much is known to date about the toxicological and immunological properties of Gallium. However, the doses identified as toxic in animal experiments are much higher than those potentially released from dental alloys. There are very few reports on allergic reactions to Gallium. Allergic reactions against Gallium contained in dental alloys are very rare.

### Manganese – Mn

Manganese is only used to a very small extent in precious metal and non-precious metal alloys. Small amounts, about one-tenth of a percent or even less, contribute to optimised strength and adhesive oxide formation. Like many other metals, Manganese is also essential to the human body.

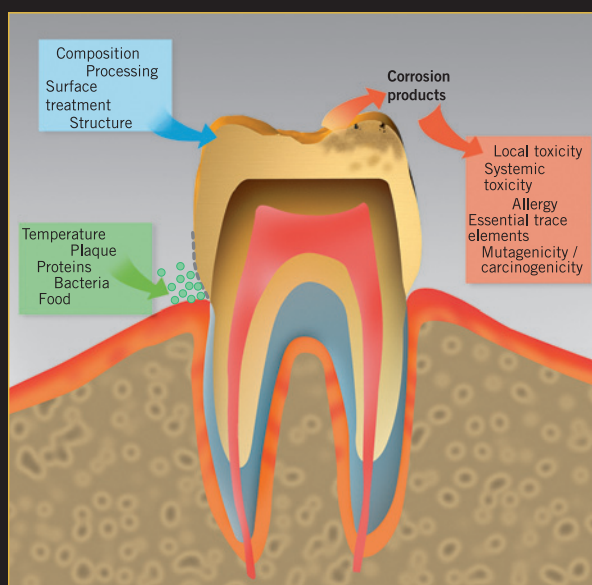
The daily requirement is about 3 mg. Reactions against Manganese have only been found in the processing of pure Manganese dust. The amounts contained in dental alloys are irrelevant to humans, since they are a thousand times smaller than the doses consumed in food, which are necessary for survival.

### Copper - Cu

Almost all gold casting alloys contain Copper. Together with Silver, Copper ensures the necessary mechanical qualities in these materials. The only coloured metal other than Gold, it also has a positive effect on the colour of the alloy, giving it a more intensive, sometimes slightly red-dish gold shade.

Copper is an essential trace element for humans and most other higher organisms. The recommended daily intake is about 3 mg. Copper is very important, particularly for the body's energy metabolism.

Because of the relatively large amounts needed by the human body, Copper allergies are extremely rare. Systemic intoxication is also only conceivable when consuming extremely high amounts of soluble copper compounds. Copper displays cytotoxic effects when in contact with microorganisms, such as the bacteria found in the oral cavity. This represents a desirable and important caries-inhibiting effect. Copper, and a little more frequently the similarly effective Silver, are therefore added to fastening cement as easily soluble compounds to reduce the incidence of secondary caries.



Corrosion products and their effects

## Cobalt – Co

In dental technology, cobalt is primarily used as the base metal for partial denture and CoCr ceramic-bonding alloys. Today, it is only rarely used as a component of precious metal alloys. Cobalt alone is not stable enough for medical use, and it must be passivated by the addition of Chromium and Molybdenum.

Very small amounts of Cobalt are essential to the human body. In particular, vitamin B<sub>12</sub> contains Cobalt. But even excessive doses of vitamin B<sub>12</sub> can cause allergies or even poisoning. About 3% of the German population exhibit allergic reactions upon skin contact with metallic Cobalt. When assessing the risks associated with Cobalt, it is important to consider that it is always contaminated with traces of Nickel. So-called nickel-free dental Cobalt materials contain less than 0.1mass% Nickel. However, even less than 0.1mass% may cause immunological problems in patients diagnosed with nickel allergy.

## Palladium – Pd

Palladium is a platinum group metal. Hence, it is a precious metal and features good corrosion resistance. As a secondary component of high gold content alloys, Palladium significantly contributes to good strength and firing stability, but it has a discolouring effect on gold alloys. Reduced-gold and gold-free precious metal ceramic alloys are also based on Palladium. Palladium provides these materials with the required corrosion resistance. Palladium-based alloys with Copper content should no longer be used because of possible processing problems; they should be replaced by copper-free palladium alloys (BGA [German Federal Health Office] 1993).

In contrast to elements such as Zinc and Copper, Palladium is not an essential element. However, Palladium is also present in the environment in small amounts (approx. 2 ppb).

High doses of Palladium in the form of soluble compounds have cytotoxic or systemic toxic effects. Doses identified as toxic in animal experimentation cannot be reached based on dental alloys.

Statements published in the early 1990s indicating that Palladium is highly toxic or even carcinogenic were shown to be indefensible.

Immunological and allergic reactions to Palladium alloys are possible. There is evidence that especially patients who exhibit allergic reactions against Nickel may also be sensitised to Palladium. Alloys containing Palladium should not be used in patients with known allergies to Palladium or its salts, such as palladium-chloride.

## Molybdenum – Mo

Together with Chromium, Molybdenum ensures adequate corrosion resistance and optimised mechanical properties in Cobalt and Nickel-based materials. Molybdenum is an essential element in the human body. There have been no reports to date on poisoning or allergies.

## Nickel – Ni

Nickel serves as the base metal for very inexpensive dental alloys and as an additive for many solders. Many orthodontic alloys contain Nickel, including those on Titanium basis. In humans, Nickel is considered the metal with the highest allergy risk upon skin contact. Nickel consumed with food is relatively nontoxic and has a lower allergenic potential. However, about 17% of the female population are already sensitised to Nickel; they are at risk if supplied with Nickel alloy restorations.

Nickel-containing dust is carcinogenic; the processing of Nickel alloys therefore requires particular caution.

## Components of dental alloys

### Platinum – Pt

In gold-based materials, Platinum is an essential component to increase strength and hardness. Its stability is equivalent to that of Gold. The only disadvantage is Platinum's discolouring effect on Gold, which makes alloys with higher Platinum content quickly appear "pale yellow". Platinum is insoluble in patients' mouths, which guarantees good tolerability. In contrast, Platinum salts produced with complex chemical agents are quite toxic and exhibit allergenic potential. However, the characteristics of these salts must not be confused with those of the pure metal. Therefore, Platinum and Gold are the basis for highly biocompatible alloys, especially for sensitised patients.

### Silver – Ag

Although Silver is considered a precious metal in the literature, it must always be combined with the much more stable metals Gold and Palladium when used in dental alloys. The passivation effect of Silver alone is not adequate in the oral environment, since various components of saliva can attack this passivation layer. Together with Copper, Silver renders Gold casting alloys hard and strong. The addition of Silver causes palladium-based alloys to flow better and melt at lower temperatures. Like Copper, Silver has a toxic effect on microorganisms. Therefore, Silver compounds are often used as a bacteriostatic additive in fastening cements. For higher organisms such as humans, Silver is much less toxic. Silver cutlery has been used for centuries. Silver has also been used in dental alloys since artificial dental restorations were first developed. Reports of Silver allergies are very rare. So-called "Silver allergies" to Silver jewellery are often caused by nickel-containing coatings.

### Tantalum - Ta

Tantalum is only added to dental alloys in very small amounts. Its content in precious metal materials is always below one percent. Nevertheless, these small amounts are often crucial to the internal structure and strength of the cast units. Special implants, such as cardiac pacemaker leads, are also made from Tantalum. Clearly, Tantalum is considered a very biocompatible metal. Toxic reactions to the amounts present in dental alloys are not expected, and no Tantalum allergies have been reported so far.

### Titanium – Ti

Small amounts of Titanium are occasionally added to precious metal alloys. Titanium has a very negative effect on structure. However, the easily oxidised Titanium is fairly unreliable in this respect, and it especially reduces recastability. The adhesion of Titanium oxide layers to ceramic veneers is also a problem. Titanium is released from precious metal alloys in quantities too small to measure. The corrosion rates of so-called commercially pure Titanium are similar to those of gold-casting alloys. In contrast to the latter, Titanium does not exhibit a reduction in corrosion rates with time. The Titanium accumulation in various organs observed in animal experimentation is likely immunologically and toxicologically irrelevant for humans. Only isolated cases of Titanium allergies have been described to date.

## Zinc – Zn

Zinc improves flowability, especially in gold-casting alloys. When combined with Platinum and other elements, Zinc is the most important “hardening” component in modern metal-ceramic alloys such as “Bio Herador N”.

After Iron, Zinc is the most important essential trace element for the human body. More than one hundred enzymes in the human body contain Zinc as an essential component. Zinc deficiency, which is relatively common, causes immune system disturbances.

As a medication, Zinc is therefore used to strengthen the body’s defences and to treat heavy metal poisoning. As another example of its importance, Zinc is required for the breakdown of alcohol in the liver.

Since Zinc is a familiar element to the body, any amounts consumed are quickly transported to parts of the body where it is needed. According to WHO recommendations, an adult requires about 15 mg of Zinc per day, which can be easily consumed with a balanced diet. Because of the high recommended daily intake, Zinc poisoning is only possible when consuming large amounts. Allergic reactions to Zinc are not known at this time, and they are not expected given the high essential dose. Higher concentrations of Zinc have a bacteriostatic effect on microorganisms. This is one reason for the great success of Zinc-phosphate cements.

## Tin – Sn

Tin is used to improve the hardness of gold-cast alloys. In reduced-gold metal-ceramic alloys, Tin improves flowability and increases hardness. In solder and palladium-based alloys, Tin is used to lower the melting range. Metallic or inorganically bound tin is only poisonous to humans in high concentrations. Most experience on this matter comes from foods conserved in Tin cans. The typical Tin concentration in canned foods is 20-50 mg/kg. The highest tolerable level is considered 250 mg/kg.

The amounts of Tin released from dental alloys are negligible in comparison. Organically bound Tin, such as was used in the past in some medications and in fungicides, etc., is quite poisonous to humans, but it is not released from precious metal dental alloys.

No allergies against Tin are known to date.

## Cerium – Ce

Cerium increases the strength of high-gold-content alloys. In addition, it improves metal-ceramic adhesion. There is not much known about the toxicology of Cerium. However, the toxic doses identified in animal experimentation are far above the Cerium content of dental alloys. Allergies against Cerium are not known to date.

## Overview of the biological effects of alloy components

The most important information on the biological effects of individual alloy components is summarised in the following overview.

Element	Essential amount/day	Intake/day	Systemic toxicity	Cytotoxicity	Allergies
Beryllium	–	0.02 mg	High, dust is carcinogenic	High	Common
Chromium	0.05 mg (uncertain)	0.1 mg	Metal and Cr(III)salts: Low, Cr(VI): High	Cr(III)salts: Low Cr(VI): High	Cr(VI): Common
Iron	18 mg	10 - 20 mg	Very low	Low	Very rare
Gallium	–	0.0005 mg	Low	Low	None reported
Germanium	–	0.4 - 3.5 mg	Very low	Low	None reported
Gold	–	0.0001 mg	Very low	Low	Metal: rare, Compounds: possible
Indium	–	0.003 mg	Low	High	Rare
Iridium	–	0.000002 mg	Very low	Low	None reported
Cobalt	0.03 mg	0.2 mg	Low	High	3% of the population
Copper	3 mg	2 - 5 mg	Low	Very high	Very rare
Manganese	3 mg	3 mg	Metal: Very low; dust: High	Low	Very rare
Molybdenum	0.2 mg	0.3 mg	Low	Low	None reported
Nickel	Uncertain	0.5 mg	Dust carcinogenic, otherwise low	Low	Very common
Palladium	–	0.001 mg	Very low	Very low	Prevalence unknown, those allergic to nickel are more commonly affected
Platinum	–	0.001 mg	Very low	Low	Metal: Very rare, Compounds: common
Rhodium	–	Not known	Very low	Low	None reported
Ruthenium	–	0.0002 mg	Very low	Low	None reported
Silver	–	0.05 mg	Low	Very high	Rare
Tantalum	–	Not known	Very low	Very low	None described
Titanium	–	1 mg	Very low	Very low	Very rare
Zinc	15 mg	20 mg	Very low	High	Very rare
Tin	–	0.2 mg	Low	Low	very rare
Cerium	–	–	Low	Low	None reported

The information on essential quantities is based on WHO recommendations. Some daily intake values are taken from the literature; others were estimated based on the composition of typical foods. Information on systemic toxicity comes from different sources in toxicological literature. Cytotoxicity information particularly takes into account examinations on murine fibroblasts. High cytotoxicity also results in a high antibacterial effect, which can certainly be considered a positive characteristic if the element has other positive biological properties (e.g. Copper). Information on the prevalence of allergies was taken from different sources.

## The epicutaneous test for metal allergies

The vast majority of allergy tests are still performed using the epicutaneous test.

Patients who have taken this test often present an allergy ID card to the dentist or dental technician, so that suitable materials can be identified for their dental restoration based on the test results.

### How does this test work?

To test for allergic sensitivity, different test substances are applied by the physician to the skin of the back or forearm. The test uses a very large number of test substances that are encountered in daily life and known to have a potential sensitising effect. In some cases, the skin is scratched beforehand to provoke a reaction of the body. After a certain waiting period, the patient is examined for typical allergic symptoms, such as pustule formation, to see if the body is reacting to the test substances. This is then a sign of allergy against the respective substance. The test for metal allergies usually uses metal salt solutions rather than the metal itself.

It has been shown that patients react much faster and more strongly to these salts than to the metals themselves. In tests for metals such as Nickel, Cobalt and Copper, this method is certainly appropriate, since these metals release ions that largely correspond to those in the salt solutions (hydrated M<sup>2+</sup> or M<sup>3+</sup> ions) when under the corrosive influence of saliva and sweat.

However, the compounds used for some metals are unsuitable in our opinion. For example, Chromium allergies are tested using potassium dichromate, a salt in which Chromium is present in the oxidation state 6, as Chromium (VI).

However, corrosive processes in Chromium alloys in the mouth only result in Chromium (III) compounds, which in addition are highly insoluble. Chromium (VI) (the test substance) is known to be at least 1000 times more toxic to humans than Chromium (III). Furthermore, Chromium (VI) compounds have a sensitising effect, even in small amounts. Studies published in the US indicate that the use of such unsuitable test substances can actually trigger the corresponding allergies. The use of salts in the epicutaneous test for precious metals is particularly problematic; two types of precious metal salts are used in this test, simple salts and complex salts.

Precious metals are unreactive since they are difficult to chemically attack or dissolve. For example, the test for Gold allergies uses so-called „aqua regia“, a mixture of concentrated hydrochloric acid and nitric acid as a solvent. It is obvious that these solutions must not be applied to the patient's skin. The acids contained in them would destroy the skin.

However, the salts (chemical combinations of metals and acids) produced by such solutions (e.g. tetrachloroauric acid) affect the skin of the patient with components other than the Gold. As a precious metal, Gold strives to leave the bond with the acid, and the salt splits into its reactants when in aqueous solution and exposed to air (such as on the skin). This means that in addition to pure gold (one part of the compound), the acid used to form the solution also acts on the skin. It is difficult, if not impossible, to differentiate with certainty the irritant effect of the acid from the allergenic effects of the salt.

One example of the practical use of this mode of action is the use of silver-nitrate, also known as lunar caustic. So-called „Silver powder“ for wound disinfection, especially of the umbilicus in neonates, works by the principle explained above. On the moist wound, silver-nitrate decomposes into black Silver powder and nitric acid. The acid, which is desirable in this case, ensures the antibiotic-free disinfection of the wound. However, silver-nitrate is certainly not very suitable for an epicutaneous test for this reason. All simple precious metal salts act in a similar manner.

Since this is known, complex salts are beginning to be used as test media for Gold allergies.



Epicutaneous test

Gold-sodium-thiosulfate and potassium-dicyanoaurate are the best known complex salts for this purpose. The former has been used as a pharmacologically active substance in rheumatism medication for some time. Allergies against gold-sodium-thiosulfate are known from this indication area. However, it is inconceivable based on current knowledge that this compound can form from gold-containing dental materials under the conditions found in the body. Furthermore, gold-sodium-thiosulfate is not contained in alloys, as is occasionally incorrectly stated on the package insert of the test substances. Potassium-dicyanoaurate, a complex salt made from gold-cyanide and potassium-cyanide, is just as problematic for use with the epicutaneous test, since a positive allergic reaction to complex salts of gold merely demonstrates an allergy against that specific salt and does not necessarily apply to other salts or even metallic materials. Unfortunately, there is currently no recognised alternative to the epicutaneous test that can be performed as easily and universally; however, supplementary diagnostic testing using the lymphocyte transformation test – LTT – appears to be an option. The sensitisation potential to the major elements of a dental restoration is performed using a blood test. This test can preventatively give an idea about potential sensitisation before a dental restoration is placed. However, LTT can also give useful information in the diagnostic clarification of potential allergic reactions to one or several components of a dental restoration that are already present. We believe that metallic test objects from the same alloy or pure metal should be used when testing for allergies to alloys, rather than using chemicals with an unknown mode of action. If there are questions when selecting materials based on an allergy ID card, please do not hesitate to contact the Heraeus specialists by phone at 0800.4372522 or by fax at 0800.4372329.

### **Metal compounds often used in the epicutaneous test**

#### **Cobalt-chloride, Cobalt-sulfate**

Cobalt salts, such as those formed when alloys corrode. In case of a positive epicutaneous test, do not use cobalt-containing alloys.

#### **Nickel-chloride, Nickel-sulfate**

Nickel salts, such as those forming when alloys corrode. In case of positive epicutaneous test, do not use nickel-containing alloys.

#### **Potassium-dichromate**

Highly toxic chromium compound that is used to test for chromium allergies but is suspected to actually trigger allergies when used in testing. Does not form from chromium-containing alloys in the patient's mouth.

#### **Potassium-dicyanoaurate**

Complex salt produced from gold-cyanide and potassium-cyanide. Contained in industrial electroplating baths. Is used to test for gold allergies. Cannot be formed in the patient's mouth and is therefore poorly suited for testing for gold allergies.

#### **Gold-sodium-thiosulfate**

Gold compound also present in medications against rheumatism. The sensitising effect of these medications has been known for a long time. In the patient's mouth, this compound cannot form from the metallic gold found in the alloy. Gold-sodium-thiosulfate's suitability as a test substance is therefore questionable.

#### **Potassium-hexachloroplatinate**

Various platinum salts are known as sensitisers in industrial practice. However, they are only formed from metallic platinum in the presence of various aggressive chemicals that are not present in the mouth. Platinum metal allergies are therefore considered extremely rare.

#### **Palladium-chloride**

Palladium salt that can be formed when alloys corrode. Avoid palladium-containing alloys in case of allergy.

#### **Phenylmercuric-borate and other mercury compounds**

indicate mercury allergies. However, the informative value of the various substances used in the test varies considerably. In case of a positive reaction, do not use amalgam as a precaution.

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