# Dental Biocompatibility and Oral Galvanism Online Learning Video Activity Script

International Academy of Oral Medicine and Toxicology (IAOMT); <a href="www.iaomt.org">www.iaomt.org</a>
Last updated October 2020

# PREFACE TO IAOMT'S DENTAL BIOCOMPATIBILITY AND ORAL GALVANISM ONLINE LEARNING VIDEO ACTIVITY

### Text on screen:

Welcome to IAOMT's Dental Biocompatibility and Oral Galvanism Online Learning Video Activity. The "Materials" tab above this video, as well as the text box below this video, contain links to references and resources cited in this activity, scientific literature related to the topics presented, and a script for this entire video. The successful completion of a quiz at the end of this activity is required for individuals participating in an IAOMT course.

In offering this activity, the IAOMT's intention is to present as much scientific information as possible on different dental materials, treatments, patient and dental staff safety, and other aspects of dentistry.

The objective of the Dental Biocompatibility and Oral Galvanism Online Learning Video is that at the conclusion of this activity, participants will be able to acknowledge the variance in patients' biochemical and immunological responses to dental materials.

The IAOMT emphasizes that health care practitioners must make their own professional judgments for the benefit of themselves and their patients and staffs. You are responsible for exercising your own judgment concerning the specific treatment options to utilize in your practice; for complying with applicable laws and regulations including local dental practice acts and informed consent requirements; and for abiding by insurance requirements including written declarations of coverage.

# Only proceed if you understand and agree with these statements.

If you are ready to proceed, the activity will begin with Steve Koral, DMD, MIAOMT, and Mark Wisniewski, DDS, AIAOMT, providing you with the coursework for this Dental Biocompatibility and Oral Galvanism Online Learning Video Activity.

### **INTRODUCTION**

Welcome to the International Academy of Oral Medicine and Toxicology, the IAOMT, training course on biocompatibility of dental materials.

Everything we use in restorative dentistry is artificial. There's no such thing as a "natural" filling material. Until we can replace body parts (including teeth) with all "self" materials, the concept of biocompatibility will always represent an approximation and a work in progress.

In this course, we will look at some of the positive and negative attributes of dental materials, consider the case of chemically sensitive people, and examine some of the ways to do individual biocompatibility testing.

By using dental materials that are less overtly toxic, and by recognizing the fact that individuals vary in their biochemical and immunological responses, we can raise the biocompatibility quotient of our practice. We will introduce some concepts of biochemical individuality and sound methods of immunological testing in this exploration to find solutions to old problems.

Our objective is to provide the information you need to help determine the least reactive materials to use with each individual patient. The more a patient suffers from allergies, environmental sensitivity, or autoimmune diseases, the more important this service becomes.

Your patients will appreciate your search for truth and knowledge and will reward you for it.

In 2001, a poll in a popular dental newsletter asked dentists about their most important criteria for choosing restorative materials. Only 4% said that biocompatibility was their highest priority. The IAOMT represents those dentists, the 4%. The fact that there are so many new ways to make dentistry work better gives us the opportunity to keep biocompatibility as our first concern.

# **Text on screen right:**

How do dentists choose a restorative material?

- 47% durability
- 22% patient's preference
- 12% esthetics
- 10% ease of use
- 4% biocompatibility



Source: Clinical Research Associates. CRA Newsletter: Clinicians' Preferences. 2001;25(12):3. [Now Gordon J. Christiansen Clinicians Report.]

# **FDA AND DENTAL MATERIALS**

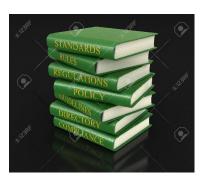
A general principle biocompatible dentistry would state is that everything we implant or leave in and around a tooth represents a systemic exposure whose impact must be accounted for and considered. The good news is there is an extensive program of testing for materials newly introduced into the market. The ISO-10993 standard and its American version, the FDA's "Blue Book Memorandum G95-1," outline these requirements.

The problem is that in the real world of the dental marketplace, this thorough testing regime is almost always bypassed by the FDA's "Grandfather Clause" section 501(K) of the FDA statute of 1976. As well, laboratory benchtop biocompatibility testing doesn't account for variations in patients' individual responses to artificial materials.



Perhaps in an attempt to improve the status quo, in 2016, the United States Food and Drug Administration (FDA) published a document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'" The purpose of the publication was to provide non-binding recommendations and to offer the "current thinking" of the FDA on the topic of risks of medical devices.

Source: U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health. Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff. June 2016. https://www.fda.gov/media/85865/download



An updated version of the ISO 10993-1 was subsequently published in August 2018. It contained some changes in regard to medical device testing, and it was stated that the primary aim of that document was "protection of humans from potential biological risks arising from the use of medical devices."

Source: ISO/TC 194 Biological and clinical evaluation of medical devices. ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process. 11.100.20 Biological evaluation of medical devices. August 2018. https://www.iso.org/standard/68936.html



However, a company that offers support for medical device testing, including "rationales for the selection or waiving tests" explained of the new version of ISO 10993-1 published in 2018: "In the new version of the standard, not all biological effects should be assessed by biological testing. Some tests can now be waived if there is a sound rationale to support the decision."

Source: Cambiaghi A. Biological Evaluation of Medical Devices as an Essential Part of the Risk Management Process: Updates and Challenges of ISO 10993-1: 2018. <a href="https://cdnmedia.eurofins.com/european-west/media/1927774/9432">https://cdnmedia.eurofins.com/european-west/media/1927774/9432</a> biological-evaluation-of-medical-devices whp.pdf



At the 2019 8th European Workshop on Visual Information Processing (EUVIP), researchers openly stated that the standard ISO 10993 is "not intended to provide a fixed set of testing methods, including acceptance criteria" and that "the final opinion is on the manufacturer." These types of comments have led many to consider these regulations as more favorable to industry's profits than protective of consumers' health.

Source: Augustynek M, Cihak J, Vilimek D, Kubicek J, Penhaker M, Fiedorova K. Biocompatibility of Medical Devices and Their Risks. In2019 8th European Workshop on Visual Information Processing (EUVIP) 2019 Oct 28 (pp. 228-231). IEEE.



Implant Files

Health authorities across the globe have failed to protest millions of patients from poorly tested implants, the first-ever global examination of the medical device industry reveals.

The situation has been gaining attention from concerned citizens and even investigative reporters. For example, the International Consortium of Investigative Journalists shared medical implant stories from their readers in November 2019. They collected "more than 3,500 responses from people affected by the medical device industry in 50 countries, bringing to life the personal cost of implants that fail." To date, they are still running news stories as part of their Implant Files.

Source: Wilson-Chapman A, Armendariz A. Readers from 50 countries share medical implant stories. International Consortium of Investigative Journalists Implant Files. November 16, 2019.

Image: Christina Chung / ICIJ and reproduced with permission from the International Consortium of Investigative Journalists.

Learn more at https://www.icij.org/investigations/implant-files/



While industry has continued to profit from the new testing guidance, injured consumers have continued to fight back. Most notably, public pressure was put on the FDA about adverse health effects from dental amalgam fillings, as well as the metal-containing birth control device Essure (which was eventually ended for distribution in the USA on December 31, 2018).

These concerns and more finally led the FDA to host a meeting of the Immunology Devices Panel about dental amalgam and metal implants on November 13-14, 2019. Prior to the panel meeting, the FDA had shared two new documents, one being a literature review on dental amalgam and the other being a review of scientific information related to metals and their uses in implants.

Food and Drug Administration

[Docket No. FDA-2019-N-3767]

Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting;

Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Immunology Devices Panel of the Medical Devices Advisory

Committee. The general function of the committee is to provide advice and recommendations to FDA on scientific issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 13 and 14, 2019, from 8 a.m. to 6 p.m.

Some IAOMT members wrote responses to the FDA highlighting risks and studies overlooked in their reviews, and Dr. Jack Kall, the Executive Chairperson of the IAOMT Board of Directors, spoke at the Immunology Devices Panel meeting to share pertinent research and express concerns. The following is an excerpt from his presentation.

#### Sources:

U.S. Department of Health and Human Services Food and Drug Administration (FDA). Epidemiological Evidence on the Adverse Health Effects Reported in Relation to Mercury from Dental Amalgam: Systematic Literature Review (2010-Present). September 2019. <a href="https://www.fda.gov/media/131151/download">https://www.fda.gov/media/131151/download</a>

U.S. Department of Health and Human Services Food and Drug Administration (FDA). Biological Responses to Metal Implants. September 2019. https://www.fda.gov/media/131150/download

Kall J, Just A. Comments in reference to Docket ID No. FDA-2019-N-3767: Immunology Devices Panel of the Medical Devices Advisory Committee Meeting on Dental Amalgam and Metal Implants. October 15, 2019.

https://www.regulations.gov/contentStreamer?documentId=FDA-2019-N-3767-0026&attachmentNumber=1&contentType=pdf

Insert clip of "Executive Chairman of the Board, Jack Kall, DMD, MIAOMT, Testifies to the FDA 2019" from IAOMT YouTube Channel: <a href="https://youtu.be/OGiNIhAAci8">https://youtu.be/OGiNIhAAci8</a>



On September 24, 2020, the FDA issued recommendations for dental amalgam that warned "harmful health effects of mercury vapor released from the device" could impact high-risk populations. In particular, the following groups are now advised by the FDA to avoid getting dental amalgam whenever possible and appropriate: pregnant women and their developing fetuses; women who are planning to become pregnant; nursing women and their newborns and infants; children, especially those younger than six years of age; people with pre-existing neurological disease such as multiple sclerosis, Alzheimer's disease or Parkinson's disease; people with impaired kidney function; and people with known heightened sensitivity (allergy) to mercury or other components of dental amalgam.

Source: United States Food and Drug Administration. FDA Issues Recommendations for Certain High-Risk Groups Regarding Mercury-Containing Dental Amalgam. September 24, 2020. Available from: <a href="https://www.fda.gov/news-events/press-announcements/fda-issues-recommendations-certain-high-risk-groups-regarding-mercury-containing-dental-amalgam">https://www.fda.gov/news-events/press-announcements/fda-issues-recommendations-certain-high-risk-groups-regarding-mercury-containing-dental-amalgam</a>.



Clearly, this is an issue in which we, as biological dentists, should continue to closely monitor: Future regulatory deliberations are inevitable based on the FDA's current stance. Meanwhile, millions of patients around the globe have these materials placed inside their bodies with little to no regard for potential side effects and variance in their biochemical and immunological responses.

# ADVERSE REACTIONS TO METAL IMPLANTS AND DEVICES

As biologically minded dentists, we strive to achieve all the goals of modern dentistry while treading as lightly as possible on our patient's biological terrain. So, while we work to maximize the positive attributes of our restorative materials: strength, durability, comfort, and esthetics; we seek at the same time to minimize the negatives: toxicity, immune reactivity, and galvanic stress.

Most of us practice dentistry in the belief that the biocompatibility of dental materials and procedures is a settled issue. It turns out, though, that our customary materials and procedures range from very benign to extremely hazardous. Some of our all-time favorites, mercury and fluoride in particular, have obvious toxic effects that can be detected when they are used "properly."

Some metals used in dentistry and medicine have no established function in the human body, and in addition to aluminum, which is both a neurotoxin and an immune stimulator, these include gold, mercury, nickel, palladium, platinum, silver, and titanium. Mercury is recognized as being toxic to humans even in low doses, and researchers have identified other materials used in implants and devices as metals of concern, including chromium, cobalt, copper, gallium, gold, iron, lead, manganese, mercury, nickel, platinum, silver, tin, vanadium, and zinc.



Researchers have also established that chronic exposure to low doses of metals can elicit autoimmunity in genetically susceptible humans. Dr. Ivan Sterzl and his colleagues have elaborated: "The key factors governing the harmfulness of metals are the cumulative concentration, duration of exposure, and genetic susceptibility. Many harmless metals may become allergens or exert toxicity if administered on a chronic basis."

For citations to support this information, see this source: Just A, Kall J. Autoimmune Diseases and Metal Implants And Devices. ChampionsGate, FL: IAOMT; 2019. <a href="https://www.theSMARTchoice.com/wp-content/uploads/Metal-Implants-and-Autoimmunity.pdf">www.theSMARTchoice.com/wp-content/uploads/Metal-Implants-and-Autoimmunity.pdf</a>

Source of quote: Sterzl I, Procházková J, Hrdá P, Bártová J, Matucha P, Stejskal VD. Mercury and nickel allergy: risk factors in fatigue and autoimmunity. *Neuro Endocrinol Lett.* 1999; 20:222.







Reactions to metal implants and devices can be manifested on the skin or in the oral mucosa, but they can also include more complex immune reactions at the site of the implant (local), at other parts of the body, and/or throughout the body (systemic). Even trace amounts of metals can potentially cause a reaction in susceptible subjects. Metal ions from these implants and devices are processed both locally and in other parts of the body, which can prompt an immune reaction and inflammation.

For citations to support this information, see this source:

Just A, Kall J. Autoimmune Diseases and Metal Implants And Devices. ChampionsGate, FL: IAOMT; 2019. <a href="https://www.theSMARTchoice.com/wp-content/uploads/Metal-Implants-and-Autoimmunity.pdf">www.theSMARTchoice.com/wp-content/uploads/Metal-Implants-and-Autoimmunity.pdf</a>



In a 2014 publication, Dr. Vera Stejskal wrote: "Metal-induced inflammation may be involved in the pathology of various autoimmune and allergic diseases, where abnormal fatigue, joint and muscle pain, cognitive impairment and other non-specific symptoms are often present."

Source: Stejskal V. Metals as a common trigger of inflammation resulting in non-specific symptoms: diagnosis and treatment. *The Israel Medical Association Journal: IMAJ.* 2014 Dec;16(12):757.









Additionally, Dr. Ivan Sterzl and his colleagues have reported: "Hypersensitivity to metals results in [a] wide range of clinical and sub-clinical symptoms such as chronic fatigue, depression, sleep disturbances and others. Patients with these symptoms often report intolerance to metal earrings and other metallic devices such as jeans buttons, watches, and intrauterine devices."

# Sources:

Just A, Kall J. Autoimmune Diseases and Metal Implants And Devices. ChampionsGate, FL: IAOMT; 2019. <a href="https://www.theSMARTchoice.com/wp-content/uploads/Metal-Implants-and-Autoimmunity.pdf">www.theSMARTchoice.com/wp-content/uploads/Metal-Implants-and-Autoimmunity.pdf</a>

Stejskal V. Metals as a common trigger of inflammation resulting in non-specific symptoms: diagnosis and treatment. *The Israel Medical Association Journal: IMAJ.* 2014 Dec;16(12):757.

Sterzl I, Prochazkova J, Hrda P, Matucha P, Bartova J, Stejskal V. Removal of dental amalgam decreases anti-TPO and anti-Tg autoantibodies in patients with autoimmune thyroiditis. *Neuroendocrinology Letters*. 2006 Dec;27:103.

One example of how an offending metal can trigger an array of possible reactions is this excerpt from the IAOMT's "Position Paper against Dental Mercury Amalgam Fillings for Medical and Dental Practitioners, Dental Students, and Patients" that lists adverse health effects scientifically associated with dental mercury exposure. You can view the original document for access to specific research articles documenting that the mercury in dental amalgam fillings has been shown to potentially exacerbate and/or contribute to each of these conditions, as well as a myriad of other health outcomes:

- Allergies
- Alzheimer's disease
- Amyotrophic lateral sclerosis (Lou Gehrig's disease)
- Antibiotic resistance
- Autism spectrum disorders
- Autoimmune disorders/immunodeficiency
- Cardiovascular problems
- Chronic fatigue, fatigue, and/or myalgic encephalomyelitis/chronic fatigue syndrome
- Complaints of unclear causation
- Dermatitis
- Fibromyalgia
- Gastrointestinal issues and/or irritable bowel syndrome
- Hearing loss
- Kidney disease
- Micromercurialism
- Multiple sclerosis
- Oral lichenoid reaction and oral lichen planus
- Orofacial granulomatosis
- Parkinson's disease
- Periodontal disease
- Psychological issues such as depression and anxiety

- Reproductive dysfunction
- Suicidal ideations
- Symptoms of chronic mercury poisoning
- Systemic lupus erythematosus
- Thyroiditis

For detailed citations to support dental mercury's association with each of these conditions, see this source:

Kall J, Robertson K, Sukel AP, Just A. International Academy of Oral Medicine and Toxicology (IAOMT) Position Statement against Dental Mercury Amalgam Fillings for Medical and Dental Practitioners, Dental Students, and Patients. ChampionsGate, FL: IAOMT; 2019. <a href="https://iaomt.org/wp-content/uploads/IAOMT-Position-Paper-Dental-Mercury-Amalgam-Full.pdf">https://iaomt.org/wp-content/uploads/IAOMT-Position-Paper-Dental-Mercury-Amalgam-Full.pdf</a>



Continuing with our example of dental mercury, we can demonstrate how an exposure to a particular material in an implant or device can influence each individual differently based on a wide range of co-existing factors. For example, each person's unique response to dental mercury can be influenced by the presence of other health conditions, the number of amalgam fillings in the mouth and/or the number of amalgam surfaces in the mouth; the type of the amalgam filling (i.e. specific content of metals); gender; genetic predisposition; dental plaque; exposure to electromagnetic fields (EMF) from magnetic resonance imaging (MRI), mobile/cellular phones, and Wi-Fi; exposure to aluminum, fluoride, lead, and other

environmental toxicants; selenium levels; consumption of milk or alcohol; methylmercury levels from fish consumption; the potential for mercury from dental amalgam fillings to be transformed into methylmercury within the human body; and many other circumstances.

For detailed citations to support this information, see these sources:

Kall J, Robertson K, Sukel AP, Just A. International Academy of Oral Medicine and Toxicology (IAOMT) Position Statement against Dental Mercury Amalgam Fillings for Medical and Dental Practitioners, Dental Students, and Patients. ChampionsGate, FL: IAOMT; 2019. <a href="https://iaomt.org/wp-content/uploads/IAOMT-Position-Paper-Dental-Mercury-Amalgam-Full.pdf">https://iaomt.org/wp-content/uploads/IAOMT-Position-Paper-Dental-Mercury-Amalgam-Full.pdf</a>

Kall J, Just A, Aschner M. What is the risk? Dental amalgam, mercury exposure, and human health risks throughout the lifespan. *Epigenetics, the Environment, and Children's Health across Lifespans*. David J. Hollar, ed. Springer. 2016. pp. 159-206 (Chapter 7). Abstract available from: <a href="http://link.springer.com/chapter/10.1007/978-3-319-25325-1">http://link.springer.com/chapter/10.1007/978-3-319-25325-1</a> 7

It is also essential to elaborate upon the association of genetic predisposition with specific, adverse effects from metal exposure. Significantly, adverse reactions are more likely to occur for individuals who are genetically predisposed to having lower excretion rates of metals. For instance, it has been found that mercury exposure from dental mercury amalgam particularly threatens individuals with the genetic variants CPOX4, APOE(3,4), and BDNF (brain-derived neurotropic factor) polymorphisms. Additional genetic traits that have been examined for association with health impairments caused by mercury exposure include metallothionein (MT) polymorphisms, catechol-O-methyltransferase (COMT) variants, PON1 variants, MTHFR mutations and other genetic aspects.

For detailed citations to support this information, see this source:

Just A, Kall J. A Comprehensive Review of the Toxic Effects of Mercury in Dental Amalgam Fillings on the Environment and Human Health. ChampionsGate, FL: IAOMT; 2019. <a href="https://files.iaomt.org/wp-content/uploads/Comprehensive-Review-Dental-Mercury.pdf">https://files.iaomt.org/wp-content/uploads/Comprehensive-Review-Dental-Mercury.pdf</a>

# **ALLERGIES AND SENSITIVITIES TO DENTAL MATERIALS**

Moreover, a significant number of people are overtly allergic or otherwise immunologically reactive to chemicals in their environment. This phenomenon ranges from true allergies to something akin to non-allergic food sensitivities. It results in a range of idiosyncratic, highly individual immune reactions in susceptible people.

As the old saying goes: "Anyone can become allergic to anything at any time."

Chemical components of dental materials have allergenic potential. The development of IgG and IgM antibodies lead to type II and III hypersensitivity. The stimulation of recognition and memory in lymphocytes lead to type IV delayed hypersensitivity. Haptenization of self-proteins leads to autoantibodies.



There is no question that patients can be allergic to dental materials used in their mouth, and even the American Dental Association recognizes this health complication. While allergic reactions have been reported to a wide range of dental products including acrylic resin, resin composite, impression materials, and eugenol-containing products, the issue of allergies to dental metals is one specific area of growing concern. Researchers have even warned that

dentists should be educated about this possible side effect: "Current data indicate that practicing dentists need to obtain further specialized knowledge about dental metal allergy in order to ensure the correct treatment of patients in their clinics."

#### Sources:

Information: Kennedy D, Just A. Metal Allergies, Genetic Susceptibility to Mercury, and Toxic Dental Materials Other than Mercury. ChampionsGate, FL: IAOMT; 2014. https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf

Quote: Hosoki M, Nishigawa K. Book Chapter "Dental Metal Allergy" in Contact Dermatitis, edited by Young Suck Ro, ISBN 978-953-307-577-8, InTech, December 12, 2011.



Nickel allergies have received a great deal of attention due to their prevalence. Research has demonstrated that approximately 10% of women and 1-2% of men are allergic to this metal. However, a number of other dental metals are also known to cause problems for sensitive and allergic patients as well. The first case of report of dental metal allergies offered clinically was in 1928 due to the mercury in amalgam fillings. Since that time, in addition to mercury and nickel, allergies have

been documented for dental metals such as titanium, gold, chromium, platinum, cobalt, tin, beryllium, and cadmium. Typically, reactions occur in the mouth, but they can also occur on the hands, feet, and other parts of the body.

For citations to support this information, see this source:

Kennedy D, Just A. Metal Allergies, Genetic Susceptibility to Mercury, and Toxic Dental Materials Other than Mercury. ChampionsGate, FL: IAOMT; 2014. <a href="https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf">https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf</a>

Researchers are currently delving deeper into understanding the complex factors that lead to the development of metal allergies. Genetics are obviously one variable being studied, and some researchers predict that specific genotypes will be correlated with adverse immune responses to metals. Additionally, there is an overall consensus that T-cells in the immune system trigger the negative reactions.

For citations to support this information, see this source:

Kennedy D, Just A. Metal Allergies, Genetic Susceptibility to Mercury, and Toxic Dental Materials Other than Mercury. ChampionsGate, FL: IAOMT; 2014. <a href="https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf">https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf</a>







Recent studies and reports tend to agree that metal allergies are on the rise. Part of this could be caused by increased exposure to metals, including ear and other body piercings, because exposure to metals has been cited as a potential trigger for the development of allergies to them. It has also been hypothesized that contact with metals during an infection could increase chances of developing a metal allergy later in life. At any extent, in a 2016 review, researchers from Harvard School of Medicine qualified: "Dermal hypersensitivity to metal is common and can affect up to 15% of the population."

#### Sources:

Kennedy D, Just A. Metal Allergies, Genetic Susceptibility to Mercury, and Toxic Dental Materials Other than Mercury. ChampionsGate, FL: IAOMT; 2014. <a href="https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf">https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf</a>

Kaplan M. Infections may trigger metal allergies. Nature. May 2, 2007.

Quote: Teo ZW, Schalock PC. Hypersensitivity reactions to implanted metal devices: facts and fictions. J Investig Allergol Clin Immunol. 2016 Jan 1;26(5):280.



However, one issue with calculating the number of patients with a negative reaction to a metallic material is that the onset of symptoms can be delayed and therefore might not be associated with the exposure. For example, research by Djerassi and Berova about amalgam allergies warns: "Sensitization appears most frequently after the amalgam has been present in the mouth for more than 5 years."

#### Sources:

Kennedy D, Just A. Metal Allergies, Genetic Susceptibility to Mercury, and Toxic Dental Materials Other than Mercury. ChampionsGate, FL: IAOMT; 2014. <a href="https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf">https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf</a>

Djerassi E, Berova N. The possibilities of allergic reactions from silver amalgam restorations. *Internat Dent J.* 1969; 19(4):481-8.

It is vital for patients to remember that sensitization to metal can develop years after an implant or device has been placed and that adverse effects can occur with or without the sign of a rash or eruption on the skin or in the mouth. It is also important to remember the wide range of symptoms patients allergic to metals can exhibit.



The most commonly reported side effects from a dental metal allergy include pustulosis palmaris and dyshidrotic eczema (usually in the form of erythema, blisters, and scaly and crusty skin), lichen planus (usually in the form of spots on the skin), glossodynia (usually in the form of pain or burning of the tongue), generalized eczema and pseudoatopic dermatitis (usually in the form of an itching rash), and atopic dermatitis (chronic eczema with itching).



For citations to support this information, see this source:

Kennedy D, Just A. Metal Allergies, Genetic Susceptibility to Mercury, and Toxic Dental Materials Other than Mercury. ChampionsGate, FL: IAOMT; 2014. <a href="https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf">https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf</a>











Yet, many other health conditions have also been linked to dental metal allergies. These include oral lichenoid lesions, autoimmune dysfunction, myalgic encephalomyelitis/chronic fatigue syndrome, multiple chemical sensitivity (MCS), metallic pigmentation, orofacial granulomatosis, fibromyalgia, multiple sclerosis (MS), infertility, and intraoral squamous cell carcinoma, a type of cancer.

For citations to support this information, see this source:

Kennedy D, Just A. Metal Allergies, Genetic Susceptibility to Mercury, and Toxic Dental Materials Other than Mercury. ChampionsGate, FL: IAOMT; 2014. <a href="https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf">https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf</a>

An announcement in January 2020 by the Lupus Foundation of America provides another case in point. Citing a literature review, they stated: "People with lupus have a high risk of metal delayed-type hypersensitivity, including nickel, gold and mercury, often present in dental materials."

Lupus Foundation of America. People with Lupus Exhibit Increased Need for Dental Management. January 8, 2020. <a href="https://www.lupus.org/news/people-with-lupus-exhibit-increased-need-for-dental-management#">https://www.lupus.org/news/people-with-lupus-exhibit-increased-need-for-dental-management#</a>



In addition to patients exhibiting allergic responses to dental metals placed in their mouths, research has also shown that dental personnel working with these metals are at risk for developing metal allergies. This includes dentists, dental technicians, and dental students.

For citations to support this information, see this source:

Kennedy D, Just A. Metal Allergies, Genetic Susceptibility to Mercury, and Toxic Dental Materials Other than Mercury. ChampionsGate, FL: IAOMT; 2014. <a href="https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf">https://iaomt.org/wp-content/uploads/Metal-allergies-toxic-materials.pdf</a>

# **REMOVING DENTAL METALS**

When most people develop symptoms possibly related to toxicity or chemical sensitivity, they consult with their medical doctor, not their dentist. And the medical doctor is unlikely to include a patient's old dentistry in a disease work up. This means that the possible connection with adverse exposure to dental materials is likely to be missed.

This could be avoided if dentists are discerning in their practice and only use materials that are known in advance to be benign for their patients.

So, the basics of a more biocompatible dental practice would be:

- avoid toxic materials
- test new materials for immune reactivity
- remove and replace toxic or reactive materials

The sicker or more reactive a person is, the more important this service is. And while this may be a good standard for treating known chemically sensitive patients, the broader population will also benefit from this precautionary level of care, even if they are not, or not aware of being, chemically sensitive.



Research supports the fact that some patients experiencing ill health can benefit from having their dental metals removed and

replaced with an alternative material. A few examples of conditions reportedly improved and/or cured as a result of removing dental metal allergens include amyotrophic lateral

sclerosis, autoimmune thyroiditis, myalgic encephalomyelitis/chronic fatigue syndrome, dermatitis, fibromyalgia, multiple sclerosis, oral lichen planus, oral lichenoid lesion, orofacial granulomatosis, and other symptoms.



For detailed citations to support this information, see this source:

Kall J, Robertson K, Sukel AP, Just A. International Academy of Oral Medicine and Toxicology (IAOMT) Position Statement against Dental Mercury Amalgam Fillings for Medical and Dental Practitioners, Dental Students, and Patients. ChampionsGate, FL: IAOMT; 2019. <a href="https://iaomt.org/wp-content/uploads/IAOMT-Position-Paper-Dental-Mercury-Amalgam-Full.pdf">https://iaomt.org/wp-content/uploads/IAOMT-Position-Paper-Dental-Mercury-Amalgam-Full.pdf</a>



The removal of metal implants and devices should only be conducted by a qualified healthcare professional who not only recognizes and appreciates the ill effects of the implant or device but also takes appropriate precautions to protect the patient and staff from exposure during the removal process. This is because an unsafe removal process of a dental implant or device can cause serious injury to the patient, in addition to the possibility of increased metal exposure. As an example, if dental amalgam fillings are removed unsafely, patients can be exposed to increased levels of mercury.

Based on scientific research, the IAOMT has developed recommendations known as the <u>Safe Mercury Amalgam Removal Technique (SMART)</u> to assist in mitigating the potential negative outcomes of mercury exposure during amalgam removal. The IAOMT also offers education about alternatives to dental amalgam fillings so that patients can opt for a more "biocompatible" replacement (i.e. one that is best suited for the patient based on safety and personal healthcare needs).



It is important to note that many factors can influence whether or not a patient improves after the removal of a metal implant or device. While many patients improve or even recover, there are some who do not. One obvious reason for this is if the patient is still being exposed to the metal or a different allergen or sensitizer through a different implant, device, or other source. Other sources could include exposure to certain pesticides, solvents, molds, or foods, as well as hormonal imbalances, stress, a sedentary lifestyle, and countless other factors. Lifestyle changes such as quitting smoking, treating another health issue, or eliminating foods in the diet might also be necessary.

In a most unfortunate circumstance, patients can even have a reaction to the new implant or device. Thus, it is critical to select a biocompatible replacement.

# ALTERNATIVES TO DENTAL AMALGAM AND OTHER DENTAL METALS



Obviously, once amalgams have been removed, they must be replaced with a different dental filling material. Alternatives to amalgam include composite resin, glass ionomer, porcelain, and gold, among other options. When given the choice, most consumers opt for direct composite fillings because the white coloring



matches the tooth better and the cost is considered moderate.



In the past, a common argument against composite fillings was that they were not as durable as amalgam. However, recent studies have debunked this claim. Researchers of a study which was published in 2016 and conducted on over 76,000 patients for over ten years found that posterior amalgam fillings had a *higher* annual failure rate than composites. Other studies have come to similar conclusions that composite fillings are more durable or just as durable as amalgam.

Source for 2016 study:

Laske M, Opdam NJ, Bronkhorst EM, Braspenning JC, Huysmans MC. Longevity of direct restorations in Dutch dental practices. Descriptive study out of a practice based research network. Journal of Dentistry. 2016 Mar 1;46:12-7. Available from: <a href="https://repository.ubn.ru.nl/bitstream/handle/2066/201886/201886.pdf?sequence=1#page=21">https://repository.ubn.ru.nl/bitstream/handle/2066/201886/201886.pdf?sequence=1#page=21</a>

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Kall J, Robertson K, Sukel AP, Just A. International Academy of Oral Medicine and Toxicology (IAOMT) Position Statement against Dental Mercury Amalgam Fillings for Medical and Dental Practitioners, Dental Students, and Patients. ChampionsGate, FL: IAOMT; 2019. <a href="https://iaomt.org/wp-content/uploads/IAOMT-Position-Paper-Dental-Mercury-Amalgam-Full.pdf">https://iaomt.org/wp-content/uploads/IAOMT-Position-Paper-Dental-Mercury-Amalgam-Full.pdf</a>

Research has further confirmed that composite resins present a lower risk for chemical exposures. In a 2016 publication co-authored by risk assessment specialist Dr. G. Mark Richardson, it was reported: "Relative risks of chemical exposures from dental materials decrease in the following order: Amalgam>Au (Gold) alloys>ceramics>composite resins."

Source: Richardson GM, Clemow SR, Peters RE, James KJ, Siciliano SD. Assessment of exposures and potential risks to the US adult population from wear (attrition and abrasion) of gold and ceramic dental restorations. *Journal of Exposure Science and Environmental Epidemiology*. 2016 Jan 1;26(1):70-7.



Yet, composite fillings have been criticized because some of them contain fluoride and/or bisphenol-A (BPA). Dentists have a variety of opinions about the safety of fluoride, BPA, and other types of bisphenol, such as Bis-GMA and Bis-DMA. Patients who are concerned about the specific components of their fillings often choose to speak with their dentists about using a material that does not contain certain ingredients. No matter which replacement material is

selected, whether it be ceramics, composites, gold, or other materials, it should be assessed for safety and biocompatibility with special consideration for the specific patient in particular.

# **TESTING AND DIAGNOSING REACTIVITY FOR DENTAL MATERIALS**

Metals are much more allergenic than we typically give them credit for. Does anyone remember being told in dental school to ask patients if their skin breaks out with jewelry? Very few patients ever report having been asked that by a dentist.

Dentist may pre-screen their materials and diagnose local reactions in the mouth. But toxic or immune illness is a medical diagnosis. Dentists are not usually allowed to make such a diagnosis under terms of a dental license. In most jurisdictions, dentists may accept a patient's request to replace specific materials, like mercury fillings, but may not independently make a diagnosis of systemic illness, like MCS or mercury "toxicity." This means that biocompatible dental practice is interdisciplinary.

While there are a number of ways that dentists can test patients for reactivity for dental materials, the IAOMT encourages its member dentists to develop good working relationships with physicians and other practitioners who understand the issues we deal with.



Allergy testing can be used to assist in identifying some of the individuals susceptible to adverse reactions to metals. Patch testing is generally regarded as the "gold standard" in allergy testing; however, patch testing has also been criticized because it involves directly applying the allergen to the skin, it can exacerbate symptoms in patients, it can result in sensitization, and the results can be affected by other conditions. Two relatively new alternatives to skin patch testing are a modified version of the Lymphocyte Transformation Test (LTT) known as MELISA and the Lymphocyte Response Assay (LRA) by ELISA/ACT.

Another option for testing has been created specifically for dental materials. If this biological testing is used, a patient's blood sample is sent to a laboratory where the serum is evaluated for the presence of IgG and IgM antibodies to the chemical ingredients used in dental products. The patient is then provided with a detailed list of which name-brand dental materials are safe for their use and which ones could result in a reaction. Two labs that currently offer this service are Biocomp Laboratories and Clifford Consulting and Research.

# **ORAL GALVANISM**

Aside from their power to provoke immune reactivity, metals are also electrically active. Different metals in an electrolyte form a battery. This is exactly the situation when different metallic restorations are placed together in a person's mouth. Oral galvanism has been talked about for well over 100 years, but dentists generally ignore it and its implications.



Suggesting that the mouth could be a battery and that teeth can have electrical potential (which can be dramatically increased with metal restorations) probably sounds blatantly bizarre to just about anyone who has not studied oral galvanism. Yet, the fact that such a situation can actually occur is quite elementary.

First, defining the scientific term *oral galvanism* assists greatly in conveying information about this dental phenomenon. Galvanism is defined as "a direct current of electricity especially when produced by chemical action." Thus, oral galvanism simply means electric currents produced by chemical action in the mouth.



Considering all of the available options for dental materials, such as fillings, crowns, bridges, wires for orthodontics, and more, the accessibility to metals to serve as the anode and cathode in the oral cavity is abundant. Obviously, a mouth with any amount of metallic dental restorations has all the metals needed to produce chemical reactions, but saliva also plays a role, serving as the electrolyte, especially due to the contents of saliva, which can contain varying levels of calcium, magnesium, potassium, and acid.

Researchers have provided a simple explanation of the process: "In dentistry application, galvanic corrosion occurs when two or more dental prosthetic devices with dissimilar alloys come into contact while subjected to oral liquids like saliva; the difference between the corrosion potentials results in a flow of electric current between them."

Source: Zohdi H, Emami M, Shahverdi HR. Chapter 7: Galvanic Corrosion Behavior of Dental Alloys. *Environmental and Industrial Corrosion – Practice and Theoretical Aspects*. 2012.



It is not surprising that the term *oral galvanism* is often used synonymously with the term *galvanic corrosion*. This is because a primary action of electrical currents in the mouth is to cause corrosion, similar to the rust that appears on batteries, cars, and other metallic objects. Indeed, it is typically accepted that electrical currents in the oral cavity result in more extreme corrosion of the dental materials and that this, in turn, can result in more metallic releases, and sometimes, in failure of the material.

A variety of factors can determine the rate of corrosion, and research has identified a number of situations that can increase corrosion, including the ones on this much abbreviated list:



- the combination of gold and amalgam
- the different surfaces of the restoration
- the composition of saliva and dentin fluid
- biting, wear and tear, increase in temperature, and acidic and salty food
- 'injury reactions' at the interfaces between gingival or root canals and the restoration metals
- periodontitis or chronic periodontitis

Similarly, a wide range of symptoms from oral galvanism have been reported in patients. Dental literature going back to the 20th century recognized that galvanic electricity generated by metallic restorations could cause localized pain, lichenoid lesions, inappropriately elevated muscle tone, jaw tension, temporomandibular joint disorders (TMD, TMJ), temporal headache, etc.

More specifically, galvanic currents have been associated with sharp pains, and galvanic corrosion has been linked to metallic tastes in the mouth, allergy, and irritation. Additionally, oral lesions, blackening of amalgam surfaces, amalgam tattoos, and *all* of the symptoms related to mercury poisoning have been linked to oral galvanism from amalgam fillings.

For detailed citations to support this information, see these sources:

Kall J, Just A. Electric Teeth: Chemical Reactions in the Mouth and the Phenomenon of Oral Galvanism. ChampionsGate, FL: IAOMT. 2014.

Pleva J. Corrosion and mercury release from dental amalgam. *J. Orthomol. Med.* 1989; 4(3): 141-158.

It must also be reiterated **with emphasis** that the issues we have discussed related to galvanism and biocompatibility are not limited to only the oral cavity. Metals can cause adverse health effects even when they don't touch each other or are not even located in the same part of the body. For example, Dr. Scott Schroeder, a foot and ankle surgeon, is doing research showing how foot implants and dental materials can jointly cause ill health. He also testified at the FDA's Immunology Devices Panel in November 2019.

Insert clip of "Dr. Scott Schroeder Testifies to the FDA 2019" from IAOMT YouTube Channel: https://youtu.be/yEM1QG5bC-s

Remember the potato clock question? That is the experiment with a copper strip in a zinc strip stuck in a potato showing this makes enough electricity to run a digital clock. We explored this experiment in the next video.

Insert video of Steve Koral, DMD, MIAOMT, potato clock: <a href="https://youtu.be/c9kj-XfVang">https://youtu.be/c9kj-XfVang</a>

# **CONCLUSION**

Nowadays, we can choose from the many contemporary, nonmetallic methods we are currently blessed with, including composite fillings, flexible nylon base partial dentures, all ceramic crowns and bridges, and even all ceramic implants.







By practicing individualized biocompatibility testing when it is appropriate and making other common-sense choices, we can almost always find a combination of professionally recognized, restorative materials that will do the job. We can fix teeth, and at the same time help our patients avoid toxicity, immune reactivity, and galvanic stress. And just as important, we can provide our patients with peace of mind.





Today, we can do better dentistry, in a less toxic, more individualized, and more environmentally friendly way than ever. We have as many choices of attitude before us as we do dental techniques and materials. By choosing to put biocompatibility first, we can look forward to practicing effective dentistry while knowing that we are providing patients with the safest experience for their overall health.







POSTFACE TO IAOMT'S DENTAL BIOCOMPABILITY AND ORAL GALVANISM VIDEO ACTIVITY

### Text on screen:

You have finished viewing the video component of this activity. If you are participating in this activity as part of an IAOMT course, you must successfully complete a quiz to obtain credit. Access to the quiz is provided in the "Activity Content" below this video, as well as on the menu to the left. Additionally, the "Materials" tab above this video contains links to references and resources cited in this activity, scientific literature related to the topics presented, and a script for this entire video. Thank you for learning with the IAOMT, as we work together to achieve safer dentistry and a healthier world.