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Review Article

Biocompatible Issues Related to Restorative Dental Material – II (Adverse Reactions)

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ABSTRACT:
Dentistry has been always considered lucrative in terms of economics and has been accepted like that since everyone knows that dental practice is largely based on materials that are not cheap. This is further amplified by the fact that materials are biocompatible which justifies the cost associated with such materials. Yet, these biomaterials have produced many adverse reactions which over the time have also helped in refining the composition. Bioactive and bioinert materials have replaced those that produce an unfavorable response. This review which is a continuation of the issue of biocompatibility addresses the adverse effects of various dental materials and have been discussed under general and specific categories. The review also presents clinical guidance and recommendations to dental practitioners regarding the specific use of each individual material. Keywords: adverse effects, methyl mercury, methylmetacrylate, beryllium, nickel, allergy, hypersensitivity.

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INTRODUCTION

Like many other occupations and their respective workplaces, dental practice also presents potential hazards and risks to the users and providers. Dental patients as well as dental health care workers are at risk for exposure to numerous work threats. Occupational hazard is the risk to a person usually arising out of employment. It can also refer to a work, a situation that causes accidents or disease, at a workplace. Dentistry in generally has lacked research regarding the epidemiology of patient safety issues and adverse effects of materials,[1,2] which is why they are not well understood.[3] Diagnostic, examination, treatment plan, communication and procedural errors have all been observed in malpractice researches.[4] Adverse reaction to drugs (β-lactam antibiotics) and anaphylactic reaction to latex are biocompatibility issues that have resulted in patient death reported across different studies.[5,6] It is also true that dental patients are prone to less harm than the counterpart medical patients since it is less aggressive that generates mild damage.[7] In dentistry there are many sources (physical, biological and chemical) that can lead to a hazard for patients in addition to those materials that are placed inside the patient. From generally used materials like gloves to specific materials from different disciplines, materials and their respective biocompatibilites will vary depending upon the component compositions. An example being the content of nickel differs in orthodontic wires when compared to its content in base metal alloys used in Prosthodontics.[8] Similarly the threshold of each patient will vary according to the previous exposure and therefore the reaction to particular antigen will also vary. All these factors play a key role in determining the biocompatible response of a particular patient to a particular component of the material.

Aspects of biocompatibility non recognized issues: Dental practice has grown commercially with the incorporation of digital advances and with it there is also an increased awareness of patients regarding their oral health. Studies have reported that on average there is increased awareness among adult patients to increase the functionality of their natural dentition to later ages,[9] which in turn has also resulted to improved dentitions in geriatric patients. Biocompatibility of a respective material may also be dependent upon the

conditions of the oral cavity of an individual person. The oral environment in terms of acidity (pH) has been reported to alter according to underlying systemic conditions like diabetes.[10] Biofilm formation on natural teeth as well as restorative materials in normal and systemically compromised patient will alter the biological response of a tissue to a particular biomaterial. The material selection is the sole responsibility of the dental practitioner, other associated health care workers also need to ensure that proper contacts and contours in indirect restorations are developed during laboratory fabrication.[11,12] Material biocompatibility also applies equally to dental technicians during fabrication of dental prosthesis especially those which can cause severe diseases and allergies like pneumoconiosis.[13,14] While most of the dental professionals are mostly focussed on preventing cross infection (hepatitis, tuberculosis),[15] larger dangers exist in inhalation of toxic substances that are present in dental clinics and laboratories.

This review therefore has been aimed to provide a comprehensive complementary review in terms of biocompatibility of different dental materials. The article is a continuation of its predecessor and includes similar methods for collecting and reviewing the article. The article reviews biocompatibility in terms of the materials that are used in general (cements, impression materials) and those which are specific to particular specialization.

A. Biocompatibility of materials used for general use

Latex allergy: Latex containing common materials used for dental include but not limited to anesthetic capsules (latex stopper and diaphragm), bite block, blood pressure cuff, endodontic stops, gloves, gutta percha, hoses (saliva ejector and hooves), instrument bands, mixing bowls, nitrous oxide masks and hoses, orthodontic bands and elastic polishing wheels and points, prophy cups, rubber dams, stethoscope, toys, prizes, stickers, balloons, widgets etc. The chance of a latex-sensitive person coming through ones door escalates every day.[16] All health care professionals need to know about this potential hazard and be able to manage it effectively if encountered.[17] Often, an individual may not be aware that it is latex that causes his or her sensitivity. Latex is a complex product of the Brazilian rubber tree Hevea brasiliensis, which is predominantly cultivated for commercial use in the Pacific Rim countries.[18] A milky fluid is tapped from the tree, in much the same way as is done with maple sap.[17] The raw product is then mixed with preservatives, accelerators, and various other chemicals. Although synthetic polymers (i.e. Polyvinyl chloride, nitrile, silicone) has replaced many natural rubber latex products, it is latex's elasticity, durability and cost-effectiveness that have made it the material of choice for many products.[16,19] Emergency management is outline in Table 1.

Table 1: Adverse Effects and their Emergency Management

Reaction Type	Irritation	Delayed Type Hypersensitivity	Immediate Hypersensitivity
Synonymn	Irritant contact dermatitis	Type IV hypersensitivity Allergic contact dermatitis Cell mediated allergy Chemical allergy	Type I hypersensitivity IgE mediated allergy Latex protein allergy
Cause	Hyperhydration Maceration Excessive occlusion Insufficient hand rinsing	Chemical contact Sensitizers: usually accelerators	Protein allergens from natural rubber latex
Immediate Intervention	N/A	N/A	Emergency treatment for anaphylaxis may be required
Prevalence	100%	7–18%	General population: <1% Health care pop.: 3– 12%
Symptom onset time	Minutes to hours	6 to 48 hours	Minutes to 1 hour
Respiratory potential	No	No	Runny nose, wheezing, difficulty breathing
Facial Involvement	If face is touched	If face is touched	Swelling of eyelids, lips, face; tearing, itchy eyes, runny nose
Systemic Involvement	No	No	Hives, nausea, abdominal cramps, rapid heart rate, low blood pressure, anaphylaxis
Potentially life Threatening	No	No	Yes
Action	Wash and rinse hands thoroughly. See dermatologist if severe.	"hypoallergenic" gloves are processed to be low in chemical sensitizers.	See an allergist, wear an alert bracelet, carry an EPI-Pen, alert fellow employees

Latex reactions:

Irritant Contact Dermatitis: Being one of the most prevalent latex producing reactions in the form of development of dehydrated, scratchy, irritated areas on the skin.[17,19] This reaction results from not following the proper protocol for glove wearing and removal (hand wash, drying, sanitization, powder exposure). Contact dermatitis caused by irritation is not a genuine allergy.[16]

Type IV (Delayed) Hypersensitivity: Latex is contaminated with chemicals during harvesting, processing, or manufacturing, which results in allergic contact dermatitis. Latex glove products utilize coagulants, accelerators, antioxidants, emulsifiers, stabilizers, extenders, colorants, stiffeners, biocides, fragrances, etc. These chemicals can cause skin reactions similar to those caused by poison ivy. The rash is typically a result of contact within 24 to 48 hours, and can develop into oozing skin blisters or spread to other parts of the skin.[17,19] This contact urticaria may represent a transitional stage in a progression between contact dermatitis and immediate hypersensitivity. Some patients initially develop delayed-type contact dermatitis, then urticaria, and finally (months to years later) systemic immediate hypersensitivity.

Type I (Immediate) Hypersensitivity: This is an IgE antibody mediated reaction to some of the protein antigen inherent in the latex.[18,19] These reactions typically cause urticaria, angioedema, rhinitis, conjunctivitis, bronchospasm, asthma and, rarely, anaphylaxis.[16-19] Affected persons must eliminate latex exposure altogether. Even very low levels of exposure can trigger allergic reactions in some sensitized individuals, but the exact amount of exposure required for sensitization or symptoms is unknown.[17,20] A common factor in anaphylactic episodes is the exposure of mucosal tissues to latex—a situation inherent in dentistry.[21] The potential for a life-threatening anaphylactic reaction underscores the importance of recognizing Type I immediate reactions.

Latex Allergens And Diagnosis: Type I Latex Allergy (IgE-mediated), also known as natural rubber latex proteins Type I immediate hypersensitivity, develops in response to water-soluble proteins that remain in the latex following the manufacturing process.[17,20,21] With more than 200 proteins, definite testing for latex allergy is inconsistent and difficult.[22] Over 50 of these proteins have been shown to have allergenic potential. Type IV Latex Allergy (cell mediated), also known as allergic contact dermatitis delayed hypersensitivity, typically is a reaction to excess residual chemicals used as accelerators and antioxidants in the manufacturing process.[19] Unfortunately, even skin testing can provoke anaphylactic reactions.[21] Occasionally, tests may fail to confirm a worker who has a true allergy to latex, or tests may suggest latex allergy in a worker with no clinical symptoms. Therefore, test results must be evaluated by a knowledgeable physician. Failure to properly diagnose latex hypersensitivity may result in unnecessary exposure to latex and serious allergic reactions. If a patient is found to have a Type I allergy, all contact with latex must be avoided.[16,18,19,21]

Diagnosis of (Type I) Latex Allergy: Diagnosis of latex allergy is based on a history of latex exposure and reactions, physical signs of latex hypersensitivity, and a positive blood test (RAST) or skin test for IgE antibodies to latex allergens.[21,22] Testing for immediate hypersensitivity to latex is particularly difficult for most physicians because of a lack of standardized,FDA-approved testing materials. Some physicians make up their own “latex serum” for skin testing.[23]

Diagnosis of (Type IV) Contact Dermatitis: Contact dermatitis makes up the majority of occupational skin diseases. Patch testing with an array of commercially available allergens is the accepted method for identifying a delayed reaction to rubber processing chemicals. The patch test is typically conducted by a qualified clinician using a standard series of patch test allergens on the upper back.[24] The patches are typically removed and the test sites examined at 48, 72, and 96 hours.[25] If positive, the patient should be provided with information regarding the offending chemical and prevention of a type IV allergy. Emergency management is outline in Table 1.

Recommendations: For the latex-allergic patient the recommendations include patient should be the first patient of the day (low latex dust), no direct contact with latex, use of nonlatex substitutes (prophy cups, dental dam, N20 mask), latex in the room must be ALARA (as low as reasonably achievable), non removable latex items must be covered, room should be close to the entrance (in case of emergency), personnel setting up the room must wear nonlatex gloves, blood pressure cuffs, instruments, laboratory work must be handled only with nonlatex gloves and thoroughly rinsed, use multi dose glass anesthetic vials or glass ampoules, medical consultation for patients taking beta blockers (these drugs interfere with the medications needed to resuscitate a patient should an emergency arise), minimal perfume and aftershave and gutta percha has a potential for cross-allergencity (an alternative is Ketac-Endo fill).

IMPRESSION MATERIALS

Elastomeric Impression Materials: Elastomers or synthetic rubbers are colloid or soft, rubber like material that is elastic in nature. These are used to take impressions for complete dentures, removable partial dentures, inlays, crowns and bridges. Chemically these are of four types (Polysulphides ,

Polysilicones –condensation type, Polysilicones-addition type, Polyether).[26] Dentistry commonly employs polysulfide rubber as an impression material. Despite being safe, there are some negative aspects such as a foreign body reaction, acute toxic reaction, periodontal destruction, and aspiration emphysema.[27] The reactions are expressed as a delayed hypersensitivity reaction of a general or dermal type among dental patients. Polysulfide rubber is an elastomeric material containing large molecules forming a three dimensional network.[26] It is supplied as a base and accelerator. The base material consists of low molecular weight organic polymer containing a reactive mercaptan (-SH) group and 20 % reinforcing agent (titanium dioxide, copper, zinc sulfate).[28] The catalyst is composed of lead dioxide with or without manganese dioxide and inert oil. A contact with living tissues in the mouth may induce adverse tissue reaction such as a foreign body reaction, toxicity and hypersensitivity.[28,29] The most likely induced problem for the patient arises from pieces of impression material being left in the sulcus. The irritations can range from minor to severe reactions. Microscopic examination of the curetted specimen shows an amorphous a cellular mass unlike human tissues. Polyether contact dermatitis and stomatitis have been reported.[28] Most of the cases are due to prolonged contact, particularly with the catalyst of the polyether rubber impression material. A delayed hypersensitivity reaction was interpreted as a positive skin reaction caused by the catalyst and the freshly mixed polyether.[28] It is stated that the polyether catalyst contains alkylbensone sulfate, which causes irritation.[29] The signs and symptoms of a delayed hypersensitivity reaction were present in this case. In condensation silicone the Catalyst (Dibutyl tin dilaurate) is responsible for cytotoxicity

Irreversible hydrocolloid: An aqueous impression material used for recording minimal details such as required to produce study models. It is unlikely to cause harmful effects under normal conditions of handling and use. Practice good hygiene. Inhalation of alginate powder can cause temporary irritation of respiratory mucosa.[30,31] Possible risk of irreversible effects of repeated inhalation of dust at high concentration (Silicosis) and pulmonary hypersensitivity. Eye contact results in temporary irritation of the eyes.

Zinc Oxide Eugenol Impression Paste: There have been few reported side effects associated with eugenol, a commonly used material in dentistry. When contacted with oral soft tissues, it is not bio-friendly.[32] Local irritation, cytotoxic effects, and hypersensitivity reactions can be caused by it.[33] Adverse effects of eugenol in the oral cavity have been reported in association with its use in surgical and periodontal packs, root canal sealers, mouthrinses, and in impression pastes. These reactions can be classified as localized irritation of the skin or allergic contact dermatitis.[34] Reactions depending upon the type and extent can be cytotoxic at high concentrations with main adverse effects being on fibroblasts and osteoblast-like cells which may result finally in necrosis and disrupts healing.[33] A delayed hypersensitivity reaction in the local area can be provoked by eugenol acting as a contact allergen in low concentrations.[34]

Dental Waxes: Primarily used for impressions and bites and various laboratory purposes, the different modes of toxicity may result from inhalation in which the fumes from molten material causes irritation of respiratory mucosa. At times a skin contact results in thermal burns to skin or eyes. Skin sensitization to solid waxes may result in allergic dermatitis while ingestion can cause low order acute system toxicity.[35]

CEMENTS

Zinc Phosphate Cement: When used as a base thick putty like mass, zinc phosphate cement is not a highly toxic substance. When used as a cement or a liner, i.e. as a thin mix, the response is very different. The initial acidity of the cement at the time of placement may elicit a pulpal response, especially when only thin layer of dentin exists between the cement and the pulp.[36]

Glass Ionomer Cement: The pulp response is classified as bland, moderate and less irritating than silicate and zinc phosphate cements, but more than zinc oxide eugenol cement. Blandness is attributed to the absence of strong acids and toxic monomers. GIC luting cements may cause prolonged hypersensitivity, varying from mild to severe.[37]

Zinc Polycarboxylate Cement: Zinc polycarboxylate cements are slightly more acidic than zinc phosphate cements when first mixed, but pH rises more rapidly than that of zinc phosphate cement.[38] Penetration of high molecular weight polymer molecules towards pulp is minimal. It has excellent biocompatibility.

Root canal sealers: Many root canal sealers are commercially available which are based on dental cements having excellent compatibility with periradicular tissues. They have been reported to cause mild to moderate to severe inflammatory changes while non inflammatory changes are also observed.[39] The response of the tissues is dependent upon the clinical techniques employed during obturation of the root canals.[40]

B. Biocompatibility of materials used for specific uses

Mercury and Amalgam: Amalgam is the most commonly used material for posterior teeth. It contains approximately 50% mercury and varying amounts of silver (30%), tin, zinc, and copper.

Mercury occurs in three forms [metal (Hgo), Inorganic ion (Hg2+), Organic forms].[41] Methyl mercury is the most toxic form of mercury.[42] The lowest known level for any observable toxic effect is 3µg/kg.[43] The sources of mercury poisoning in dental clinic are due to accidental spillage, stored raw material, unset amalgam, amalgam scraps, finishing and polishing, removal of amalgam restorations.[43] Breathing toxic mercury vapor while the dentist is drilling into a "silver" filling while replacing a filling or placing a crown or root canal is a common procedure. A chemical and electrical reaction in the mouth, called oral galvanism can occur in the presence of an incompatible dental material against amalgam.[41] This occurs when a dentist places an incompatible material in the mouth that interacts chemically and electrically with the mercury in dental fillings. This causes mercury to start leaching out of the filling and after ingestion can cause mercury poisoning. Examples being gold crowns placed over top of or close by a mercury filling, Nickel in braces and bridgework interacting with mercury filling. Stainless steel contains nickel and nickel can cause cancer. Stainless steel interacting with bridgework can cause oral cancer in the mouth.[43] High metals, like nickel in low quality porcelain crowns placed over top of a mercury filling or close to a mercury filling can cause mercury to start leaking from the filling faster. The amount of mercury vapor in the average mouth is 80 times above the established safety limits for mercury vapor exposure, according to U.S. Government standards.[42] Whole body reactions to mercury (as contained in silver fillings) are universal and have been categorized into five major divisions chiefly neurological, cardiovascular (chest pains, altered or rapid heart beats, pounding heart), collagen diseases (arthritis, joint pains, bursitis, lupus, scleroderma), immune problems (inability to fight off infections) and allergies (food, environment, and /or chemicals).[41,43]

Base Metal Alloys: Despite advances in ceramics mainly zirconia and alumina based, base metal alloys still continue to provide significant advantages than ceramics when it comes to replacing posterior teeth through fixed partial dentures. While full coverage restorations influences health of the supporting structures,[44] there are multiple factors that influence selection of material to be used in replacing missing natural teeth.[45] these factors come more into play if the restorations are complex designed where base metal alloys are more favorable than all ceramics since they allow possibility of such designs.[46] Base metal alloys that raise biocompatible issues and are used for construction of fixed and removable partial dentures include nickel, chromium and beryllium based dental alloys. Nickel being the common component of many dental alloys including used for crowns, fixed partial dentures, removable partial dentures, orthodontic wires, and endodontic files (although the duration through this route is far shorter). Nickel is the most allergenic metal known, with an incidence of 10% to 20%.[47] Hypersensitivity to nickel is more common in women because of chronic exposure to nickel jewellery.[48] Greater concern for patients is intra oral exposure to nickel. Because of concerns over the carcinogenic potential of nickel, Occupational safety and health administration (OSHA) adopts a standard to limit employee exposure to inorganic nickel in the laboratory or office to 15µg/m3, determined as time weighted average (TWA) concentration for up to 10 hrs work shift.[49] Also there is known cross reactivity between nickel and palladium allergy.[47] Virtually all patients who are allergic to palladium will be allergic to nickel, whereas only about 33% of those allergic to nickel will be allergic to palladium.[49] Palladium-based alloys have been reported as causative agents in cases of stomatitis,[50] oral lichenoid reactions,[51] and disseminated urticaria.[49] Chromium/cobalt alloys have an excellent history of biocompatibility, although there are some reports of tissue sensitivity in a very limited population.[48] Beryllium is used in Ni-Cr alloy in concentration of 1wt% to 2wt% to increase the castability of these alloys, but its use is controversial because of its biological effects.[50] Acidic environment enhances the release of Be from the alloy. Physiological responses vary from contact dermatitis to severe chemical pneumonitis which can be fatal.[50] Beryllium containing particles are inhaled and reach the alveoli of the lungs causing chronic inflammatory condition known as Berylliosis. Chronic disease state is characterized by symptoms persisting for more that 1 year. Symptoms range from coughing , chest pain, and general weakness to pulmonary dysfunction.

Restorative Resins: Dental composite resins are used as filling materials, dentin adhesives, cements or as luting agents for inlays, crowns, veneers and orthodontic brackets. Composite materials contain the organic matrix, in addition to a variety of different dimethacrylates, a number of reactive chemicals to make the materials optimal as dental restorative materials.[52] These components include initiators, such as benzoyl peroxide or camphorquinones; Accelerators, such as toluidines, anilines, aminobenzoic acid.[53] Natural teeth have a hardness of 300 on the Vickers Hardness Scale. Composites are typically much softer with a hardness of only 30.[53] Therefore, opposing teeth can quickly wear out and break down the softer composites resulting in restoration breakdown and begin leaking.[52] Composite restorations irrespective of their location routinely have been reported to leak, erode and decay the tooth due to marginal leakage that results due to polymerization (incomplete polymerization) shrinkage.[54] Partial polymerization is an inherent drawback which leads to degradation and leaching into adjacent tissue.[52,54] Both matrix and filler have been reported to leach thus causing sometimes rapid

degradation which reflects clinically into surface irregularities over the restoration that allows more plaque accumulation.[29,52] The permeability of the gingival epithelium allows penetration of leachable components and, thus, there is potential for toxicity and allergic reactions with composite materials. Lichenoid reactions in the oral mucosa in contact with resin-based composite materials have been described .

Denture Base Resins: appliances and prosthesis are invariable fabricated from plastic resins that are customized for each individual patient. For both patients need to adapt the oral tissues against the presence of a hard substance.[55] They are also used in different forms to guide surgeries (cleft lip and palate, immediate denture, implant placement) or at times to assess the therapeutic benefits of a particular treatment (diagnostic occlusal splints).[56,57] Their use is widespread in Prosthodontics but is not limited to other specialities wherein much of the work is performed in the dental laboratory.[58] Compared to restorative resins these do not contain any filler which results in the higher monomer content.[59] The oxidation process produces two main non biocompatible substances (Methylmethacrylate and formaldehyde) which are allergic agents that have been associated with mucosal injuries.[60] In some cases the methylmethacrylate has caused both dermatitis and allergic stomatitis.[29,58] Exposure of the lungs and trachea to methylmethacrylate vapor is harmful.[29] Significant pathologic changes or loss of cilia of tracheas and bronchial respiratory epithelium hyperplasia of peribronchiolar lymphoid follicles - respiratory capillary hyperaemia. The acrylic teeth with artificial dentures are indispensable due to the dynamic ability of shock absorption causing less bone resorption and ability to be customized.[61]

C. Highly biocompatible materials

Dental Ceramics: Dental ceramics consists primarily of glasses, porcelains, glass ceramics or highly crystalline structures. The biological side effects of dental ceramics are considered to be less common than those of other restorative materials. The most inert material used for dental restorations is generally considered to be conventional dental ceramics. Ceramic restorative materials are not known to cause biological reactions, except for wear on the opposing dentition and/or restorations.[62]

Direct Filling Gold: Gold foil is a stable and relatively insoluble restorative material. In extremely rare circumstances (estimated at 1:1 million),[63] patients sensitized to gold may react to gold restorations. These reactions include burning sensations of the oral mucous membrane in contact with the gold alloy, lichenoid lesions, and general systemic reactions. Pulpal inflammation, destruction of odontoblasts, and hemorrhage were attributed to direct filling gold mainly due to the technique (compact filling) and not due to gold components.[64]

D. Clinical factors

The biological response of a particular material is also dependent upon the type of treatment it receives before being placed in the oral cavity. An implant fixture if contaminated before being inserted in the bone will not produce the desired results and instead of osseointegrating within the bone will produce fibrous tissue. This implies the significance of sterilization and disinfection procedures to achieve a biocompatible response from the biotissues.[65] Similar results in biocompatibility may be produced if cements are contaminated by saliva before or after being placed under the restorations.[29] While for dental practitioners the goal is to satisfy a patient in terms of esthetics,[66] it is imperative for him to understand that each material will respond differently in different patients under different situations. Besides a vast number of risk factors associated with the use of the material in the oral cavity, one must also be conscious of the fact that plaque accretion around tooth/gingiva junction will initiate inflammation which may not be related to the material that is in touch with gingiva.[67]

CONCLUSION

Use of material plays crucial role in it's biocompatibility. The clinician should consider whether the material's proposed use is new and whether it has been tested before its proposed use. Likewise, small changes in composition of the material or processing of the material may effect the biocompatibility and this should be taken into consideration. The degree of risk must be carefully weighed against the possible benefits. Furthermore, these risks must be communicated clearly and thoroughly to the patient so that he or she can decide whether the benefits outweigh the risks. This communication is the essence of the informed consent, and no where in dentistry is this process more important than in evaluating the biological effects of materials. Biocompatibility is a complex and rapidly evolving research area. These issues should be of concern to every clinician because these issues have profound ethical, social, technical and legal implications in a dental practice.

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