SAFETY AND HAZARDS OF MATERIALS USED IN THE FABRICATION OF DENTAL PROSTHESES

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ABSTRACT

Many materials ranging from impression materials, waxes, investments and luting cements to fabricating materials are needed when directly or indirectly making dental prostheses. In general, they comprise metal alloys, ceramics, and polymers. Irrespective of the role, these materials play, they may remain in contact with oral tissues for as little as a few minutes to many decades or even for the remaining lifespan of patient. Despite the fact that currently there exists neither substantial data nor robust evidence to contraindicate the discontinuance of any of these materials, oral release of compounds from prosthodontics biomaterials remains a major concern with the likelihood of adverse reactions that could follow such dental treatments. There are reports from many different countries about contact allergy ensuing from alloys containing gold and palladium, of components from polymer-based materials and of alloys containing chromium and nickel. This review of clinical and research literature relating to prosthodontic biomaterials shows that despite the marked variation in dental alloy composition and the general lack of data on biocompatibility for prosthodontic materials, the efficacy of fixed and removable restorations is well established. At the same time, it is also felt that the raised level of concern about adverse reactions and safety of some of these materials mainly reflects the predominant influence of the dental manufacturing and marketing industry without clear-cut research information. Reliable research information using robust methodology is thus needed to clarify the various safety issues and frequency of adverse reactions in general dentistry, including prosthodontic treatment.

INTRODUCTION:

Prosthodontic restorations and appliances consist of many designs including conventional and implant-supported crowns, fixed prostheses (dental bridges) and removable prostheses or dentures. Some are fixed using precision attachment and screws or cemented to teeth or implants with minimal contacts with gingival or other oral soft tissues. Others are either fully supported by the oral mucosa and are removable or resting on both hard tissues of teeth or their analogues (implants) and soft tissues. Different materials, including metals, polymeric materials, ceramics and several types of cements are used when fabricating and fitting prosthodontic appliances for patients. In fact more than 75% of all the existing dental materials are directly or indirectly used or involved when fabricating and providing prosthodontics restorations to be placed in the oro-facial complex of patients¹. For the purpose of this review, prosthodontics materials are defined as those used in the making of indirect restorations. These restorations are constructed in the dental laboratory on casts obtained from impressions and other chair-side recordings. Some of these materials including gypsum, casting waxes and investment are required only in the fabrication of prostheses in the laboratory. These usually do not come in direct contact with the patient tissues. Thus, any adverse effects, if any, are largely limited to dental personnel handling them. The consequent adversities that arise during laboratory procedures may be due to their contact with skin, exposure to dust from mixing, grinding and polishing and inhalation of fumes and vapors. Of particular concern are all those who are frequently exposed to particles or dust in the dental laboratory and dental clinical area including staff and patients during the chair-side adjustment and finishing of prostheses². Most of these potential problems can be handled by using the recommended safety or protective devices to improve the working environment, e.g. use of face masks, gloves and local and central dust and fumes extraction systems²³. When evaluating adverse reactions to materials used in prosthodontic appliances, a variety of
situations must therefore be taken into consideration. This is because some materials come only in brief contact with the patients such as when making an impression or registering a bite of the patient. In contrast, dental prostheses are intended to remain in situ for decades. A number of factors need to be taken into account when estimating adverse biological reactions to prosthodontic materials. Among these include; the type, form, contour, extent of the prosthesis, any medication used by the patient, salivary flow rate, xerostomia, oral hygiene, quality of fit and function of the prosthesis. All these conditions may affect local reactions in addition to those caused by the materials per se. Biological films, ‘pellicles’, of salivary origin will also accumulate on the materials. They differ in composition depending on the material and on the properties of the patients’ saliva. Meager information is available on these films. The irrigating effect of saliva is also difficult to assess. However, a distinct difference exists between material reactions intra-orally and extra-orally, with those on skin being more frequent and more severe. Skin patch testing is therefore of limited value, even if specifically designed series of tests for dental materials are employed.

BIOCOMPATIBILITY TESTS
Many preclinical biocompatibility tests are available to minimize the risk of adverse reactions to dental materials. These tests are categorized on the basis of their applicability levels. Initial tests include cell culture tests, hemolytic tests, systemic toxicity tests, and tests estimating teratogenic and carcinogenic effects and potential. Secondary tests cover implantation tests, skin and mucous membrane irritation tests and sensitization tests. Usage tests take into account the manner in which the materials are intended to be used in clinical practice. Oral mucosa tests based on reactions to materials in contact with the hamster-cheek pouch is considered to be a short-term usage test for prosthodontic materials and relatively less invasive and traumatic especially to suturing the skin to secure the material in contact with the mucosa. If a holding device is used, uncertainty exists regarding the position and pressure exerted by the test specimen. Plaque accumulation around the test specimen will also affect the reactions. Specially designed appliances for testing prosthodontic materials have not received widespread use, probably because of the inherent problems with the test or the cost involved. Development of usage tests for prosthodontic materials should therefore receive greater attention and should become a research priority.

ADVERSE / SIDE EFFECTS OF PROSTHODONTIC MATERIALS
Unexpected biological side effects to prosthodontic materials may occur as a result of their direct contact with soft or mineralized tissues, or by exposure to leachable components resulting from corrosion and degradation products. Concurrent and combined presence of dental prosthetic restorations made in more than one alloys with differing compositions will tend to enhance the corrosion caused by galvanic action. Since these components may be ingested, both local and systemic reactions may occur.

Prosthodontic materials and their corrosion / degradation products comprise components that are known to be allergenic, toxic and carcinogenic in specific situations. Local mechanical irritation due to an overhanging margin of a restoration or an overextended denture must also be considered as adverse effects. Thus, a number of potential problems exist. However, few side effects of prosthodontic materials have been reported in the literature. Similarly, no detailed investigations have been carried out to assess the incidence of adverse effects. An assessment of biological side effects to prosthodontic materials is therefore challenging, and it is important to differentiate between potential and documented side effects.

INCIDENCE OF ADVERSE / SIDE EFFECTS
An overall incidence of side effects to dental materials of one per 700 patients, or of one patient per approximately 3.5 years of practice, was reported in one study. Over 13000 patients were examined for acute and long-standing adverse effects during a 2-week period. Prosthodontics and orthodontic treatments were somewhat over-represented compared to dental
treatments of general nature with involvement of many dental materials. The incidence for individual materials, or even groups of materials was too low to establish an incidence rate. Lichenoid reactions in the oral mucosa related directly to a restorative material were the most commonly reported side effect.

Many of the signs of the noted reactions were symptom-less in patients and even remaining un-noticed to them. A questionnaire survey among prosthodontists\textsuperscript{11} indicated adverse patient reactions in one out of 300 patients or one patient in approximately 2 years per prosthodontist.

ADVERSE REACTIONS TO PROSTHODONTIC MATERIALS

Due to the low incidence of side effects to prosthodontic materials, it will be pertinent to limit this discussion to groups of materials rather than specific types of materials including polymeric materials, alloys, implant materials, and cements. Ceramic materials are generally regarded as inert, but dust particles of these materials arising during when handling, manipulating and adjusting and finishing the fabrication represent a potential problem, both for the laboratory and clinical personnel as well as patients\textsuperscript{12}.

Polymeric Restorative Materials

Resin-based materials comprising of liquid methyl-meth-acrylate (MMA) monomers and poly-methyl–meth-acrylate (PMMA) powder are the most commonly used polymers in dental prostheses. Polymerization may be initiated by heat, light, or by chemical activators at room or mouth temperatures. Apart from containing accelerators (amines), they contain co-polymers, such as butyl-meth-acrylate (BMA), plasticizing agents such as di-butyl-phtalate, and inhibitor such as hydroquinone. In addition, cadmium salt-based colouring agents are also added. These ingredients as well as the added cadmium salts are not considered to represent any problems for patients but they may pose potential hazard to technicians routinely grinding and finishing prostheses made in resin-based materials\textsuperscript{13}. MMA monomer may result in toxic reactions and allergic responses in previously sensitized individuals, especially in under cured appliances\textsuperscript{14}. It is often difficult to differentiate between these two fundamentally different types of reactions because the clinical manifestations are similar, i.e. redness and swelling of the affected mucosa. A differential diagnosis of fungal infections must also be made. Physical trauma caused by overextended or poorly fitting dentures may also present as local reactions. These are difficult to differentiate from other types of local lesions. It is important in this context to keep in mind that formaldehyde is a degradation product of several monomers used in dentistry, including denture-base polymers and restorative resin based composites. In fact, about half of all reported side effects to prosthodontic materials have been associated with polymeric materials\textsuperscript{11}.

Heat-cured acrylics are well tolerated by the gingival tissues. In comparison, cold-curing acrylic resins may result in gingival reactions\textsuperscript{15}. This has been attributed to the presence, in higher concentration, of the residual monomer in cold-cured resins as compared to heat-cured acrylics. The consequent diffused or localized burning sensation in the mouth because of direct mucosal irritation may be erroneously taken for the entity of “Burning Mouth Syndrome (BMS). In fact the burning sensation may result from the intra-oral manipulation of resin or because of the presence of residual monomer. Consequently, this may elicit either an allergic response or cause direct irritation of the mucosa by the monomer or by the heat generated during its curing in the mouth\textsuperscript{16}. In this case the obvious signs of inflammation and irritation for the burning sensation may be sufficient not to consider this as the entity of BMS. Allergic reactions to an ethylene amine activator used in several polymeric materials, including impression materials and temporary crown materials are one of two most commonly reported adverse effects to prosthodontic materials\textsuperscript{17}.

Prosthodontic Alloys

About 550 different dental alloys are available in the USA\textsuperscript{18}. A great variety of major and minor metal components are present in these alloys. In addition, traces of metals are present unintentionally as impurities. Some of the metals used in dental alloys are known to be biologically active or potentially hazardous, such as nickel, chromium, cobalt, cadmium and beryllium. About one in four reactions to materials used in prosthodontic treatments are related to metals, especially chromium, cobalt, nickel, and gold alloys used for metal ceramic restorations\textsuperscript{18}.  

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Literature indicates that allergic reactions to gold-based restorations were more common than to nickel-containing alloys. This agrees with the findings of a survey of mucosal reactions to more than 1000 prosthetic units. One case report indicated a possible association between a defective gold crown and cancer of the tongue. Hildebrand et al. reviewed 139 published cases of allergy to base-metal alloys in removable partial dentures (RPDs). Gingivitis and stomatitis were the most common clinical symptoms, but remote reactions occurred in almost 25% patients. However, mucosal reactions to metal-based partial dentures are rare. The more frequently observed gingival signs and symptoms could be considered as effects of direct pressure contact and the consequent trauma ensuing from the same rather than the side effect of alloys or materials used in the RPD fabrication.

Biological reactions to casting alloys are dependent on the release of components from the alloys, which would seem to indicate that they should be dependent on the degree of corrosion. However, no correlation seems to exist between mucosal reactions to fixed prostheses and corrosion and tarnish. This lack of correlation may indicate that the biological reactions observed are caused by factors other than the material per se. Palladium alloys are generally better tolerated than base-metal alloys or gold alloys for metal-ceramic restorations, although they tend to tarnish more than other casting alloys. However, palladium alloys have also been reported to cause adverse reactions, and palladium may be linked to a cross-reactivity with nickel. Cadmium has been used in solders, but its presence is not considered to have an effect on patients because of the minimal amounts present. However, technicians who frequently braze alloys above their melting point are at risk because in the process of soldering and welding, cadmium will evaporate. This represents a problem with the need for availability of an adequate fume extraction system. In response to this hazard, the use of solders containing cadmium has also been largely discontinued. Alloys are among the materials used for the making of conventional cast posts and cores. A variety of metal combinations are in common use, sometimes with stainless steel pins. Of particular concern is to exercise care not to combine the simultaneous use of two different alloys for the post and cast core/crown when preparing post retained crowns because the galvanic corrosion may cause root fractures.

**Implant Materials**

A wide variety of materials have been used in dental implants, including polymeric materials, alloys, ceramics, and synthetic hydroxyapatite. The most frequently used materials have been cobalt-chromium alloys, vitreous carbon, titanium and aluminum oxide. Numerous investigations have been performed to assess the biological properties of dental implants. Much attention has focused on the bone tissue / implant interface and on the in-growth of bone into the porous implant fixture. The concept of ‘osseointegration’ associated with titanium implants, as demonstrated by Brånemark, has provided much of the biological basis for modern implantology. The presence of a gingival-attachment mechanism at the epithelium / implant interface is important for the success of the implant. Any untoward effect of the implant material is difficult to differentiate from failures. These failure commonly result because of improper surgical procedures, problems with the loading of the implant, and infection. So far our understanding is clear regarding the inert nature of pure titanium implants.

**Cements**

Zinc-phosphate cement has been, and still it is, the most frequently used luting agent for crowns and bridges. Pulpal reactions initially occurring in deep cavities will subside over the time. Uncertainty has also existed about glass-ionomer cements, because clinical reports have indicated a high frequency of post-luting sensitivity. Pulp studies generally indicate slight reactions, but somewhat more to the luting type than to the restorative type of glass-ionomer materials. A recent clinical study of pulp sensitivity following cementation with zinc phosphate and glass-ionomer cements showed less sensitivity to zinc phosphate than to glass ionomer during the first 2 weeks, but after 3 months, there were no differences. The pressure on the dentine exerted during cementation was thought to play a possible role on the observation. Modern resin-based luting cements are also well tolerated by the pulp. The importance of establishing a hermetic seal by the cements has been stressed. Eugenol is a known cytotoxic and allergenic substance. Zinc oxide eugenol is used extensively in temporary cements, and it also forms the basis for certain impression materials. The relatively
short-term use of these materials calls for attention to allergic reactions, but chronic toxic reactions are unlikely.

CONCLUSION
Despite the marked variation in dental alloy composition and the general lack of data on biocompatibility for prosthodontic materials, the efficacy of fixed and removable restorations is well established. Many potential problems exist, but few documented adverse reactions have been published. Much attention has been focused on the presence of nickel. In some Scandinavian countries, the health authorities have made strong recommendations against using nickel-containing alloys on humans. These recommendations are based on the fact that nickel is a potent allergen, a carcinogen and can be distributed to various organs in experimental studies in animals. It is important to keep in mind that extrapolating data from industrial settings or handbooks to dental applications is not justified. Furthermore, demonstration of a toxic agent in any tissue is not the same as an adverse effect. In fact, nickel is an essential trace element and intraoral use of nickel-containing alloys may induce immunological tolerance to nickel, which may have a beneficial effect even on nickel-allergic patients.

In addition, extensive clinical experience with nickel-containing alloys in prosthodontic practice calls for a re-evaluation of their use. Future evaluation of dental materials, including those used in prosthodontics, will include more attention to biological and clinical properties. International standardization presently under development will outline methods for testing the materials, and the certifying bodies will establish criteria for certification of the materials to be used. It is expected that one requirement will be for clinicians and manufacturers to report biological side effects associated with use of the materials to certifying bodies or health authorities. With the low incidence of adverse effects of the materials in present use, this will satisfy the needs of the patients and those handling the materials. On rare occasion when side effects occur, the use of alternative materials will be the treatment of choice. Meanwhile it is important to maintain, by keeping a national register, a record of all adverse reactions and side effects noted in institutions and practices. For this to happen, an effective liaison and monitoring system at the health ministry (Federal & Provincial) would be necessary. Similarly, for monitoring and evaluation of hazardous effects in dental personnel, their regular screening strategies need to be incorporated.

REFERENCES