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Dental materials: Need to consider the other side

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In the past few decades, there has been an increase in demand for safety evaluation and control of dental materials used daily in dentistry; however, this task is difficult. Dental materials that are passive and do not react with the oral environment will be more stable and have superior durability. It is expected that dental materials will be universally accepted and will not cause harm or injury to the surrounding structures in the oral cavity. This is an entirely negative approach to the material tolerance and biocompatibility, and hides the possibility that some positive gains can be achieved, with the long history of use of many materials in dentistry. It is important, however, not to forget that the potential exists for adverse tissue responses to synthetic materials used in repair, augmentation, and repair of natural tissue structures. As new materials and repair techniques become available and the sophistication of cell-level and sub-cellular response evaluations increases, the concerns to be addressed and the methods to be used may change. Side-effects of dental materials are believed to be rare, and generally, those that have been reported are mild. But there is a need to think the other side.

Biocompatibility is "the ability of a material to elicit an appropriate biological response in a given application in the body". It is measured on the basis of localized cytotoxicity [such as pulpal and mucosal response], systemic & allergic responses as well as carcinogenicity. "Biocompatible" is distinct as being harmonious with life and not having toxic or injurious effects on biologic function". It is a dynamic process, not a static one. The response of body to a material is dynamic because the body may change through disease or aging, the material may change through corrosion or fatigue, or the loads placed on material may change through change in occlusion or diet. The science of dental biomaterials must be based on a broad information base of certain biologic considerations that are associated with the use of materials designed for the oral cavity.

Based on these criteria, the requirements for dental material biocompatibility include the following: Harmless to the pulp and soft tissues, Nontoxic so that diffusible substances that can be released and absorbed into the circulatory system will not cause a systemic toxic response. It should be free of potentially sensitizing agents that are likely to cause an allergic response. It should have no carcinogenic potential.

Relevance to Dentists: Dentists potential concerns about biocompatibility can be organized in to 4 areas:

1) **Safety of the Patient:** One of the primary concern of any dental practitioner is to avoid harming the patient. Evidence has shown that, although adverse reactions to dental materials are not common, they can occur for many types of materials, including alloys, resins and cements.

2) **Safety of Dental Staff:** In many situations, the risk of adverse effects of biomaterials is much higher for dental staff than for the patient. The staff may be chronically exposed to materials when they are being manipulated or while setting. e.g:- 1) Amalgam – Mercury vapors, Chronic exposure to latex and resin based materials.

3) **Regulatory Compliance Issues:** Biocompatibility issues are closely linked to regulations that affect dental practice. e.g.: Dental amalgam. Because of the biologic concerns about mercury, regulators have considered monitoring and restricting amount of mercury in waste water for dental practice.

4) **Legal Liability:** Biocompatibility issues also influence liability issues that affect dental practitioners. Because dental materials can affect the well-being of patients and dental auxillaries, practitioners assume a legal risk when using these materials.

Biocompatibility tests are classified on three levels, with the most rapid and economical occurring at primary level. The purpose of biocompatibility tests is to eliminate any potential product or component of a product that can cause harm or damage to oral and maxillofacial tissues. Group I: Primary Tests, Group II: Secondary Tests & Group III: Pre-clinical Usage Tests. There are certain measurements for regulation of standards of biocompatibility. The first efforts of ADA to establish guidelines for dental materials came in 1926. One of early attempts to develop a uniform test for all materials was the study by DIXON and RICKERT in 1933, in which toxicity of most dental materials in use at that time was investigated by implanting the materials into pockets in subdermal tissue.

In 1972 the council on Dental materials, instruments, and equipment of ANSI / ADA approved Document No. 41 for recommended standard practices for biological evaluation of Dental materials. Initial tests include in vitro assays for cytotoxicity, red blood

cell membrane lysis (haemolysis) mutagenesis and carcinogenesis at the cellular level.

Based on the results of these initial tests, promising materials are tested by one or more secondary tests in small animals (in vivo) for inflammatory or immunogenic potential. And finally, materials that pass secondary tests and still hold potential are subjected to one or more in vivo usage tests: tests for pulpal and bone response. ISO 10993 (international standard: 1992)

It contains 16 parts, each dealing with a different aspect of biological testing. e.g: part 3: test for genotoxicity, carcinogenicity and reproductive toxicity, part 4: tests for interactions with blood.

This standard divides tests into "initial" and "supplementary". Initial tests for cytotoxicity, sensitization, systemic toxicity. Supplementary tests are tests such as chronic toxicity, carcinogenicity and biodegradation.

The literature has high lightened the reaction of oral soft tissues to many restorative materials. Restorative materials may cause reactions in the oral soft tissues such as gingiva. Conditions that promote retention of plaque: rough surfaces or open margins increase inflammatory reactions in gingiva around these materials. Released products of restorative materials also contribute either directly or indirectly to this inflammation, particularly in areas where the washing effects of saliva are less, such as in interproximal areas, in deep gingival pockets or under removable appliances. Cements exhibit some cytotoxicity in the freshly set state, but this decreases substantially with time. The buffering and protein – binding effects of saliva appear to mitigate against cytotoxic effects. Composites are initially very cytotoxic in vitro tests. The cytotoxicity is most probably primarily from un-polymerized components in the air inhibited layer that leach out from the materials. Amalgam restorations carried in to gingival crevice may cause inflammation of gingiva because of products of corrosion or bacterial plaque. Denture base materials, especially methacrylates (residual monomer), has been associated with mucosal irritation and sensitization of tissues. Laboratory personnel suffer most as they are exposed repeatedly to a variety of un reacted components. Soft tissue responses to soft denture liners and adhesives are of concern because of intimate contact between these materials and gingiva. Plasticizers, which are incorporated into some materials to make them soft and flexible, are released in vivo and invitro: can cause inflammatory reactions. In animal tests also, several of these materials have caused significant epithelial changes.

Recently, reaction of bone & soft tissues to implant materials has been mentioned in the articles. These are four basic materials used in implant fabrication: ceramics, carbon, metals and polymers. Most Ceramic implant materials have very low toxic effects on tissues, either because they are in an oxidized state or are corrosion resistant. They are non-toxic, non immunogenic, non carcinogenic. But are brittle and lack impact and shear strength. If root surface porosities are more than 150 nm in diameter, the implants often become firmly bound to bone. If porosities are smaller, the tissue usually forms only fibrous in growth. Reactions to pure metals and alloys include a variety of implant materials like stainless steel, chromium-cobalt-molybdenum, titanium and its alloys (most common). Titanium is a pure metal which forms a thin film of various titanium oxides, which is corrosion resistant, allows bone to osseointegrate in the soft tissue. The bond, epithelium forms with titanium is morphologically similar to that formed with the tooth. Peri-implantitis is now a documented disease around implants and involves many of same bacteria as periodontitis.

Thus, the biocompatibility of a dental material depends on its composition, location and interactions with oral cavity. Diverse biological responses to these materials depend on whether they release their components and whether those components are toxic, immunogenic, or mutagenic at released concentrations. So, one must consider not only strength, esthetics, or functional aspects of the material, but its biocompatibility as well.