

Definition:

Ability of a material to elicit an appropriate biological response in a given application in the body.

Placement of a material creates an interface that is not normally present.

Interface = Not static, includes dynamic interactions

Activity of interface depends on: location of material, duration in body, properties of material and health of host.

Property of a Material and Its Environment:

Interaction

Organisations That Test Dental Materials:

- > Food and Drug Administration (FDA)
- > American National Standards Institute
- > American Dental Association (ADA)
- > International Organization for Standardization

In-vitro Testing:

Performed outside an organism

First screening test done in test tubes, cell culture dish, flask.

Material is placed in direct/in-direct contact with some biological organism.

Advantages:

- > Fast
- > Inexpensive
- > Easily standardised
- > larger scale screening conditions can be tightly controlled to provide the highest quality of scientific rigor.

Disadvantages:

- > Potential lack of relevance to the in vivo use of material.
- > Lacks the complex co-ordination of systems (immune system, inflammatory system, circulatory system)

Animal Testing:

Place a material into contact with an intact organism

Distinct difference, exposure without regard to the material's final use

Advantage: Ability to allow an intact biological system to respond to a material.

Disadvantages:

- > interfere with the many complex biological systems
- > expensive
- > difficult to control
- > ethical considerations
- > questionable

Usage/Invitro Testing:

Material is placed in an environment, clinically relevant to the use of the material in clinical practice

Humans (clinical trial) and Animals closely resembling humans

Advantage: Gold standard

Disadvantage:

- > Expensive
- > Approval
- > Legal liabilities
- > Time consuming

Key concepts of Biocompatibility:

Biomaterials are not biologically inert:

There are no inert materials. Interactions depend on the material, the host and forces/conditions placed on the material. Material affects the host and host affects the material.

Dynamic Process:

Body may change due to aging/disease. Material may change due to corrosion/fatigue. Changes may alter conditions where initially an appropriate/desired biological response took place. Biological response to a material is an ongoing process.

Measuring Biocompatibility of Materials:

Location:

Important to it's overall biological response. Determines if material will be covered by soft or mineralized tissue, will it be external to oral epithelium or if it will communicate through epithelium and will the material be directly exposed to bone, tissues , blood and saliva or will there be a barrier (such as enamel or dentin).

Duration:

More stringent tests for longer duration.

Stress:

Stresses placed on material (physical, chemical, thermal or occlusal or reaction to salivary proteins) may react unfavourably.

Adverse Affects from Dental Materials:

1. Toxicity:

normally the first screening test.

2. Inflammation:

second fundamental type of biological response resulting either from allergy/ toxicity, first infiltration of neutrophils, then monocytes and other lymphocytes.

3. Allergic Reaction:

the most common to lay people. **Type I** - refers to an immediate atopic /anaphylatic reaction when an antigen reacts with mast cell/basophils. **Type II** - is a cytotoxic hypersensitivity reaction. **Type III** - immune-complex hypersensitivity reaction. **Type IV** - delayed or cell-mediated hypersensitivity. **Type V** - stimulating-antibody reaction. **Type VI** - antibody dependent, cell mediated cytotoxicity reaction.

Adverse Affects from Dental Materials: (cont)

4. Mutagenicity:

results when the components of a material alter the base-pair sequences of DNA in cells.

Local and Systemic Effects:

Local: Pulp of the tooth, periodontium, root apex, soft tissues (buccal mucosa/tongue)

Systemic: Ingestion, absorption in the gut, inhaled vapor, release at the tooth apex, absorption through the o/mucosa. As well as, Systemic biological response depends on; duration and concentration of the exposure, excretion rate of the substance, site of exposure.

Principles of Adverse Effects:

Degradation process: The biological response to the corrosion products depends on the amount, composition, and form of these products as well as their location in the tissues.

Surface characteristics: research has shown that for all dental materials, the surface is very different compared to the interior.

Examples:

Latex: (3 categories: irritant, allergic & type 1 hypersensitivity reaction) In dentistry; rubber dam, gloves, bite blocks etc. Reactions to latex; localized rashes, swelling to a more serious wheezing and anaphylaxis. Dermatitis of the hands (most common).

Principles of Adverse Effects: (cont)

Mercury&Amalgam: No data to show that mercury released from dental amalgam is harmful.

Estrogenicity: Ability of a chemical to act as the hormone estrogen in the body. The placement of composites has been questioned. Xenoestrogen bisphenol A (BPA) synthetic starting point for all Bis-GMA composites. Fear is that the release of these substances might alter normal cellular development or maintenance if the BPA has estrogenic effects.

Nickel: Common component of many dental alloys including those used for crowns, fixed partial dentures, removable partial dentures and some orthodontic appliances.

Endodontic files. Reactions are often subtle, resemble periodontal inflammation. Occurs primarily outside the mouth.

Beryllium:

if inhaled cause chronic inflammatory condition- berylliosis, the lung is engorged with lymphocytes and macrophages. T cells in susceptible individuals proliferate locally in the lung tissue, in delayed hypersensitivity reaction to the beryllium metal. Occurs in individuals with a hypersensitivity to beryllium and may occur from inhalation of beryllium dusts, salts, fumes as those encountered when casting beryllium-containing alloys.

Adverse Effects of Restorative Material:

TABLE 5: Biocompatibility considerations of various dental restorative materials^{60,61}

Restorative Material	Biocompatibility Consideration
Dental Amalgam:	<ul style="list-style-type: none"> No adverse pulpal responses from mercury Corrosion may limit marginal leakage, but in the long term may lead to breakdown of marginal integrity, especially with low-copper amalgams Lichenoid reactions reported Thermal conduction to pulp Mercury allergy (8%)
Resin-Based Composites:	<ul style="list-style-type: none"> Documented estrogenicity issue Very little research on systemic biocompatibility Allergic to resin composite ingredients (8%) Incomplete polymerization leading to degradation, leaching, and imperfect bonding Predisposed to polymerization shrinkage Associated with adverse local pulpal and dentin reactions, development of recurrent caries, and pain Higher proportion of streptococcus mutans leading to secondary caries
Glass Ionomer Cements:	<ul style="list-style-type: none"> Few documented systemic adverse effects Early pulpal reactions, although less than with cements or composite resins, and with rapid recovery Hydraulic pressure and etching during placement may irritate the pulp Good adhesives, minimal leakage at margins, high biocompatibility Leaching of component materials offers opportunity for slow release of fluoride
Gold-Filled and Cast Alloys:	<ul style="list-style-type: none"> Inert; sensitivities are rare Potential pulpal reactions due to condensation Gold contact allergy (23%)
Ceramics:	<ul style="list-style-type: none"> Inert material No long-term data on biocompatibility Possibility of silica granulomas

