AN OVERVIEW OF BIOCOMPATIBILITY OF ORTHODONTIC MATERIALS

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Abstract: There are various types of orthodontic materials used in treatment of malocclusion. These materials are not inert materials. They undergo chemical or electrochemical reactions with environment resulting in dissolution or formation of chemical compound in oral environment. Thus biocompatibility of orthodontic materials is important clinical aspect of orthodontic treatment in patients as well as for appliance durability. Present article highlighted various factors responsible for biocompatibility of materials as well as possible protective measures.

Key words: Biocompatibility, corrosion, orthodontic materials, Nickel sensitivity

1. Introduction:
On widely accepted definition of biocompatibility is the ability of a material to “elicit on appropriate biological response in a given application.” This definition implies on interaction biocompatibility host, a material and an expected function of the material. All three factors must be considered and be in harmony before the material can be considered biocompatible. (Fig. 1).

1.1 KEY POINTS:
1.1.1 First Key point about biocompatibility to understand is "there are no truly inert biomaterials". When a material is placed into living tissues interaction with the complex biological systems around it will occur and those interactions will result in some sort of the biological response. The interactions that occur will depend upon the material, the host and what forces and conditions are imposed on the material (its function).

1.1.2 Second Key point “Biocompatibility is a dynamic ongoing process, not a static one"
1.1.3. and habits of the patient when assessing the e.g. the practitioner must of there are corrosion properties of arch wires may be different. Does the patient ingest many acidic drinks? The corrosion properties of arch wires may be different. The practitioner must consider the particular clinical application and patient and not assume that because a certain alloy is biologically acceptable as an arch wire, it will be acceptable, as a bracket or a band or a spring. Resin materials that are biologically acceptable as removable appliances may or may not be acceptable as resin based cements.

Finally the practitioner must monitor the patient over time. A patient who is not allergic to nickel today might become allergic in future. 4

3. ORTHODONTIC MATERIALS AND BIOCOMPATIBILITY PROBLEMS

Biocompatibility issues should be of concern to every practitioner because these issues have profound ethical and legal implications for dental practice.

The practitioner potential concerns about biocompatibility can be organized into four areas.

1) Safety of the patient
2) Safety of Dental team
3) Compliance with regulatory issues
4) Liability

3.1 SAFETY OF THE PATIENT

One of the primary concerns of any dental practitioner is to avoid harming the patient, this concern is especially important in orthodontic practices where many patients are children or young adults.

Adverse reactions can occur for many types of materials used in orthodontics including alloys, resins & cements.

“Leakage of heavy metals-corrosion”.

The prevalent biocompatibility problems in the oral environment are caused by leakage of heavy metals. 3, 5, 6 Acting together, the ionic, thermal microbial and enzymatic environment can lead to the biodegradation of metals. Often contributing to the phenomenon is improper assembly of the attachments, with some components being “nobler” having a different electronegativity than the others. This often occur in orthodontics at the brazing alloy=stainless steel interfaces. Thus in case of combined brackets, if the brazing is nobler (gold), the steel may dissolve. If the brazing is less noble,, the reverse is true. 7, 8 In some instances, “galvanism” is evey unwilfully enhanced as seen in a bracket made by laminating different alloys together. 9 In continuous contact and in the presence of an electrolyte (saliva), the system acts as an electric cell, releasing heavy metals. Such phenomenons often are accompanied by “galvanic lesions” which appear in the vicinity of the affected area. Starting with the slightest effect, the foul taste, attachment corrosion can go so far as to cause necrosis or serious allergies.
Nickel

Nickel is found in many alloys found in orthodontics can have carcinogenic, mutagenic and allergic effects. Nickel allergies are more common in females as compared to males.

To avoid liability, U.S. manufactures post warnings on their products, such as “This product contains nickel and chromium and should not be used for individuals with known allergic sensitivity to these metals”. (Ormco) & “this product contains nickel, which may have a severe allergic effect on some individuals” (GAC).

To amount of nickel ions leached from Niti arch wires may not be sufficient to cause problems, unless major surface defects are present. Caused by drawing or improper handing, surface defects may cause pitting corrosion.

Stainless steel is particularly susceptible to intergranular corrosion during brazing and welding, this can occur at temperatures as low as 350°C. Heating leads to reaction of chromium with the carbon in the steel to form chromium carbide (sensitization). As chromium was used up, the alloy becomes more susceptible to corrosion.

Other metals such as cobalt and chromium-58 are also sometimes known to induce hypersensitivity.

Introduced by means of ingestion, inhalation, or by the topical (dermal) route, heavy metal leakage can lead to symptoms such as inflammation and swelling of the mucosa, redness and aphtha of the gingival, tongue and cheeks, peri-oral and facial eczema and itching irritation pharyngitis, sinusitis and rhinitis. First exposure of mucosa to heavy metals may lead to mild sensitization. There after biological reactions can occur, such as swelling, redness, burning sensation, vesiculation, ulceration and even necrosis. Such lesions caused by leaching appliances can be cleared up by removing the appliances and using a protective coating.

3.1.1 Protective measure

1) To reduce corrosion, patient should avoid eating too much salty food, should clean or change the elastics frequently.

   • Empty pockets at the bracket/adhesive interface should be prevented. The formations of deposits lead first to pits on the attachments, then to crevices and pockets, in which corrosion accelerates in the absence of oxygen.

   • Clinician should select attachment, made of alloys that are less susceptible to corrosion, should avoid intermetal contacts whenever possible and should follow proper storage, maintenance and sterilization procedures.

   • Indiscriminate use of heat or disinfection as well as thermal recycling should be avoided.

   • Orthodontic arch wires and brackets can be coated with either titanium nitride or an epoxy resin. The former is used to improve hardness and reduce friction, the later improves esthetics. Epoxy coating also improves corrosion resistance.

   • Another method or reducing corrosion of metals is to add a corrosion inhibitor to a solution into which the material is placed.

The second major biocompatibility problem that orthodontists have faced in recent years is the question of the estrogenicity of dental resins, particularly those containing the chemical bisphenol-A, one of the two components that react to form Bis-GMA. Estrogenicity is the ability of the chemicals from the environment called xenoestrogens, to mimic hormone estrogen in the body of exposed person. Because natural estrogens have many powerful and wide-spread effects on the growth and developments, xenoestrogens is concern.

3.2 SAFETY OF DENTAL TEAM

The area of biocompatibility of materials is also relevant to the practitioner from the stand point of health of dental team than for the patient because of the chronic exposure of the dental team and the manipulation of materials when they are being placed, setting or being removed.

The primary risk for the dental team in orthodontics appears to be contact with latex based and resin based materials. These adverse effects can be from cumulative irritation or from allergic responses.

3.3 COMPLIANCE WITH REGULATORY ISSUES

Practitioners are affected by biocompatibility issues because these issues are closely linked to regulatory issues that govern dental practice. Most dental practitioners in U.S. are keenly aware of many regulations imposed by OSHA (occupational health and safety administration) on dental practice. These regulations are basically designed to minimize the risk to dental personals from agents in dental restorations and devices.
3.4 LIABILITY

Biocompatibility issues also influence liability issues, which affect dental practitioners. Because dental materials can affect the well being of patients or dental auxiliaries, the practitioner assumes a legal risk when using these materials.

4. MEASUREMENT OF BIOCOMPATIBILITY

Types of biocompatibility tests are presented briefly in Table-1

<table>
<thead>
<tr>
<th>Type of test</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In Vitro Tests</strong></td>
<td>➔ Experimentally controllable</td>
<td>Questionable relevance if structured incorrectly</td>
</tr>
<tr>
<td><strong>(cell culture)</strong></td>
<td>➔ Relatively fast</td>
<td></td>
</tr>
<tr>
<td></td>
<td>➔ Relatively Inexpensive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>➔ Avoid use of human subjects</td>
<td></td>
</tr>
<tr>
<td></td>
<td>➔ Avoid use of animals (sometimes)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>➔ Avoid ethical issues</td>
<td></td>
</tr>
<tr>
<td><strong>In Vivo Tests</strong></td>
<td>Intact organism ➔</td>
<td>➔ Time consuming</td>
</tr>
<tr>
<td></td>
<td>Measure complete biological response</td>
<td>➔ Expensive</td>
</tr>
<tr>
<td></td>
<td>➔ Can measure responses that are not possible</td>
<td>➔ Can be difficult to Control experimentally</td>
</tr>
<tr>
<td></td>
<td>to observe in vitro</td>
<td></td>
</tr>
<tr>
<td></td>
<td>➔ Avoid use of human subjects</td>
<td>➔ Ethical issues. Animal use.</td>
</tr>
<tr>
<td></td>
<td>➔ Avoid some ethical issues</td>
<td></td>
</tr>
<tr>
<td><strong>Usage Tests</strong></td>
<td>➔ Relevant</td>
<td>➔ difficult to control experimentally</td>
</tr>
<tr>
<td><strong>(Clinical trials)</strong></td>
<td>➔ Measure complete biological response</td>
<td>➔ Time consuming</td>
</tr>
<tr>
<td></td>
<td></td>
<td>➔ Expensive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>➔ Ethical issues (humans)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>➔ Legal issues (humans)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>➔ Difficult to interpret experimentally</td>
</tr>
</tbody>
</table>

4.1 Usage Tests

Usage tests are essentially clinical trials of the material. The usage test is by definition the most relevant biocompatibility test and all other tests must be measured against if for relevance.14

4.2 Schemes for testing biocompatibility

I) The oldest scheme used unspecific toxicity tests first followed by “specific” toxicity tests and then clinical trials only materials that passed one level are tested further. (fig. 2) Unspecific tests were those in which the conditions of the test did not necessarily reflect those of materials used.

II) This scheme (Fig.3) employs primary, secondary and usage tests and it is still commonly employed today. This scheme differs from (I) because; It emphasizes many cellular reactions in addition to toxicity. Primary tests measure basic biological properties such as toxicity and mutagenicity of the materials. Secondary tests assess more advanced properties such as allergenicity. Usage tests are equivalent to clinical trials.

Newer schemes recognize that the evaluation of biocompatibility of a material is an ongoing process. (Fig.4)
All these types of biocompatibility tests continue to be useful throughout the evaluation of a material and during the clinical service.

5. Standards and Biocompatibility testing

The need for standards in biocompatibility testing stems from the extreme complexity of these types of tests. Because of this complexity, the outcome of any test for biocompatibility depends heavily on the design of the test.

Since the conclusion about the safety of material relies upon the results of these tests, standardization is the only way currently known to help reduce confusion and compare materials fairly.

Standards for biological testing have been published by the:

- American Dental Association (ADA, specification, No. 41)
- International Organization for Standardization (ISO standard No. 10993)
- European Union (EN standards)
- American Society for testing and materials (ASTM standards)
- British standards institution and many others......

6. Relevance to Dental and orthodontic practitioner

Practitioners must try to be aware of which standards were required to bring the material to the market and must keep in mind the practical weaknesses and limitations of any standards. The practitioner should also be aware that nonstandard tests may be used (appropriately or inappropriately) to market a material.15,16

Most importantly, the practitioner must decide on the safety and use of a material based upon his/her own philosophy of practice. Ultimately, the responsibility for using a material rests with the practitioner and the selection of a material must reflect that fact.

7. Conclusion

During orthodontic treatment, the oral tissues may be exposed to fixed metallic appliances such as molar bands, brackets, transpalatal bars, facebows, archwires, and retainers with auxiliary devices such as springs and hooks. Resin based materials in bonding systems and removable appliances along with ceramic brackets, add to the range of orthodontic biomaterials. Altogether, ortho appliances can compromise a considerable surface of biomaterials in contact with the oral nucosa for a prolonged period of time, and portions may also extend to the skin of the chin and neck. Because adverse reactions may occur following the use of these materials, consideration should be given to their biocompatibility problems as these effect the general health and well being of patients. The allergenic role of nickel should be emphasized.

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ERRATA

Dr. Navneet Arora article, “Can ICON replace PAR and IOTN? - A Comparative evaluation of three occlusal indices (PAR, IOTN and ICON) based on the treatment need of Indian population” which was published in JIOS Vol. 42, No. 2, April - June 2008 issue. But, due to some unfortunate reasons, there are some printing errors like the information about the author, correspondence, name of co-authors and the name of the college is missing.

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The error is regretted.

— Editor