SUNTEXT REVIEWS

SunText Review of Dental Sciences
ISSN: 2766-4996

Open Access
Editorial Article
Volume 1:4

Importance of Biocompatibility of Dental Restorative Materials

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Received date: 15 December 2020; **Accepted date:** 25 December 2020; **Published date:** 31 December 2020

Citation: Kulshrestha R (2020). Importance of Biocompatibility of Dental Restorative Materials. SunText Rev Dental Sci 1(4): 121.

DOI: https://doi.org/10.51737/2766-4996.2020.021

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Ideally, a dental material that is to be used in the oral cavity should be harmless to all oral tissues-gingiva, mucosa, pulp, and bone. Furthermore, it should contain no toxic, leachable, or diffusible substance that can be absorbed into the circulatory system, causing systemic toxic responses, including teratogenic or carcinogenic effects. The material also should be free of agents that could elicit sensitization or an allergic response in a sensitized patient. Rarely, unintended side effects may be caused by dental restorative materials because of toxic, irritative, or allergic reactions. They may be local and/or systemic. Local reactions involve the gingiva, mucosal tissues, pulp, and hard tooth tissues, including excessive wear on opposing teeth from restorative materials. Systemic reactions are expressed generally as allergic skin reactions. Side effects may be classified as acute or chronic.

Standards and Testing

The oral environment is especially hostile for dental restorative materials. Saliva has corrosive properties, and bacteria are ever present. This environment demands appropriate biological tests and standards for evaluating any material that is developed and intended to be used in the mouth. Such tests and standards, which have been developed in the past 10 to 15 years, serve as the basis for recommending any dental restorative material. Until a few years ago, almost all national and international dental standards and testing programs focused entirely on physical and chemical properties. The physical and chemical requirements set forth in the specifications for dental materials have been based on published clinical studies and clinical use of the materials; that is, the specifications lag materials development. Today, however, dental materials standards require biological testing as well. The science of dental materials now encompasses a knowledge and appreciation of certain biological considerations associated with the selection and use of materials designed for use in the oral cavity.

In accordance with existing standards, all dental materials should pass primary tests (screening to indicate cellular response), secondary tests (evaluating tissue responses), and usage tests in animals before being evaluated clinically in humans. Testing programs for dental materials are based on specifications or standards established by national or international standards organizations, such as the American National Standards Institute (ANSI) and International Standards Organization (ISO). The oldest and largest of these programs has been operated continuously by the ADA since the late 1920's. Evaluation of dental products for safety and efficacy has historically been the purview of both the ADA and the FDA. The U.S. Medical Device Amendments of 1976 were the first regulations that emphasized the need for biological standardization and testing of dental, as well as medical, materials. In accordance with these regulations, all dental materials are reviewed for safety and effectiveness and classified by the FDA as Class I, II, or III, according to risk.

Class I materials are those considered to be of low risk in causing adverse reactions and, thus, require only "general controls," such as good manufacturing practices and record-keeping by the producer. Materials in Class II must satisfy the requirements outlined in the current ANSI/ADA specifications. The most extensive testing is required for Class III materials, which includes full safety and efficacy assessments prior to marketing.