FDI POLICY STATEMENT

Bioactive Restorative Materials

Adopted by the FDI General Assembly: September 2022, Geneva, Switzerland

CONTEXT

The term "bioactive" has become popular and is increasingly used in advertisements and in scientific publications to describe restorative dental materials. In addition, some journals include the term bioactive in their title. Many definitions for this term have been provided in the medical and dental literature,[1-4] but controversy remains concerning its use. Furthermore, so far, there is no description of this term issued by an international dental organization. Consequently, it is now necessary to have a description to prevent misuse of the term bioactive and thus protect dentists and patients, clarify the term for regulatory purposes and allow for future developments.

SCOPE

The term “bioactive” will be limited in this Policy Statement to restorative dental materials, including those used for direct or indirect restorations, non-adhesive and adhesive (bonding to tooth structures by micromechanical or chemical means) procedures and for indirect and direct pulp capping.

DEFINITIONS

Restorative material: Material designed to be used for rebuilding or correcting the form and function of the tooth.

Indirect pulp capping: Dressing for conserving the vitality of the pulp of a tooth infected with a penetrating carious lesion, the complete removal of which could result in exposure of the pulp.[5]

Direct pulp capping: Dressing of an exposed pulp with the aim of maintaining pulpal vitality. [5]

PRINCIPLES

The prefix “bio” (Greek term for “living”), in this context, can be related to:

- the process/mechanism of action;
- the target tissues, here mainly enamel, dentine, pulp and bacteria/biofilms.

Whereas the term bioactive is neutral and can be applied to desired or undesired effects, in daily dental practice, this term is generally attributed to desired, local and intended effects. For this Policy Statement, such effects are repair (and regeneration) of or other interaction with adjacent tissues, or an interaction with bacteria/biofilm on or next to restorative materials.[4,6,7]

According to the biological process/mechanism of action, three levels may be distinguished:

- by solely biological means (e.g., through exogenous growth factors or pharmaceuticals, which may be incorporated into dental restorative materials);
- by mixed biological and chemical means (e.g., through materials inducing endogenous growth factor release/activation, such as calcium hydroxide preparations, or through materials decreasing or preventing bacteria/biofilms);
- by materials causing purely chemical effects (e.g., through ion release from bioactive glass fillers).

POLICY

The use of the term “bioactive restorative material” should be limited for material advertisement/information to those materials that meet all five of the following criteria:

- the mechanism is clearly defined and described (biological, mixed, chemical);
- a scientifically documented bioactive effect in vitro or in situ and most preferably also in clinical studies;
- a stated duration of the effect, especially for antibacterial effects;
- no significant adverse biological side effects (including the development and spread of antimicrobial resistance);
- the prime purpose, for instance, to be used to rebuild the form and function of lost tooth substance or lost teeth, is not impaired, as demonstrated by data from in vitro and clinical studies.

KEYWORDS

Restorative materials, pulp capping, antimicrobials, ion release, growth factors

DISCLAIMER

The information in this Policy Statement was based on the best scientific evidence

available at the time. It may be interpreted to reflect prevailing cultural sensitivities and socio-economic constraints.

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