



FDI POLICY STATEMENT

Alternative direct restorative materials to dental amalgam

Adopted by the FDI General Assembly: September 2023, Sydney, Australia

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CONTEXT

3 The use of dental amalgam is declining worldwide. The Minamata Convention has
4 provided direction for a phase down of its use as a restorative material to eliminate
5 the release of mercury into the environment. Alternative direct dental restorative
6 materials have improved with time, but still have limitations. Adequate knowledge of
7 these limitations is critical for appropriate material selection and optimal patient care.
8 Ease and costs of placement, preservation of tooth tissue, performance in high
9 stress areas, caries risk status, adverse reaction to the material as well as the
10 relevance of ion release by such materials are important issues to consider when
11 selecting from these alternatives to dental amalgam.

12 Existing alternatives have a range of physical and chemical properties that influence
13 their application and longevity. Placement of resin-containing materials requires
14 rigorous moisture control and is technically more demanding and costly than
15 placement of dental amalgam. Moreover, these materials contain unreacted
16 molecules, potentially including bisphenol-A (BPA) and others, that can leach from
17 the material and may be associated with adverse effects in patients. The major mode
18 of failure of these resin-containing materials is fracture and secondary caries. To
19 prevent the latter, optimal oral hygiene is important. Placement of glass ionomer
20 materials is technically less demanding and less costly. Glass ionomer
21 biocompatibility is comparatively high. Failure of these materials largely relates to
22 their limited fracture toughness, with restorations fracturing or wearing. Glass
23 ionomers have been found to release measurable amounts of (fluoride) ions that
24 may minimize the incidence of secondary caries adjacent to the material. Other ion
25 releasing materials have more recently been introduced to the market and more
26 clinical performance data is needed.

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SCOPE

29 This policy statement aims to provide a basic understanding of significant issues
30 around direct restorative materials that are not dental amalgam, mainly of resin-
31 containing composites, glass ionomers, or resin composite – glass ionomer
32 combinations.

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34 **DEFINITIONS**

35 **Restorative material:** Material (medical device) designed to be used in rebuilding
36 or correcting the form and function of lost tooth substance.

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38 **PRINCIPLES**

39 Clinical success of direct restorations depends on individual factors, e.g. location
40 and extent of the defect, number of surfaces involved, the interaction between
41 material and tooth, the individual's caries risk (oral hygiene, dietary factors, fluoride
42 intake, reduced saliva flow and certain medical conditions), behavioural aspects
43 (e.g. bruxism) and operator skills. Preparation of cavities to be restored using direct
44 materials should be minimally invasive. There are multiple alternative materials for
45 dental amalgam, but no single material is an amalgam replacement for all clinical
46 situations.

47 The use of alternative materials may impact the cost of treatment, and may
48 necessitate more complex treatment techniques.

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50 **POLICY**

51 FDI recommends:

- 52 • using a patient-centred approach instead of a purely material-centred
53 approach when selecting a restorative material, taking individual and material
54 factors into consideration, including:
 - 55 ○ location and size of the planned restoration as these impact the required
56 physical and biological properties of the material;
 - 57 ○ caries risk of the individual as fluoride-releasing materials may be
58 preferred in high-risk individuals;
 - 59 ○ systemic risk and medical conditions including allergies as alternative
60 materials (specifically resin-containing ones) may induce allergic
61 reactions;
 - 62 ○ protection of the provider by use of a no-touch-technique when handling
63 resin-based materials, as well as relevant physical, chemical and
64 biological personal protective measures including protection against
65 blue light emitted from curing devices;
 - 66 ○ use of copious water spray when adjusting or removing restorative
67 materials for sufficient cooling and to mitigate the presence of
68 nanoparticles;
 - 69 ○ cost and reimbursement policies for placing different materials in
70 different countries;
 - 71 ○ patients' expectations and demands as the material of choice should be
72 the result of shared decision-making;
 - 73 ○ informed consent for using a specific material should be sought;
- 74 • further research is needed to improve overall material properties and,
75 eventually, their clinical performance and cost-effectiveness;
- 76 • oral health professionals are encouraged to remain up-to-date as research
77 continues.

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79 **KEYWORDS**

80 minimal intervention, resin-based composite, glass ionomer cement, dental
81 amalgam

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83 **DISCLAIMER**

84 The information in this Policy Statement was based on the best scientific evidence
85 available at the time. It may be interpreted to reflect prevailing cultural sensitivities
86 and socio-economic constraints.

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