Problem Solving in Dentistry:

Estimating the Biological Effects of Dental Treatment and Materials

Asbjørn Jokstad

Institute of Clinical Dentistry, University of Oslo, Norway
Topics

- Who are the stakeholders?
- Doesn’t somebody test our materials?
- Causality – how to prove that something is safe or harmful?
- The amalgam dispute
- Composites - reasons for concern?
- What about other dental materials?
- So what is the situation for the GPs?
- Suggested strategy in daily clinical practice
Clinical use of restorative materials and biological concerns

- Mutagenic potential
- Acute allergy
- Chronic allergy
- Postoperative sensitivity
- Dentin and pulp reactions
- Pulp capping
- Systemic toxicity
- Local toxicity
- Secondary caries
- Beirut, August 2003
Beirut, August 2003

**Stakeholders**

- Your patients
- You and the dental team
- Dental technician
- Society - environment

Diagram:
- Dental Products
- Degradation products
- Unreacted components
- Waste, bi-products, dust, aerosols

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Topics

- Who are the stakeholders?
- Doesn’t somebody test our materials before usage?
Standard Screening Tests for Biocompatibility
ISO, CEN, ANSI, etc.

- Acute systemic toxicity (Animal LD₅₀)
- Cytotoxicity (Cell cultures LD₅₀)
- Mutagenicity (Salmonella typhoidea)
- Implantation, local toxicity (Animals)
- Pulpal & gingival reactions (Animals)
- Sensitisation (Guinea pig)

Beirut, August 2003
Topics

- Who are the stakeholders?
- Doesn’t somebody test our materials?
- Causality - how to prove that something is safe or harmful?
Knowledge can be conveyed – but not Wisdom.

Hermann Hesse
Three relevant terms

- Association
- Risk
- Cause
Two variables appear to be related by a mathematical relationship. A change of one appears to be related to the change in the other.

Necessary for a causal relationship to exist, but association alone does not prove that a causal relationship exists.

E.g. surface discolouration and wear are often associated, but there is no causal relationship.
Risk

- The likelihood that a specified outcome will develop in a defined time period.
- E.g. risk of bulk fracture within five or ten years of a ceramic inlay.
- A risk factor is an attribute (intrinsic characteristic) or exposure (external environment) that is positively or negatively associated with the occurrence of a specified outcome.
- E.g. Little thickness of ceramic inlay.
Cause

- **Combination of necessary and sufficient factors**, the presence of which, alone or in combination, at some time inevitably result in an incidence of interest.

- A **necessary factor/cause** is a risk factor that must be, or have been, present for a specified outcome to occur.

- A **sufficient factor/cause** is the minimal or combination of risk factors that inevitably results in a specified outcome.
Causality

Henle-Koch Postulates (1877)
Germ theory, today archaic

Hill-Evans Postulates
Mill's Eliminative Methods of Induction (System of Logic, 1843)
Hill's Criteria of Causation (1965)
Evan's Postulates (1976)
Tests for causation

- a. Prevalence of the disease should be significantly higher in those exposed to the risk factor than those not.

- b. Exposure to the risk factor should be more frequent among those with the disease than those without.

- c. In prospective studies, the incidence of the disease should be higher in those exposed to the risk factor than those not.

- d. The disease should follow exposure to the risk factor with a normal or log-normal distribution of incubation periods.

- e. A spectrum of host responses along a logical biological gradient from mild to severe should follow exposure to the risk factor.
Tests for causation

- **f.** A measurable host response should follow exposure to the risk factor in those lacking this response before exposure or should increase in those with this response before exposure. This response should be infrequent in those not exposed to the risk factor.

- **g.** In experiments, the disease should occur more frequently in those exposed to the risk factor than in controls not exposed.

- **h.** Reduction or elimination of the risk factor should reduce the risk of the disease.

- **i.** Modifying or preventing the host response should decrease or eliminate the disease.

- **j.** All findings should make biological and epidemiological sense.
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- The amalgam dispute
I decided long time ago to not understand. If I wish to understand something I begin immediately to bend facts, and I have decided to stick with facts...

Dostojevskij: The Karamasov brothers
The Law Offices of Shawn Khorrami is committed to serving clients and providing the best legal services available. We represent clients across the Country. The firm was built on a philosophy of serving people and helping the community with the problems it may be facing. For this reason we have committed our efforts and resources toward individuals and small businesses with real problems rather than large corporations which are better equipped and adapted to cope with difficulties.

The majority of our firm's cases involve injuries and death caused by environmental/toxic exposures. We also handle a substantial number of cases involving product defect, vaccine injury, pharmaceutical products, discrimination, and employment law.
Topics

- Who are the stakeholders?
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Composites - reasons for concern?
Composite resin components

Monomers: BIS-GMA... TEGDMA...
**HEMA**... UDMA.. BIS-PMA... UPGDMA...
EGDMA... DEGMA... PRDMA... BIS-DMA...

Additives and contaminants: CQ...
BPE...DPO...MBEP...HMBP...CEMA...BPA...

Degradation products: MMA... BEA...
MAA... Formaldehyde...

Beirut, August 2003
800588 2-Hydroxyethyl methacrylate (stabilised with hydroquinone monomethyl ether) for synthesis

CLICK here for Structural formula

Chemical formula:
C_6H_{10}O_3

Synonyms:
2-Hydroxyethyl 2-methylpropenoate, HEMA, Methacrylic acid 2-hydroxyethyl ester

Categories of danger: irritant, sensitizing

Molar mass: 130.14 g/mol
Density: 1.07 g/cm³ (20 °C)
CAS number: 868-77-9
EINECS: 212-782-2
EG index number: 607-124-00-X
HS Code: 2916 14 90
Storage class (VCI): 10-13 (Other liquids and solids)

Hazard signs:

WGK: 1 (Slightly water polluting substance)
Disposal: 1
Poison class
CH: 4 (Substances and products that must be considered harmful)
R Phrase: R
36/38-43
S Phrase: S 26-28.1
Material Safety Data Sheet

SECTION 1. ------------------- CHEMICAL IDENTIFICATION -------------------

CATALOG #: 436909
NAME: DIURETHANE DIMETHACRYLATE, MIXTURE OF ISOMERS

SECTION 2. ---------------- COMPOSITION/INFORMATION ON INGREDIENTS ----------------

CAS #: 72869-86-4
MF: C23H38N2O8
EC No: 276-957-5

SECTION 3. ------------------- HAZARDS IDENTIFICATION -------------------

LABEL PRECAUTIONARY STATEMENTS
POSSIBLE RISK OF IRREVERSIBLE EFFECTS.
POSSIBLE CARCINOGEN.
POSSIBLE SENSITIZER.
WEAR SUITABLE PROTECTIVE CLOTHING.

SECTION 4. ------------------- FIRST-AID MEASURES -------------------

IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES.
IN CASE OF CONTACT, IMMEDIATELY WASH SKIN WITH SOAP AND COPIOUS
Anaphylactoid reactions in children have been reported following the placement of fissure sealants, which are based on the same ingredients as composite materials.

Signals from the Sweden about asthma attacks in relation to restorative therapy using resin based materials cannot be verified by data from the Dental Biomaterials Adverse Reaction Unit in Norway.
Kanerva et al., Contact Dermatitis, 1999: Finnish dentists have the highest risk of any occupation for developing occupational allergic contact dermatitis. The risk is 6.4-fold as compared to the general working population.

Wallenhammar et al., Contact Dermatitis, 2000: The prevalence of contact allergy to acrylates was below 1% in the population of responding dentists, and in most cases did not have serious medical, social or occupational consequences.
Engelmann et al., J Dent Res, 2001:
TEGDMA is not only cytotoxic, mutagenic and acts as a surfactant-like agent, but may have a toxic potential which can result in higher susceptibility of cells for subsequent damages or injuries from other xenobiotics.

Hume & Gerzia, Crit Rev Oral Biol Med, 1996:
There are no data which suggest that systemic toxicity is a risk with any of these materials.
Olea et al., Environ Health Perspect, 1996:
The use of BIS-GMA-based resins in dentistry, and particularly the use of sealants in children, appears to contribute to human exposure to xenoestrogens.

American Dental Association. www.ada.org, 2001:
There is no evidence to suggest a link between any adverse health condition and Bisphenol-A leached out of dental sealants.

Beirut, August 2003
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Urinary platinum levels associated with dental gold alloys.

Schierl R.

Institute and Outpatient Clinic for Occupational and Environmental Medicine, University Munich, Munchen, Germany.

Platinum concentrations were determined in 50 urine and 20 saliva samples obtained from 50 subjects who had gold dental restorations. In addition, 42 urine and 35 saliva samples were collected from subjects who did not have gold dental restorations. Subjects with gold alloys had significantly (p < .001) higher urinary platinum excretion (mean = 11.9 +/- 8.5 ng/gm creatinine, range = 1.9-45.8 ng/gm creatinine) than controls (mean = 6.2 +/- 3.2 ng/gm, range = 1.9-14.4 ng/gm creatinine). Mean saliva concentrations were significantly higher in subjects with dental gold alloys (526 pg/gm vs. 8.5 pg/gm; p < .001). A laboratory test with 5 commercially available dental gold/platinum alloys showed that 0.1% sodium chloride mobilized platinum within 1 hr (i.e., 1-18 pg/ml) of its introduction. In conclusion, dental gold/platinum alloys appear to be the main source for urinary platinum excretion from the occupationally unexposed population.

PMID: 11480507 [PubMed - indexed for MEDLINE]

Sidhu SK, Schmalz G.

Department of Restorative Dentistry, The Dental School, University of Newcastle, Newcastle upon Tyne, United Kingdom. S.K.Sidhu@ncl.ac.uk

Since their introduction in the market, some 30 yrs ago, the biocompatibility aspects of glass-ionomer cements (GICs) have been intensively studied. In general, cytotoxicity of fully set conventional preparations in previous studies was shown to be minimal. However, a resin-modified preparation proved to be cytotoxic under these conditions. This product was also observed to be mutagenic, but data in this area are sparse and difficult to interpret. There is also evidence that certain GICs exert some antibacterial properties which is claimed to be related to the fluoride release; however, the mechanisms for this fluoride release are still unclear. Pulp response studies have shown conflicting results. However, unfavorable initial reactions, if present, resolved with time if a bacterial layer under the restoration and pulp exposures were prevented. Pain reactions after cementation of cast restorations with GICs have been reported in the past but there are no such reports in the more recent literature.

Publication Types:
- Review
- Review, Tutorial

PMID: 11949800 [PubMed - indexed for MEDLINE]
Dental Material

Otologic surgery (Cochlear implant fixation, repair of the tympanic chain, eustation tube obliteration, ear ossicles ...)

Neurosurgery

Oral and reconstructive surgery
Cytotoxicity of dental glass ionomers evaluated using dimethylthiazol diphenyltetrazolium and neutral red tests.

Lonnroth EC, Dahl JE.

Department of Human Work Sciences, Lulea, University of Technology, Sweden. emma@arb.luth.se

The purpose of this study was to assess the cytotoxicity of some commonly used glass ionomers. Three chemically cured glass ionomers (Fuji II, Lining cement, and Ketac Silver) and one light-cured (Fuji II LC) were tested. Extracts of mixed non-polymerized materials and polymerized specimens were prepared in accordance with ISO standard 10993-12. The polymerized specimens were cured and placed either directly in the medium (freshly cured), left for 24 h (aged), or aged plus ground before being placed in the medium. The cytotoxicity of extracts was evaluated on mouse fibroblasts (L, 929), using dimethylthiazol diphenyltetrazolium (MTT) and neutral red (NR) assays. Further, the concentrations of aluminum, arsenic and lead were analyzed in aqueous extracts from freshly cured and aged samples, and the fluoride levels analyzed in aqueous extracts from freshly cured samples. All extracts except that of non-polymerized Ketac Silver were rated as severely cytotoxic in both assays. Extracts of polymerized material were significantly more cytotoxic than extracts of non-polymerized material. All freshly cured glass ionomers released aluminum and fluoride concentrations far above what is considered cytotoxic (aluminum >0.2 ppm and fluoride >20 ppm). Extracts from freshly cured Lining Cement contained the highest concentrations of aluminum and fluoride (215 ppm and 112 ppm). Extracts from freshly cured Ketac Silver had the lowest concentrations of aluminum and fluoride but the highest of lead (100 ppm). It can be concluded that all extracts from non-cured, freshly cured, and aged glass ionomers contained cytotoxic levels of substances. Curing did not reduce the toxicity significantly.
The following feature article appears in "Dentistry", 7 February 2002. "Dentistry" is a popular dental magazine with a national circulation.

WHAT CONSTITUTES UNINFORMED CONSENT?

Tony Lees presents the case against glass ionomers

Carolyn Smith is a well educated, intelligent woman. She has a degree and takes a keen interest in environmental matters. She is concerned about the safety of mercury amalgams and water fluoridation. So, when, last year, she needed dental treatment, she was very relieved when her dentist placed a tooth coloured filling and not a toxic mercury filling. She would not have consented to a mercury filling as she is unwilling to have any toxic material placed in her mouth.

Some days after the filling session, Carolyn began to feel unwell; she developed a constant headache, her stomach was upset, she had a marked thirst, her teeth ached and she felt short of breath. She suspected that the filling that she had received might be the cause of her problems and asked her dentist what he had used to fill her tooth. Her dentist replied that a glass ionomer (GI) filling had been placed. These fillings are known to release fluorides and other substances. So, Carolyn consulted a doctor who specialises in fluoride intoxication and who was of the opinion that her symptoms were consistent with sub acute fluoride toxicity and recommended magnesium and calcium supplements to absorb as much of the fluoride as possible until she could get the filling replaced. This treatment eased her symptoms but she was not free of problems until her dentist removed the glass ionomer filling and substituted with a composite.

Carolyn's unfortunate experience led her to ask two questions:

- 1 Are CI fillings toxic?
- 2 Has my right to informed consent been violated by having a toxic substance implanted into my mouth without my knowledge or consent?
Biocompatibility of dental casting alloys.

GeurtSEN W.

Department of Conservative Dentistry and Periodontology, Medical University Hannover, D-30623 Hannover, Germany.

Most cast dental restorations are made from alloys or commercially pure titanium (cpTi). Many orthodontic appliances are also fabricated from metallic materials. It has been documented in vitro and in vivo that metallic dental devices release metal ions, mainly due to corrosion. Those metallic components may be locally and systemically distributed and could play a role in the etiology of oral and systemic pathological conditions. The quality and quantity of the released cations depend upon the type of alloy and various corrosion parameters. No general correlation has been observed between alloy nobility and corrosion. However, it has been documented that some Ni-based alloys, such as beryllium-containing Ni alloys, exhibit increased corrosion, specifically at low pH. Further, microparticles are abraded from metallic restorations due to wear. In sufficient quantities, released metal ions-particularly Cu, Ni, Be, and abraded microparticles-can also induce inflammation of the adjacent periodontal tissues and the oral mucosa. While there is also some in vitro evidence that the immune response can be altered by various metal ions, the role of these ions in oral inflammatory diseases such as gingivitis and periodontosis is unknown. Allergic reactions due to metallic dental restorations have been documented. Ni has especially been identified as being highly allergenic. Interestingly, from 34% to 65.5% of the patients who are allergic to Ni are also allergic to Pd. Further, Pd allergy always occurs with Ni sensitivity. In contrast, no study has been published which supports the hypothesis that dental metallic materials are mutagenic/genotoxic or might be a carcinogenic hazard to man. Taken together, very contradictory data have been documented regarding the local and systemic effects of dental casting alloys and metallic ions released from them. Therefore, it is of critical importance to elucidate the release of cations from metallic dental restorations in the oral environment and to determine the biological interactions of released metal components with oral and systemic tissues.
Patients with local adverse effects from dental alloys: frequency, complaints, symptoms, allergy.

Garhammer P, Schmalz G, Hiller KA, Reitinger T, Stolz W.

Department of Operative Dentistry and Periodontology, University Clinics of Regensburg, Germany.

Data on the prevalence of adverse effects from dental cast alloys and on the characteristics of the related patient groups are scarce. Therefore, the aim of the present study was to investigate patients in a defined part of Germany attributing oral complaints or symptoms to dental cast alloys. All dentists in the area of Eastern Bavaria (with 1 million inhabitants) were asked to send corresponding patients to our department during a 3-year period. Out of this collection, patients with complaints or symptoms in the oral cavity were recruited and characterized with regard to number, age and sex distribution, type of subjective complaints and objective intraoral symptoms, and allergy status based on an alloy analysis. Patients reporting to our department with suspected local adverse effects from dental cast alloys represented 0.01% of the population. Thirty-four percent of the patients were 50-59 years old, with females prevailing (76%). A great variety of subjective complaints was reported, which mainly resembles those reported by patients with adverse effects attributed to other dental materials like amalgam or denture base materials. The main objective intraoral symptoms were gingivitis, anomalies of the tongue (lingua plicata, lingua geographica), discoloration of the gingiva, redness of the palate or tongue and lichenoid reactions of the oral mucosa. In not more than 10% of the patients, allergy was diagnosed as contributing to the complaints or symptoms.

PMID: 11800437 [PubMed - indexed for MEDLINE]
Topics

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- The amalgam dispute
- Composites - reasons for concern?
- What about other dental materials?
- So what is the situation for the GPs?
Confusion
Why confusion?

There is little reliable information with respect to the biological interactions between components in dental materials and biological tissues.
Why confusion?

Little reliable information on biological interactions between components and biological tissues:

1. Variables in planned studies influence the outcomes.
   - Controlled, Uncontrolled, Confounding variables
   - Synergy of variables?
In vitro studies; e.g. elution of leachable components- variables

- Surface oxygen inhibition
- Time after curing before immersion
- Type of solvent; water, ethanol
  - Selective extraction
- Time in solvent
- Unreacted components vs. degradation
  - Oxidation
  - Hydrolysis
In vitro / In vivo studies; variables, organic materials

- Light intensity & Spectral distribution
- Access of light & Depth of light cure
- Curing time
- Conversion rate
- Polymerization shrinkage
- Microleakage
- Wear
- (Enzymatic) biodegradation
Long-term quantification of the release of monomers from dental resin composites and a resin-modified glass ionomer cement.

Mazzaoui SA, Burrow MF, Tyas MJ, Rooney FR, Capon RJ.

School of Dental Science, The University of Melbourne, Australia.

This study quantified the release of monomers from polymerized specimens of four commercially available resin composites and one glass ionomer cement immersed in water:ethanol solutions. Individual standard curves were prepared from five monomers: (1) triethylene glycol dimethacrylate (TEGDMA), (2) 2-hydroxy-ethyl methacrylate (HEMA), (3) urethane dimethacrylate (UDMA), (4) bisphenol A glycidyl dimethacrylate (BISGMA), and (5) bisphenol A. The concentration of the monomers was determined at Days 1, 7, 30, and 90 with the use of electrospray ionization/mass spectrometry. Data were expressed in mean micromol per mm² surface area of specimen and analyzed with Scheffe's test (p<0.05). The following monomers were found in water: monomers (1) and (2) from Delton sealant, monomer (5) from ScotchBond Multipurpose Adhesive and Delton sealant, monomer (3) from Definite and monomer (4) from Fuji II LC, ScotchBond Multipurpose Adhesive, Synergy and Definite. All these monomers increased in concentration over time, with the exception of monomer (1) from Delton sealant. Monomers (3) and (5) were found in extracts of materials despite their absence from the manufacturer's published composition. All monomers were released in significantly higher concentrations in water:ethanol solutions than in water. The greatest release of monomers occurred in the first day. The effect of the measured concentrations of monomers (1-5) on human genes, cells, or tissues needs to be considered with the use of a biological model. Copyright 2002 Wiley Periodicals, Inc.

PMID: 12115761 [PubMed - in process]
Why confusion?

Little reliable information on biological interactions between components and biological tissues.

1. Variables in planned studies influence the outcomes.

2. All study designs are correlated with a probability of error.
1 Systematic review of randomized clinical trials (RCT) & Individual RCTs

2 Systematic review of cohort studies & individual cohort studies & Low quality RCTs

3 Systematic review of case-control studies & Individual case-control studies

4 Case-series & Poor quality cohort and case-control studies

5 Laboratory research & Expert opinion without explicit critical appraisal & Rationale basis on physiology & Case descriptions
Information overload

Meetings/ courses

Dental literature

Advertising
- producers
- colleagues

Colleagues

WWW

Patients & (-groups)

Popular magazines & Media

Dental 'science'
700 journals: 25 000 articles/yr

Beirut, August 2003
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- So what is the situation for the GPs?
- Suggested strategy in daily clinical practice
Strategy in daily clinical practice

1. Practice evidence-based dentistry
Learn critical appraisal: EBM

Generating evidence from research

Synthesising the evidence

Making clinical decisions

The patient's circumstances

The evidence

The patient's wishes
Secondary ebd and systematic reviews

The Cochrane Library

2000, Issue 4

The best single source of reliable evidence about the effects of health care

The patient's circumstances

The evidence

The patient's wishes

Making clinical decisions

Appraise for reliability, validity and results

Synthesising the evidence

Generating evidence from research
Systematic reviews & guidelines

The patient's circumstances

The evidence

The patient's wishes

Making clinical decisions

Generating evidence from research

Synthesising the evidence

Developing evidence based clinical policies

Applying the policies
Strategy in daily clinical practice

1. Practice evidence-based dentistry
2. Identify potential hazards
3. Read producer's safety sheets
4. Uphold an adequate risk attitude
Beirut, August 2003


Aim: Establish safe routines for handling of resin materials in dentistry according to new work regulations 1994/95:

- 150 individuals in dental care had developed allergy toward resins
- New regulations for handling resins introduced in dental sector
- Brochure and poster produced and distributed to all dental clinics in Sweden
- Inspections of all importers and producers
- Survey to 3000 employers of dental clinics, (Replies 2680= 91%)
- 19634 individuals registered - 6372 dentists
- 22% clinics reported health problems related to resins
- 6% of all individuals reported health related problems (n=1234/19634)
- Only 99 of these had been reported to national register for adverse reactions
- 8% of all dentists reported health related problems (n=511/6372 dentists)
- 3% had allergy documented by physician (n=217 / 6372 dentists)
- Multiple inspections by work authorities
- Many breaches of regulations (n=1234)
- Several follow-up inspections
Identify hazards

Read Safety Data Sheets

- Uncured material: Direct contact can cause eye and skin irritation.
- The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.
1. Commercial product name and supplier
   1.1 Commercial product name / designation
   1.2 Application / use
   1.3 Producer
   1.4 Supplier
   1.5 TOX emergency number
   1.6 Product No.
EC Safety Data Sheet

1. Commercial product name and supplier
2. Composition
3. Hazards identification
4. First aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls / personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information
**Chemical characterisation**

- Dimethacrylates, inorganic fillers, ytterbium-trifluoride, initiators, stabilizers and pigments

**Hazardous components**

- < 10 % Bis-GMA (CAS No. 1565-94-2)
- < 4 % Triethylene glycoldimethacrylate (CAS No. 109-16-0)
- < 8 % Urethanedimethacrylate (CAS No. 72869-86-4)

**Further information**
EC Safety Data Sheet - Hazards identification

- Uncured material: Direct contact can cause eye and skin irritation.
- The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.
Acute toxicity
The oral LD-50 for rats is > 5000 mg/kg

Subacute / chronic toxicity
Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals

Further information
No hazards anticipated from swallowing small amounts incidentally to normal handling

Beirut, August 2003
Learn First Aid measures

Eye contact
- Flush with plenty of water. Consult a physician if irritation persists

Skin contact
- Wash thoroughly with soap and water

Ingestion
- No hazards anticipated from swallowing small amounts incidentally to normal handling

Inhalation
- Remove to fresh air
Employ adequate handling and storage & personal protection

Handling

Personnel that handle composite resins must be adequately trained

Personal protective equipment

Respiratory protection

Hand protection  Gloves - replace if contaminated

Eye protection  Safety goggles

Check light source regularly for power output
Resumé - topics

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- What about other dental materials?
- So what is the situation for the GPs?
- Suggested strategy in daily clinical practice
Thank you for your kind attention.