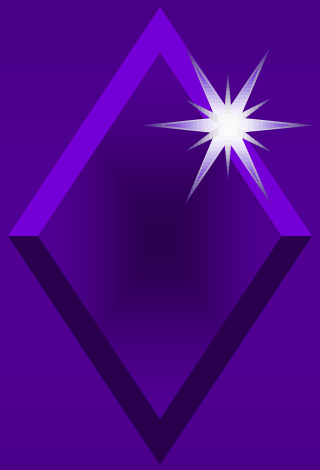
Dental Restorative Materials and General Health

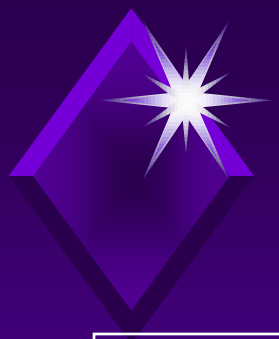


Effects of Dental Treatment and Materials

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



Mutagenic potential

Acute allergy

Systemic toxicity

Clinical use of restorative materials and biological concerns

Chronic allergy

Local toxicity

Postoperative sensitivity

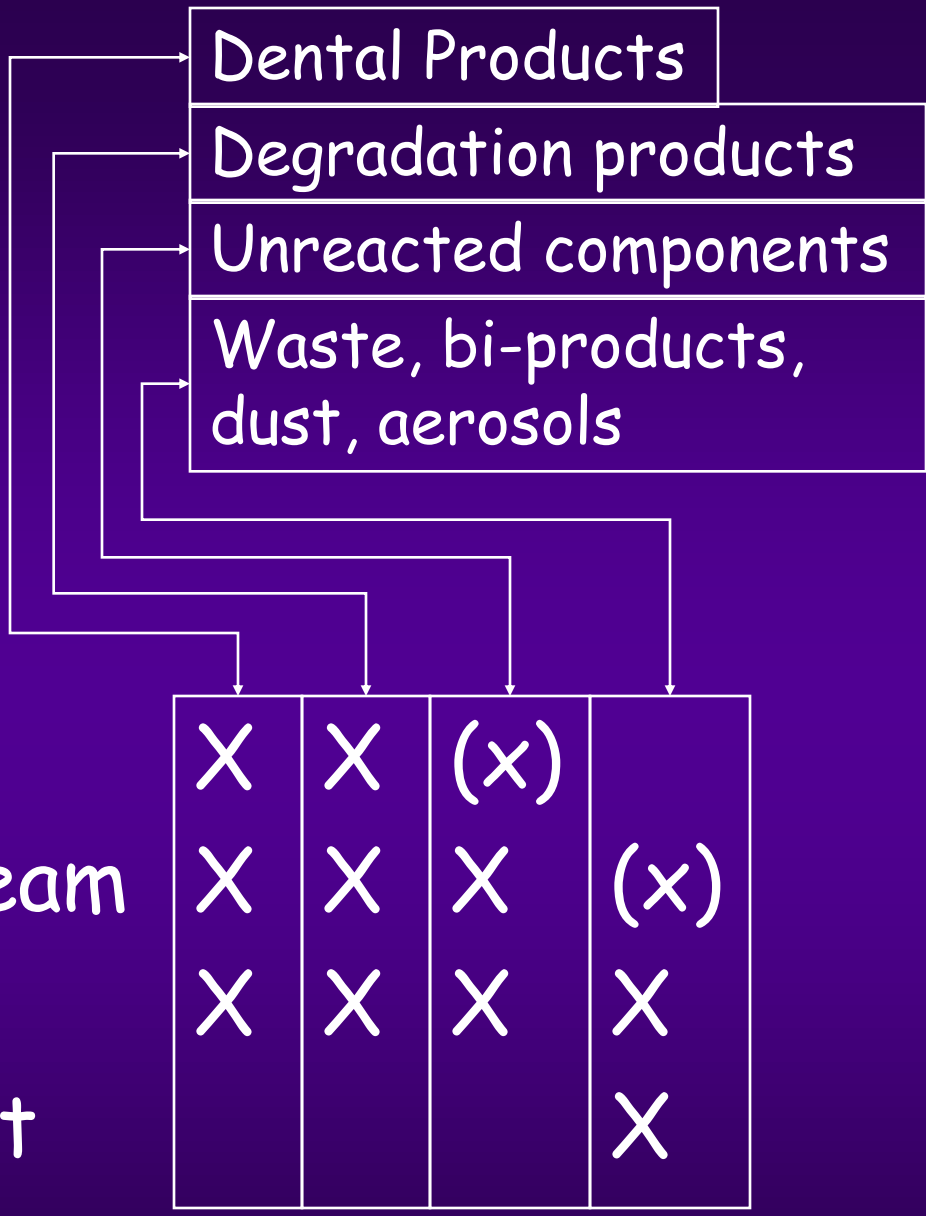
Secondary caries

Dentin and pulp reactions

Pulp capping

Stakeholders

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



Topics

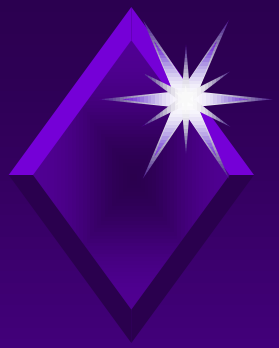
- Who are the stakeholders?
- Doesn't somebody test our materials before usage?

Standard Screening Tests for Biocompatibility
ISO, CEN, ANSI, etc.

- Acute systemic toxicity (Animal LD_{50})
- Cytotoxicity (Cell cultures LD_{50})
- Mutagenicity (Salmonella typhoidea)
- Implantation, local toxicity (Animals)
- Pulpal & gingival reactions (Animals)
- Sensitisation (Guinea pig)

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

Association

- 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

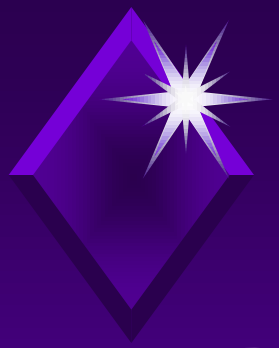
- a. Prevalence of the disease should be significantly higher in those exposed to the risk factor than those not.
- b. Exposure to the risk factor should be more frequent among those with the disease than those without.
- c. In prospective studies, the incidence of the disease should be higher in those 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.

Topics

- Who are the stakeholders?
- Doesn't somebody test our materials?
- Causality – how to prove that something is safe or harmful?
- 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 Client

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.

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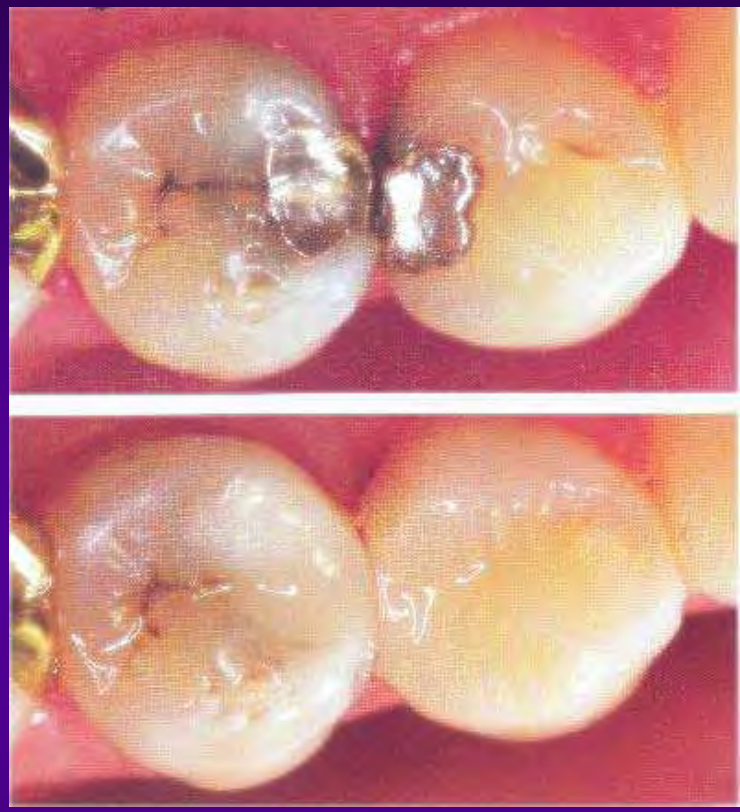
Topics



- Who are the stakeholders?
- Doesn't somebody test our materials?
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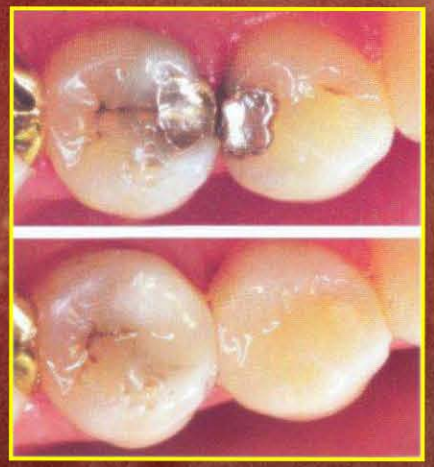
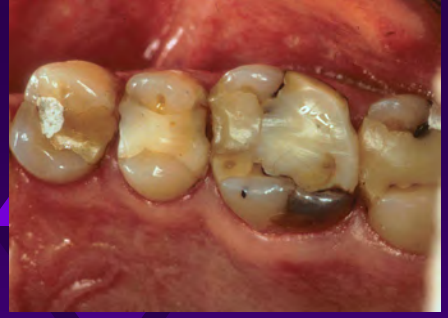
- The amalgam dispute
- Composites - reasons for concern?



FDI Vienna 3.10.2002



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…

Chemical companies, information

Bookmarks Netsite: http://www.merck.de/english/services/chemdat/index.htm What's Related

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- Bioseparation
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- Environmental analysis
- Hygiene monitoring
- Medical laboratory
- Microbiology
- Microscopy
- Research reagents

Product Info

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- Toxicological Data
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- Storage Transport
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- Specifications
- Packing Information
- Technical Data Sheet
- Safety Data Sheets
- Certificates of Analysis

Navigation

Back to New Search

800588 2-Hydroxyethyl methacrylate (stabilised with hydroquinone monomethyl ether) for synthesis

CLICK here for Structural formula

Formula Hill: $C_6H_{10}O_3$

Chemical formula:

$CH_2=C(CH_3)COOCH_2CH_2OH$

Synonyms:

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

Categories of danger: irritant, sensitizing

Hazard signs:

Xi

Molar mass: 130.14 g/mol

Density: 1.07 g/cm^3 (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)

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

Chemical companies information

Product Number: **436909**
Product Name: **Diurethane dimethacrylate, mixture of isomers**

Product Information
Description / Pricing
Cert. of Analysis
MSDS
Options
Print Preview
Bulk Quote
Ask A Scientist

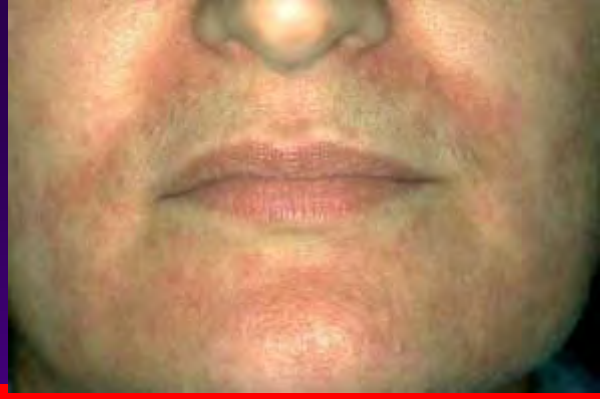
Valid 11/2000 - 01/2001

Aldrich Chemical Co., Inc.
1001 West St. Paul
Milwaukee, WI 53233 USA
Phone: 414-273-3850

M A T E R I A L S A F E T Y D A T A S H E E T

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

Acute allergy



Hensten-Pettersen, Eur J Oral Sci, 1998:

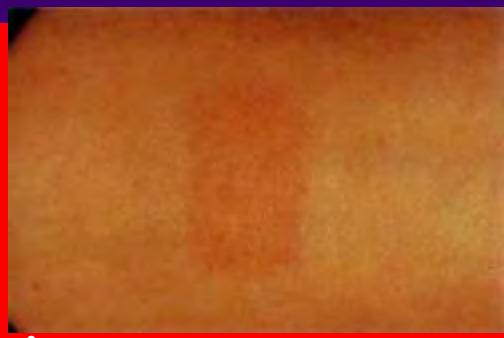
Anaphylactoid reactions in children have been reported following the placement of fissure sealants, which are based on the same ingredients as composite materials

Björkman & Helland, Nor Dent Assoc J, 2001:

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.

Chronic allergy

1-3%?



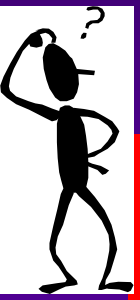
Kanerva et al., Contact Dermatitis, 1999:

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.

Systemic toxicity



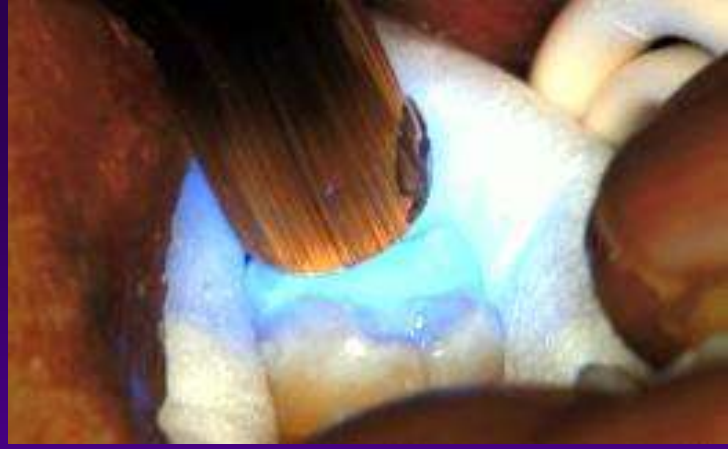
Engelmann et al., J Dent Res, 2001:

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.

Estrogenic potential



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.

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?

1: Arch Environ Health 2001 May-Jun;56(3):283-6 Related Articles, Books, LinkOut

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]

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1: Am J Dent 2001 Dec;14(6):387-96 Related Articles, Books, LinkOut

The biocompatibility of glass-ionomer cement materials. A status report for the American Journal of Dentistry.

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

1: Acta Odontol Scand 2001 Feb;59(1):34-9

Related Articles, Books, LinkOut

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

Lonnroth EC, Dahl JE.

Department of Human Work Sciences, Lule a, 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?

1: Crit Rev Oral Biol Med 2002;13(1):71-84

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 periodontitis 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.

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1: Clin Oral Investig 2001 Dec;5(4):240-9

Related Articles, Books, LinkOut

Clinical Oral Investigations

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

- Who are the stakeholders?
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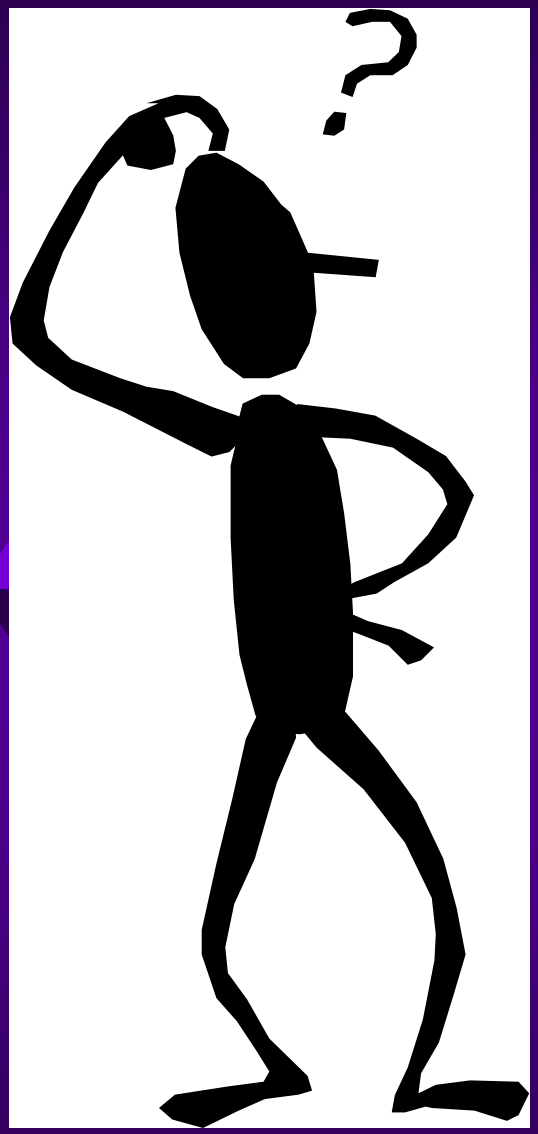
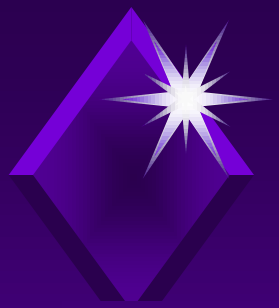
- Composites- reasons for concern?
- What about other dental materials?
- So what is the situation for the GPs?



Confusion



Why confusion?

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

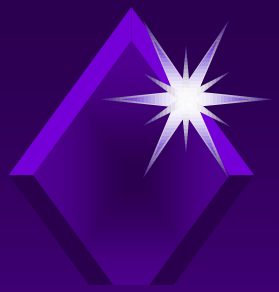
Why confusion?

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

1: J Biomed Mater Res 2002;63(3):299-305

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 mm(2) 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.

Appraisal of harm; study design and probability of error

http://cebm.jr2.ox.ac.uk/docs/levels.html

1 Systematic review of randomized clinical trials (RCT) & Individual RCTs

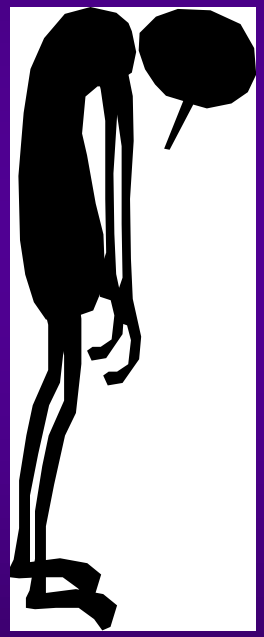
2 Systematic review of cohort studies & individual cohort studies & Low quality RCTs

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



Advertising
- producers
- colleagues

Dental literature

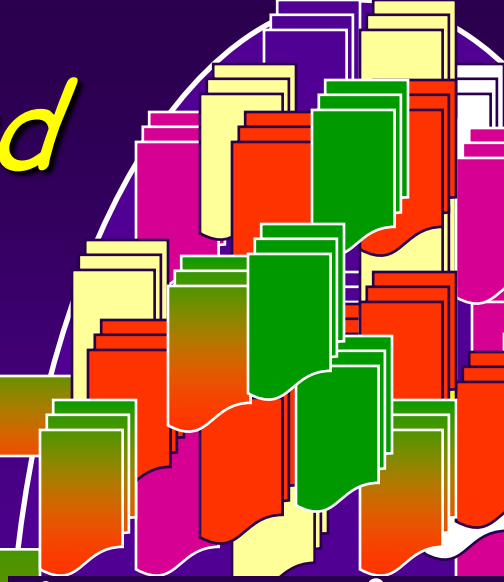
Meetings/ courses

Colleagues

WWW

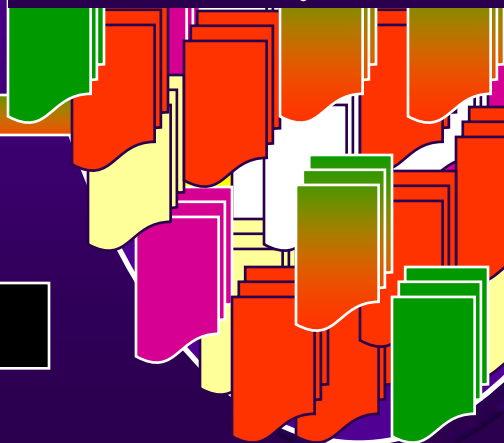
Patients & (-groups)

Popular magazines & Media



Dental 'science'

700 journals:
25 000 articles/yr



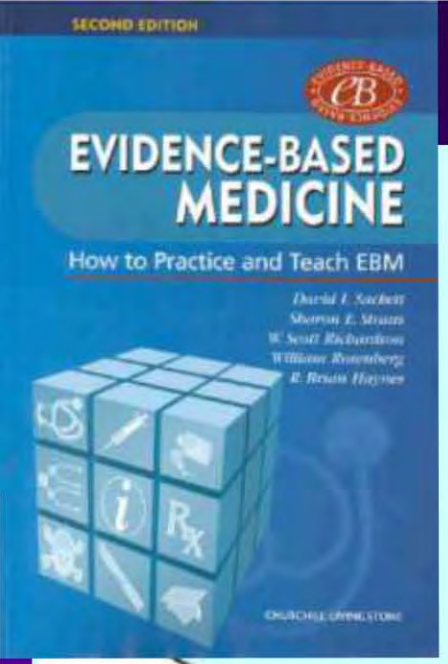
Topics

- 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

Strategy in daily clinical practice

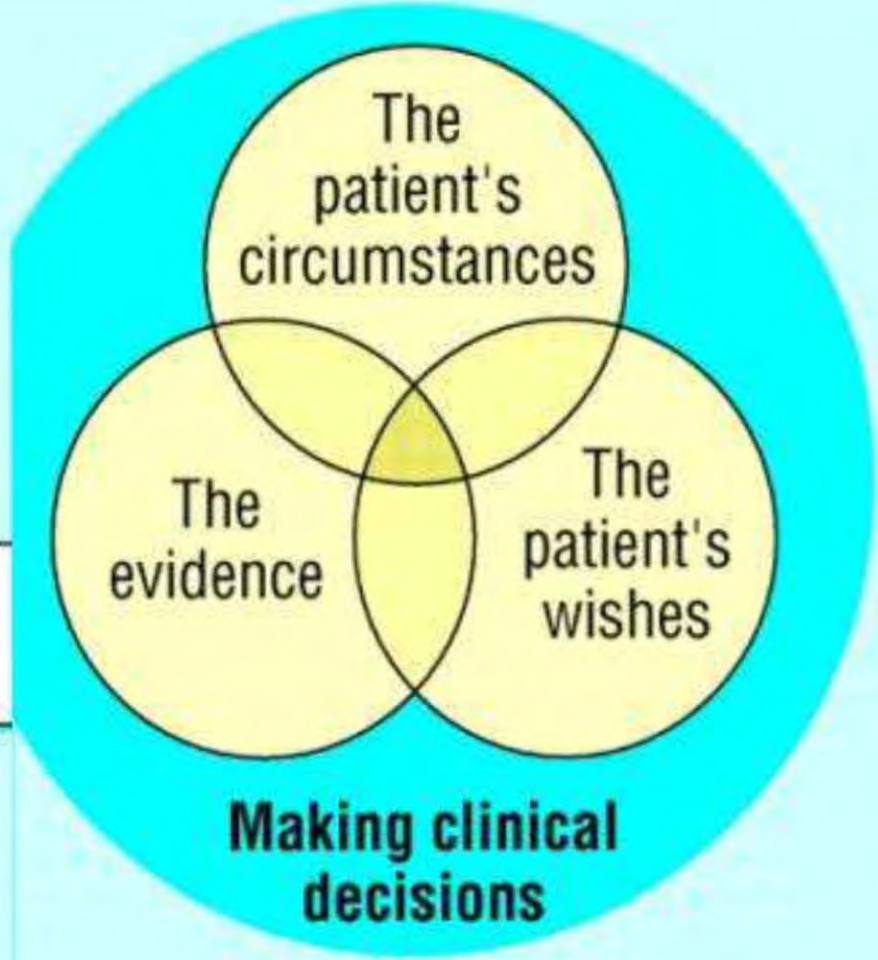
1. Practice evidence-based dentistry

Learn critical appraisal: EBM



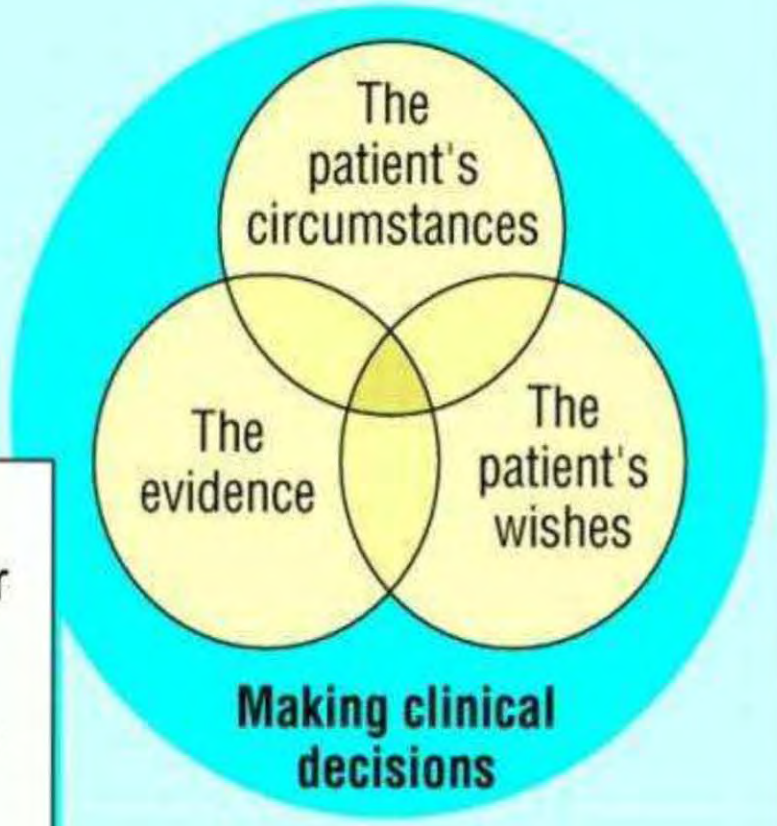
Generating evidence from research

Synthesising the evidence



Secondary ebd and systematic reviews

Evidence-Based Dentistry

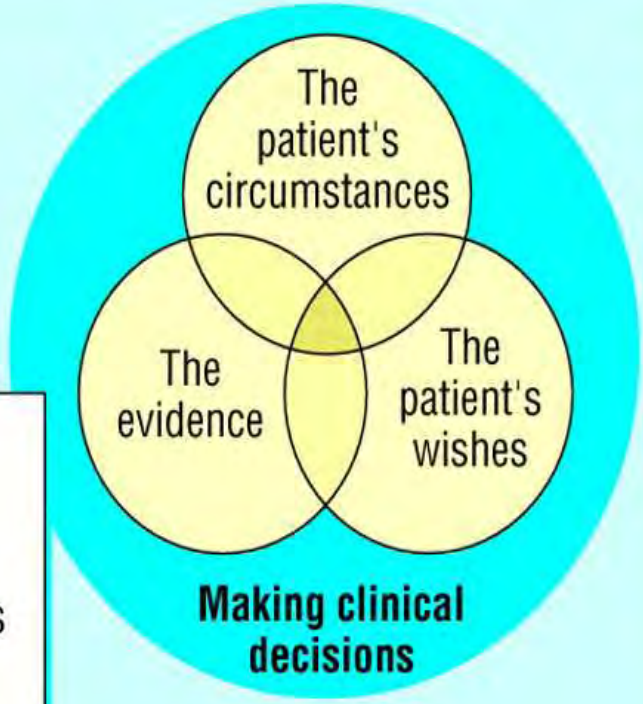


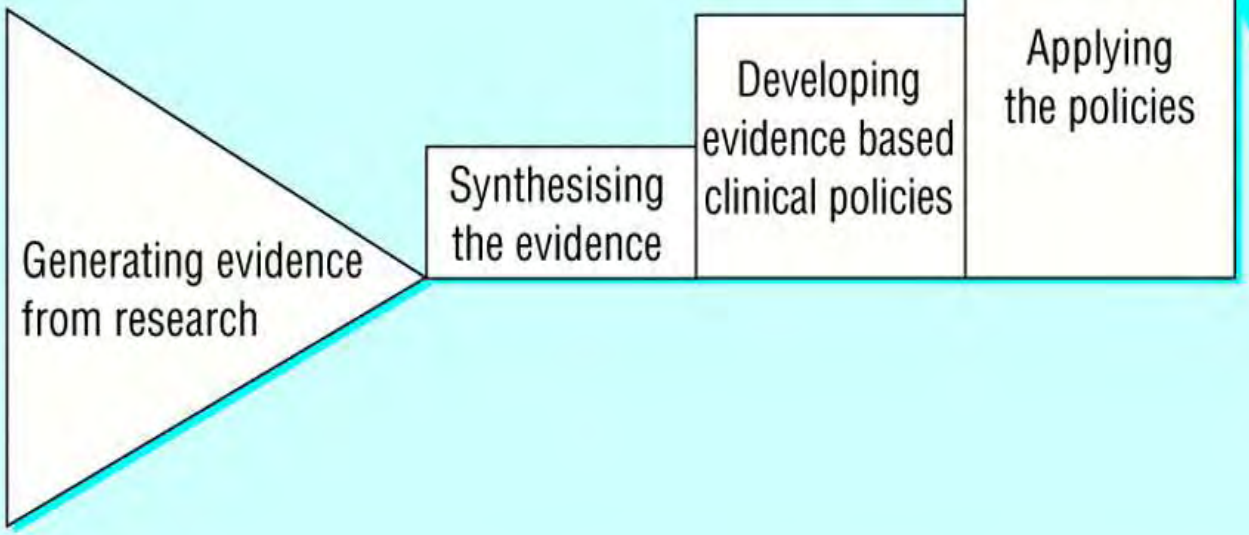
Generating evidence from research

Synthesising the evidence

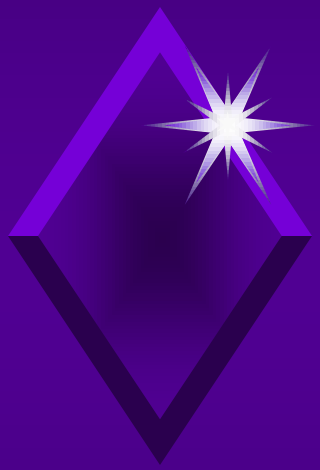
Appraise for reliability validity and results

Systematic reviews & guidelines





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

- 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.

EC Safety Data Sheet

- Date of issue / Reference
- Replaces version
- Date of printing
- Company

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

EC Safety Data Sheet - Composition

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 toany of the ingredients of the product

EC Safety Data Sheet - Toxicological information

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

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

<u>Check light source regularly for power output</u>

Resumé - topics

- Who are the stakeholders?
- Doesn't somebody test our materials?
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- The amalgam dispute
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Thank you for your kind attention