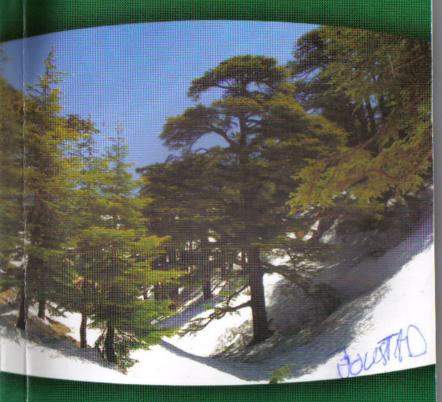
BOOK OF ABSTRACTS



Lebanese Dental Association

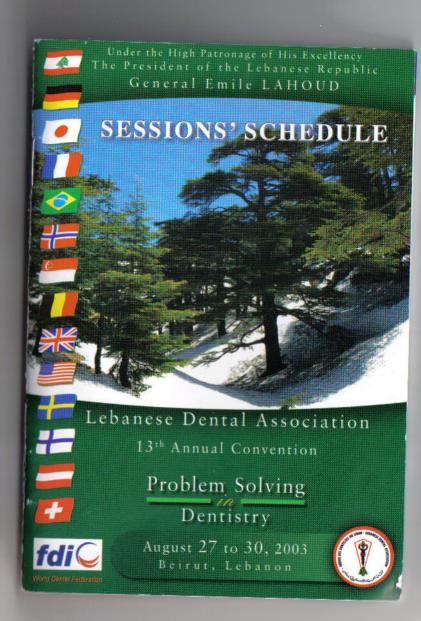
13th Annual Convention

Problem Solving
Dentistry



August 27 to 30, 2003
Beirut, Lebanon





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



Mutagenic potential

Acute allergy

Systemic toxicity

Local toxicity

Secondary caries

Clinical use of restorative materials and biological concerns

Chronic allergy

Postoperative sensitivity

Dentin and pulp reactions

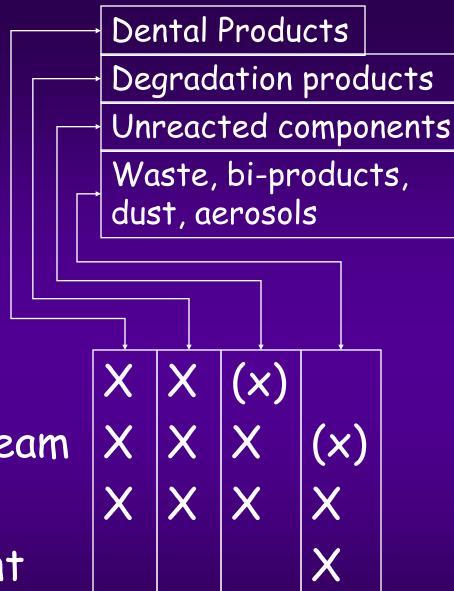
Pulp capping

Beirut, August 2003



Stakeholders

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





- ♦ 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)



- ♦ Who are the stakeholders?
- ◆ Doesn't somebody test our materials?
- Causality how to <u>prove</u> 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.



- 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 <u>risk factor</u> 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 <u>necessary factor/cause</u> is a risk factor that must be, or have been, present for a specified outcome to occur.
- A <u>sufficient factor/cause</u> is the minimal or combination of risk factors that inevitably results in a specified outcome



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.

Beirut, August 2003

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.

 Beirut, August 2003



- ♦ Who are the stakeholders?
- ◆ Doesn't somebody test our materials?
- ◆ Causality how to <u>prove</u> 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.



Resources Recruiting Contact Us Disclaimer

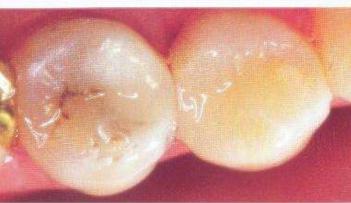
Law Offices of SHAWN KHORRAMI

14550 Haynes Street, Third Floor, Van Nuys, California p/818.947.5111 f/818.947.5121



- ♦ 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?









Composite resin components

Monomers: BIS-GMA... TEGDMA...
(HEMA). UDMA.. BIS-PMA... UPGDMA...
EGDMA... DEGMA... PRDMA... BISDMA...

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

<u>Degradation products</u>: MMA... BEA... MAA... Formaldehyde...

Chemical companies, information 🥉 Bookmarks 🉏 Netsite: http://www.merck.de/english/services/chemdat/index.ht



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Deutsch Español





Chemical Database

Analytical Reagents

Bioprocessing

Bioseparation

Chromatography

Environmental analysis

Hygiene monitoring

Medical laboratory

Microbiology

Microscopy

Research reagents

Product Info

> Product At A Glance

Toxicological Data

Safety Information

Storage Transport

Application/Literature

Specifications

Packing Information

Technical Data Sheet

Safety Data Sheets

Certificates of Analysis

Chemical/physical Data

HEMA.

canacrylic acid 2-hydroxyethy. ter

Categories of danger: irritant,

800588 2-Hydroxyethyl methacrylate

hydroguinone monomethyl ether) for synthesis

CLICK here for Structural formula

Formula Hill: C6H10O3

Chemical formula:

CH2=C(CH2)COOCH2CH2OH

Synonyms:

2-Hydroxyethyl 2-methylpropenoate,

sensitizing

Hazard signs:



(stabilised with

Navigation

Back to New Search

@2000 schlaepfer.com

Molar mass: 130.14 q/mol

Density: 1.07 q/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)

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

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Search Center



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

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

LABEL PRECAUTIONARY STATEMENTS

POSSIBLE RISK OF IRREVERSIBLE EFFECTS.

POSSIBLE CARCINOGEN.
POSSIBLE SENSITIZER.

WEAR SUITABLE PROTECTIVE CLOTHING.

SECTION 4. - - - - - - - FIRST-AID MEASTRES- - - - - - - -

IN CASE OF CONTACT, IMMEDIATELY FLUSH YES WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES.

IN SATE OF CONTACT THE LARLY 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

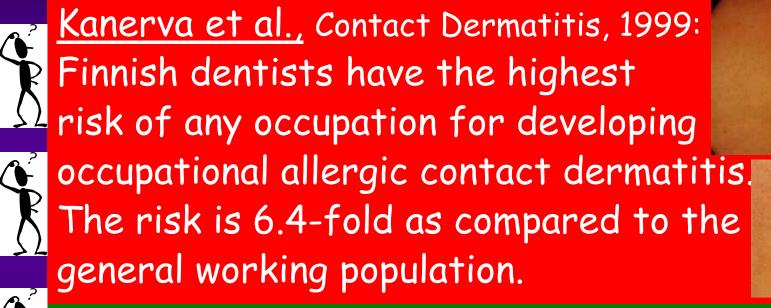
Björkman & Helland, Nor Dent Assoc J, 2001:

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



Wallenhammar et al., Contact Dermatitis, 2000:

The prevalence of contact allergy to acrylat

The prevalence of contact allergy to acrylat

The prevalence of contact allergy to acrylat

The population of responding The prevalence of contact allergy to acrylates was 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.



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

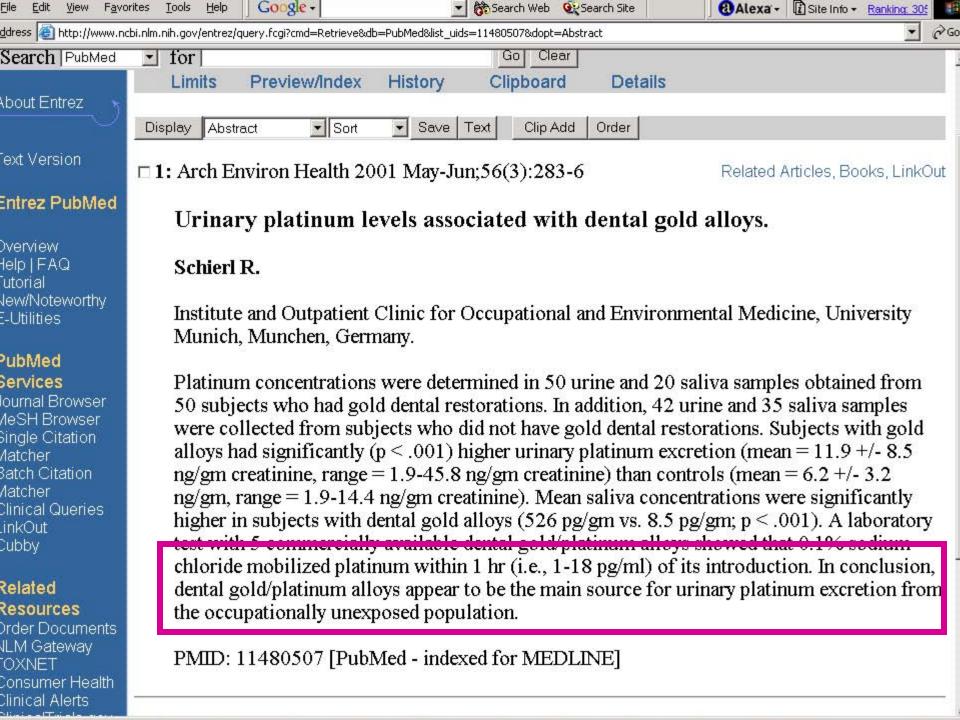


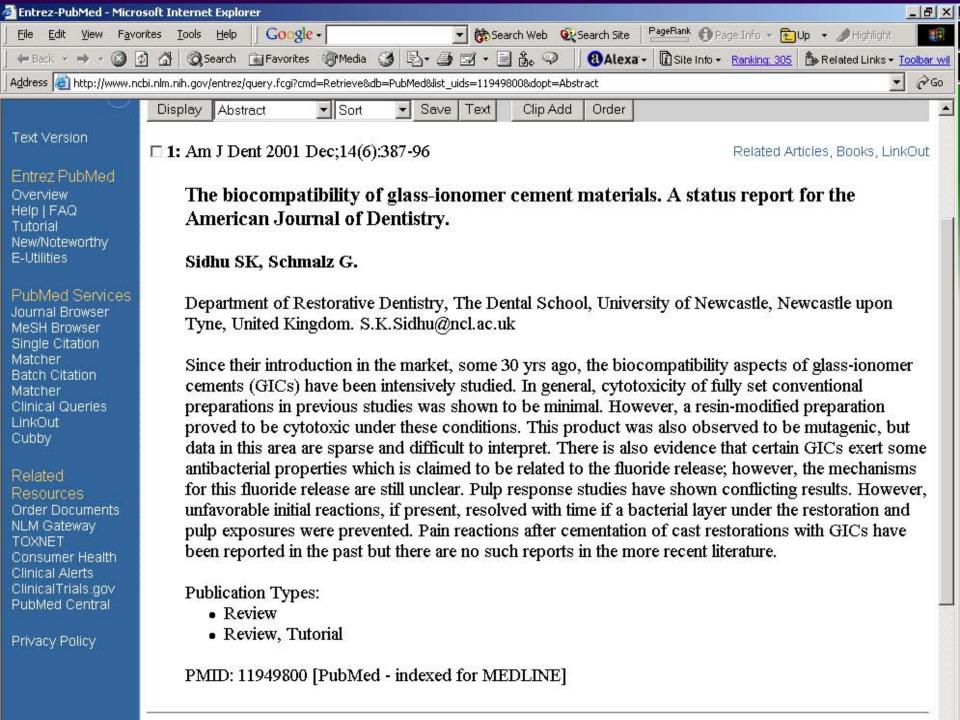


There is no evidence to suggest a link between any adverse health condition and Bisphenol-A leached out of dental sealants.



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- What about other dental materials?







Dental Material

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

Neurosurgery

Oral and reconstructive surgery



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Tutorial
New/Noteworthy
E-Utilities

PubMed Services
Journal Browser
MeSH Browser
Single Citation
Matcher
Batch Citation
Matcher
Clinical Queries
LinkOut
Cubby

Related
Resources
Order Documents
NLM Gateway
TOXNET
Consumer Health
Clinical Alerts
ClinicalTrials.gov
PubMed Central

Privacy Policy

Display Abstract Sort Save Text Clip Add Order

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

Related Articles, Books, LinkOu

CatchWord

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

Lonnroth EC, Dahl JE.

significantly.

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 Ketae 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

e)

Internet



The following feature article appears in "Dentistry", 7 February 2002. "Dentistry" is a popular dental magazine with a national circulation.

WHAT CONSTITUTES UNINFORMED CONSENT?

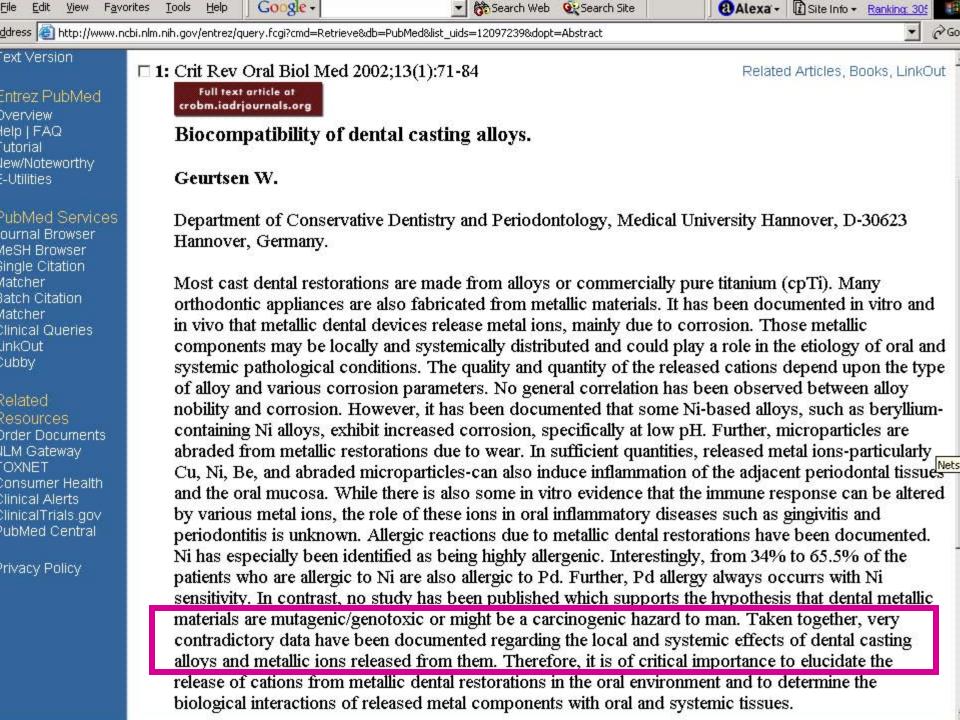
Tony Lees presents the case against glass ionomers

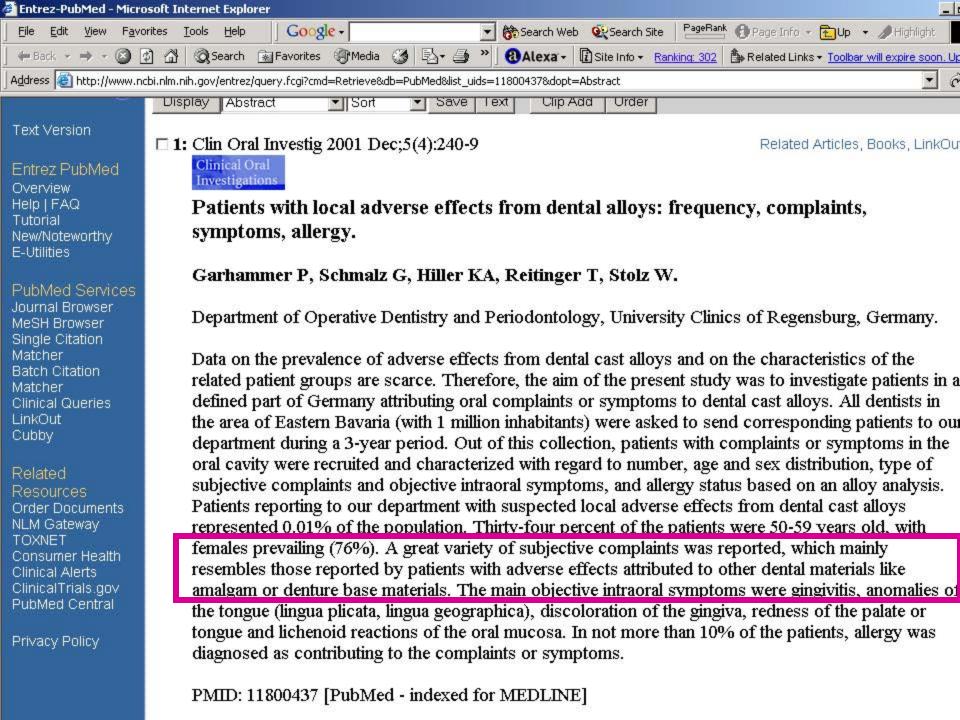
Carolyn Smith is a well educated, intelligent woman. She has a degree and takes a keen interest in environmental matters. She is concerned about the safety of mercury amalgams and water fluoridation. So, when, last year, she needed dental treatment, she was very relieved when her dentist placed a tooth 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:

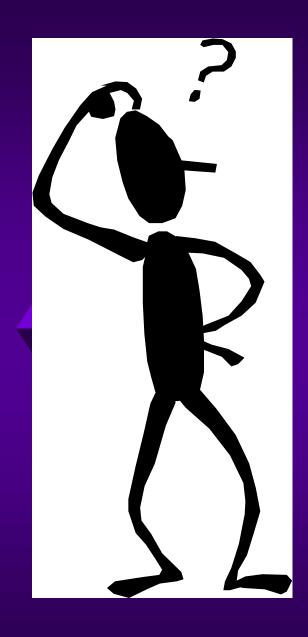
- 1 Are CI fillings toxic?
- 2 Has my right to informed consent been violated by having a toxic substance implanted into my mouth without my knowledge or consent?







- ♦ 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?

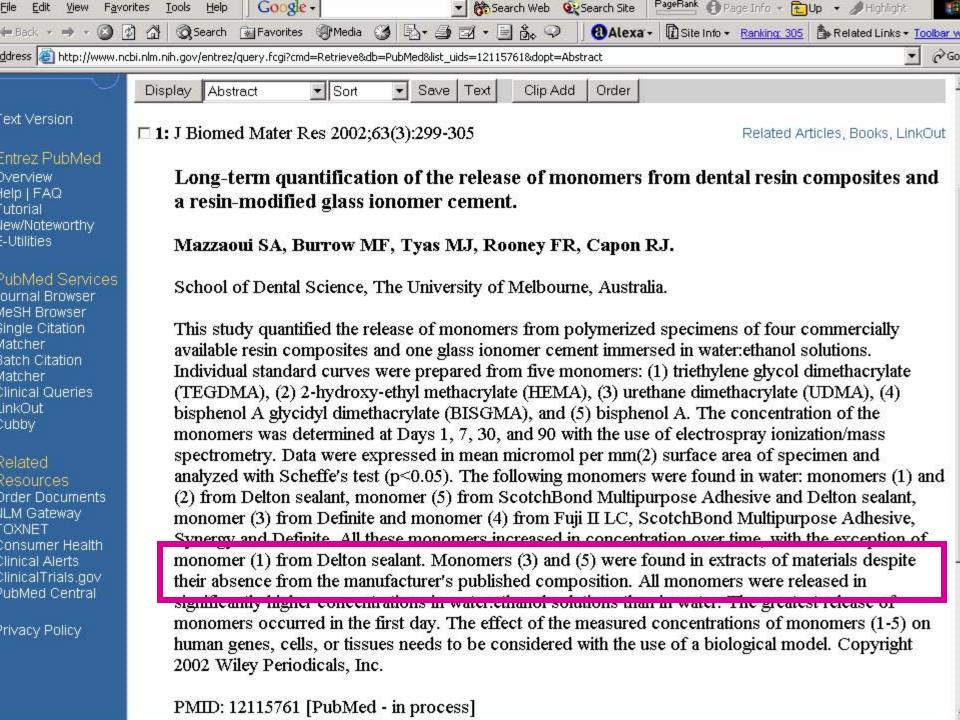
In vitro studies; e.g. elution of leachable components-variables

- 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



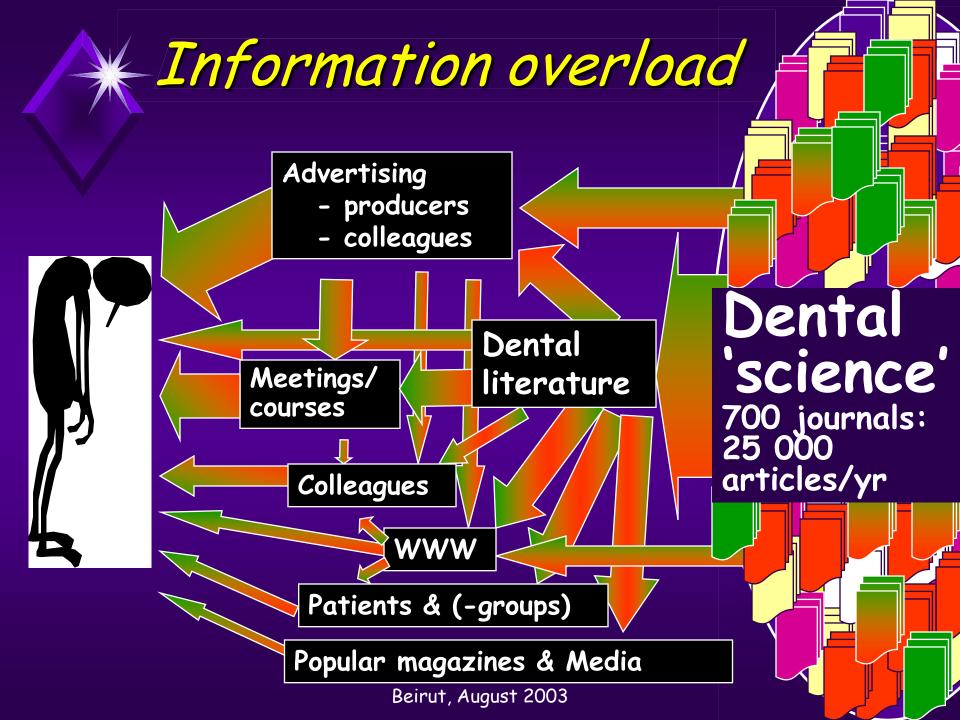


Why confusion?

- 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 casecontrol studies
- 5 Laboratory research & Expert opinion without explicit critical appraisal & Rationale basis on physiology & Case descriptions

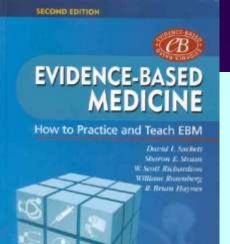




- ♦ Who are the stakeholders?
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- ◆ Composites- reasons for concern?
- ♦ What about other dental materials?
- ◆ So what is the situation for the GPs?
- Suggested strategy in daily clinical practice

Strategy in daily clinical practice

1. Practice evidence-based dentistry

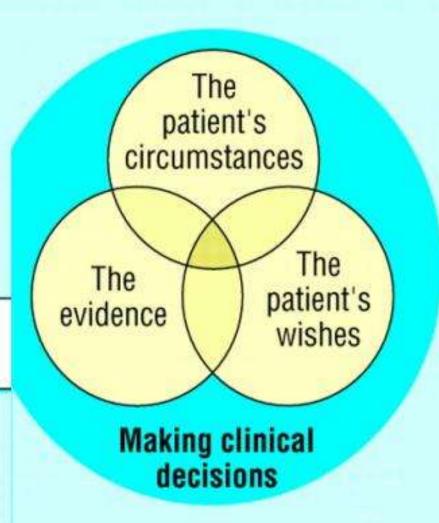


Learn critical appraisal: EBM

Generating evidence from research

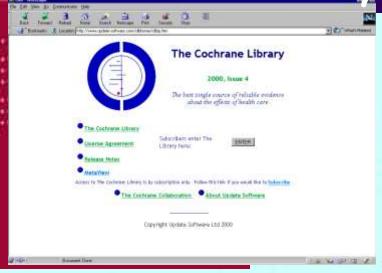
DELICHED ENVIRONMENTON

Synthesising the evidence



Evidence-Based Dentistry

Secondary ebd and systematic reviews

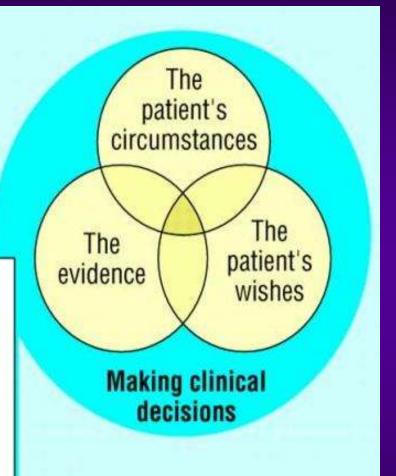


Synthesising

the evidence

reliability

Appraise for validity and results



Generating evidence from research



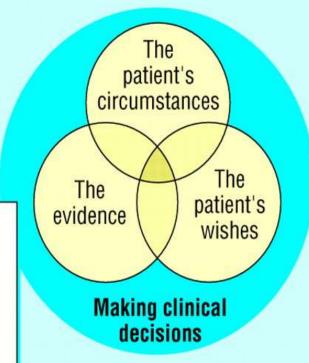
Systematic reviews & guidelines



Synthesising

the evidence

Developing evidence based clinical policies Applying the policies



Generating evidence from research

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

SKYDDSÅTGÄRDER för tandvårdspersonal vid arbete med plastmaterial



Allt ljushärdat material kan innehålla ohärdade komponenter.

BRA SKYDD OCH BRA HYGIEN MINSKAR RISKERNA

Läs varuinformationen noga innan du använder en produkt.

SKYDDSGLASÖGON/VISIR/HANDSUG Använd dessä för att skydda ögon och andningsvägar mot stänk och damm.

ÖGONDUSCH Råkar du få damm eller droppar av ohårdat plastmaterial i ögonen, spola med vatten minst 15 minuter och kontakta läkare.

BYT KONTAMINERADE HANDSKAR OCH KLÄDER

Byt snarast när du får ohärdat material eller adhesiver på handskar eller kläder. Det finns inga handskar som stoppar ohärdat material någon längre tid.

TVÄTTA MED TVÅL OCH VATTEN Får du ohärdat material på huden, tvätta omedelbart med tvål och vatten.

AVFALL Tättslutande avfallsbehå lare ska finnas och användas.

Märk den "HÄLSOFARLIGT AVFALL", "INNEHÄLLER AKRYLAT", "KAN GE
ALLERGI VID HUDKONTAKT". Använd alltid handskar vid avfallshantering.
Se till att städpersonal och sterilbiträden inte kan komma i kontakt med
ohärdat material.

UTBILDNING Se till att ha utbildning om riskerna i arbetet.

ANMÄL ARBETSSKADOR via arbetsgivaren till Försäkringskassan, Socialstyrelsens nationella biverkningsregister och även Tandläkarförbundet.









Afflucheo grundar sig på Arbeitankyddicityrebiens besochlyr ACH 491. Dentala plastet amakar aflengin Affluch 499 berutali film Arbeitankyddicityretiene hybraliationsservice. Indefaco 887-309 700, file 80-730 98 17.

- 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 Beirut, August 2003



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

Check light source regularly for power output



Resumé - 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



Thank you for your kind attention