NIOM
Nordic Institute of Dental Materials

NEWSLETTER
APRIL – 2015

OPINION OF BISPHENOL A (BPA) IN MEDICAL DEVICES PRESENTED

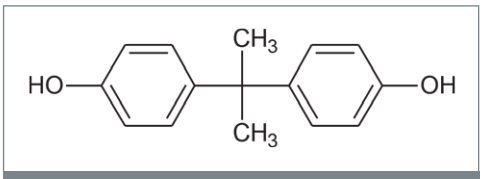
The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) is a committee within the European Commission for risk assessment. SCENIHR has recently published an opinion on the use of bisphenol A (BPA) in medical devices1. Contribution to the opinion was given by SCENIHR members and external experts including Prof. A Hensten, UiT The Arctic University of Norway, and Dr. H Molvig Kopperud from NIOM.

One key question in the task of the working group was to determine whether levels of exposure to BPA from the use of the various medical devices, such as implants, catheters, and dental devices, containing BPA could raise health concerns. Bisphenol A is a building block of some dental monomers, such as Bis-GMA, Bis-EMA and BADGE used in restoration materials, and is also used for the production of many polycarbonate materials. Discussions on the exposure and health risks related to BPA from dental materials have been going on with varying intensity since the mid 90's.

Vials for analysis of components

Risk for adverse effects of BPA may exist when BPA is directly available for systemic exposure after non-oral exposure routes.

SCENIHR evaluated several exposure scenarios accounting for the material used, information related to BPA leaching, the duration of a single treatment and the frequency of treatments. For dental materials two scenarios were considered: short-term exposure (<24 h after treatment) and exposure due to long-term contact with the materials. BPA exposures were estimated for different scenarios and were for dental materials found to be from 140 to 200 ng/kg bodyweight/day for children and adults, respectively, due to contact with dental materials for less than 24 h, and from 2 to 12 ng/kg bodyweight/day due to long-term contact. Both short-term and long-term exposures were similar to or well below the values of exposure due to dietary intake.



The structure of Bisphenol A

SCENIHR adopted the temporary oral tolerable daily intake (t-TDI) of 4 µg/kg bodyweight/day derived by the European Food Safety Authority (EFSA)2. The SCENIHR opinion considered that BPA has low systemic bioavailability by the oral route.

Oral exposure to BPA from dental materials poses a negligible risk for human health

"The SCENIHR concludes that risk for adverse effects of BPA may exist when the BPA is directly available for systemic exposure after non-oral exposure routes, especially for neonates in intensive care units, infants undergoing prolonged medical procedures and for dialysis patients ... However, better data on exposure would be beneficial for the refinement of the present risk assessment, to be carried out when new data on exposure via medical devices will be available."

With regards to dental materials the conclusion was made that long-term oral exposure to BPA was approximately 2 ‰ of the t-TDI, thus posing a negligible risk for human health.

NIOM
Nordic Institute of
Dental Materials
Sognsveien 70A,
NO 0855 Oslo, Norway.
phone: (+47) 67 51 22 00
e-mail: niom@niom.no
www.niom.no

References:
1) SCENIHR, Safety of the use of bisphenol A in medical devices, 18 February 2015. ISBN 978-92-79-30133-9, doi:10.2772/75546. 2) Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA Journal 2015; 13(1): 3978, doi:10.2903/j.efsa.2015.3978.

NIOM
Nordic Institute of Dental Materials

MECHANICAL PROPERTIES

Wax model mould

Mechanical properties describe a material's response when exposed to various mechanical impacts such as tension, pressure or deflection or even temperature change. As such they are crucial in evaluating the quality of a dental material or indeed any material. To get an insight into the topic mechanical properties, there are many concepts that must be understood in order to make correct selections of materials for dental restorations. Properties like elasticity, plasticity, brittleness, ductility, fracture toughness and strength, may differ widely from one material to another. This may be due to differences in grain or atomic structure or in chemical composition. Restorations require properties suited to their specific use. Particularly, when a restoration is a combination of different materials, an appropriate match between the mechanical properties of the materials is necessary to achieve a well-functioning and long-lasting restoration.

Restorations require properties suited to their specific use

NIOM possesses equipment for mechanical testing of dental materials. Whether it concerns polymer-based materials, metals, alloys, cements or ceramics we are able to offer testing of the elastic, plastic and fracture properties of a dental material.

Tensile testing

The mechanical tests are performed at NIOM on two universal test machines; a Zwick 10 kN instrument with macro extensometer and a Lloyd LRX 2.5 kN table top machine. The Zwick machine is calibrated to class 0.5 and the Lloyd machine to class 1. This means that the accuracy of measurement is better than ± 0.5 % and ± 1 %, respectively. Testing is performed in accordance with international (ISO) standards, for which NIOM is accredited for a range of test methods of mechanical properties. These cover biaxial or 3-point flexure tests, bond strength between metals or high strength ceramics and porcelain, bonding of artificial teeth to denture base materials, adhesion of bonding materials to dentin or enamel in addition to traditional tensile and compression measurements.

NIOM possesses equipment for mechanical testing of dental materials

A Zwick-instrument for non-accredited hardness determination by Vickers, Brinell or Knoop hardness measurement methods, with loads from 10 g to 30 kg, is also available.

NIOM
Nordic Institute of Dental Materials
Sognsveien 70A,
NO 0855 Oslo, Norway.
phone: (+47) 67 51 22 00
e-mail: niom@niom.no
www.niom.no

NIOM
NORDIC INSTITUTE OF DENTAL MATERIALS

KNOWLEDGE – INNOVATION – QUALITY

The Nordic Institute of Dental Materials (NIOM) is responsible for promoting a continuing Nordic collaboration in the field of dental biomaterials. NIOM maintains a distinct Nordic profile through broad contacts with the Nordic dental educational institutions and research centres. The Institute undertakes research, materials testing, standardisation and research-based consulting directed towards health authorities and dental health services in the Nordic countries. Our research and consulting are required to be scientifically founded and applicable to clinical dentistry.