Launching a Dental Materials Research Agenda

The 2009 WHO report “Future Use of Dental Materials for Dental Restoration” held in 2009, in cooperation with UNEP, that concluded, “existing alternative dental materials are not ideal due to limitation in durability, fracture resistance, and wear resistance. Therefore, the meeting recognized the need for strengthening of research into the long-term performance, possible adverse effects, and viability of such materials.”

London, December 2012; International meeting held to set out Dental Materials Research agenda, building on recommendations of 2009 WHO Report to achieve phase down of dental amalgam

Participating stakeholders and actors included:

- WHO
- UNEP
- IADR
- FDI
- IFDEA
- Sentinel centers for dental materials research
- Representatives of government agencies
- Representatives from research departments of leading dental manufacturers

Commitment

The dental profession and dental research community are committed to develop a prioritized- agenda and global action plan to address individual and population-level health with environmental compatibility and economic feasibility dental materials.

Areas of research recognized and viewed as priorities:

- Identify performance gaps in current dental restorative materials
- Phase IV studies in clinical and community practice settings for materials in use.
- Given the need for different properties at the floor of a cavity (closer to the pulp) versus at the surface of the tooth facing the oral environment, there may be a need for two materials or a gradient in materials in a single cavity.
- While advances in polymer sciences are being made, there is a concern that we may need to move away from bis-GMA polymer based materials for human safety and environmental reasons due to their potential for BPA trace contamination and BPA degradation potential.
- Laboratory tests which reliably predict clinical material performance over the lifetime of the materials must be established and, ultimately, integrated into specifications for acceptance of new materials/products.
- New materials need to be developed that are easy to use in a variety of clinical and community settings.
- Complete human and environmental safety studies for all existing and new materials.
- Randomized clinical trials for new materials.

The ideal new material should have a similar gradient in properties from cavity floor to surface, as in a natural tooth, and be cost effective and non-toxic to human health and the environment. It would seal the interface between the tooth and the restoration, be adhesive to the tooth with little to no shrinkage, interact favorably with carious dentin and enamel (preferably with healing/remineralizing properties), be clinically easy to use in a variety of settings, and be fracture and wear resistant and repairable.
Summary

The Dental Materials Innovation Workshop

Sponsored by International Association for Dental Research (IADR), King's College London (KCL), and FDI World Dental Federation

Co-sponsored by: World Health Organization (WHO) and United Nations Environmental Programme (UNEP)

On December 10-11, 2012, the IADR, KCL, and FDI sponsored the Dental Materials Innovation Workshop held on the campus of King's College London. The goals of the workshop were to identify performance gaps in our current armamentarium of dental restorative materials, identify promising areas of dental materials research, and to develop a prioritized-agenda and global action plan in dental materials research to address individual and population-level health with environmental compatibility and economic feasibility.

The starting point for the workshop was the WHO meeting “Future Use of Dental Materials for Dental Restoration” held in 2009, in cooperation with UNEP, that concluded, “existing alternative dental materials are not ideal due to limitation in durability, fracture resistance, and wear resistance. Therefore, the meeting recognized the need for strengthening of research into the long-term performance, possible adverse effects, and viability of such materials.”

Background Presentations: Public Health and the Environment

The workshop opened with background and introductory comments from Poul Erik Petersen, WHO Responsible Officer for the Global Oral Health Programme (WHO GOHP), and David Piper, UNEP Deputy, Chemicals Branch.

WHO GOHP

The shortcomings of existing dental restorative materials were reviewed and the WHO called for the oral health research community to strengthen operational research in relations to the development and use of new dental restorative materials for public health settings. The WHO recognized the role of IADR was to advance research and to facilitate the communication and application of research findings, IFDEA’s role to develop competence based curricula based on evidence and best practice, while FDI’s role is to enable the effective implementation of research and promote a new paradigm shift from restorative to a preventive / health promotion model. WHO acknowledged dental manufacturers role in product research and development. WHO would assist governments in oral disease prevention and promotion of health and UNEP would assist governments in maintaining a safe environment.

UNEP

An overview of the background to the UNEP INC process was presented, highlighting the need for a legally binding treaty on mercury. UNEP described how the INC process was included within the Rio+20 declaration and integrated into the Strategic Approach to International Chemicals Management (SAICM). Workshop participants found the discussion around some of the SAICM emerging global issues useful, as some of the alternatives to dental amalgam have their own chemicals management concerns.
IADR: Risk to human health of current dental restorative materials

The risk to human health of current dental restorative materials was presented and reviewed. Safety is defined as freedom from unacceptable risks. In terms of clinical risk all restorative materials can be described as safe, with less than 0.1% chance of reactions, which are local, compared to 12% for cosmetics.

All dental restorative materials release substances, which are then resorbed. The clear difference between elemental mercury, inorganic mercury, methyl mercury and dental amalgam was made and their distinctly differing health risks. The mercury in dental amalgam is predominantly bound to metals (silver, zinc, copper, tin) and does not pose the health risk that methyl mercury does, for example.

Current evidence notes that there is little apparent systemic toxicity related to current dental restorative materials (caveat; possibly some from bisphenol-A from composite resins). However local allergic hypersensitivity reactions can rarely occur with any of the dental restorative materials (notably to the resin monomer hydroxyl-ethyl methacrylate).

In terms of clinical longevity of the restoration, dental amalgams are superior to resin-based composites, which are superior to glass ionomers. Durability and reparation are important factors as each replacement restoration usually involves the removal of more tooth structure, a larger restoration, and eventual risk for tooth extraction.

Environmental considerations

UNEP estimated that dental amalgam accounts for roughly 2% of anthropogenic mercury emissions to air and roughly 8% of mercury demand or consumption in processes and products. While participants voiced concerns the estimates may be inflated, all were committed to the goal of the workshop to develop a research agenda for better dental materials so that dental amalgam could be phased down.

U.S. data presented noted that dental amalgam was estimated to contribute about 0.4 ton to surface waters via publicly-owned treatment work (POTW) effluents and sewage sludge incinerators. The use of dental amalgam separators can reduce these discharges to roughly 0.1 ton, but at a cost of between $273 million to $1.2 billion.

There is currently no data available on the environmental impact of the main alternatives to dental amalgam, i.e. resin composites and glass ionomers.

Promising Areas of Research

The most exciting aspect of the workshop was bringing in both dental material scientists and material scientists from outside the health field to share and cross-fertilize ideas and approaches to materials development. Speakers noted that there will continue to be developments in our current resin-based adhesive restorations, such as the addition of matrix metalloproteinase inhibitors, anti-bacterial properties, and improved remineralizing potential.

Glass ionomer cements will continue to improve with high-strength properties, along with hybrid materials such as the resin-modified glass ionomer cements and the developing improvements in the tri-calcium silicates. However, these relatively incremental improvements are unlikely to completely supplant the clinical need for a material with all the properties of dental amalgam.

One novel approach presented is the use of polymer nanocomposites, which combines block copolymers with inorganic nanoparticles, thus merging polymer sciences with inorganic/solid-state chemistry. One example would be an epoxy filled with silica nanoparticles. These structures can then be toughened, resulting in increased fracture toughness and new strengthening mechanisms including crack deflection, crack pinning, microcracking, and plastic void growth. A block copolymer can be modified with a rubbery layer to improve its properties.
Rubber (CSR) nanoparticles are commercially available. Nanocomposites can also be developed that are more wear resistant.

Another approach presented looked to nature for inspiration. The abalone shell is a biologic composite that uses platelets rather than fibers to reinforce the material and performs extremely well when loaded in any direction. Researchers have been able to mimic this structure at the micro- and nano-scale by controlling the orientation and spatial distribution of reinforcing elements to improve our composite systems. Platelets can be aligned with an ultra-high magnetic response.

**Design Parameters for the Ideal Dental Restorative Material**

There are a wide range of properties that must be assessed for any dental material, including, physical, chemical, mechanical, biologic, and clinical properties. In addition, the material must have an ease of clinical manipulation and be stable in different environments. The longevity of a restoration is a function of the operator, design, material, location, and patient.

In the near-term, we should see continued improvements in traditional synthetic biomaterials, but in the longer-term future, a move to more biologic biomaterials. The importance of the operator’s skills or ease of clinical use in a variety of settings was emphasized. The ideal new material would seal the interface between the tooth and the restoration, be adhesive to the tooth with little to no shrinkage, interact favorably with carious dentin and enamel (preferably with healing/remineralizing properties), be clinically easy to use in a variety of settings, and be fracture and wear resistant and repairable. Ideally, the material should have graded properties from cavity floor to surface, similar to a natural tooth, and be cost effective and non-toxic to human health and the environment.

Consideration must also be given to manufacturing and distribution costs, including climate constraints for shipping and storage throughout the world. Funding schemes/mechanisms and government-generated policies for reimbursement must also be incorporated into considerations of alternatives.

**Dental Materials Research Agenda**

In summary, the need for the following areas of research were recognized and viewed as priorities:

- Identify performance gaps in current dental restorative materials
- Phase IV studies in clinical and community practice settings for materials in use.
- Given the need for different properties at the floor of a cavity (closer to the pulp) versus at the surface of the tooth facing the oral environment, there may be a need for two materials or a gradient in materials in a single cavity.
- While advances in polymer sciences are being made, there is a concern that we may need to move away from bis-GMA polymer based materials for human safety and environmental reasons due to their potential for BPA trace contamination and BPA degradation potential.
- Laboratory tests which reliably predict clinical material performance over the lifetime of the materials must be established and, ultimately, integrated into specifications for acceptance of new materials/products.
- New materials need to be developed that are easy to use in a variety of clinical and community settings.
- Complete human and environmental safety studies for all existing and new materials.
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