

## Conference Report: Materials Research in Maxillofacial Prosthetics

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Maxillofacial prosthetics is the science and art of anatomical, functional, or cosmetic reconstruction by means of artificial substitutes of head and neck structures that are missing or defective. Loss of parts of the head and neck can be caused by surgery, trauma, or developmental malformations. Despite improvements in reconstructive and plastic surgery, replacement of the more intricate facial structures still requires the use of man-made materials as external prostheses. Recent problems with silicone gel implants can be expected to focus more attention on external prosthetic replacements.

The incidence of head and neck cancers is increasing. People live longer, and a greater number of cancer patients survive. Environmental changes such as the ozone deficiency make the possibility of skin cancers more immediate. Surgical defects, traumatic injuries to the face, and birth deformities can be concealed by extra-oral maxillofacial prostheses (EMFP) which allow the sufferer to return to the mainstream of society. This rehabilitative method solves a medical problem with a dental solution.

Support for research in rehabilitative EMFP often falls to institutions and governments, but much progress in this orphan field is left to individual clinics, clinicians, and the laboratories of prosthodontists, prosthetists, ocularists, anaplastologists, colorists, and dental technicians.

There has not been a conference dedicated to EMFPs since the early 1970s. On February 14, 1992, the University of Louisville and the Academy of Dental Materials co-sponsored a conference on "Materials Research in Maxillofacial Prosthetics" in Chicago, IL, at the Ritz-Carlton Hotel. The program chairmen for the conference were Drs. Lawrence Gettleman and Zafrulla Khan, both from the University of Louisville. Over 80 registrants representing 20 states and four countries attended. External funding for the conference came from medical centers in Louisville, Kentucky: Alliant Health Systems, the James Graham Brown Cancer Center, Humana Hospital-University of Louisville, Jewish Hospital, and the University of Louisville.

Discussions between presentations were recorded for inclusion in the forthcoming *Transactions* of the Academy of Dental Materials, Vol. 5. Contact Dr. Gettleman at the University of Louisville School of Dentistry to obtain a copy of the *Transactions*.

Dr. Tsun Ma of the University of Washington, Seattle, began with a clinical overview of materials for EMFP. Five major materials available commercially are poly(methyl methacrylate), latexes, vinyl polymers and copolymers, polyurethane elastomers, and silicone elastomers. None is considered an ideal material. Different elastomers have their own physical and mechanical properties and share a few common clinical problems: (1) discoloration over time (intrinsic and extrinsic discoloration due to environmental factors and the loss of external pigmentation), and (2) degradation of physical and mechanical properties (tears at the margins, changes to surface texture, elongation at the margins, lack of compatibility with medical adhesives, weakening of margins by colorants, adhesives, solvents, and cleansers, and deterioration of static and dynamic mechanical properties). Most discoloration and tearing occur when patients remove prostheses or adhesives.

Dr. Ma reviewed the literature and recommended that future research be directed at two major areas: improving physical and mechanical properties for more lifelike behavior; and the search for color-stable agents. He concluded that a correlation must be drawn between clinical performance and laboratory data.

A survey conducted among members of the American Academy of Maxillofacial Prosthetics, the American College of Prosthodontists, and the American Anaplastology Association was reported by Dr. Carl Andres of Indiana University, Indianapolis. The majority of

respondents use room-temperature vulcanizing or heat-accelerated silicone materials, or a combination of the two. Dry earth pigments, rayon flocking fibers, and/or artist's oil pigments were cited as the colorants for intrinsic coloring; common extrinsic coloring methods include Dow Corning's Medical Adhesive Type A mixed with xylene as a retardant or thinner, and tinted with dry earth pigments or artist's oils.

Respondents cited cost and availability along with lack of sufficient technical information as disadvantages in using other materials. They concurred that ideal material properties included: increased tensile and tear strength; variable consistency; adhesive compatibility; rapid polymerization in a simple mold system; repeatable and consistent color results; repairability; and a life expectancy of from one to five years.

Mr. Eric Rommerdale of the University of Mississippi (Jackson) discussed present and ideal polymers for EMFPs. Existing silicone rubbers cannot match the elastic modulus of skin or mimic the durometer firmness of skin. He suggested the need for a clay-like, light-curing material applied as a spray directly to a seated or standing patient as a solution to problems caused by posture.

Mr. Rommerdale described a technique of making a picture of the desired color and laminating the photograph into color tabs to achieve long-term color matching. A participant mentioned that using CAD/CAM before and after surgery has enabled him to make a master cast in styrofoam rather than by using impression material.

Endosseous implants have achieved success as retention devices for EMFP. Dr. Norman Schaaf of Roswell Park Cancer Institute, Buffalo, NY, explained the advantages of implant-retained prostheses, including: (1) mild positive pressure applied to thin, flexible margins, (2) margins less likely to tear because of no adhesive pull, (3) less prosthesis deterioration due to chemicals in the adhesive, (4) extra-oral prostheses stabilizing an intra-oral one in a continuity defect, and (5) reduced skin irritation from adhesives. Dr. Schaaf described his protocol where implants are put in place at the time of cancer surgery to allow for EMFP retention.

In working with radiation therapists, Dr. Schaaf assumes several things: Radiated bone may have lost its capacity to remodel and resorb; infection may be controlled when implant sockets are completely tapped, with no space between the implant and the bone; and, because he uses titanium implants, radiation therapists are not concerned about concentrating further radiation around the implant. He prefers to use magnets because patients need to come close only when the prosthesis is positioned. When a prosthesis comes into direct contact with the skin, Dr. Schaaf determined that peroxide is the best cleansing agent.

Almost all of the silicones used today have been developed for a specific purpose in markets other than extra-oral maxillofacial prosthetics. John McFall of Factor II, Lakeside, AZ, described his company's work with manufacturers to ensure availability of materials. The small size of the prosthetic field makes it difficult to obtain some materials. He noted that when research is done and a paper is published, projects are not finished. In this smaller, concentrated field, discussing results with a manufacturer is needed if new materials are to be marketed. Orthotics and prosthetics programs remain the mainstay for researchers, including Animatronic producers. The size of the market is a problem.

Research into colorant formulation for extra-oral maxillofacial prosthetics by William Johnston of The Ohio State University, Columbus, was concentrated into two areas: absorbance of light, and diffuse reflectance. The inherent optical properties of an EMFP material may be described by its absorption and scattering coefficients. From the optical constants of the pigments in an elastomer,

color differences can be estimated by means of color theory. To minimize the sum of color differences, more than one illuminant may be used. Dr. Johnston explained that some absorption peaks, which are less prominent in an unhealthy person, are due to oxyhemoglobin in the blood. Natural pigments have not been used in artificial skin because of instability. He uses organic and inorganic compounds to duplicate the spectral characteristics and minimize metamerism.

Dr. John Lontz from the Veterans Administration Medical Center, Wilmington, DE, outlined the VA's development of standards for safe and effective molding compositions for prostheses. Polydimethyl (PDM) silicone was developed in four technical phases: (1) modification of stock PDM elastomer with low-molecular-weight oligomers to approximate the elasticity of human skin and ensure biomechanical equivalency based on tensile measurements; (2) adjustment of the structure for feather edge and tear resistance equal to human skin; (3) provision of dispersed internal pigmentation to ensure at least 80 to 90% transparency so that underlying natural coloration of the skin will show through and give the broad range of racial colorations; and (4) to satisfy performance standards such as resistance to light, exposure to oleaginous secretions, and repeated hygienic maintenance with soaps and disinfectants. Standard test methods of biocompatibility were developed based on cell cultures derived from orofacial tissues.

Silicone block copolymers, as presented by Dr. Andrew Koran of the University of Michigan, Ann Arbor, consist of blocks of dissimilar oligomeric segments linked together linearly. If the blocks are thermodynamically incompatible and are sufficiently long, the condensed phase of such copolymers can form micro-phase domains that can range in size from tens of nanometers to micrometers. With current technology, it should be possible for new elastomers to be synthesized with excellent potential for long-term clinical success. In evaluating silicone block copolymers for maxillofacial materials, control of mechanical and physical properties of the copolymers should range between those of the corresponding homopolymers.

Dr. Koran presented a project where silicone-PMMA block copolymers were synthesized in several different ways. The three syntheses were: (1) one-step anionic polymerization for preparation of silicone-PMMA block copolymers; (2) condensation polymerization of functional PDMS and PMMA precursors; and (3) free radical polymerization of acrylic monomers using PDMS macroiniferters. The results of the study may identify new elastomers that have potential when compared with current materials.

Dr. Joseph Antonucci of the National Institute of Standards and Technology in Gaithersburg, MD, spoke on polymers and elastomers for EMFPs. Polyetherurethanes, chlorinated polyethylenes, and the vinyl addition siloxanes have gained ascendancy over conventional acrylic polymers as polymeric maxillofacial materials in recent years. Though still far from ideal, new acrylics fall into two major classes: (1) high-molecular-weight resins with relatively few polymerizable vinyl groups, *e.g.*, bulky difunctional monomers, oligomers, and macromers, and (2) high-molecular-weight difunc-

tional monomers, oligomers, and macromers with a propensity for cyclopolymerization. These new acrylics can be synthesized to provide autopolymerizable resins that incorporate sizeable molecular blocks of any type of polymer desired into a prosthesis. Also, the new resins exhibit both high conversions of their acrylic vinyl groups and low shrinkage on polymerization. They also should be readily processed by conventional dental stone mold technology and, perhaps, future processing technologies, *e.g.*, microwave, stereolithography, and the various CAD/CAM techniques.

Dr. Lawrence Gettleman, University of Louisville, KY, described chlorinated polyethylene (CPE) and polyphosphazenes for use in maxillofacial prostheses. After CPE is blended with chlorinated paraffin, low-density polyethylene, calcium stearate, anti-oxidant, UV absorber, and pigments, this thermoplastic material is laid into a dental gypsum mold and heated at 110°C for 30 min until, after one or two re-packs, the prosthesis is free of voids. The surface is characterized with inorganic pigments and flock, then laminated beneath a sheet of unpigmented CPE and cycled again for 30 min, producing a protected pigmented layer.

Polyphosphazene fluoroelastomer (PNF) was used in the development of Novus, a permanent resilient denture liner, and consideration was given to using this material for facial prostheses. Formulated with cross-linking acrylics without fillers, the material provides controlled softness, biocompatibility, permanent resilience, high-energy absorbance, and ease of processing. Liabilities include the initial cost and edge strength, which are not much better than those of silicone rubber. The material feels lifelike and will be developed further in an on-going project in phosphazene chemistry.

At the close of the day-long conference, one common thread was seen throughout all presentations: There is a great need for improvement in materials for maxillofacial prostheses. Existing materials have limited longevity, fray and tear, discolor, may have problems with tissue compatibility, and require extended curing times. An ideal long-lasting EMFP material would have a skin-like consistency, cure quickly, and could be applied directly to the defect.

Polymer manufacturers have little incentive to support improvements for facial and somatic prosthetics because of low volume. Significant advances must continue to come from the support of governmental agencies, schools, and hospitals.

The technology exists to create a "bionic man", but that is not what the field is about. We restore patients who have suffered injuries...patients who can be returned to healthy, active lives.

—Z. Khan

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