The dental polymer implant concept

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The replacement of man's wornout or depleted parts with human or animal tissues or synthetic materials has been in man's mind and imagination for centuries. In the early 1900's, Alexis Carrel transplanted every major organ in animals. His famous two-headed dog was proof that transplant failures were not the result of surgical or technical difficulties.

The built-in immune mechanism, a specificity that permits the prevention of certain diseases by vaccination, also acts to prevent the success of transplants, and immunologic rejection results. This is a fundamental biologic reaction and was adequately demonstrated by the outstanding research of Medawar on rabbit skin transplants. He demonstrated that there was an immunization of the animal with the first graft and subsequent accelerated rejection of the second graft. It was now clear that homologous and heterologous transplants failed due to an immunologic response. Transplant failures result from the ability of the host to identify another tissue as containing a foreign protein and to be able to reject this tissue through the development of specific antibodies. Lymphocytes are instrumental in this phenomenon, since they are responsible for the elaboration of antibody.

To overcome this, scientists have tried to control the immune response by suppressing the bone marrow by the use of radiation, globulins, immunosuppressive drugs, and cortisone-type drugs.

All these methods seriously endanger the life of the transplant recipient, placing him in a delicate balance between immunologic rejection and death from uncontrollable infection, since one of the body's major defensive mechanisms against pathogenic microorganisms has been removed.

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This problem has not been solved; it exists today.

One can hardly justify the use of bone-marrow suppressive measures for other than life-saving reasons and obviously not for tooth replacement.

Our laboratory, recognizing that circumventing the immunologic response is of the utmost importance, is working with nonviable and/or attenuated viable materials. Bioengineering principles are employed with biologically tolerable substances. Polymers are the basic building blocks for oral reconstruction and this laboratory is studying methods of implanting polymers into the jaws of experimental animals and human beings.

Polymers were selected for the following reasons:
1. They can be "tailor-made" to specific needs, since ingredients can be added or deleted to change the physical characteristics of the polymers. For example, they can be made more or less porous, harder, softer, purer, etc.
2. They are easy to handle for fabrication purposes and permit accuracy of reproduction.
3. They do not emit microwaves of electrolytic current as do metals.
4. Fibrous connective tissue attachment to the polymer implants has been shown to be possible.
5. Microscopic evaluation is easier than with metals.

RESEARCH DESIGN

The baboon is used to test the biologic acceptance of materials and soundness of techniques used. It is obvious that procedures can be carried out on experimental animals that cannot be undertaken with human beings. Clinical results can be evaluated, and histologic studies can be performed. Microscopic evidence lends important information for new leads and future direction, as well as evidence of accomplishment.

When animal studies indicate that results will be satisfactory, human implants are performed under appropriate circumstances.

The animal most suitable for these studies was found to be the baboon (Figs. 1 to 5). It is obtainable, its size allows for easy handling, and it is physiologically very similar to man.

The baboon is the experimental subhuman primate of choice for implant studies, for it closely simulates the human in dentition as well as in physiology. These facts lend credence to the applicability of animal data to the human—the investigator's ultimate concern.

HANDLING OF BABOONS

The best method of handling these subhuman primates involves the use of phenylcycloidine (Sernylan) as a tranquilizer and preanesthetic.

The baboon is squeezed forward in a specially constructed cage and 5 mg. of phenylcycloidine is injected intramuscularly per kilogram of body weight. Within ten minutes the animal, although conscious, can be transported safely and uneventfully to the operating area. If examination is desired, this can be done adequately. If implantation procedures are to be done, pentobarbital sodium is administered intravenously to the desired effect, or by deep intramuscular injection.
Fig. 1. A gelada baboon.

Fig. 2. Two mandibular molar implants in a baboon.

Fig. 3. Two mandibular molar polymer coated metal tripod implants in a baboon.

Fig. 4. A low-power photomicrograph of a maxillary incisor implant in a baboon. The implant was removed prior to making the histologic preparation of the tissue, leaving the periodontal membrane and bone.

Fig. 5. A high-power view of the periodontal membrane in Fig. 4. The orientation of the fibers tends to be vertical.
The explosive nature of the animal, coupled with its great strength, make careful handling mandatory.

**METHODS AND MATERIALS**

Autopolymerizing and heat-processed polymethacrylate, alone or combined with grated cancellous freeze-dried calf bone (anorganic) are the main materials which have been used to develop the polymer implant concept. This combination, when in proper percentages, has been used in several ways since it is biologically acceptable and does not cause untoward immunologic reactions. The term polymer implant refers to polymer materials that, when combined with additives, can change their physical properties to improve their acceptance by the host for a specific purpose.

The plastic or plastic-bone mixture, a material developed in this laboratory, has been used successfully for the tooth replica implant. By immediately fabricating the implant, the replica of the extracted natural tooth is placed in the socket within 45 minutes after its extraction or loss.

The tooth replica implant is fabricated in the following manner: The natural tooth requiring extraction is removed and any defect is corrected with wax. A mold is made by investing the corrected natural tooth in stone or plaster using a flask. When multirooted teeth are to be reproduced, thin-bodied heat-resistant silicone is used. It is best applied by using an injection gun with the silicone directed into the inner trifurcation or bifurcation sections of the roots. Strands of silicone are placed to extend through the root areas so that, when the tooth with silicone attached is invested vertically in a flask, the hardened plaster will anchor the silicone; when the natural tooth is removed from the finished mold the silicone will not be displaced. The implant material is test packed with very little excess, for large excess causes the implant to elongate when silicone is used.

After the tooth is removed, a hydrocolloid separating medium is applied to the plaster, and the polymer is packed into the flask and heat processed at a temperature and time that is proper for each specific polymer material. For example, the implant of 20 per cent grated anorganic bone, 78 per cent polymethacrylate, and 2 per cent foaming agent is processed at 300°F. for 30 minutes. Once heat cured, the flask is cooled and opened, and the implant is finished, sandblasted, and compared with the natural tooth for accuracy of shape and size (See Fig. 13). It is placed into zephirin chloride for approximately 10 minutes, and then inserted into the alveolar socket. The implant is then splinted to adjacent teeth or implants.

In many of the tooth replica polymer implants, openings were made through the implants’ roots (Figs. 6, 7, and 8). These openings of 2 mm. or more were placed at different distances and positions from the apices. In other tooth replica implants, no holes were made through the implants roots.

These procedures were carried out with pure polymethacrylate and with bone-polymethacrylate, with and without foam agents. Other variations of the basic materials mentioned will be reported subsequently.

The plastic bone mixture has been used successfully as a coating for metals in baboons and human subjects (Figs. 9 and 10). A technique for making polymer-
Fig. 6. Lateral and central maxillary incisor implants in a baboon.

Fig. 7. A radiograph of an incisor implant showing bone formation developing in channels cut into the root of the polymer implant.

Fig. 8. A histologic section demonstrating connective tissue and bone developing in the root channel.

Fig. 9. A tripod metal implant with a polymer layer covering the metal pins except at the apices. New polymer-coated metal pins are completely coated.

Fig. 10. A tripod method pin implant with a polymer crown and a polymer covering on the pins. The tripod implant had been in place in a baboon for 6 months. In this gross specimen of the jaw, the bone has been dissected away to reveal the firmly held pins.
coated metal pins has been developed and described, so that uniform coatings can be applied to metals in such a manner that they will not flake or peel, and will resist abrasion. These pins are inserted via modified techniques of Scialom and are suitable for edentulous regions.

Workers in this laboratory have also placed discs of the various materials mentioned in rat skulls with very interesting initial clinical and histologic findings. These studies will be reported subsequently. Clinical examinations are carried out with regularity. They include detailed written records, radiographs, and photographs.

Tissue blocks are prepared with the plastic tooth in situ and also with it removed. Some blocks were decalcified in fluid-containing chelating agents in dilute HCl. Other blocks were decalcified with 10 per cent nitric acid. Adequacy of decalcification was tested grossly by palpation of the specimens for flexibility. Following decalcification, the blocks were rinsed in running water for several hours and placed in 80 per cent ethyl alcohol for five days. Processing of the tissues was done in an automatic processing and embedding machine. There were two changes in 80 per cent ethyl alcohol for one hour each, three changes of 95 per cent ethyl alcohol for 1½ hours each, three changes of 100 per cent ethyl alcohol for 2 hours each, two changes of xylene for 1½ hours each, and two changes of paraffin for 1 hour each. The tissue blocks were then vacuum embedded until no bubbles appeared at a vacuum reading of 15 to 20 inches or 400 to 500 mm. The tissue blocks were then embedded routinely. The tissues were sectioned at a thickness of 8 to 12 microns for microscopic study.

When the implants were not removed, the plastic of their roots sectioned with relative ease. However, the thicker crown could be sectioned only near the surface.

Sections were floated on the water bath to which a small amount of gelatin had been added. Sections were then placed on slides, air dried at room temperature for two days, and then placed in a slide warmer in order to melt the excess paraffin. The slides were then stained with hematoxylin and eosin.

The Boplant-Methacrylate* implants appeared to section more easily than the pure methylmethacrylate implants.

RESULTS AND DISCUSSION

This laboratory is exploring the use of plastic and "plastic-bone" by itself, and as a coating for metals in other parts of the body, such as in cranioplasties, cysts, and other bone-depletion areas. It may be useful some day in the replacement of digits and in artificial limbs and other nonrubbing prostheses throughout the body. Polymer-coated metals and polymers used alone in living tissues do not emit microwaves of electrolytic current, unlike exposed metals. Insertion of connective tissue into this material has been shown to take place, resulting in tissue attachment to the implant. This is not possible with metals alone.

Research is proceeding with the hypothesis that a better means of tooth replacement can be achieved by the use of biologically acceptable polymers which

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*Methacrylate with bone embedded in it.
are synthetically fabricated to the proper shape, size, and color and can be functionally excellent. A product of this hypothesis is the tooth replica polymer implant. It is the only endosteal implant that can be used as an immediate replacement for extracted natural teeth. It has been placed in single and multirupted tooth sockets with good success in experimental animals (dogs, monkeys, baboons) and human beings. Initially it was made of pure heat-processed polymethacrylate. It was later made of grated anorganic bone (cancellous) and heat-processed polymethacrylate. Bone was incorporated into the mixture since it was known to have a chemical composition similar to cementum. The polymethacrylate is nondegrading, for it is not broken down by animal cells, whereas anorganic bone degrades, leaving openings into which the periodontal fibers may insert more easily, resulting in gradual strengthening of the periodontal attachment to the implant.

The 20 per cent by weight anorganic bone and 80 per cent by weight polymethacrylate tooth replica implant appears to be an improvement over the pure polymethacrylate implant. Histologic findings have shown that the collagenous fibers of the periodontal ligament insert into the implant more thoroughly than into the pure heat-processed polymethacrylate implant, forming a stronger attachment; this substantiates the concept of the connective tissue fiber attachment. The fibers enter deeply into the implant and often form a network in the root area. Clinically, the polymethacrylate anorganic bone implant is better at self support. Passive gingival recession is less, the epithelial attachment is excellent, and the gingival tone, texture, and consistency are good. However, when over 30 per cent anorganic bone is used, immunologic rejection (heterograft) results.

There is conclusive proof that osseous bridges with surrounding periodontal ligaments form through premade holes in the implant roots, especially when holes are placed in the apical third of the implant. This finding allows for better implant anchorage and longer duration of clinical success. When the channels in the implant roots were placed too high coronally, inflammation analogous to a periodontal abscess developed.

Evidence of the good biologic acceptance of tooth replica polymer implants is established by the following significant findings:

1. A regular, functional periodontium is restored.
2. A regular periodontal membrane is formed about the polymer implant. With extraction of the natural tooth, the periodontal membrane is destroyed; yet histologic evidence clearly establishes that a new periodontal membrane forms about the implant and lies between the plastic and alveolus. The connective tissue between the polymer implant and the alveolar bone of the socket is similar to a natural periodontal membrane, except that the collagen fibers tend to be aligned parallel to the polymer implant rather than following a more transverse orientation as seen about the natural tooth (See Figs. 4 and 5).
3. Normal osteoblastic and osteoclastic activity is found at the surface of the alveolar bone preserving the bony architecture adjacent to the implant. Active osteogenesis along the periodontal membrane is invariably noted in successful implants.
4. The epithelium of the gingiva is attached to the plastic surface with an appearance similar to that of the gingival epithelial attachment to natural teeth.
5. Minimal inflammatory reaction, comparable to that found in the gingiva adjacent to natural teeth, was observed.\textsuperscript{13}

6. The gingival sulcus is of relatively normal depth and periodontal pockets are not encountered more frequently than in control areas.\textsuperscript{13}

7. No evidence of carcinogenesis has been observed to date.\textsuperscript{13}

8. Clinically, the polymer implants have withstood extremes of masticatory stresses in the mouths of untamed animals for 8 years. The tissues have remained healthy in spite of the fact that these animals have not received hygienic mouth care. Furthermore, the baboon's occlusal forces are extremely powerful and large cuspids introduce further lateral and torque stress.

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\caption{Fig. 11. A maxillary left second bicuspid with an extensive carious lesion and pulpal involvement. Fig. 12. The extracted tooth. Fig. 13. A polymer tooth replica compared to the extracted tooth. The carious defect was corrected in the replica. Fig. 14. The polymer bicuspid implant is in position after 2 weeks. Gingival inflammation and enlargement is evident. Fig. 15. The polymer bicuspid implant is in position after 10 years. The gingival health is excellent and the sulcus depth is normal.}
\end{figure}
9. Implants (tooth replica polymer) have been implanted successfully in human beings for ten years (Figs. 11 to 15).

The polymethacrylate and bone-polymethacrylate coated metal implant offers encouragement for success of the edentulous endosteal implant. It is assumed that there is fiber insertion by the periodontal membrane into the bone-polymethacrylate Vitallium coated implant. Early histology is favorable, and continuing studies will be reported subsequently. The idea of eliminating metal corrosion while at the same time allowing for connective tissue attachment appears to be well founded.

SIGNIFICANCE OF RESEARCH

It is hoped that these studies will result in improved methods of tooth replacements. Immunologic rejection reactions associated with transplants are circumvented by using biologically acceptable nonliving or attenuated living matter. It is significant also that tooth banks most likely will not be necessary and the many problems associated with obtaining and storing teeth will be overcome, for polymer implants can be fabricated to proper color, shape, and size as they are needed.

The validity of the polymer implant concept has been established by extensive studies in the baboon. The excellent tissue acceptance, function, and appearance of the polymer implants has been demonstrated. There has been no evidence of rejection, toxicity, or neoplastic transformation of tissues. Tooth replica polymer implants have withstood extremes of masticatory stresses over long periods of time.

An implant material, “plastic-bone,” is being tailor-made which could be of significance for jaw, neurosurgical, and orthopedic rehabilitation purposes by itself or as a coating for metals. It is significant that much is being learned about the true nature of the periodontium and, for that matter, of the masticatory apparatus itself. These things have been learned: (1) The periodontal membrane can become re-established once destroyed. (2) Osseous bridges can form through premade holes in the roots of implants. (3) A network of fibrous tissue can insert from the reformed periodontal membrane into the polymethacrylate-anorganic bone. (4) An epithelial attachment to the polymer can occur. (5) A synthetic substance can be accepted biologically by its host.

It is planned to conduct controlled studies which will include the toxicologic, chemical, engineering, and physical disciplines. It is necessary to categorize and characterize the polymer implants before the lessons learned from animal studies can be applied to the human being for general clinical usage.

CURRENT INVESTIGATIONS

Current investigations involve numerous projects in both baboon and man.

1. Polymer materials are being studied in terms of chemical and physical qualities so that the materials can be characterized and categorized for more widespread clinical usage in implants.

2. Techniques are being refined in the baboon for the placement of polymer implants in surgically created sockets. This approach will have a wide application in human subjects for the placement of implants in edentulous regions.

3. Foaming agents are being used in the fabrication of the polymer and polymeric-bone implants with the purpose of producing a greater porosity at the implant root
surface. This may facilitate penetration of the polymer by granulation tissue and connective tissue, speeding the fibrous attachment of periodontal tissues to the implant and perhaps resulting in a stronger attachment. Initial observations appear to suggest promising results.

4. Natural extracted teeth are being coated with polymer. Extracted teeth of baboons are dried and the roots are scraped and sandblasted. The root canals are filled with silver points and a sealer. The roots are dipped in a loose mixture of plastic and the tooth with polymer coated roots is heat processed. After processing, the tooth is placed in the socket and splinted for stability. This entire procedure requires 30 to 45 minutes. The teeth with polymer-coated roots show no resorption radiographically after periods up to 6 months. All control tooth replants demonstrate evidence of root resorption.

5. Implant teeth are being fabricated with the use of varying mixtures of polymethacrylate and finely ground up roots of natural teeth. Initial results in baboons appear promising.

References


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