

The Introduction and History of HTR® Polymer



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"Luck," the cliché goes, "is the residue of perseverance." As Gary Player, the professional golfer, once said, "The harder I practice, the luckier I get." But what about the difference between capabilities and effectiveness? As an example, one can be capable as a dentist or a businessman, but to be effective, one must use those capabilities to achieve a certain amount of success. In today's world, our peers judge us by our achievements. People who are truly effective show *results* because they are effective in selling their ideas and themselves. If people want to present new ideas to others, however, they must be more than just capable or effective. They must 1) believe in their ideas and 2) persevere until fruition. "Paying your dues" is nothing more than persevering over time. What I have done, it seems, is persevere for 21 years.

I would like to discuss briefly the history and development of HTR® polymer and, in doing so,

this symposium on HTR® polymer possible. My readers will have to judge whether perseverance has brought its luck.

As a dentist who practiced and did research on his own ideas, the most difficult decision I have ever had to make was to finance my own research and to put my resources where my ideas were. This has been difficult over the years because many times the resources were not there, and many times the long hours devoted to business and research kept me away from my loved ones and friends. All of the distinguished researchers at this symposium are successful and can recognize this type of sacrifice.

I would like to provide some background on how HTR® polymer started and on how, perhaps, we have evolved to where we are today.

Within the last several years we have seen the emergence of a new class of restorative materials in dentistry, ie, synthetic bone. The magnitude of new uses for this material and its adaptability in solving old problems make it a welcome addition to the dentist's armamentarium.

The discovery of an "ideal" synthetic bone substitute has been the goal of researchers for many years. In attempting to achieve this goal, dental practitioners

freeze-dried bone, and allografts of plastic, carbon, and the apatite compounds. The literature is replete with cases that have used all of these materials, and, for good reason, the drawbacks of the materials were often apparent. Some of these negatives included resorption after successful placement, difficulty in handling, brittleness, and difficulty in obtaining the material.

The materials mentioned above often become infected, cannot be molded, are not microporous (and, therefore, do not allow tissue integration) and, in general, are not user friendly. These materials fall far short of the goal of being the ideal bone substitute. What, then, *is* the ideal material? What are we all looking for?

I believe that the most important characteristics of an ideal, nonresorbable synthetic bone include the following: 1) biologic compatibility, 2) microporosity that provides a scaffold for the formation of new bone, 3) radiopacity, 4) nonmigratory particles that stop bone bleeding, and, of course, 5) osteogenicity or, at least, the ability to facilitate new bone formation.

HTR® polymer seems to fit these criteria for the ideal bone substitute. In addition, HTR® polymer has many more valuable

testing procedures. Paul mainly was responsible for developing and changing the material into what we know today. For example, he was responsible for adding the polyhema to the surface, which gave the material the desirable characteristics of being hydrophilic and easy to handle, and which allowed a molded piece to be fabricated in three minutes instead of three hours.

We then went back to Columbia University and started testing the material in animals. This was in 1973 or '74. Our early work resulted in a paper co-authored by Dr. Mel Moss, who was then the dean of Columbia University. The paper appeared in the *Journal of Prosthetic Dentistry*.⁹

The problems that we had initially encountered seemed to disappear as we improved the material. In approximately 1975, we began giving HTR[®] polymer to friends all over the world, who used it as an implant material. At approximately the same time, we started using HTR[®] polymer in particulate form as well as in the molded forms. Most of the papers written at this time described animal studies. However, some clinical experiences also were reported. The clinical uses reported were mainly in the area of dentistry, and these reports resulted in the issuance of six worldwide patents. The first statistical analysis of the results reported by the 64 periodontists, oral surgeons, and general practitioners who first used HTR[®] polymer showed a surprising 97.9% success rate in 647 clinical cases over two years.¹ Some of the practitioners thought that HTR[®] polymer could be the "ideal" bone substitute that everyone was looking for, mainly because of its handling characteristics and the surprisingly good clinical results obtained. Patients also healed quickly and uneventfully and had little postoperative discomfort.

My continued collaboration with Dr. Bruins resulted in five more patents worldwide. However, perhaps one of the most important things that happened to me occurred while I was lec-

turing in Israel. I met Dr. Itzak Binderman. Dr. Binderman is a dentist whose interest is in bone, and he has a bone lab at the University of Tel Aviv. Itzak suggested that perhaps we could do some grafting on the surfaces of HTR[®] polymer. His was the suggestion to put a calcium graft on the surface. It was a very good suggestion because the material's properties were greatly improved.

We learned later through animal studies both at the University of Tel Aviv and at Cornell University in New York that long bones that had been fractured could be repaired with HTR[®] polymer. We decided to see what would happen with nonunion fractures, and so we kept fractured tibias 3 to 4 mm apart. The tibias were immobilized, and HTR[®] polymer was placed into the 3- to 4-mm gaps. To our surprise, new bone formed across the gaps within 29 days in Tel Aviv and within 36 days at Cornell. The new bone was just as strong as the bone on the control side.¹⁰ This was amazing because we had what appeared to be a very inductive material, and yet, by the strict definition of the word, it was not inductive. Obviously, if HTR[®] polymer is placed under the skin, it will not form bone. However, we found that something was happening, and we looked into the phenomenon more closely. We found that HTR[®] polymer, when in contact with marrow cells, is extremely osteogenic.¹⁰ This was one of our first enlightenments, and it definitely placed HTR[®] polymer in a class by itself. HTR[®] polymer was no longer like other synthetic bone substitutes. It was responsible for the formation of new bone.

Our successes continued, and more studies were done.¹¹⁻¹⁵ In approximately 1985, various companies became interested in marketing and further improving HTR[®] polymer. United States Surgical Corporation of Norwalk, Connecticut acquired the material and, much to their credit, they have initiated good, clinically controlled research at universities, which is essential for

the continued credibility of the product.

What we are doing with HTR[®] polymer is truly exciting, and I am sure that my fellow participants in today's symposium will have much to add regarding their successes, their concerns, and, above all, their valued opinions.

Thank you.

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