

# Human Clinical and Histologic Responses to the Placement of HTR Polymer Particles in 11 Intrabony Lesions\*

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ELEVEN INTRABONY PERIODONTAL LESIONS in five volunteer patients received surgical debridement followed by site implantation of a porous particulate polymeric composite (HTR polymer). These patients were observed over time periods varying from 4 weeks to 26 weeks. At the end of the individual observation periods, treated sites were surgically removed in block for histologic analysis. Clinical observations indicated a reduction in pocket depth following treatment which consisted of both gingival recession and gain in clinical closure. No untoward effects were observed clinically in any treated patient during the observation periods. Histologic responses varied from gain in closure by epithelial adhesion to new attachment of varying magnitude. Such varied responses were seen within the same patient and between patients. Graft particles were present at sites from 4 weeks to 26 weeks after implantation and were surrounded by connective tissue capsules. At the periphery of some particles, limited bone formation was present. The alveolar bed was remodeling, at times surrounding specific particles. In our sample, HTR polymer, therefore, appeared to be a well tolerated synthetic graft material when implanted in human intrabony lesions. *J Periodontol* 1990;61:269-274.

**Key Words:** Periodontal disease/surgery; periodontal pockets/surgery; bone regeneration; dental implants; biocompatible materials.

Periodontal treatment goals include attempts at regeneration of lost attachment. This requires new cementum formation accompanied by newly inserted functionally oriented fibers at a root site previously exposed to the oral environment. Intrabony lesions have shown such regenerative responses particularly when osseous grafts were placed into the debrided defect to enhance new attachment.<sup>1,2</sup> Since human bone graft materials in limited, synthetic grafts have been devised to substitute and/or augment human bone material. Among such substitutes are particles composed of hydroxyapatites,<sup>3</sup> tricalcium phosphate<sup>4</sup> and porous hydroxyapatites.<sup>5,6</sup> In general, these synthetic bone substitutes have not enhanced new attachment, but rather served as well-tolerated fillers.

The present series of case reports presents human histologic responses to placement of a non-resorbable, microporous, synthetic bone grafting material in intrabony lesions. The material combines a polymethylmethacrylate, polyhydroxyethylmethacrylate (PHEMA) and calcium in a patented process which results in a biocompatible composite.<sup>7</sup>

It is marketed as HTR polymer.<sup>†</sup> In our study HTR-40 was used exclusively.

## MATERIALS AND METHODS

Eleven intrabony lesions in five volunteer patients (ages 33 to 61 years; 3 males and 2 females) were monitored clinically and histologically to study the effects of HTR polymer implants on the healing of these lesions. All participants were in good health and every patient received an explanation of the study and signed an informed consent as part of the protocol requirements. Sites/teeth treated in this study were diagnosed as having a hopeless prognosis by an independent dental examination.

All clinical measurements and surgical procedures were performed by the same periodontist (S.J.F.). Prior to surgery, initial therapy, oral hygiene procedures, temporary occlusal splinting (where mobility created patient discomfort), and similar cause-related therapy was performed, except at sites selected for HTR polymer implantation. Surgery was performed when the plaque control index was less than 10%. At that time, radiographs and clinical photographs of

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the site were taken. Clinical photographs were also obtained during the surgical procedures for pictorial documentation.

### Measurements

Prior to surgery and at least 6 weeks after initial therapy, a horizontal notch was made in the root at the level of the gingival margin using a 1/2 round bur. A vertical notch (steering groove) was placed in the crown of the tooth at each study site to guide the positioning of the silver point used for measurements. All measurements were made to the nearest 0.1 mm using an endodontic silver point, a locking plier, and a Boley gauge. The distance from the gingival notch to the base of the clinical pocket was then recorded as was the degree of tooth mobility. Following flap reflection, a second notch was placed through the most apical extent of calculus at the involved root site and the following measurements obtained: 1) Distance from calculus notch to deepest point of the osseous defect; and 2) distance from calculus notch to crest of defect. The defect was also classified according to the number of osseous walls remaining.

### Surgical Procedure

After obtaining local anesthesia, a full-thickness mucoperiosteal flap was elevated. After root/calculus notching, the lesion was then thoroughly debrided and measurements taken. Root planing was performed using ultrasonic scalers and hand instruments until all visible root accretions were removed and the root surface felt smooth to an explorer. Following intramarrow penetration, the site was overfilled with the porous graft material. The flap wall was then positioned as incisally as possible, and complete closure was attempted. Interrupted silk sutures (4.0) were used and a periodontal dressing applied over the sutured site. All pre- and immediate post-surgical measurements, photographs, and radiographs were taken during this time. Patients were then placed on penicillin 250 mg four times daily for 10 days. Ten to 14 days after graft placement, dressings and sutures were removed and the site lightly debrided and irrigated. All patients received weekly professional plaque

removal of the surgical site for the first 6 weeks and then once every 2 to 4 weeks until the block was removed. At the time of block removal, clinical photographs and radiographs were taken of the specific sites and pocket depth, recession, and gain in clinical closure were recorded using the gingival notch as the fixed point of reference.

Upon block removal, all specimens were decalcified and prepared for histologic study. Step-serial, mesiodistally cut sections (8 $\mu$ ) were prepared and selectively stained with hematoxylin-eosin and Mallory-trichrome stains.

### OBSERVATIONS

For both clinical and histologic observations, the reader must note that the data reflect case reports, rather than results of a controlled clinical study. The difficulties in obtaining human blocks for histologic analysis of treatment results limits the controlled trial approach. Thus, the questions to be answered by these cases are essentially: 1) What were the clinical responses to this treatment modality? 2) Was this material tolerated by the host? 3) Were there predictable histologic responses? and 4) Was new attachment part of these histologic responses?

#### Clinical

As shown in Table 1, preoperative pocket depth at the 11 sites treated in this series ranged from 7.5 to 15.0 mm (average 9.0 mm) and the intraosseous depth ranged from 2.0 to 9.4 mm (average 3.5 mm). The osseous configurations were essentially one to two wall lesions. Mobility varied from slight to severe (Miller classification). At the time of block removal, pocket depth ranged from 2.1 to 9.2 mm (average 4.6 mm) and gingival recession ranged from 0 to 4.1 mm (average 3.0 mm). Gain in clinical closure ranged from 0.5 to 3.4 mm (average 1.8 mm). Mobility patterns were not altered significantly. Clinical healing responses did not relate to length of observation time.

#### Histologic

**Case Report 1.** Patient A.A. had two sites in which HTR polymer was placed, m24 and d25. Table 1 records the

Table 1: HTR Polymer Pre- and Post-Surgical Clinical Findings at Implant Sites

Patient	Age (Years)	Tooth Site(s)	Observation Period (weeks)	Initial Pocket Depth*	Initial Osseous Depth*	Final Pocket Depth*	Final Gingival Recession*	Gain in Clinical Closure*
A.A.	61	m24	4	10.8	2.7	7.1	3.2	0.5
		d25	4	8.0	2.0	4.5	2.9	0.6
D.M.	33	m 3	11	11.4	7.5	8.0	0.0	3.4
T.T.	51	m 7	18	8.5	2.3	2.1	3.0	3.4
		d 8	18	8.6	2.4	2.2	3.0	3.4
		m 8	18	8.6	2.1	4.2	3.4	1.0
		m 9	18	8.2	2.2	2.9	3.1	2.2
		d 9	18	8.2	2.8	3.0	4.1	1.1
		m10	18	7.5	3.1	3.1	3.3	1.1
J.S.	36	m29	24	8.0	3.6	4.3	3.2	0.5
L.C.	49	m19	26	15.0	9.4	9.2	4.0	1.8
Average:				9.0	3.5	4.6	3.0	1.8
Range:				7.5-15.0	2.0-9.4	2.1-9.2	0.0-4.1	0.5-3.4

\* = mm.

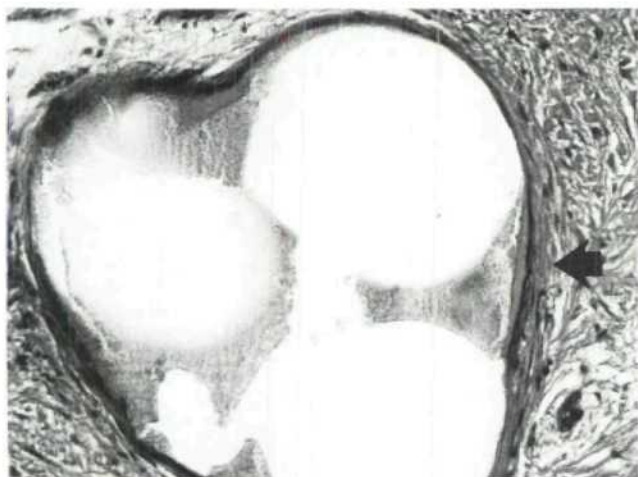


Figure 8. Higher magnification of graft particles shown in Figure 6. Arrow points to limited peripheral osteogenesis at a graft particle. Original magnification, x64.



Figure 9. Patient T. T. Debrided lesions.

observed in this patient (Table 1), three sites showed limited evidence of new attachment within the calculus notch area at times associated with root (dentin) resorption, and three sites presented no evidence of new attachment. The reason for this variation in healing responses could not be determined at this level of investigation.

The clinical gains in closure as reported in Table 1 did not reflect specific histologic closure mechanisms found at the sites, nor did the longer observation periods indicate a more frequent incidence of new attachment to have taken place within the tested sites.

#### COMMENTS

As reported previously,<sup>8</sup> the use of HTR polymer graft particles in human intrabony lesion led to gains in clinical closure. Similar clinical gains in closure have been reported by debridement alone and with the use of a variety of debridement and augmenting procedures.<sup>9</sup> Histologically, the most significant gain in new attachment in the human model

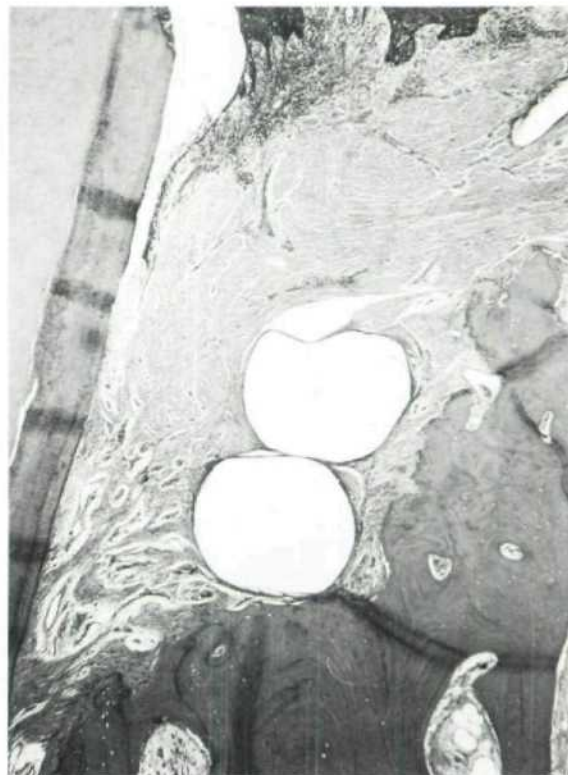


Figure 10. Overview of site m8 shown in Figure 9 18 weeks after graft placement. No evidence of new attachment is seen. H&E stain. Original magnification, x10.

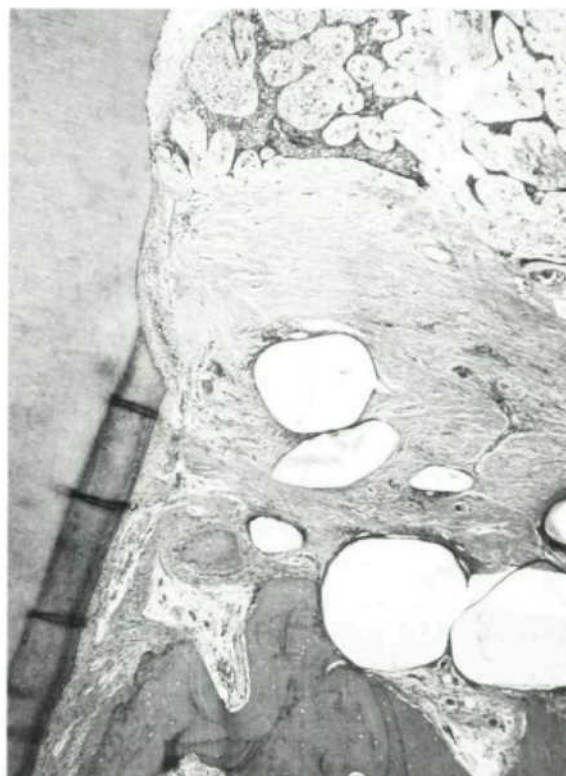


Figure 11. Overview of site d9 shown in Figure 9 18 weeks after graft placement. Note cementogenesis at base of notch. H&E stain. Original magnification x10.

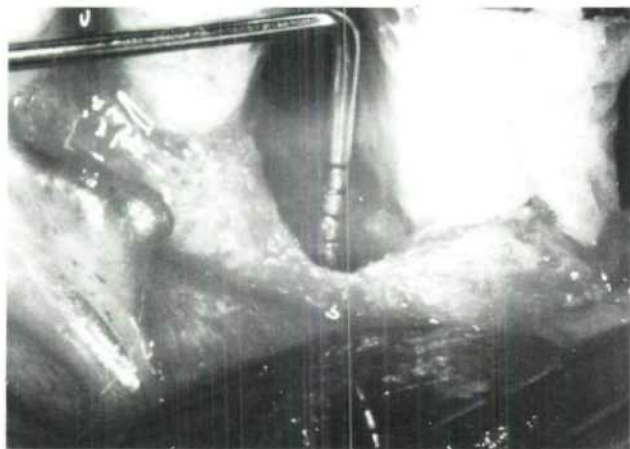


Figure 4. Patient D. M. Debrided lesion.



Figure 5. Patient D. M. Radiogram of site m3, 11 weeks after graft placement.

case was by long J.E. New attachment was not present and connective tissue encapsulated the particles.

**Case Report 5.** Patient L.C. had one site (m19) which was removed after 26 weeks. Closure at this site was by epithelial adhesion. Graft particles were found to be surrounded by new bone in some areas within this site.

**Summary of Histologic Observations.** Overall histologic responses demonstrated that the HTR polymer graft particles were well tolerated by the host and caused no aberrant tissue responses. In most instances, the particles were surrounded by dense collagen and appeared well encapsulated. At times, active bone formation was seen to surround the collagen capsules. At graft peripheries, bone formation was seen occasionally.

However, the primary question in using synthetic grafts is not whether they act as biocompatible fillers, but rather whether they enhance new attachment and increase bone mass. Histologically, the 11 specimens examined showed varying responses at the different sites. Such variations were



Figure 6. Overview of histologic appearance of grafted site shown in Figure 4, 11 weeks after graft placement. Note epithelial adhesion within calculus notch. Apical to notch, cementogenesis is seen adjacent to graft particles. H & E stain. Original magnification,  $\times 10$ .

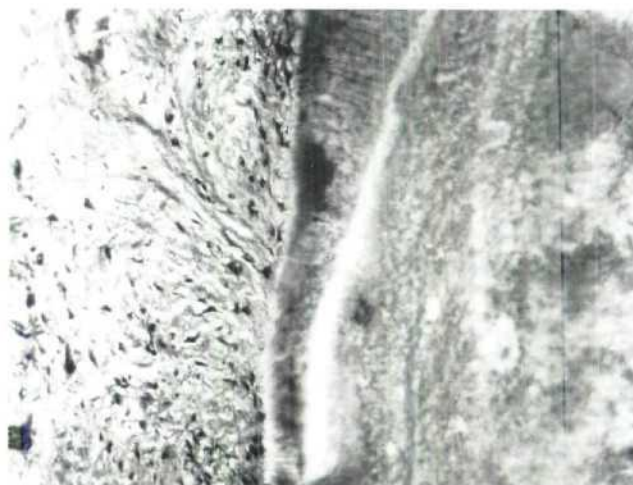


Figure 7. Higher magnification of site shown in Figure 6. Note fiber insertion into newly formed cementum. Mallory-Trichrome stain. Original magnification,  $\times 64$ .

seen between hosts, and at different sites within the same host. Thus, the clinical gain in closure noted in Table 1, consisted of a long epithelial adhesion (J.E.) without evidence of new attachment in seven sites, and limited evidence of new attachment in four sites.

Of particular interest was the response variation within sites of the same host (Patient T.T.) which were removed at the same time (18 weeks post surgery). At the six sites

clinical measurements at these sites. Figure 1 shows the sites debrided and Figure 2 demonstrates the radiogram of the sites at the time of block removal 4 weeks after graft placement. Histologically, closure was by epithelial adhesion (long J.E.) without evidence of new attachment (Fig. 3). Since marked recession took place, the gingival margin was located apical to the reference notch.

**Case Report 2.** Patient D.M. had one site in which HTR was placed (m3). Table 1 records the clinical measurements. Figure 4 shows the debrided lesion and Figure 5 is the final radiogram, taken at the time of block removal 11 weeks after graft placement. Histologically, the calculus notch shows epithelial adherence. Immediately apical to the notch, new cementum has formed adjacent to the graft particles (Fig. 6). The new cementum shows functional fiber orientation (Fig. 7). The particles are surrounded by collagen encapsulation and show bone formation at some of their peripheries (Fig. 8).

**Case Report 3.** Patient T.T. had six sites in which HTR was placed, (m7, d8, m8, m9, d9, and m10). They were removed 18 weeks after graft placement. Table 1 records the clinical measurements. Figure 9 depicts the debrided sites. Figure 10 shows site m8 in which no new attachment occurred. Closure was by epithelial adhesion which was present at the apical portion of the notch and extended apically. Graft particles were seen at the base of the defect and were surrounded by collagen. By contrast, site d9 (Fig. 11) demonstrated functionally oriented, connective tissue attachment to new cementum in the apical portion of the notch (Fig. 12). Out of six sites observed in this patient, new attachment was seen within or adjacent to the notch in three. No new attachment was observed in the remaining three sites.

**Case Report 4.** Patient J.S. had one site (m29) which was removed 24 weeks after graft placement. Closure in this



Figure 1. Patient A. A. Debrided lesion.



Figure 2. Patient A. A. Radiogram of site (d25), 4 weeks after graft placement.

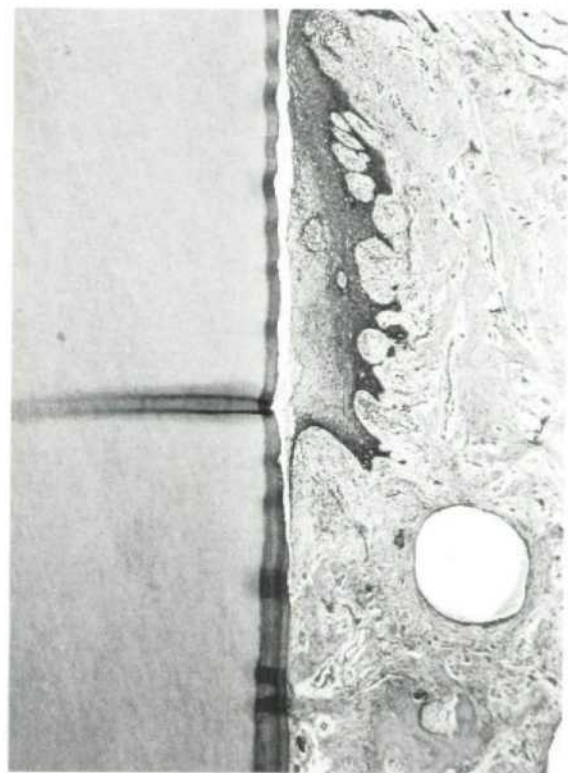


Figure 3. Block section of site shown in Figure 1 4 weeks after graft placement. Closure occurred by epithelial adhesion (long J.E.). No new attachment or significant osteogenesis was seen. H & E stain. Original magnification,  $\times 10$ .



Figure 12. Higher magnification of area of notch showing cementogenesis seen in Figure 1. Fiber insertion into the new cementum can be visualized. Original magnification, x64.

has been demonstrated following debridement and use of human bone graft material.<sup>2</sup> Synthetic bone substitutes essentially have acted as biocompatible fillers<sup>9</sup> without evidence of new attachment associated with their use.

Since our HTR polymer treated sites provided a gamut of healing responses, they do not allow for definitive conclusions regarding the predictability of the histologic healing response following the use of this material. Therefore, we are not able to identify a possible "causative" role played by HTR polymer in enhancing new attachment. This conclusion is particularly important, since human clinical and limited histologic observations have reported gains in closure by methods ranging from epithelial delay/exclusion at the wound site,<sup>10,11</sup> to biochemical root treatments;<sup>12,13</sup> to use of various grafting materials;<sup>9,14</sup> and to physical manipulation of the wound tissues.<sup>15,16</sup> Since these techniques differ markedly from each other in biologic and clinical terms, and yet report gains in closure, we may conclude that etiologic factors controlling closure and new attachment have not yet been identified. However, research identifying factors responsible for regeneration of periodontal attachment should lead to the development of clinically predictable techniques.

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