

Human Clinical and Histologic Responses to Durapatite* Implants in Intraosseous Lesions†

Case Reports

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THE HEALING response following implantation of a nonresorbable ceramic (durapatite) into human periodontal osseous defects was evaluated clinically and histologically. Four tooth-containing blocks were obtained from four patients who had received durapatite implants in osseous defects, each exceeding 4 mm in depth. Each patient was seen for 5 to 13 postsurgical maintenance visits. Teeth in block section were removed between 8 weeks and 8 months postgraft surgery. Clinical evaluation of the repair process demonstrated that pocket depth decreased in all four cases. Histological evaluation of the repair process showed no indication of new periodontal attachment, osteogenesis or cementogenesis, in the host tissues adjacent to the graft particles. Pocket closure appeared to occur by means of a long junctional epithelium and connective tissue adhesions. There was minimal or no evidence of inflammation in all sections associated with the implant. The graft material therefore acted as a biocompatible foreign body within the gingival tissue.

The clinical success using graft and nongraft procedures for regeneration of lost attachment has been described (see extensive reviews).¹⁻⁵ However, several studies have questioned the validity of clinical documentation in demonstrating new attachment.⁶⁻⁹ Limited human histological documentation has supported the possibility of gaining new attachment with the use of autogenous intraoral and iliac bone graft procedures⁹⁻¹⁴ as well as with debridement alone.⁹⁻¹⁵ Since autogenous donor bone is limited, attempts have been made to find synthetic substitute materials. Recently a clinical study reported on the success of a nonresorbable ceramic (durapatite) in obtaining osseous defect fill.¹⁶

The present study was undertaken to evaluate histologically the nature of the healing after implantation of durapatite into human periodontal osseous defects.

MATERIALS AND METHODS

Four teeth in four patients were selected from individuals participating in a clinical study using durapatite

ceramic grafts at the Veterans Administration Medical Center, New York. In these patients, durapatite grafts were placed into severe osseous lesions. The patients had consented to tooth extraction of these sites *en bloc* prior to restorative dental treatment.

At the start of the clinical study, rigorous documentation was obtained according to the FDA and human research committee including a complete medical history, physical examination, blood workup, chest films and a dental history and examination. Strict criteria were also employed as to the types of osseous defects included in the study (Table I).

Each intrabony defect had to measure ≥ 4 mm in depth to be included in the study. This determination was made at the time of surgical exposure of the defect. All measurements were recorded from a fixed reference point immediately before surgery and at various time intervals after surgery. An Omnivac acrylic stent was fabricated from 0.10 mm thickness surgical tray material to serve as the fixed reference point. All measurements were recorded to the nearest 0.1 mm using an endodontic silver point, locking pliers and a Boley gauge. The stent was grooved in an occlusal-apical direction to allow reproducibility of the position of the silver point when taking repeated measurements.¹⁷ All measurements were performed by the same operator to eliminate inter-examiner discrepancies. Intra-examiner variability was evaluated using the same distances, measured at different

* Durapatite is a high density, high purity form of hydroxylapatite, marketed by Cook Waite Laboratories, Inc. as Periograf™.

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Table I
Patient and Lesion Description

	Age (years)	Medical status	Tooth No. and site	No. of re-call visits	Length of post treatment (weeks)
Case I	60	Chronic arthritis	29	13	48
Case II	38	Renal insufficiency	Distal 23	5	10
Case III	47	Noncontributory	Mesial 11	5	16
Case IV	55	Noncontributory	Mesial 31	7	8
			Mesial		

Table II
Pre- and Postoperative Measurements of Durapatite Treated Sites

Case	Preoperative probing depth (mm)	Preoperative intraosseous depth (mm)	Type of osseous defect	Postoperative pocket depth (mm)
I	8.9	4.6	1- 2- 3-Wall	4.8
II	10.0	4.2	3-Wall circumferential	7.0
III	13.2	8.6	3-Wall wide	8.0
IV	12.3	4.1	1-Wall circumferential	6.3

**Figure 1.** Case I: Preoperative probing.

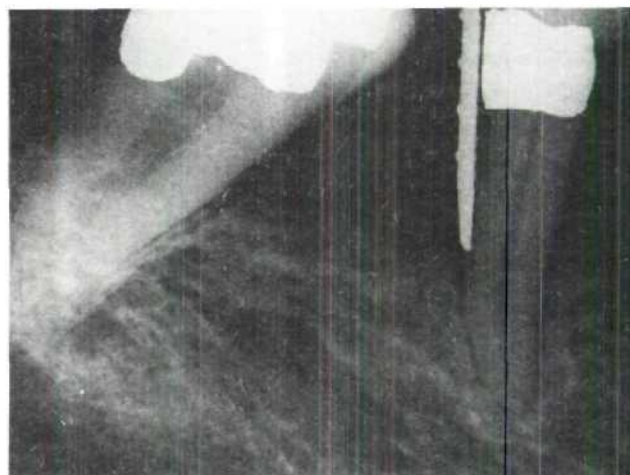
times. The calculated error was not statistically significant. The following measurements were recorded:

Presurgical

- (a) stent to gingival margin
- (b) stent to pocket depth
- (c) stent to cementoenamel junction to test for the complete seating of the stent

At the time of surgery

- (d) stent to crest of the defect
- (e) stent to the deepest part of the defect
- (f) stent to cementoenamel junction

**Figure 2.** Case I: Preoperative radiogram.

Two weeks prior to block section measurements a, b and c were repeated (Table II).

Photographic and radiographic documentation of the surgical sites was obtained preoperatively and at various postoperative time intervals. In all cases initial therapy consisted of oral hygiene instruction, scaling, root planing and adjustment for gross occlusal interferences where necessary. A Navy Plaque Index and Bleeding Index were used to monitor oral hygiene and clinical inflammation. Only when the indices approached zero was surgery performed. Initial therapy therefore varied from 4 to 12 weeks in the four patients studied. Since all cases showed similar clinical and histological responses, only two specimens will be presented in detail.

Case I

A 60-year-old male presented for routine periodontal treatment with moderate to severe periodontitis. His medical history was unremarkable except for chronic arthritis. Initial periodontal treatment consisted of oral hygiene instruction, scaling, root planing and occlusal adjustment where indicated. A surgical reevaluation was performed 2 weeks after 5 weeks of initial therapy.

At that time, it was decided to place durapatite grafts on the mesial of the mandibular right second molar and into the mesial and distal defects of the right second

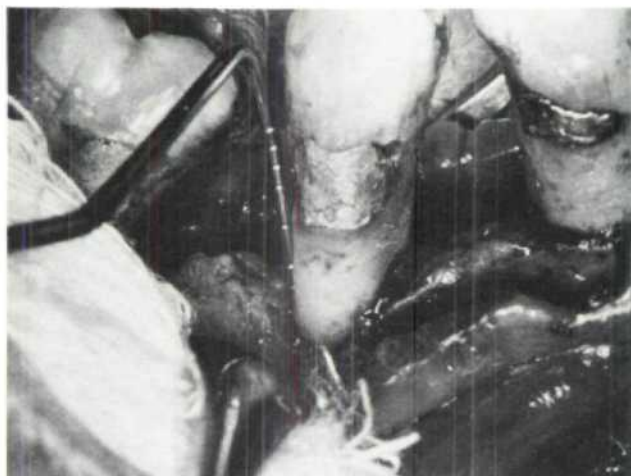


Figure 3. Case I: Debrided defect.

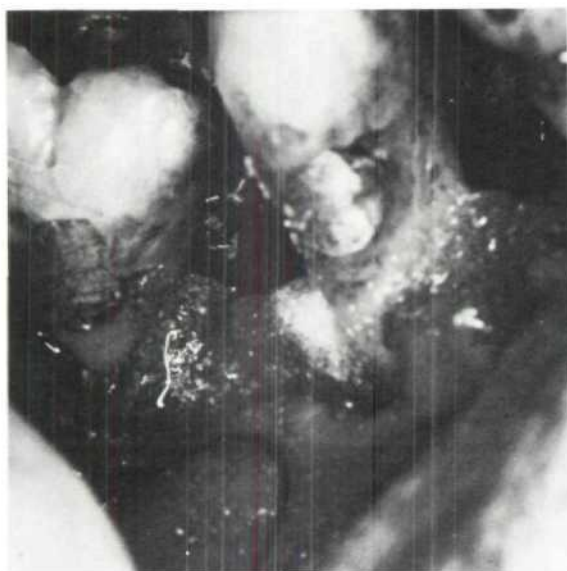


Figure 4. Case I: Durapatite in place.

premolar tooth. Presurgical photographs and radiographs were taken and the clinical healing at the premolar tooth will be described in detail. Similar clinical responses were seen at the molar (Figs. 1 and 2). Presurgical probing from a fixed reference point with a silver point and boley gauge revealed mesial and distal pocket depths of 7.6 mm and 8.9 mm respectively. A full thickness mucoperiosteal flap was reflected and revealed 1-, 2- and 3-wall combination defects, narrow on the mesial, and wide on the distal measuring 3.1 and 4.6 respectively in depth (Fig. 3). The defects were debrided and overfilled with durapatite graft particles (Fig. 4). The flap was sutured with interrupted 4-0 silk sutures attempting to coapt the interproximal tissue to completely cover the graft and position the tissue at or close to the presurgical level. A periodontal dressing was placed and the patient was prescribed erythromycin, 1 gm per day for 1 week.

One week postsurgery the dressing and the sutures were removed, the area scaled and repacked for an

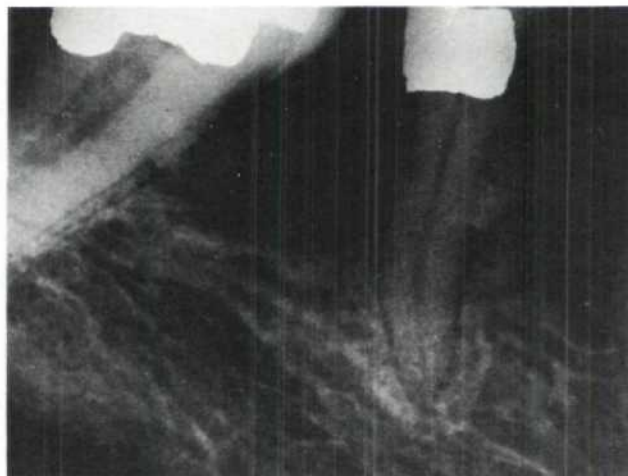


Figure 5. Case I: Radiogram of experimental site, 6 months postoperative.

additional week. At the second postsurgical visit a radiograph was taken which revealed the graft in place. Following this visit the patient was unable to return for 2 months. The patient was then seen twice a month for postsurgical maintenance for approximately 5 months. Forty-eight weeks postsurgery, significant mobility was present at the premolar and it was decided to extract this tooth. A radiograph was taken prior to extraction (Fig. 5). At this time probing depth measured 4.1 mm and 4.8 mm respectively on the mesial and distal aspects of this tooth (Fig. 6). At the time of extraction, a modified block section was taken for histologic evaluation primarily of the distal defect. The entire area healed uneventfully.

Case II

A 38-year-old male with a medical history of renal insufficiency presented for periodontal treatment. The patient was undergoing regular hemodialysis therapy and medical clearance was obtained from his physician. It should be noted that the medical condition makes regulation of calcium/phosphorus levels uncertain.

The mandibular incisors exhibited Class II mobility and interproximal osseous defects. The left lateral incisor, which was endodontically treated 10 months prior to periodontal evaluation, was extruded, had Class III mobility and was diagnosed as hopeless. With the patient's consent it was decided to retain and treat this tooth with a durapatite graft. At the same time the adjacent incisors were being treated with open debridement procedures.

Because of the severe mobility, the incisors were stabilized with a wire splint from mandibular right to left canine (Fig. 7). Presurgical radiographs, with inserted Hirschfeld points approaching the apex of the incisor, recorded the depth of the defect (Fig. 8). Pocket depth measurements of 10 mm and 8 mm respectively were recorded on the mesial and distal aspects of the lateral incisor. Periodontal surgery included reflection of a full-thickness mucoperiosteal flap revealing a circumferential

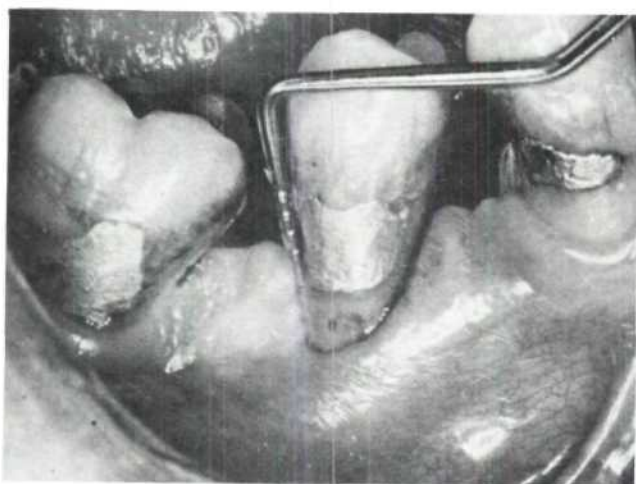


Figure 6. Case I: Six months postoperative, clinical appearance.

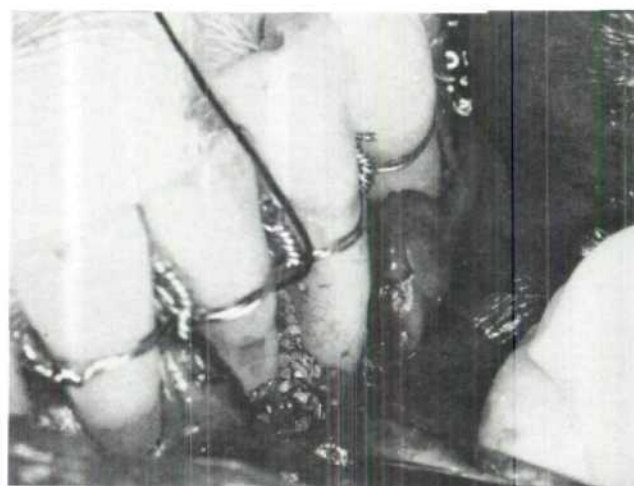


Figure 9. Case II: Durapatite in place.

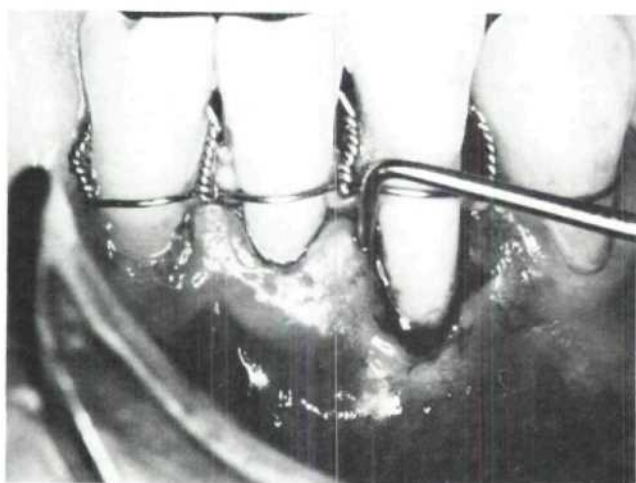


Figure 7. Case II: Preoperative probing.

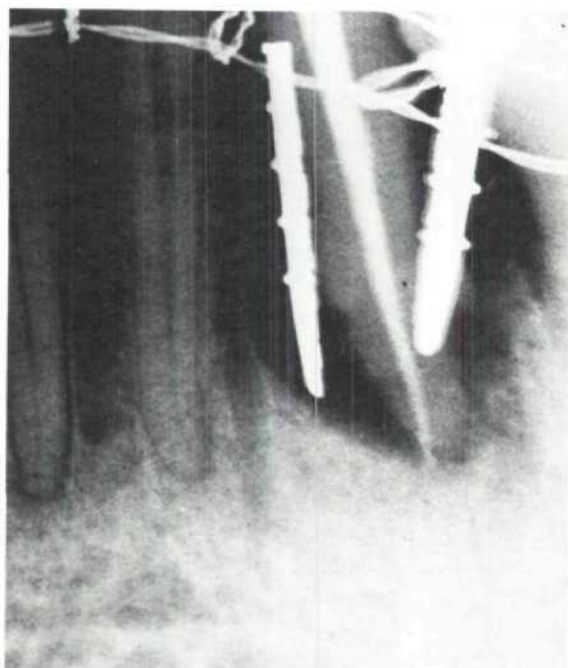


Figure 8. Case II: Preoperative radiogram.

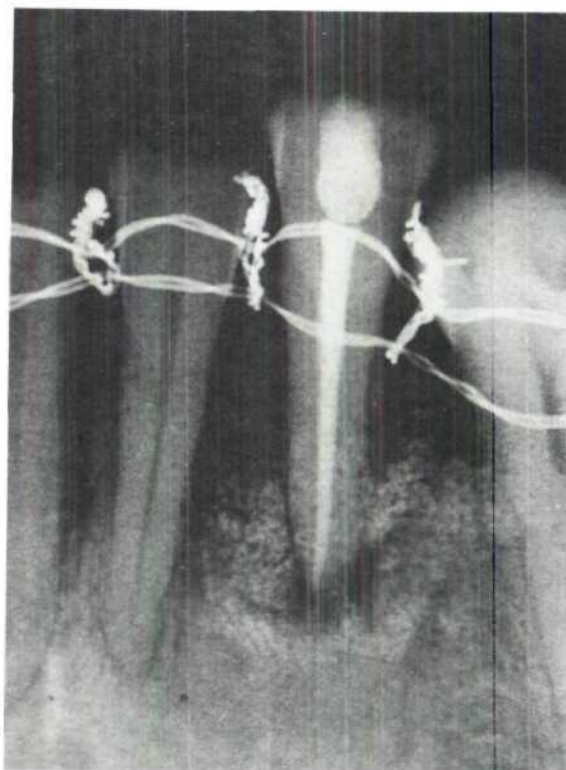


Figure 10. Case II: Radiogram of experimental site 10 weeks post-surgery. Note graft in place.

osseous defect on the distal buccal and mesial surfaces of the tooth measuring 4.2 mm in depth. The entire defect was overfilled with durapatite particles (40-60 mesh) (Fig. 9). The flap was sutured with interrupted 4-0 silk sutures and a periodontal dressing was applied. The sutures were removed 1 week post-surgery. A radiograph taken at that time revealed the graft to be in place, although it did not fill the defect to its base. The patient returned every 2 weeks for scaling and oral hygiene review. During this time it was noticed that in spite of the splint the tooth continued to extrude slightly. Ten weeks postsurgery pocket depth measured 7 mm on the

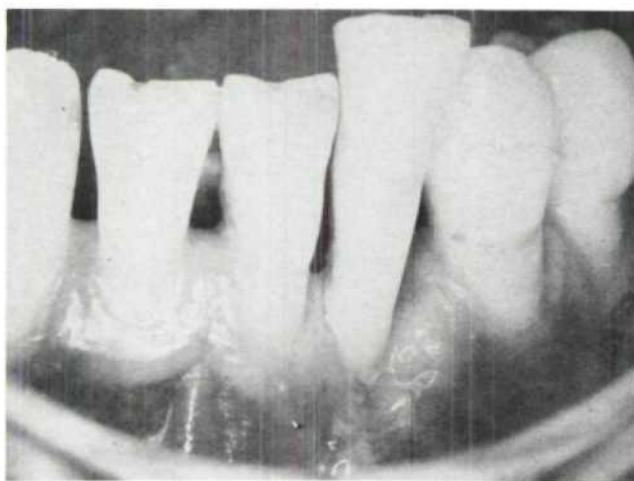


Figure 11. Case II: Clinical appearance of postoperative site 10 weeks postsurgery.



Figure 12. Case I: Low magnification of specimen (H&E stain). Note spaces within collagen fiber bundles denoting decalcified sites of durapatite.

mesial and 5 mm on the distal aspects of the tooth. A radiograph revealed some of the durapatite graft in place (Fig. 10). Removal of the splint indicated a Class III mobility of tooth No. 23 (Fig. 11). At this time it was decided to extract the tooth in a modified block section for histologic evaluation primarily of the mesial lesion. The area healed uneventfully.



Figure 13. Case I: Higher magnification (25X) of specimen shown in Figure 12. Note no evidence of osteogenesis at the borders of the graft particles. The alveolar border demonstrates osseous resorption.

HISTOLOGICAL OBSERVATIONS

The human block sections demonstrated healed periodontal lesions of varying post-surgical duration. All sections demonstrated limited gingival inflammation. While we are only detailing specific sites of healing responses, the overall histologic evaluation of our total material indicated healing patterns identical to those demonstrated in our illustrations. Within the gingival collagen empty areas (decalcified graft sites) were seen. These spaces were surrounded by dense collagen without evidence of inflammation. There was no indication of osteogenesis at the graft borders, nor was there any indication of osteogenesis or cementogenesis in the host tissues adjacent to the graft particles. The implant material therefore responded like a well-tolerated foreign body within the host connective tissue into which it was placed. These responses were essentially similar in all specimens and thus appeared not to be time-linked within the experience of our cases (Figs. 12-15).

In one specimen (Case III), particles were observed in an area of intense inflammation. Here, too, no evidence of osteogenesis was seen at the seams of the particles, nor did they affect the osseous borders of the lesion (Figs. 16 and 17). This case, while not described in detail,

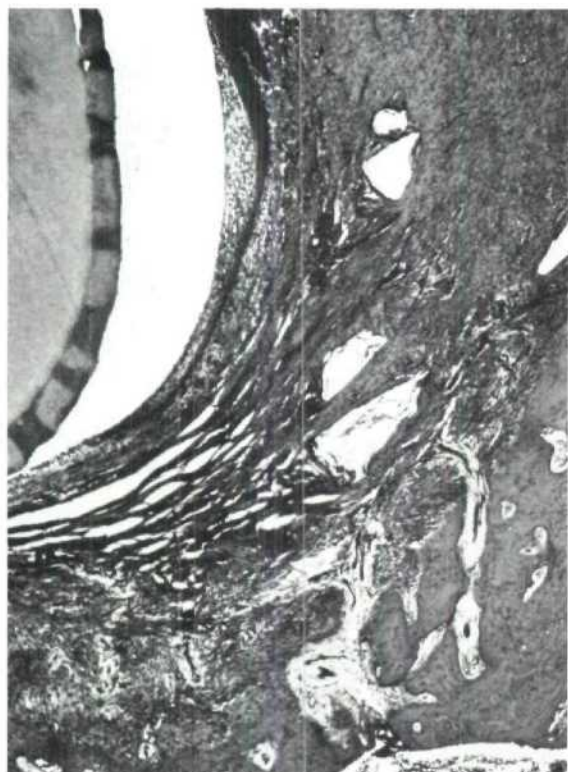


Figure 14. Case II: Low magnification of specimen (H&E stain). Note spaces within collagen bundles denoting sites of decalcified durapatite.

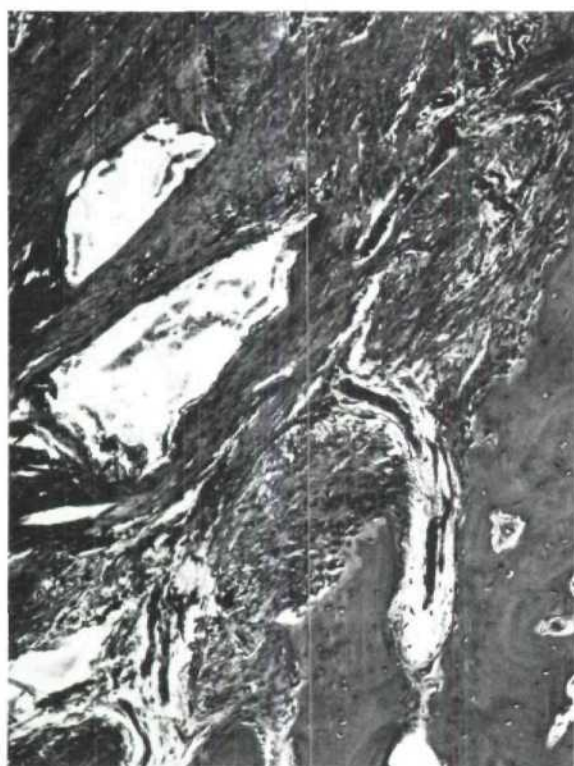


Figure 15. Case II: Higher magnification (25 \times) of specimen shown in Figure 14. Note dense collagen surrounding graft sites. The alveolar border shows limited osseous deposition and resorption.

is presented because it is the only lesion in which marked clinical signs of inflammation were present before therapy and throughout the entire experimental period.



Figure 16. Case III: Low magnification of specimen (H&E stain). Note marked inflammatory infiltrate surrounding graft particle sites.



Figure 17. Case III: Higher magnification (25 \times) of specimen shown in Figure 16. Note the density of the inflammatory infiltrate surrounding the particle sites.

COMMENTS

The cases presented show clinically acceptable therapeutic results. However, histologically the synthetic graft material did not enhance regeneration of lost periodontal structures. The graft material essentially appeared encapsulated by collagen but showed no evidence of osteogenesis at its seams. The implant therefore must be considered as a tissue tolerated foreign body "fill". The periodontal therapeutic value of such a "fill" material thus appears not to lie in regeneration of pathologically destroyed periodontal tissues, but may have use in the plastic reconstruction of oral tissue defects.

Finally, it should be noted that some of our patients were medically compromised and that the degree of inflammation varied significantly from site to site within the patient group. Yet, as stated earlier, the healing response to the implant material was essentially the same at all sites tested.

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