The Use of a Porous Hydroxylapatite Implant in Periodontal Defects*

I. Clinical Results after Six Months

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TWENTY-FIVE PATIENTS WITH ADVANCED periodontal destruction were used in the study. Following initial therapy, two angular interproximal defects were selected in each patient. During flap surgery a porous hydroxylapatite implant shaped to fit the periodontal defect was placed in one defect, the other defect was used as nonimplanted control. The material used for implantation was a hydroxylapatite replicate of coral from the genus *Porites*, with a pore size of 190 to 220 μm. Clinical parameters were measured prior to flap surgery for each of the defects. An occlusal acrylic stent was used to give a stable reference point for pocket depth, attachment level and gingival margin height measurements. Also gingival fluid, gingival inflammation, plaque index and tooth mobility were recorded. Periapical radiographs using a standardized positioning device were also taken. At the time of surgery, the depth of the osseous defect and the height of the alveolar crest were recorded. After 6 months the clinical measurements were repeated and a re-entry surgery was carried out in 15 selected sites. Results showed that the porous implant produced statistically significant reduction in pocket depth, in the depth of osseous lesion, and a statistically significant gain in attachment level, as compared to control areas.

The regeneration of a periodontium destroyed by inflammatory periodontal disease has been an elusive goal sought by all who treat periodontal problems. When significant alveolar bone destruction has occurred, there is currently no procedure that will result in a predictable regeneration of bone, periodontal ligament and cementum. Published reports of success in clinical trials have failed to lead to acceptable procedures for the day to day treatment of periodontal defects.[1-8] This failure of acceptance is due to the fact that clinical successes have been inconsistent in appearance and insufficient in magnitude.

Osseous autografts, using intraoral and extraoral sites as donor areas, have been the most widely used graft materials in periodontal defects.[1,3-5,8] There are clinical reports and clinical trials that have shown some bony fill in the deepest portions of osseous defects.[1-4,6,8] but these have all failed to provide a basis for a predictable procedure for treating periodontal defects. Also, some of these materials, such as marrow and cancellous bone, have lead to root resorption and have been discountinued.[5] Autografts are not only unpredictable but the paucity of suitable donor tissue has been a deterrent to their use. Allografts and xenografts have been tried but no substantial evidence of success has been evident.[2,7-10] Because of the inadequacies of the autogenous osseous implants there has recently been a great deal of interest in the development and use of synthetic implants for bone regeneration.

One of the first synthetic implant materials used in periodontics was plaster of Paris,[11] but later reports showed that this material had no osteogenic potential.[12] Tricalcium phosphate has also proven to be of little value.[13] Currently emphasis has been placed on the utilization of hydroxylapatite as powdered implant materials for periodontal defects.[14,15] These materials appear to have limited value as agents for stimulation of regeneration of periodontal tissues and their ability to stimulate osteogenic activity in periodontal defects has not been demonstrated.[14-16]

Various synthetic materials have been manufactured as replicates of the structure of a natural coral of the genus *Porites* to produce microporous implant mate-

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rials called replamineforms.[17–20] A synthetic bone graft material can be manufactured by the hydrothermal conversion of the calcium carbonate of the coral to hydroxylapatite. This material is available in a block with pore sizes of 190 to 220 μm (Fig. 1). Originally this material was called replamineform and now has the designation Interpore 200®. Coralline-based hydroxylapatite replamineform implants have been shown to stimulate connective tissue infiltration and bone formation in periodontal defects in dogs.[21] Implants of this material have been used to stimulate bone formation in the long bones of dogs,[22] in defects in dog mandibles[23,24] and in alveolar ridge augmentation procedures in dogs.[25]

The purpose of the present study was to use this Interpore 200 implant material in a block form, shaped to fit the defect, in order to investigate the effects of a stable structural framework within periodontal osseous defects.

MATERIALS AND METHODS

Twenty-five adult subjects were used in this study. There were 14 females and 11 males. The mean age was 38.30 ± 9.87 years. The subjects were chosen on the basis of having a health-history free of systemic disease and the presence of at least two interdental, angular osseous periodontal defects, with initial pocket depths 5 mm or greater, in the same quadrant.

Each subject was treated with an initial phase of therapy involving oral hygiene instruction, root planing with local anesthesia and occlusal adjustment if trauma from occlusion was present. Following this, standard sulcular incisions for nonrepositioned, muco-periosteal flaps were performed under local anesthesia to expose the defects. Two similar defects were selected for the study based on the preoperative clinical and radiographic findings (Figs. 2 and 10). These defects were interproximal lesions which did not involve furcations.

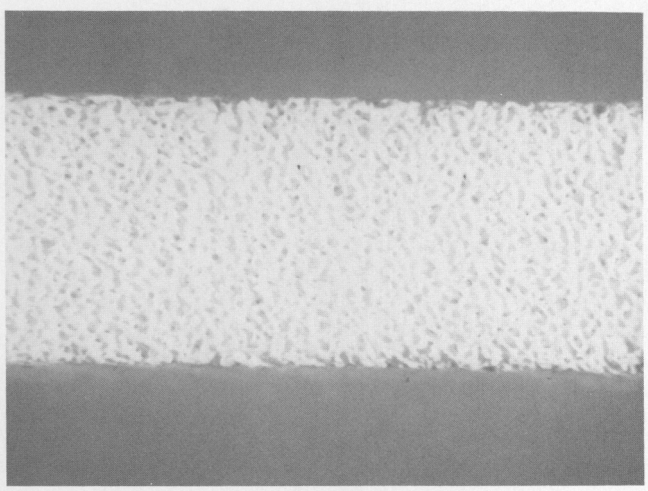

Figure 1. *Block of Interpore 200 showing porous structure with a pore size of 190 to 200 μm.*

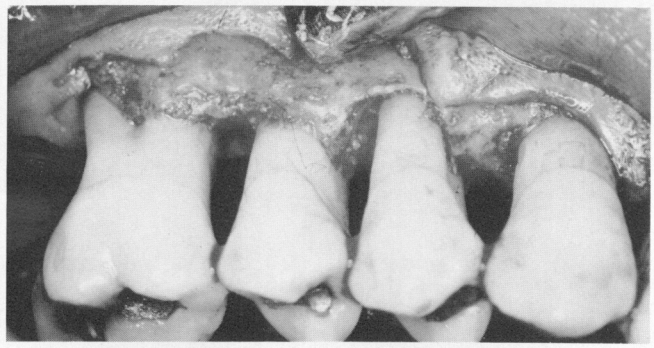

Figure 2. *Case 1—Osseous defects at time of initial surgery. Site to receive implant is distal of first premolar. Mesial of first molar is control defect.*

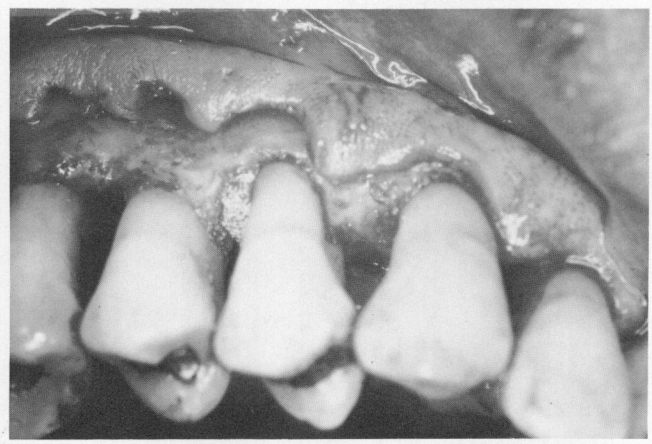

Figure 3. *Case 1—Hydroxylapatite implant shaped to fit defect on distal of first premolar.*

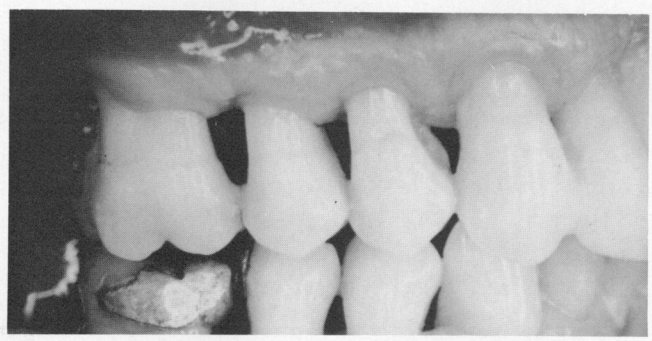

Figure 4. *Case 1—Six months postsurgery. Note excellent tissue response to hydroxylapatite implant.*

In each patient one defect was randomly chosen as a control defect and the other was used for placement of a hydroxylapatite implant. The implanted sites received a contoured piece of Interpore 200® shaped to restore the osseous defect to the most coronal level of the adjacent alveolar process. The piece for implantation was cut from a block (Fig. 1) and was shaped to conform to the defect using a high speed handpiece and a fine diamond bur. The implant was tried for fit into the defect and the shape refined until it filled the defect space (Figs. 3 and 11). The periodontal flaps were positioned at their original level with silk sutures, with

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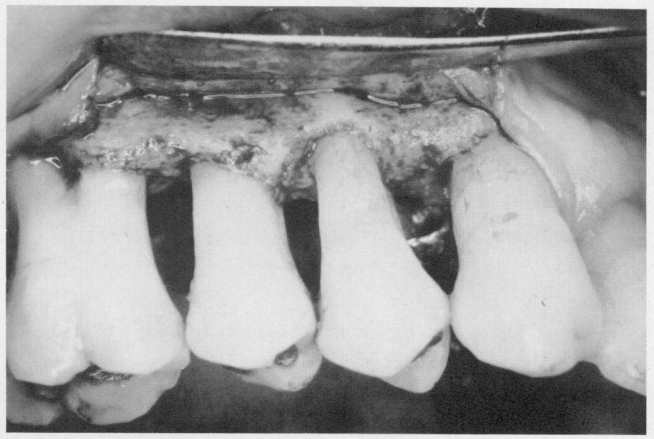

Figure 5. *Case 1—Six-month re-entry procedure showing obliteration of defect on distal of first premolar.*

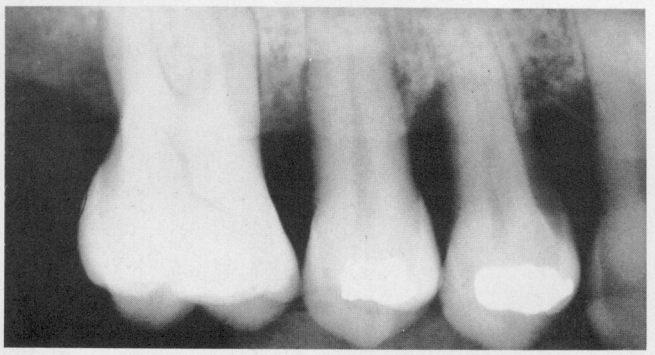

Figure 6. *Case 1—Presurgical radiograph.*

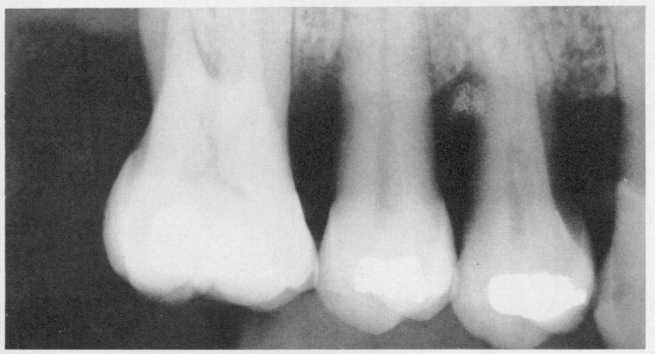

Figure 7. *Case 1—Radiograph immediately after placing implant.*

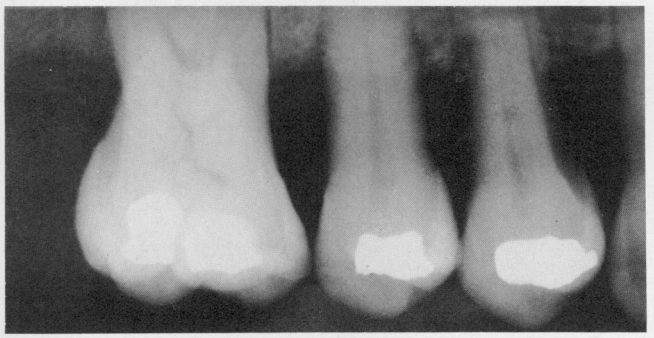

Figure 8. *Case 1—Six-month postsurgery radiograph. Note blending of implant into surrounding osseous tissue.*

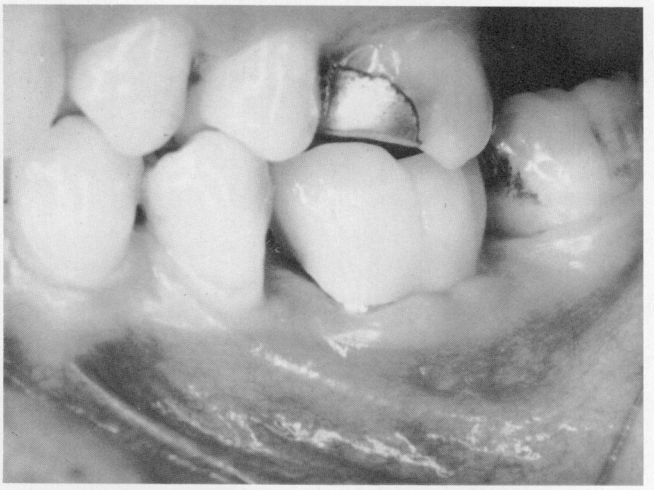

Figure 9. *Case 2—Presurgical view. Area to be implanted is on the distal of the first molar.*

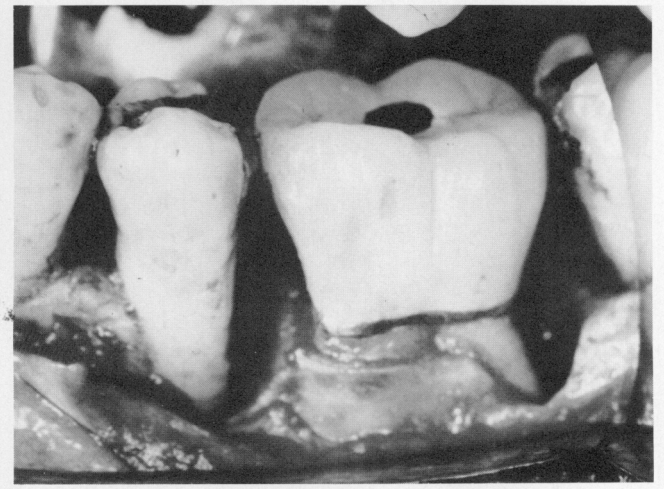

Figure 10. *Case 2—Osseous defects at time of surgery. Control defect in distal of second premolar area to be implanted is on distal of first molar.*

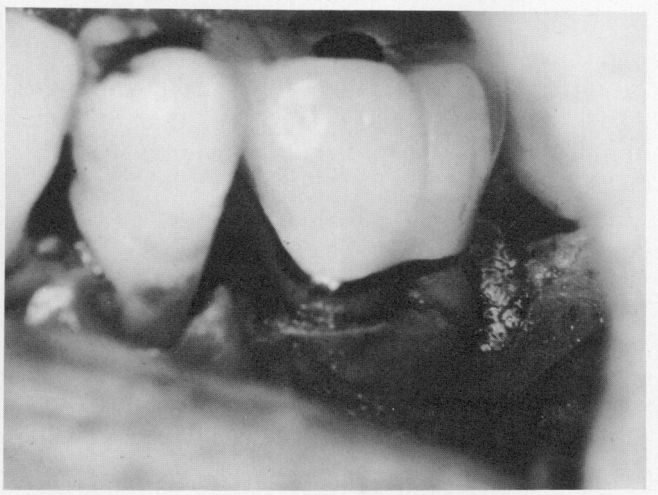

Figure 11. *Case 2—Hydroxylapatite implant placed on defect on the distal of first molar.*

special care being taken to ensure closure of the interproximal wound. A periodontal dressing was placed over the surgical area. Postoperative care included the use of oral analgesic tablets and the use of an oral antibiotic for 6 days postsurgery. The antibiotic used was penicillin, 250 mg 4 times a day. In three patients who were allergic to penicillin, tetracycline, 250 mg 4 times a day, was used instead. One week postoperatively the patients returned for dressing and suture removal and reinforcement of oral hygiene instruction.

Presurgical radiographs were taken using a customized occlusal stent.[2] A similar radiograph was taken immediately on completion of the surgery with the implanted material in place.

Immediately prior to surgery the following clinical measurements were recorded.

1. Pocket depth and level of attachment were measured with an acrylic occlusal stent using grooves to ensure a reproducible placement of the probe.[26] Pocket depths were recorded using the gingival margin as the point of reference; attachment levels were recorded using the stent as the reference point. For these measurements care was taken to angle the periodontal probe so that it reached the deepest part of the periodontal pocket interproximally. Gingival recession of the tip of the interdental papilla was measured using the same template.
2. The following indices were also measured for each surgical area: Plaque Index[27] and Sulcular Bleeding Index.[28] Gingival fluid measurements were taken from the interproximal areas using the Periotron® for volumetric measurement.[29] Mobility of each tooth was assessed using a scale of 0 to 5, as follows: teeth were displaced facio-lingually with the metal handle of a mouth mirror. If no discernible movement occurred, a score of 0 was given. A score of 1 was used for 0 to 0.5 mm movement, 2 for 0.6 to 1.0 mm, 3 for 1.1 to 1.5 mm, 4 for 1.6 to 2.0 mm, and 5 for greater than 2.0 mm.

At the time the flaps were opened, additional clinical measurements were taken. These were the distance from the occlusal template to the deepest apical depth of the osseous defect using a groove for aligning a periodontal probe, and a similar measurement from the template to the alveolar crest immediately coronal to this first measurement.

Three months after the surgical appointment the patients were seen again for a routine recall appointment. At this time the tissue response to therapy was evaluated, another standardized radiograph was taken and the areas were gently cleaned with a rubber cap and polish. Oral hygiene procedures were again emphasized for each area.

Six months after the surgery was completed each subject was seen again (Figs. 4 and 12). At this time, all of the clinical parameters measured prior to surgery were repeated and a standardized radiograph taken of each area. Fifteen control and fifteen implanted sites underwent surgical re-entry procedures. When the flaps were opened for the re-entry procedure (Figs. 5 and 13), the height of the osseous defect and the alveolar crest were measured using the same template used preoperatively. The grooves allowed a reproducible position of the probe in the same alignment as used previously. Minimal flap retraction was carried out at this time and the flaps were positioned at their original level and sutured. Postoperative dressings and medications were used as previously described, with the exception that no antibiotic was given to any of the patients at this time.

The results presented in this study will be concerned with the comparison of the presurgical measurements with those seen at 6 months. Statistical analysis of data

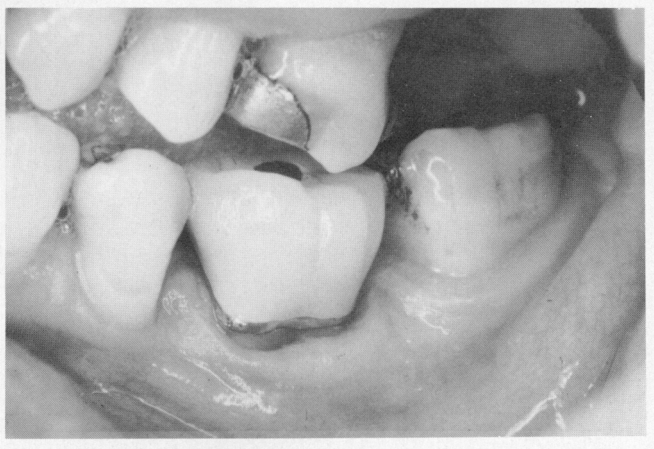

Figure 12. *Case 2—Six months postsurgery. Note slight recession over control and grafted areas and excellent tissue response.*

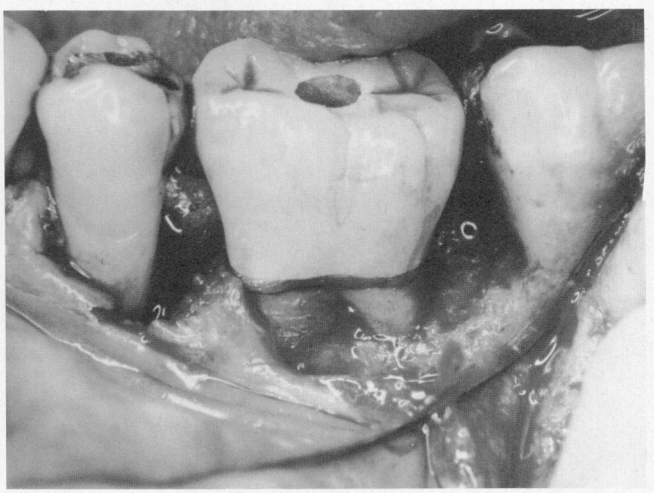

Figure 13. *Case 2—Six-month reentry. Note the closure of the defect on the distal of the first molar and remodelling of bone over the buccal roots. The control area on the distal of the second premolar is unchanged.*

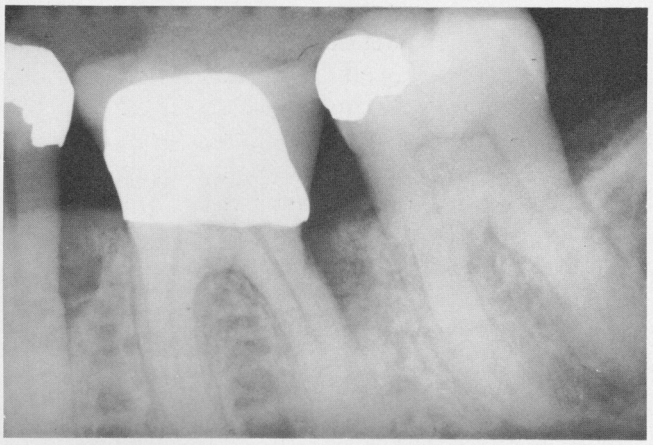

Figure 14. *Case 2—Presurgical radiograph.*

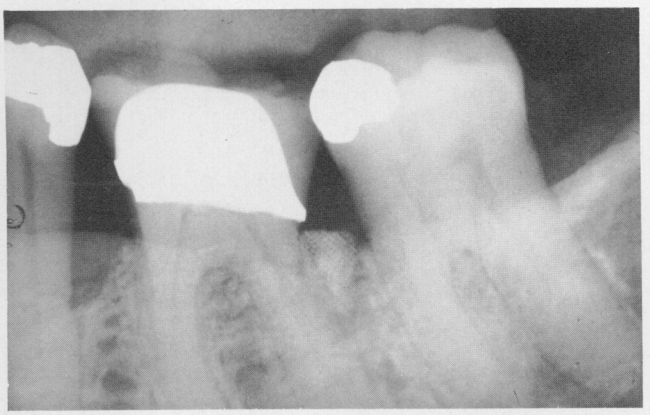

Figure 15. *Case 2—Radiograph immediately after placement of implant.*

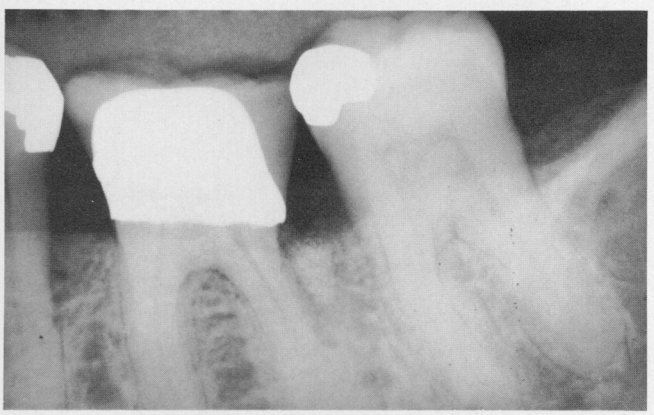

Figure 16. *Case 2—Radiograph six months postsurgery. The implant has lost some definition and appears to be blending into the surrounding osseous tissue.*

was carried out using a 2-tailed t test for comparison of differences between experimental and control sites (Figs. 2–8 and 9–16 illustrate two representative cases).

RESULTS

The control and experimental areas both had clinically significant periodontal destruction, but the mean preoperative pocket depth was less in the control group. However, at 6 months, the pocket depth was less in the experimental group than in the control group.

Table 1 shows pocket depths for the implanted and control sites preoperatively and at 6 months. At 6 months all sites showed an improvement in pocket depth readings, with the most dramatic changes being evident in the implanted regions. There was a statistically significant difference between control and implant sites ($P < 0.001$). Attachment level changes followed a similar pattern with the gain in attachment of the implanted areas being statistically significant (Table 2).

Postsurgically there was evidence of gingival recession from the original presurgical position. This ranged from 1.21 mm for the implanted area to 1.07 mm for the control areas. These changes were not significantly different (Figures 9, 13).

The Sulcular Bleeding Index, gingival fluid measurements and Plaque Index all showed a decrease when the presurgical measurements were compared with the postsurgical recordings, but there were no significant differences between the experimental and control sites. Tooth mobility was also decreased in all teeth evaluated; however, the decrease was not clinically important nor statistically significant (Table 3).

The postsurgical measurements of depth of the osseous defects showed that there were significant changes in the implanted areas while the control areas showed very small improvement over the presurgical data.

Table 1
Means and Standard Deviations of Pocket Depths in Millimeters

Variable	Control	Implanted
Initial	6.24 ± 1.70	7.24 ± 1.54
6 Months	3.76 ± 1.26	2.96 ± 1.34
Mean Changes	2.48 ± 1.38*	4.28 ± 2.09*

* Statistically significant $P \leq 0.001$.

Table 2
Gains in Attachment Level in Millimeters at 6 Months (Means ± Standard Deviation)

Control	Implanted
1.24 ± 0.83*	3.64 ± 2.45*

* Statistically significant $P \leq 0.001$.

Table 3
Changes in Clinical Parameters (Means ± Standard Deviations)

	Initial	Six Months
Sulcular Bleeding Index		
Control	1.36 ± 0.57	0.36 ± 0.49
Implanted	1.44 ± 0.51	0.40 ± 0.65
Gingival Fluid		
Control	61.40 ± 26.51	38.40 ± 22.11
Implanted	61.72 ± 27.36	39.36 ± 28.72
Plaque Index		
Control	0.80 ± 0.64	0.60 ± 0.70
Implanted	0.88 ± 0.78	0.64 ± 0.81
Tooth mobility		
Control	0.72 ± 0.84	0.60 ± 0.58
Implanted	1.44 ± 1.22	1.08 ± 0.90

Table 4
Means ± Standard Deviations of 6-Month Changes in Osseous Defect Measurements from Presurgical Levels (Millimeters)

Variable	Control	Implanted
Depth of defect	0.73 ± 0.54*	3.53 ± 2.47*
Alveolar crest of defect	0.18 ± 0.75†	0.09 ± 0.83†
Number of sites	15	15

* Statistically significant $P \leq 0.0002$.
† Not statistically significant.

These differences between control and implanted sites were statistically significant ($P \leq 0.0002$). There were no postsurgical changes of importance in the measurements of the level of the alveolar crest in either control or experimental areas (Table 4).

All subjects included in this study had uneventful postoperative experiences. There was minimal pain and no evidence of infection or swelling. The hydroxylapatite appeared to be well tolerated by the gingival tissues during initial healing and thereafter including the 6-month evaluation period.

Radiographically the hydroxylapatite implant could be seen as a radiopaque mass with a slightly more dense appearance than the surrounding alveolar process. At 6 months this difference in density was not so obvious, and apparently there was a blending of the material into a similar radiopacity to that seen in the adjacent bone. The control sites showed no obvious radiographic changes when the preoperative radiograph was compared to the 6-month radiograph (Figures 6, 7, 8, 14, 15, 16).

At the time of the original surgery all the defects were categorized as to the number of walls in the osseous defect. Analysis of data did not show any significant difference in response to therapy that could be related to the number of bony walls of the defects.

DISCUSSION

The clinical results showed improvements in the periodontal status in all subjects at 6 months postsurgery. The control group of defects had reduction of pocket depth, gain of attachment, improved gingival health and a slight increase in gingival recession. These results are in accord with previous reports of success using a modified Widman flap.[30] The implanted defects showed greater improvement in the means of these clinical parameters than the controls, and in each subject the experimental site always showed a larger improvement than the control.

The re-entry data coincided with the clinical data. Thus, when there was a measurable improvement in the gain of attachment level this was duplicated with an equivalent improvement in the depth of defect seen at re-entry. The significance of the re-entry data is that apparently the porous hydroxylapatite material was well tolerated by the surrounding tissue and had the appearance of being incorporated into the alveolar bone.

Previous studies using durapatite implants have not found that postoperative measurements of attachment level are parallel to the amount of defect fill.[14,15] This has been explained on the basis of probe penetration of tissue. The present study suggests that it is possible to have re-entry data that is similar in magnitude to attachment level data with a porous hydroxylapatite ceramic implant.

At the time of re-entry, the implanted sites all showed dramatic evidence of obturation of the original defect. It was very difficult to visualize any differences between the implant and the surrounding bone. No mobility of implant material was seen, and it appeared that the porous hydroxylapatite was incorporated into the surrounding bone. In these initial studies it is not possible to ascertain if these results are due solely to retention of the implant material with minimal inflammatory response, or if there is an osseous incorporation of the implant. We are currently preparing histologic material to further investigate these phenomena.

The radiographs showed evidence of changes in the appearance of the implant material at 3 months and more apparent changes at 6 months. These changes were consistent with osseous incorporation of the hydroxylapatite. Previous reports with solid hydroxylapatite in periodontal defects have not shown any indication of osseous changes around the particles but rather a fibrous encapsulation occurred.[15,16] However, Holmes[23] was able to demonstrate an initial fibrous ingrowth into replamineform porous implants in dog mandibles followed by calcification and ossification within the implant and evidence of resorption of the implant. Piecuch et al.[25] also reported resorption of replamineform implants at 12 months postridge augmentation surgery in dogs. This porous implant apparently has two advantages over the powdered ceramic implants. Firstly, it has the potential to stimulate development of osseous tissue within the pore structure and secondly, it is apparently slowly broken down by the tissues within it.

The use of a porous biocompatible implant in angular periodontal defects is biomechanically very different from the placement of a particulate material. The porous block material gives a stable scaffolding adjacent and in direct contact with the alveolar process. This, then, provides for fibrous ingrowth which binds the implant to the supporting bone. Powdered or particulate implants cannot give such a scaffolding effect and probably function primarily as radiopaque inert fillers in periodontal defects. This function, as inert fillers, probably makes powdered materials inherently more suitable for alveolar ridge augmentation than they are for treatment of periodontal defects. We are currently comparing granular porous hydroxylapatite implants with Interpore 200 implants in periodontal defects to further explore these differences.

The radiographs used in the present study provide

confirmation of the clinical measurements and the reentry results. We do not believe that it is possible under the present protocol to use the radiographic findings for reliable numerical data. The reason for this reticence is that it was difficult to get absolutely reproducible radiographs in all cases and the interpretation is further complicated by the fact that the image of the implant is similar in density to the surrounding bone. There was no radiographic evidence of root resorption in any of the cases reported in this study.

All areas, except for the one where the implant was exposed, healed without complication. Two cases showed transient gingival inflammation in both the control and implanted sites after surgery. This was related to plaque accumulation in the area, and was resolved with improved oral hygiene. Apparently this material is well tolerated by periodontal tissues, providing care is taken to cover the implanted area with a well fitting unthinned mucoperiosteal flap. It is also necessary to be sure that the defect is not overfilled with the graft, and that plaque accumulation is minimized throughout the healing and maintenance periods.

The exact nature of the tissue response to the porous hydroxylapatite material cannot be visualized in this study as no block sections were obtained. However, placement of this material in periodontal defects in dogs has resulted in ingrowth of connective tissue through the pores of the implant and also there were areas of ossification within the material.[21] Future studies using human tissue for histologic evaluation will be necessary before any definitive statement concerning the exact nature of the periodontal response can be made.

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