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A Clinical Evaluation of Resorbable Hydroxylapatite for the Repair of Human Intra-osseous Defects

Abstract

One of the goals of periodontal therapy is actual hard- and soft-tissue regeneration or at least the functional repair of periodontal defects. Alloplastic materials used in the past included dense hydroxylapatite grafts which were non-resorbable and often exfoliated. A new resorbable hydroxylapatite biomaterial [OsteoGen® (HA RESORB)™] was used during flap surgery. After the usual initial therapy, full-thickness flaps were elevated. A thorough debridement of the roots and osseous defects was accomplished. The defects were measured and then filled with OsteoGen®.

The mean initial bone defect depth was 4.47 mm. These defects were re-evaluated by the probing of bone levels after a 4-6-month healing period. A mean of 2.26 mm of new bone fill was obtained. This represents an average fill of 51%. Seventeen of the 22 defects had 42% or more actual new bone fill. No foreign body reaction or exfoliation occurred.

Introduction

In the last decade, a variety of alloplastic graft materials has been used in osseous defects. Most of the commercially available products have been sintered (ceramic) hydroxylapatite (HA), which is relatively dense and essentially non-degradable. Recently, a biodegradable, porous HA has become available [OsteoGen® (HA RESORB)™, Impladent, Inc., 198-45 Foothill Ave., Holliswood, NY 11423]. Potentially, this type of graft could fill an intra-osseous defect for a period of three to six months, thus allowing osteoblasts and other reparative cells to use it as a resorbable mineral scaffold during the repair process. This graft may also retard epithelial migration during this time. The complete biodegradation of the graft allows for predictable regeneration of bone and connective tissue rather than retention of a foreign body which may be exfoliated at a later date.

Materials and Methods

OsteoGen® (HA RESORB)™ is a highly microporous, non-sintered (non-ceramic), bio-active bone grafting material with a predictable, controlled resorption rate. As it resorbs, OsteoGen® acts as a mineral reservoir and induces new bone formation *via* osteoconductive mechanisms. The most remarkable property of OsteoGen® is its apparent ability to enhance the ossification process in host bone and be totally replaced with new bone *without* the fibrous encapsulation which so often characterizes non-resorbable implant materials (Judy, 1986; Wagner, 1989; Whittaker *et al.*, 1989).

During the course of periodontal flap surgery, 24 periodontal intra-osseous defects were randomly selected to be filled with OsteoGen®. The 24 defects occurred in 16 patients, with each patient having as few as one defect or as many as three defects treated. The surgical procedure consisted of sulcular incisions; reflection of full-thickness flaps; and debridement of the defects and roots with hand instruments and finishing burs. Measurements were made with a standard periodontal probe with Williams markings (PQW) estimating to the nearest 0.5 mm. Measurements were made from the cemento-enamel junction to the base of the defect and from the crest of bone to the base of the defect (defect depth). OsteoGen® was mixed with sterile saline to form a thick putty-like con-

TABLE
OSSEOUS REPAIR FOR 22 DEFECTS WHERE OSTEOGEN® (HA RESORB)™ WAS USED

Tooth	CEJ Base Defect (mm)	Initial Defect Depth (mm)	CEJ Base Defect* (mm)	Fill (−) 0.3 mm (mm)	Percentage
4 m	7	2	5	1.7	85%
2 m	7	2	5	1.7	85%
28 d	7	4	4	2.7	67.5%
30 d	7	4	5	1.7	42%
4 d	7	4	5	1.7	42%
4 m	7	5	4.5	2.2	44%
30 d	8	5	4.5	3.2	64%
19 d	11	7	7.5	3.2	46%
31 m	9	4.5	6	2.7	60%
19 d	8	4.5	5	2.7	60%
14 m	9	7	5	3.7	52.8%
31 m	7	4	4.5	2.2	55%
13 d	8	5	5	2.7	54%
14 d	10	5	8	1.7	34%
14 d	9	5	7.5	1.2	24%
12 m	10	3	7	2.7	90%
15 m	10	3	7	2.7	90%
30 d	9	4.5	7	1.7	37.7%
29 d	10	4	7	2.7	67.5%
5 m	7.5	4.5	6	1.2	26.6%
5 m	10	6.5	8	1.7	26.2%
15 m	8	5	5.5	2.2	44%
Means:		4.47		2.26	51%

N = 22
*4-6 mo. post-operative evaluation by the probing of bone level.

sistency and was compressed into the defect with slight overfilling. Primary closure of the flap with 4-0 silk sutures was attempted. All areas were covered with periodontal dressings. All patients received a prescription for Tetracycline HCl 250 mg q.i.d. for seven days. The surgical site was re-packed at one week. Sutures were removed after seven days. Thereafter, patients were recalled monthly for light scaling and oral hygiene instruction. Each site was re-evaluated four to six months post-surgically. The area was anesthetized and probed from the same point at the CEJ to bone (the deepest point). A recent study by Renvert *et al.* (1981) showed a close relationship between probing bone levels and entry/re-entry bone height determinations (0.3 mm greater probe penetration with re-entry) "indicating that both methods are equally useful to determine the height of the alveolar bone. Accordingly, re-entry procedures for the purpose of post-operative measurements may be omitted in future studies." Selected areas were re-entered, however, so that the residual defect would be further reduced. This was done particularly in cases where the tooth involved was to be used as an abutment for a fixed bridge.

Results

Twenty-two of the original 24 defects were re-evaluated (Table). Two of the original patients could not be recalled. The mean bone defect depth measured at the time of the flap entry was 4.47 mm. At the time of re-evaluation by probing of the bone level (with anesthesia), the mean defect depth was 2.56 mm. This was adjusted by subtraction of 0.3 mm to compensate for the difference between the original entry measurement and the re-evaluation by bone probe, according to Renvert *et al.* (1981). The net 2.26-mm mean fill represents 51% fill of the original defect. Measurements were made from the CEJ to the deepest point of the defect. The amount of fill from the base of the defect ranged from 1.2 mm to 3.7 mm (after a −0.3 mm adjustment). The median fill after adjustment was also 2.2 mm. Another method used in prior studies for evaluation of the response of graft materials in bone defects is recording the number of sites that have 50% or more fill (Sanders *et al.*, 1983). In this study, 12 of the 22 had 50% or more fill. However, five additional defects were 42 to 46% filled, so that 17 of 22 (or 77% of the defects) had substantial fill.

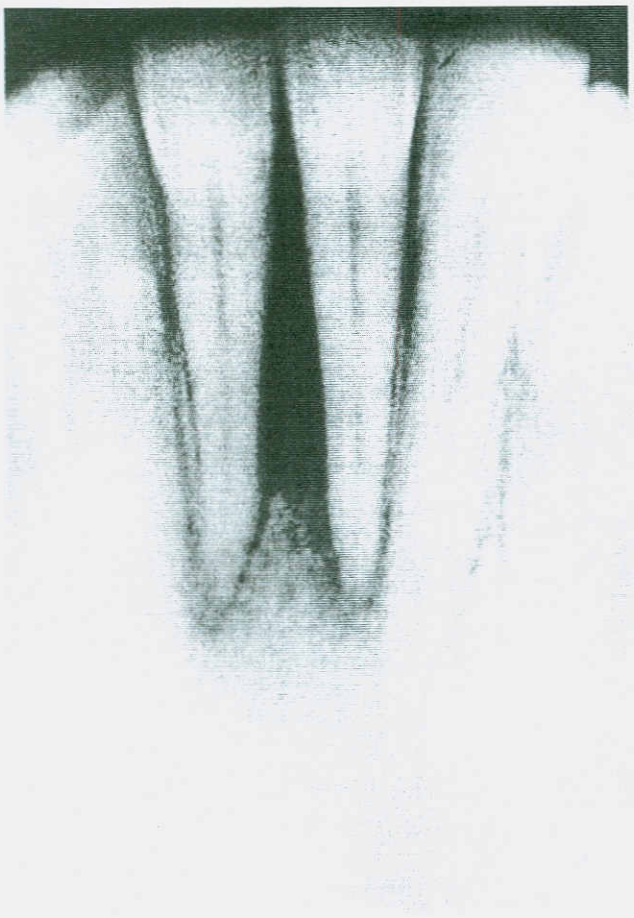

Figure A. A pre-surgical radiograph showing bone near the apices of teeth (numbers 24 and 25).

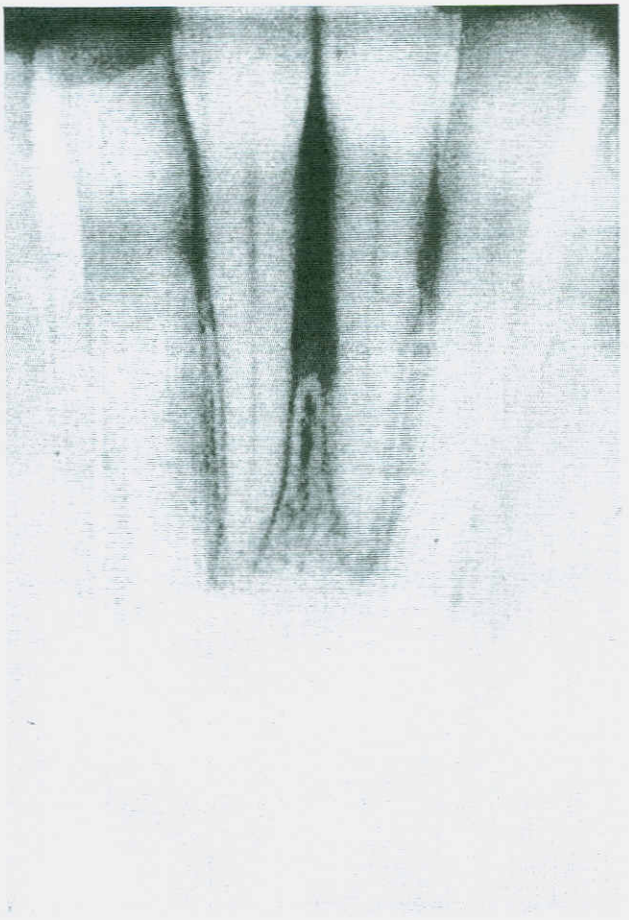

Figure B. A two-year post-surgical radiograph. OsteoGen placed during flap surgery has been resorbed and replaced by new bone to the mid-root level.

Discussion

The results of this study demonstrate that a degradable, porous HA graft material [OsteoGen® (HA RESORB)™] is most useful in the treatment of intra-osseous defects. The material was well-tolerated by the patient in all cases. No exfoliation of implant particles was seen. The soft tissue response observed was one of minimal acute inflammation from the first week post-surgery. The percentage of bone fill (51%) was greater than the percentages reported in studies with open debridement (9%-30%) (Krejci *et al.*, 1987; Yukna *et al.*, 1985). The percentage of fill was also greater than reported in most studies that used other alloplastic graft materials (23%-50%) (Krejci *et al.*, 1987; Yukna *et al.*, 1985; Barnett *et al.*, 1989). The actual amount of fill (2.26 mm) and percentage of fill (51%) were comparable with but not quite as good as those reported with autogenous bone or demineralized freeze-dried bone allografts (DFDB) (Barnett *et al.*, 1989; Froum *et al.*, 1976). However, all defects in this study were associated with posterior teeth, which generally do not respond as well to regenerative surgery due to the presence of furcations. When its safety and low cost are considered, OsteoGen® is an effective and practical option. It may be used alone or as a graft expander in combination with autogenous bone or DFDB. A recent animal study showed the effective use of HA in combination with Deoxytetracycline, 2 to 1 mix by volume, in bone defects (Waleed *et al.*, 1989).

In all cases, the OsteoGen® graft material had resorbed concurrently with tissue regeneration when re-entry procedures were done. This would make OsteoGen® especially useful (alone or in combination with autografts or allografts) for filling voids around dental implants placed in extraction sockets, since there would be no potential problem with exfoliation of the graft when the implant is uncovered after the integration period. Allografts seem to have more osteogenic potential.

However, some patients have voiced concerns regarding the possibility of viral material being transmitted with this type of graft if sterilization procedures are inadequate. Autogenous grafts have had a long record of usefulness and safety. However, the quantity of autogenous bone available is often inadequate. The combination of an autogenous graft and OsteoGen® might be an ideal solution when used together to repair bone defects. OsteoGen® is an easy material to prepare and mix. It is also hemophilic and hydrophilic, readily absorbing blood or saline. Figs. A and B show a two-year post-surgical result with an unusual increase in crestal bone height.

Conclusion

Twenty-two intra-osseous defects in humans were treated with OsteoGen®, a porous HA graft material that is predictably degradable (resorbable). A mean of 2.26 mm of bone fill was obtained. This represents an average fill of 51%. Twelve of the 22 defects had 50% or greater bone fill. No foreign body response or exfoliation was seen. OsteoGen® is a graft material that is most useful in the predictable healing and actual regeneration of bone and connective tissue involving periodontal defects or peri-implant defects.

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