

Original Article

# Clinical Evaluation of Hydroxyapatite with Polyglactin-910 Membrane in the Management of Intraosseous Periodontal Defects

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## ABSTRACT

**Purpose:** To evaluate and compare clinically the efficacy of BONE-GLASS<sup>®</sup> with and without VICRYL-MESH<sup>®</sup> (Polyglactin-910) in the management of intrabony defects in humans suffering from periodontal disease. **Material & Method:** Ten patients with comparable bilateral periodontal intrabony defects in relation to the posterior teeth, as determined by clinical and radiological evaluation were selected for the study and divided on basis of split mouth design. In Group I, BONE-GLASS<sup>®</sup> and in Group II, BONE-GLASS<sup>®</sup> with VICRYL-MESH<sup>®</sup> were given. Each patient received initial phase I therapy scaling root planing and occlusal adjustments etc as required. Soft tissue parameters viz, the probing depth, the attachment levels and gingival recession were recorded clinically from fixed point on acrylic occlusal stent at baseline and 6 months. Hard tissue measurements were made on radiographs exposed using paralleling technique at baseline and 6 months. **Results:** Both groups showed statistically highly significant ( $p < 0.01$ ) probing pocket depth (PPD) reduction, clinical attachment (CAL) gain, and defect fill from baseline to 6 months. In comparison to Group I, highly significant ( $p < 0.01$ ) pocket depth reduction and defect fill was detected for Group II after 6 months.

**KEY-WORDS:** Intraosseous defects, Hydroxyapatite, GTR membrane

## INTRODUCTION

Most serious consequence of the periodontal disease, which is one of the most prevalent afflictions worldwide, is the destruction of the tooth supporting structures. Various types of osseous defects produced by the periodontal disease are horizontal, vertical, osseous craters, bulbous bone contours, inconsistent margins, ledges etc.<sup>1</sup> Vertical or angular or intrabony defects are those that occur in an oblique direction leaving a hollowed out trough in the

base alongside the root. Goldman and Cohen<sup>2</sup> classified angular defects according to the location and number of osseous walls remaining around the defect. The morphology of osseous defect will largely determine the treatment technique to be used. One-walled angular defects (Hemiseptum) usually have to be surgically resected. Three-walled defects (intrabony) can be successfully treated with techniques that aim at new attachment and bone regeneration. Two-walled angular defects can be treated with either method depending on their depth, width and general configuration.

The challenge of periodontal regeneration has come to the forefront of periodontal research and practice and thus regenerative approaches have enhanced the long term prognosis of the teeth that have advanced periodontal destruction. One of first synthetic implant material used in periodontics was Plaster of Paris, but later report showed that this material had no osteogenic potential.<sup>3</sup> The calcium phosphate system and in particular Hydroxyapatite (HA) has been the

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subject of intensive investigation because it is from this system that vertebrate tooth and bone mineral is derived. The most widely investigated calcium phosphate biomaterials are composed of either hydroxyapatite  $[Ca_{10}(PO_4)_6(OH)_2]$  or tricalcium phosphate  $[Ca_3(PO_4)_2]$ .<sup>4</sup>

BONE-GLASS® (Rushkin Innovative Group, Ahmedabad) is a synthetic graft material consisting of bioceramic hydroxyapatite granules of 300 to 355 microns. It consists of calcium and phosphate ions which are common constituents of vertebrate hard tissue systems. BONE-GLASS® exhibits mechanical properties similar to cortical bone and has a calcium/ phosphate ratio of 1.67 equivalent to living bone.

The use of physical barriers (GTR membrane) to promote new attachment has been an area of intense interest since its inception in 1980's. The initial membranes developed were non-resorbable that required a second operation, and therefore resorbable membranes were developed. The search for resorbable membranes include tests with rat collagen, bovine collagen, cargin membrane derived from the cecum of ox, polylactic acid, VICRYL-MESH® (Polyglactin 910), synthetic skin (Biobrane), and freeze-dried dura mater.<sup>1</sup> Resorbable knitted polyglactin 910 membrane (VICRYL MESH®, Ethicon Lab, Johnson and Johnson) has been reported to be economical, easily available, easy to manipulate with no abnormal immunological response and requires single surgical procedure with resorption time of 3-12 weeks. The purpose of this clinical study was to evaluate the efficacy of BONE-GLASS® (alloplastic material) with and without VICRYL MESH® (Polyglactin-910 membrane) in management of intraosseus periodontal defects.

## MATERIALS AND METHOD

**Patient selection:** A general assessment of subjects was made through their history, clinical examination and routine investigations. Intraoral periapical radiographs of regions of interest were taken. All subjects were treated with initial Phase-I therapy involving oral hygiene instructions, scaling and root planing and occlusal adjustment, if needed. After clearance from local ethical committee, ten systemic healthy, non-smoker, co-operative patients,

showing acceptable oral hygiene during pre-surgical (Phase-I) therapy in the age group of 35-45 years, suffering from moderate to advanced chronic periodontitis were selected amongst the patients visiting the department of periodontics. Based on radiographic observations along with clinical probing depth of at least 6 mm, selected patients had two almost identical intrabony defects, one on the either side of the mandibular arch, having 3-walled or combined defects when viewed on surgical exposure. Teeth with furcation defects were excluded from the study. Selected sites were randomly divided into two groups and were treated according to split mouth design technique as Group-I sites received BONE-GLASS® (bioceramic hydroxyapatite granules of 300 to 355 microns, Rushkin Innovative Group, Ahmedabad) and Group II sites received BONE-GLASS® and VICRYL-MESH® (resorbable polyglactin 910 knitted mesh, Ethicon Lab, Johnson and Johnson).

All instruments and linen to be used in the surgery were sterilised by autoclaving (temperature 121°C, at 15 psi pressure for 15 minutes). The facial skin all around the oral cavity was scrubbed with 5% povidone-iodine solution (betadine) and intraoral surgical site was painted with 5% povidone-iodine solution.

Local anesthesia was administered by either nerve block (inferior alveolar nerve, lingual nerve, mental nerve and buccal nerve) or local infiltration to adequately anaesthetize the surgical site.

**Surgical technique:** Conventional flap surgery with crevicular incision was performed. The defect was debrided of all the granulation tissue and root surface was scaled and planed with the help of scalers and curettes. As per manufacture's instruction, the BONE-GLASS® (graft material) stored in sterile vials was taken out in the sterile dappen dish, mixed with saline and with the help of an amalgam carrier, packed into the defect (Figure-1 to Figure-3). In group II site, VICRYL-MESH® (stored in a vacuum dessicator) was cut to fit and sutured in place with 5/0 Vicryl sutures over the BONE-GLASS® (graft material) which was already placed in the defect. The flaps of both sites were then approximated as close as possible and sutured

with 4-0 black silk. The surgical areas were covered with periodontal dressing (COE-PAK®) on both the sites. Written post-operative instructions were given and analgesic (Ibuprofen 400 mg twice daily) was prescribed for 3 days. Doxycycline (Orobiotic® 100 mg b.d.) and 0.2% chlorhexidine (Hexidine®, ICPA) mouthrinse was instructed for 2 weeks after surgery. Sutures retaining the flap were removed 2 weeks after the surgical procedure and patients were asked to maintain meticulous oral hygiene. The areas were kept covered with periodontal dressing for 4 weeks where possible, and the patients were instructed to avoid the area if the pack came off. The mesh retaining sutures were absorbed.

**Clinical and Radiographic Parameters:** All the clinical measurements were standardized using customized acrylic occlusal stents (Fixed reference point) with grooves which were prepared on the study model of the patients. The recordings were made using a silver cone and then transferred to the 0.5 mm scale. The occlusal stent for vertical grooving was made using self-cured pink acrylic which was made to cover the occlusal as well as coronal 1/3<sup>rd</sup> of the buccal and lingual surfaces of the tooth involved and one tooth mesial and distal of the involve tooth. Vertical grooves were made to guide the silver cone penetration vertically in the same plane every time; it was inserted for recording measurements. The upper limit of the vertical grooves was made as the fixed reference point (FRP) for the vertical probing depth. Clinical parameters were recorded at the baseline (at and before surgery) and 6 months after the surgical procedure. Vertical measurements for determination of Probing Pocket Depth (PPD),

Clinical Attachment Level (CAL) and Gingival Recession (gingival margin position-GR) were measured from; fixed reference point (FRP) to the base of the pocket (BOP), fixed reference point (FRP) to the cemento-enamel junction (CEJ), and fixed reference point (FRP) to gingival margin.

Intraoral periapical radiographs of each defects was exposed at baseline and 6 months, using extension cone paralleling (XCP) instrument (paralleling technique) with a calibrated grid (Person Dental Company, Los Angeles, USA) of

1x1 mm<sup>2</sup> copper wire, keeping mandibular arch parallel to the floor, concurrent with the studies of Gager and Schultz.<sup>13</sup> All surgical procedures were performed by the same clinician and both pre-operative and post-operative measurements were recorded by identical individual.

The recorded measurements were statistically analyzed using ANOVA and Student-‘t’ test.

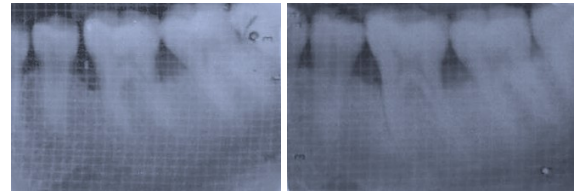


Figure 1 (a): Radiograph showing intrabony defect in group 1: baseline (b): in group 1: at 6 months

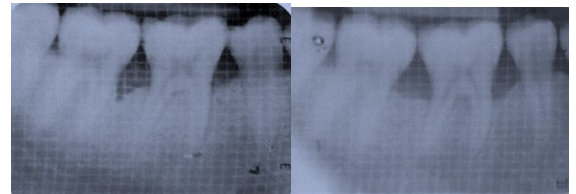


Figure 2 (a): Radiograph showing intrabony defect in group 2: baseline (b) in group 2: at 6 months

## RESULTS

Both the materials were well tolerated by all the patients with no adverse reaction, infection or delayed healing during the course of study. A mean probing pocket depth (PPD) reduction in Group I between baseline and 6 months as  $2.40 \pm 0.65$  mm (highly significant,  $p < 0.001$ ), and that in clinical attachment gain (CAL) as  $2.25 \pm 1.08$  mm (highly significant,  $p < 0.001$ ).

Mean value change for gingival recession (GR) of approximately  $0.70 \pm 0.75$  mm (significant,  $p < 0.05$ ) with hydroxyapatite after 6 months was observed. Mean defect fill in Group I between baseline and 6 months was  $1.64 \pm 0.40$  mm (highly significant,  $p < 0.001$ ), but mean change in alveolar crest was not significant.

In Group II mean PPD reduction and CAL gain between base line to 6 months was  $3.45 \pm 0.69$  mm (highly significant,  $p < 0.001$ ) and  $2.60 \pm 0.65$  mm (highly significant,  $p < 0.001$ ) respectively. For Group II mean change in gingival margin position (gingival recession) after 6 months was  $0.95 \pm 1.09$  mm (significant,  $p < 0.05$ ).

Mean defect fill in Group II after 6 month was 2.60 ± 0.80 mm (highly significant). Comparison

of mean change in clinical and radiographic parameters are summarized in Table 1

**Table 1: Mean change in various parameters of group I and II (in millimeters)**

Parameters	Time Interval	Group	No.	Mean change	Mean difference	T	P	S
Probing pocket depth	Baseline and 6 months	I	10	2.40 ± 0.65	1.14 ± 0.04	3.76	<0.01	HS
		II	10	3.54 ± 0.69				
Gingival position from fixed reference point	Baseline and 6 months	I	10	0.70 ± 0.75	0.25 ± 0.34	0.95	>0.05	NS
		II	10	0.95 ± 1.09				
Clinical attachment loss		I	10	2.25 ± 1.08	0.35±0.57	0.87	>0.05	NS
		II	10	2.60 ± 0.65				
Mean distance from CEJ to alveolar crest	Baseline and 6 months	I	10	0.00 ± 0.00	0.05 ± 0.15	0.16	>0.05	NS
		II	10	0.05 ± 0.15				
Mean defect fill	Baseline and 6 months	I	10	1.64 ± 0.40	0.56±0.40	3.34	<0.01	HS
		II	10	2.60 ± 0.80				

**DISCUSSION**

Regeneration of lost periodontium remains the ultimate goal and to achieve this objective, bone grafts/ substitutes alone or in combination have been tried and studied. Van Meekran in 1668 was first to make an attempt to repair a cranial defect in a Russian soldier with a dog’s skull bone but later was forced to remove the bone graft or else suffer excommunication,<sup>14</sup> later Merrem in 1809 reported the first successful autogenous bone graft.<sup>15</sup> Macewen in 1878 transplanted allogenic bone successfully in clinic patients<sup>15</sup> and Hegedus in 1923 was credited with the first use of bone grafts in periodontal therapy.<sup>16</sup> Hiatt *et al*<sup>17</sup> in a retrospective study based on histologic evaluation of 100 human block sections and extracted teeth from sites treated via bone and marrow autograft and non-graft regenerative procedures and revealed new cementum and bone formation.

Calcium phosphate system are alloplastic grafts materials which are available in different forms viz. hydroxyapatite, fluorapatite and tricalcium phosphate.<sup>5</sup> In the present study selected sites were randomly divided into two groups and were treated according to split mouth design. In Group I BONEGLASS® alone and in Group II BONEGLASS® with VICRYLMESH® was used. BONE-GLASS® is bioceramic hydroxyapatite granules of 300 to 355 microns. Hydroxyapatite

(HA) also referred to as hydroxylapatite is a calcium phosphate bioceramic. It is generally recognized as the natural mineral component of vertebrate hard tissue composing of 60-70% of bone and 98% of dental enamel.<sup>6</sup> It’s chemical formula is Ca<sub>10</sub>(PO<sub>4</sub>)<sub>6</sub>(OH)<sub>2</sub> and has Ca/P ratio of 1.67 which is identical to that of bone mineral.<sup>7</sup>

Probing depth, clinical attachment level and position of gingival margin were measured from fixed point on occlusal stent, which appear to be more reliable than subgingival CEJ readings.<sup>18</sup>

The evaluation of the hard tissue changes after regeneration therapy can be done either by clinical or by radiographic assessment. Clinical measurements require a second surgical intervention which is usually not acceptable to the patient. Furthermore it may cause a disturbance of the new connective tissue attachments which is then replaced by long junctional epithelium.<sup>19</sup> Radiographic assessment provides the non-invasive method for evaluating the changes in hard tissue.

It was observed that both the materials were well tolerated by the patients as no unusual findings with regard to the post-operative healing as well as no sign or symptom of any other allergic manifestation was elicited.<sup>3,4,13,20,21</sup> Our results showed a highly significant (p<0.001) mean PPD reduction and CAL gain in Group I between baseline and 6 months similar to other



studies.<sup>3,20,22-24</sup> Brown *et al.*<sup>22</sup> shows mean value change for GR of approximately similar to the present study (significant,  $p < 0.05$ ) with hydroxyapatite after 6 months. Highly significant ( $p < 0.001$ ) mean defect fill in Group I was observed, but mean change in alveolar crest was not significant.<sup>4,20,24-26</sup> Hydroxyapatite is remarkably biocompatible. The substance has ability to adhere to connective tissues in general and to the bone in particular. Hydroxyapatite provokes little inflammatory responses when implanted within a tissue.<sup>8</sup> Hydroxyapatite biomaterials are generally non-bioresorbable over periods of many years and they dissolve far less readily in a variety of fluids. Cultured human fibroblasts have been demonstrated to attach readily to the surface of calcium phosphate ceramics. Although devoid of any demonstrable osteogenic effects, the chemical nature of calcium phosphate materials is believed to facilitate osseous integration.<sup>9,10</sup> Jahn<sup>11</sup> has suggested that hydroxyapatite acts as an amphoteric ion exchanger. Selective accumulation of calcium and phosphate ions occurs as a consequence of the negative charges on the hydroxyapatite surface. This leads to the formation of more apatite and stimulates the formation of new bone. The excellent bonding between new bone and calcium phosphate implants has been characterized in detail by various investigators.<sup>10,12</sup>

In Group II mean PPD reduction and clinical attachment gain between base line to 6 months was highly significant, ( $p < 0.001$ ). Mean PPD reduction and clinical attachment gain was more for group II as compared to Group I and although, the difference for PPD between the two groups was highly significant after 6 months, but insignificant for CAL. Added advantage of GTR and bone graft for pocket reduction and clinical attachment gain was shown by other studies also.<sup>13,27-34</sup>

Decrease in pocket depth may be attributed to gingival shrinkage alone, gingival shrinkage along with coronal movement of junctional epithelium or gingival shrinkage with closed adaptation of gingival epithelium. Gain in clinical attachment may be due to new attachment and/or formation of long junctional epithelium. Although various studies are available that shows

GTR membrane results in new attachment,<sup>35</sup> however the exact nature of attachment gain and there by probing depth reduction could not be ascertained due to lack of histological findings. Similar to present study, Schallhorn and McClain,<sup>32</sup> Gouldin *et al.*<sup>33</sup> also shows decrease in recession while using GTR membrane alone or GTR membrane along with bone graft. VICRYL-MESH® is resorbable polyglactin 910 knitted mesh which is prepared from a copolymer of glycolide and lactide. Woven mesh is difficult to handle as it has tendency to “fray” whereas knitted mesh is easier to work with and has property of adaptation. Also placing a double layer of the knitted material approximates the smaller pore dimension of the woven material. Since Vicryl is absorbable there is no need for any subgingival irrigation to remove it, as occurs with removal of non-resorbable membranes.<sup>13</sup>

Similar to Bowen *et al.*<sup>36</sup> present study also reported bone repair of 2.1 mm after 6 month. Mean defect fill in Group II cases was more in comparison to Group I and the difference between highly significant ( $p < 0.01$ ). In the present study radiographs taken at 6 months after surgery had shown decrease in depth of defect due to defect fill and this radiographic defect fill was more when both graft and GTR membrane are used. Gager and Schultz<sup>33</sup> in their study also reported increased radiopacity indicative of radiographic fill at 3 and 6 months after surgery. Mean change in alveolar crest in Group I and Group II was  $0 \pm 0$  and  $0.5 \pm 0.15$  mm respectively, which was not significant. Concurrent results which show either resorption or no significant change in alveolar crest by others also.<sup>29,30</sup>

The combination of barrier techniques with bone graft and other methods has been suggested and procedures following these ideas are proposed by several authors.<sup>25,27,28,37</sup> The function of a grafting material in association with GTR is to act as a scaffold to provide and maintain space whenever the membrane may have the possibility to collapse and therefore reducing the chances for periodontal ligament cells to repopulate the previously exposed root surface.<sup>38</sup> Hence, no collapse of vicryl mesh occurs when it is supported by bone graft material.

## CONCLUSION

Within the limits of the study both BONE-GLASS® alone and BONE-GLASS® with VICRYL-MESH® proved to be beneficial in the management of intraosseous defects but more pocket reduction, gain in clinical attachment and defect fill are observed when both materials are used in combination. It is important to emphasize that the data generated by this study derive from 6 months observations only. Hence, the long term studies are suggested to evaluate the efficacy of materials and techniques.

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