Use of Fisiograft in Intrabony Defects- A Clinical and Radiological Study

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ABSTRACT

Aim: To evaluate the efficacy of Polylactic Acid/Polyglycolic Acid (PLA/PGA - Fisiograft®) with Open Flap Debridement (OFD) and OFD alone in the treatment of intrabony defects over a period of 9 months.

Material and Methods: Twenty Nine systemically healthy subjects with total of 30 defects were included in the present, randomized, controlled and two arm parallel study. Tests were treated with OFD along with Fisiograft® and controls with OFD alone.

Results: On intra-group comparison, clinical parameters at 6 and 9 months showed statistically significant results. On comparing between the two groups, the reduction in Defect Specific Bleeding Score (DSBS), Defect Specific Plaque Score (DSPS), Probing Depth (PD) and gain in Clinical Attachment Level (CAL) revealed no statistical significances other than Recession Depth (REC) which was more in controls. The mean radiographic parameters at 9 months post-operatively in both the groups were statistically significant. However, the inter-group comparison revealed no statistically significant values.

Conclusions: The overall results at the end study proved that the adjunctive use of Fisiograft® was not beneficial when compared with OFD alone.

Clinical Significance: Synthetic bone replacement graft materials are commonly used for periodontal regeneration. The present study was conducted by using PLA/PGA reveals no additional benefit over OFD alone in treatment of intrabony defects.

Key words: Fisiograft®, Intrabony defects, Open flap debridement, PLA /PGA

INTRODUCTION

The main aim of any periodontal intervention is the maintenance of the natural dentition in health and to retain its functional state [1]. Conventional periodontal treatment, such as root planing, gingival curettage and scaling are highly effective at cessation of disease progression and leads to formation of long junctional epithelium which is not desirable since, it is vulnerable for breakdown by bacterial re-colonization. To achieve true regeneration [1] in periodontal defects, regenerative materials like bone graft, Guided Tissue Regenerative (GTR) membranes etc have been tried with varying success rates.

Bone grafting is consider to be as regenerative modality, a material or technique must histologically demonstrate that bone, cementum and a functional periodontal ligament can be formed on a previously diseased root surface. Bone grafts and their synthetic substitutes have been used in an attempt to gain this therapeutic endpoint. Among the graft materials to date, only autogenous bone of extra-oral and intra-oral sources [2-4] is considered as the ‘gold standard’ because it provides the three elements required for bone regeneration – osteogenesis, osteoconduction and osteoinduction [5]. However, autografts have been associated with several shortcomings such as, procurement of enough bone material for recipient site. Alternate substitutes are allografts, alloplasts and xenografts which have been used of late [6,7]. Alloplasts are biodegradable, biocompatible inorganic synthetic grafting material. The degradation rates depend on their chemical composition, structure and physical nature [8]. They are broadly classified as ceramics and polymers. Polyomers are further classified as degradable and non degradable [9].

The copolymers of Polylactide (PLA) and Polyglycolic acid (PGA) have already been extensively and successfully used in orthopaedics and crano-maxillo-facial-for more than a decade. The other applications of PLA/PGA in dentistry are surgical sutures, absorbable membranes which are used in guided tissue regeneration [10,11]. Recent years absorbable synthetic biopolymers have been used as bone fillers in periodontology, proving effective stimulants to bone regeneration in some cases [12,13] but still they remain controversial regarding there regenerative potential.

In the present study, PLA/PGA is used as regenerative material in treatment of intrabony defect.

MATERIAL AND METHODS

This study is a prospective, randomized, parallel-arm clinical trial which was carried out in the Department of Periodontology and Oral implantology. The study sample included 30 periodontal intra-bony defects in patients, 15 females and 14 males, aged between 25-50 years who were seeking care for moderate to severe chronic and aggressive periodontitis. They were divided into two groups (test and controls) that consisted of 15 sites each, followed up for a period of 9 months. This study was approved by institutional ethical committee. The inclusion criteria was patients with good general health without any history of systemic disease or compromising medical conditions, clinical and radiographic evidence of periodontal pocket depths more than 5mm. Patients having unacceptable oral hygiene during presurgical phase (phase 1 therapy), gave a history of antibiotics or other medications affecting the periodontium within the previous 6 months, pregnant and lactating females, smokers, third molars, teeth affected by endodontic lesions and/ or inadequate endodontic treatments, overhanging margins or grade III mobility were excluded from study.

Initial therapy (pre-surgical phase) consisted of oral hygiene instructions, thorough full mouth scaling and root planing. Following 6 weeks the patients who showed consistently low level of plaque scores were recruited, randomization was done by using coin toss method. Clinical parameters that is Defect Specific Plaque Score (DSPS), Probing Depth (PD) and gain in Clinical Attachment Level (CAL) revealed no statistical significances other than Recession Depth (REC) which was more in controls. The mean radiographic parameters at 9 months post-operatively in both the groups were statistically significant. However, the inter-group comparison revealed no statistically significant values.
nine months were recorded by using UNC-15. Radiographs were taken by using paralleling cone technique at the baseline and at the end of study.

**Surgical Technique:** Surgical procedure was performed as outpatient basis under aseptic conditions. After administering local anaesthesia, sulcular incisions were given and full thickness mucoperiosteal flaps were elevated.

**Preparation of the site**

On surgical exposure 2-wall and 3-wall defect sites were thoroughly scaled and root planed with both hand and ultrasonic instruments. All granulomatous tissue was removed along with very thin portions of bone, which if not adequately vascularized can become necrotic: therefore, the use of curettes, low speed drills and if necessary bone rongeurs of an appropriate size for obtaining the best possible preparation of the receiving site. All the bone cavity, at the end of the treatment, sufficiently had thick borders and without any irregularities.

The test site [Table/Fig-1] was completely filled by using fisiograft (sponge) to the coronal border of the bone defect. The Sponge is cut by means of a scissor or sterile scalpel into fragments with a dimension appropriate for the receiving site. This technique was applied for small pieces, in order to make the graft more malleable it can be hydrated with blood or saline, the fragments were lightly packed by using a cylindrical or ball shaped compactor, until it was completely filled.

Flaps were replaced and closed by using 3-0 black silk interrupted sutures. Periodontal dressing was given with COE-Pack®. Controls were treated with same technique as mentioned above but without using graft [Table/Fig-2].

Post-operative care included 0.2% 10ml chlorhexidine gluconate rinse three times daily for a period of 6 weeks. Sutures were removed after two weeks of surgery. Antibiotics amoxicillin 500 mg, metrogyl 400 mg T.I.D for 7 days were prescribed along with analgesic to be used as per required.

Follow up and plaque control was done on the 14th and 30th day respectively. Periodic recall visits were scheduled at 3, 6 and 9 month interval. At these visits, professional oral prophylaxis was done if necessary and oral hygiene instructions were reinforced.

**Radiographic assessment**

The percentage of bone fill in radiographs was assessed using a software, Corel Draw [Table/Fig-3-6] with the help of the formula stated below.

A. Pre-Operative intrabony component (Value A) =
\[
\frac{CEJ \text{ to Bone depth} - CEJ \text{ to Alveolar crest}}{CEJ \text{ to Root apex}} \times 100
\]

B. Post-Operative intrabony component (Value B) =
\[
\frac{CEJ \text{ to Bone depth} - CEJ \text{ to Alveolar crest}}{CEJ \text{ to Root apex}} \times 100
\]

C. Amount of bone fill = Value A – Value B

Total percentage of bone fill = \[
\frac{\text{Amount of bone fill}}{\text{Preoperative intrabony component}}
\]

**STATISTICAL ANALYSIS**

All the data collected was analyzed using SPSS® software. Intra-group comparison was done by using ANOVA test*. The independent t test was used to compare the inter-group changes at various time intervals of the study.

**RESULTS**

The DSPS, DSBS, PD reduction and CAL gain observed no significant differences other than REC seen more in controls compared to tests [Table/Fig-7-9].

**Amount of defect fill**

The amount of defect fill in both groups from baseline to 9 months was statistically significant (p<0.05). The percentage defect fill at nine months post-surgery was 36.933 ± 24.697 and 46.800 ± 30.086 in control and test group respectively. But on comparing the two groups there was no statistical difference in mean percentage defect fill [Table/Fig-10].

[Table/Fig-1]: Elevation of flap using Kirkland technique and placement of fisiograft mesial to 26 (test site)

[Table/Fig-2]: Elevation of flap using Kirkland technique showing intrabony defect in relation to 26 (control site)

[Table/Fig-3]: IOPA at nine months along with measurements done using corel draw in relation to 46 (test site)

[Table/Fig-4]: IOPA at baseline showing intrabony defect along with measurements done using corel draw in relation to 46 (test site)

[Table/Fig-5]: IOPA at baseline showing intrabony defect along with measurements done using corel draw in relation to 26 (control site)

[Table/Fig-6]: IOPA at nine months along with measurements done using corel draw in relation to 26 (control site)

<table>
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<th>Group</th>
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<td>Clinical Attachment level</td>
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<tr>
<td>Defect specific bleeding score</td>
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<td>1.000 ± 0.000</td>
<td>1.000</td>
</tr>
<tr>
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<td>Defect specific plaque score</td>
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<td>Test</td>
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</table>

**Table/Fig-7**: Various parameter - control and test group – Base Line

**Table/Fig-8**: Various parameter - control and test group – Base Line

**Table/Fig-9**: Various parameter - control and test group – Base Line

**Table/Fig-10**: Various parameter - control and test group – Base Line

**Table/Fig-11**: Various parameter - control and test group – Base Line
DISCUSSION

On considering various bone grafting materials used in the treatment of intrabony defects, biomaterials/bone substitutes have been used with varying success rates to accomplish the re-construction of the lost periodontal attachment apparatus. Resorbable synthetic polymers have been developed by the biomedical research over the last decades among them PLA/PGA has been used as an osteoconductive material both medical and dental fields.

It is a low density copolymer of polylactide-polyglycolide, displays a good handling properties during the surgery; degradation occurs through “bulk erosion” by hydrolysis in a period ranging from 3 to 6 months, depending on the host factors, location of implanted material and degree of circulation of the area. The small mass and large surface area of Fisiograft® permit fibroblasts to easily penetrate and initiate its absorption and cell colonization of the material that is implanted. In addition the spongy structure does not provide any hindrance to the advancing osteocytes, there bone formation and mineralization.

The present study aims at evaluation of the regenerative potential of the Fisiograft® in treating intrabony periodontal defects. So far, to the author's knowledge three clinical trials [14-16] have been done using various forms of Fisiograft® in intrabony defects showing contradictory results.

On comparison, our study results correlate with the Minnena et al., study [14] which showed no significant changes in clinical parameters, CAL gain and PD reduction among the groups at the end of the study period, however gingival margin position showed statistically significant apical shift in controls, whereas Minnena reported no significant differences in recession depth among groups [Table/Fig-7-9]. The study results are in contrast with studies of Stratul et al., [15] and Bansal et al., [16].

On radiographic examination the amount of defect fill in controls and tests showed no significant changes at 9 months which is in accordance with Minnena et al., [14] and contrast to Straul et al., [15] and Bansal et al., study [16] [Table/Fig-10].

Bertoli et al., [17] compared fisiograft with autogenous graft and Platelet Rich Plasma (PRP) in the treatment of human osseous defects and fisiograft showed statistically significant results over 6 months but promotes delayed bone healing.

On further comparing the results with similar studies by using polymers Yuka et al., [18] showed the use of HTR in treatment of intrabony defects gave superior results over OFD alone. The use of HTR polymer once again proved to be an effective regenerative material in Prakash et al., study [19] showing significant results over OFD alone.

In a comparative study by Meadows [20], the use of Polyactic Acid (PLA) in intrabony defects did not prove effective over OFD alone with Decalcified freeze dried bone allograft and OFD alone.

Systematic review on graft materials and their biological agents by Trombelli et al., [21]. PLA granules when used as intrabony defects showed no significant results over other graft biomaterials in CAL gain and PD reduction when compared to OFD procedure.

CONCLUSION

The synthetic copolymer used in this study did not prove to be efficacious regenerative material. The clinical and radiological parameters on intergroup comparison did not give any statistically significant results however, gingival margin showed greater apical shift in controls.

The material was biocompatible as it did not show any inflammatory changes in any subject of the test group. Overall, the results in this study indicated a limited adjunctive effect of biodegradable polymer in periodontal reconstruction procedure.

The limitations of the study are small sample size and to add more authenticity to the study, histological examination would have been done to evaluate regeneration in both groups.

### REFERENCES

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