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"COMPARATIVE EVALUATION OF COPOLYMERIZED POLY LACTIC ACID (PLA) AND POLYGLYCOLIC ACID (PGA) FISIOGRAFT® GEL IN THE TREATMENT OF PERIODONTAL INTRAOSSEOUS DEFECTS: A CLINICO-RADIOGRAPHIC STUDY"

Periodontology

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ABSTRACT

BACKGROUND: The primary goal of periodontal treatment is the maintenance of natural dentition in health and function. Present study was under taken to evaluate the efficacy of PLA-PGA copolymer(Fisiograft®) gel in the treatment of infra-bony defects as compared with open flap debridement alone.

METHODOLOGY: Ten patients, aged 25-50 years with moderate to severe periodontitis. Two or more sites with ≥5 mm probing depth(PD), radiographic evidence of intra-osseous defects on opposite sides were selected. One defect was treated with Fisiograft® gel(Test), other with open flap debridement alone(Control). At baseline, 3, 6, & 9 months clinical parameters and radiographs were evaluated and statistically analysed.

RESULTS: Study exhibited statistically no significant difference with both treatment modalities with all clinical parameters and radiographically with the defect fill.

CONCLUSION: This study showed use of copolymer(Fisiograft®) gel did not provide additional benefits over open flap debridement.

KEYWORDS

Bone Grafts, Infrabony Defects, Periodontitis

INTRODUCTION:

Periodontitis is a chronic disease frequently of bacterial origin involving loss of supporting tissues of the teeth. The goal of periodontal therapy is the regeneration of lost tissue. Conventional periodontal therapy includes removal of the etiologic agents and diseased tissues through scaling and root planning and surgical flap therapy which helps in arresting the progression of periodontal diseases.[1] Currently, periodontal surgery requires use of bone grafts to provide structural support during healing of bone and to replace damaged or diseased tissue.[2] The use of osseous grafting materials such as autografts, allografts and xenograft in treatment of periodontitis has shown success and found to be effective in reconstruction of periodontal attachment apparatus, although each has drawbacks. The use of autografts prolongs the treatment time and sometimes requires additional surgical site to obtain the volume of graft material to fill periodontal defect and may lead to patient discomfort. Allografts present disadvantages of additional expenses and transmission of diseases. Many alloplastic grafting materials have been used in periodontal surgical therapy with varying degree of success. [1] Most of the synthetic materials as biodegradable polymers especially those belonging to the family of polylactic acid (PLA) and polyglycolic acid (PGA), are playing an increasingly important role in bone reconstructive procedures. Which are osteoconductive[3] materials available in powder, sponge and gel.[4] It is extensively studied in orthopaedics and in oral and maxillofacia1 surgery.[5,6] In recent years, this material is used for regeneration of bone around implants,[2] for sinus lift procedures[7] and in extraction sockets, which are close analogous of intrabony periodontal osseous defects. Therefore, attempt is made to evaluate & compare the regenerative efficacy of Fisiograft® gel, copolymer of PLA-PGA and open flap debridement in the treatment of infrabony periodontal defects.

MATERIALS & METHODS:

Ten patients aged 25-50 years reporting to Department of Periodontics A.B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangalore with moderate to severe periodontitis, two or more sites showing periodontal osseous defects in different quadrants with attachment loss ≥6mm which exhibit clinical and radiographic evidence of infrabony defects were included. Subjects having systemic disease, on antibiotic therapy, previous periodontal surgery within 12 months, smoking, endodontically treated teeth, and poor oral hygiene were excluded from the study.

A duly signed informed consent of all patients were obtained and instructed about plaque control measures and subjected to scaling and root planning. For standardisation a customized acrylic stent was fabricated for each patient,[8] for reproduceable clinical measurements. A split mouth was designed as it allows determination of superiority of the treatments and statistics.[9] Two of the bilateral defects were randomly selected as Site I-(test) flap debridement with use of alloplastic bone graft material Fisiograft gel Site 2-(control) open flap debridement only.

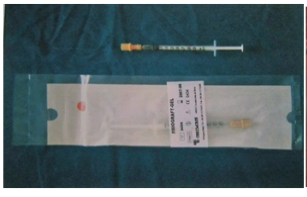
Clinical Parameters includes Plaque Index (Sillness and Loe), Gingival Index (Loe and Sillness), Probing Depth (PD)[10,11] — it is recorded by measuring from reference point (RP) to t Base of the pocket (BP) minus reference point to gingival margin (GM). PD = (RP to BP) – (RP to GM), Clinical attachment level (CAL)[11] measured from RP to BP minus RP to Cementoenamel junction (CEJ). CAL= (RP to BP) — (RP to CEJ). All the clinical parameters were measured at baseline, 3,6, & 9 months.

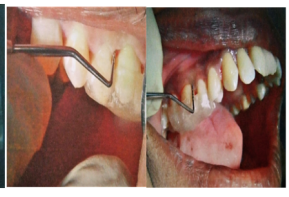
Surgical procedure:

Sites selected were randomly designated as test or control. Following local anaesthesia, full thickness mucoperiosteal flap is reflected, debridement and saline irrigation was done. The control sites were then sutured with 4-0 silk sutures. The test sites were treated in the same manner. However, following debridement of the root and bone defect, Fisiograft gel(pictrue1) was utilized to fill the defects to the most coronal level of osseous walls and care was taken not to overfill the defect. Sutures were placed to obtain primary closure (picture2-4). A periodontal dressing was placed on surgical area. Postoperative antibiotics and analgesics were prescribed for 7 days and oral hygiene instructions were given. Sutures were removed after 7 days.

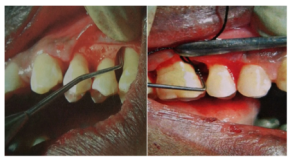
Intra oral periapical radiographs were taken using long cone paralleling technique. Radiographs were obtained in a reproducible plane using film holders, film grids were used to measure amount of bone fill[12](picture5). Radiographs were evaluated at 6 and 9 months postoperatively. Bone defect depth was measured at baseline,6 months and 9 months, as distance from alveolar crest to base of the bone defect. Amount of defect fill was calculated as the difference between initial and postsurgical defect depth thereafter percentage of defect fill was calculated (picture6-8). The data obtained were subjected to statistical analysis. The Wilcoxon singed ranks test was used to compare the results between test and control groups.

Site 1 site 2

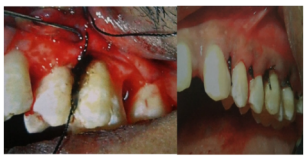




PICTURE1: Fisiograft Gel **PICTURE 2:Probing depth**

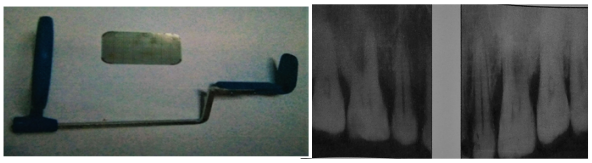


PICTURE3: Osseous defect



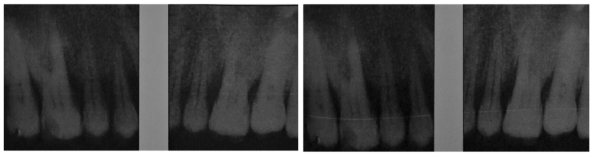
PICTURE4: Fisiograft gel in the defect & sutures plced

SITE 1 SITE 2



PICTURE5: Film holder & Grid

PICTURE 6: Baseline



PICTURE7: At 6 months

PICTURE8: At 9 months

RESULTS:

This study included ten patients with two or more sites showing periodontal osseous defects on contra lateral sites. Of which, four patients did not follow-up. The healing phase progressed uneventfully. No signs of inflammation, infection, and/or allergy were noted. The data obtained were compiled and statistically analysed. For all the parameters, subject mean was basis for statistical analysis.

Plaque index:

No statistical significant difference exists in the mean values for the plaque index between the test and control group at baseline (p=0.564), 3months (p=0.157), 6 months (p=1.000) and nine months(p=1.000). (Table-1)

TABLE – 1: Plaque index – between site1(test) & site2(control) at baseline, 3 months, 6 months & 9 months

	N	MEAN±SD	Z	P
Baseline s1	6	0.875±0.262	-0.577[a]	0.564
Baseline s2	6	0.833±0.258		
3 months s1	6	0.958±0.368	-1.414[a]	0.157 N.S
3 months s2	6	0.7917±0.3680		
6 months s1	6	0.9583±0.1882	0.000[b]	1.000 N.S
6 months s2	6	0.960±0.290		
9 months s1	6	0.7917±0.1882	0.000[a]	1.000 N.S
9 months s2	6	0.792±0.188		

a) Based on positive ranks.
b) The sum of negative ranks equals the sum of positive ranks.
c) Wilcoxon signed ranks test.

Gingival index:

There is no significant difference in the mean values for gingival index between test and control group at baseline (p=0.564), 3months (p=1.000), 6 months (p=1.000) and nine months(p=0.655). (Table-2)

TABLE – 2: Gingival index – between site1(test)& site2(control) at baseline, 3 months, 6 months & 9 months

	N	Mean±SD	Z	P
Baseline s1	6	0.750±0.1581	-0.577[a]	0.564
Baseline s2	6	0.7917±0.1882		
3 months s1	6	0.6667±0.1291	0.000[b]	1.000 N.S
3 months s2	6	0.667±0.303		
6 months s1	6	0.750±0.224	0.000[b]	1.000 N.S
6 months s2	6	0.750±0.158		
9 months s1	6	0.7500±0.1581	-0.447[c]	0.655 N.S
9 months s2	6	0.708±0.188		

a) Based on positive ranks.
b) The sum of negative ranks equals the sum of positive ranks.
c) Based on positive ranking.
d) Wilcoxon signed ranks test.

Probing depth:

The intra group comparison of probing depth in test and control group at baseline, 3, 6 & 9 months, were significant. However, no statistical significant difference was noticed in the mean values for probing depth between the test and control group at baseline (p=0.739), 3months (p=0.221), 6 months (p=0.141) and nine months(p=0.141). (Table-3)

TABLE – 3: Probing depths – between site1(test) & site2(control) at baseline, 3 months, 6 months & 9 months.

	N	Mean±SD	Z	P
PD-0 S1	6	7.83±0.75	-0.333[a]	0.739
PD-0 S2	6	8.00±1.67		
PD-3 S1	6	5.17±0.98	-1.225[a]	0.221 N.S
PD-3 S2	6	6.17±1.72		
PD-6 S1	6	4.17±0.75	-1.473[a]	0.141 N.S
PD-6 S2	6	5.33±1.51		
PD-9 S1	6	3.83±0.75	-1.473[a]	0.141 N.S
PD-9 S2	6	5.00±1.55		

a) Based on positive ranks.
b) Wilcoxon signed ranks test.

Clinical attachment level:

The intra group comparison of clinical attachment level in the test and control group at baseline, 3, 6 & 9 months,were significant. However, no statistical significant difference was noticed in the mean values for clinical attachment level between the test and control group at baseline (p=0.480), 3months (p=0.285), 6 months (p=0.223) and nine months (p=0.223). (Table-4)

TABLE – 4: Clinical attachment level – between site1(test) & site2(control) at baseline, 3 months, 6 months & 9 months.

	N	Mean±SD	Z	P
CAL-0 s1	6	5.83±0.75	-0.707[a]	0.480
CAL-0 s2	6	6.17±1.47		
CAL-3 s1	6	4.50±2.26	-1.069[a]	0.285 N.S
CAL-3 s2	6	5.50±1.97		
CAL-6 s1	6	3.83±1.72	-1.219[a]	0.223 N.S
CAL-6 s2	6	5.33±2.16		
CAL-9 s1	6	3.17±2.14	-1.219[a]	0.223 N.S
CAL-9 s2	6	4.67±2.34		

a) Based on positive ranks.
b) Wilcoxon signed ranks test.

Amount of bone fill:

The intra group comparison of percentage of bone fill in the test and control group at baseline to 6 months & baseline to 9 months, were significant. However, no statistical significant difference was noticed in mean values percentage of bone fill between test and control group at baseline (p=1.000), 6 months (p=0.279) and nine months (p=0.461). (Table-5)

TABLE – 5: Percentage of bone fill – between site1(test) & site2(control) at baseline, 6 months & 9 months.

	N	Mean±SD	Z	P
Baseline s1	6	0.00	0.000[a]	1.000
Baseline s2	6	0.00		
6 months s1	6	34.783±31.684	-1.084[b]	0.279 N.S
6 months s2	6	19.50±16.25		
9 months s1	6	40.375±26.859	-0.736[b]	0.461 N.S
9 months s2	6	27.83±24.96		

a) The sum of negative ranks equals positive ranks.
b) Based on positive ranks.
c) Wilcoxon signed ranks test.

The alveolar crest resorption was compared between the test & control group at baseline, 6 months and 9 months the p value obtained were 0.257 & 0.257, were not significant. (Table-6)

TABLE –6: Alveolar crest resorption – between site1(test) & site2(control) at baseline, 6 months & 9 months.

	N	Mean±SD	Z	P
Baseline s1	6	0.00	0.000[a]	1.000
Baseline s2	6	0.00		
6 Months s1	6	0.33±0.52	-1.134[b]	0.257 N.S
6 Months s2	6	0.83±0.75		
9 Months s1	6	0.33±0.52	-1.134[b]	0.257 N.S
9 Months s2	6	0.83±0.75		

a) The sum of negative ranks equals positive ranks.
b) Based on negative ranks.
c) Wilcoxon signed rank tests.

DISCUSSION:

The aim of regenerative periodontal therapy is to reconstruct the lost periodontal tissues.[13] Deep intrabony defects present a major challenge in achieving this goal, as it increases the risk of disease progression and recurrence after traditional periodontal therapy.[14] The current trend in periodontal surgery is to use technique that conserves periodontal tissue and increase the potential for healing. The ideal result of periodontal surgery would be regeneration of periodontal ligament attached to new cementum and regenerated bone thus achieving a return to the original anatomical relationship.[15] The use of bone graft for reconstructing osseous defects produced by periodontal disease dates back to Hegedus (1923) and was reviewed by Nabers and O'Leary (1965). Since then, number of techniques have been used for regeneration.

Historically autogenous and allografts have been used with some success with certain disadvantages like, additional surgical site, increase chair time and disease transmission has driven the market to produce biocompatible alternatives to allografts.[16] Various Inorganic synthetic graft materials are available for regeneration. Recent reviews regarding these materials have showed significant improvements in probing depth and clinical attachment levels and bone fill in human intra-osseous defects and crestal bone level.[14,17,18] However, synthetic graft materials function primarily as biocompatible defect filler.[19] Polylactic acid (PLA) and polyglycolic acid (PGA) is a commercially available synthetic copolymer as Fisiograft® is biocompatible, well tolerated, completely absorbed and degraded in Krebs cycle forming carbon dioxide and water as final metabolic by products. PLA-PGA copolymer used in patients with periodontal, post extraction and implant pathologies. Studies were conducted with clinical and radiological controls. PLA-PAG copolymer was used in all three forms, sponge, powder and gel. The radiological analyses were done every three months for one year showed progressive filling of the defect in the patient that had undergone periodontal procedure, extractions and implants. [2] The copolymer of PLA-PGA was used to fill defect around the implant. The radiographic follow up was done postoperatively immediately up to 7 months showed complete bone filling at the time of second exposure. [20] Histological investigation of Fisiograft® PLA-PGA copolymer used as filler for bone defects in human biopsies of sinus lifts where Bio-Oss and Fisiograft® gel were applied as graft material. Bone regeneration was satisfactory in all sinus lifts.[7] Different biomaterial used for sinus augmentation for the placement of implant. Nine biomaterials were used one of which was Fisiograft®. All implants were stable and radiographic examination showed dense bone around the implants. All the biomaterials examined were biocompatible and seemed to improve new bone formation in maxillary sinus lift.[21] Acellular dermal matrix allograft (Alloderm) in combination with PLA/PGA (Fisiograft®) around immediate implants, the combination technique between the bone graft and the membrane proved to be successful to overcome dehiscence and osseous defects around immediate implants.[22] Sponge form of Fisiograft® was used as a graft material and compared with open flap debridement alone for the treatment of intraosseous defects, Fisiograft® showed better results in terms of both clinical as well as radiographic assessment.[23] Long-term outcome of resorbable PLA-PGA bone fixation of maxillary and mandibular osteotomies showed near or complete bone fill by 18months postoperatively.[5] Clinical outcome of reconstructive surgery in human deep intra bony defects were evaluated with the use of PLA-PGA copolymer graft verses open flap debridement. However, the use of PLA-PGA did not provide an additional benefit in terms of clinical attachment level gain and probing depth reduction compared with open flap debridement.[24] The efficacy of Polylactic Acid/Polygycolic Acid (PLA/PGA -Fisiograft®) with Open Flap Debridement (OFD) and OFD alone in the treatment of intrabony defects over a period of 9 months was evaluated, the overall results at the end study proved that the adjunctive use of Fisiograft® was not beneficial when compared with OFD alone.[25] Our study compared soft tissue and hard tissue changes with the use of flap and alloplastic graft material, Fisiograft® gel, versus that of open flap debridement alone in the treatment of periodontal intra osseous defects. Assessment of all the clinical parameters PI, GI, PD & CAL was done at baseline, 3 months, 6 months and 9 months and percentage of defect fill and alveolar crest resorption at 6 months and 9 months radiographically. The plaque and gingival indices showed no significant differences between the test and control groups. Similarly, within the test and control groups differences between the values at various time intervals were not significant, the results could be due to the lack of improvement in home care. The results of this study showed that there was a marked reduction in the probing depth in both test and control sites from baseline to 9 months. However, there was no statistical significant difference in probing depth reduction between the control and test site. Although, there was statistically significant gain in the attachment level from baseline to 9 months in both test and control sites. However, there was no statistically significant difference between test and control sites. This result is in agreement with study done by Minenna L.[24] Healing of the bone defect is combination of bone fill and alveolar crest resorption. The percentage of bone fill and crestal bone loss at 6 and 9 months was not statistically significant between test and control sites.

CONCLUSION:

The pathological hallmark of periodontitis is the destruction of the supporting structures of the teeth. At present, bone replacement grafts are one of the modalities of therapy for which there is histologic evidence in humans, of regeneration of new bone, cementum and periodontal ligament coronal to the base of the previous osseous defect. Within the limitations of our study it can be presumed that adjunctive use of Fisiograft® gel did not offer any advantage over open flap debridement, this outcome is might be because of small sample size, flowability and transparency of the graft material used However, further studies using large sample are needed to determine the efficacy of Fisiograft® gel alone or in combination with other bone graft, as a bone substitute material in the regeneration of periodontal intra-osseous defects.

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