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Efficacy of gelatin sponge vs beta tricalcium phosphate as regenerative materials in periodontal intra bony defects - An interventional clinical and radiological

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Abstract

Context: Periodontitis causes a plethora of bone defects. Amongst them vertical or angular bone defects are more suitable for regenerative periodontal therapy. Many materials have been utilized for periodontal regeneration with moderate success. Amongst the newer regenerative materials, absorbable gelatin sponge (Abgel) and ß tri calcium phosphate have been implicated in a few studies to aid regeneration.

Aims: To compare the therapeutic efficacy of absorbable gelatin sponge Vs beta tri calcium phosphate in intra bony defects of patients with periodontitis.

Settings and Design: It was a randomized parallel arm interventional clinical trial undertaken in the outpatient ward, department of periodontics of a tertiary referral care centre in Hyderabad.

Methods and Material: The samples were 22 patients equally split into groups A and B. After Nonsurgical periodontal therapy, the clinical parameters were re-examined and the patients under Group A were treated with conventional flap surgery using abgel for the defects after debridement, whereas Group B patients were treated with conventional flap surgery and application of beta tricalcium phosphate in the defects after debridement. The

study was approved by the Institutional ethical committee (PERIO/DN/0174-17). Informed consent was taken at the start of the study and it was registered. (CTRI/2018/12/016741)

Statistical analysis used: IBM SPSS statistic 20.0 was utilised for the study. Descriptive statistics, Friedman's test, Wilkoxon's test, Mann Whitney test were applied.

Results: Both test groups showed good improvement in periodontal parameters postoperatively at 3 months,6months and 9 months respectively, within the groups, ($p<0.01$). Nonetheless on intergroup comparison the results were not significant statistically.

Conclusions: Both test groups were effective in improving clinical, radiographic parameters, when used in intra bony defects. However, studies, employing a bigger sample size to be applied.

Keywords: Intra bony defects, Abgel, β tri calcium phosphate, CBCT

Key Messages: Newer regenerative materials like abgel and β tricalcium phosphate proved to be beneficial in intrabony defects. Longitudinal studies however, are mandatory to assert their efficacy when used as monotherapy.

Introduction

Periodontitis a disease prevalent worldwide, happens because of a discord in the relationship of the microorganisms with the host.[1] The treatment protocol for this disease includes implementation of phase I therapy initially. But in cases wherein there are intra bony defects and involvement of the furcations of multirooted teeth, it becomes mandatory that regenerative periodontal surgical procedures must be done. Many regenerative materials are effective to treat defects of such magnitude. Alloplasts, though synthetic have shown promise as regenerative materials, and a lot of work has been done using ß tricalcium phosphate for the same. However, the use of abgel in intra bony defects has not been examined. Hence this study was done to understand if abgel could be employed as a graft in intra bony defects and to compare its effects with that of ß tricalcium phosphate.

Material and Methods

To achieve a difference of 1.37 mm in the defect depth, post operatively between the test groups with error probability of 0.05 and power of 85%, it was decided that 22 samples would suffice for participation in the study. This study analyzed the treatment outcome of the intra bony defects both clinically (UNC-15 Probe) and radiologically (Cone beam computed tomography-CBCT). Patients aged between 25 -50 years having pocket probing depth ≥ 5mm with relative clinical attachment loss ≥3mm and Intra bony defects ≥3mm participated in the study. Patients who had undergone treatment six months prior, pregnant and lactating mothers, noncompliant patients, patients with known allergic conditions and systemically compromised subjects did not participate in the study. Investigator KRR screened and randomly allocated the patients in sealed envelopes into Group A and Group B. Investigator TS performed the surgeries. (Fig 1)

Text

Clinical parameters assessed were the Gingival index (GI), Plaque index (PI), Pocket probing depth (PPD), Relative clinical attachment level (RCAL) and gingival recession (GR). The patients were examined at baseline, 6months and 9months after periodontal surgery. The clinical examination was done using a customized stent and University of Carolina (UNC-15) probe. The radiographic assessment involved CBCT which was analyzed pre and 9 months postoperatively. All the radiographic examinations were done by the same investigator.

The primary outcome assessed was the defect fill whereas GI, PI, PPD, RHCAL and GR where the secondary outcomes assessed. The participants underwent phase I

therapy and were given instructions on both mechanical and chemical plaque control. They were examined 8 weeks after the phase I therapy to finalize their participation in the surgical protocol. The site to undergo surgery was anaesthetized using local anesthetic (2%Lignocaine HCL with 1:80,000 Adrenaline). A no 15 Bard parker blade was used to give the crevicular and interdental incision. The muco-periosteal flap was then reflected with the help of a periosteal elevator, and the necrotic tissue was debrided from the defect site using gracey curettes by investigator TS. After debridement, the area was thoroughly irrigated with 0.9% normal saline. For the sites allotted under Group A absorbable gelatin sponge was placed (Ab gel 80 mm x 50 mm x10 mm, manufactured by Shri Gopala Krishna Labs Pvt Ltd, Mumbai, India) and for the sites allotted under Group B, beta tri calcium phosphate (SYBOGRAF-T 200-300 Microns particle size, manufactured by Eucare Pharmaceuticals (P) Ltd, Chennai, India) was placed The flaps were then secured with interrupted sutures using 3-0 black silk suture material and periodontal dressing was given.

All the patients received appropriate antibiotics (Amoxicillin 500mg thrice a day for five days) and analgesics (Aceclofenac 100 mg thrice a day for five days) after post-operative instructions. The post-operative care included chlorhexidine gluconate rinses (0.12%) twice a day for 2 weeks. After 2 weeks the sutures were removed, and the patients were instructed to brush with a soft type of toothbrush. The oral hygiene was reinforced, and clinical parameters were reassessed at 3 and 6months postop.

Results

The clinical parameters PI, GI, PPD and RHCAL, showed an improvement from baseline to 6 months and 9 months within both the test groups A and B which was statistically significant ($p < 0.001$). However, pertaining to the GR in both the test groups no change was noticed ($p=0.368$), (Table 1). When a comparison was made between the groups, pertaining to the clinical parameters it was observed that there was no difference which could be measured statistically (Table 2).

The defect length and defect width at baseline in Group A was 5.07±1.24 and 3.21±0.62 respectively (Fig1) whereas in group B the defect length and defect width at baseline was 4.71±0.59 and 2.96±0.46 (Fig 3). Postoperatively after 9 months the defect length and width in group A was 3.02±0.83 and 2.88±1.16 (Fig 4) and in group B the defect length and width after 9 months was3.37±0.79 and 2.45±0.65 (Fig 5). Though there was an improvement in defect length and width from baseline to 9 months within the groups (Table 3) on intergroup comparison the results were not statistically significant. (Table 4)

Discussion

Periodontitis is a chronic inflammatory disease and as the disease progresses it is quite often observed that dual action of both the micro-organisms and exaggerated host response causes a plethora of defects, among which the angular or intra bony have shown promising results with regenerative therapy.[2] We are familiar with the one walled or hemi septal defects, the two walled or crater like defects and the three walled or saucer shaped defects which happen as the disease progresses. The best prognosis is in three wall defects as they have a substrate for graft placement and retention, which favors the regenerative cascade of events to follow. [3]

Some researchers reported that intra bony defects occurred more in the lower molars than the upper. They also stated that there is an Increase in the frequency of bone loss with increasing age.[4] The diagnosis of periodontal disease has been aided by manual probes like the William's probe, Naber's probe, UNC-15 probe. These probes have been

designed with markings in millimeters to help in measurement of the periodontal parameters. The drawback of using manual probes is the inter examiner variability due to differences in the angulation, force applied, by individuals when measuring periodontitis. To overcome this limitation some researchers fabricated stents which had vertical grooves made, guiding in accurate probe placement and ensuring reliability and reproducibility for future comparisons.[5]

Clinical parameters like PPD and RCAL were measured by UNC-15 probe using the acrylic stent for standardization. Defects in the bone however could not be assessed by manual probes, this is where the radiographs helped immensely.

Conventional radiographs can diagnose bone defects only when more than 60% has been affected and therefore newer imaging techniques like Computed tomography (CT), Cone beam computed tomography (CBCT) have been introduced. CBCT has the potential to allow precise assessment of bone defects caused by periodontal disease. It can show the structures in axial images, summation of which facilitates the interpretation of the structures in 3D format.[6]

Some authors in their study evaluated the bone defects by comparing the images taken by a periapical radiograph and CBCT on lower molar teeth. The CBCT images were more precise as they showed the depth of furcation involvement as well as bone loss around the distal root, which could not be deciphered on the intraoral radiograph. It was stated that CBCT is a valuable tool in diagnosing periodontal defects.[7]

Other researchers stated that CBCT was very precise in the determination of periodontal defects with a good accuracy in measuring the vertical depth of the defect. CBCT was utilized in this study to diagnose intra bony defects as well as to assess their improvement after regenerative therapy. [8]

Treatment of intra bony defects has been done using various grafts. Though autografts and allografts have the best regenerative potential, clinicians have tried using xenografts and alloplasts as well. Absorbable gelatin sponge (AbGel) is a water-insoluble material of porcine source. This hemostatic device has supportive and mechanical properties. The sponginess of the gelatin hastens clot formation and stabilization. Platelets make up a huge portion of a blood clot and function as a reservoir of natural growth factors essential for tissue healing and regeneration. Thereafter, several growth factors such as bone morphogenetic protein (BMP), platelet derived growth factor (PDGF), and transforming growth factor beta TGF-ß may aid in bone regeneration.[9]

Abgel was used as a graft material in a study wherein the authors observed that the blood clot gets immobilized with absorbable gelatin sponge fragments. Moreover, the slow degradation of the gelatin sponge, helped in the controlled release of growth factors from the clot, which maximized wound healing in the periodontal defects.[10]

Some researchers performed a study on 25 patients requiring surgical removal of bilateral impacted mandibular wisdom teeth and placement of graft distal to the second molar. The surgical sites were randomly divided into two 2 groups, group1 received hydroxyl apatite +collagen, and group2 received Gelatin sponge (AbGel). Patients were recalled on 1st and 7th postoperative days and 3rd and 6th postoperative month. It was observed that the soft tissue wound healing, as well as bone levels improved better in group 1(HA+collagen) when compared to group 2(AbGel). [11]

Another study was done wherein abgel was placed in teeth affected by severe periodontitis treated using three different surgical protocols namely open flap debridement,

intentional tooth replantation (IR) and ridge augmentation. It was observed that there was good alveolar bone regeneration in all the three surgical procedures with no evidence of ankylosis on radiological examination. [12]

In another study abgel was used as a carrier for harvested autologous periodontal ligament stem cells (PDLSCs)in regeneration of intrabony periodontal defects bypassing ex vivo culture. The PDLSCs adherent to the root of an extracted wisdom tooth were used to restore another intrabony defect of a molar in the same patient. One-year follow-up revealed 6 mm of gain in the attachment level. The percentage of the defect fill was 44.5% and there was a change in radiodensity of the defect area, suggestive of improvement in newly formed bone. [13]

Yet another study evaluated the effect of abgel mixed with hydroxyapatite and β tricalcium phosphate in socket preservation after distal root resection of an endodontically treated mandibular molar tooth. After six months it was observed both clinically and radiologically that the defect fill was good, and the tooth was functional. [14]

In this study also it was observed that patients administered abgel after open flap debridement, showed a statistically significant improvement in the clinical parameters as well as the defect length from baseline to 9 months within the group. (Table 1 and table 3).

Sybograft-T resorbable tissue replacement granules are less than 10 µm in diameter. This property facilitates the colonization of the graft by osteoblasts. Thus, this material has been used often for maxillofacial procedures.[15]

Some other authors stated that the beta-tricalcium phosphate is a synthetic ceramic bone graft material which has been used successfully in orthopedics, periodontology and maxillo-facial surgery. [16]

Yet another study assessed Inter proximal bony defects of 25 patients who were treated with open flap debridement and placement of Hydroxyappatite and biphasic calcium phosphate. Improvement in the clinical parameters and the defect fill were assessed 6 months post-surgery. It was observed that HA-ßTCP (biphasic calcium phosphate) provided an added regenerative effect in promoting the clinical resolution of intra bony three-wall defects in patients with periodontitis.[17]

Another study was conducted on 24 sites in 12 patients wherein one side (A) was treated with Bioabsorbable membrane+ Autogenous bone graft (as graft material) and the other side (B) was treated with ß tricalcium phosphate + Autogenous bone graft (as graft material) .Clinical parameters like PI, PPD, CAL and Gingival recession were recorded at baseline and after1, 3,6,12 months along with radiography to evaluate defect fill. The results obtained showed that ß Tricalcium phosphate+ Autogenous bone graft (B)was slightly better, in comparison to Bioabsorbable membrane+ Autogenous bone graft (A) although statistically not significant.[18]

One more study was done on ten patients with bilateral interproximal bony defects which were treated with either platelet rich plasma in combination with ßTCP or ßTCP alone. PI, GI, PPD, CAL was assessed at baseline and 6 months after surgery. It was observed that both therapies resulted in significant PPD reduction, CAL gain and it was inferred that PRP with ßTCP does not have additional improvements when compared with ßTCP alone after 6 months follow up.[19]

In this study there was a marked improvement in both the clinical and radiological parameters from baseline to 9months, in patients who were administered ßTCP after open flap debridement (Group B) (Table1andTable 3). However, a comparison between both the test groups pertaining to both outcome measures did not yield statistically significant results. (Table 2 and Table 4).

Limitation: This study was not a split mouth design and the sample size was not large. Moreover, the follow up period in this study was 9 months only.

Conclusion

Both modalities of treatment (AbGel and ßTCP) were effective in improving clinical, radiographic parameters, and regenerative outcomes when used in human intra bony defects. Nevertheless, studies, employing bigger samples should be employed to emphasize the efficacy of each of these regenerative materials when used alone.

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Legend Tables

Group	Variable	Baseline		6 Months		9 Months		Chi square value	P value	Post hoc analysis
		Mean	SD	Mean	SD	Mean	SD			
Group A	PI	3.21	0.72	2.09	0.57	1.34	0.39	20	<0.001**	1>2>3
	GI	1.18	0.32	0.56	0.34	0.16	0.10	20	<0.001**	1>2>3
	PPD	8.10	1.60	5.80	1.48	4.30	1.25	20	<0.001**	1>2>3
	CAL	6.10	1.60	3.70	1.57	2.30	1.25	20	<0.001**	1>2>3
	GR	0.40	0.70	0.30	0.48	0.30	0.48	2	0.368NS	-
Group B	PI	3.07	0.74	2.00	0.44	1.54	0.24	20	<0.001**	1>2>3
	GI	1.19	0.32	0.71	0.23	0.35	0.20	20	<0.001**	1>2>3
	PPD	8.70	1.42	5.80	1.23	3.60	0.70	20	<0.001**	1>2>3
	CAL	6.70	1.42	3.90	1.20	1.60	0.70	20	<0.001**	1>2>3
	GR	0.30	0.67	0.20	0.42	0.20	0.42	2	0.368NS	-

**P<0.05 statistically significant,NS-Not significant;SD-Standard deviation; PI-Paque Index; GI-Gingival Index;PPD-Probing pocket depth;CAL-Clinical attachment level;GR-Gingival Recession

Table 2 : Intergroup Comparison of Clinical Parameters

Time interval	Variable	Group A		Group B		Mann Whitney U	P value
		Mean	SD	Mean	SD		
Baseline	PI	3.21	.72	3.07	0.74	44.50	.68NS
	GI	1.18	.32	1.19	0.32	48.50	.90NS
	PPD	8.10	1.60	8.70	1.42	45.00	.70NS
	CAL	6.10	1.60	6.70	1.42	45.00	.70NS
	GR	0.40	.70	0.30	0.67	45.50	.65NS
6 Months	PI	2.09	.57	2.00	0.44	49.50	.97NS
	GI	0.56	.34	0.71	0.23	31.50	.15NS
	PPD	5.80	1.48	5.80	1.23	50.00	1.00NS
	CAL	3.70	1.57	3.90	1.20	46.50	.79NS
	GR	0.30	.48	0.20	0.42	45.00	.61NS
9 Months	PI	1.34	.39	1.54	0.24	33.50	.21NS
	GI	0.16	.10	0.35	0.20	22.50	.02*S
	PPD	4.30	1.25	3.60	0.70	34.50	.21NS
	CAL	2.30	1.25	1.60	0.70	34.50	.21NS
	GR	0.30	.48	0.20	0.42	45.00	.61NS

*P<0.05 Statistically significant, SD-Standard deviation; NS-Not Significant;S-Significant; PI-Paque Index; GI-Gingival Index;PPD-Probing pocket depth;CAL-Clinical attachment level;GR-Gingival Recession;

Table 3: Intragroup Comparison of Radiological Parameters

Group	Variable	Baseline		9 Months		z	p value
		Mean	SD	Mean	SD		
Group A	D-LENGTH	5.07	1.24	3.02	0.83	-2.8	0.01**
	D-WIDTH	3.21	0.62	2.88	1.16	-1.78	0.07NS
Group B	D-LENGTH	4.71	0.59	3.37	0.79	-2.8	0.01**
	D-WIDTH	2.96	0.46	2.45	0.65	-2.8	0.01**

**P<0.05 Statistically Significant,NS-Not Significant,SD-Standard deviation;D-Length-Defect length;D-Width-Defect width;

Table 4: Intergroup Comparison of Radiological Parameters

Time interval	Variable	Group A		Group B		Mann Whitney U	P value
		Mean	SD	Mean	SD		
Baseline	D-LENGTH	5.07	1.24	4.71	0.59	48.50	.91NS
	D-WIDTH	3.21	.62	2.96	0.46	36.50	.31NS
9 Months	D-LENGTH	3.02	.83	3.37	0.79	37.00	.32NS
	D-WIDTH	2.88	1.16	2.45	0.65	36.00	.29NS

*P<0.05 Statistically significant,NS-Not Significant,SD-Standard deviation; D-Length-Defect length;D-Width-Defect width

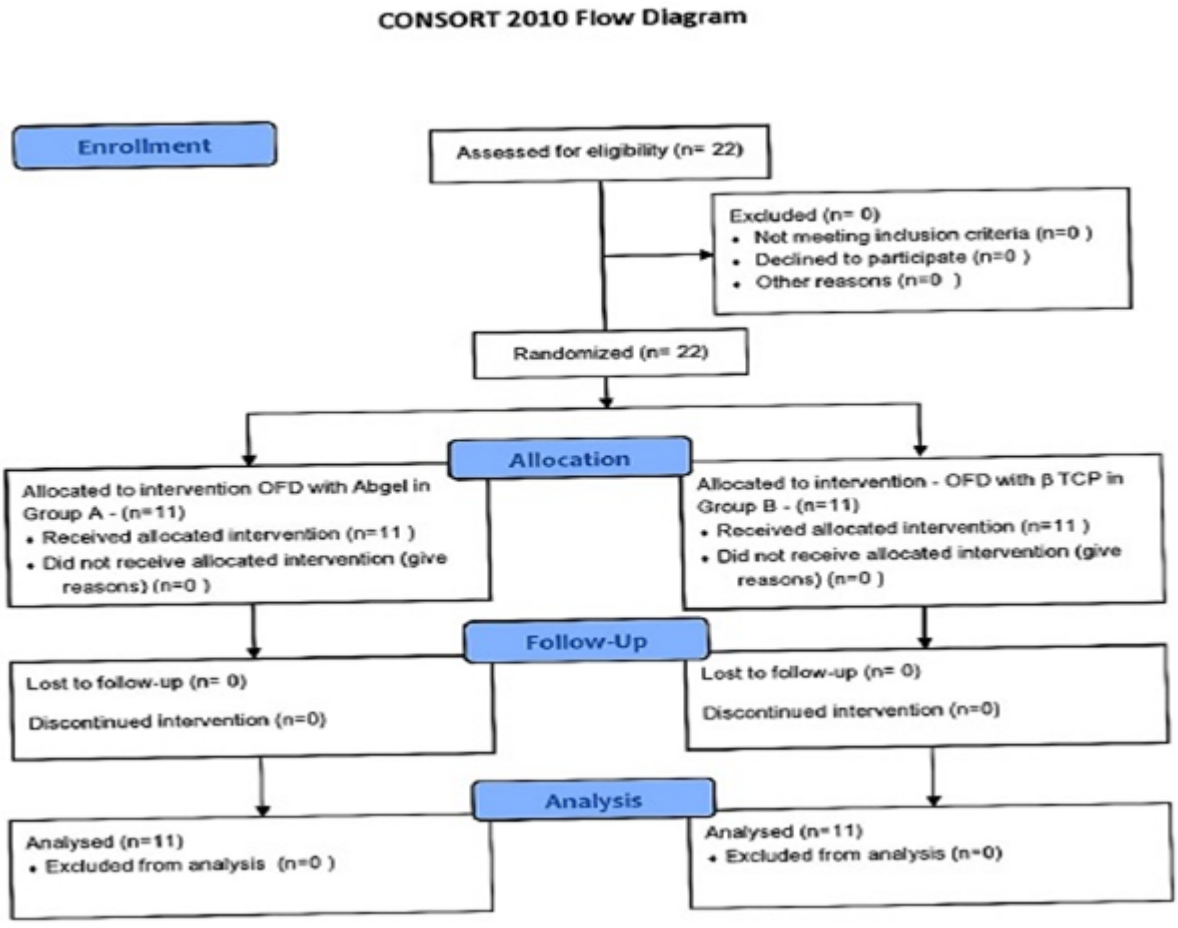

Figure 1: Consort flow diagram

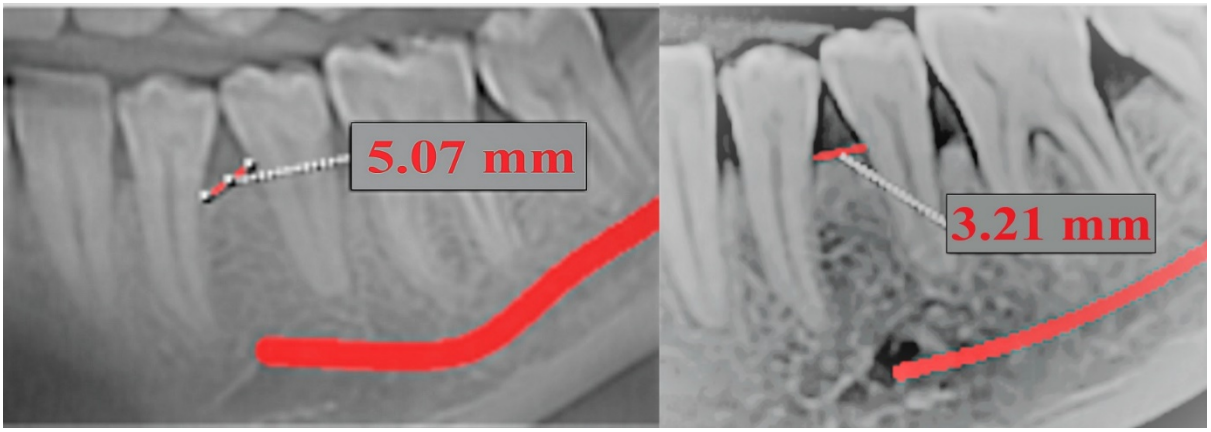

Figure 2: Radiological findings at baseline in group A

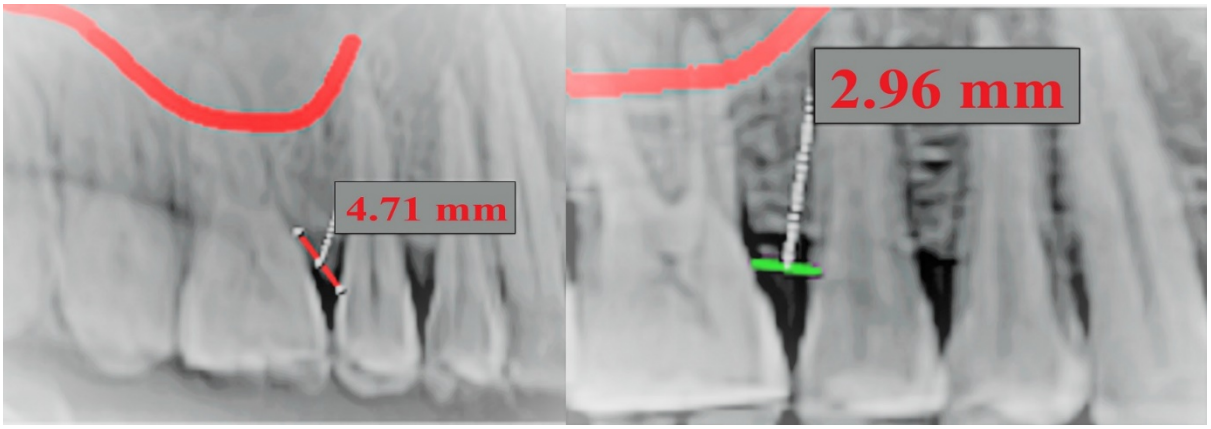

Figure 3: Radiological findings at baseline in group B.

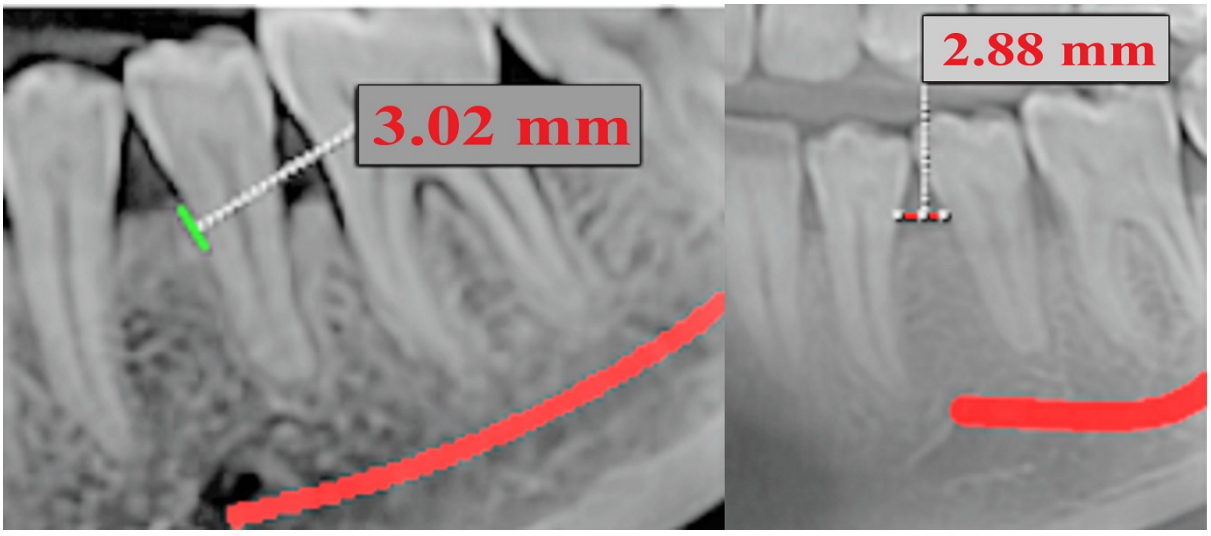

Figure 4: Radiological findings at 9 months in group A.

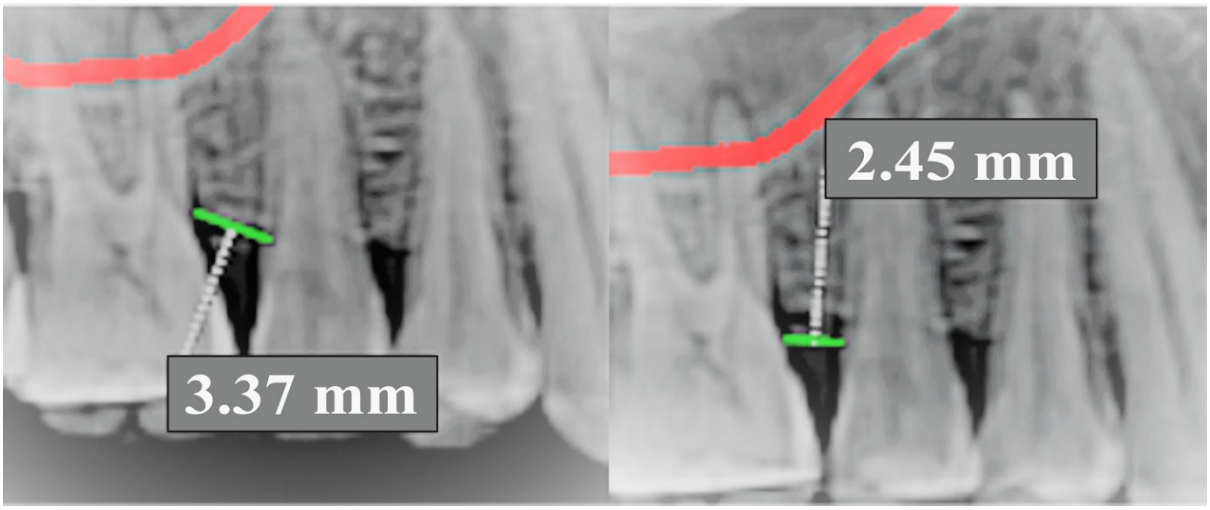

Figure 5: Radiological findings at 9 months in group B.