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Original Research Article

Evaluation of concentrated growth factor as an adjuvant on crestal bone levels around dental implants

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ABSTRACT

Background: Dental implants have a long-term success rate when the osteointegration is maintained with minimal crestal bone loss yearly. The present study evaluates the crestal bone loss around Osseointegrated implants using a concentrated growth factor as an added factor to preserve the crestal bone levels.
Methods: Total of 20 patients with a single edentulous site were included in the study and divided into test and control groups. Test group concentrated growth factor is placed along with implant, and the control group implant placed without concentrated growth factor. Soft tissue parameters like modified sulcus bleeding index (mSBI) and modified plaque index (mPI) were done three and nine-month after implant placement. Hard tissue parameters like crestal bone levels (CBL), bone density, and volume were done immediately after implant placement and nine-month of implant placement using cone-beam computed tomography (CBCT).
Results: Intragroup comparison from baseline to nine-month in the test group showed a significant difference at nine months at different points compared to the control group in hard and soft tissue parameters. On intergroup comparison was statically insignificant.
Conclusions: Concentrated growth factor aids in enhancing bone density and faster healing around dental implants, so it can be used as an advancement in personalized medicine and promoting osseous regeneration by increasing the density and volume of bone around the dental implants.

Keywords: Concentrated growth factor, Bone density, Modified sulcus bleeding index, Modified plaque index

INTRODUCTION

Dentistry has been upgraded with varieties of technologies to replace the missing tooth. Apart from multiple options like a removable partial denture, fixed partial denture, and complete denture, dental implants made their way to improvise the form, function, and restoration of aesthetics at the edentulous site.[1] crestal bone levels are essential for implant survival after loading. Usually, a minimum of 1.5 mm of crestal bone loss and 0.2 mm of crestal bone loss after one year of loading is usual and physiologically acceptable.[2] However, crestal bone loss of more than 1.5 mm due to some disturbances in the prosthesis, occlusal forces, traumatic surgical procedures, minimal tissue thickness leads to failure of osseointegration around implants.[3] There are many routes to preserve the crestal bone levels around dental implants such as platform switching, multiple implants for load sharing, preoperative preparation for accurate placing implant in position and

angulation, soft tissue and hard tissue augmentation before implant placement in inadequate soft and hard tissue around the edentulous site.[4] Many adjuvants have been used to minimize crestal bone loss around the dental implant. Biologic ways to preserve crestal bone levels using platelet concentrates like platelet-rich plasma, platelet-rich fibrin, and its various forms. The concentrated growth factor is new generation platelet concentrate has rich growth factors with fibrin network.[5] As far as now, few studies used concentrated growth factor in periodontal intrabony defects and dental implants but no studies evaluated crestal bone loss, bone density, and bone volume around conventionally two-stage dental implant placement. The present study evaluates the effectiveness of the concentrated growth factor and its unique properties that enhance the osseointegration and maintain bone volume and density and soft tissue healing around conventionally two-stage dental implants.

METHODS

This prospective clinical study was done in a government dental college and hospital, Vijayawada between November 2019 and July 2020. Ethical committee approval from Dr. NTR University of health and sciences was obtained. All the subjects are signed in their informed consent before the procedure. All subjects referred to the department of periodontics and implantology in the government dental college were recruited. The sample size was estimated based on a previous study with 95 percent power.20 subjects were enrolled and divided into test and control groups. Patients aged between 20-55 years, partially edentulous patients with missing teeth in the maxillary and mandibular posterior region, patients with good general health, and patients with good oral hygiene were included in the study. Uncontrolled diabetes, pregnancy, poor oral hygiene, alcoholic patients, patients on bisphosphonate drugs, psychiatric problems, severe bruxism and clenching, and active infection or severe inflammation at the proposed implant site were excluded from the study.

Study design

The implant system used for the study was the 'Myriad dental implant' system. The patients were randomly selected using a computer-generated randomization table and divided into two groups: “Test” (10 patients): Dental implants placed with CGF application. “Control” (10 patients): Dental implants placed without CGF application

Pre-operative work up

Detailed case history and clinical examination were carried out on all patients. Impressions of upper and lower arches were taken, and casts were fabricated with dental stone. Preoperatively cone beam computed tomography (CBCT) was taken to assess bone quality and quantity and locate the anatomical structures.

Preparation of concentrated growth factor (CGF)

Under aseptic conditions, around 10ml of whole venous blood was collected from patients in a sterile vacutainer tube of 10ml without anticoagulant. The vacutainer tube was then placed in the centrifugal machine with one step centrifugation protocol: 30 sec-acceleration, 2 min-2700 rpm, 4 min-2400 rpm, 4 min-2700 rpm, 3 min-3000 rpm, 36 sec-deceleration, and stop (Figure 1).[6]

Surgical procedure

A single preoperative dose of 1gm oral Amoxicillin is given to the patient before surgery. All the surgical procedures were performed under local anesthesia (2% lignocaine HCl with 1:80,000 adrenaline). A pre-procedural 1 min 0.2% chlorhexidine rinse was given to each patient. Implants used in this study were bone-level titanium implants with a diameter of 3.3 mm, 3.8 mm, 4.5 mm, and 5.7 mm and lengths of 8 mm, 9.5 mm, 11 mm,13 mm and 15 mm. Under aseptic conditions, a full-thickness mucoperiosteal flap was raised and reflected after giving a crestal and sulcular incision with a B.P blade. Considering the surgical stent as a guide, a lance drill was used to establish depth and align the long axis of the implant recipient site. Then a series of drills 2.0 mm, 3.3 mm, 3.8 mm, 4.5 mm, and 5.7 mm in diameter whereas in length 8.0 mm, 9.5 mm, 11.0 mm, 13.0 mm, and 15.0 mm in a sequential manner were used to prepare the osteotomy site. Implants were then placed into the site. In the study, group implants were placed after CGF placement and the control group without CGF. CGF is a gel-like material compressed with the implant and flows towards crestal bone level (Figure 2). In both groups, flaps were approximated and sutured using 3-0 non-absorbable sutures after placing cover screws.

Post-operative care

Amoxicillin 500 mg (3 times a day) was continued for 5-7 days; Ibuprofen 400 mg was prescribed three days post-surgery. Instruction for good oral hygiene measures was also given. Patients were instructed to rinse with 0.2% chlorhexidine twice daily for two weeks. Further advice included adhering to a soft diet and avoiding trauma to the gingival tissue at the implant site, especially in the first few weeks. The patient was advised to take immediate postoperative CBCT to evaluate crestal bone levels.

Follow-up visits

Suture removal was scheduled 1 week after. Patients were then scheduled for a follow-up visit 3 and 9 months after surgery. Implants were functionally loaded by the end of the third month. Postoperative CBCT took after 9 months to evaluate crestal bone level (Table 1).

Prosthetic procedure

At the end of the third month, surgical re-entry was done under local anesthesia; the cover screw was exposed and removed. A healing cap was then placed for 2 weeks. After that, the impression was made using silicone rubber base material to fabricate a working cast then the final restoration of porcelain fused to metal was fabricated and cemented on the abutment (Figure 3).

Table 1: Visits and follow ups of the patients.

Visits		Procedure
Visit I	Presurgical visit	Modified plaque index, modified sulcular bleeding index, scaling and root planning, oral hygiene instructions, pre-operative CBCT
Visit II	Baseline (0)	Surgical procedure, oral hygiene instructions, immediate post-operative CBCT
Visit III	1 week after implant placement	Suture removal at surgical site, record any adverse event, oral hygiene instructions
Visit IV	3 months after implant placement	Modified plaque index, modified sulcular bleeding index, scaling and root planning, prosthesis placement, record any adverse event, oral hygiene instructions
Visit V	9 months after implant placement	Modified plaque index, modified sulcular bleeding index, record any adverse event, scaling and root planning, oral hygiene instructions, post-operative CBCT

Clinical parameters

Modified Plaque Index and modified Sulcus Bleeding Index were calculated at postoperative intervals of 3 months, 6 months, and 9 months. The evaluation of soft tissue was done with a graduated plastic periodontal probe. Radiographic bone measurements were done with cone beam computed tomography. The CBCT is made with the Classic i-CAT® apparatus (Imaging Sciences International®, Hatfield, PA, USA) with an amorphous silicon flat-panel detector type with the following set of parameters: 120kVp, 5mA, 20 seconds scan, and FOV of 16 cm (width), 13 cm (height). For measuring crestal bone loss, after activating the "Measurement mode" in CS 3D Imaging Software, two reference points, one at the implant-bone first contact point and the second at the apical end of the implant, were marked.

Figure 1: concentrated growth factor obtained after centrifugation.

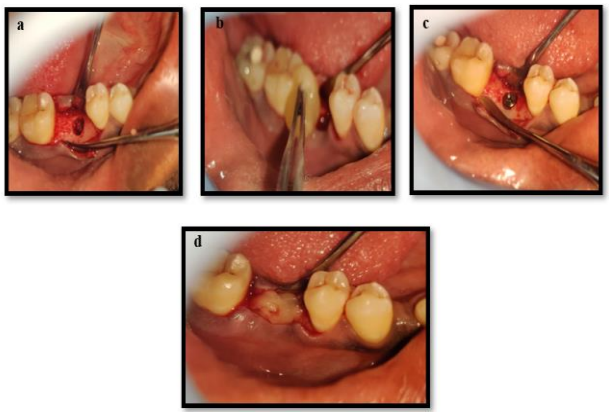

Figure 2: (a) Osteotomy site is prepared with drills, (b) concentratetd growth factor is placed in the osteotomy site, (c) implant placement done along with cover screw, (d) concentrated growth factor on crestal bone after implant placement.

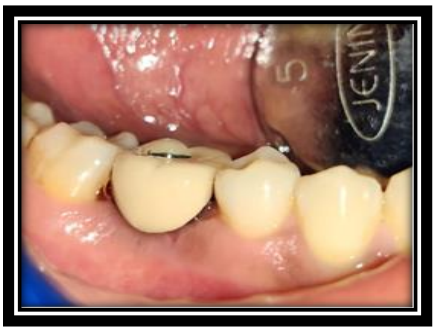

Figure 3: Prosthesis given after 3 months of implant placement.

The distance available between the two mentioned reference points was noted. This was repeated immediately and after nine months of implant placement, and bone loss was calculated at each interval (Figure 4). Volumetric radiographic measurements around the implant were done with cone beam computed

tomography using fixed reference points: cementoenamel junction, root apex of adjacent teeth, and apex of the placed implant. The bone volume was measured around the implant by using the volumetric analysis tool in INVIVO 5.3 Software (Figure 5). Bone density was measured at three measurement regions of the grey values: apical (1), middle (2), and cervical (3). The values were registered from a distance of 2 mm from implant in a spot diameter of 1 mm (Figure 6).

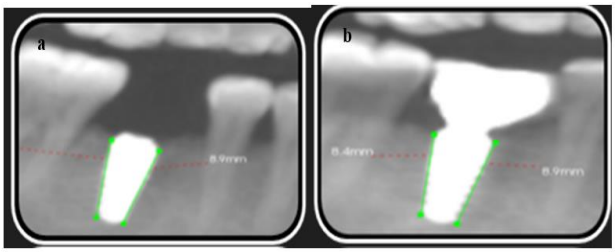

Figure 4: (a) Measuring crestal bone level on mesial and distal aspect of implant at baseline (immediately after implant placement) through CBCT, (b) measuring crestal bone levels on mesial and distal aspect of implant at 9 months of placement through CBCT.

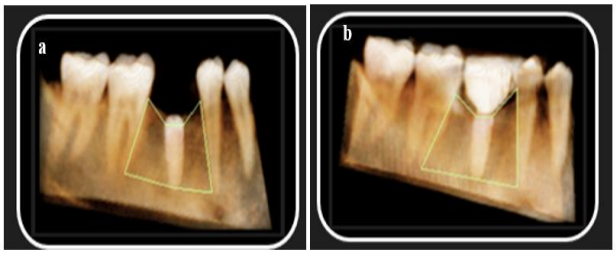

Figure 5: (a) Measuring bone volume around implant at baseline through CBCT, (b) measuring bone volume around implant at 9 months of implant placement through CBCT.

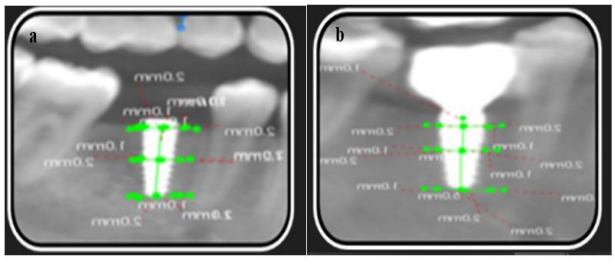

Figure 6: (a) Measuring bone density around implant at baseline through CBCT, (b) measuring bone density around implant at 9 months of implant placement through CBCT.

RESULTS

Demographic details of the study participants is given in (Table 2). In the test group mean crestal bone loss difference from baseline to nine months was 0.51±0.27 mm (mesial) and 0.51±0.42 mm (distal).

Table 2: Demographic data.

Group	Male	female	Age range (years)
Test	5	5	25-35
Control	5	5	27-37

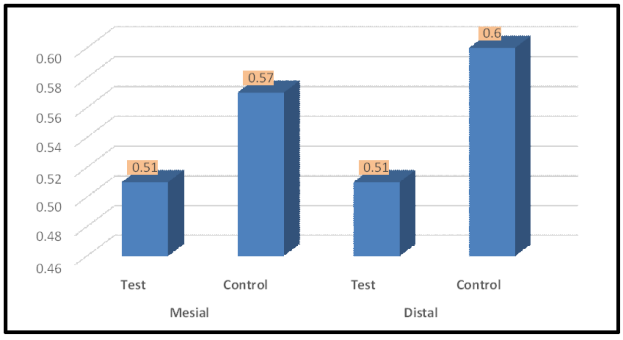

Figure 7: Intergroup comparison of crestal bone levels between the test and control group.

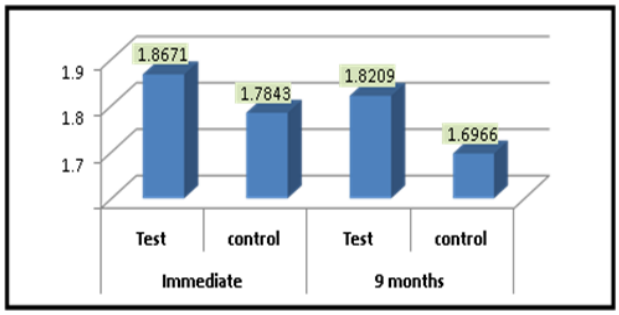

Figure 8: Volumetric bone level comparison between the test and control group.

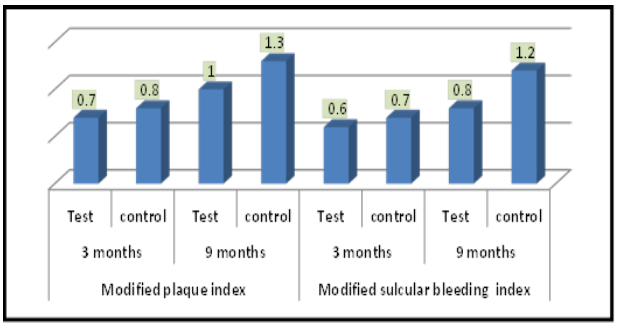

Figure 9: Comparison of modified plaque index and sulcular bleeding index scores between the study groups at different time points.

The control group was 0.57±0.18 mm (mesial) and 0.60±0.23 mm (distal). There was a reduction in crestal bone levels from baseline to nine months in both the test (p=0.754) and control (p=1.000), which was statistically insignificant.

Table 3: Inter group comparison of crestal bone loss between the test and control groups.

Surface	Group	Mean (mm)	Standard deviation	Mean±SD (mm)	P value
Mesial	Test	0.5100	0.27669	0.06±0.09	0.578
	Control	0.5700	0.18886		
Distal	Test	0.5100	0.42804	0.09±0.19	0.566
	Control	0.6000	0.23094		

Table 4: Volumetric bone level comparison between the test and control group.

Groups		Mean (cc)	Standard deviation	Mean±SD (cc)	P value
Immediate	Test	1.8671	0.43914	0.08±0.22	0.242
	Control	1.7843	0.21239		
9 months	Test	1.8209	0.49657	0.14±0.21	0.161
	Control	1.6966	0.21619		

Table 5: Comparison of modified plaque index and modified sulcular bleeding index scores between the study groups at different time points.

Parameter	Groups	Time points	Mean	Standard deviation	Mean±SD	P value
Modified plaque index	3 months	Test	0.7000	0.42164	0.1±0.06	0.628
		Control	0.8000	0.48305		
	9 months	Test	1.0000	0.47140	0.3±0.01	0.044
		Control	1.3000	0.48305		
Modified sulcular bleeding index	3 months	Test	0.6000	0.51640	0.1±0.03	0.660
		Control	0.7000	0.48305		
	9 months	Test	0.8000	0.42164	0.4±0	0.048
		Control	1.2000	0.42164		

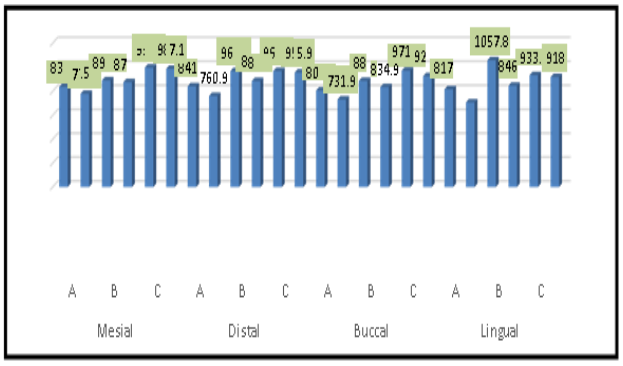

Figure 10: Comparison of bone density between the test and control group based on the area of at 9 months.

On intragroup comparison, Crestal bone loss was slightly higher in the control group than in the test group (Table 3, Figure 7). On an intergroup comparison, the mean crestal bone loss difference between the test and control groups for mesial and distal was 0.06±0.09 mm and 0.09±0.19 mm, respectively. The control group had slightly higher crestal bone loss than the test group, which was not statistically significant in both mesial (p=0.578) and distal (p=0.566), respectively (Table 3). On an intergroup comparison, the mean bone volume from baseline to nine months was 0.08±0.22 cc and 0.14±0.21 cc in both groups. There was a reduction in volumetric bone levels in both test (p=0.242) and the control group (p=0.161) from baseline to nine months and was not statistically significant. However, the control group demonstrated a slightly higher bone volume reduction compared to the test group (Table 4, Figure 8). The mean value of the Modified plaque index at three and nine months in the test group was 0.7±0.42 and 1.0±0.47, and in the control group was 0.8±0.48 and 1.3±0.48, respectively. Plaque index values among the control group were found to be statistically significant (p=0.005) (Table 5, Figure 9). The mean value of the Modified sulcus bleeding index (mSBI) at three and nine months in the test group was 0.60±0.51 and 0.80±0.42, and the control group was 0.70±0.48 and 1.20±0.42, respectively. Significantly better modified sulcus bleeding index scores were found in the test group for three months (p=0.660) and nine months (p=0.048) follow-up (Figure 9). In the present study Statistical comparison of bone density from baseline to 9 months at different points and different surfaces in both the study groups revealed non-significant differences. But the bone density was higher in test group compared to control after 9 months of implant placement (Table 6, Figure 10).

Table 6: Comparison of bone density between the test and control group based on the area of at 9 months.

Area	Point	Time point	Mean	Standard deviation	P value
Mesial	A	Test	836.60	140.51	0.037
		Control	779.50	139.91	
	B	Test	890.60	101.84	0.050
		Control	875.80	103.67	
	C	Test	997.30	91.19	0.048
		Control	987.10	110.10	
Distal	A	Test	841.50	142.95	0.016
		Control	760.90	97.11	
	B	Test	967.90	358.23	0.027
		Control	885.60	126.16	
	C	Test	968.40	118.17	0.044
		Control	955.90	142.22	
Buccal	A	Test	806.50	134.67	0.036
		Control	731.90	103.79	
	B	Test	887.00	144.30	0.034
		Control	834.90	124.51	
	C	Test	971.70	107.09	0.028
		Control	925.80	123.11	
Lingual	A	Test	817.40	128.32	0.031
		Control	707.40	67.79	
	B	Test	1057.80	469.12	0.019
		Control	846.00	94.53	
	C	Test	933.70	120.28	0.035
		Control	918.00	100.73	

DISCUSSION

Several studies have evaluated the crestal bone levels around dental implants with or without adjuvants. To the best of our knowledge, no studies report using concentrated growth factor alone to evaluate the crestal bone loss, bone volume, and density using cone-beam computed tomography. In the test group mean crestal bone loss difference from baseline to nine months was 0.51±0.27 mm (mesial) and 0.51±0.42 mm (distal). The control group was 0.57±0.18 mm (mesial) and 0.60±0.23 mm (distal). There was a reduction in crestal bone levels from baseline to nine months in both the test (p=0.754) and control (p=1.000), which was statistically insignificant. On intragroup comparison, Crestal bone loss was slightly higher in the control group than in the test group (Table 3, Figure 7). The results obtained were similar to the study by Hehn et al and Hafez et al.[7,8] On an intergroup comparison, the mean crestal bone loss difference between the test and control groups for mesial and distal was 0.06±0.09 mm and 0.09±0.19 mm, respectively. The control group had slightly higher crestal bone loss than the test group, which was not statistically significant in both mesial (p=0.578) and distal (p=0.566), respectively (Table 3, Figure 7). This is maybe because CGF contains autologous osteo inductive platelet growth factors and an osteoconductive fibrin matrix. It plays a significant role in the cellular events of bone regeneration and healing. Platelet-derived growth factor (PDGF), Epidermal growth factor (EGF), and transforming growth factor-beta (TGF-β) present in CGF which act on fibroblast, osteoblasts, mesenchymal stem cells that induces angiogenesis, collagen biosynthesis and stimulating new granulation tissue formation. Results were in accordance with Boora et al.[9] On an intra-group comparison, the mean bone volume of the test group from baseline to nine months was 1.86±0.43 cc and 1.82±.0.49 cc, and in the control group, 1.78±0.21 cc and 1.69±0.21 cc, respectively. The result is statistically insignificant in both the test group (p=0.485) and the control group (p=0.00). Bone volume values were better in the test group when compared to the control group (Table 4, Figure 8). On an intergroup comparison, the mean bone volume from baseline to nine months was 0.08±0.22 cc and 0.14±0.21 cc in both groups. There was a reduction in volumetric bone levels in both test (p=0.242) and the control group (p=0.161) from baseline to nine months and was not statistically significant. However, the control group demonstrated a slightly higher bone volume reduction than the test group (Table 4, Figure 8). This may be due to the basic fibroblast-derived growth factor (BFDGF) and vascular endothelial growth factor (VEGF) present in CGF, which accelerates neo-vascularization in soft and hard tissues and potentially induces new bone formation. Vascular endothelial growth factor (VEGF) was one and a half times more in CGF than PRF enhanced cell proliferation of fibroblasts, endothelial cells, and osteoblasts involved in angiogenesis, tissue remodeling, and regeneration. These findings are similar to the study conducted by Abbas Ahmed et al. [10] The results of the present study were in contrast to the study done by Yang et al and Shetty et al.[11] In this study, soft

tissue parameters are the mPI and mSBI given by Mombelli et al recorded at intervals of three and nine months.[12] The mean value of the Modified plaque index at three and nine months in the test group was 0.7±0.42 and 1.0±0.47, and in the control group was 0.8±0.48 and 1.3±0.48, respectively. Plaque index values among the control group were statistically significant (p=0.005) (Table 5, Figure 9). The results obtained are similar to the study done by Anand et al and were in contrast with the study done by Isle et al.[13,14] The mean value of the Modified sulcus bleeding index (mSBI) at three and nine months in the test group was 0.60±0.51 and 0.80±0.42, and the control group was 0.70±0.48 and 1.20±0.42, respectively. Significantly better modified sulcus bleeding index scores were found in the test group for three months (p=0.660) and nine months (p=0.048) follow-up. The results obtained were similar to studies by Avula et al.[15]

Modified sulcus bleeding index can be considered a clinical indicator for the absence or presence of inflammation. There was no suppuration detected during the follow-up period. Decreased incidence of gingival inflammation can be attributed to the application of CGF as it has platelet, leucocyte, and growth factor-rich fibrin biomaterial and elevated CD34-positive cells in vascular maintenance, neovascularisation, and angiogenesis. The mean value of the Modified sulcus bleeding index in the study group compared to the control group is less at the end of nine months. It was observed that the mean value of both mPI and mSBI parameters was increased from three months to nine months in both the study groups. Still, the difference was statistically significant only in the control group. The test group exhibited better Modified sulcular bleeding index scores than the control group after nine months of implant placement. results were in contrast with a study done by Ghonima.[16] Primary implant stability is directly proportional to bone density, which describes the amount of bone tissue in a particular bone volume. Bone density measurements around implants were calculated at three different points on mesial-distal and buccal-lingual sides. This is in accordance with Hasan et al in which density was measured at three measurement regions of the grey values: apical (1), middle (2), and cervical (3).[17] The values were registered in a spot diameter of 1 mm at a distance of 2 mm from the implant. In the present study Statistical comparison of bone density from baseline to 9 months at different points and different surfaces in both the study groups revealed non-significant differences. But the bone density was higher in test group compared to control after 9 months of implant placement (Table 6, Figure 10). This may be because Insulin-like growth factor (IGF-1) and Bone morphogenic protein (BMPs) that are abundantly present in CGF increase the viability of cartilage grafting and induce new bone and cartilage formation directly or indirectly. PDGF (platelet-derived growth factor) and Transforming growth factor-beta (TGF-β) are especially known to ameliorate tensile strength and callus formation, benefiting soft tissue and bone healing. The results were in accordance with Gulsahi et al and Manoj et al.[18,19] The improvement in clinical parameters and bone level in the experimental group suggests the effectiveness of CGF on crestal bone levels. These results may be attributed to the contents, namely fibrin, platelets, leukocytes, growth factors, and cytokines. The fibrin matrix plays an essential role in four highly specific aspects of healing, i.e., neoangiogenesis, immune control, harnessing the circulating stem cells and wound protection by the epithelial cover.[20]

Limitations

Limitations of current study were; limited number of study participants, implant stability was not evaluated, long-term follow-up studies on a larger sample of patients are needed, nevertheless, more studies and clinical trials are needed to investigate the potential application of CGF in dental implant surgery.

CONCLUSION

The present study uses the concentrated growth factor around dental implants because of its superior composition, clinical efficacy, consistency, and Substantivity. By observing the results obtained in the current study, it concludes that the concentrated growth factor is significantly better in improving bone density around the dental implants when compared with the non-concentrated growth factor group. Although concentrated growth factor showed improved bone mineralization, there are no substantial differences in crestal bone levels between the two groups from baseline to nine months. Considering this data, the application of concentrated growth factor could be used in cases where bone density and volume are compromised. However, evidence supporting this study is limited. Clinicians should be prudent enough to consider using concentrated growth factor therapy before clinical studies regarding its effectiveness and safety measures. The concentrated growth factor is a simple and better autologous platelet concentrate biomaterial in reconstructive and regenerative medicine, advancing personalized medicine and promoting osseous regeneration by increasing the density and volume of bone around the dental implants. Nevertheless, long-term clinical, histological, and histomorphometric studies on concentrated growth factors must confirm or refute these findings. Remarkably, future studies with only concentrated growth factor placed around dental implants should be carried out in humans.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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