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EFFECT OF OSTEON™ II COLLAGEN IN THE TREATMENT OF CHRONIC PERIODONTITIS PATIENTS: A CLINICAL AND RADIOGRAPHICAL STUDY

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ABSTRACT

Background and objectives: One of the periodontal diseases is chronic periodontitis. It is an inflammatory disease that lasts for a long time and affects the soft and hard tissues around the teeth. The ultimate goal of periodontal therapy is to regenerate the lost periodontal tissue for optimal function and aesthetics. The aim of this study was to evaluate the clinical and radiographic effects of Osteon™ II collagen, in comparison with open flap debridement (OFD) in the treatment of chronic periodontitis patients.

Material and methods: 30 periodontal bony defects in 7 systemically healthy patients that had at least 3 defects, within the age range of 25–40 years, viewing moderate to severe chronic periodontitis were selected and randomly divided into two groups, control group(n=15) was treated by open flap debridement (OFD) alone and test group(n=15) was treated by OFD with placement of Osteon™ II Collagen. All the selected periodontal defects were evaluated with the clinical and radiographic parameters such as plaque index (PI), gingival index (GI), probing pocket depth (PPD), clinical attachment level (CAL), and radiographic defect depth. All the clinical and radiographic parameter values attained at (baseline and 6 months) were subjected to statistical analysis.

Results: Significant lessening in PI, GI, PPD, CAL and radiographic defect depth were detected after 6 months of periodontal surgery as compared to baseline in both groups (P<0.05). Superior decrease in PPD, gain in CAL and radiographic defect fill was seen in test group after 6 months.

Conclusion: In terms of reducing probing pocket depth (PPD), increasing clinical attachment level (CAL), and filling bone defects, Osteon™ II collagen showed significant clinical, radiographic, and statistical improvements compared to open flap debridement (OFD) alone.

***KEYWORDS*:** Bone graft, Chronic periodontitis, Osteon II collagen, Open flap debridement, Periodontal regeneration.

1. INTRODUCTION

Chronic periodontitis is a periodontal condition. Both the soft and hard tissues surrounding the teeth are affected by this common, chronic inflammatory process (Natto *et al*., 2018). Bacteria and the host's immune system's inflammatory response interact together to create periodontitis (Silva *et al*., 2015). The most significant consequence of periodontitis is the destruction of the periodontal supportive tissues, including the gingiva, cementum, periodontal ligament, and alveolar bone (Mopur et al., 2013). Destructive periodontal disease results in the damage of the tooth's connective tissue attachment, which creates pockets and causes the alveolar bone to resorb (Könönen *et al*., 2019). Regenerating the lost periodontal tissue is the main objective of periodontal treatment for the highest suitable function and aesthetic (Bansal *et al*., 2014).

Removal of supragingival and subgingival plaque, Scaling and root debridement, individual education and motivation for dental hygiene, and periodontal surgical therapy are all included in periodontal therapy. The key objective of periodontal surgical procedures is to eliminate necrotic cementum and necrotic epithelial pocket tissue by means of an open incision with visual control. The majority of periodontal surgical procedures remove or reduce the soft tissue that is present in periodontal pockets and create a new epithelial attachment (Gojkov-Vukelic *et al*., 2017). In recent years, periodontal regeneration procedures have gained popularity as a means of repairing the damaged support structures of the periodontium (Cho *et al*., 2021).

The two techniques with the most evidence-based of periodontal regeneration are bone grafting and guided tissue regeneration (GTR) (Santosh Kumar *et al*., 2013). Osteoconduction, osteoinduction, and osteogenesis are the three mechanisms by which bone formation occurs at the grafted area (Rajamani *et al.,* 2019). Alloplastic bone substitutes, as well as autogenous, allogenic, and xenogenic bone grafts, have been utilized in periodontal regeneration (Varghese *et al*., 2022). Because of its histocompatibility, osteoinductivity, and low cost, bone autograft is the gold standard in bone restoration. It is, however, restricted in supply and requires a second operation location. Furthermore, it is subject to partial necrosis or resorption, so that bone substitutes have been needed (Titsinides, 2019).

Osteon™ II Collagen (GENOSS, Co. Ltd, Suwon, Korea) is a block-type graft material with cylinder form (8 mm diameter and 2 mm vertical height). It is a bone graft material composed of synthetic bone graft (Osteon™ II, Genoss. Co. Ltd, Suwon, Korea) and bovine type I collagen, with a weight percentage of collagen at 4% (Lee *et al*., 2015).

Osteon II is an alloplastic material consisting of 30% hydroxyapatite (HA) and 70% beta-tricalcium phosphate (β-TCP) (Ku et al., 2019), which closely resembles the mineral composition of human bone (Abid and Mukhtar, 2019). It is an osteoconductive material that acts as a framework for the formation of bones. It has a similar linked porosity structure to human cancellous bone (Abdullah *et al*., 2020).

β-TCP has a limited ability for space maintenance but is more quickly biodegraded and replaced by newly formed bone (Farha and Abdulghani, 2017). HA, on the other hand, is highly stable and can efficiently preserve space, although it has a poor osteoconductivity (Ihghaf et al., 2015). As a result, a material made up of hydroxyapatite (HA) and beta-tricalcium phosphate (β-TCP),known as Osteon II, was established to overcome the disadvantages of each material (Ihghaf *et al*., 2015). Numerous studies have demonstrated that HA/β-TCP can be used successfully as bone grafts (Lee *et al*., 2015). Bovine type I collagen was added to Osteon II to make it easier to manipulate and shape during the grafting operation, as well as to improve the osteoconductivity of the material (Abdullah *et al*., 2020).

Clinical and radiographic evaluation of the use of Osteon™ II collagen to enhance periodontal regeneration, particularly in moderate to severe chronic periodontitis, is necessary because this is the first study to evaluate and compare the effect of Osteon™ II collagen with open flap debridement alone in the treatment of human chronic periodontitis.

2. MATERIALS AND METHODS

Setting and time of the study

The current research was conducted in Duhok city, Periodontics Branch /College of Dentistry/ University of Duhok. The patients were joining the Branch of Periodontics. The research was conducted by an only one dentist and information were also collected by the same dentist with data collected from November 2021 until October 2022.

Study population and design

The study design is a randomized controlled clinical trial to evaluate and compare clinical and radiographic consequences of treating chronic periodontitis patients by open flap debridement (OFD) with and without Osteon™ II Collagen (GENOSS, Co. Ltd, Suwon, Korea). The study included seven systemically healthy patients with at least three periodontal defects each, for a total of 30 defects. The were of both sexes (male and female) and aged between 25 and 40 years. All patients were attending the periodontal department.

The research ethics committee of the college of dentistry at Duhok University gave its approval to the current study. All patients received full information about the study's nature, the surgical procedure, and its objectives. Each patient received information on the treatment advantages, potential negative effects, and required follow-up visits. Each participant in the research then signed a formal consent form after receiving all necessary information.

The participants were included in the study based on the following inclusion and exclusion criteria.

Inclusion criteria:

1. Patients between the ages of 25 and 40 years who are in good general health and don't have any contraindications for receiving periodontal surgery.
2. A patient with probing pocket depth (PPD)≥5mm, clinical attachment level (CAL) ≥3, and radiographic defect depth ≥3 mm of at least one tooth with moderate to severe chronic periodontitis.
3. Vital or non-vital teeth.
4. Patients should be non-smokers.

Exclusion criteria:

1. Patients with uncontrolled diabetes.
2. Patients on anticoagulant/immunosuppressive medication, and/or patients with other systemic diseases.
3. Patients who are unable to complete normal oral hygiene practices.

All 7 patients with 30 defects (19 in the maxilla and 11 in the mandible) received initial therapy, which comprised complete mouth supragingival and subgingival scaling and root debridement two weeks before surgery, after a primary assessment, diagnosis, and treatment plan. Comprehensive plaque control instructions were given to each patient.

The study population divided randomly into the following two groups:

Group 1 (control group): included fifteen surfaces treated by open flap debridement (OFD) alone.

Group 2 (test group): included fifteen surfaces treated by open flap debridement with placement of Osteon^{TM} II Collagen (GENOSS, Co. Ltd, Suwon, Korea).

Clinical measurements

For all research participants, all clinical periodontal parameters were assessed at baseline and six months following surgical therapy. Plaque Index (PI), Gingival Index (GI), Probing Pocket Depth (PPD), and Clinical Attachment loss (CAL) are clinical periodontal parameters measuring by using a UNC-15 probe with an occlusal stent (Fig. 1A & 2A).

Radiographic parameter

An intraoral periapical radiograph using long cone-paralleling technique were obtained from each patient for the selected defects before surgical procedure and 6-month after surgery. All radiographs were attained by the same X-ray machine (i-sensor, Woodpecker, Chine); using 70kvp; 15 mA, and with a fixed exposure time of 0.8 second. The linear radiographic depth (in mm) of the defect was calculated using software after all radiographs were digitalized using the digital radiography camera and transmitted to the computer.

The radiographic depth was measured from cementoenamel junction (CEJ) to the most apical point of the base of the defect (BD) (Vaid *et al*., 2021). On the image, the cemento-enamel junction (CEJ) and the apical extension of the defect were identified for measurement. From the CEJ to the defect's apical extension, a line was drawn. The line's length was shown in the image. The distance between these two places was then presented by the software (Fig. 1 B&G).

Surgical protocol

The surgical technique was carried out under local anesthesia using 2% lidocaine hydrochloride with a 1:100,000 epinephrine concentration (Duopharma, Malaysia). After obtaining the required level of anesthetic, a crevicular incision was performed using a No. #15 blade. Both patient groups received debridement using hand instrument (Gracey curettes, Medesy, Italy). After a full-thickness mucoperiosteal flap was elevated with the aid of a periosteal elevator (Fig. 1C&2C). Following cleaning, sterile saline was used to irrigate the surgical region. The surgical region was thoroughly examined to make sure the debridement procedure had been successfully finished.

In the test group, the defect was filled with Osteon^{TM} II Collagen (GENOSS, Co. Ltd, Suwon, Korea) (30% hydroxyapatite (HA) and 70% beta-tricalcium phosphate (β-TCP) + bovine type I collagen). With the aid of a sickle scaler, the necessary amount of graft material was moved to a sterile dappen dish, mixed with saline, and gradually inserted into the bony defect or sometimes, the graft material was moistened with blood in the defect and was condensed with an amalgam condenser till the defect was totally filled (Fig. 1D).

The defects in the control group were left empty after open flap debridement, full root debridement, and irrigation of surgical site was done with normal saline.

After that, the soft tissue flap was returned back in its original location and closed with a 3-0 non-absorbable silk suture (DemeTECH, USA) (Fig. 1E&2D). As part of their postoperative regimen, all participants received instructions. For a period of 14 days, the patients were instructed to rinse their mouths with 10 ml of 0.2% chlorhexidine mouthwash twice daily. For ten days, they were instructed to avoid brushing or otherwise manipulating the surgical site or biting on it. The prescribed drugs included antibiotics (500 mg of Amoxicillin every six hours for five days) and painkillers (400 mg of Ibuprofen every 8 h).

Post-surgical protocol

Sutures were removed one week after the surgical procedure, and the region was extensively saline-irrigated. The patient was instructed to come for regular follow-up and motivation appointments once a month to just

observe for oral hygiene without using a periodontal probe. Six months after surgery, patients were assessed clinically and radiographically. Clinical parameters (PI, GI, PPD, and CAL) and radiographic assessments for the control and test groups were obtained during the recall visit after six months (Fig. 1F&G, 2E&F). During this appointment, oral hygiene instructions were given, and scaling was performed as required.

Statistical analyses

The level of clinical parameters and radiographic defect depth was presented in mean and standard deviation. The comparisons of general information between the control group (OFD) and test group (bone graft) were examined in an independent t-test and Pearson chi-squared test. Comparison of Clinical periodontal parameters and radiographic defect depth at baseline and 6 months after periodontal surgery in control and test groups were examined in a paired t-test. Comparison of changes in clinical periodontal parameters and radiographic defect depth between the control group and the test group at 6 months were studied in an independent t-test. The significant level of difference was determined by a p-value of less than 0.05. The statistical calculations were achieved by JMP Pro 14.3.0.

Fig. (1): Treatment of the periodontal defects in the test group. **(A)** Pre-operative probing pocket depth using acrylic stent and UNC-15 probe. **(B)** Pre-operative radiograph measurement of defects. **(C)** Intraoperative view of the debrided defects. (**D**) Placement of bone graft (Osteon II collagen). **(E)** Sutures placed. **(F)** Reduction probing pocket depth after 6 months of surgery. **(G)** Reduction radiographic measurements of defects after 6 months of surgery

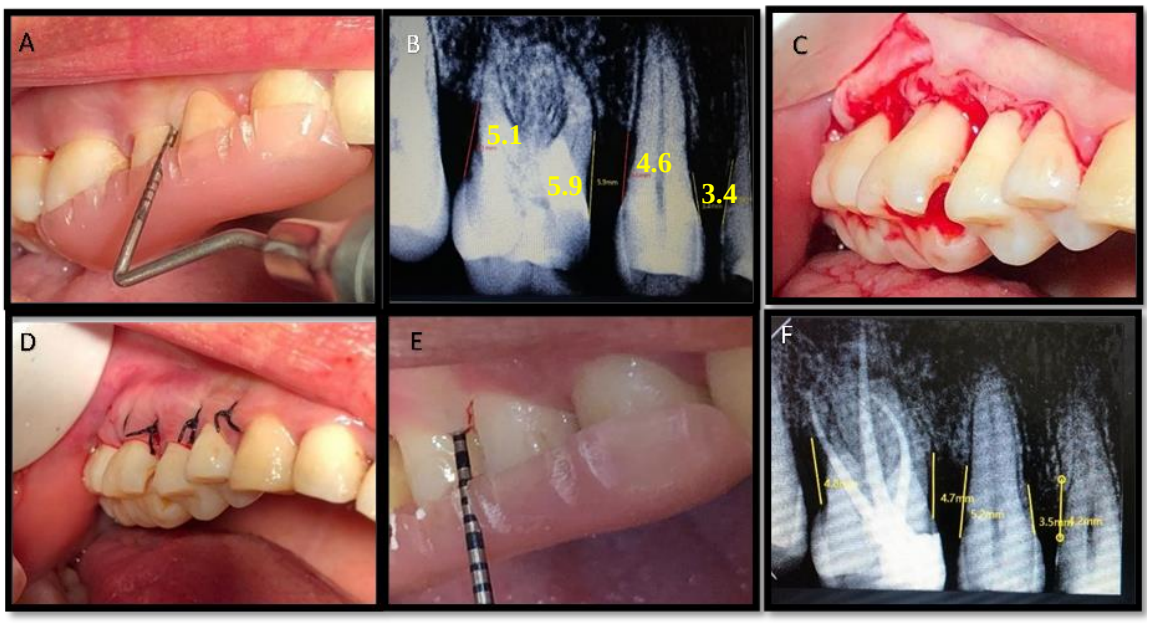

Fig. (2): Treatment of the periodontal defects in the control group. **(A)** pre-operative probing pocket depth using acrylic. **(B)** Pre-operative radiograph measurement of defects. **(C)** Intra-operative view of the debrided defects. **(D)** Sutures placed. **(E)** Probing pocket depth 6 month after surgery **(F)** Radiographic measurements of defects after 6 months of surgery.

4. RESULTS

Comparisons of Baseline characteristics between Control and Test Groups.

Table 1 summarizes the overall characteristics of the study's control and test groups. There were no statistically significant differences (p>0.05) between the two groups in terms of age, gender, or defect location (Figures 3 & 4).

The clinical periodontal parameters (plaque index [PI], gingival index [GI], probing pocket depth [PPD], and clinical attachment level [CAL]) and radiographic defect depth at baseline between the control and test groups. There were no statistically significant differences (P > 0.05) between the two groups.

Table (1): Comparisons of general characteristics between control and test groups at baseline

General characteristics	Study groups at baseline		p-value (two-sided)
	Test group (n=15) (Mean &SD)	Control group (n=15) (Mean &SD)	
Age	36.13 (3.40)	35.33 (4.17)	0.5692[a]
Defects in gender			0.7104[b]
Defects in male	5 (33.33%)	7 (46.67%)	
Defects in female	10 (66.67%)	8 (53.33%)	
Upper/Lower defects			1.0000[b]
Lower	6 (40.00%)	5 (33.33%)	
Upper	9 (60.00%)	10 (66.67%)	
Clinical parameters			
PI	1 (0.00)	1 (0.00)	NA
GI	1 (0.00)	1 (0.00)	NA
PPD	6.07 (1.16)	5.63 (0.64)	0.2104
CAL	5.63 (1.54)	4.53 (0.85)	0.0620
Radiographic defect depth (CEJ-BD)	6.45 (1.32)	5.64 (0.51)	0.0910

[a] an independent t-test and [b] Pearson chi-squared tests were performed for statistical analyses.

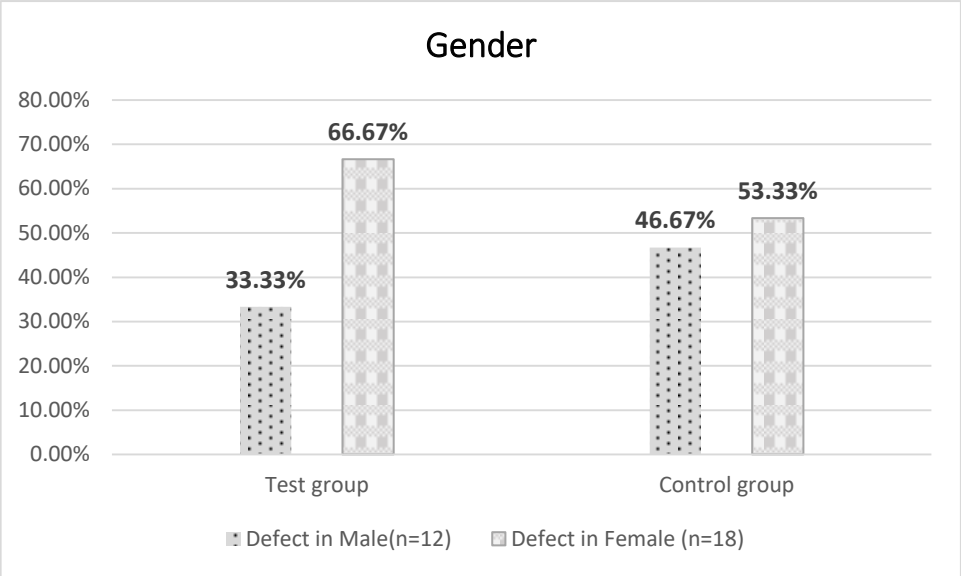

Fig. (3): Distribution of study defects by gender.

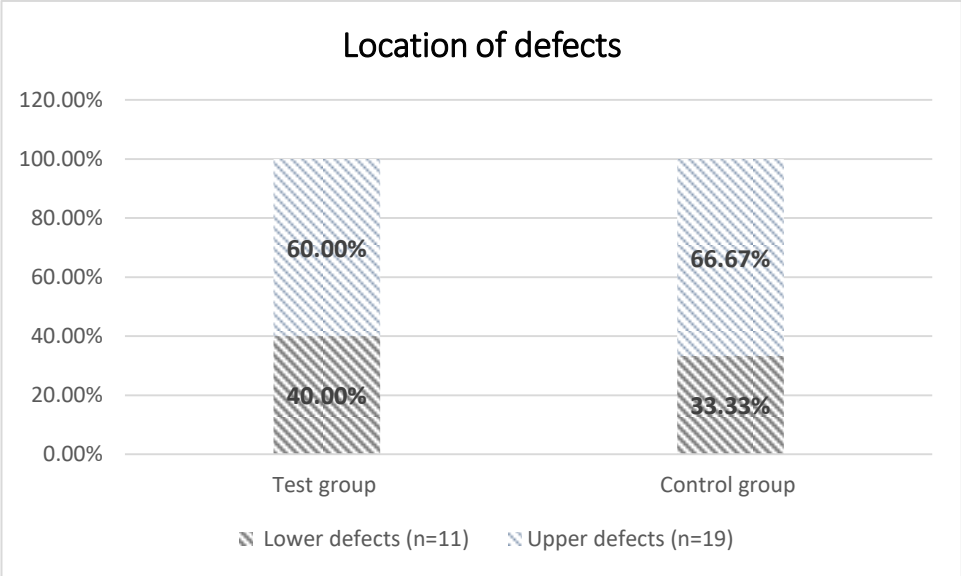

Fig. (4): Distribution of study defects by location.

Comparison of clinical periodontal parameters (plaque index [PI], gingival index [GI], probing pocket depth [PPD], clinical attachment loss[CAL]), and radiographical defect depth (CEJ-BD) at baseline and 6 months after periodontal surgery in control and test groups.

Control group

In the control group, after six months of open flap debridement (OFD) alone, there was a statistically significant reduction in mean plaque index score from 1.0 (0.00) at baseline to 0.60 (0.51), with a mean reduction of 0.40 (0.67 to 0.13) (P = 0.0038).

The mean gingival index score was also significantly reduced from 1.0 (0.00) at baseline to 0.53 (0.64) after 6 months of OFD alone, with a mean reduction of 0.47 (0.75 to 0.19) (P = 0.0033).

The mean PPD at baseline was 5.63 (0.64) mm, which significally declined to a mean of 3.60 (0.71) mm after 6 months of OFD alone, with a mean reduction of 2.03 (2.41 to 1.65) mm (P <0.0001).

The mean CAL also significantly decreased from 4.53 (0.85) mm at baseline to 2.47 (0.67) mm after 6 months of OFD, with a mean decreasing of 2.07 (2.54 to 1.59) mm (P

<0.0001).

The mean radiographic defect (CEJ-BD) decreased from 5.64(0.51) mm to 5.2 (0.76) mm at baseline after 6 month of OFD alone , with a mean difference in the reductions of 0.44 (0.81 to 0.07) mm, the difference in reduction was statistically significant (P = 0.0270) (Table 2).

Test group

The mean plaque index score was significantly reduced from 1.0 (0.00) at baseline to 0.53 (0.52) after 6 months, with a mean reduction of 0.47 (0.75 to 0.18) (P = 0.0035).

The mean gingival index score was also significantly reduced from 1.0 (0.00) at baseline to 0.47 (0.52) at 6 months, with a mean reduction of 0.53 (0.82 to 0.25) (P = 0.0013).

The mean PPD at baseline was 6.07 (1.16) mm which significantly declined to a mean of 3.00 (0.00) mm after 6 months of periodontal surgery, with a mean reduction of 3.07 (3.71 to 2.42) mm (P <0.0001).

The mean CAL also significantly declined from 5.63 (1.54) mm at baseline to 2.45 (1.48) mm after 6 months following periodontal surgery, with a mean reduction of 3.18(3.90 to 2.46)mm (P <0.0001).

The mean radiographic defect depth (CEJ-BD) was 6.45 (1.32) mm at baseline which declined to a mean of 3.66 (1.04) mm at 6 months of periodontal surgery. The difference in reduction was 2.79 (3.72 to 1.86) mm which was found to be highly significant (P= 0.0012) (Table 2).

Table (2): Comparison of clinical periodontal parameters (PI, GI, PPD, and CAL) and radiographical defect depth at baseline and 6 months after periodontal surgical treatment in control and test groups.

	Time		Mean diff (95% CI)	p-value (two-sided)
Clinical parameters and groups	**Baseline**	**6 months**		
Control group				
PI	1.00 (0.00)	0.60 (0.51)	-0.40 (-0.67 to -0.13)	0.0038
GI	1.00 (0.00)	0.53 (0.64)	-0.47 (-0.75 to -0.19)	0.0033
PPD	5.63 (0.64)	3.60 (0.71)	-2.03 (-2.41 to -1.65)	<0.0001
CAL	4.53 (0.85)	2.47 (0.67)	-2.07 (-2.54 to -1.59)	<0.0001
Radiographic defect depth (CEJ-BD)	5.64 (0.51)	5.2 (0.76)	-0.44 (-0.81 to -0.07)	0.0270
Test group				
PI	1.00 (0.00)	0.53 (0.52)	-0.47 (-0.75 to -0.18)	0.0035
GI	1.00 (0.00)	0.47 (0.52)	-0.53 (-0.82 to -0.25)	0.0013
PPD	6.07 (1.16)	3.00 (0.00)	-3.07 (-3.71 to -2.42)	<0.0001
CAL	5.63 (1.54)	2.45 (1.48)	-3.18 (-3.90 to -2.46)	<0.0001
Radiographic defect depth (CEJ-BD)	6.45 (1.32)	3.66 (1.04)	-2.79 (-3.72 to -1.86)	0.0012

Paired t-test was achieved for statistical analyses.
The red numbers show the significant differences.

Comparison of changes in clinical periodontal parameters and radiographical defect depth between control group (OFD) and test group (bone graft) at 6 months.

1. Plaque index

At 6 months, the mean PI score improvement was 0.47 (0.52) for the test group and 0.40 (0.54) mm for the control group. However, there was no significant difference between the groups (p =0.3343).

2. Gingival index

At 6 months, the mean GI score improvement was 0.53 (0.52) for the test group and 0.47 (0.51) for the control group. However, there was no significant difference between the groups (p =0.3450).

3. Probing pocket depth (PPD)

At 6 months, the mean PPD reduction was 3.10 (1.16) mm for the test group and 2.00 (0.00) mm for the control group. The test group had a

significantly greater reduction in mean PPD than the control group (p =0.0180), with an additional reduction of 1.07 mm PPD compared to the control group.

4. CAL

The gain in clinical attachment level was 3.18 (1.31) mm for test group and 2.07 (0.86) for the control group. The test group had significantly more gain in CAL than the control group (p = 0.0141), with an additional 1.11 mm CAL gain compared to the control group (Table 3).

5. For the radiographic defect depth

Results showed after 6 months, the mean gain in radiographic defect fill was 2.79 (0.93) mm for the test group and 0.44 (0.37) mm for the control group. The test group had a significantly greater improvement in mean radiographic defect depth than the control group (p <0.0001), with an additional 2.35mm of radiographic bone fill compared to the control group (Table 3)

Table (3): Comparison of changes in clinical periodontal parameters and radiographical defect depth between control group (OFD) and test group (bone graft) at 6 months

Clinical parameters and radiographic changes	Study groups		Difference in change	p-value (two-sided)
	Test group	Control group		
PI change	-0.47 (0.52)	-0.40 (0.54)	0.07	0.3343
GI change	-0.53 (0.52)	-0.47 (0.51)	0.06	0.3450
PPD change	-3.10 (1.16)	-2.00 (0.00)	1.07	0.0180
CAL change	-3.18 (1.31)	-2.07 (0.86)	1.11	0.0141
Radiographic defect depth change	-2.79 (0.93)	-0.44 (0.37)	2.35	<0.0001

An independent t-test was achieved for statistical analyses.
The red numbers show the significant differences.

5. DISCUSSION

Periodontal treatment aims to regeneration of damaged periodontium. Scaling and root debridement, two common periodontal therapies, are very successful in treating disease-related abnormalities and reducing the development of the periodontitis, but they cannot promote the regeneration of damaged periodontal tissue. Regenerative periodontal surgery such as, guided tissue regeneration (GTR), enamel matrix derivative, bone grafts, growth factor delivery, and the combination of cells and growth factors with matrix-based scaffolds have been developed to target the restoration of lost tooth-supporting tissues, such as periodontal ligament, alveolar bone, and cementum (Liang *et al*., 2020).

Among the most popular method for regeneration periodontal-supporting tissues lost as a result of periodontitis is bone replacement grafts, such as autografts, allografts, xenografts, and alloplasts (Varghese *et al*., 2022). Studies have demonstrated that open debridement flap treatments alone give 10-30% bony fill in periodontal defects, while a mean defect fill of 60-70% may be predicted with use of bone additional grafts (Kamboj *et al*., 2016; Atchuta *et al*., 2020).

The current study used Osteon^{TM} II collagen (GENOSS, Co. Ltd, Suwon, Korea) as a bone material. Osteon II collagen is an osteoconductive material composed of 30% of hydroxyapatite (HA) and 70% of beta-tricalcium phosphate (β-TCP) (Ku *et al*., 2019), which closely mimics the mineral component of human bone (Abid and Mukhtar, 2019). In order to improve the osteoconductivity of the Osteon II material, bovine type I collagen was also added. Where, after assisting with the initial shape, the collagen is absorbed gradually over a few weeks (Abdullah *et al.*, 2020). This was consistent with findings made by Bae *et al*., (2010) who discovered that the benefit of joining an insoluble HA with a resorbable β-TCP is that the slow-resorbing HA will retain volume while the faster-resorbing β-TCP will enhance bone regeneration.

Our study used open flap debridement alone as the treatment for defect in the control group, which is consistent with previous research showing that open root debridement left the

affected region free from calculus depositions than the closed debridement approach (Elkhatat *et al*., 2015). Additionally, Schmitt *et al*., (1989) noted in their study that it was difficult to use a typical periodontal equipment to reach the base of the vertical defect. The flap surgery was intended in such a method that it could overcome the difficulties of defect access and the complex anatomy of the defects.

The current study revealed a significant reduction in plaque and gingival index scores before surgery that persisted throughout the clinical trials' observation period, which might be qualified to the efficiency of phase I therapy and patient cooperation. Parallel results were described by Elkhatat *et al*., (2015) who reached the conclusion that maintaining adequate oral hygiene is essential for the management of periodontal defects prior to surgery.

The present study has included only those sites that had probing depth ≥ 5mm following phase I therapy and radiographic sign of bone loss ≥3mm deep. This was in contract with study done by Laurell *et al*., (1998) who has shown that to benefit from regenerative procedures, depth of defect should be at least 3-4 mm.

The plaque index was evaluated at the baseline and after six months. The study's findings revealed a statistically significant decline in the plaque index between baseline and six months in both the control group and the test group. There was no statistically significant difference between the two groups. This finding may be related to the rigorous oral hygiene preservation program, consistent follow-up appointments once a month to just observe without using a periodontal probe , and ongoing patient education on oral hygiene over the study period. These results are in agreement with those of Chandrashekar & Saxena (2009), who reached the conclusion that suitable plaque control of the surgical place plays a significant role in the healing of periodontal defects following the use of biphasic calcium phosphate composed of hydroxyapatite and beta-tricalcium phosphate in a weight % ratio of nearly 70:30.

The gingival index was assessed at baseline and after six months. According to the study's findings, both the control group and the test group's gingival index significantly decreased over the period of six months from baseline. However, there was no statistically significant difference between the two groups. This enhancement in gingival health may be attributable to the surgery and recurrent reinforcement of oral hygiene maintenance. Similar results were presented by (Lee *et al*., 2012; Bansal *et al*., 2014).

At 6 months of surgery , both the test group and the control group showed statistically significant mean PPD reduction and mean CAL gain. A comparison of the consequences at 6 months displayed that there was an extra 1.11 mm PPD reduction and 1.00 mm CAL gain in the test group. These decrease in PPD in the test group can be attributed to improvements in soft and hard tissues following the resolution of inflammation and to the osteoconductive potential of bone graft materials used in the study. The increase CAL gain can be attributed to periodontal regeneration, the formation of long junctional epithelium, and/or soft-tissue healing at the base of the pocket. These finding are in agreement with studies, which report that synthetic bone grafts produce superior results in the treatment of chronic periodontitis (Stein *et al*., 2009; Chandrashekar & Saxena, 2009; Lee *et al*., 2012; Mopur *et al*., 2013; Gojkov-Vukelic *et al*., 2017; Elbattawy & Ahmed, 2021).

The PPD and CAL outcomes in the control group were different from those reported by Elkhatat et al. (2015), who demonstrated no significant reduction in PPD and CAL using the OFD approach alone. These differences in the OFD group's outcomes might be influenced by the surgical method, the characteristics of the baseline defect, and the operator's expertise (Singh *et al*., 2012). control group's comparable gain in the clinical attachment level and PPD reduction might be attributable to the development of the long junctional epithelium

Radiographic depth was calculated from the cementoenamel junction (CEJ) to the base of the most apical point of the defect. Both the test group and the control group had statistically significant mean defect fills at 6 months after treatment. A comparison of the data at 6 months revealed that the test group had an extra 2.35 mm of radiographic bone fill. This result is consistent with previous research supports the use of synthetic bone graft in periodontal treatment (Chandrashekar & Saxena, 2009; Singh *et al*., 2012; Mopur *et al*., 2013; Chacko *et al*., 2014; Suprabhan *et al*., 2020; Pavani *et al*., 2021).

The increase in bone fill may be attributed to the osteoconductive properties of the Osteon II collagen bone graft, which acts as a scaffold for new bone development that is sustained by native bone. In addition, Osteoblasts from the

margin of the defect are being repaired using the bone graft substance as a framework on which to spread and produce new bone.

Superior results regarding PPD, CAL, and bone fill were achieved by Figliuzzi *et al*., (2016) using hydroxyapatites bone graft at 18 months. This may be related to the longer follow up interval that allows for permit further bone deposition. Therefore, long-term studies are recommended to assess the sustainability of the results.

Moreover, the current study found no tissue responses, antigenic or unintentional reactions throughout the trial, indicating the safety of these bone grafts as therapeutic materials.

However, longer-term histological research on experimental animals is suggested to determine the precise nature of the variations in the assessed parameters, namely the decrease in PD, improvement in clinical attachment, and change in bone fill.

6. CONCLUSIONS

In conclusion, the use of Osteon™ II collagen bone graft demonstrated superior therapeutic outcomes compared to open-flap debridement alone in the treatment of chronic periodontitis with bony defects. In both test and control groups, Clinical attachment level improved and the depth of the probing pocket decreased statistically significantly as a result of the therapy. The test group observed significantly greater clinical attachment level gain and a greater decrease in pocket depth as compared to the control group. Radiographic assessment also demonstrated a high percentage of defect fill in the test group, confirming the graft material's effectiveness in stimulating bone regeneration. These results validate the use of Osteon™ II collagen bone transplant as a potential treatment option for chronic periodontitis with bony defects . Nevertheless, more long-term studies are advised to examine the findings' durability, as well as histology research to better comprehend the processes behind the observed improvements in clinical parameters and bone fill

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