

# AL-AZHAR Assiut Dental Journal

The Official Publication of The Faculty of Dental Medicine, Al-Azhar Assiut University, Egypt

**AADJ, Vol. 7, No. 2, October (2024) — PP. 189:**197

ISSN 2682-2822

## **Evaluation of the Effect of Nano Calcium Sulphate in Treatment of Intra bony Defects In Periodontitis Patients**

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Codex: 06/2024/10

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#### **KEYWORDS**

Nano calcium sulphate, bone graft, probing depth, periodontitis, intrabony defects.

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#### **ABSTRACT**

Aim: This study was performed to evaluate clinically and radiographically the effect of nano calcium sulphate bone graft in treatment of intra-bony defects in periodontitis patients Subjects and Methods: Twenty patients were selected from those attending at the Outpatient clinic, Oral Medicine and Periodontology Department, Faculty of Dental Medicine, Al-Azhar University (Assiut Branch) diagnosed as periodontitis cases having intra bony defect with probing depth > 6 mm and clinical attachment loss  $\ge 5$  mm. They were divided into two groups. Group I: included 10 periodontitis patients with intra bony defects were received open flap surgery combined with nano calcium sulphate bone graft. Group II: included 10 periodontitis patients with intra bony defects were received open flap debridement alone. Results: Both groups showed high statistically significant differences between baseline and 6 months in all clinical parameters (PI,GI,CAL,PD) and radiographic parameter (bone density BD). There was statistically significant difference in group I when compared to group II in (CAL,PD,BD) at 6 and 12 months. Conclusion: Using nano calcium sulphate bone graft in treatment of intrabony defects is effective in treatment of intra-bony defects in periodontitis patients and it is better than open flap debridement alone.

#### INTRODUCTION

Periodontitis is one of the most ubiquitous diseases and is characterized by the destruction of connective tissue and dental bone support following an inflammatory host response secondary to infection by periodontal bacteria in dental plaque<sup>(1)</sup>.

Treatment of periodontitis aims to prevent further disease progression, to minimize symptoms and perception of the disease, possibly to restore lost tissues and to support patients in maintaining a healthy periodontium (2).

Non-surgical periodontal therapy is considered as the gold-standard for the management of periodontitis. It mainly consists of oral hygiene instructions and scaling and root planning. The aim of the periodontal treatment is to remove adherent and unattached bacterial biofilms as well as deposits of calculus<sup>(3)</sup>. Surgical treatment modalities are often considered as the next phase of therapy. The primary aims of periodontal surgery are to create accessibility for proper professional scaling and root planing and to establish a gingival morphology that facilitates efficient infection control, as well as reconstructing, and when possible regenerating, the lost (periodontal) tissues<sup>(4)</sup>.

Periodontal regeneration has been defined as the formation of new cementum, alveolar bone, and a functional periodontal ligament on a previously diseased root surface <sup>(5)</sup>.

A bone graft is defined as a material capable of promoting bone healing, transplanted into a bony defect, either alone or in combination with other materials. The main function of bone grafts is to provide mechanical support and stimulate osteo-regeneration, with the ultimate goal of bone replacement. The four fundamental biological properties of bone graft including osseointegration, osteogenesis, osteoconduction, and osteoinduction, are paramount in performing this role effectively <sup>(6)</sup>.

Bone grafts are divided according to the source of origin into autografts, allgrafts, xenografts and synthetic bone grafts substitutes (alloplasts)<sup>(7)</sup>.

Calcium sulphate (CS) have demonstrated potential in surgical therapy for more than 100 years. It has been found to be biocompatible, biodegradable, osteoconductive, safe and nontoxic and also exhibits angiogenic, hemostatic and barrier membrane properties (8).

Although CS is a desirable osteoconductive material and potential carrier in its presently available state, it has some deficiencies, including slow and variable degradation rate and weak mechanical properties. Nanocalcium sulphate (nCS), composed of particles with dimensions below 100 nm, will have enhanced physical properties such as increased

surface area for osteoblastic cell attachment and subsequent growth and differentiation, improved potential for controlling the rate of degradation and release of adsorbed material and superior mechanical strength (after setting) for optimal osteoconductivity and resistance to fractures<sup>(9)</sup>.

The present study was designed to through the light on the possible effects of nanocalcium sulphate (nCS) in treatment of intra-bony defects of periodontitis patients.

#### PATIENTS AND METHODS

Patients: twenty patients of both sex (12 males and 8 females) ranged in age from 28-62 years old from those attending at the Outpatient clinic, Oral Medicine and Periodontology Department, Faculty of Dental Medicine, Al-Azhar University (Assiut Branch). On the basis of patient history, clinical and radiographic examination, all patients diagnosed as periodontitis cases having intra bony defect with probing depth > 6 mm and clinical attachment loss ≥ 5 mm.

#### **Inclusion criteria:**

All patients were selected free from any systemic disease according to the criteria of Modified Cornell medical index (10).

#### **Exclusion criteria:**

Pregnant or taking contraceptive pills female patients. Smokers and un-cooperative patients. Patients were subjected to periodontal therapy in previous 6 months or antibiotics in previous 3 months.

#### Patients grouping and randomization:

**Group I:** included 10 periodontitis patients with intra bony defects were received open flap surgery combined with nano calcium sulphate bone graft.

**Group II**: included 10 periodontitis patients with intra bony defects were received open flap debridment alone.



#### **Periodontal intervention:**

All patients were received phase 1 therapy including Patient education and motivation, mechanical plaque control, Correction of restorative and prosthetic irritational factors and Full-mouth scaling and root planing was performed in 2-4 sessions within 2 weeks.

Four weeks following phase I therapy, a periodontal evaluation was performed to confirm the suitability of the sites for the study.

#### **Clinical evaluation:**

All patients were evaluated clinically at; baseline, 6 and 12 months post surgically using the following periodontal parameters:

Plaque index (PI), Gingival index (GI), Probing depth (PD), Clinical attachment level (CAL).

#### Radiographic evaluation:

Radiographic evaluation for the bone density of the surgical defects were done at; baseline and at 6 and 12 months post surgically.

#### **Surgical procedures:**

In group I patients, patients were received open flap debridement and bone graft substitute of nano-calcium sulphate (NanoGen®, Orthogen, LLC, Springfield, NJ) were grafted to the defect and condensed with spherical plugger.

**In group II** patients, patients were received open flap debridement alone.

#### **Postsurgical medications:**

Systemic antibiotic therapy, 0.12% Chlorhexidine digluconate as mouth wash twice daily for 4 weeks and analgesic and anti-inflammatory.

#### Statistical analysis

The mean and standard deviation values were calculated for each group in each test. Paired sample t-test was used to compare between two groups in related samples. Pearson correlation was used to find the correlation between different parameters.

The significance level was set at P≤0.05. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.



#### RESULTS

This study was conducted on 20 patients of both sex (12 males and 8 females ranged in age from 28-62 years with mean age 44.65 years suffering from periodontitis and having intra-bony defect with probing depth > 6 mm and clinical attachment loss ≥ 5 mm. The patients were divided randomly into two groups; **Group I:** received open flap debridement combined with nano calcium sulphate bone graft and **Group II:** received open flap debridement alone.

Results of clinical parameters and radiographic bone density were recorded, tabulated and statistically analysed.

#### 1. Demographic data:

There was no statistical significant difference between the studied groups at beginning of study regarding number, age and sex (P>0.05).

#### 2. Changes in the clinical parameters

#### A) Plaque index (PI):

#### a- The difference within each group:

**Group I:** there were a statistically significant difference between baseline versus (vs) 6 months and 12 months (P<0.001). A non-statistically significant difference was found between 6 months and 12 months (P>0.05).

**Group II:** A statistically significant difference were found between baseline versus (vs) 6-m, and 12-m (P>0.001 respectively). Also there was statistically significant difference between 6 months and 12 months (P<0.01). Table 1

#### b- The differences between the groups:

There were difference between mean of PI scores of group I and II but this difference was no statistically significance regarding baseline and 6 months (P>0.05), this become statistically

significant differences between both groups at 12 month (P < 0.05). Table 2

#### **Gingival Index (GI):**

#### a- The difference within each group

**Group I**: A statistically significant difference was found between (Baseline vs 6-m), (Baseline vs 12-m) P value <0.001 and (6 -m vs 12-m) P value<0.05.

**Group II:** There was statistically significant difference between Baseline and each of 6-m and 12-m (P<0.05). Table1

#### b- The differences between the groups:

The mean GIs did not show any statistically significant difference between both groups at the different intervals (P>0.05). Table 2

#### C) Probing depth (PD):

#### a. The difference within each group:

**Group I:** there were a statistically significant difference between baseline versus (vs) 6 months and 12 months (P<0.001) and between 6 months vs 12 months (P<0.01).

**Group II:** A statistically significant difference were found between baseline versus (vs) 6-m, and 12-m (P<0.001) respectively. Also there was statistically significant difference between 6 months and 12 months (P<0.01). Table 1

#### b. The differences between the groups:

There were difference between mean of PI scores of group I and II but this difference was no statistically significance regarding baseline (P>0.05), this become statistically significant differences between both groups at 6 months (P<0.01) and 12 months (P<0.001). Table 2



#### D) Clinical attachment level (CAL):

#### a. The difference within each group:

**Group I:** there were a statistically significant difference between baseline versus (vs) 6 months and 12 months (P<0.001) but there was no statistically significant difference between 6 months vs 12 months (P>0.05).

**Group II:** A statistically significant difference were found between baseline versus (vs) 6-m, and 12-m (P>0.001) respectively but there was no statistically significant difference between 6 months and 12 months (P>0.05). Table 1

#### b. The differences between the groups:

There were difference between mean of CAL scores of group I and II but this difference was no statistically significance regarding baseline (P>0.05), this become statistically significant differences between both groups at 6 and 12 month (P <0.001). Table 2

#### Changes in radiographic parameter:

#### A) Bone density (BD):

#### a. The difference within each group:

**Group I:** there were a statistically significant difference between baseline versus (vs) 6 months and 12 months (P<0.001) also there was statistically significant difference between 6 months vs 12 months (P<0.001).

**Group II:** A statistically significant difference were found between baseline versus (vs) 6-m, and 12-m (P<0.001) respectively. But there was no statistically significant difference between 6 months and 12 months (P>0.05). Table 1

#### b. The differences between the groups:

There were difference between mean of BD scores of group I and II but this difference was no statistically significance regarding baseline (P>0.05), this become statistically significant differences between both groups at 6 and 12 month (P<0.001). Table 2

**Table (1)** Illustrating Mean  $\pm$  SD of PI, GI, PD, CAL and BD and paired t-test level of significance within each group at different intervals in studied groups.

Parameter		G-I	G-II		G-I		G-II	
		Mean± SD	Mean± SD		t-test	P-value	t-test	P-value
PI	BL	2.44±0.22	2.58±0.19	BL vs 6m	26.3	***P<0.001	31.27	***P<0.001
	6m	$0.40 \pm 0.14$	0.46±0.12	BLvs12m	13.99	***P<0.001	27.29	***P<0.001
	12m	$0.53 \pm 0.24$	0.77±0.25	6 vs 12m	1.42	ns P>0.05	3.51	** P<0.01
GI	BL	$2.50 \pm 0.25$	$2.50 \pm 0.20$	BL vs 6m	19.25	***P<0.001	21.09	***P<0.001
	6m	$0.52 \pm 0.10$	$0.45 \pm 0.16$	BLvs12m	14.01	***P<0.001	10.45	***P<0.001
	12m	$0.72 \pm 0.26$	0.98 ±0.37	6 vs 12m	2.85	*P<0.05	3.85	** P<0.01
PD	BL	$6.2 \pm 0.30$	$6.18 \pm 0.35$	BL vs 6m	16.47	***P<0.001	14.23	***P<0.001
	6m	$2.89 \pm 0.58$	$3.72 \pm 0.53$	BLvs12m	18.59	***P<0.001	12.44	***P<0.001
	12m	$3.57 \pm 0.36$	$4.41 \pm 0.36$	6 vs 12m	4.19	**P<0.01	3.83	**P<0.01
CAL	BL	$5.88 \pm 0.40$	$6.04 \pm 0.56$	BL vs 6m	19.78	***P<0.001	7.60	***P<0.001
	6m	$2.39 \pm 0.39$	$3.71 \pm 0.58$	BLvs12m	15.15	***P<0.001	13.90	***P<0.001
	12m	$2.38 \pm 0.49$	$3.66 \pm 0.35$	6 vs 12m	0.05	ns P>0.05	0.23	ns P>0.05
BD	BL	$88.10 \pm 4.91$	$91.20 \pm 3.79$	BL vs 6m	19.94	***P<0.001	9.86	***P<0.001
	6m	170.30± 12.12	114.10± 6.71	BLvs12m	24.73	***P<0.001	15.14	***P<0.001
	12m	$152.50 \pm 7.84$	$120 \pm 8.14$	6 vs 12m	7.80	***P<0.001	2.04	ns P>0.05

**Table (2)** Illustrating t- test, P- value and level of significance between both groups at different intervals in studied groups.

		Baseline	6 months	12 months	
PI	t-test	1.53	0.96	2.17	
	P-value	ns P>0.05	ns P>0.05	* P<0.05	
GI	t-test	0	1.11	1.80	
	P-value	ns P>0.05	ns P>0.05	ns P>0.05	
PD	t-test	0.31	3.36	5.23	
	P-value	ns P>0.05	**P<0.01	***P<0.001	
CAL	t-test	0.77	5.94	6.75	
	P-value	ns P>0.05	***P<0.001	***P<0.001	
BD	t-test	1.58	12.83	9.09	
	P-value	ns P>0.05	***P<0.001	***P<0.001	

ns P>0.05 \*P<0.05 \*\* P<0.01 \*\*\*P<0.001

#### DISCUSSION

Periodontitis is an infectious bacterial disease, characterized by loss of attachment and bone, leading to gingival recession and pocket formation which results in loss of tooth if left untreated. The etiology of the disease is multifactorial, that is from pathogenic plaque microflora to systemic factors and host immune responses resulting in direct or host-mediated tissue injury (1).

Periodontal treatment can be achieved with nonsurgical and surgical therapy. The ultimate goal of periodontal treatment is the regeneration of periodontal tissues lost during the disease process so these defects often require access flap surgery alone or in association with bone replacement grafts<sup>(2)</sup>.

The present study was performed to evaluate the possible effects of nano-calcium sulphate as a regenerative bone graft material in treatment of intra-bony defects in periodontitis patients.

Plaque index, gingival index, probing depth, clinical attachment level and bone density are the parameters that were used for the evaluations and comparison between the two groups of patient in this study to evaluate the effect of the bone graft material. They were recorded before surgery, after 6 month and after 12 month of surgery.

The results of the present study showed that; reduction in plaque and gingival indices in both groups after surgical intervention, these indices were taken to record the oral hygiene maintenance and inflammatory condition of the patients, numerous clinical studies have shown a direct relationship between oral hygiene status, the quality of plaque, and the prevalence and severity of periodontal diseases. Plaque control is the removal of dental plaque on a regular basis and the prevention of its accumulation on the teeth and adjacent gingival surfaces. It is a critical component of dental practice, permitting long-term success of periodontal and dental care (11). As well as the ability to detect inflammatory lesions in gingival tissues is essential for the diagnosis and monitoring of changes in gingival status. Gingival index is based on clinical features of inflammation, and it contain components that are assessed noninvasively, by visual examination (e.g., color, texture, changes in form, spontaneous bleeding) and components that are assessed invasively (e.g., bleeding on stimulation or provocation (12).

The reduction in plaque accumulation in this study showed high significant difference in both groups at the different intervals when compared to the baseline that indicates the good hygienic condition of the patients who participated in this study which was observed at 6,12 months follow up period, this is very important factor in periodontal regeneration and this finding was in parallism with other study<sup>(13)</sup>.

High improvement in gingival inflammation which was observed in both groups at the different intervals when compared to the baseline indicates patient's good oral hygiene and continuous plaque control during study follow up period (14).



Probing depth showed high significant reduction in measurements in both groups at the different intervals when compared to the baseline which indicates improvement in the two groups after surgery, but high significant reduction was observed in group I when compared with group II at 6 month and 12 months of surgery indicates more improvement in group I than in group II. This result was in agreement with finding of other study (15).

The present study showed Clinical attachment level (CAL) gain in both groups at the different intervals when compared to the baseline representing improvement in CAL scores in both groups, but high significant improvement observed in group I when compared with group II at 6 and 12 month of surgery indicates more improvement in group I in CAL gain. This finding was in accordance with other study compared between nanocrystalline calcium sulphate bone graft (NanoGen) and platelet rich fibrin (PRF) in the treatment of periodontal intrabony defects which concluded gain in CAL was observed in both groups. In intergroup comparison the group which was treated with nano calcium sulfate bone graft showed statistically significant gain in CAL compared to the group which was treated by PRF at all-time intervals. Fibroblast growth factor is released in an active form from calcium sulphate and the release of the growth factor was directly proportional to the degradation rate of calcium sulphate, which facilitates migration of gingival fibroblasts and cell attachment and spreading, resulting in decrease of PPD and gain of CAL(16).

Bone density showed high significant difference in both groups at the different intervals when compared to the baseline representing improvement in both groups but high significant improvement in bone density observed in group I when compared with group II at 6 and 12 months of surgery representing more improvement in bone gain and better regeneration in group I than in group II. In this study we concluded that group I which was treated by nano calcium sulphate bone graft has better im-

provement in probing depth, CAL and bone density clinically and radiographically than group II which was treated by open debridement alone. Bone gain in group I is higher than group II and this result is parallel with other studies concluded that nCS has better effect in bone gain and regeneration (17).

From the results of the present study both treatment modalities; open flab debridement and nCS groups showed statistically significant clinical improvement and defect resolution at 6 months and 12 months as compared to baseline with highly effective treatment was associated with grafting material.

#### **CONCLUSIONS**

Using nano calcium sulphate bone graft in treatment of intra-bony defects is better than open flap debridement alone. Nano calcium sulphate bone graft is effective in treatment of intra-bony defects in periodontitis patients. Open flap debridement is considered to be effective in improvement of periodontal parameters in patients with intra-bony defects.

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AADJ, Vol. 7, No. 2, October (2024) — PP. 197

### تقييم تأثير نانو سلفات الكالسيوم في علاج العيوب العظمية الداخلية لدى مرضى التهاب اللثة

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#### الملخص:

الهدف: أجريت هذه الدراسة لتقييم تأثير التطعيم العظمي باستخدام كبريتات الكالسيوم النانوية سريرياً وشعاعياً في علاج العيوب داخل العظم لدى مرضى التهاب اللثة.

المواد والاساليب: تم اختيار عشرين مريضا من المراجعين بالعيادة الخارجية بقسم طب الفم واللثة بكلية طب الأسنان جامعة الأزهر (فرع أسيوط) الذين تم تشخيصهم على أنهم حالات التهاب اللثة مع وجود عيب داخل العظم بعمق فحص> 6 م وفقدان الارتباط السريري 5 ملم. تم تقسيمهم إلى مجموعتين. المجموعة الأولى: شملت 10 مرضى التهاب اللثة الذين يعانون من عيوب عظمية داخلية وقد تم إجراء عملية جراحية مفتوحة لهم مع تطعيم عظمي بكبريتات الكالسيوم النانوية. المجموعة الثانية: شملت 10 مرضى التهاب دواعم السن الذين يعانون من عيوب داخل العظم وتم إعطاؤهم تنضير السديلة المفتوحة فقط.

النتائج: أظهرت كلا الجموعتين فروق ذات دلالة إحصائية عالية بين خط الأساس و6 أشهر في جميع المعلمات السريرية (PI, GI, CAL, PD) والمعلمة الشعاعية (كثافة العظام BD). كان هناك فروق ذات دلالة إحصائية في الجموعة الأولى بالمقارنة مع الجموعة الثانية في (CAL, PD, BD) عند 6 و 12 شهرا..

الاستنتاج: إن استخدام طعم عظمي يحتوي على كبريتات الكالسيوم النانوية في علاج العيوب داخل العظم فعال في علاج العيوب داخل العظم لدى مرضى التهاب اللثة وهو أفضل من تنضير السديلة المفتوحة وحدها.

الكلمات المفتاحية: نانو كبريتات الكالسيوم. ترقيع العظام. عمق الفحص. التهاب اللثة. العيوب داخل العظم