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## Original Research Article

# Overall bone gaining after using calcium sulfate bone graft simultaneously to dental implantation

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**Abstract – Objectives:** this study was carried out to evaluate the gaining occurring in the bone gaining after the simultaneous grafting with calcium sulfate around dental implants. **Materials and methods:** 24 implantation sites in the anterior area of the maxilla were included in this study. Dental implants were inserted, bone grafting was done simultaneously and post evaluation of the overall bone gaining 6 months after the grafting process (T2 time) was done to study the changes. **Results:** Paired Samples T-Test revealed a significant difference between the three time points (before the implantation, the day after it, six months later) (*P-value* = 0.000) at the confidence level of 95%. Furthermore, two-way comparisons between the three follow-ups was done to determine where the difference was. The test showed that there is a significant difference (*P-value* $< 0.05$) between all time points. by doing two-way comparisons between the three follow-ups, it was shown that the significant difference (*P-value* $< 0.05$) was in each comparison. **Conclusion:** We conclude within the limits of this study that an adequate amount of bone gain was found 6 months after the bone grafting process.

## Introduction

The appropriate bone volume to which dental implants are inserted is considered the most critical way to achieve implant success; as inadequate bone volumes negatively affects long-term prognosis and implant survival [1]. The presence of sufficient bone is important not only for the cosmetic aspects but also for the biomechanical aspects of the prosthesis [2]. Moreover, local conditions or diseases, such as traumatic extraction, periodontal diseases, and trauma could complicate this pathological condition, making dental implants placement difficult or unfavorable from both a functional and aesthetic perspective [3]. The resorption is documented on alveolar ridges after tooth extraction and the greatest amount of bone resorption occurs in the horizontal plane and occurs mainly in the buccal aspect of the alveolar bone [4]. Many techniques have been developed to reconstruct resorbed alveolar ridge for dental implants placement by the same time of grafting procedure or in two-stages surgery after bone graft healing [5]. Here are some of the techniques used to solve the problem of bone resorption: autogenous onlay bone grafts, guided bone regeneration (GBR), ridge split technique and alveolar distraction osteogenesis (ADO). It is known for all that each technique of them have many advantages and disadvantages [6]. Nowadays, to overcome this limitation guided bone regeneration represents the gold standard in bone regeneration for implant placement and is the most documented technique in literature [1].

In order to make the necessary assessment for the treatment process, the bony defects around dental implants were categorized into five groups depending on the shape of the bony defect around implants (Tab. I) [7].

Basic criteria are required to aid in the success of the one-stage procedure including the availability of sufficient blood supply and maintaining the consistency of the bone graft applied. The absence of periodontal vascularization requires in particular a bone thickness of 2 mm around the implants, in order to avoid peri-implant alveolysis. Indeed, the quantity of bone around the implants is not important only for biomechanical and cosmetic reasons, but also for biological reasons of vascularization [6,7].

Calcium Sulfate bone graft (CS) consists of a dihydrate of calcium sulfate, also called gypsum. When gypsum is subjected to heat to 110 °C, through a mechanism called calcification, it misses water, at which stage the result is called calcium sulfate hemihydrate or Paris gypsum hemihydrate (semi-aqueous calcium sulfate) [8].

It is classified as an Alloplastic material or Synthetic graft, and these materials act as a scaffold in which new bone grows by absorption and positioning from the surrounding bone and is called creeping substitution [9,10].

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**Table I.** Bone defects according to Benic and Hämmerle.

| Bone defects | Description |
|---|---|
| Class 0 | Site with a ridge contour deficit and sufficient bone volume for standard implant placement |
| Class 1 | Intra-alveolar defect between the implant surface and intact bone walls |
| Class 2 | Peri-implant dehiscence, in which the volume stability of the area to be augmented is provided by the adjacent bone walls |
| Class 3 | Peri-implant dehiscence, in which the volume stability of the area to be augmented is not provided by the adjacent bone walls |
| Class 4 | Horizontal ridge defect requiring bone augmentation before implant placement |
| Class 5 | Vertical ridge defect requiring bone augmentation before implant placement |

The aforementioned substance (CS) was widely used for clinical use and gave very good results in various fields of dentistry, it was licensed by the FDA in 1996 [11].

It has many indications; Bone defects repair [12], as a membrane in GTR [13,14], socket preservation [15,16], in sinus lifting augmentation procedures [17,18], and treatment of peri-implantitis [19,20].

Calcium sulfate is a graft that is bioresorbable, osteoconductive, easy to handle and place and cost-effective. In addition, it acts as a soft tissue barrier and improves osseointegration [11]. For that reason, we used CS as it has many beneficial characteristics that could give us the passion to study.

The aim of this trial is to measure the radiographical and clinical overall gaining in the width of resorbed alveolar ridges after inserting dental implants simultaneous to bone grafting. This is to determine the efficacy of using CS bone graft alone in bone defect repair in one-stage surgery.

The null hypothesis of this study: there is no gain in the width of the alveolar ridge after the CS grafting neither radiographically nor clinically.

## Materials and methods

### Study design

This study is an interventional clinical trial. Approval for this clinical trial was received by the scientific research Committee of Damascus University on 14/05/2019 with ID: 2576/557. We followed the principles provided in the accordance with the declaration of Helsinki on scientific studies concerning human subjects.

This research was registered as a clinical trial with an **ID**: 41619166 in ISRCTN database which is recognized by the World Health Organization (WHO).

### Study population

24 implants (SGS Dental Implant System – St. Gallen, Switzerland) were inserted with a total of 12 patients (8 males and 4 females) were involved in this study. G power version 3.1.9.2 (Franz Faul, University of Kiel, Germany) was used to calculate sample size. It was estimated that 18 implants were sufficient to get a statistically significant difference with the effect size of 0.4. However, the sample size was raised by 25% in order to overcome any expected drop out of the participants.

The inclusion criteria to which patients were selected were: (a) teeth were extracted at least 6 months before surgery in the anterior region of the upper jaw, (b) only horizontally absorbed alveolar ridges with the width of bucco-palatal bone ranges from (3.5–5.5 mm) and with the accordance to class 2 of Benic & Hämmerle [7] classification of the bony defect formed around dental implants. The omission was made for patients with poor oral hygiene, systemic conditions that can be considered as contraindication to minor surgery or local anesthsia, prior irradiation medical care, alcohol intake, vertical bone abnormalities and parafunctional attitudes.

This study was performed in the oral and maxillofacial department of Damascus University.

### Surgical procedure

Before starting the study phase, all patients signed a written informed consent.

Diagnostic CBCT radiographs were done using (Vatech PAX-i3D GREEN, Hwaseong-si, Gyeonggi-do, Korea) at (T0) time point (before the surgical intervention) to determine the primary radiographic width of the native bone in the planned implantation site on the alveolar ridge. Another CBCT was taken after surgery in T1 (after one day) and T2 (after six months).

Patients who were selected to be enrolled within this study have undergone the surgical stage as the following:

- The oral cavity was disinfected before the surgical procedure begins with 0.12% chlorhexidine oral rinsing. Then, we used topical anesthesia (Benzocaine 20% gel) and local anesthesia lidocaine HCL 2% with epinephrine (1: 80,000).
- We released the flap to expose bone: implant site was prepared by leaving less than 1 mm on the buccalsite, which will be dehiscenced after implant insertion. After that, CS bone graft (DentoGen®- orthogencorp 505 Morris Ave, Suite 104, Springfield, NJ, 07081) was used to cover the defect simultaneously by applying it for 2–4 min until it gets hard.
- Suturing was performed using 4/0 suture.

**Table II.** Two-way comparisons to study the differences between means of changes in the alveolar width overall gain radiographically in (T0-T1-T2) times.

| Radiographic variables | Time of measurements | Mean ± SD (95% CI) | MIN | MAX | *T test*-value | *p-value* |
|---|---|---|---|---|---|---|
| ROBW* | T0 | 4.133 ± 0.5433 | 3.3 | 5.4 | −20.919 | >0.05 |
| | T1 | 8.9050 ± 0.76737 | 7.76 | 10.30 | | |
| | T0 | 4.133 ± 0.5433 | 3.3 | 5.4 | −12.316 | >0.05 |
| | T2 | 7.2742 ± 0.81268 | 5.73 | 8.56 | | |
| | T1 | 8.9050 ± 0.76737 | 7.76 | 10.30 | 5.177 | >0.05 |
| | T2 | 7.2742 ± 0.81268 | 5.73 | 8.56 | | |

*ROBW: Radiographic Overall Bone Width, CI, confidence interval; SD, standard deviation.

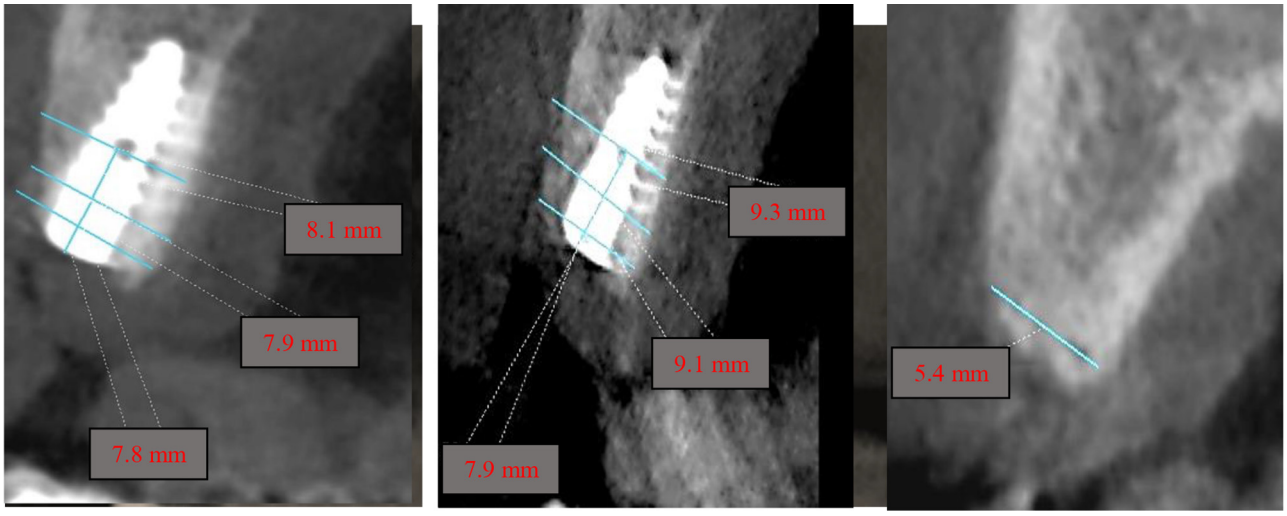


**Fig. 1.** Radiographic evaluations to show the overall width at T0, T1, T2 times.

- Patients were instructed with the suitable prescription and instructions with a follow-up appointment after 7 days for suture removal.
- The prescription, which was given to all patient for 7 days after the surgery to control microorganism effect on the wound and to reduce the post-pain and edema, was as follows:

I. Augmantin® (Amoxicillin 875 mg + Potassium Clavulanate 125 mg) 1000 mg ctd tab Bid.
II. Flam-k® (Diclofenac Potassium 50 mg) ctd tab Tid.
III. Adanaz- forte 10 mg tab Tid.
IV. Zak (ChlorhexidineGluconate 0.12%) MW.

## Study outcomes

As a Primary outcome, we measured the radiographical width of the bone in the implantation area to determine the overall bone gaining, and we measuered the clinical width of the working area to determine the overall clinical width as a secondary outcome. Both of the measured outcomes were reported in three separate evaluation appointments; T0 (before implant placement), T1 (after one day) and T2 (after 6 months).

## Radiographic measurement

The radiographic study was done according to the following steps:

- EZ3D-i/plus software of cone beam computed tomography (CBCT) was used to study all the images taken for this research.

In T0, T1and T2 times, bone width was studied according to the following method:

- The width of the native bone in the planned implantation region was registered at T0 Time.
- At T1 and T2 Times all measurements were taken in a standardized way on the sagittal section according to three levels (1-3-6 mm) away from implant shoulder, the average of these measurements is calculated and considered as the overall bone width at these time points (Fig. 1).

## Clinical measurement

Measuring the clinical overall bone gaining was done by using caliper set at the level 3 mm apically to the gingival line on the top of the socket. Figure 2 shows a clinical case at T2.

### Statistical analysis

We used the SPSS 24.0 statistical package for statistical analysis. Observational data was identified by the mean and standard deviation of overall radiographical and clinical bone gaining of the alveolar ridge width at T0, T1 and T2 times.

Paired Samples T-Test was performed to compare the means of T0, T1 and T2 of overall bone gain at 0.05 significance level, by doing two-way comparisons between the three times.

## Results

A total of 24 implants were placed using (SGS Dental Implant System – St. Gallen, Switzerland) in the planned area. After that, grafting was carried out simultaneously at the time of implantation. No complications occurred during implants placement or in follow up evaluation appointments.

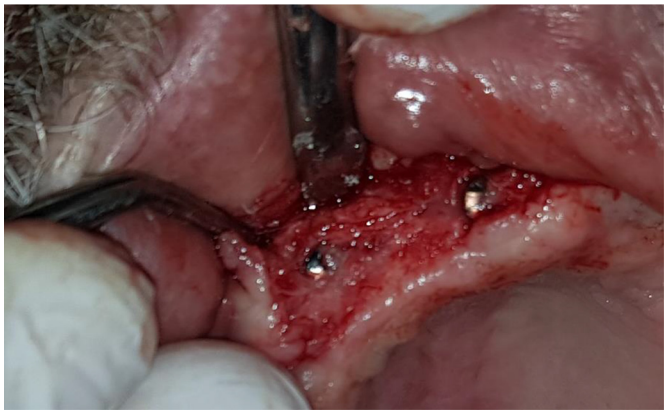

**Fig. 2.** Clinical case reveals the new formed bone after 6 months.

The mean radiographic width measurement of the alveolar crest at (T0) was 4.133 ± 0.543 mm. Whereas, the day following the application of calcium sulfate bone graft (T1) it increased to 8.90 ± 0.767 mm. On the other hand, the mean of overall bone thickness was decreased to 7.27 ± 0.812 mm in the (T2) appointment (after 6 months) (Fig. 3).

To study the differences between means of changes in the radiographic alveolar width overall gain,Paired Samples T-Test was performed. This test revealed a significant difference between the three time points (*P-value* = 0.000) at the confidence level of 95%. Furthermore, two-way comparisons between the three follow-ups was done to determine where the difference was. The test showed that there is a significant difference (*P-value* < 0.05) between all time points (T0 T1 and T2) (Tab. II).

The mean clinical width measurement of the alveolar crest at (T0) was 8.44 ± 1.51 mm. However, it raised to 13.46 ± 2.07 mm the day following the application of calcium sulfate bone graft (T1). 6 months after treatment (T2), it declined to 11.81 ± 2.21 mm.

To study the differences between means of changes in the clinical alveolar width overall gain, Paired Samples T-Test was performed. This test revealed a significant difference between the three times (*P-value* = 0.000) at the confidence level of 95%. In similarly, by doing two-way comparisons between the three follow-ups, it was shown that the significant difference (*P-value* < 0.05) was in each comparison (T0 T1 and T2).

## Discussion

Bone defects are one of the most challenging problems while inserting dental implants. In that concept, many different techniques are used to reconstruct such defects.

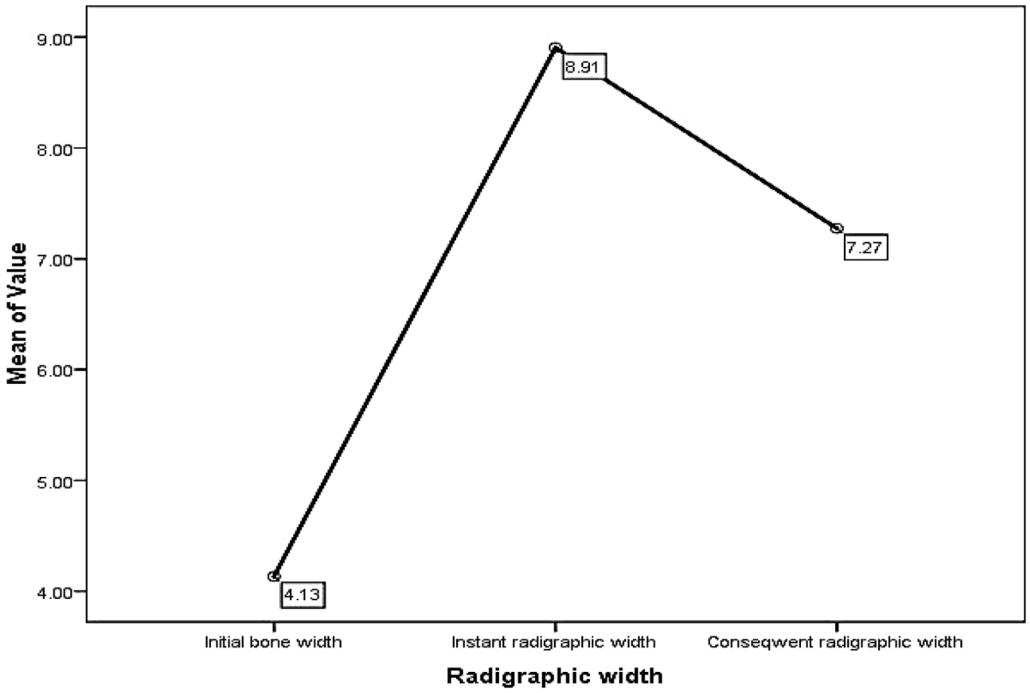


**Fig. 3.** Mean radiographic overall width measurement changes of the alveolar crest at T0, T1 and T2.

Some of them reconstruct the bone prior to implantation (two-stage procedure) and another techniques use the bone grafts simultaneously to implant placement (one-stage procedure). The last mentioned methods have many advantages; shorter treatment plan, simplified procedure for both the clinician and the patient and cost effective technique to be used with giving reliable results [21]. On the other hand, there are different indications that are confined with each technique. In that context, one stage procedure can only be performed when implant primary stability can be achieved.

This trial was aimed to study simultaneous grafting with calcium sulfate hemihydrate to repair the bony defect formed during implants placement.

The method followed in this study is one-stage procedure for implant placement in narrow ridges. This was done by simultaneous bone grafting to completely cover the defect formed at the time of implantation. calcium sulfate hemihydrate (DentoGen® - orthogencorp 505 Morris Ave, Suite 104, Springfield, NJ, 07081) was used as a grafting material. This type of graft was used due to itsunique properties, as there is no need for a barrier membrane. This is because it acts as a membrane by preventing soft tissue ingrowth into the defects and it can be used to cover other types of bone grafts [22]. In addition, its ability to be rigid and to harden depending on the long-term literature that mentioned it as an augmentation materialas reported in thousands of scientific articles during 120 years [23].

The results of this study showed a $3.14 \pm 0.883$ mm of the radiographic overall gain in the area of work at the T2 time according to CBCT radiography, this gaining can be justified due to the reparative properties of the calcium sulfate and by the small amount of expansion of the implantation socket during implant placement.

Strocchi and colleagues at 2002 have conducted a research on experimental animals to repair bone defects and to evaluate the presence of blood vessels in a tissue by counting the microvessels. Bone defects were repaired using calcium sulfate in two groups and autogenous bone graft in the third one, groups of calcium sulfate showed results of bone filling superior to the third group and confirmed the ability of angiogenesis of calcium sulfate which is critical for the development, remodeling, and healing of most tissues, including bone. This property can explain in our thought the high reparative ability of this material, which led to allow achieving such gain in bone width [24].

A study of Kumari *et al.* [16] conducted to evaluate the effectiveness of two commercial types of CS graft in preserving the socket after 60 tooth extraction for patients by clinical and radiological examination 4 months after the grafting process. the results showed the effectiveness of both types of CS grafts in preserving the socket and improving the quality of the formed bone with improved soft tissue healing, On radiographic evaluation the mean percentage of socket fill with the first type was $76.7 \pm 11\%$ and the second type $76.47 \pm 12.43\%$ after 4 months of interval [16]. This confirms the reparative distinctive of the calcium sulfate that it can repair bone defects and fill the space with efficacy and can serve as a bone grafting material.

The results of our study revealed that the clinical overall gaining amount mean was $5.02 \pm 1.84$ mm. The amount of clinical gaining was higher than bone gaining amount that can be attributed to the effect of calcium sulfate on soft tissue by inducing soft tissue proliferation. In addition, it can aid in bone growth by depositing a calcium phosphate trellis, preventing in growth of soft tissues in to the graft material, and aiding in the release of growth factors that stimulates blood vessel formation [14]. Those mentioned factors can led to improve the healing process of bone and soft tissue as well in the grafted area and that can explain the results of our study.

Limitations of the study: Some limitations have to be mentioned. It would be better and more reliable to do such study with a bigger sample size and with a long term follow up period. In addition, the study needs a histologic analysis of the tissues resulted.

## Conclusions

Within the limits of our results, we conclude that the use of calcium sulfate hemihydrate bone graft to cover the defect formed during implantation as simultaneous procedure gave acceptable results with a simple technique.

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## Conflicts of Interests

The authors declare no conflict of interests with this research.

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