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Impact of Zoledronate Gel on the Outcomes of Immediate Dental Implant (Clinical, Radiographic and Biochemical Study)

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ABSTRACT

Aim: The present study was designed to evaluate; the clinical and radiographic effect of topically applied Zoledronate gel on the outcomes of immediate dental implant placement and Biochemical assessment of RANKL level in GCF around dental implant. Subjects and methods: Patients were classified into two groups; group1: Included 9 Patients received immediate dental implant alone. Group 2 Included 9 Patients received immediate dental implant with locally applied zoledronate gel. Modified plaque index (mPI), Modified Bleeding Index (mBI), Pre-implant probing depth (PPD), Implant stability, Biochemical analysis: (RANKL LEVEL) were recorded at base line, 3, 6, 9 and 12 months post-surgically. All patients were evaluated radiographically by CBCT and Standardized periapical radiographs before, after implant placement and after 6 months post-operatively for marginal bone loss. The data were collected, tabulated, computed and statistically analyzed. Results: There was a statistically significant difference between 6 months and 12 months post-operative in modified Bleeding Index, Pre-implant probing depth, marginal bone loss (p=0.030), (p=0.036), (p=0.015) respectively. While there was no significant difference in modified plaque index and Implant stability (p=0.576). Biochemical analysis: (RANKL LEVEL) There was a statistically significant difference after (3m) between (Group1) and (Group2) where (p=0.095). Conclusion: From the results the present study, we can conclude that: The use of zoledronate gel at the time of implant placement improves the implant stability, suggesting that might be used as adjunct for initial implant osseintegration.

KEYWORDS

Zoledronate gel, RANKL, GCF, CBCT, dental implant, plaque index

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INTRODUCTION

Immediate dental implant placement in fresh extraction sockets was introduced, in order to reduce the number of surgical procedures and potentially limit physiological bone resorption [(1)]. However, immediate implant placement may not always provide successful clinical outcomes [(2,3)] and has been documented that this surgical protocol fails to prevent the horizontal and vertical ridge alterations[(4)]. This may result in impaired esthetics [(5)] such as marginal soft tissues recessions, especially if treating the buccal side of maxillary sites in patients with a high smile line [(6)].

Many researchers have advanced the idea of immediate implant placement. Lazzara [7] in 1989 was one of the initial surgeons to attempt it. His rationale was better maintenance of alveolar architecture, the use of longer implants and shortened treatment times. Grunder and pollizzi[8] in a 1999 multicenter prospective study reported the success rates of implants placed immediately into extraction sites. Gomez-Roman et al[9] in 1997, using a tapered implant system reported a 98.84% five-year success rate with 83 implants placed immediately after extraction.

Stability of an implant can be defined as its capacity to withstand loading forces in axial, lateral, and rotational directions. Sennerby & Roos in 2007 stated that primary implant stability is determined by bone quality and quantity, implant design, and surgical technique [10]. When primary stability is unattainable, the procedureshould not be carried out[11]. Ostman in 2007 found significant higher initial implant stability, measured with resonance frequency analysis, with wider implants compared to narrow/regular implant designs [12].

Bone quality has been suggested as an important prognostic indicator of dental implant success and is of special importance when considering immediate implants. Lekholm and Zarb's bone type classification is widely accepted. In general, bone quality and quantity are superior in the mandible; hence, immediate implant success is greater in the mandible as compared to the maxilla [13]. Cited studies with mandibular success rates of 95% and maxillary success rates of 92%. When type IV bone is encountered, an overall dental implant failure rate of 35% has been reported [14].

It is well known that success in implant dentistry depends on several parameters that may improve considering both biologic and mechanical criteria.

Osseointegration was defined by Brnemark as the direct connection of living bone with the surface of an implant subjected to a functional load. This definition has been modified over the years. The tissue contact with the osseointegrated implant is the result of a process of new bone growth that involves continuous modeling and remodeling. Thus, it is important to understand that integration of bone with the implant is a dynamic process. Moreover, the formation and stability of new bone around the implant is a combination of resorption and bone apposition. The balance between these processes is affected by various types of stimuli, including biomechanical forces in the dental prosthesis and the potential presence of inflammation (mucositis and peri-implantitis) [15].

Bisphosphonates are used in many clinical settings, including prevention and treatment of primary and secondary osteoporosis, Paget's disease of bone, hypercalcemia, multiple myeloma and osteolysis associated with bone metastases of malignant tumors. They may directly inhibit the bone-resorbing activity of osteoclasts by mechanisms that can lead to osteoclast apoptosis [16].

The principal pharmacologic action of zoledronic acid is inhibition of bone resorption. Although the anti resorptive mechanism is not completely understood, several factors are thought to contribute to this action. In vitro, zoledronic acid inhibits osteoplastic activity, also known as Zoledronate(ZOL) , is a medication used to treat a number of bone diseases These include osteoporosis, high blood calcium due to cancer, bone breakdown due to cancer, and Paget's disease of bone. It is given by injection into a vein [17]. It is in the bisphosphonate family of medications, works by blocking the activity of osteoclast cells and thus decreases the breakdown of bone [18].

Fischer et al [19], describes a patient who was receiving treatment with IV bisphosphonates for osteoporosis and who was a candidate for dental implant placement and reviews the underlying evidence to support decision-making and treatment

planning in similar cases. They also evaluate important risk factors and the decision-making pathway in such cases. On the basis of existing evidence, receipt of a single IV infusion of zoledronic acid for the treatment of osteoporosis does not appear to be an absolute contraindication to implant placement. Typically, the required dosage has been achieved by systemic oral administration, but IV administration is increasingly the treatment of choice.

RANKL, through its ability to stimulate osteoclast formation and activity, is a critical mediator of bone resorption and overall bone density. Overproduction of RANKL is implicated in a variety of degenerative bone diseases, such as rheumatoid arthritis and psoriatic arthritis. In addition to degenerative bone diseases, bone metastases can also induce pain and other abnormal health complexities that can significantly reduce a cancer patient's quality of life. Some examples of these complications that are a consequence of bone metastasis are: hypercalcemia, pathological fractures and spinal cord compression Some findings also suggest that some cancer cells, particularly prostate cancer cells, can activate an increase in bone remodeling and ultimately increase overall bone production. This increase in bone remodeling and bone production increases the overall growth of bone metastasizes. The overall control of bone remodeling is regulated by the binding of RANKL with its receptor or its decoy receptor, respectively, RANK and OPG [(20)].

So, the primary research question in the present study was that:

Upon the proved efficacy of zoledronic acid as an inhibitor to osteoclastic chemotaxis and activity in addition to its bone forming potentiality, does application of zoledronate gel locally as adjunctive to immediate dental implant can be enhance the treatment outcomes?

SUBJECTS AND METHODS

This study was designed as a randomized controlled clinical trial carried out on 18 patients of both sex (9 females and 9 males ranged in age from 31-45years), with mean age 30±6.3 years. All patients were selected from those attending at the Out-Patient Clinic, Oral Medicine and Periodontology Department, Faculty of Dentistry, Al-Azhar University, Assiut Branch. Seeking immediate dental implant. Informed consents were obtained from all patients before any study procedures were performed. No identifying information such as patients' images, names, initials, or telephone numbers, has been included in this study. This study was approved by the ethical committee, Faculty of Dentistry, AL Azhar University, Assiut Branch.

Inclusion criteria

- At least 18 years old.
- Systemically healthy patients were selected for implant surgery according to the criteria of Cornell medical index and its modifications [(21)].
- All patients had badly decayed hopeless tooth indicated for extraction and seeking implant placement.
- Sufficient bone height and widths around the implant.
- Sufficient bone width to prevent dehiscence during implant placement.
- Patients were cooperative, motivated, and had very good oral hygiene.
- The recipient sites of the implant were free from any pathological conditions.

Groups and interventions:

Sample size calculation and power analysis:

For the sample size calculation, the power analysis were performed using G power system

for a one_ way fixed effects analysis of variance (ANOVA) .The criterion for significance was set at A= 0.005 (Type1 error) and B =0.20 (type II error). The sample size is 9 cases per group.

The selection of the technique of each group by coin flipping, and grouping was done as following:

Group 1: Included 9 Patients received immediate dental implant alone.

Group 2: Included 9 Patients received immediate dental implant with locally applied zoledronate gel.

Periodontal preparation:

- Supportive periodontal therapy was given following clinical examination as required.
- At the time prior to the intervention, 1-minute rinses with Chlorhexidine gluconate 0.12% were recommended. Lips and perioral area were also cleaned with Chlorhexidine.

Pre-surgical Evaluation:

1. Radiographic Evaluation: All patients were evaluated radiographically by CBCT and Standardized periapical radiographs before, after implant placement.
2. Clinical evaluation: A thorough medical and dental history, followed by clinical examination was carried out for all patients.

Periodontal Evaluation:

The following clinical parameters were used and recorded before and after implants at base line, 3, 6, 9 and 12 months post-surgically:

Modified plaque index (MP I) [21], Modified Bleeding Index (mBI) [21].

Pre-implant probing depth (PPD) [22], Implant stability [22].

Biochemical assessment:

Biochemical assessment to determine RANKL level in GCF around implant in 3, 6,9,12 months.

Preparation of zoledronate gel (1%):

Zoledronate gel was prepared as described by Reddy, et al. [23]. Briefly; zoledronate (Alfa Aesar, Thermo Fisher Scientific, Germany) was dissolved in a required amount of distilled water to achieve 1% zoledronate concentration. A weighed quantity of carbopol 934P (2% w/w) was taken and added to the distilled water. The mixture was gradually stirred and carbopol was allowed to soak for 2 h. 1% triethanolamine was added to neutralize the carbopol solution and to form the gel. The pH was adjusted to 6.8. Finally, the required amount of methylparaben (0.1%) and propylparaben (0.05%) were dissolved in ethanol and added to the gel.

Surgical procedures:

A traumatic tooth extraction was done. A forceps of anatomic design was used to rotate the root in a clockwise-counterclockwise fashion to retrieve the root from the alveolus.

All granulation tissues were carefully removed from the socket using bone currete, and the site of surgery was carefully rinsed with chlorhexidine gluconate 0.12% solution.

Standard implant was placed in the site, with the rough surface positioned at the level of the alveolar ridge crest. This allows the implant shoulder to be located at the gingival level.

Implant head should be 3 mm apical, gingivally to an imaginary line Connecting the cemento–enamel junctions of the adjacent teeth and apical to the interproximal and crestal bone. This will assure a proper implant emergence profile and facilitate proper implant restoration.

Implants were placed within the body of the alveolus. Torque wrench was used to ensure a good

primary stability. In group I patients received immediate implant alone. While; In Group 2 patients received immediate implant with locally applied zoledronate gel.

The final wound closure was performed by interrupted 0/4 non-resorbable sutures.

After 6 months healing abutment was positioned for 2 weeks then the second stage abutment was placed and the final porcelain prosthesis was cemented.

Post-operative instructions and medications:

Standard post-surgical instructions and medications were given to the patients as the pre-operative therapy for 7 days and chlorhexidine mouth rinsing for 15 days. The patients were instructed to avoid incising food in the operated sites for 6 weeks. Sutures were removed between 10 and 14 days after surgery and all patients recurrently checked for any complications every 4 weeks.

RESULTS

There was a statistical significant difference between baseline 3,6,9, 12months post-operative in modified Bleeding Index, Pre-implant probing depth, marginal bone loss (p=0.030), (p=0.036), (p=0.015) respectively. While there was no significant difference in modified plaque index and Implant stability (p=0.576). Biochemical analysis: (RANKL LEVEL) There was a statistically significant difference after (3m) between (Group 1) and (Group 2) where (p=0.095). (Table 1).

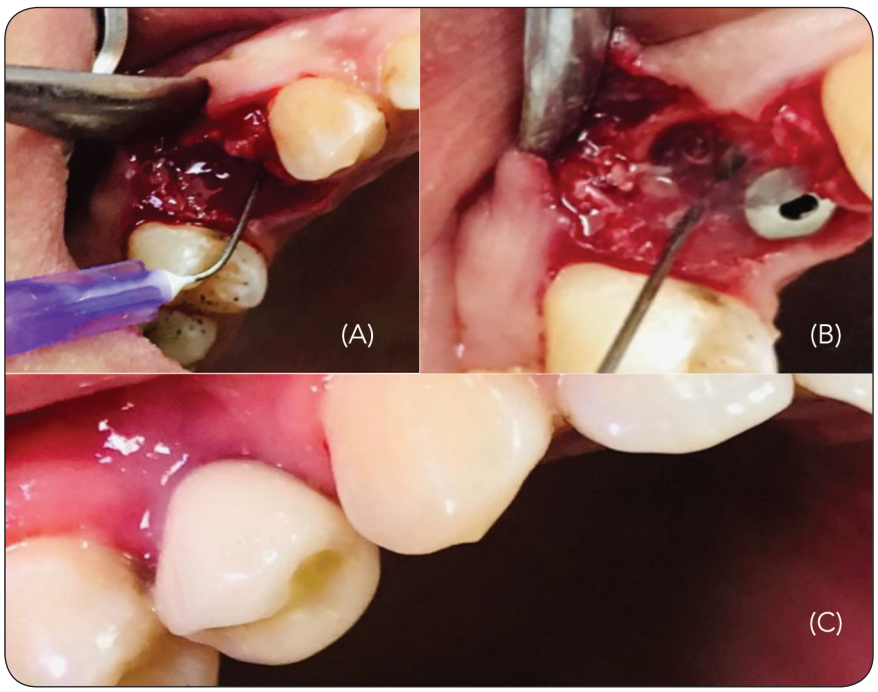

Fig. (1) Clinical photographs for a female patient of 35 years old with missing upper right premolars received an immediate dental implant with application of zoledronate gel (1%). (A) Zoledronate application. (B) Immediate implant with Zol gel (1%) application. (C) Final prosthesis.

Table (1) *Compare between group 1and group 2 in mean and standard deviation of different parameters in different intervals.*

		GP 1		GP 2		
		mean	SD	mean	SD	P value
Implant stability	Base line	68.67 bA	3.71	69.33 bA	4.42	**0.733ns**
	6 month	76.89 aA	4.62	78.22 aA	5.26	**0.576ns**
	P value	**<0.001***		**<0.001***		
MPI	Base line	0.08 bA	0.13	0.11 bA	0.13	**0.638ns**
	3 month	0.36 aA	0.18	0.36 aA	0.13	**0.797ns**
	6month	0.50 aA	0.22	0.33 aB	0.13	**0.030ns***
	9month	0.36 aA	0.22	0.39 aA	0.13	**0.698ns**
	12month	0.44 aA	0.21	0.33 aA	0.13	**0.234ns**
	P value	**0.001***		**0.014***		
PPD	Base line	4.00 aA	0.43	4.06 aA	0.39	**0.779ns**
	3month	3.11 bA	0.49	2.83 bA	0.43	**0.219ns**
	6month	2.83 bA	0.50	2.56 bA	0.46	**0.240ns**
	9month	2.50 cA	0.56	2.06 cA	0.53	**0.102ns**
	12month	2.50 cA	0.43	1.94 cB	0.58	**0.036***
	P value	**<0.001***		**<0.001***		
Biochemical analysis (ng/ ml)	Base line	0.90 abA	0.21	0.96 aA	0.20	**0.534ns**
	2 W	1.03 aA	0.30	0.92 aA	0.19	**0.371ns**
	1month	0.83 bcA	0.20	0.77 bA	0.16	**0.504ns**
	3month	0.73 cA	0.11	0.62 cA	0.11	**0.045***
	P value	**0.005***		**<0.001***		
MBL	Base line	0.00 cA	0.00	0.00 cA	0.00	**1ns**
	3month	0.32 dA	0.05	0.27 dB	0.03	**0.027***
	6month	0.51 cA	0.10	0.38 cB	0.06	**0.005***
	9month	0.57 bA	0.12	0.50 bA	0.05	**0.101ns**
	12month	0.78 aA	0.12	0.64 aB	0.10	**0.015***
	P value	**<0.001***		**<0.001***		

DISCUSSION

The Previous animal studies have shown that it is possible to obtain stronger fixation and osseointegration by coating bisphosphonate on the surface of both steel and titanium implants [24]. Moreover, the motivation for the use of bisphosphonates is based on the uncoupling of resorption and formation in traumatized bone. When osteoclast activity is reduced, osteoblast activity is maintained, yielding a positive balance and a gain in the amount of bone, which explains the improved fixation in animal experiments [25].

Zoledronate (Zol) is a new generation intravenous BP that demonstrates high affinity for hydroxyapatite, which promotes the longest retention of existing bone minerals in comparison to other BP. As such, ZOL is currently the most potent drug in the BP family. It has been hypothesized that ZOL may aid in osseointegration and dental implant fixation by opposing the reduction of bone mineral density in osteoporosis [26].

The present study was conducted on medically free patients and excluded smokers, pregnant and lactating women and medically compromised patients, because these conditions affect the response to treatment in the form of healing term and pattern which reflects on and affect the accuracy of the study results. This was notched with Grossi et al [27].

A traumatic extraction technique was used in the present research; this is very important for the success of implants and facilitates maintenance of the maximum amount of bone. This based on study Douglass and Merin [28].

The used implant system in this study is SGS Swiss dental implant®(R SGS international Ltd system holding-st. Gallen, Switzerland) was used in this study. It is one and two-stage self-tapping implant system designed for conventional and immediate loading applications with variable lengths and diameters according to the site of implant placement.

RANKL is essential for the complete differentiation of osteoclast precursor cells and plays a critical role in periodontal bone resorption. The level of RANKL mRNA has been reported to be highest with bone destruction in advanced periodontitis and decreased with bone formation after periodontal treatment or in healthy group [29], so the present study used GCF level of RANKL as an indicator to the process of bone regeneration in treatment of implant site.

The observational periods for the present investigation were kept at 6, 12 months which considered enough for clinical, radiographic and biochemical evaluation of the regenerative process included in conservative clinical trials. Moreover, no clinical measurements were taken from the base line up to 3 months post treatment in an attempt to avoid adverse effect of healing tissues which is fragile and could be damaged with probing process in accordance with previous a study.

As regard to the follow up period in the present study it was 3, 6, 9 and 12months post operatively as most implant complications and failures are most likely to occur in the first year of placement of dental implant as the study of Rosenberg et al [30], they concluded that complete implant failure ranging from 3% to 8% after an implant has been restored and placed in function for the first year. Moreover, another study suggested that failure rates are dramatically reduced and have been reported to be around 1 % after one year [31].

During of the evaluation period, patients showed generally good oral hygiene habits and very good soft tissue around the implants. In accordance the results of the present study showed a significant difference in both modified plaque and gingival inieces after 3 and 6 months when compared to baseline in the two groups (p<0.001) which may be due to the decrease of bacterial amount with subsequent reduced inflammation by supportive periodontal therapy, strict instructions, patients cooperation and motivation during the observation

period of the study. While there was a statistical significant difference in modified gingival index in group II when compared to group I after 3months only (p=0.001), that may be explained by the anti-inflammatory effect of zoledronate [32].

During measurement of peri-implant pocket depth (PPD) showed good values at all point's examination. This study revealed that, the mean PPD were 2.50 ±0.43 for the (group 1) and 1.94± 0.58 for the (group 2) with a significant difference of peri-implant pocket depth between the two groups.

According to the previous reports[33], there were different thresholds are referred to as peri-implantitis: > 6mPPD; ≥ 4mm initial peri-implantitis, ≥ 6mm moderated peri-implantitis and ≥ 8mm severe peri-implantitis. Moreover, in another study [50] used two PPD; ≥ 4mm and ≥ 6mm, to distinguish the different levels of peri-implantitis severity. Therefore, the peri-implant probing is essential for establishing a diagnosis of peri-implant disease.

The maintenance primary stability, the greater retention of the implant in the bone, and the reduced per-implant bone loss may improve the treatment success rate as well as reducing implant failure. Clinically the implant stability may be assessed either by recording the insertion torque value or by using the resonance frequency analysis. Insertion torque measurement is a well-established method however; it may asses only the primary stability during implant placement. While, resonance frequency analysis may use at any time during implant life [34].

The reported ISQ levels for successfully integrated implants, after one year range from 57 to 82, with a mean ISQ of 69[35] .The present findings demonstrate the mean value of ISQ was 78.22±5.26 for the group 2and 76.89±4.67 for the group 1. There was a difference between the two groups due to the effect of zoledronate gel but not statistically significant. These findings are in agreement with study of zufletti et al [36]; they concluded that the use of bisphosphonate solution as adjunct might be beneficial to the initial implant osseointegration.

Also, the present study is in accordance with the previously experimental studies; Meraw and collegues [37], reported that the use of zoledronate at the implant surface increased the percentage of bone surrounding the implant.

Meraw and collegues [38] revealed that the topical administration of alendronate in dogs' rehabilitation of peri –implant defects favored initial bone formation around implant.

The results of the present study are in accordance with a study [39], demonstrated that the topical use of bisphosphonates in human in order to prevent peri-implant osteolysis and also to improve a new bone formation around the implants. In addition, 3 year follow up study demonstrated that the oral administration bisphosphonates (alendronate and risendronate) may increase the percenting of successful implant therapies.

Finally, the important factor that may influence bone healing is the timing of drug administration. In this study ZOL gel has been used at the time of extraction and implant placement. This based on a study reported that early administration of BP could potentially reduce the anabolic response and result in a negative effect on the rate of bone formation. In fact, if there is a lack of an affinity between the drug solution and implant, when the implant is placed into the implant site, air pockets can be created between the implant and the drug, which may push part of the solution toward the outside, expelling the drug from the site of action. The air pocket may remain and thus reducing the pro-ossifying activity and the implant stability. Instead, if the solution adheres in balance way to all surfaces, no air pockets are formed, and the entire space between the walls of the implant site and the implant remains contact by the drug solution [40].

Conclusion: From the results the present study, we can conclude that: The use of zoledronate gel at the time of implant placement improves the

implant stability, suggesting that might be used as adjunct for initial implant osseintegration. Receptor Activator of Necrosis Factor-ϰB Ligand (RANKL) can be considered a good bone biomarker, not only to determine periodontal disease progression but also to evaluate treatment outcomes through the strong correlations with clinical and radiographic parameters.

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تاثير جيل الزيلدرونيت على نتائج على غرسات الاسنان الفورية (دراسه اكلينيكيه, اشعاعيه, بيوكميائيه)

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الملخص :

الهدف : تهدف هذه الدراسة لتقييم تاثير جيل الزيلدرونيت على نتائج على غرسات الاسنان الفورية عن طريق استخدام الفحص الاكلينيكي والاشعة وعينات من سائل الجيوب اللثوية لتعين نسبة منشط مستقبلات العامل النووى كاباب

المواد والاساليب:تم اختيار تسعه عشر مريض من الجنسين (9اناث و9ذكور) تتراوح اعمارهم مابين 30-45 سنة لدى كلا منهم سنة ميؤوس منها في الفك العلوي نتيجة (فشل في علاج الجذور,اسنان ذات جذور مكسورة, وجود تاكل داخلي او خارجي فى الجذور اوبواقي اسنان لبنية). تم تقسيم المرضى إلى مجموعتين: المجموعة الأولى: تحتوى علي 9 مرضى استقبلوا غرسات فورية فقط. المجموعة الثانية: تحتوي علي 9 مرضى استقبلواغرسات فورية مع استخدام جيل الزيلدرونيت.وقد تم اخذ القياسات الاكلينيكية وبالاشعة وعينات من سائل الجيوب اللثوية للتقييم قبل البدء في العلاج ثم تتابع التقييم عند اسبوعين وشهر وثلاثة شهور للمجموعتين علي التوالى. وفى المجموعة الثانية تم تعريض الانسجة المحيطة بالغرسة الفورية جيل الزيلدرونيت تمت في يوم الزراعة.

النتائج: اظهرت نتائج هذه الدراسة عدم وجود فروق احصائية عند بدء الدراسة بين المجموعتين فى ثبات الغرسة ومؤشر اللطخة الجرثومية المعدل ومستوي RANKLE. اظهرت نتائج هذه الدراسة وجود فروق احصائية عند فترة الثلاثة اشهربين المجموعتين مؤشر نزيف اللثه معدل قياس الجيوب اللثوية مستوي العظام علي الجانبين: مستوي RANKLE عند فترة الثلاثة اشهروالسته اشهر واثني عشراشهر على التوالى بين المجموعتين

الخلاصة: ابدي استخدام جيل الزيلدرونيت اثناء وقت عمليه غرس الا سنان تحسنا ملحوظا فى مستوى ثبات الغرسه ويعتبر هذه مقترحا لاستخدامه كعامل مساعد فى بد اية الاندماج العظمى الاولى للغرسه.

الكلمات المفتاحية: جيل الزيلدرونيت ، منشط مستقبلات العامل النووى كابا ب ، سائل اللثوى، الاشعه المقطعيه المخروطيه، غرسة الاسنان , مؤشر البلاك.