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The use of Local Vitamin D3 Gel in Immediate Dental Implants: A Randomized Controlled Study

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ABSTRACT

Aim: This study was performed to evaluate the osteogenic efficacy of vitamin D3 on immediate dental implant by clinical and radiographic assessments. **Subjects and methods:** This was a prospective randomized, clinical study including 30 patients with decayed hopeless tooth indicated for extraction and seeking implant placement. Patients were selected from those attending at the outpatient clinic of Oral Medicine and Periodontology Department, Faculty of Dental Medicine, Al-Azhar University "Assiut branch" seeking extraction and dental implant placement. The patients were divided into two groups: Group (1): 15 patients received immediate dental implant placement alone used as control group, and Group (2): 15 patients received extraction combined with dental implant placement plus local application of vitamin D3 gel on the socket as test group. **Results:** There was no statistically significant difference between two groups in visual analogue scale (VAS) at day 1, and 14 but there was a statistically significant decrease in group 2 at day 3, and 7 compared to group 1. According to modified plaque index, there was no statistically significant difference between two groups at 3 months and at 6 months. Moreover, the modified plaque index means were statistically different across different time periods in group 1 only, but not statistically different in group 2. Regarding probing depth, there was no statistically significant difference between the two groups at baseline, 3 months and 6 months. However, the probing depth means were statistically significant different across different time periods when compared in each study group (decreases by time). **Conclusion:** The current study showed that topical application of Vitamin D3 in immediate dental implant placement mildly improves osseointegration and may induce anti-inflammatory effect in peri-implant status.

KEYWORDS

Immediate, Implant, Vitamin D3, Gel

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INTRODUCTION

A dental implant is one of the treatments modalities to replace missing teeth. Dental implants have several advantages over conventional fixed partial denture including a high success rate (above 97% for 10 years), a decreased risk of caries and endodontic problems of adjacent teeth, improved maintenance of bone in edentulous site, decreased

sensitivity of adjacent teeth [1]. Single or multiple implants can be placed in edentulous bone, grafted bone, or fresh extraction sockets. However, the timing of implant placement after tooth extraction was noted that there is presently insufficient evidence to define the disadvantages or advantages of immediate, immediate-delayed, and delayed implants. None of these techniques appear superior to the others in terms of implant success or failure [2].

The research has focused on improving bone substitutes and implant surfaces to achieve faster and better osseointegration by morphologic or biochemical modification [3]. These modifications can improve bone quality and quantity around dental implants, reducing economic costs and treatment times, improving osseointegration, and consequently survival time. Biochemical modifications consist of the application of biological mediators over the implant surface or into the biomaterial to induce specific cell and tissue responses, such as growth hormone, melatonin, or vitamin D [4-6].

Osseointegration, is defined as formation of a direct interface between implant and bone, it is key for the success of a dental implant. It is important that the implant to be integrated into the bone during the initial healing period; this results in a clinically asymptomatic fixation under functional load, and this integration has to be maintained over time[7,8]. Osseointegration of dental implants depends on several different factors: surgical and prosthetic factors (surgical technique and operator experience, timing and type of prosthetic loading, and quality of prosthetic rehabilitation), implant-related factors (material, design, and surface), and patient-related factors (bone volume/quality at the recipient site and host response) [9].

Successful osseointegration is one of the key criteria for a prosperous dental implant therapy which is achieved by a functional ankylosis [10]. As well as osseointegration of dental implants also depends on bone metabolism, there is the possibility that low levels of vitamin D in the blood can affect healing processes and new bone formation on the implant surface [11, 12].

Vitamin D is a steroid hormone which can be synthesized in the skin when sun irradiation is sufficient (290–315 nm) and successfully converted in the liver and kidneys and commends a group of fat steroid hormones. These hormones can be found in several forms such as ergocalciferol (vitamin D2) and cholecalciferol (vitamin D3). Vitamin D3 is formed by the skin from cholesterol under the UV exposure, and the most active form is 1α, 25-dihydroxyvitamin D3 (1α, 25-(OH) 2D3), named as calcitriol. This biomolecule has a fundamental role in bone and calcium homeostasis, acting directly in calcium absorption in the intestines and kidney, and it enhances bone reabsorption and reduces calcium and phosphate excretion. [13] Vitamin D receptors are present in osteoblasts and have direct effect on cells by regulating gene expression, as well as other proteins involved in bone formation like osteocalcin. Vitamin D plays a major role on bone health[14]. This study was performed to evaluate the osteogenic efficacy of vitamin D3 on immediate dental implant by clinical and radiographic assessments.

PATIENTS AND METHODS

Study setting and population

This was a prospective randomized, clinical study including 30 patients with decayed hopeless tooth indicated for extraction and seeking implant placement. Patients were selected from those attending at the outpatient clinic of Oral Medicine and Periodontology Department, Faculty of Dental Medicine, Al-Azhar University "Assiut branch" seeking extraction and dental implant placement. The study was performed in the period from August 2020 to December 2022.

Eligibility criteria of population:

We included the following: Adult patients with age range of 18-45 years, both sexes, patients who had badly decayed hopeless tooth indicated for extraction and seeking implant placement, patients were medically free disease according to the normal criteria of Modified Cornell medical index [15], had no contraindications to oral surgery, nonsmokers, cooperative, motivated and had good oral hygiene, implant sites having sufficient vertical inter-arch space to accommodate the restorative components, the opposing natural teeth were without drifting, malposition or over erupted to the implant site, and patients who were able understand instructions with good oral hygiene and provide informed consent.

Patients with the following criteria were excluded from the study: Patients with previous failed intervention of the same tooth, patients having any allergies, infectious or autoimmune diseases, poor health or any other medical, physical or psychological reason that might affect the surgical procedure or the subsequent prosthodontics treatment and required follow up, pregnant and lactating woman, dental history of bruxism, para-functional habit such as smokers and alcohol or drug dependency, and inability to give informed consent or patients refuse to participate in the study.

Patients grouping and intervention:

The patients were divided into two groups: Group (1): 15 patients received immediate dental implant placement alone used as control group, and Group (2): 15 patients received extraction combined with dental implant placement plus local application of vitamin D3 gel on the socket as test group.

Preparation of vitamin D3 gel

Active vitamin D3 gel was prepared by pharmaceutical department, Faculty of Pharmacy Sohag University. It was made by weighted methyl cellulose added to amount of biocompatible solvent to prepare methyl cellulose gel. This mixture was heated at 50°C to 60°C and well shaked with a mechanical shake to obtain clear solution. Weighted amount of aqueous solution of vitamin D3 (active material manufactured by MUP Company, Vidrop) was added to the previous solution and dissolved completely to obtain a homogenous gel which was loaded in sterile plastic syringes and stored in dry cool environment for use. The concentration of Vitamin D3 gel was similar to concentration used in previous studies [16]. Each 25 ml of gel contains vitamin D3 (80 I.U), 2 gm Hydroxyl propyl methylcelluolose and 10gm water.

Patient evaluation

Visual analogue scale

Visual analogue scales (VAS) unidimensional measure of pain intensity, which has been widely used in diverse adult populations. (Figure 1)

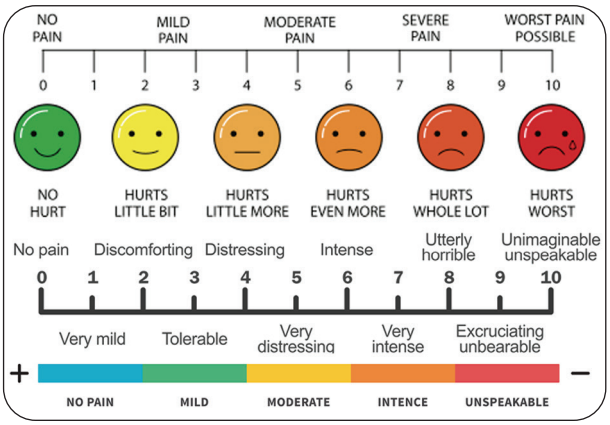

Fig. (1) Visual analogue scale

Periodontal evaluation

The following clinical parameters were recorded for all patients at baseline and 3 months and 6 months

Modified plaque index [17].

It is a clinical parameter that assess the quality of oral hygiene through clinical observation (using mirror and explorer) of the biofilm on tooth surface

and measure the 4 surfaces of the tooth (mesial, distal, buccal and lingual)and calculate the mean of these 4 scores and the score calculated ,the score is graded from 0-3, as 0 score mean no plaque on tooth surface and 1means thin layer of plaque detected only by explorer and 2 means plaque layer can detect by naked eye and inter dental space still free from plaque and 3 means that there is huge plaque layer and fill the inter dental space .

Modified Sulcular Bleeding index

Used for assessment of gingival bleeding around the implant and also inflammation, bleeding after probing was evaluated after 10 seconds of probing (at mesial and distal angles and at the center of buccal and lingual aspect), the average score of these six sites was measured and calculated. It used for assessment of gingival bleeding around the implant and inflammation, bleeding after probing was evaluated after 10 seconds of probing (at mesial and distal angles and at the center of buccal and lingual aspect), the average score of these six sites was measured and calculated. Modified bleeding index score graded from 0-3 as 0 means there is no bleeding when periodontal probe passed along the gingival margin, 1 means small visible spots after passing periodontal probe along gingival margin, 2 means bleeding appear as a continuous red line on gingival margin and 3 means profuse bleeding seen after passing the periodontal probe along the gingival margin.

Probing depth

Periodontal probe was used to measure the distance in millimeter from the gingival margin crest to most deep point around dental implant. To standardize the probing force, about (0.15 N) was used to measure in 1-mm increments with the six points (mesial and distal angles and centers of the buccal and lingual walls) and average score was calculated.

Radiographic evaluation

Measuring of marginal bone level (periapical radiograph)

Marginal bone level around the implant was evaluated using periapical radiographs (by image plate sensor size 2 Veatch) were taken after implant placement on the same day (baseline) and after 3 and 6 months in follow up visits. The distance from reference point at the implant to the most coronal point of bone formed and contact with implant was measured in millimeters mesially and distally of the implant and the marginal bone level was calculated.

Measuring of bone density

Bone density at implant placement day (baseline) and after 3, and 6 months on follow up visits average of bone density was measured at marginal, middle and apical bone around implant using image plate sensor (vatech) software.

Research Approval by Ethical Committee

Before the beginning of the study and in accordance with the local regulation followed, the protocol and all corresponding documents were declared for Ethical and Research approval by the Oral Medicine and Periodontology Department, Faculty of Dentistry, Al-Azhar University.

Statistical analysis

The data were collected, tabulated, and statistically analyzed by statistical package for social sciences (SPSS) version 22 that was programmed to produce the statistical analysis including: Paired t-test used for comparison between the baseline reading and the subsequent readings within the same group, and unpaired t-test used for comparison between the two groups. The p-value was considered significant if it was less than or equal 0.05 and highly significant if it was less than 0.01. The graphs were performed using the Microsoft excel 2020 program.

RESULTS

This study was conducted on 30 patients of both sexes 20 males and 10 females with mean age 27.93 with badly decayed teeth seeking for dental implant. The patients were divided randomly into two groups: Group 1:15 patients (10 male and 5 female) with mean age 28 ± 3.98 years who received immediate dental implant, and group 2:15 patients (10male and 5 female) with mean age 27.87 ± 3.11 years who received immediate dental implant with local application of vitamin D3 gel. There was no statistically significant difference between two groups in age nor gender as p-value was higher than 0.05. (Table 1)

Table (1) *Demographic data between two study groups*.

Variable	Group 1	Group 2	P-Value
Age, mean ± SD	28 ± 3.98	27.87 ± 3.11	0.919
Male, n (%)	10 (66.67%)	10 (66.67%)	1.00

N: number, SD: standard deviation

Regarding VAS, there was no statistically significant difference between two groups at day 1, and 14 as p-value was higher than 0.05, but there was a statistically significant decrease in VAS in group 2 at day 3, and 7 compared to group 1 as p-value was lower than 0.05. (Table 2)

Table (2) *Visual analogue scale follow-up between two study groups*.

Median (IQR)	Group 1	Group 2	P-Value
VAS (Day1)	3 (2 – 4)	3 (2 – 3)	0.983
VAS (Day3)	2 (2 – 3)	2 (1 – 2)	**0.002***
VAS (Day7)	2 (2 – 2)	1 (0 – 2)	**0.012***
VAS (Day14)	1 (21 – 2)	1 (0 – 2)	0.159

*VAS: visual analogue scale, IQR: interquartile range, *: statistically significant*

According to modified plaque index, there was no statistically significant difference between two groups at 3 months and at 6 months. Moreover, the modified plaque index means were statistically different across different time periods in group 1 only, but not statistically different in group 2. (Figure 2)

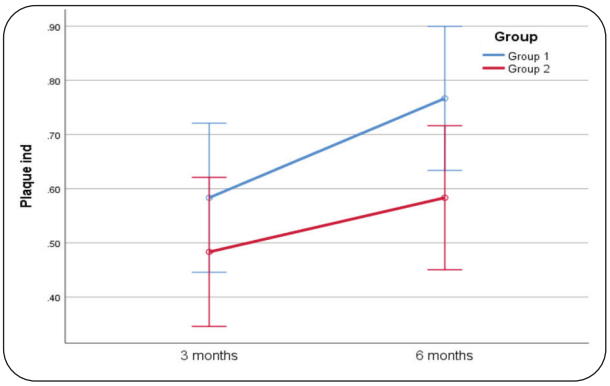

Fig. (2) Plaque index across time follow-up between two study groups.

Regarding modified bleeding index, there were statistically significant differences between two groups at 3 months and at 6 months (higher in group 1 compared to group 2). Moreover, the modified bleeding index means showed no statistically significant difference across different time periods in each group (Figure 3) .

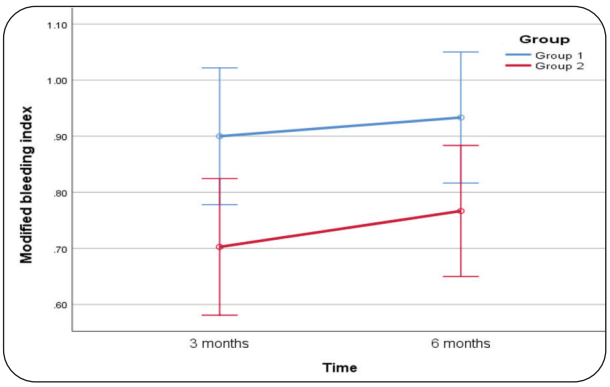

Fig. (3) Modified bleeding index across time follow up between two study groups.

Regarding probing depth, there was no statistically significant difference between the two groups at baseline, 3 months and 6 months.

However, the probing depth means were statistically significant different across different time periods when compared in each study group (decreases by time). (Figure 4)

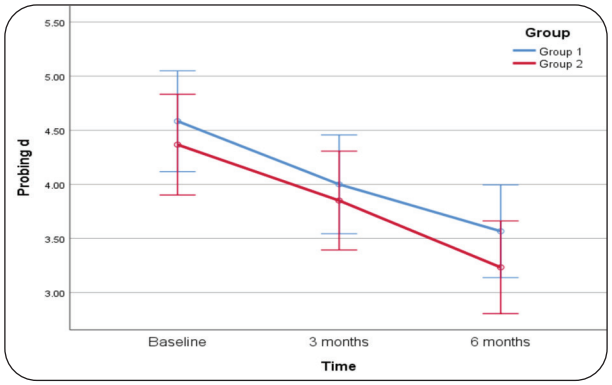

Fig. (4) Probing depth across time follow-up between two study groups.

According to bone density, there was no statistically significant difference between two groups at baseline, 3 months and 6 months. However, the Bone density means were statistically significant different only between baseline vs. 3 months and baseline vs. 6 months, when compared in each study group (increases by time). (Figure 5)

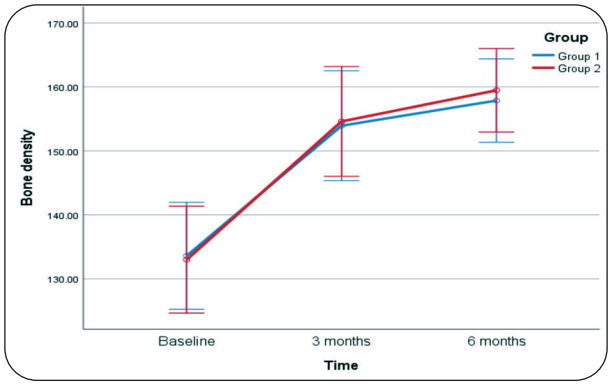

Fig. (5) Bone density across time follow-up between two study groups.

Regarding marginal bone level, there was no statistically significant difference between two groups at baseline, 3 months and 6 months. However, the marginal bone level means were statistically significant different across different time periods when compared in group 1 but were statistically significant different between baseline vs. 3 months and baseline vs. 6 months, when compared in group 2. (Figure 6)

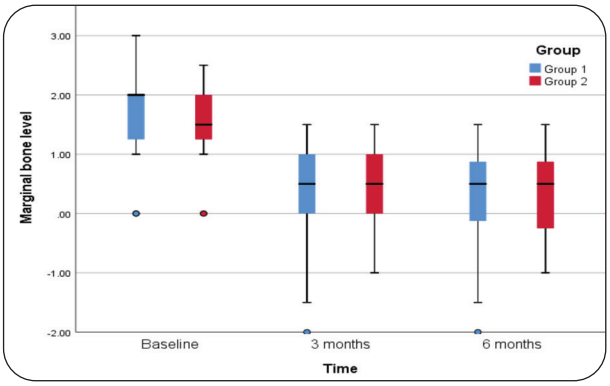

Fig. (6) Marginal bone level across time follow up between two study groups.

DISCUSSION

Osseointegration can be defined as a direct contact between the bone and metallic implants without interposed soft tissues layers or direct structural and functional connection between ordered, living bone and the surface of a load carrying implant. Osseous tissue approximating the surface of the implant without apparent soft tissue interface at light microscopic level This implant–bone bond and how it is used for embedding a dental prosthesis is of key importance to implant prosthetic treatment [18].

Long-term stable implants are the primary target of dental implantology and implant survival and hence osseointegration are known to be dependent on several factors. Current research describing the mechanism of implant failure includes tobacco use, diabetes, bone preparation, and local bone necrosis due to heat generation during implant placement. Failures, especially due to lack of osseointegration, are serious problems and may be related to the patient's systemic health status. Recognition of systemic risk factors has shown that failure rates can be reduced, and predictability can be increased[19].

Because the processes of bone remodelling are very dynamic in the period of actual

osseointegration, it is necessary to obtain the correct concentration of vitamin D3 metabolites in blood serum. After implantation, primary stabilization is obtained. The remodelling of bone tissue that occurs over the next few months leads to integration of the implant with bone, which is called secondary stabilization. During osseointegration, the influence of calcitriol on calcium and phosphate metabolism, as well as on the processes of activation and differentiation of osteoblasts and osteoclasts, is of significant importance. It was found that osteoclasts (osteoclast cells) which by the way have no vitamin D receptors, are formed as a result of the fusion of about 5 to 10 precursor cells influenced by vitamin D. Osteoblasts (osteogenic cells) have that receptor, and the bone modeling process occurs through osteoclasts contacting osteoblasts via RANK and RANKL receptors [20].

The aim of this study was to evaluate the clinical effect of vitamin D3 on immediate dental implant stability and the osteogenic efficacy of vitamin D3 on immediate dental implant through radiographic evaluation.

Topical application of Vitamin D was used in this study because it has been shown to play an essential role in bone mineral homeostasis and in its active form, 1α,25-dihydroxyvitamin D3 [1.25-(OH)2D3], may act as a bioactive protein promoting new bone formation also it is known that VD3 plays an important role in bone mineral homeostasis and its active form (1a,25-dihydroxidevitamin D3) may also act as a bioactive protein, which augments osteogenesis [21].

It is known that the continuing success of implant treatment, maintaining the optimal condition of tissues at the implant site is as important as obtaining stabilization. The cause of implant disintegration after achieving osseointegration may be gradual loss of bone tissue around the implant, which results from the inflammation in the region [22].

Local factors effecting peri-implant healing include tobacco usage, periodontal disease, surgical procedure and oral hygiene, while systemic factors may include presence of systemic disease, pregnancy, etc. Medical risk factors identified to negatively affect osseointegration include diabetes and osteoporosis. However, other systemic conditions and medications that interfere with wound healing [23].

Smoker patient was excluded from the present study due to implants placed in smokers presented a statistically significant higher risk of failure as well as a higher mean marginal bone loss than implants placed in non-smokers. There are some possible explanations for the higher implant failure rate in smokers. Much is believed to be associated with the negative effects of the smoking toxins on bone metabolism and osteogenesis, and on angiogenesis, which are important in osseointegration and in the long-term maintenance of implants. As well as smoking causes an alteration in the composition of bone matrix and also worsens bone mineralization, which consequently leads to bone fragility. The exposure to smoke results in a reduction in bone trabeculae thickness, which is associated with a decrease in mineralizing surface as well as in the mineral deposition rate. All of this consequently leads to lower bone formation rate and longer mineralization time [24].

Immediate implant was used in this study in order to circumvent the problem of post-extraction and implant-related bone resorption. It was suggested that this approach could not only limit physiological bone resorption leading to better esthetic outcomes but also minimize the number of surgical procedures. An initial histological study demonstrated osseointegration of immediate implants [25].

Marginal bone loss is considered as one of important biological criterions to determine implant success. Various aetiologies have been proposed for marginal bone loss. It has been attributed to inflammation from biomechanical stress due to an incorrect occlusal prosthesis design or from a

foreign-body reaction to cement in the soft tissues around cemented-retained prostheses [26].

This is a prospective randomized, clinical study including thirty patients with decayed hopeless tooth with periapical infection or indicated for extraction and seeking implant placement, 66.7% of patients were males, while 33.3% were females. The study divided into two equal groups each had 15 patients. Group (2): Patients received immediate dental implant placement with application of vitamin D3 and group (1): Patients received immediate dental implant placement alone. The mean age of the studied group was 27.93 ± 3.51 years ranged from 22 to 35 years. There is non-significant difference between the two groups ($P > 0.05$).

Patient's evaluations were at three times; at baseline, post 3 months and post 6 months for modified bleeding index, plaque index, probing depth, bone density and marginal bone level (Modified bleeding index and plaque index not assessed at baseline). Modified bleeding index, plaque index and bone density were increased across the 3 follow ups, while probing d and marginal bone level were decreased across the 3 follow ups.

According to bone density in the current study, there was insignificant difference between the two groups at baseline, 3 months and at 6 months ($p > 0.05$). However, the bone density means were statistically different only between baseline Vs. 3 months & 6 months, when compared in each study group ($p < 0.05$). As regard marginal bone level, there was no statistically significant difference between two groups at baseline, 3 months and at 6 months ($P > 0.05$). However, intergroup study shows that the marginal bone level means were statistically different in both groups when compared baseline with 3 and 6 months postoperatively in both study groups. The results of the present study were parallel with other findings showed no significant difference in new bone formation around implants with and without VD3 coatings [27, 28].

In contrast to the present findings; inserted implants with vit. D coating in the rabbit's tibiae. osseointegration level was determined through bone implant contact BIC values. Test implants showed higher total BIC values than control implants and statistically significant differences were found between the two groups they conclude that topical application of Vitamin D may stimulate bone formation adjacent to the surface of implants inserted into bone [29].

Other study found that vit. D/Ca supplementation increased new bone formation and bone density, and reduced crestal bone loss when compared to non-supplemented groups [30].

The evidence from the literature which could prove a potentially beneficial role for Vit. D, when used as an adjunct for bone regeneration. Since the number of studies evaluating the role of Vit D on bone regeneration alone was limited, the review was expanded to include studies assessing bone regeneration around implants and those studying Vit. D as an adjunct to tissue engineering through target cells. Unfortunately, no clinically relevant studies evaluating the adjunct role of Vit. D on bone regeneration, either within osseous defects or around implants, were identified during the selection process. Incidentally, in a similar review published recently [31].

Because it participates in bone metabolic processes and controls the immune system, vitamin D is currently of particular interest to doctors who perform implant procedures. It is assumed that the correct concentration of this prohormone correlates positively with the osseointegration process [32].

During the postsurgical phase and also after loading the implant with a prosthetic restoration, the subsequent influence of vitamin D metabolites on the processes of homeostasis with bone tissue adjacent to the implant surface, which determines the correct induction of osteoclasts and osteoblasts, is particularly important. The function of vitamin D

reducing inflammation around the implant is also particularly noteworthy. In addition, at the boundary between the implant and the prosthetic crown, vitamin D induces regional cells of the immune system (e.g., production of 1-alpha-hydroxylase by monocytes) [33].

According to plaque index, there was no significant difference between two groups at 3 months and at 6 months ($p > 0.05$). Moreover, the plaque index means were statistically different across different time periods in group (1) only ($P<0.05$), but not statistically different in group 2 ($P>0.05$). These findings were parallel with other finding that indicated high maintenance in measures in all implants received patient [34].

Regarding probing depth, there was no significant difference between two groups at baseline, 3 months and at 6 months ($P>0.05$). However, the probing d means were statistically different across different time periods when compared in each study group ($P<0.05$). The improvement and the reduction of peri-implant probing depth indicated improvement of the collagen fibers arrangement and density around dental implant that preventing peri-implantitis and increasing of osseointegration. The evidence indicating that the initial maturation and stabilization of the peri-implant mucosa occurs within the first 4 weeks after implantation [35]. The results of this study was in accordance with other evidence that; bleeding on probing has been implicated as a valuable parameter in the diagnostic process for peri-implant mucositis, while probing depth has been adapted from periodontal diagnosis to assess soft tissue pathology and loss of bony support around osseointegrated oral implants [36].

In the present study, pain was evaluated with VAS which slightly decreased in study group than in control group. there was significant difference at third and seventh day in group 2 indicating the effect of vitamin D3 in these patients but no significance difference at first and after 2 weeks that may indicate rapid action and rapid degradation of vitamin D3.

There was a controversy over the efficacy of vitamin D3 supplementation in terms of osteogenic efficacy on dental implant The main problem during performing this study was there were very few reports about the local application of vitamin D.

Recommendations of this study should be taken in consideration including large sample size, long follow up evaluation of the treatment by 3D radiograph and the lack of histological assessment because small number of cases that may interfere the accuracy of statistical analysis and many risk factors may be missed as well as the follow-up period of this study is considered a relatively short period (6 months).

CONCLUSION

The current study showed that topical application of Vitamin D3 in immediate dental implant placement mildly improves osseointegration and may induce anti-inflammatory effect in peri-implant status.

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استخدام جل فيتامين د3 الموضعي في زراعة الأسنان الفورية: دراسة عشوائية محكومة

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الملخص :

الهدف: أجريت هذه الدراسة لتقييم فعالية فيتامين د3 في تكوين العظام على زراعة الأسنان الفورية من خلال التقييمات السريرية والشعاعية.

المواد والاساليب: كانت هذه دراسة سريرية عشوائية مستقبلية شملت 30 مريضًا يعانون من تسوس الأسنان ميؤوس منها والمشار إليهم بالخلع ويسعون إلى وضع زراعة الأسنان. تم اختيار المرضى من أولئك الذين حضروا إلى العيادة الخارجية لقسم طب الفم وأمراض اللثة، كلية طب الأسنان، جامعة الأزهر «فرع أسيوط» الذين يسعون إلى الخلع ووضع زراعة الأسنان. تم تقسيم المرضى إلى مجموعتين: المجموعة (1): تلقى 15 مريضًا زراعة الأسنان الفورية وحدها كمجموعة ضابطة، والمجموعة (2): تلقى 15 مريضًا الخلع مع وضع زراعة الأسنان بالإضافة إلى وضع موضعي لهلام فيتامين د3 على التجويف كمجموعة اختبار.

النتائج: لم يكن هناك فرق كبير إحصائيًا بين المجموعتين في مقياس التناظر البصري (VAS) في اليوم الأول والرابع عشر، ولكن كان هناك انخفاض كبير إحصائيًا في المجموعة الثانية في اليوم الثالث والسابع مقارنةً بالمجموعة الأولى. ووفقًا لمؤشر اللويحة المعدل، لم يكن هناك فرق كبير إحصائيًا بين المجموعتين في الشهر الثالث والسادس. وعلاوة على ذلك، كانت متوسطات مؤشر اللويحة المعدل مختلفة إحصائيًا عبر فترات زمنية مختلفة في المجموعة الأولى فقط، ولكنها لم تكن مختلفة إحصائيًا في المجموعة الثانية. وفيما يتعلق بعمق الفحص، لم يكن هناك فرق كبير إحصائيًا بين المجموعتين في البداية، وفي الشهر الثالث والسادس. ومع ذلك، كانت متوسطات عمق الفحص مختلفة بشكل كبير إحصائيًا عبر فترات زمنية مختلفة عند مقارنتها في كل مجموعة دراسة (تتناقص بمرور الوقت).

الخلاصة: أظهرت الدراسة الحالية أن التطبيق الموضعي لفيتامين د3 في وضع الغرسة السنية الفورية يحسن بشكل طفيف من التكامل العظمي وقد يسبب تأثيرًا مضادًا للالتهابات في حالة ما حول الغرسة.

الكلمات المفتاحية : فوري، زرع، فيتامين د3، جل