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MELATONIN APPLICATION WITH INDIRECT MAXILLARY SINUS LIFT IMPLANT PLACEMENT: A PROMISING NEW APPROACH

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ABSTRACT

Objectives: Dental implant replacing missing teeth is of a big concern in the maxillary posterior region due to pneumatisation of the maxillary sinus. To overcome this problem, indirect maxillary sinus floor augmentation is the technique of choice. This pilot study compared the outcomes of indirect maxillary sinus lift and simultaneous implant placement with and without melatonin application.

Materials and Methods: 20 patients with missing maxillary molars or premolars were selected to receive 20 dental two-pieces implants simultaneously with indirect maxillary sinus lifting using sinus crestal approach (SCA) kit. These 20 patients were randomly divided into two groups, where group 1 included patients received local melatonin gel at osteotomy site while group 2 included patients who had no melatonin. Immediate implant stability test was performed using the Osstell Monitor. Patients were recalled for follow up at three, six, and nine months for clinical changes, three and nine months for radiographic evaluation.

Results: All implants were considered successful after nine months of follow up. A high statistically significant difference in implant stability and bone density in group I with local melatonin application (P =0.0005), and both buccal and palatal sides bone density, P = 0.009 & 0.042, respectively.

Conclusions: This pilot study is the first to test the indirect sinus lift technique combined with melatonin gel application and simultaneous implant placement. After nine months of follow up, predictable outcomes are evident in all patients who presented initially with posterior maxilla resorption due to sinus pneumatisation.

KEYWORDS: Crestal sinus lift, implant placement, melatonin

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INTRODUCTION

The posterior atrophic maxilla is considered one of the most challenging areas to restore. Clinicians and researchers have been working extensively to overcome this challenge.[1] Several surgical techniques have been developed to improve bone volume and facilitate implant placement. Dental implants may sometimes be placed simultaneously with the grafting procedure or later in a separate visit after performing the graft surgery first.[2]

More than 50% of dental implants placed in the posterior maxilla would require Sinus Floor Elevation (SFE). There are two basic approaches of SFE which are Direct and Indirect. The suitable approach is selected by the clinician according to multiple parameters, which include but not limited to; residual bone height and width, patient's compliance, anatomy of the maxillary sinus. The direct SFE technique is quite invasive and the clinicians have looked for an easier, predictable and less morbid approach to rehabilitate posterior maxilla.[3]

Sinus augmentation with lateral access has been widely studied and is considered safe with highly predictable outcomes. Additionally, it is recommended to provide adequate support to implants in an extremely atrophic maxilla.[4] In 1994, Summers has proposed the indirect sinus lifting technique to overcome the disadvantages of the lateral window technique.[5] This technique is a conservative surgical method; it provides a sinus augmentation that is more localized with less post-operative morbidity and a shorter period will be required to load an implant afterwards.[6]

Melatonin is a crucial stimulator of bone formation. In vitro applications of micromolar concentrations of melatonin stimulated collagen type I fibers synthesis and proliferation of osteoblasts.[7] In addition, melatonin promoted rats preosteoblast cultures to express bone sialoprotein, osteocalcin, osteopontin, and alkaline phosphatase and enhanced the differentiation of preosteoblasts into osteoblasts; from 21 to 12 days.[8]

In ovariectomized female rats, Clafshenkel et al,[9] showed that calcium melatonin scaffolds implanted into critical size calvarial bone defects enhanced tissue infiltration and scaffold biodegradation after 3 and 6 months. In dogs, Guardia et al,[10] used melatonin with dental implants and declared that 2 weeks following implant placement, melatonin could significantly increase osteointegration; bone-to-implant contact ratio (BIC), inter-thread bone, total peri-implant bone and new bone formation. This study showed obvious increase in the bone density formed around implants associated with topical melatonin as compared to control implants.

In the view of this background, the present pilot study aimed to evaluate the efficacy of melatonin gel as a graft material with indirect maxillary sinus lifting and simultaneous implant placement. We compared the outcomes of melatonin topical application versus graftless crestal sinus lifting and simultaneous implant placement

MATERIALS & METHODS

The present study was conducted in accordance with the seventh revision of Helsinki Declaration in 2013 and approved by Ethical Committee of Faculty of Dentistry, Mansoura University, Egypt number (A06100522). Patients were selected from outpatient clinic in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Mansoura University. Twenty patients with missing maxillary premolars and molars were involved in the study and signed an informed consent. Patients with chronic sinusitis, long standing nasal obstruction, systemic diseases, smokers, or psychologically ill were excluded from the study.

For a complete pre-surgical evaluation, a diagnostic cast, surgical stent and preoperative cone beam computed tomography (CBCT) were prepared for each implant site. Residual ridge height

was assessed on CBCT by measuring the distance between the crest of alveolar ridge and the inferior border of the maxillary sinus. Participating patients were selected so that the residual ridge height is > 5.5 mm. Patients were randomly divided into 2 groups; in the study group (group 1), patients received implants with local application of melatonin gel at the osteotomy site while in the control group (group 2), patients received implants without melatonin.

Surgical approach

20 endosseous two-pieces titanium dental implants which are of the screw type (Neo-biotich, Korea) were used to restore missing upper posterior tooth in 20 different patients who needed maxillary sinus lift for proper positioning of the implant. Implants used were 10–13 mm in length and 3.5–5 mm in width. All patients were instructed to use Chlorhexidene 0.12% (Oraldene; Chlorohexidine hydrochloride 125 mg/100 ml solution. EDCO, Egypt) mouth wash 3 times daily for 2 weeks, starting one day before surgery. They were prescribed Amoxicillin 875 mg and Clavulanic acid 125 mg twice daily (Augmentin 1 gm tablets, Smithkline Beecham Pharmaceuticals Co., Brentford, England) or Levofloxacin 500 mg once daily (Larivex, 500 mg tablets, Euro-Egy-Pharm, Egypt) in case penicillin allergy , for seven days.

Posterior superior alveolar nerve, infraorbital nerve and greater palatine nerve blocks, and local infiltration were performed by administration of Articane HCL 40 mg/ml with epinephrine 1:200.000. (Articaine HCL 4% with Epinephrine 1:200,000, Inibsa Co., Spain). A crestal incision of 2-3 mm was made and a full-thickness mucoperiosteal flap was reflected and retracted. With the guidance of the surgical stent a round bur was used to mark the implant position on the ridge bone. Pilot drill was used to prepare an implant bed that is 1-2 mm below the sinus floor. A series of drills were used to prepare the implant site up to 1 mm below the sinus floor. After finishing the osteotomy site preparation, the appropriate S-reamer (sinus crestal approach kit, Neo-biotech) was used with a stopper for adjusting the exact height where the sinus floor is found, each stopper was adjusted on the S-reamer to make 1 mm longer than the last implant drill used. The cortical bone forming the sinus floor was ground with the S-reamer until the dropping through was felt. At each osteotomy site, the required amount of melatonin gel was injected (1ml of 1.2mg/ml) at the sinus floor just below the sinus membrane and condensed with an osteotome until the desired elevation height was achieved. Melatonin gel was prepared previously by mixing 1.2 mg of melatonin powder with 1 ml propylene glycol to act as a carrier. According to Cutando et al,[11] In this study, we used melatonin gel for each implant in group 1 (Fig 1) while no melatonin was used in group 2 (Fig 2). An implant fixture was installed, covered, and the flap was replaced and sutured with 4.0 black silk sutures. An immediate CBCT was taken postoperatively to be considered as a baseline radiograph.

Patients were instructed to follow proper oral hygiene measures, eat soft diet for the first three days postoperatively, and use cold packs for the first 24 hrs and warm packs for the next 48 hrs. All patients were prescribed Ibuprofen 400 mg (Brufen, Abbott India Ltd) for pain control 3 times a day and xylometazoline 1% (Otrivin, Novartis, Germany) nasal drops was prescribed 3 times a day post-surge. In addition, patients were prescribed Fexofenadine HCI 120 mg tablets (Telfast 120 mg tablets, Sanofi Aventis) two times a day as a systemic antihistamine for five days post-surgery. Two weeks later, the sutures were removed, and patients presented for clinical evaluation after one and three weeks when the sutures were removed, then, monthly for ninemonths after implant placement. CBCT scans were taken at three and nine months post-surgery for radiographic evaluation.

Prosthetic phase

Three months post-implant placement and under local anesthesia, a healing abutment replaced each cover screw. After two weeks, soft tissue healing

was reassessed around the implant and a polyvinyl siloxane impression was taken with an open tray technique for the fabrication of cement-retained porcelain fused to metal crown. The final crown was ready for cementation on the abutment after one week. Occlusion of permanent crowns was adjusted to obtain contact during centric occlusion only.

Clinical evaluation

At baseline (implant placement), three, six, and nine months post-implant placement, implants stability was recorded by the Osstell Implant Stability Quotient (ISQ) device (Osstell, Integration Diagnostics, Göteborg, Sweden). ISQ values were interpreted based

On the manufacturer's guide, the scale ranges from 1 to 100, with higher values indicating greater stability. The acceptable stability range lies between 55–85 ISQ values. The overall average ISQ value of all implants over time was approximately 70. [12]

Radiographic evaluation

All patients were CBCT scanned at baseline (implant placement), three and nine months post-implant placement by a Cranex® 3Dx (WL: 615 WW: 3357, zoom: x1.0 (0.305)). Digital Imaging and Communications in Medicine (DICOM) data were analyzed using On-Demand® software to monitor the changes in the relative bone density (RBD), residual bone height (RBH), implant protrusion (IP) and grafted sinus height (GSH).

Relative bone density (RBD)

The density values in both groups were measured by CBCT in cross-sectional view using in the On-Demand® software at nine months after surgery. Calculation of the bone density values is defined as the gray density values; a rectangle with the same spatial co-ordinates was drawn in each patient from both groups and the gray density value inside this rectangle was determined.[13] Two different measurements were taken for each implant site at both buccal and palatal aspects, at the exact position on each CBCT to maximize the accuracy of measurements.

Residual bone height (RBH)

The distance from the alveolar crest to the floor of the maxillary sinus at the intended implant placement site was measured.

Implant protrusion (IP)

The distance from the maxillary sinus floor to implant apex was measured.

Statistical analysis

Numerical data were analyzed for normality with Kolmogorov-Smirnov and Shapiro-Wilk tests. Data is shown as mean ± standard deviation (SD) values. Changes within each variable by time were analyzed by Friedman's test and pair-wise comparisons were analyzed by Wilcoxon signed-rank test when Friedman's test showed significant results. The level of significance was set at $P < 0.05$ and the collected data was analyzed with SPSS software (version 20; IBM Corporation, NY, USA).

RESULT

Demographic data

A total of twenty patients were included in this study and each has received one dental implant at a posterior maxillary tooth site with sinus lift, and with or without melatonin application at the oste otomy site. Patients' age in group 1 ranged from 20 to 45 with an average of 34±8.3 years while in group 2 the range was between 21 and 45 with an average of 34.9±9 years. All demographic and restored teeth information of both groups is presented in (table 1, and 2).

All 20 implants placed in this study showed signs of success up to nine months of follow up. With a survival rate of 100%, all implants achieved excellent stability with no signs of inflammation,

TABLE (1): Demographic data include age, sex and number of treated teeth in each group:

Parameter	Group		c^2 / t value	P value
	Group 1 (n = 10)	Group 2 (n = 10)		
Age (years)	34 ± 8.3	34.9 ± 9	t= -0.232	0.819
Sex:				
Male:	1 (10%)	1 (10%)	0.000	1.000
Female:	9 (90%)	9 (90%)		
number of treated teeth:				
second premolar	5 (50%)	4 (40%)	0.222	1.000
first molar	4 (40%)	5 (50%)		
second molar	1 (10%)	1 (10%)		

P value by Chi-square for sex, Chi-square test (Monte Carlo significance) for number of treated teeth and by Independent-samples t-test for age.

P: significance when ≤ 0.05.

infection or pain. Porcelain fused to metal crown was placed after three months post-implant insertion. Implant stability was measured at three, six and nine months post-implant placement, and radiographically at three and nine months post-implant placement.

Clinical evaluation

Implant stability

Implants stability values of both groups were measured by Osstell ISQ, (table 3). The mean of ISQ values of group I was 63.3±6.78 at the time of implant placement, 65.9±6.33, 69.6±6.22 and 73.7±6.14 after three, six and nine months post-implant placement, respectively. The change in implant stability in group 1 was significant, P_2 = 0.001. The mean of ISQ values of group 2 was 65.5±5.60 at time of implant placement, 66.6±6.02, 70.1±5.29 and 72.2±5.86 after three, six and nine months post-implant placement, respectively. The change in implant stability in group 2 was significant, P_2 = 0.005. The difference in implant stability values between both groups was significant, P_1 <0.0005.

Radiographic evaluation

Relative bone density (RBD)

Relative bone density was measured only at nine months post-implant placement (table 4). The amount of RBD buccally was 709.7±181.6 and 521.7±90.9 in group 1 and 2, respectively. On the palatal side, the RBD was 674.3± 149.7 and 557.2±78.5 in group 1 and 2, respectively. There difference between both groups was significant on both buccal and palatal sides, P = 0.009, and 0.042, respectively. This result reflects the favorable effect of melatonin on bone density around implants in group 1.

Residual bone height (RBH)

Residual bone height was measured using the preoperative CBCT scan of each patient, (table 5). The initial RBH values in melatonin group 1 ranged between 5.8 mm and 8.0 mm with a mean value of 7.05±0.89 mm, while in control group 2, values ranged between 6.7 mm to 8.0 mm with a mean value of 7.17±0.38 mm. No significant difference was found between the two groups in the initial RBH values, P = 0.719.

TABLE (2): Statistics of implant length and size used in the study groups:

Parameter	Group		Z value	P value
	Group 1 (n = 10)	Group 2 (n = 10)		
Implant length	11.5 (10 – 11.9)	11.5 (10 – 11.9)	0.000	1.000
Implant diameter	4.5 (4.3 – 4.5)	4 (4 – 4.5)	- 2.260	**0.024**

Data are presented as median (IQR). P value by Mann-Whitney U test.

P: significance when ≤ 0.05.

TABLE (3): Implant stability over time between both groups:

Time P value	Group I Mean ± SD	Group II Mean ± SD	P 1 Value
T0 (postoperative)	63.3 ± 6.78 (2.1)	65.5 ± 5.60 (1.77)	
T3 (after 3 months)	65.9 ± 6.33 (2.0)	66.6 ± 6.02 (1.90)	
T6 (after 6 months)	69.6 ± 6.22 (1.97)	70.1 ± 5.29 (1.66)	<0.0005
T9 (after 9 months)	73.7 ± 6.14 (1.94)	72.2 ± 5.86 (1.86)	
P 2 Value	0.001	0.0005	

P value by repeated-measures ANOVA test . P: significance when ≤ 0.05. SD = Standard Deviation

P1 represent change in implant stability over time between two groups.

P2 represent change in implant stability over time between each group.

TABLE (4): Relative bone density around dental implant between both groups:

Parameter	Group		t value	P value
	Group 1 (n = 10)	**Group 2 (n = 10)**		
Buccal	709.7 ± 181.6 (57.4)	521.7 ± 90.9 (28.8)	2.927	**0.009**
Palatal	674.3 ± 149.7 (47.3)	557.2 ± 78.5 (24.8)	2.190	**0.042**

Data are presented as mean ± SD (SEM). P value by Independent-Samples t T P is significance when ≤ 0.05

TABLE (5): residual bone height at intended implant placement site between both groups:

Statistic	Group		t value	P value
	Group 1 (n = 10)	Group 2 (n = 10)		
Mean± SD	7.05 ±0.89	7.170.38±	- 0.369	0.719

SD = Standard Deviation. P value by Independent-Samples t Test. P: significance when ≤ 0.05.

TABLE (6): Amount of sinus lifting by measuring implant protrusion in both groups over time:

Group	Time	Mean ± SD (SEM)	F value	P value	Partial h^2
Group 1 (Melatonin group)	Postoperative	3.84 ± 0.65 (0.21)	0.243	0.685	**0.026**
	After 3-months	3.78 ± 0.54 (0.17)			
	After 9-months	3.80 ± 0.54 (0.17)			
Group 2 (Graftless group)	Postoperative	3.92 ± 0.996 (0.31)	1.704	0.223	0.159
	After 3-months	3.83 ± 0.995 (0.31)			
	After 9-months	3.79 ± 0.993 (0.31)			

P value by Repeated-Measures ANOVA test. P significance when ≤ 0.05.

Implant protrusion (IP)

Implant protrusion values were measured as the distance from the initial sinus floor to the implant apex to reflect the amount of sinus lift achieved, (table 6). Sinus lift values achieved in melatonin group 1 were 3.84±0.65 at implant placement, 3.78±0.54, and 3.80±0.54 at three and nine months post-implant placement, respectively. In the control group 2, the sinus lift values were 3.92±0.0996 at implant placement, 3.83±0.995, and 3.79±0.993 at three and nine months post-implant placement, respectively. No statistical significant difference between the two groups in the sinus lift values, P = 0.280. The changes in amount of sinus lift in each group was not significant either, P = 0.685 and 0.223 in group 1 and 2, respectively (Fig 1, and Fig 2).

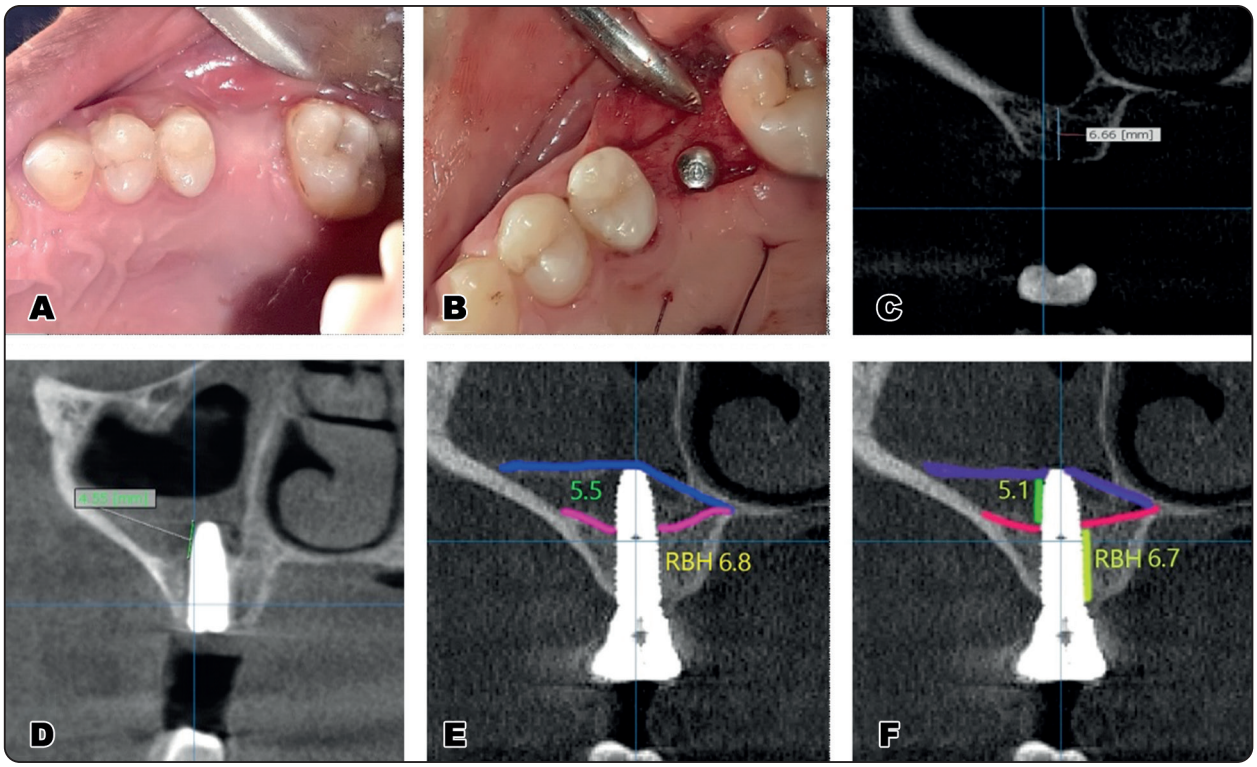

Fig. (1) Clinical, surgical, and radiographic photos for Group 1 case with Melatonin; A) pre-operative clinical photo of missing upper first molar. B) Intra-operative photo after sinus lifting and implant fixture was installed. C) pre-operative cross-sectional view of CBCT showing residual bone height. D) immediate post-operative cross-sectional view of CBCT showing placed implant and lifted sinus. E) cross-sectional view of CBCT at three months showing the difference between residual bone height and implant protrusion and grafted sinus height. F) cross-sectional view of CBCT at nine months showing more bone maturation at grafted sinus height.

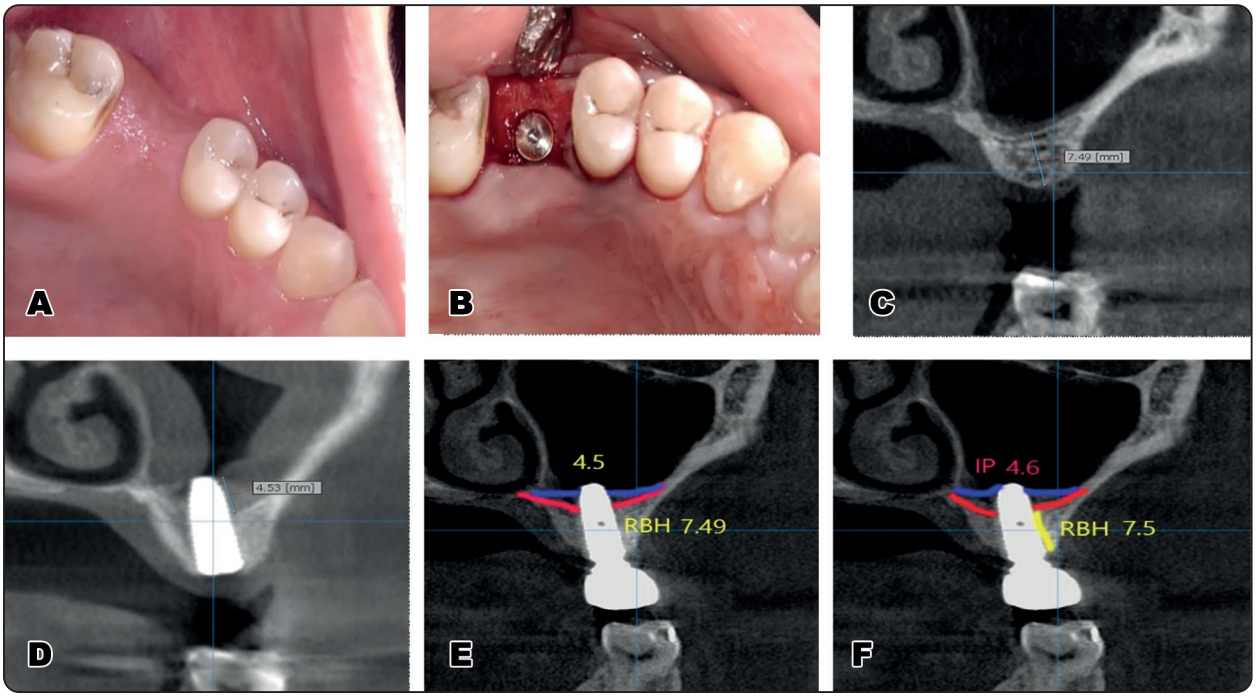

Fig. (2) Clinical, surgical, and radiographic photos for Group 2 case graft-less; A) pre-operative clinical photo of missing upper first molar. B) Intra-operative photo after sinus lifting and implant fixture was installed. C) pre-operative cross-sectional view of CBCT showing residual bone height. D) immediate post-operative cross-sectional view of CBCT showing placed implant and lifted sinus. E) cross-sectional view of CBCT at three months showing the difference between residual bone height and implant protrusion and grafted sinus height. F) cross-sectional view of CBCT at nine months showing more bone maturation at grafted sinus height

DISCUSSION

More than half of the implants placed in the posterior maxilla require Sinus floor elevation (SFE). The need for this procedure is explained by continuous ridge resorption in an apical direction after tooth extraction combined with progressive sinus pneumatization in addition to poor bone quality that is frequently seen in the maxilla.[14]

The maxillary sinus lift is an essential adjunctive procedure of dental implant surgery. It is a highly successful method of improving bone volume of the atrophied posterior maxilla for dental implants placement.[15] Different techniques using multiple instruments have been used for crestal and lateral sinus lifting.[16]

Melatonin has been proved to stimulate the osteogenic activity of bone. There was an increase in osteogenesis in bone around implant gained by local melatonin application.[17] Melatonin was used in an experimental study where dental implants were placed in dogs. The results showed an increase in all the parameters of osteointegration after 2 weeks after implant placement.[11]

Topical application of melatonin may act as a biomimetic agent in the placement of implant, acts on osteoclast to decrease resorption of osseous matrix in different forms as melatonin, being an antioxidant, is able to affect the process detoxifying free radical, that are produced during osteoclastogenisis, leading to inhibition of bone resorption.[18]

Melatonin can induce osteoblastic activity while inhibiting osteoclastic activity. In addition, melatonin helps in maintain bone heath through free-radical scavenging effect. Recently, melatonin has been used in bone- grafting procedures, and in treating periodontal diseases.[19]

It had been proved that topical melatonin application enhance osteointegration of immediate loaded dental implants in poor bone quality.[20] On the other side, graftless sinus lifting without bone augmentation has been an approved technique, due to the presence of osteogenesis activity of the sinus membrane, the average amount of bone gain could be achieved was 4.5 mm.[21]

Furthermore, Si MS et al,[22] concluded that osteotome sinus floor elevation (OSFE) with or without augmentation both showed a predictable bone gain inside the sinus during their study follow-up period.

Palma et al,[23] found that the sinus membrane, in addition to its osteogenic properties could also act as a barrier membrane to protect the blood clot during the healing process after surgery. In addition to, the help of tenting effect of the protruded implant tip to the elevated sinus membrane.

The osteotome sinus floor elevation was first introduced by Tatum (1986)[24] and modified by Summers (1994)[5] later. With the improved techniques, the osteotome is gradually being replaced by other surgical methods that provoked less tapping-induced complications. The reaming drilling approach is one of the techniques that do not tear the membrane during the osteotomy.[25]

In this study, crestal sinus lifting was done by using a SCA KIT (sinus crestal approach). The use of bone reamers drills is better than the conventional osteotomes because it is safer and quick bone removal, more control over the subcortical bone removal. The availability of stoppers that can be mounted on the reamers ensures that membrane perforations can be prevented. Also, the drilling mechanism of the reamers offers lesser intraoperative patient discomfort and considered a minimal invasive maneuver when compared to the malleting effect of the conventional osteotomes.[26, 27]

In the present study, all implants included were successfully osseointegrated with survival rate 100%. The mean residual bone height was 7.05 mm in group 1 and 7.17 mm in group 2 (range: 6 to 8.13 mm). The results in the two groups were similar to Zhou et al.[27]

In our study, no complication of crestal sinus lifting was recorded such as; sinus membrane perforation. These results were similar to Hassan MA,[28] this may be due to accurate selection of patients.

Although, the primary implants stability is highly important factor for dental implant success. The local application of melatonin proved to accelerate the healing process by stimulation of growth factors locally.[29]

This study used magnetic resonance frequency analyzer Osstell™ (Göteborg, Sweden) for recording the implant stability. The significant difference in implant stability observed within each group when comparing implant stability at three months to initial stability and stability at six and nine months then showed a slight decrease in ISQ scores for both groups after three months of implant placement and then stability were measured showing an increase at six and nine months post insertion. This change in stability was consistent with the stability pattern seen in placed implants in the routine non-sinus lift cases. The differences in ISQ values reflect the biological changes at the bone-implant interface. This finding is similar to what is reported in our study.[30]

In our study, all implants in study groups had ISQ values ranging from 51 to 74 for group 1 and from 52 to 72 for group 2, indicating adequate primary stability, which is very important for dental implant success.

A positive correlation was found between bone density (calculated with cone beam computed tomography) and implant stability was measured by ISQ values. They found the higher stability ISQ values resulted from areas of higher bone density in the anterior mandible.[31]

Conventional multislice computed tomography (CT) is contraindicated for dental use in some cases due to presence of some disadvantages such as; cost, time, and high radiation dose in comparison to Cone Beam Computed Tomography (CBCT). It can also; aid in assessment of relative bone density which correlates significantly with implant stability parameters.[32] In our study, CBCT was used for relative bone density assessment rather than CT for the previously mentioned reasons.

In this study, there was a change (increase) in bone density over time in both groups, and a statistically significant difference between group 1 and group 2 where study group is higher than control group.

CONCLUSION

Safe end drills techniques an alternative modality for crestal sinus floor elevation. Topical application of Melatonin gel acts as a biomimetic agent around implants shows increase in osteointegration. There was no significant difference between melatonin group and graftless group in amount of sinus floor elevation measured by implant protrusion and in implant stability throughout different time intervals of follow-up. There is significant difference between melatonin group and graftless group in relative bone density in both buccal and palatal aspects of implant after nine months due to the biological effect of melatonin on bone.

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