

The esthetic effect of connective tissue graft addition around immediate dental implants in the esthetic zone: A randomized clinical trial

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TO CITE THIS ARTICLE

Abd El- Aziz NF, Abd El-Rahman AR, El-Barbari AM, Elarab AE. The esthetic effect of connective tissue graft addition around immediate dental implants in the esthetic zone: A randomized clinical trial. *J Osseointegr* 2022;14(2):97-106.

DOI 10.23805 /JO.2022.14.8

KEYWORDS Immediate dental implant; Connective tissue graft; Pink Esthetic Score; Tissue biotype; Keratinized tissue width; Crestal Bone Level.

ABSTRACT

Aim It is not easy to maintain natural aesthetic appearance of implant-supported restorations in the esthetic zone. Immediate dental implant is a predictable solution in terms of decreased patient morbidity, in addition to the fact that it acts as socket preservation. The aim of the present study was to evaluate the esthetic outcome and stability of gingival tissue and crestal bone level over immediate implants using connective tissue graft (CTG).

Materials and methods 16 patients with a single non-restorable tooth in the aesthetic zone were randomly assigned to either receiving immediate implant alone or immediate implant with CTG with a six-month follow-up. Tissue biotype, width of keratinized tissue (WKT), crestal bone level (CBL) were measured at baseline and after 6 months, Pink Esthetic Score (PES) was measured at 8 months in addition to patient satisfaction.

Results Immediate implant with CTG had a statistically significant higher effect on PES ($P=0.004$), WKT ($P=0.001$) and tissue biotype ($p=0.002$) outcomes; while a statistically non-significant difference was found in CBL ($P=0.619$). No difference was found between groups with respect to patient satisfaction.

Conclusion Immediate implant in combination with CTG showed better aesthetics with natural appearance resembling natural teeth. PES, tissue biotype and WKT were significantly higher with CTG compared with immediate implant alone. CBL was more preserved when using CTG with immediate implants.

INTRODUCTION

Preservation of natural esthetic appearance especially in the esthetic zone, with maintenance of soft tissue volume and soft tissue contour in harmony with the adjacent soft tissue of the neighboring teeth, is considered an essential demand. However, postponing implant placement until hard and soft tissues completely heal, usually leads to more surgical intervention steps, such as guided bone regeneration or ridge splitting or implant placement in undesirable positions with low esthetic appearance to overcome the resorption of the alveolar ridge (1, 2).

Immediate implantation was proved to be a very successful treatment modality with several advantages, as it prevents bone loss after tooth extraction and provides good esthetics. It also reduces time between tooth extraction and prosthesis placement as well as the number of surgical treatments and provides better position and orientation of the final restoration (3).

Despite the advantages of immediate dental implants in preserving the alveolar bone and reduction of the treatment time, there was a fear of implant failure due to decreased primary stability especially with bone resorption due to previous infection. Thus, studies were performed to achieve high primary stability through osteotomy preparation and implant design (4, 5).

On the other hand, disadvantages related to esthetic outcome has been reported, showing facial gingival recession and metal display that occur following the first year of function due to labial bone plate resorption (6-8). Studies were directed to enhance soft and hard tissues healing around dental implants. Connective tissue graft is still considered as the gold standard used to preserve and

augment peri-implant tissue. The most common site of harvesting CTG is the palate due to histologic similarity with keratinized attached gingiva and the simplicity of obtaining graft (9, 10). CTG could provide a dual blood supply, better color match and could stimulate the epithelial differentiation which leads to increase in keratinized tissue gain (11, 12).

Based on the available data from the literature, the objective of our study was to evaluate the esthetic improvement after the use of connective tissue graft with immediate dental implants.

PATIENTS AND METHODS

This randomized clinical trial was carried out on 16 patients (1 male and 15 females) with age range between 21-46 years, attending the outpatient clinic in Oral medicine, Periodontology and Diagnosis Department-Faculty of Dentistry of Cairo University (Egypt). The study was conducted from January 2018 to October 2020.

The study protocol was approved by the Research Ethics Committee of the Faculty of Dentistry, Cairo University (Approval number: 18 – 4 – 27) and the Centre for Evidence-Based Dentistry, Cairo University.

The trial was registered in clinicaltrials.gov (registration number NCT03425864) and was prepared based on the CONSORT guidelines for reporting of randomized controlled trials.

Inclusion criteria were: patients aged between 20 to 50 years with single non-restorable teeth located within the maxillary anterior area and premolars; patients had good oral hygiene and presented sufficient vertical inter-arch space upon centric occlusion. Radiographic assessment was performed to ensure the integrity of the labial/buccal bone plate (13).

Exclusion criteria were: patients with any systemic disease that could affect normal tissue healing and predictable outcome, patients with any habits that might affect osseointegration, such as heavy smoking and alcoholism, pregnant women, patients with untreated periodontal disease or the presence of pathologic condition at implant site, patients with parafunctional habits that produce overload on the implant such as bruxism and clenching and shallow palate (13).

Based on a previous paper by Yoshino et al., the Pink aesthetic score difference between control and augmented group was expected to be 1.92 ± 1.55 . Using power 80% and 5% significance level, 6 patients were included in each group to be able to reject the null hypothesis that the population means of the test and the control groups are equal. This number was increased to 8 to compensate for possible losses during the follow-up (14).

Sample size calculation was achieved using PS: Power and Sample Size Calculation software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA). The study was single

blind, where clinical, radiographic assessors (A.S. and P.A.), and statistician were unaware of the sequence generation or allocation concealment or surgical performance. Patients were divided by the use of a software program (www.random.com) to either control or test group by A.E. The control group received immediate dental implant alone while the test group received immediate dental implant with CTG.

Intraoral periapical radiographs were taken at the time of the initial examination to reveal the absence of periapical lesions and Cone Beam Volumetric Tomography (CBVT) was taken for the area to be implanted for proper planning, selection of implant size and position and for recording preoperative and postoperative bone height as well as width measurements for comparison by superimposition technique (15, 16) (Fig. 1C, 2C).

Tissue biotype and width of keratinized gingiva were measured by Williams graduated periodontal probe. Width of keratinized gingiva (WKG) was recorded as the distance from the mucogingival junction (MGJ) to the free gingival margin of the related tooth by means of a graduated periodontal probe (17) (Fig. 1D 2-D). Tissue biotype was measured by penetrating the gingiva perpendicular to the tooth with the periodontal probe down to the bone after giving local anesthesia to determine the thickness of the tissue at the vertical bisecting midline with reference to the cemento-enamel junction of the adjacent tooth (18, 19) (Fig. 1E, 2E).

All the surgical procedure was performed by the same operator N.F. under local anesthesia (4% articaine with 1/200,000 adrenaline solution) with infiltration technique. Patient received implants with diameter of 3.2 and 3.5 and lengths were between 11, 13 and 15 mm except one implant was 10 mm which was used in the test group.

The implant system used was J Dental Care system, Sand-blasted, Large-Grit, and Acid Etched (SLA) (JD Evolution®PLUS+, Italy).

Immediate implant placement was performed in both groups as follows. Atraumatic extraction procedure of the tooth was done by periosteal and bayonet forceps and clinical evaluation of labial/buccal plate thickness was performed. The socket was irrigated with sterile saline solution and carefully examined with periodontal probe to assess that the socket wall was intact.

Sulcular incision was performed buccally and palatally on the target tooth, including the interdental area. In the control group a full thickness flap was elevated on the buccal and palatal area to show the crestal bone only, while in the test group, after raising full thickness flap in the buccal area, a split thickness flap was done by 15c blade, to prepare CTG recipient site (6).

Drilling began with a pilot drill in an angled direction to form a ledge to prevent slipping of the drill, and then the drill was changed in the direction in which the implant was inserted. The buccal bone crest was used as a reference point for drilling, the osteotomy preparation was extended 1.5 to 2.5 mm beyond the apex of the

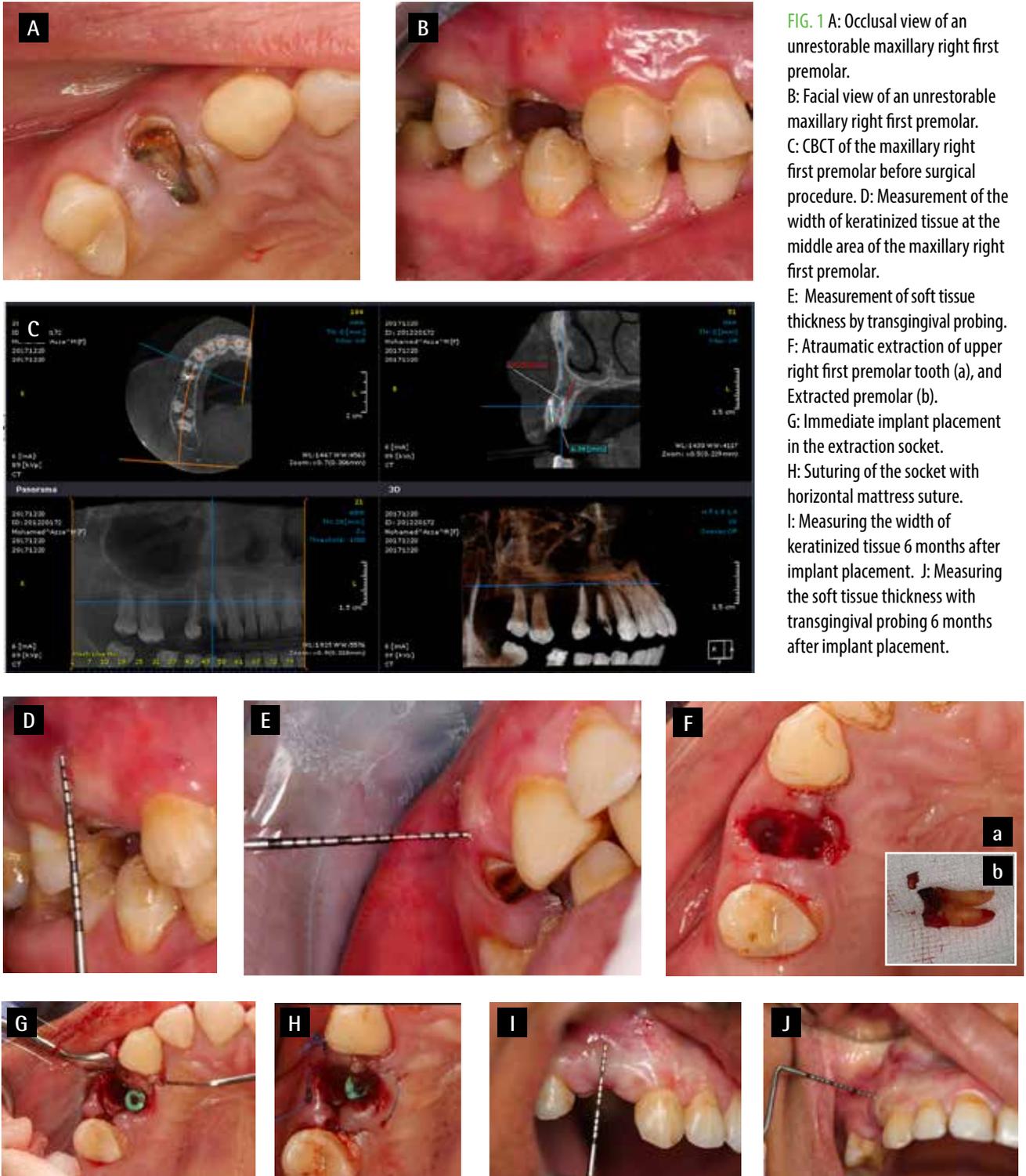


FIG. 1 A: Occlusal view of an unrestorable maxillary right first premolar. B: Facial view of an unrestorable maxillary right first premolar. C: CBCT of the maxillary right first premolar before surgical procedure. D: Measurement of the width of keratinized tissue at the middle area of the maxillary right first premolar. E: Measurement of soft tissue thickness by transgingival probing. F: Atraumatic extraction of upper right first premolar tooth (a), and Extracted premolar (b). G: Immediate implant placement in the extraction socket. H: Suturing of the socket with horizontal mattress suture. I: Measuring the width of keratinized tissue 6 months after implant placement. J: Measuring the soft tissue thickness with transgingival probing 6 months after implant placement.

socket to gain primary stability after implant placement. After preparation of an osteotomy site, the longest and widest possible implants were placed. In the test group, connective tissue graft was harvested from the palate with a trapdoor technique, approximately 2 mm below the palatal gingival margin from the distal site of the canine or premolars to that of the first molar, the graft was approximately 2 mm in thickness. The

length and width of the graft was determined by the mesio-distal dimension of the socket as well as its bucco-lingual dimension. The graft was immediately placed into the recipient site and was extended 6 mm apical to the crest buccally, continuing to cover the implant extending 2 mm beyond the alveolar crest palatally (Fig. 1D, 2D). Horizontal mattress suture was used to ensure graft stability in the recipient site using resorbable suture

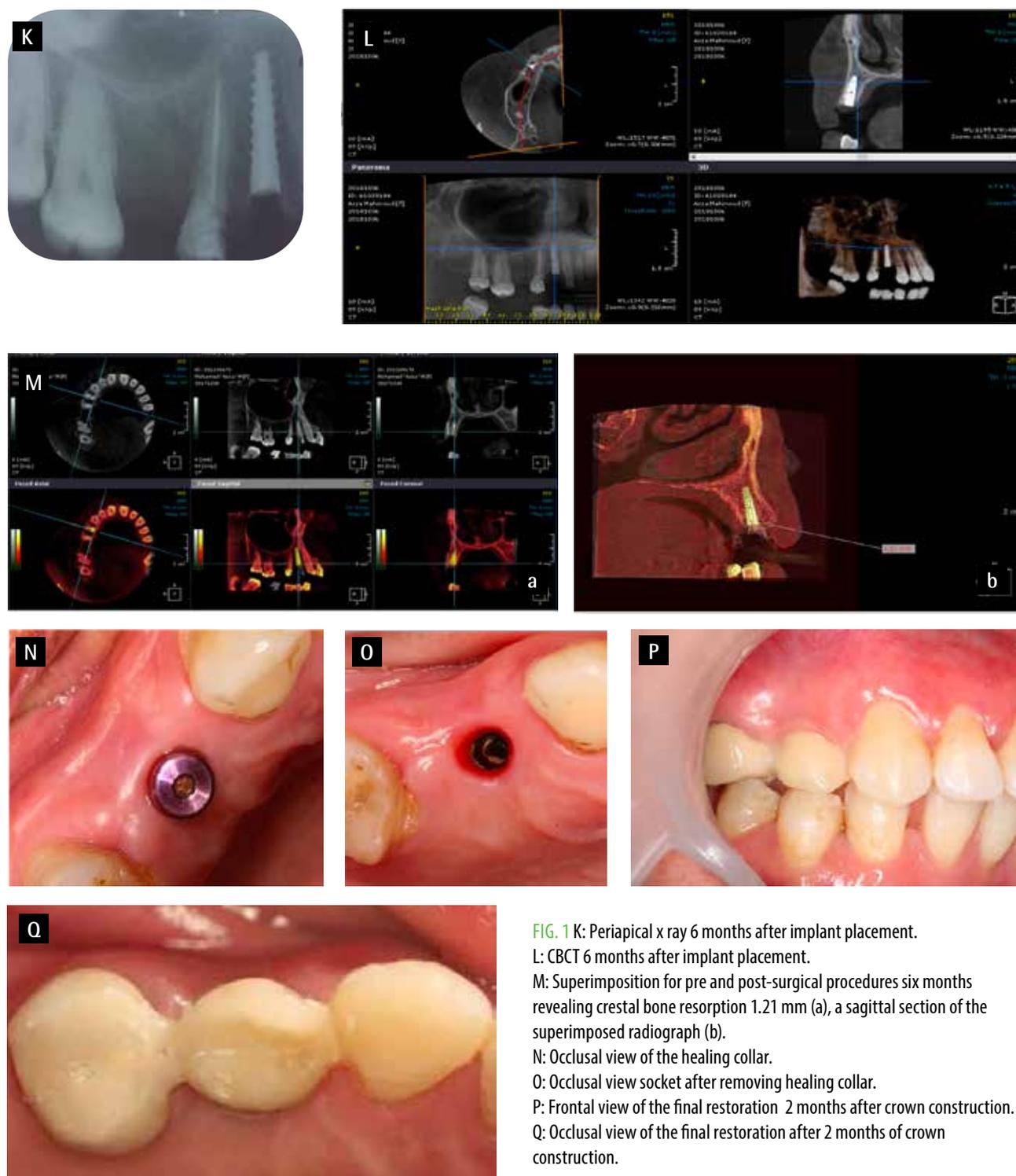


FIG. 1 K: Periapical x ray 6 months after implant placement.
 L: CBCT 6 months after implant placement.
 M: Superimposition for pre and post-surgical procedures six months revealing crestal bone resorption 1.21 mm (a), a sagittal section of the superimposed radiograph (b).
 N: Occlusal view of the healing collar.
 O: Occlusal view socket after removing healing collar.
 P: Frontal view of the final restoration 2 months after crown construction.
 Q: Occlusal view of the final restoration after 2 months of crown construction.

(Vicryl 5.0, Assut suture 5-0, Switzerland). Flaps were closed with interrupted sutures at both sites and figure eight using non-resorbable suture (Blueproline 5.0 suture, Assut suture 5-0, Switzerland) in both groups (Fig. 1F-1H, 2F-2N).

All patients were administered: Amoxicillin 500 mg capsules (Amoun pharmaceuticals, El Obour city, Cairo, Egypt) 1 hour prior to surgery for prophylaxis then every

8 hours after surgery and continued for 5 days, Brufen 600 mg (Sanofi Aventis manufactured, Egypt) once daily for 5 days, chlorhexidine mouthwash (Hexitol mouthwash 100ml, ADCO, Alexandria, Egypt) was prescribed twice daily for two weeks postoperatively.

For the first week, all patients were instructed to stop brushing or flossing at the gingival margin and to stop chewing hard food on the surgical site; oral hygiene was done to the other sites. Sutures were removed after 14 days.

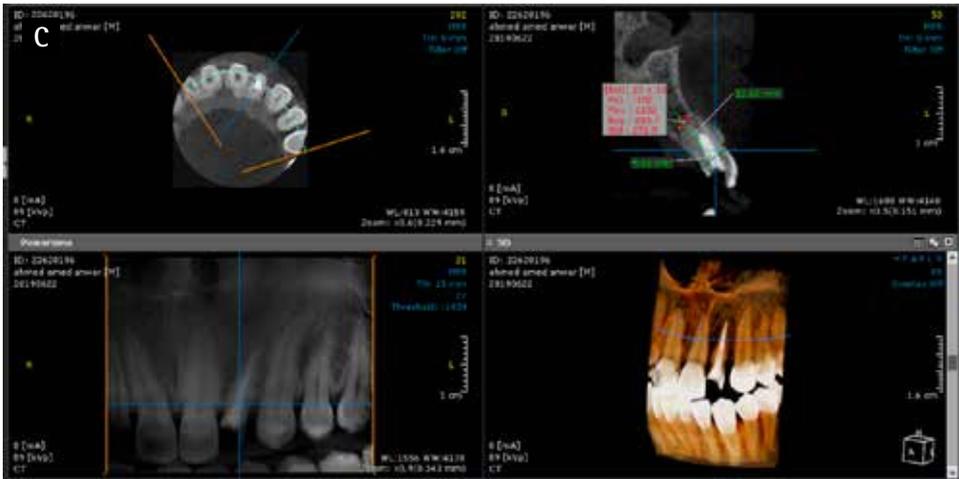
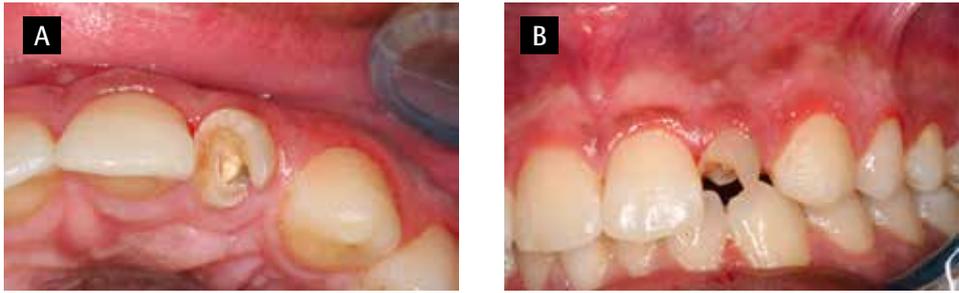


FIG. 2 A: Occlusal view of un-restorable maxillary left lateral incisor.

B: Frontal view of unrestorable maxillary left lateral incisor.

C: CBCT for the maxillary left lateral incisor before surgical procedure.

D: Measurement of the width of keratinized tissue at the middle area of the maxillary upper left lateral incisor.

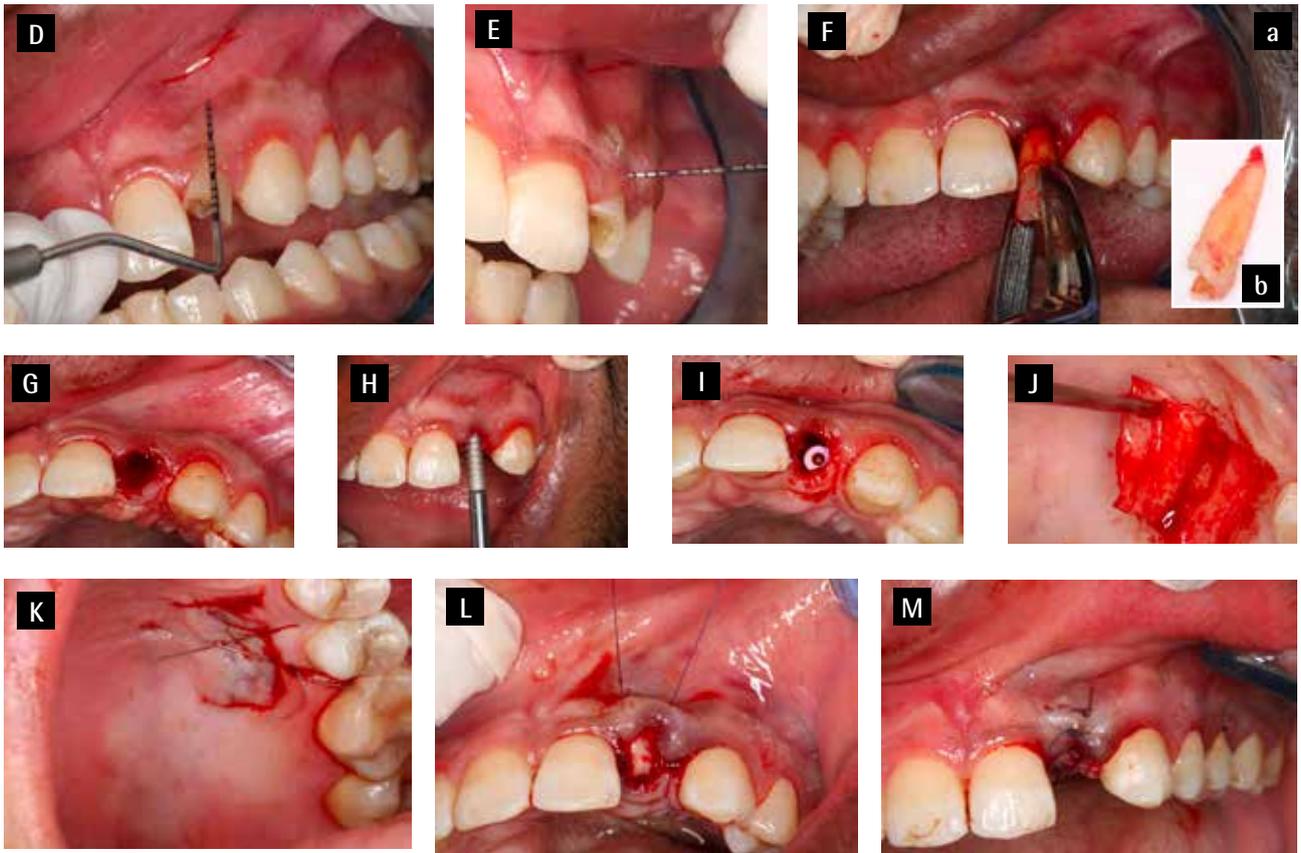
E: Measurement of soft tissue thickness by transgingival probing.

F: Atraumatic extraction of upper left lateral incisor tooth (a) and extracted lateral incisor tooth (b). G: Socket after atraumatic extraction.

H: Immediate implant placement.

I: Immediate implant placement in the prepared osteotomy.

J: Trap door incision to harvest connective tissue graft from the

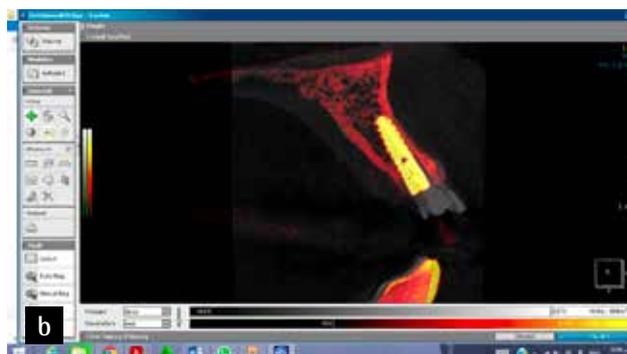
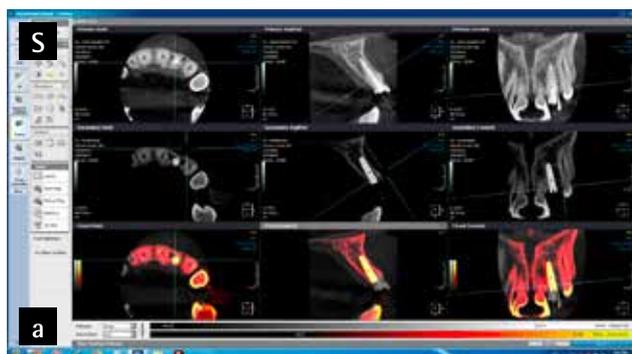


mesial aspect of maxillary left first premolar to the distal side of maxillary left first molar.

K: Cross suture to close the donor site.

L: Occlusal view of the secured the graft in the buccal flap with horizontal mattress suture.

M: Front view of the closure of the recipient site with cross over suture.



N: Occlusal view of the cross over suture.
 O: Transgingival probing of soft tissue thickness 6 months after implant placement and CTG. P: Measurement of the width of keratinized tissue in the middle area 6 months after implant placement and CTG.
 Q: Periapical x ray 6 months after implant placement.
 R: CBCT 6 months after CTG and implant placement. S: Superimposition of pre and post-surgical (6 months) images showing zero crestal bone resorption (a), a sagittal section of the superimposed radiograph (b).
 T: Occlusal view of the healing collar.
 U: Occlusal view of the socket after removing healing collar. V: Frontal view of the final restoration 2 months after placement.
 W: Occlusal view of the final restoration 2 months after placement.



Post-operative phase

After 6 months from implant placement, changes in tissue biotype, keratinized tissue width and crestal bone level were evaluated and recorded; then implant exposure was performed under local anesthesia for placement of the healing collar for one week, which was eventually replaced by the permanent abutment. Impression was taken, then the metal crown with facing porcelain was fabricated and cemented. After 8 months from implant placement, Pink Esthetic Score (PES) and patient satisfaction were evaluated and recorded (Fig. 1I, 1J, 2O, 2P).

Post-operative assessment

Buccal crestal bone level change was measured by using pre-operative CBCT and CBCT 6 months after implant placement in both groups by segmenting the area of interest from the CBCT (software: On Demand 3D APP, Version: 1.0.10.4304, field view: 6.8 cm, voxel size: 200 μm and with parameters: MA: 8, KVP: 90) data set with the isolation of the tooth to be implanted (before surgical intervention) and implant area (after 6 months of implant placement), then the manual superimposition technique was used as follows (15) (Fig. 1L, 1M, 2R, 2S).

PES was measured 2 months after prosthetic procedure (score range 0–14). Each single implant was photographed (one facial and one occlusal photograph) with a digital camera. The PES comprises the following seven variables for evaluation: mesial and distal papilla, soft tissue level, soft tissue contour, alveolar process deficiencies, soft tissue color, and texture, and a score of 2, 1 or 0 was assigned to all seven PES parameters, where 0 is the poorest score and 14 is the highest score. Two blinded observers (A.S. and P.A.) evaluated all photographs. Observers applied the PES index for the soft tissue around the implants (20, 21) (Fig. 1P, 1Q, 2V, 2W).

Patient satisfaction was assessed with the help of a self-administered questionnaire provided to the patient at the end of the study after placement of the final restoration. It consisted of several questions regarding function,

aesthetics and general satisfaction of the final restoration and peri-implant mucosa. Responses were dichotomized into agree/disagree or satisfied/not satisfied except for the last question (percentage), that represents the general satisfaction about treatment (16).

Statistical analysis

Data were analyzed using the IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 21 (SPSS Inc., Chicago, IL). Numerical data were described as mean and standard deviation or median and range. Categorical data were described as numbers and percentages. Data were explored for normality using the Kolmogorov-Smirnov test and Shapiro-Wilk test.

Comparisons between the two groups for normally distributed numeric variables Student's t-test was used, while for non-normally distributed numeric variables the Mann-Whitney test. Comparisons between categorical variables were performed by the chi square test. A p-value less than or equal to 0.05 was considered statistically significant. All tests were two tailed.

RESULTS

At the 8-month follow up, the median and interquartile range (IQR) values of PES was 10.50 (1.00) in the control group and 13.00 (0.00) in the test group. The mean difference was -2.67 with statistically significant difference between groups as shown by the results of Mann Whitney U test (p = 0.004) (Table 1).

After 6 months, there was significant increase in tissue thickness in the test group (3.90±1.08), while tissue thickness was stable in the control group till the end of the study. The change in tissue thickness was 3.30±0.97 in the test group, which was statistically significant than the unchanged tissue thickness in the control group (p=0.002) with insignificant difference between both groups at base line (Table 2).

Parameter	Control group	Test group	Mean difference	(95% CI)		U-value	p-value
				Lower	Upper		
Median (IQR)	10.50(1.00)	13.00(0.00)	-2.67	-4.15	-1.18	29.50	0.004*

*significant (p ≤ 0.05)

TABLE 1 Median and interquartile range (IQR) values for the Pink Esthetic Score in both groups.

Follow-up	Mean±SD		Mean difference	(95% CI)		t-value	p-value
	Control group	Test group		Lower	Upper		
Baseline	0.92±0.38	0.60±0.22B	0.32	-0.10	0.74	1.727	0.121ns
6 months	0.92±0.38	3.90±1.08A	-2.98	-4.31	-1.66	-5.866	0.002*
Difference	0.00±0.00	3.30±0.97	-3.30	-4.51	-2.09	-7.571	0.002*

TABLE 2 Mean and standard deviation (SD) for tissue biotype (mm) in both groups.

Superscript letters indicate a statistically significant difference within the same vertical column

*significant (p ≤ 0.05)

ns: non-significant (p>0.05)

Follow-up	Mean±SD		Mean difference	(95% CI)		t-value	p-value
	Control Group	Test Group		Lower	Upper		
Baseline	6.17±1.60A	5.60±1.08A	0.57	-1.28	2.42	0.696	0.505ns
6 months	4.75±1.84B	6.50±0.94A	-1.75	-3.75	0.25	-2.038	0.078ns
Difference	-1.42±0.49	0.90±0.82	2.32	1.30	3.33	5.534	0.001*

Different superscript letters indicate a statistically significant difference within the same vertical column
*significant ($p \leq 0.05$) - ns: non-significant ($p > 0.05$)

TABLE 3 Mean and standard deviation (SD) values for the keratinized mucosa width (mm) in both groups.

Mean±SD		Mean difference	(95% CI)		t-value	p-value
Control group	Test group		Lower	Upper		
-1.19±1.48	-0.62±0.87	-0.57	-3.18	2.05	-0.522	0.619ns

ns: non-significant ($p > 0.05$)

TABLE 4 Mean and standard deviation (SD) values for the crestal bone level change (mm) in both groups.

Median(IQR)		U-value	p-value
Control Group	Test Group		
100(1.50)	100(0.00)	12.00	0.394ns

ns: non-significant ($p > 0.05$)

TABLE 5

Median and IQR value for patient satisfaction score.

The mean value in keratinized mucosa width in the test group (6.50 ± 0.94) was higher than in the control group after 6 months (4.75 ± 1.84), with no significant difference ($p = 0.505$) till the end of the study. The change in keratinized mucosa width was 0.90 ± 0.83 in the test group which was statistically significant, while the change in keratinized mucosa width in the control group was -1.42 ± 0.49 ($p = 0.001$) (Table 3).

The mean and standard deviation (SD) values for crestal bone level change (mm) 6 months after follow up was -1.19 ± 1.48 in the control group and -0.62 ± 0.87 in the test group. The mean difference was -0.57 with no significant difference between both groups ($p = 0.619$) (Table 4).

All patients in both groups were satisfied with eating, speaking, the colour and form of crowns and the colour of mucosa. Only one patient in the control group was not satisfied with the form of mucosa at implant site with no significant difference between groups. All patients in both groups did not reject the choice of treatment and recommended this treatment to other patients. Regarding general satisfaction, there was not any significant difference between groups (Table 5).

DISCUSSION AND CONCLUSION

The aesthetic harmony of the gingival form and contour at implant site with that of the neighboring teeth is considered to be essential in restoring hopeless teeth

in the esthetic zone. According to Schropp et al., preservation of the crestal bone level from resorption affects not only aesthetics but also function of the final restoration (22).

Many studies recommended the use of immediate dental implants, especially in the esthetic zone as they reported an obvious reduction in treatment time till fabrication of the final restoration. They also showed a reduction in the number of surgical interventions; however, there is still a big debate in terms of preserving crestal bone level from resorption (23-25). The successful outcome of using CTG in covering the exposed roots and in increasing the width of the keratinized mucosa (WKM) led to the investigation of its use in conjunction with immediate dental implants to improve their final aesthetic results (26).

In the present study we considered several outcomes such as crestal bone level change, tissue biotype and keratinized tissue width, as recommended by Levine et al., because those parameters affect the esthetic outcome of the implant restoration. According to Cardaropoli and Casentini, the optimal integration of the final restoration with peri-implant hard and soft tissues is a mandatory concern in order to achieve an aesthetically acceptable dental implant (27, 28).

This study reported one implant failure in the test group that may be due to the use of an implant with 10 mm in length. Resnik considered this length to be a risk factor for implant failure in immediate dental implant procedure. As for our clinical observation of patients

in the test group, we observed necrosis and sloughing of the superficial layer of the exposed CTG; however complete healing eventually took place within weeks (3).

PES was assessed by blinded and independent outcome assessors to obtain reliable and accurate extracted data. In the present study, PES in the test group showed a statistically significant difference compared to the control group ($p=0.004$). In addition, 33% patients of the test group showed the maximum PES (14), while none of the patients of the control group achieved this result.

The findings of the current study are in line with the study of Migliorati et al. that compared between two groups; a control group (immediate loading implant treated without raising a flap) and an intervention group (immediate loaded implant treated with CTG inserted with the tunnel technique). In both groups, the jumping gap was filled with bone graft. The findings showed a statistically significant better PES score in the intervention group (29).

This finding is in contradiction with a RCT study by van Nimwegen et al. that compared a control group that received no connective tissue graft, with an intervention group that received a connective tissue graft harvested from the tuberosity area and inserted at the buccal aspect of the implant. The possible explanation of contradiction may be related to the quality of harvested tissue from tuberosity and its extension only on the facial aspect without extension (30).

As for the change in tissue biotype, our findings revealed a statistically significant difference between groups at 6 months with a higher mean value in the test group (3.30 ± 0.97) than control group (0.00 ± 0.00). The findings of the present study are in agreement with the study of Abd el Samie et al. and Sharafuddin et al., which showed a significant increase in the gingival tissue biotype in the group treated with CTG in conjunction with the immediate dental implant. Wiesner et al. and Cairo et al. studies demonstrated that the increase in gingival tissue biotype has an important role in preventing bone resorption (31–34).

The crestal bone level change in the present study did not show a statistical significance difference between groups ($p=0.619$) (-0.57 , 95%CI, (-) 3.18 - (+) 2.05) with less mean change in the test group (-0.62 ± 0.87) than control group (-1.19 ± 1.48). Despite our findings that showed no statistically significant difference, a clinically significant difference could be detected on the superimposition of CBCT, and we found zero bone level change, i.e. zero crestal bone resorption, in 50% of the test group cases; as for the control group, none of the patients reported zero bone resorption.

According to the present study, it can be concluded that CTG could not enhance the formation of new bone, but it provides a preservative effect on alveolar bone. When CTG is used to cover the inserted immediate

dental implant, healing will occur with minimal or no bone resorption mostly as CTG acts as a sponge filled with water and blood to prevent bone dehydration. This explanation is supported by a recent histological study by Utku who studied the composition and mechanical properties of the newly formed dried bone through compression between the basic mineralized collagen fibril. The findings revealed that dry bone showed deformation in collagen fibril orientation and form with less mechanical properties compared to wet bone (35). In the present study, the change in keratinized mucosa width showed a statistically significant difference between both groups ($p=0.001$). Our results were supported by a systematic review by Lee et al., that demonstrated an increase in keratinized tissue width in groups treated with CTG in conjunction with immediate implant (36).

In the era of evidence based practice, patient reported outcomes are highly recommended to assess the success of any treatment modality. In the present study, patients in both groups reported their opinion in the treatment in terms of function (eating and speech), aesthetic appearance of gingiva (color, form and similarity with the adjacent teeth), aesthetic appearance of the final crown (color and shape), overall satisfaction and if he/she will recommend this treatment to others. Our findings showed no difference between the two groups. The same finding was also reported by the study of Wiesner et al., who reported no statistically significant difference in patient satisfaction between the groups (33).

Competing interests

None.

Funding

No funding or grant was received from funding agencies or Oral and Maxillofacial department. The research is self-funded.

Authors' contributions

The manuscript has been read and approved by all authors; A.E., A.R. and A.M. All of the listed authors have contributed to prepare each step of the manuscript; experiment, writing and analysis. A.E.: samples collection, methodology, review and editing of manuscript; AR and AM: writing, review and editing of manuscript.

Acknowledgment

We acknowledge Dr. A. Sharafuddin and Dr. P. Abd el Samie for doing the assessment part, Dr. M. Gamal for doing superimposition technique and the statistician Dr. B. Abulnoor for the statistical analysis of the results.

Conflict-of-interest

No conflict of interest.

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