Esthetic Outcome of Computer-Guided Versus Free-Hand Immediate Implant Placement In Fresh Extraction Sockets in Esthetic Zone, A Randomized Clinical Trial

Ahmed Kotb[1], Maha Elkerdawy[2], Mahmoud Elfar[2]

1. MDS, Assistant Lecturer, Prosthodontic Department, Faculty of dentistry, Cairo University, Egypt,
2. DDS, Professor of Prosthodontics - Faculty of Dentistry -Cairo University, Egypt.

Abstract

Aim: to compare the esthetic outcome of two surgical techniques used in single immediate implant placement (computer guided vs free hand) in the esthetic zone in terms of pink esthetic score (PES) and gingival recession (GR).

Methods: This was a randomized clinical trial, where twenty patients with a failing tooth in the esthetic zone were recruited for immediate implant placement and restored with non-functional provisional crowns. They were randomly allocated to either computer guided (test group) or free hand (control group). Six months after surgery the patients were restored with their definitive crowns. Pink esthetic score was recorded twice (after surgery and after definitive crown), while gingival recession was recorded after the definitive crown.

Results: No statistically significant difference was found between the mean differences of pink esthetic score between both groups and within each group overtime. Regarding gingival recession, 2 implants showed gingival recession in the computer guided group while none in the free hand group.

Conclusions: Within the limitations of this study (sample size and follow-up duration), immediate implant placement using computer guided surgical guides would consume more time, effort and expenses yet it provided similar results with the free hand which seems beneficial for the learning curve for unexperienced clinicians.

Key-words: *Computer guided implant, free hand implant, gingival recession, pink esthetic score*

Introduction

Immediate implant placement for a failing single tooth in the esthetic zone is becoming a very popular treatment option that is gaining acceptance nowadays due to the evolving society and the growing need of patients to shorten the treatment period. [1] This treatment modality also provides preservation of the alveolar ridge, provide similar survival rates when compared to delayed implant placement, provide better esthetics and finally provide psychological acceptance for the patients especially if combined with immediate restoration of a prosthesis [1–3].

The anatomical architecture in the maxillary anterior zone is very critical where 90% of humans have suboptimal thickness of facial supporting bone (less than 1 mm) especially in the crestal and mid root portion of the maxillary anterior natural teeth [4], emphasizing the importance of placing implants in the correct three-dimensional position during immediate implant placement.

Computer guided implant placement has provided a tremendous evolution in implant therapy for the past

Corresponding Author:
Ahmed Mustafa Hashim Kotb
Address: 11 Elsaraya Street, Manial, Cairo, Egypt
Phone numbers: +201006697790
E-mail address: ahmed.kotb@dentistry.cu.edu.eg

decades which proved its reliability by recent clinical researches regarding accuracy of transfer from virtual plan to actual implant placement. [5,6]

Therefore, the combination of the precision of computer guided surgery and immediate implant placement might help in placing implants into an optimum position avoiding the fenestration of thin labial bone and consequently reducing the risk of gingival recession. So, the aim of this study was to compare immediate implant placement using either computer guided or free hand technique in single tooth replacement in the esthetic zone regarding PES and gingival recession.

Methods

This was a randomized clinical trial, triple blinded, two arm parallel group, with allocation ratio 1:1. The study was conducted in research clinic, Prosthodontic department, Faculty of dentistry, Cairo university, Egypt and was approved by Ethics Committee of Scientific Research at Faculty of Dentistry with registration number 17-8-2. It was registered online at clinicaltrial.gov with identifier registration number **NCT03211819**.

Based on a previous paper [7] the expected difference between computer-guided and free- hand immediate implant placement in pink esthetic score was 3± 1.89. Using power 80% and 5% significance level, we needed to study 7 in each group to be able to reject the null hypothesis that the population means of the experimental and control groups were equal. This number was increased to 8 to correct for non-parametric usage and again to 10 each group to compensate for possible losses during follow up. Sample size calculation was achieved using PS: Power and Sample Size Calculation Software Version 3.1.2

So, a total of 20 patients were recruited from the period September 2017 till September 2019, from the outpatient clinics of Prosthodontic, Oral Surgery and Endodontic departments, who met the inclusion criteria. Medical history was taken from the patients willing to participate in the trial and signed an informed consent form.

The inclusion criteria were:

· Patients with teeth or remaining roots indicated for extraction in the esthetic zone (from tooth number #15-25) and eligible for immediate implant placement

· Sufficient bone labially (at least 1.5-2 mm) assessed after cone beam computer tomography (CBCT) scan

· Presence of adequate mesio-distal length (at least 7mm) between the adjacent natural teeth measured on the study cast

· Presence of adjacent natural teeth to the tooth/root to be extracted

Exclusion criteria:

· Presence of active signs or symptoms of acute infection in the tooth or the remaining root to be extracted

· Heavy smokers (more than 2 packs per day)

· Parafunctional habits (clenching or bruxism)

· Patients with poor oral hygiene

· Pregnant women

· Any systemic condition that may interfere with osseointegration (as uncontrolled diabetes, recent head and neck radiation)

· Sever over eruption of the opposing teeth related to the tooth to be extracted

The patients were randomly allocated to either computer guided group (test group) or free hand group (control group) using a computer-generated table of random numbers by third personnel. The primary outcome was the pink esthetic score (PES) which is a scoring checklist proposed by Fürhauser in 2005. "The PES is based on seven variables: mesial papilla, distal papilla, soft tissue level, soft-tissue contour, alveolar process deficiency, soft-tissue color and texture. Each variable was assessed with a 2-1-0 score, with 2 being the best and 0 being the poorest score". [8] This makes the maximum score that could be reached 14 and the minimum score zero.

Intervention for both groups

After diagnosis and history taking, the patients were sent to perform a CBCT scan. Scans were examined using Blue Sky ® planning software (Bluesky plan4,

Bluesky Bio,USA). Eligible patients were then recalled for preliminary impressions (Tropicalgin; Zhermack SpA -Via Bovazecchino, Italy). After pouring of the impression, the tooth or root to be extracted was modified on the cast and an artificial tooth (Acrostone Manufacturing and Import Co., Cairo, Egypt) was placed, and a vacuum sheet (1 mm hard) was then pressed on the cast.

Small papers were sequentially numbered from 1-20 and placed (double folded) inside opaque sealed envelopes for random allocation of patients. During the visit of impression making after the CBCT scan, the participant selected one of these concealed opaque envelopes. During the planning stage, the principal investigator opened the envelope of the participant and informed the co-supervisor with the enclosed code and in return she informed him with the allocation group.

Due to the nature of the trial the principal investigator couldn't be blinded during the planning and surgical phase. Assessment of the outcomes (PES; gingival recession) was assessed on coded photographs, making the outcome assessor blinded. The data analyst was also blinded to the data collected as data were sent with codes.

Virtual planning was done for both groups using Blue Sky ® implant planning software. For the computer guided group, the primary cast was optically scanned (Freedom HD scanner, DOF, Seoul Korea) and the stl file was imported and superimposed on the CBCT scan. The surgical guide was virtually fabricated and exported to the 3D printing machine (Zenith 3D printer, Dentis, Daegu- Korea) to be printed. Then a metallic sleeve was placed and adapted to the surgical guide in the proposed implant site using adhesive.

Surgical procedure:

Prophylactic antibiotics (Amoxicillin 1 gm (Capsules), GSK. Egypt) were prescribed twice/day for all patients 1 day prior to the surgery and for 5 days after surgery. Then on the day of surgery, the patient was locally anaesthetized (Septanest SP [Articaine hydrochloride 4%]. France) and the remaining root or tooth was extracted in an atraumatic procedure using lancet, periotome, adequate forceps with minimal force and rotational movement (Figure 1,2). After extraction, the socket was examined for intact labial and palatal bone.

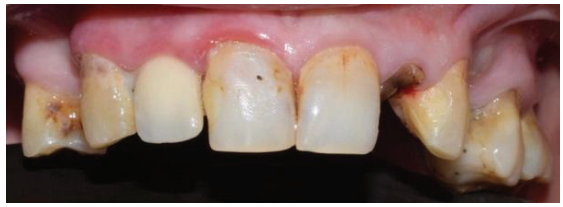

Figure 1: Preoperative photo for remaining root #22

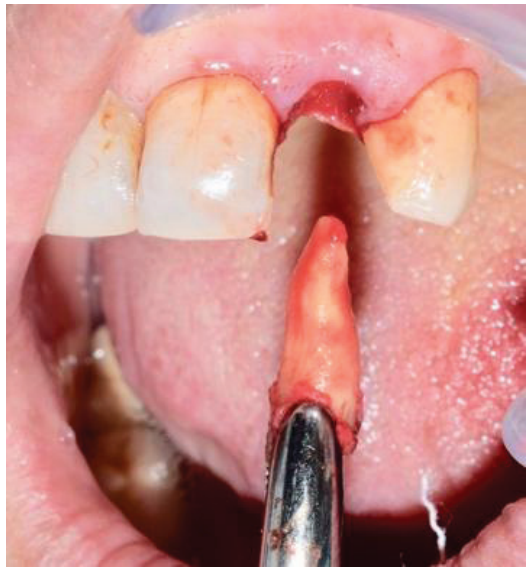

Figure 2 Extraction using forceps

Computer guided group

In the test group, computer guided implant surgical kit was used (Simple guide, DENTIS, Korea) (Figure3). Drilling was done using initial, intermediate and final drills through computer guided surgical guide (Figure 4). Implant (OneQ S clean, Dentis, DENTIS CO., LTD., Daegu, South Korea) was inserted through the guide using implant driver till resistance was met. Then a torque wrench was used to continue tapping the implant till it submerged 2 mm from bone level and reached at least 30 Ncm torque (Figure 5).

Figure 3: Computer Guided surgical kit

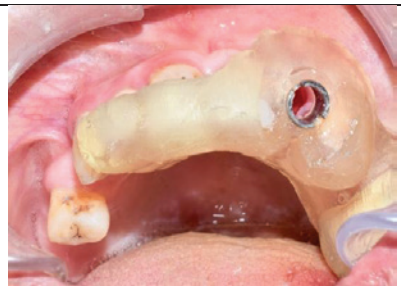

Figure 4: Computer guided surgical guide intraorally

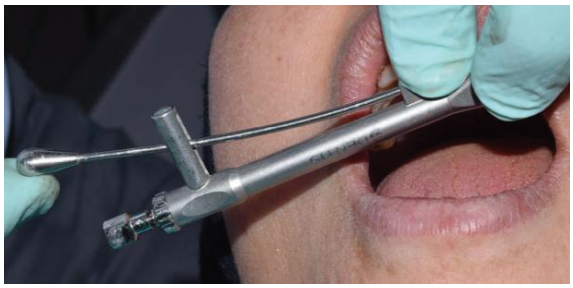

Figure 5: Checking torque to be 30 Ncm

Free hand group

In the control group, the same surgical procedures for extraction were done, then osteotomy site preparation was initiated by a pilot drill through the palatal surface of the extraction socket with extreme care, avoiding slippage of the drilling towards the labial bone. Then intermediate and final drills were used subsequently (Dentis, DENTIS CO., LTD., Daegu, South Korea). The implant (Dentis, DENTIS CO., LTD., Daegu, South Korea) was then placed into the osteotomy site using an implant driver until resistance was met, which was followed by a torque wrench to continue tapping the implant. The wrench was supported to avoid any slippage towards the buccal plate of bone until the implant was submerged 2 mm below the bone level and torqued till 30 Ncm.

Then in both groups chair-side provisional crowns were fabricated and made out of occlusion both in centric and eccentric movements (Figure 6). The patient was instructed to avoid eating or incising any hard food for at least six weeks. After a week (first follow up), patients were recalled for inspection and postoperative photos to be taken for PES assessment for both groups using a standard camera. Photos were taken at pre-calculated distance with the patient seated upright showing the provisional crown and the contralateral tooth in case of anterior tooth or the adjacent tooth in case of premolar tooth. Photos were then coded and placed into folders.

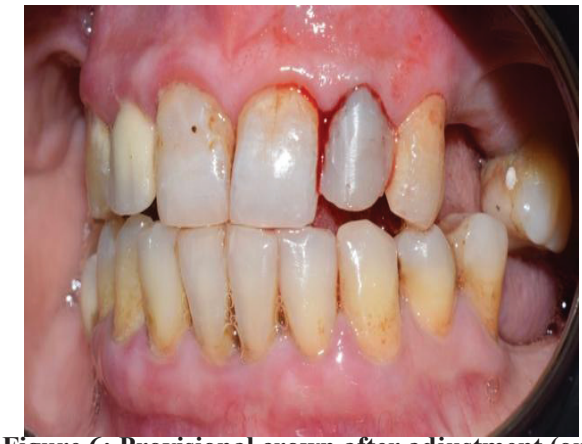

Figure 6: Provisional crown after adjustment (out of occlusion)

Definitive crown fabrication

After a period of 6 months the patients were recalled to remove the provisional crowns and start fabricating the definitive crown. Open tray impression technique and condensation silicon (Zetaplus, Zhermack SpA, Badia Polesine, Italy) were used to make the final impression to fabricate a metal ceramic crown. At the appointment of the delivery, the abutment was tightened using torque wrench till 25 Ncm. After occlusal adjustment the crown was cement retained using zinc phosphate cement (Dental zinc phosphate cement, Medental, Florida). After setting, excess cement was removed (Figure 7).

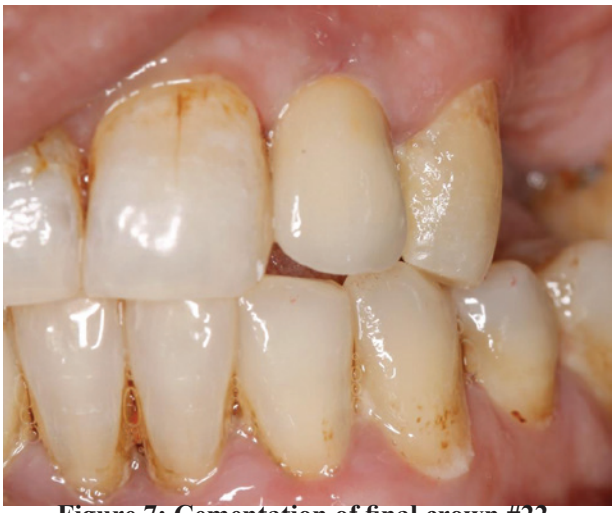

Figure 7: Cementation of final crown #22

After a week of definitive crown delivery, the patient was recalled to take the postoperative photos (6 months follow up) using the same standard camera while the patient sitting upright and at the pre-calculated distance. Photos were again coded and placed into folders. PES was measured and the scores were given to each of the parameters in the PES index and tabulated for analysis.

Secondary outcome assessment

The presence or absence of gingival recession more than 1 mm was observed on the postoperative photographs taken 1 week after definitive crown delivery and tabulated for analysis.

Statistical methods

Data management and statistical analysis were performed using the Statistical Package for Social Sciences (SPSS) version. Numerical data were summarized using means and standard deviations. Data were explored for normality by checking the data distribution and using Kolmogorov-Smirnov and Shapiro-Wilk tests. PES comparison between 2 groups was done using the t-test and PES overtime in each group was done by paired-t test. P-values ≤0.05 were considered significant.

Results

Twenty patients were recruited in the study, of which three implants failed to osseointegerate, one in the computer guided group and two in the free hand group and one patient loss to follow up in the free hand group. The total sixteen patients had their definitive crowns after a healing period of six months at which the follow up assessment was done.

The mean difference in PES at base line between both groups was 0.10 (95%CI -1.8-2.2) which was non statistically significant. After 6 months the mean difference between both groups in the PES was 0.75 (95% CI -3.5-1.9) which also presented a non-statistically significant difference (Table 1).

	Test group		**Control group**		**Mean difference**	
PES Score	Mean	SD	Mean	SD	(95% CI)	p value
At the baseline	11.40	1.7	11.30	2.1	0.10(-1.8,2.2)	0.870
After 6 Month	10.75	2.1	11.5	2.3	0.75(-3.5,1.9)	0.529

Table 1: Mean, standard deviation for comparing for PES of the tested groups (test group: Computer Guided, control group: Free Hand).

The mean difference in the PES in the test group from baseline till six months decreased by 0.65 presenting a 5.5% reduction. While in the control group the mean difference in the PES from baseline till six months increased by 0.2 presenting 1.4% increase. However, both results were statistically insignificant (Table 2).

Pink esthetic score (PES)	Baseline		6 Months		Mean	95%CI of MD		%	
	Mean	SD	Mean	SD	Difference	Lower	Upper	change	p value
Test group	11.40	1.7	10.75	2.1	0.65	-1.2	2.4	-5.5	0.435
Control group	11.30	2.1	11.5	2.3	0.20	-1.8	1.5	1.4	0.809

Table 2: Mean and Standard deviation, paired t test for comparing PES at baseline and 6 months postoperative (test group: Computer Guided, control group: Free Hand).

Regarding the gingival recession: In the computer guided group, 1 implant failed to osseointegrate, and out of the remaining 9, two implants showed gingival recession more than 1 mm. And in the free hand group, 2 implants failed to osseointegrate and 1 patient lost to follow-up, and out of the remaining 7, none showed gingival recession more than 1 mm.

Discussion

Pink esthetic score (PES) of ≥ 10 was considered an optimum esthetic outcome, while a PES of less than 7 was used to define an esthetic failure. [9,10]

Results of our study showed that the mean PES in the computer guided group one week postoperatively was 11.40 which represents an acceptable score for esthetics, which might be due to the proper case selection and proper positioning of the implants guided by the surgical guide. Furthermore, the mean PES in the free hand group one week postoperatively was 11.30 which might be due to the care taken during drilling and implant placement to be more palatal and avoid slippage towards the facial bone. These results are in accordance to previous studies, but the main difference lies in that latter ones used bone grafts and/or connective tissue grafts to fill the gap between the implants and alveolar bone. The average PES of these studies was 11.385 range [11.1-11.67]. [11–14] However, the PES of the present study was higher than other studies, where they placed implants after raising a flap which might have affected the blood supply to the surgical site reducing the PES to 10.30 (SD 1.89) and 10.48 (SD 2.47). [7,9]

Higher PES 12.55 after 1 year was reported in a study which used xenograft and enamel matrix derivative (EMD) in contact with the soft tissue of the newly formed socket which had a positive effect on early periodontal soft tissue wounds and showed earlier gains in soft tissue density and lead to increase in PES. [15]

On the other hand, the PES after 6 months follow-up in the free hand group showed non-statistical increase to 11.5, which might be due to the growth of soft tissue around the immediately placed and provisionalized implants.[16] However, the non-statistical reduction of the PES to be 10.75 after 6 months follow-up in the computer guided group could be attributed to the slight reduction in bone level due to reduced irrigation effect during guided flapless drilling through computer guided surgical guides that might have caused non-destructive heat-induced necrosis and inevitable bone loss that might have reduced the amount of support to the overlying soft tissue thus reducing the PES. [17,18]

Regarding gingival recession, only two implants out of the whole sample showed gingival recession more than 1 mm representing 12.5 %. This is in accordance to a previous study which reported that 87.5 % of the cases involved in the study showed a discrepancy between gingival margin and “ideal” facial margin based on the corresponding natural control tooth was equal or less than 1 mm. This might be attributed to marginal bone and soft tissue preservation by means of immediate implant placement and provisionalization in post-extraction sites in properly selected cases. [19]

Although immediate implant placement using computer guided surgical guides would consume more time, effort and expenses yet it provided similar results with the free hand. The benefit one could gain is that implants could be placed immediately in fresh extraction

sockets without needing very high level of clinical experience in this critical zone.

Conclusion

Within the limitations and the results obtained, it could be concluded that:

On comparing pink esthetic score in computer guided vs free hand immediate implant placement at 1 week after provisional crown and 6 months follow up no statistical difference was found. Regarding gingival recession, immediate implant placement and provisionalization provided an acceptable treatment modality for achieving good soft tissue results in the esthetic zone in both computer-guided and free hand groups with less than 1 mm gingival recession.

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