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Original Article

Esthetic outcome of immediately placed and nonfunctionally loaded implants in the anterior maxilla utilizing a definitive abutment: A pilot clinical trial

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ABSTRACT

Background: Immediate dental implants placement and loading utilizing definitive abutments might save time and cost when an esthetic final result is anticipated. The objective of this prospective clinical trial was to evaluate the esthetic outcome of immediate implantation and immediate nonfunctional loading utilizing definitive abutments, with and without bony substitutes filling the peri-implant gap.

Materials and Methods: In this clinical trial study a total of 11 implants were placed utilizing a flapless immediate post extraction approach in the maxilla (second premolar to second premolar). Atraumatic extraction was performed and implants were immediately placed. The gap was either left without grafting or filled with particulate bone material. Immediate nonfunctional loading was performed utilizing a definitive abutment. The pink esthetic scores (PESs) were assessed preoperatively, at 1- and 2-year follow-up periods. Dental casts were obtained at respective time intervals; scanned, registered, and closest point distances were measured. For all statistical tests, value of $P = 0.05$ was set as a statistical significance level.

Results: The mean of PES at baseline was 9.4 ± 1.69, at 1 year was 9.5 ± 2.07, at 2 years was 10.2 ± 2.75, for the graft group 10.3 ± 2.8, and for nongrafting group was 10.2 ± 2.59. There were no statistically significant differences in PESs at baseline when compared to 1- and 2-year intervals, and for grafting group versus nongrafting group ($P = 0.24$). Distances between the two time points for all cases were <1 mm in all reference planes.

Conclusion: Immediate placement and nonfunctional loading utilizing a definitive abutment appear to result in a stable result as far as esthetic outcome and alveolar process sufficiency are concerned.

Key Words: Dental implants, esthetics, immediate dental implant loading, single-tooth implants

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INTRODUCTION

Single-tooth immediate implant placement in the esthetic zone with immediate restoration is considered a reliable treatment option for replacing a failing tooth, thus reducing treatment time and providing patients with a secure "fixed" provisional replacement

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of unsalvageable teeth.[1-7] The main challenge in the esthetic zone remains in the establishment and maintenance of healthy peri-implant hard and soft tissues.[8-12] Therefore, several consensus statements and clinical recommendations have been drawn up in recent years to guide clinicians toward the best treatment options for such procedures.[13-15]

A recent prospective study by Covani *et al*.[16] reported on a 10-year follow-up of 159 implants placed in fresh extraction sockets, confirmed the long-term predictability of immediate implant placement and immediate provisionalization. It has also been shown that this type of treatment results in a high survival rate, minimum peri-implant bone loss, very good esthetics, and satisfactory patient-related outcomes after a mean follow-up period of 4 years.[17] The provision of an immediate restoration may lead to improved esthetic outcomes as evidenced by higher median pink esthetic scores (PESs) when compared to delayed restoration.[18]

The gingival biotype, the facial bone crest level, the implant insertion three-dimensional position, and the distance between implant shoulder and facial socket wall seem to have a great impact on the final esthetic outcome.[19-21] It has been shown that creating a facial gap of at least 2 mm on immediate implant placement results in new bone formation coronal to the receding facial bone wall.[22] The positive effect of applying a grafting material between the socket wall and the implant on facial bone preservation and esthetics has been previously documented.[23,24] However, a recent systematic review reported that it was not conclusive whether grafting between the implant and the facial bone had any effect on soft-tissue levels around implants placed using the immediate placement and restoration protocol.[25] Weigl and Strangio[26] revealed excellent results for immediately placed and immediately restored single implants in the anterior maxilla. The authors stated that the possible choice for flapless surgery without grafting the peri-implant gap allows for minimally invasive surgery, keeping in mind strict patient selection criteria.

Another element implicated in crestal bone loss, and marginal periapical tissues is the repeated disconnection/reconnection of the healing caps and/or abutments as a part of the conventional prosthetic treatment protocol. It was demonstrated that repeated disconnection causes disruption of the epithelial seal, bleeding and ulceration of the site leading to inflammatory responses and epithelial apical migration.[27] A recent meta-analysis of randomized controlled trials[28] confirmed that minimizing abutment disconnection and reconnection seems to decrease peri-implant bone level changes.

The aim of this pilot prospective clinical trial was to evaluate the esthetic outcome of immediate implant placement and nonfunctional loading utilizing definitive abutments in the esthetic area of the maxilla (incisors, canines, and premolars), with or without bone substitute. The first null hypothesis was that PES will not differ significantly between grafting and nongrafting groups. The second null hypothesis was that PES will not differ significantly between baseline time point before extraction and 2 years after definitive crown installment for either group. The third null hypothesis was that there will be no significant difference of buccal contours between baseline and 2 years after definitive loading.

MATERIALS AND METHODS

Thirteen consecutive patients requiring the replacement of a maxillary tooth (centrals, canines, and premolars) with an implant were included in this prospective clinical trial. All implants were placed in the Dental Department of Jordan University Hospital. Ethical approval for the study was obtained from the Human Research Ethics Committee at the University and the University's Hospital. Informed consent was obtained from all individual participants included in the study.

Inclusion criteria

All of the following criteria had to be met for inclusion in the study:

1. Males and females aged at least 21 years
2. Present with at least one failing tooth in the maxillary anterior region (incisors, canines, and premolars)
3. Intact socket walls evident on cone beam computed tomography and confirmed on the day of extraction
4. Natural teeth present adjacent to the tooth being replaced in addition to a natural counterpart tooth present for esthetics criteria evaluation
5. Adequate bone apical to the tooth to be replaced with a minimum primary stability of 30 Ncm
6. Thick gingival biotype.

Exclusion criteria

1. The presence of active infection around the failing tooth or adjacent teeth

2. The presence of active periodontal disease and gingival recession in the esthetic area
3. Thin gingival biotype
4. Bruxism and parafunctional habits
5. Labial plate dehiscence, fenestration, or loss after tooth extraction
6. Inability to achieve primary stability after implant placement
7. Any medical, physical, or psychological reasons that might affect the outcome of treatment (smoking, alcohol abuse, drug dependency, uncontrolled metabolic disease, and poor health).

Surgical and prosthetic procedures

The tooth to be replaced was extracted atraumatically using a flapless approach, and socket walls were inspected for their integrity using a UNC 15 periodontal probe. Any fenestration or dehiscence of the facial socket wall led to exclusion of that patient from the study. This was followed by implant placement according to the surgical sequence protocol provided by the manufacturer (NobelActive, Nobel Biocare, Goteborg, Sweden). Care was taken to engage the palatal and apical bone to achieve a high primary stability. As for three-dimensional positioning of implants, an attempt was made to place the implant with a gap of at least 2 mm from the inner surface of the facial cortical plate facio-palatally, and in the range of 3–4 mm from future gingival margin in a corono-apical direction.[29] After the placement of the implant, the gap between the implant and the inner surface of the buccal cortical plate was either left without grafting or filled with natural bovine bone mineral granules (Cerabone, Botiss biomaterials GmbH, Germany) based on a coin toss method. Following implant placement, a definitive titanium abutment was selected and attached to the implant and cement-retained provisional restorations were fabricated and relieved of any contact with the opposing dentition in centric, lateral, and protrusive movements. Special care was given to the contours of the provisional restorations at the cervical area to help in creating a proper emergence profile. The provisional crowns were left in the place for 12 weeks after which definitive cement-retained full ceramic crowns were placed by the same prosthodontist. Intra-oral photographs, PES, and alginate impressions were obtained and poured for each patient preoperatively, at 1- and 2-year post installation of the definitive crown.

Esthetic evaluation

Esthetic evaluation was performed using the PES.[30] PES includes seven variables: mesial papilla, distal papilla, midfacial level, midfacial contour, alveolar process deficiency, soft-tissue color, and soft-tissue texture. Each parameter is assessed using the contralateral tooth as a reference with a 0–1–2 score resulting in a maximum possible score of 14. PES scores for baseline (PES0), 1-year (PES1), and 2-year (PES2) follow-up time points were calculated. PES assessments were performed by two independent blinded assessors (prosthodontists).

Casts measurements

Casts of the preoperative stage as well as follow-up casts at 1 years and at 2 years were optically scanned using an imes-icore GmbH (Eiterfeld, Germany) table-top scanner. The obtained STL (standard tessellation language) files were imported into Slicer CMF 4.1 (Kitware Inc. USA) (www.slicer.org) (cmf.slicer.org). Scans were cropped to include the area of interest and a tooth on both sides, in an attempt to remove the outliers that may result from differences in other areas on that cast. The cropped casts scans were then registered using surface-to-surface registration module in Slicer CMF 4.1, and then signed closest point distances were measured between the registered casts. Linear measurement for the difference in shape between the two casts was reported on the X, Y, and Z reference planes. All image analysis steps and measurements were performed by a blinded assessor (an oral and maxillofacial radiologist).

Statistical analysis

Statistical analysis was performed using SPSS Statistics 23 (IBM; Armonk, NY, USA). Descriptive statistics were reported. Pearson's Chi-squared test was applied to test for any statistically significant differences in PES scores for different points of time and for graft group versus nongrafting group. Data were tested for normal distribution and independent sample *t*-test was applied to test for any statistically significant differences for the cast scans in X, Y, and Z reference planes between graft group and nongrafting group. For all statistical tests, $P = 0.05$ was set as a statistical significance level.

RESULTS

A total of 13 implants were placed in 12 patients (6 males: 6 females) (mean age was 46.3 years) in

the esthetic area of the maxilla (centrals, canines, and premolars). Two patients were lost to follow-up after the installation of definitive crowns as they moved out of country. Therefore, a total of 11 implants (10 patients, as one patient received two single implants) completed the 2 years evaluation. All implants remained osseointegrated and restorations were functional at the end of the 2-year follow-up period. Patient gender distribution, implant site and size, and reason for extraction are presented in Table 1 and Figure 1 demonstrates an example case at different time points.

The range of the gap left between the implant and the inner surface of the facial plate varied from 2 mm to 4 mm. The means of PES score were as following: PES0 = 9.4 ± 1.69, PES1 = 9.5 ± 2.07, PES2 = 10.2 ± 2.75, PES (graft group) = 10.3 ± 2.8, and PES (nongrafting group) = 10.2 ± 2.59. There were no statistically significant differences in PES scores at different points of time both collectively (P = 0.19 for PES0 vs. PES1, P = 0.24 for PES0 vs. PES2, and P = 0.52 for PES1 vs. PES2), and when compared for the grafting group versus nongrafting group (P = 0.24 for PES2 graft vs. PES2 nongrafting). Table 2 summarizes PES scores at different points of time and for the graft versus nongrafting groups. Figure 2 demonstrates the changes in each individual PES item overtime for all cases.

As for casts scans, the surface distances between the two time points for all cases were < 1 mm in all reference planes and there were no statistically significant differences between the graft group and nongrafting group (P = 0.15 for the mean changes in [X] plane, P = 0.12 for [Y] plane, and P = 0.19 for [Z] plane). This reflects a stable surgical outcome of this approach.

Based on those results, all null hypotheses were accepted.

Table 3 presents mean change of distances at buccal contour as measured on casts from baseline to 2 years after definitive crown installation among grafting and nongrafting cases. Figure 3 shows overlapping casts scans of grafting and nongrafting cases at baseline and 2 years point of time demonstrating stable results with no significant loss of alveolar process or tissue support.

Table 1: Patient gender distribution, implant site and size, and reason for extraction

Variable	*n* (%)
Gender	
Male	6 (55)
Female	4 (45)
Tooth#	
UR5	1 (9.1)
UR4	3 (27.3)
UR2	1 (9.1)
UR1	1 (9.1)
UL1	1 (9.1)
UL3	1 (9.1)
UL5	3 (27.3)
Reason for extraction	
Fracture of endodontically-treated tooth (nonrestorable remaining part of the tooth)	11 (100)
Diameter of implants (mm)	
3.5	2 (17)
4.3	7 (66)
5.0	2 (17)

DISCUSSION

Survival rates for immediately placed, immediately restored implants have been shown to be

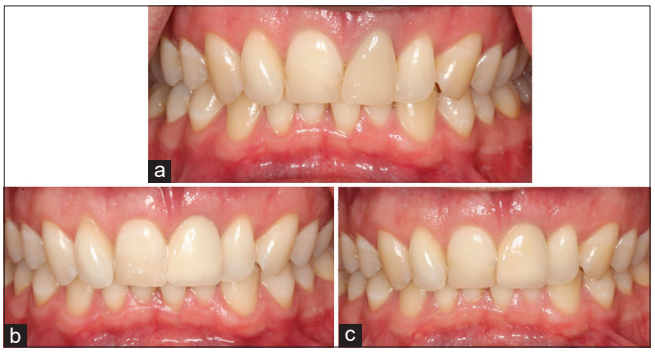

Figure 1: (a) Upper left central incisor before extraction, (b) at 1-year post definitive crown installation, (c) at 2-year postdefinitive crown installation, demonstrating an acceptable esthetic result and soft tissue levels.

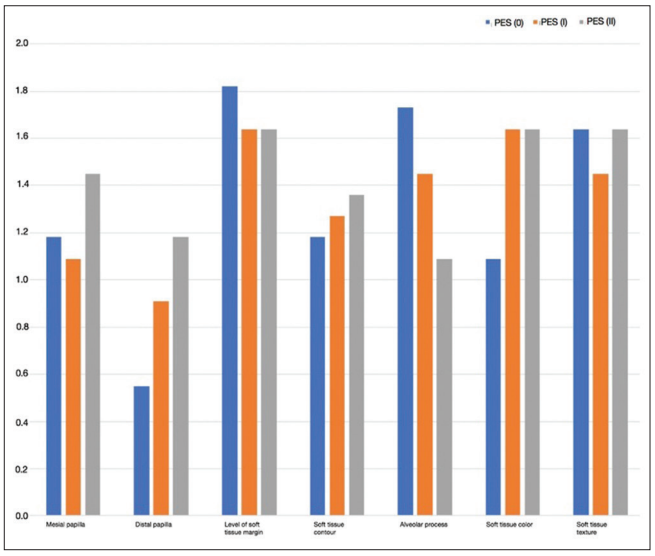

Figure 2: The change in individual pink esthetic score items from baseline to the 2-year follow-up point.

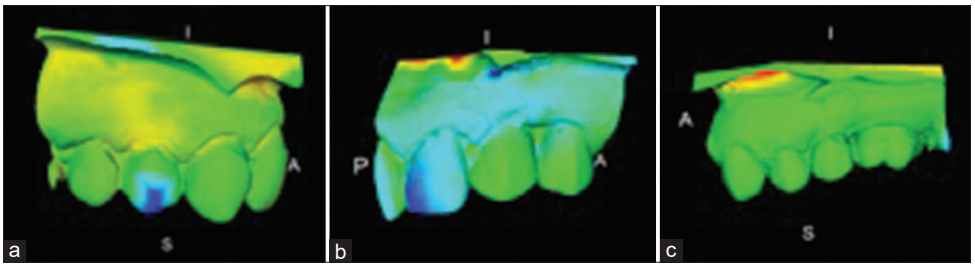

Figure 3: Overlap of a scanned impression model taken 2 years after installation of definitive crown. (a) A nongrafting case. A slight increase can be noticed in the alveolar process prominence related to the implant site #14 as indicated by the yellow color. (b) A grafting case. A slight decrease can be noticed in the alveolar process prominence as well as papillary fill related to the implant site #23 as indicated by the blue color. (c) A nongrafting case for implant site 25 was neither loss nor gain in tissues indicated by the stable green color overtime.

Table 2: Pink esthetic scores for the three points of time (baseline, 1 year, and 2 years) as well as for the graft and nongrafting groups

Implant position	Grafting of the peri-implant gap	PES (0)	PES (I)	PES (II)	PES graft	PES no-graft
UR4	No	9	12	13		13
UR4	No	9	10	10		10
UL5	No	7	6	5		5
UR4	No	11	10	11		11
UL5	No	9	8	11		11
UL1	Yes	12	13	13	13	
UL3	Yes	7	7	5	5	
UL5	Yes	9	9	10	10	
UR2	Yes	9	9	11	11	
UR5	Yes	12	11	11	11	
UR1	Yes	9	9	12	12	
Mean±SD		9.4±1.69	9.5±2.07	10.2±2.75	10.3±2.8	10.2±2.59
Median		9.00	9.00	11.00	11.00	11.00

SD: Standard deviation; PES: Pink esthetic score

Table 3: Means of differences in distance measurements for casts at baseline compared to 2 years points of time in the three reference planes

Mean change in (X) axis (mm)±SD	Mean change in (Y) axis (mm) ±SD	Mean change in (Z) axis (mm) ±SD	Grafting status
−0.019±0.37	−0.015±0.61	−0.003±0.44	Graft
0.007±0.36	−0.021±0.28	−0.018±0.38	Graft
0.002±0.23	−0.004±0.24	−0.006±0.24	Graft
0.028±0.35	−0.001±0.34	0.018±0.40	Graft
0.003±0.35	−0.006±0.25	0.009±0.33	Graft
0.014±0.29	0.039±0.34	−0.065±0.38	Graft
0.034±0.69	−0.065±0.64	−0.006±0.65	No graft
−0.007±0.55	0.013±0.64	−0.013±0.62	No graft
−0.039±0.54	−0.008±0.43	0.005±0.52	No graft
0.019±0.36	0.028±0.38	0.006±0.52	No graft
−0.013±0.93	−0.039±0.59	−0.016±0.74	No graft
P=0.15	*P*=0.12	*P*=0.19	

P values are representing the difference between graft and nongrafting groups in each plane according to the independent *t*-test applied *P* values represent the result from independent *t*-test for each plane depending on the grafting status showing no statistically significant differences in all planes between graft and nongrafting groups. SD: Standard deviation

favorable.[3,5,7,31-34] Nevertheless, there is limited evidence in the literature on the esthetic outcomes of immediate nonfunctional loading. In this study, success rate of the implants and the associated restorations was 100% at 2-year post definitive crown installation, and PES score was 10.2 (±2.75) for the same point of time, which represent a favorable outcome and is in accordance with most previously reported results

on immediately placed and provisionalized implants. Hartlev *et al*. reported PES 9.9 for a mean follow-up period of 33 months.[35] Vidigal *et al*.[36] in their study reported PES 8.63 for an average follow-up of 51 months. In a more recent study,[18] the immediate placement and provisionalization group had higher PES scores compared to delayed group, although not statistically significant at a mean follow-up period of 3 years.

The results of this study showed that immediate implant placement and provisionalization might improve the facial soft-tissue level, provided that proper case selection criteria and proper implant placement protocol are respected. Saito *et al*.[37,38] reported that the use of properly contoured provisional restorations can function as a substratum for cellular adhesion and may provide a platform to promote peri-implant soft-tissue healing and minimize remodeling of the buccolingual ridge dimension. Tarnow *et al*. and Amato *et al*. stressed on the importance of the provisional restorations in maintaining the original volume and shape of the peri-implant tissue.[39,40] Both studies reported that the least amount of resorption was observed when an immediate provisional restoration was placed with grafting as opposed to tissue grafting alone. These reports are in concordance with our results where PES-graft group was slightly higher than PES nongraft group although not statistically significant ($P = 0.24$).

Therefore, it seems that using a flapless approach and supporting both the hard and soft tissue by immediately inserting a provisional restoration and graft material appears to preserve the tissue volume and enhance the final esthetic results. The results of this study are in agreement with previous studies reporting on the effect of the flapless approach[41] and grafting the peri-implant gap[42] in reducing dimensional changes that normally occur after tooth extraction. The peri-implant gap that occurs between the implant surface and the facial bone wall in an extraction socket may heal predictably with new bone formation and defect resolution without grafting materials,[43-45] and Ferrus *et al*.[46] reported that bone fill in gaps ≥1 mm was substantial. In a study[47] on immediate implant placement with or without tissue grafting, the authors noticed bone resorption occurrence in all groups; nevertheless, this resorption was more pronounced in the nongrafted group. However, in their study, no immediate provisionalization was attempted.

Regarding the use of definitive abutments for immediate provisionalization and definitive crown insertion, Canullo *et al*.[12] in a randomized controlled trial reported that at 36 months after the final restoration, there was statistically significant greater bone loss in the group that received a provisional restoration using a provisional titanium abutment (0.55 mm) as opposed to those who received a definitive titanium abutment (0.34 mm). Similarly, in a recent meta-analysis of randomized controlled trials,[28] most of the selected scientific literature confirmed that the use of a prosthetic procedure which minimizes abutment disconnection and reconnection seems to decrease peri-implant bone-level changes. Definitive abutments placed at implant insertion and never removed might prove to preserve peri-implant hard and soft tissues, especially when immediate placement is attempted along with immediate nonfunctional loading in the esthetic zone.[12,28,48,49] When considering immediate placement and immediate restoration, case selection cannot be overemphasized. Factors such as presence of facial bone and thick gingival biotype are mandatory when attempting this modality of treatment.

To our knowledge, this is the first prospective clinical trial to perform immediate implant placement with provisionalization using the definitive abutment on implants with platform switching and internal connection design, with the sample divided into two groups (grafted vs. nongrafted group), and assessments of PES and linear cast measurement analyses in three reference planes at different intervals for up to 2 years of observation period.

Limitations of this study were the small sample number, and the fact that the majority of the sample teeth were premolars, as it has been reported before that the fill of the horizontal gap is more pronounced at implant sites in the premolar segment.[46] Therefore, larger and randomized controlled trials are necessary to confirm the value of immediate provisionalization over grafting alone. This might result in a more cost-effective treatment approach for single-tooth extraction cases, while neither using additional bone graft nor temporary abutments, nonetheless bearing in mind, the strict case selection criteria followed in the present study.

CONCLUSION

Within the limitations of this study, patients who need to replace a single tooth in the esthetic area of

the maxilla can predictably be treated with immediate implant placement and provisionalization utilizing a definitive abutment that preserves the tissue volume and contours regardless of grafting the peri-implant gap. More studies and larger samples are needed to further validate this conclusion.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial in this article.

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