

# Immediate Restoration of Single Tapered Implants with Nonoccluding Provisional Crowns: A 5-Year Clinical Prospective Study

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## ABSTRACT

**Background:** Dental literature has limited number of publications regarding long-term outcome data of immediate restoration of single missing teeth with an implant-supported provisional crown.

**Purpose:** This 5-year study evaluated hard and soft tissue responses to the immediate placement of single implant-supported provisional crowns.

**Materials and Methods:** Twenty patients received one dental implant restored immediately with a provisional acrylic resin screw-retained crown. Crestal bone loss was evaluated from standardized periapical radiographs collected at 3-month intervals for the first 21 months followed by a 5-year evaluation. Historical controls acquired from available dental literature were used for comparison.

**Results:** One implant failed within 2 months of surgical placement, presenting with pain and mobility. The remaining implants demonstrated no infection, pain, or radiolucencies. Nineteen implants were clinically immobile, osseointegrated, and asymptomatic at 21 months. At 5 years, one patient died, three patients were noncompliant, and 15 implants were evaluated as functional. Mean bone loss (MBL) at 1 year and 21 months was approximately  $0.5 \pm 0.5$  mm and  $0.70 \pm 0.26$  mm at 5 years. There was no statistically significant difference between MBLs at  $p < 0.05$ .

**Conclusions:** Immediate provisionalization of single dental implants compares favorably with conventional loading protocols. Long-term data suggest that immediate provisionalization of single dental implants is a viable treatment option.

**KEY WORDS:** bone loss, clinical outcomes, dental implants, immediate provisional

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## INTRODUCTION

Endosseous implant-supported dental restorations have been shown to be a reliable treatment alternative for the replacement of missing teeth.<sup>1</sup> Successful implant therapy is dependent on achieving and maintaining osseointegration.<sup>2</sup> Early experiences with implant treatment relied on the surgical placement of implants followed by a healing period of 3 to 6 months during which the implants were protected from externally applied forces.<sup>3,4</sup>

The replacement of single missing teeth with implant-supported crowns may be indicated in situations where adjacent teeth are intact and healthy, where adjacent teeth are periodontally compromised and incapable of serving as prosthetic abutments, or where esthetic demands cannot be met with conventional

restorative approaches. Clinical studies for single implant restorations indicate high success rates.<sup>5-8</sup>

With the development of new implant types, surface technology, and advanced knowledge about the physiology of osseointegration, the requirement for delayed restoration of dental implants has been challenged.<sup>6,9</sup> Interest has surfaced with regard to placing a dental restoration on the day of surgical implant placement to foster early esthetic improvement, guide appropriate healing of the peri-implant soft tissues, increase patient comfort, and decrease treatment time.

Immediate loading of dental implants using different types of restorations has been successfully accomplished in animal models<sup>10,11</sup> and then in humans.<sup>12-16</sup> The restoration of single missing teeth with implant-supported crowns has been routinely performed by clinicians recently.<sup>17,18</sup> Although clinical studies presenting short-term outcomes of immediately loaded implants supporting single crowns are available,<sup>19-21</sup> there are only a few studies regarding long-term results (5 years or longer) of immediately loaded implants supporting single crowns available.<sup>22,23</sup>

This prospective cohort clinical study was designed to determine the success rate and clinical outcomes of

a single dental implants restored immediately following surgical placement with nonoccluding provisional restorations by evaluating the response of the hard and soft tissues adjacent to the implant over a 5-year period.

## MATERIALS AND METHODS

This prospective, nonblinded, nonrandomized cohort clinical study consisted of 20 patients. Patients were recruited into this study by solicitation through advertisements and review of dental records currently on file in the University of Texas Health Science Center at San Antonio (UTHSCSA), Dental School. Patients were screened and selected by a prosthodontist and an oral surgeon. A complete medical history, dental history, and subject interview were conducted by the investigators to ascertain the subjects' current state of health and to identify any contraindications to participation in the study (Table 1). Initial evaluations included the following: (1) discussion of the research project; (2) review of the patients' medical and dental histories; (3) measurement of blood pressure and pulse; and (4) standard intraoral and extraoral dental examinations. Following the initial evaluation, when the patient fulfilled

**TABLE 1 Inclusion and Exclusion Criteria. The following is a List of the Inclusion and Exclusion Criteria That Was followed as Part of the Screening Process for the Study**

- a. Patients must be present for treatment and follow-up examination according to the scheduled requirements of the research project.
- b. Patients must at least 18 years of age.
- c. Patients must be free of uncontrollable diabetes, existing malignancy, and must not be receiving immune suppressive therapy, such as radiation therapy, chemotherapy, or chronic steroid therapy.
- d. Patients must have intact dentitions, except for single missing tooth from the maxilla or mandible. Only one implant may be placed in any patient participating in this study.
- e. Patients must have sufficient space in the edentulous area for satisfactory implant restorative procedures.
- f. Patients must be free of active periodontal disease. Tooth mobility must be physiologically acceptable and all periodontal pockets less than or equal to 3 mm at the time of implant placement.
- g. Presurgical evaluation must provide convincing evidence that the final implant-support restoration will demonstrate a crown-to-implant ratio of at least 1:2.
- h. All proposed implant sites must have sufficient bone volume to accommodate an implant with a 3.7 to 4.7 mm-diameter and a length of at least 13 mm.
- i. All proposed implant sites must possess at least 2 mm of attached keratinized tissue. If unavailable, grafting procedures must be accomplished so that 2 mm of attached keratinized tissue can be generated.
- j. Patients with advanced cardiovascular disease, pulmonary disease, renal disease, liver disease, or significant alcohol ingestion will be excluded from the study.
- k. Patients with a Plaque Index of 1 and a Modified Gingival Index of 1 must be amenable to professional oral prophylaxis and oral hygiene instructions. Three weeks after the oral prophylaxis, the patient must demonstrate improved oral hygiene and improved periodontal conditions before being considered a candidate for the study.

inclusion criteria (see Table 1), a panoramic radiograph was made and evaluated. Once accepted for participation in the research project, each patient signed a consent form, which was approved by the UTHSCSA Institutional Review Board.

A complete diagnostic work-up was then undertaken consisting of a comprehensive oral examination, appropriate photographic and radiographic imaging, and diagnostic casts.

Irreversible hydrocolloid (Jeltrate, Dentsply Caulk, Milford, DE, USA) impressions were made of the maxilla and mandible to produce diagnostic casts. The casts were mounted in a semi-adjustable dental articulator. A full contour, diagnostic wax-up of the proposed coronal restoration, incorporating optimal occlusal anatomy and contacts, was accomplished. The completed diagnostic wax-up of the proposed coronal restoration was used to construct the following: (1) a surgical template to provide guidance during implant site preparation; (2) an occlusal matrix for use in transferring the implant position to the diagnostic cast following implant placement; and (3) a pressure-formed matrix to aid in fabrication of the provisional crown. The proposed vertical position of the dental implant was 3 mm apical to the cemento-enamel junction of the adjacent teeth.

A restrictive surgical guidance was provided for the 2.3 mm-diameter pilot drill. Screw-retained crowns were selected as the treatment of choice due to the fact that the crowns could be easily removed for visual inspection of the soft tissue and to allow for direct measure of the height of the gingival tissue height around the implant as well as eliminate any concerns of soft tissue response to remnants of provisional cements. An acrylic resin, occlusal matrix was constructed. This matrix was used to make an intraoperative registration of the implant position in order to position the implant replica in the cast so that an indirect provisional crown could be fabricated.

At the time of surgery, local anesthesia with or without sedation was administered. After crestal incisions were made, full-thickness mucoperiosteal flaps were elevated. After the osteotomy was completed using the surgical template, the implant was placed. All implants were placed in healed sites, which did not require bone grafting. All implants (Tapered Screw-Vent implants, Zimmer Dental, Carlsbad, CA, USA) in the study were at least 13 mm long.

An implant was judged to be stable if the insertion torque was greater than or equal to 35 Ncm. When the implant was judged to be mechanically stable, the fixture mount was used as a direct transfer impression post. The occlusal matrix was positioned on the teeth adjacent to the implant site. A light-activated resin (Triad Gel, Dentsply International, York, PA, USA) was used to attach the fixture mount to the occlusal matrix. When the resin had cured, the matrix was removed and taken to the laboratory for provisional crown construction.

The surgical area was irrigated and closed with 4.0 chromic sutures. Patients were placed on an appropriate antibiotic and prescribed an analgesic. A periapical radiograph was made immediately following the surgical procedure.

In the dental laboratory, an implant analogue was fastened to the fixture mount/occlusal matrix assembly. A hole was prepared in the diagnostic cast to receive the implant replica when the occlusal matrix was properly positioned on the cast. With the occlusal matrix held firmly to the cast, dental stone was added around the implant replica adhering it in position. Upon set of the dental stone, a provisional crown (Integrity, Dentsply Caulk) was constructed using a plastic temporary abutment (Hex-lock, Zimmer Dental) and the pressure-formed matrix. The provisional crown was evaluated for fit and form and necessary adjustments completed. Occlusal contacts were adjusted so that no occlusal contacts were present in the maximum intercuspal position; shim stock drags through the occlusal contact. All eccentric contacts were eliminated. The access channel was obturated with a temporary filling material (Fermit, Ivoclar Vivadent, Inc., Amherst, NY, USA).

After a 3-month healing period for mandibular implants and 6 months for maxillary implants, a final impression was made. An implant analogue was attached to the impression post, and the assembly repositioned into the impression. The final impression was poured using a type IV dental stone (Silky-Rock, Whip Mix Corp., Louisville, KY, USA).

Definitive metal-ceramic crowns were fabricated using standard laboratory procedures. The occlusal scheme used was individualized to the patient's needs. Typically, occlusal contacts were adjusted so that light occlusal contacts were present in the maximum intercuspal position; shim stock drags through the occlusal contact. The shim stock held with maximum occlusal force. All eccentric contacts were eliminated. Mutually

protected occlusion was generally considered optimal. When appropriately adjusted for fit, form, and function, the final crown was screw fastened to the implant. Following placement, a periapical radiograph was made to assure complete seating of the crown. A temporary filling material was placed in the screw access channel.

Each patient was examined and experimental data were collected by the investigators at the time of provisional crown insertion (baseline), every 3 months for 21 months, and then at approximately 5 years postimplant placement. Three photographs were made of the crowns at each follow-up appointment to include the following: (1) facial view; (2) occlusal view; and (3) lingual view. Dental occlusion and proximal contacts were examined at each visit. Criteria for implant success were those of Albrektsson and colleagues.<sup>24</sup> Patient examination and data collection included the following:

The primary efficacy variable, immobility of the implant, was assessed beginning at the 3-month recall visit following placement of the definitive restoration. To be considered a success at the primary level, the implant had to demonstrate no visible mobility. Implant mobility was measured using a two-point scale (shown below). The implant restoration was held between two dental instruments and moved buccolingually to determine the score.

Grade Clinical Impression

- 0 = No visual movement upon application of a displacing force.
- 1 = Visually mobile.

The secondary level of success was evaluated using measurement of infection/pain and radiolucency. To be considered successful, the implants could not demonstrate persistent and/or irreversible signs of pain and/or infection. Any infection or pain experienced by the subject outside of normal postoperative discomfort was recorded as an adverse event, and that implant was considered a failure at the secondary level.

A three-point custom scale termed the Wound Healing Index (WHI) was used to assess the presence of infection. A value of 2 indicates infection as described below.

Grade Clinical Impression

- 0 = Uneventful, pink tissue, no gingival edema, no exudate, no subject discomfort, or material exposure.

- 1 = Uneventful, with slight edema, erythema, or subject discomfort. Minimal material exposure or exudate.
- 2 = Poor healing, significant edema, erythema, and/or subject discomfort. Significant exudate and material exposure.

Gingival health, levels of gingival recession, and the amount of plaque accumulation around the implant were recorded. The Modified Gingival Index (MGI) was used to evaluate the peri-implant soft tissues.<sup>25</sup> A five-point scale was used.

Grade Clinical Impression

- 0 = Absence of inflammation.
- 1 = Mild inflammation; slight change in color, little change in texture of any portion of but not entire marginal or papillary gingival unit.
- 2 = Mild inflammation, criteria as above but involving the entire marginal or papillary gingival unit.
- 3 = Moderate inflammation; glazing, redness, edema, and/or hypertrophy of the marginal or papillary gingival unit.
- 4 = Severe inflammation; marked redness, edema, and/or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion, or ulceration.

Gingival bleeding has been associated with various forms of periodontal disease<sup>26,27</sup> and peri-implantitis.<sup>28,29</sup> During probing, bleeding was assessed and recorded along with the height of the tissue cuff from the top of the implant. The implants were examined with a calibrated periodontal probe that standardizes force delivery during pocket depth determination (Pressure Standardized Probes, Ivoclar Vivadent, Inc.). With the crown removed to improve access, six sites were probed for each implant including direct facial, direct lingual, mesial-lingual line angle, distal-lingual line angle, mesial-facial line angle, and distal-facial line angle sites. Measurements were recorded and entered into the computer database. The six clinical measurements were averaged as well as evaluated individually. To avoid disrupting gingival maturation, probing was not initiated until the prostheses have been in place for 3 months.

The Plaque Index (PI)<sup>30,31</sup> was applied to assess the patients' ability to clean and maintain the implant

restorations. To measure and record supragingival plaque on the implants and restorations, the following four-point scale was used:

**Grade Clinical Impression**

- 0 = No plaque.
- 1 = Thin film of plaque at the gingival margin and adjacent area of the restoration, visible only when scraped with an explorer.
- 2 = Moderate amount of plaque along the gingival margin, adjacent area of the restoration, and within the gingival sulcus; interproximal space free of plaque; plaque visible with the naked eye.
- 3 = Heavy accumulation of plaque at the gingival margin, adjacent area of the restoration, and within the gingival sulcus; interproximal space filled with plaque.

The implant must demonstrate an absence of a radiolucent border. Investigators examined the subjects' radiographs for normal healing and no radiographic evidence of intraosseous abnormalities. Standardization of radiographic technique and bone loss measurements were achieved by using the following:

- XCP technique (Extension Cone Paralleling Technique) with a film holder for each subject (XCP Film Holding Instrumentation, Dentsply/Rinn Corp., Elgin, IL, USA), where the device was used to hold the film perpendicular to the central x-ray beam;
- Using the implant threads (with known distance between the threads) as a reference point to measure bone loss;
- Standard film (Kodak InSight, Eastman Kodak, Rochester, NY, USA), milliamperage, voltage, and developing conditions at each study site.

The height of the crestal bone, relative to the collar of the implant, was measured and recorded. All measurements were made by digitizing the standardized periapical radiographs. One investigator performed the periapical radiograph evaluations. Radiographs were made before and after immediate provisional crown placement, at definitive crown placement, and at 3-month follow-up intervals up to 21 months and again at 5 years. The diameter of the implant was used to calibrate the computer software for measurement. Mesial and distal measurements of each implant were made.

## Statistical Considerations

Historical controls were used for comparison to the experiment group in this study. The primary disadvantage of using historical controls is the inability to do the following: (1) blind the examiners; (2) control bias; and (3) make direct comparisons between the experimental and control groups. To minimize this disadvantage, our success criteria are based on a previously proposed industry standard for dental implants.<sup>24</sup> This helped to ensure that our results can be appropriately compared with existing literature.

The data collected for each variable have been summarized using descriptive statistics, means, and standard deviations. The data for each measure were treated individually. However, as more than one surface was evaluated for each implant restoration, values were averaged when appropriate based on the statistical analysis.

All information collected was analyzed in the following ways. First, a paired *t*-test was done to determine if there were significant differences in the change in bone level (loss or gain) related to arch position, length of implants, etc. A paired *t*-test was also computed for probing depth and attached gingival width to determine differences between the treatment conditions. A Wilcoxon *t*-test (nonparametric) was computed for the bleeding index and PI variables due to the nature of the measurement scale.

## RESULTS

This study provides data for 5 years. The patient population comprised 8 males and 12 females. The patients' ages at time of implant placement ranged from 29 to 76 years. The average of the patients was 45.9 years. Four of the implants placed were 16 mm in length; the remaining patients received 13-mm implants.

All insertion torque values were greater than or equal to 35 Ncm. Nineteen of 20 implants osseointegrated, were clinically immobile, asymptomatic, and deemed successful at 21 months. The failed implant was lost within 2 months of implant placement, presenting with pain and mobility. The remaining implants had elicited no infection/pain, radiolucencies, or mobility.

At the 5-year recall, one patient had died, three patients could not be contacted, and five patients were noncompliant (did not return for the 5-year recall appointment). All clinical and radiographic data evaluated at the 5-year recall are based on the 10 patients who returned to the clinic for examination (Figures 1–3).



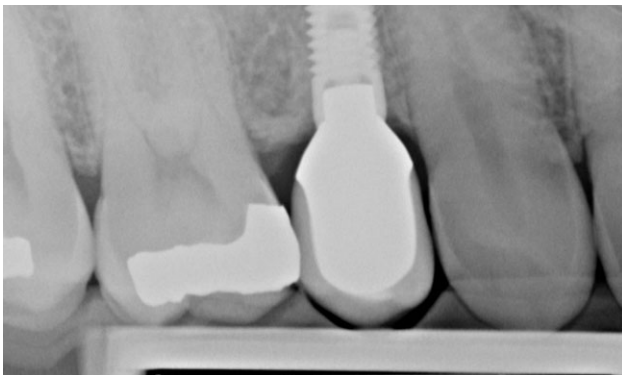


**Figure 1** Facial (a), lingual (b), occlusal (c) views of the implant-supported crown at 5-year recall.

Survival data, however, are based on telephone interviews of those patients from whom the researchers were able to elicit that the implants and restoration were in function as well as those the researchers were able to clinically observe. The combined total of implants (observed or confirmed by telephone) in function was 15.

The means for all clinical and radiographic data are based on the number of patients who were compliant for that recall interval (were present for their recall

appointment) within the timeline. If a patient was non-compliant by missing a recall appointment but returned for the subsequent appointment, the patient data were included for the interval in the timeline in which they were present. The difference between the number of subject observations at the 1-year and 21-month recall clinical and radiographic evaluations is due to patients declining the radiographic examination.



**Figure 2** Periapical radiograph of the implant at 5-year recall.



**Figure 3** Occlusal view of the implant after the crown was removed for soft tissue measurements at 5-year recall.

**TABLE 2 Comparison of Clinical Variables Evaluated Over Time**

Time	Mobility			WHI		
	<i>n</i>	Mean $\pm$ SD*	Mean Rank**	<i>n</i>	Mean $\pm$ SD*	Mean Rank**
Surgery	20	0 $\pm$ 0	31	20	0 $\pm$ 0	29
1 year	17	0 $\pm$ 0	31	17	0.12 $\pm$ 0.33	32
21 months	14	0 $\pm$ 0	31	14	0.07 $\pm$ 0.27	31
5 years	10	0 $\pm$ 0	31	10	0.10 $\pm$ 0.32	32

Time	MGI			PI		
	<i>n</i>	Mean $\pm$ SD*	Mean Rank**	<i>n</i>	Mean $\pm$ SD*	Mean Rank**
Surgery	20	0 $\pm$ 0	28	20	0 $\pm$ 0	26
1 year	17	0.24 $\pm$ 0.44	35	17	0.35 $\pm$ 0.70	33
21 months	14	0.14 $\pm$ 0.36	32	14	0.14 $\pm$ 0.36	30
5 years	10	0.10 $\pm$ 0.32	31	10	0.50 $\pm$ 0.53	40

Clinical variables between surgery, 1 year, 21 months, and 5 years were examined using analysis of variance\* and Kruskal-Wallis test\*\*. MGI = Modified Gingival Index; PI = Plaque Index; WHI = Wound Healing Index.

Table 2 represents the mean data of the clinical variables over time from the time intervals of baseline – 5 years: mobility, WHI, MGI, and PI. Clinical variables between surgery (baseline) and 1 year, 21 months, and 5 years were examined using analysis of variance (ANOVA) and Kruskal-Wallis test. The statistically significant level was set at  $p \leq .05$ . Results showed no statistically significant difference in the clinical variables between baseline and 1 year, baseline and 21 months, and baseline and 5 years.

Table 3 presents the clinical data regarding gingival tissue height at baseline, 1 year, 21 months, and 5 years. The variables were examined using ANOVA and Kruskal-Wallis test. The statistically significant level was set at  $p \leq .05$ . The mean clinical variables of probing gingival tissue height revealed no statistically significant difference at 1 year from baseline or at 21 months and at 5 years from baseline.

The difference in changes in bone level at 1 year between the mesial and distal surfaces of the implants was examined using the unpaired *t*-test and paired *t*-test (Table 4). The statistically significant level was set at  $p < .05$ . The one year recall radiographic evaluation is representative of 17 patients while the 21 month data represents 14 patients, and the 5-year represents 10 patients. The results showed no statistically significant difference between bone change on the mesial or distal surface of the implant at 1 year, 21 months, or 5 years.

Using the ANOVA (see Table 5), the difference in changes in bone level between 1 year, 21 months, and 5

years was examined. Fisher's protected least significant difference multiple comparison test of the means was applied when the *F*-test in ANOVA was significant. The statistical level was set at  $p < .05$  for all tests. Results showed no statistically significant difference for bone loss for mesial and distal surfaces between 1 year, 21 months, and 5 years.

## DISCUSSION

The study evaluated the midterm success of single implants immediately restored with acrylic resin crowns adjusted to avoid occlusal contacts. Careful and meticulous restoration and clinical evaluation provided important information regarding this beneficial dental restorative approach.

Although the failed implant had an insertion torque greater than 35 Ncm, it failed prior to the 3-month recall appointment. The implant replaced a maxillary left second premolar. Upon inspection of the implant and provisional crown after removal of the implant, it was noted that the crown-to-implant ratio was 1:1. It was hypothesized by the investigators that the biomechanics of 1:1 crown to root during functional activities such as eating may have played a role in the loss of the implant at the early stages of bone healing. However, the results of previous studies investigating the influence of the crown/implant (c/i) ratio on the outcome of implant treatment are heterogeneous. Some authors reported a positive correlation between an increased c/i ratio and a higher risk for

**TABLE 3 Clinical Variable of Probing Gingival Tissue Height at 1 Year, 21 Months, and 5 Years**

Probing	Time	n	Mean $\pm$ SD*		Mean Rank**
			Actual	Relative	
MF	Baseline	19	3.32 $\pm$ 1.11	0	25
	1 year	17	3.47 $\pm$ 1.18	0.18 $\pm$ 1.33	27
	21 months	14	4.14 $\pm$ 1.18	1.00 $\pm$ 1.11	36
	5 years	10	4.55 $\pm$ 1.54	0.85 $\pm$ 2.06	39
ML	Baseline	19	3.58 $\pm$ 1.26	0	27
	1 year	17	3.47 $\pm$ 1.23	-0.06 $\pm$ 1.30	25
	21 months	14	4.29 $\pm$ 1.07	0.71 $\pm$ 1.38	37
	5 years	10	4.55 $\pm$ 1.50	0.55 $\pm$ 1.98	37
F	Baseline	19	2.63 $\pm$ 1.30	0	29
	1 year	17	2.52 $\pm$ 1.34	-0.03 $\pm$ 0.72	29
	21 months	14	2.93 $\pm$ 0.92	0.14 $\pm$ 1.10	33
	5 years	10	2.80 $\pm$ 0.75	-0.20 $\pm$ 0.95	31
L	Baseline	19	2.84 $\pm$ 1.46	0	27
	1 year	17	3.06 $\pm$ 1.56	0.18 $\pm$ 0.53	30
	21 months	14	3.32 $\pm$ 1.23	0.32 $\pm$ 0.62	34
	5 years	10	3.45 $\pm$ 1.46	0.15 $\pm$ 1.94	34
DF	Baseline	19	3.84 $\pm$ 1.39	0	31
	1 year	17	3.71 $\pm$ 1.36	-0.12 $\pm$ 0.78	30
	21 months	14	4.07 $\pm$ 0.92	0.24 $\pm$ 1.42	34
	5 years	10	3.55 $\pm$ 1.21	-0.55 $\pm$ 1.92	26
DL	Baseline	19	3.79 $\pm$ 1.58	0	29
	1 year	17	3.53 $\pm$ 1.46	-0.24 $\pm$ 0.65	26
	21 months	14	4.29 $\pm$ 0.99	0.29 $\pm$ 1.38	35
	5 years	10	4.41 $\pm$ 1.38	0.21 $\pm$ 1.68	35

Clinical probing between baseline, 1 year, 21 months, and 5 years were examined using analysis of variance\* and Kruskal-Wallis test\*\*.

DF = Distofacial, DL = Distolingual, F = Facial, L = Lingual, MF = Mesiofacial, ML = Mesiolingual.

peri-implant marginal bone loss<sup>32</sup>; others failed to find such a correlation.<sup>33,34</sup>

Investigators examined the subjects' radiographs for normal healing and found no radiographic evi-

dence of intraosseous abnormalities. Additionally, the height of the crestal bone, relative to the collar of the implant, was measured. Some concerns about the radiographs to determine marginal bone loss have

**TABLE 4 Mean Change in Marginal Bone Levels over Time in Millimeters**

	n	Mean $\pm$ SD	Mode	Median	p
(a) Changes in bone levels for 1 year (in mm)					
Mesial	17	-0.53 $\pm$ 0.53	0	-0.4	.877 (unpaired <i>t</i> -test)
Distal	17	-0.50 $\pm$ 0.53	-0.53	-0.3	.803 (paired <i>t</i> -test)
(b) Changes in bone levels for 21 months (in mm)					
Mesial	14	-0.56 $\pm$ 0.49	-0.55	-0.55	.76 (unpaired <i>t</i> -test)
Distal	14	-0.50 $\pm$ 0.54	-0.36	-0.44	.63 (paired <i>t</i> -test)
(c) Changes in bone levels for 5 years (in mm)					
Mesial	10	-0.70 $\pm$ 0.26	-0.71	-0.71	.55 (unpaired <i>t</i> -test)
Distal	10	-0.78 $\pm$ 0.31	-0.55	-0.71	.42 (paired <i>t</i> -test)



**TABLE 5 Mean Changes in Bone Levels over 5 Years (in Millimeters)**

Time	Mesial			Distal		
	<i>n</i>	Mean $\pm$ SD	<i>p</i>	<i>n</i>	Mean $\pm$ SD	<i>p</i>
1 Year	17	-0.53 $\pm$ 0.53	.63	17	-0.50 $\pm$ 0.53	.30
21 months	14	-0.56 $\pm$ 0.49		14	-0.50 $\pm$ 0.54	
5 Years	10	-0.70 $\pm$ 0.26		10	-0.78 $\pm$ 0.31	

been raised by other studies.<sup>35,36</sup> According to Benn,<sup>35</sup> the achievement of valid measurements of bone loss less than 0.2 mm around osseointegrated implants has proven to be difficult, even with the use of optimum techniques. Currently, there is no “gold standard” for standardizing and measuring bone loss around implants using radiographic film images. The method that was documented by Borg and colleagues<sup>36</sup> to provide the most precision using film images is to view the radiographs with a magnifying lens ( $\times 7$ ) equipped with a measuring scale divided in 0.1-mm increments. The main problem in achieving validity for comparison of multiple radiographs is in producing a constant relationship among the x-ray beam, implant, and film position. Repositionable film holders have been created in an attempt to standardize irradiation geometry. The long-cone paralleling technique uses a device to hold the film perpendicular to the central x-ray beam.<sup>37,38</sup> There is currently a lack of standardization and readily available methods to quantify bone loss using radiographic film.<sup>38</sup>

The survival rate of the implants from this study after 21 months was 95%. For the 5-year survival rate, the patient who died was excluded from the data set. If the patients who could not be contacted are considered to be failures, the survival rate is 79%; however, if those patients are eliminated as data, then the survival rate is 94% after 5 years, which is similar to the results presented in earlier studies.<sup>5-7</sup> Wolfinger and colleagues placed two hundred fifty implants in one hundred twenty-five molar sites in one hundred five patients. All implants were submerged. They did not use any immediate loading protocols using provisional crowns. Five of the two hundred fifty implants failed, resulting in a cumulative survival rate (CSR) of 98.0%. They followed two hundred fifty implants for 3 years, one hundred three implants for 7 years, and 17 implants for 10 years.<sup>5</sup> Kan and colleagues<sup>6</sup> evaluated 35 patients clinically and radiographically at presurgical examination, immedi-

ately after immediate implant placement and provisionalization, 1 year after implant surgery, and the latest follow-up appointment. They reported a survival rate of 100% after a mean follow-up time of 4 years (range, 2–8.2 years). At the latest follow-up appointment, the mean mesial and distal marginal bone losses were 0.72 and 0.62 mm. Koo and colleagues<sup>7</sup> aimed to evaluate the 1- to 5-year CSR for single-tooth implants placed in the second molar region and the effects of associated factors. Four hundred eighty-nine patients (two hundred ninety-eight males and one hundred ninety-one females) were treated with single-tooth implants in the second molar region (two hundred twenty-seven maxillary implants and two hundred ninety-four mandibular implants; total: five hundred twenty-one implants). Fifteen of the five hundred twenty-one implants failed between placement and the follow-ups. The 1- to 5-year CSR was 95.1%. There were no statistically significant differences in CSRs between implants placed in maxillae and mandibles (96.3% vs 94.9%), one- and two-stage implants (95.6% vs 94.7%), short and long implants (100% vs 95.1%), and standard- and wide-diameter implants (93.8% vs 96.8%). The authors concluded that the use of single-tooth implants in the second molar region was a reliable treatment modality.

The differences in mean bone loss on the mesial and distal surfaces of the implant were compared at the 1-year, 21-month, and 5-year time interval. Results showed no statistically significant difference between changes in bone levels on the mesial or distal surface of the implant at 1 year, 21 months, or 5 years. The study by Kan and colleagues<sup>6</sup> did not show any statistically significant differences between marginal bone losses on the mesial or distal surface of the implant.

The differences in bone levels were then compared across time intervals using an unpaired *t*-test. The results showed no statistically significant difference in bone levels at the 1-year, 21-month, or 5-year time interval. The statistically significant level was set at  $p \leq .05$ .

This study evaluated placing a provisional crown immediately after implant placement in mature healed bone. The number of subjects returning for the 5-year recall illustrates an important problem associated with long-term clinical studies. Patients are often lost to a study due to moving out of the area, lack of interest to return for further follow-up appointments, illness, and death. The dropout rate fluctuates in the earlier studies. The dropout rates were 34.8 and 54.7% after 5 years in studies by Wolfinger and colleagues<sup>5</sup> and Koo and colleagues,<sup>7</sup> respectively. The dropout rate for this study had been anticipated to be 20% with a dropout rate of 35% still providing a sufficient sample size to determine clinically significant differences in the proposed experimental variables based on a power analysis. Based on the power analysis, an  $n$  of 13 would be sufficient. All the 1-year and 21-month data meet this benchmark. For the 5-year follow-up period, only the 5-year survival data met the benchmark, while the clinical and radiographic data are based on 50% of the original sample size. Although the 5-year sample size is small, it must be emphasized that there was no statistically significant difference between it and 1 year and 21 months which were of sufficient size. Further long-term studies with larger numbers of patients to compensate for larger dropout rates due to the longer length of the study may be needed. Additionally, future areas of research related to nonoccluding immediate provisionalization of single dental implants that should be investigated are the immediate provisionalization of single dental implants in augmented bone. An evidenced based timeline needs to be developed with regard to loading of dental implants in bone graft materials.

## CONCLUSION

Within the limitations of this study, immediate provisionalization of single dental implants compared favorably with the historical delayed healing protocols. Immediate nonoccluding provisionalization of single dental implants is a viable treatment option.

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