IMMEDIATE LOADING OF SINGLE-TOOTH RESTORATIONS: ONE-YEAR PROSPECTIVE RESULTS

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Immediate loading of splinted implant restorations is a growing trend, but limited clinical documentation hampers evidence-based treatment planning for single-tooth applications. This study prospectively evaluated the clinical efficacy of placing implant-supported, single-tooth restorations into immediate, full-occlusal loading. Sixty consecutive patients (intent-to-treat group) with 1 missing tooth between 2 intact teeth were treated with a total of 69 implants. At placement, final impressions were made and implants were provisionalized with nonoccluding prostheses. Definitive prostheses were delivered 2 weeks later. A claim of noninferiority was made with a 95% confidence interval (Mann-Whitney *U* test) if the success rates between the experimental group and a 97% historical control was >7%. Standardized radiographs taken at placement and bimonthly intervals were analyzed for crestal bone changes at a type I (alpha) error level of .05; significance levels were not adjusted for multiplicity (Fisher exact tests and Student *t* tests). Sixteen patients (18 implants) were withdrawn for protocol deviations. The resulting treated-per-protocol group consisted of 44 subjects with 51 implants. Cumulative implant success rates were 98.55% (n = 68/69) for the intent-to-treat group and 98.04% (n = 50/51) for the treated-per-protocol group. There were no significant adverse events or statistically significant differences between the experimental and historical control groups. At 12 months mean crestal bone loss was 1.05 mm, and ranged from 0.38 to 1.5 mm (77%) and 1.6 to 2.69 mm (23%). Immediate full-occlusal loading of single-tooth restorations was safely performed in selected subjects when good primary implant stability and an appropriate occlusal load were achieved.

Key Words: immediate loading, single tooth, implant

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Introduction

The importance of utilizing reliable scientific data to support clinical decisions is well established in implant dentistry.[1,2] Rapid changes in dental implant materials, technologies and procedures, however, have frequently outpaced the ability of the research community to provide objective scientific data to support such evidence-based decision-making. In recent years, patient demands for immediacy and the desire to eliminate the compromised esthetics, function, discomfort, and inconvenience associated with traditional 2-stage implant procedures have fostered growing clinical interest in early and immediate implant loading. Research on the immediate, full-occlusal loading of dental implants has been limited primarily to splinted restorations.[3–5] In a meta-analysis of 13 prospective clinical studies involving 1266 implants, Ioannidou and Doufexi[6] reported that implant failure occurred slightly less often with early loading and slightly more often with immediate loading compared with conventional 2-stage implant placement, but concluded that the differences were not statistically significant.

Implant-supported, single-tooth restorations subjected to conventional delayed loading have exhibited excellent results in the limited number of studies that report long-term data.[7–11] Their ability to function freestanding preserves intact adjacent teeth,[9] may offer an improved cost/effectiveness ratio compared with conventional, fixed partial dentures,[12] and can provide better long-term predictability than splinting to compromised dentition.[6] Single-tooth restorations may thus represent an optimal parameter of care for selected patients with single missing teeth.[13]

Available data on immediate loading of single-tooth restorations tend to be short-term with occlusal contact that ranges from unspecified[14,15] or non-occluding[16,17] to lightly[18] or fully occluding.[19–21] High implant success rates have been reported in the majority of these studies.[14–28] Several studies[21–23] conducted in animal models observed comparable clinical success rates regardless of whether the single-tooth restorations were subjected to immediate, early, or delayed loading. At the histomorphometric level, however, immediately loaded implants with machined surfaces[22] achieved less bone-to-implant contact than similar implants subjected to delayed loading, but this difference was not observed in studies that utilized implants with modified surface textures.[21,23]

In the human model, Cannizzaro and Leone[24] treated 2 demographically similar groups of 14 patients each with single-tooth restorations. Implants subjected to immediate, full-occlusal loading in the experimental group achieved 100% success while implants in the delayed loading control group achieved 92.9% success after 2 years of clinical function.[24] Several other human studies[20,25–27] have reported comparable results with immediately loaded and fully occluding single-tooth restorations on dental implants. In contrast, implant-supported, single-tooth restorations placed into immediate, full-occlusal loading by Glauser et al[20] achieved 78.5% success after 1 year of function, but the majority of implants were placed in low-density bone.

Ormianer and Palti[28] conducted a long-term (mean follow-up = 67.5 months; range = 1–94 months), prospective clinical study that placed and immediately restored 100 tapered, multi-threaded implants (Tapered Screw-Vent MTX, Zimmer Dental Inc, Carlsbad, Calif) with fully occluding single-tooth restorations in patients.[28] After 5 years of clinical loading, implant success was 99% with no measurable crestal bone loss utilizing standardized techniques.[28] The study reported that the tapered implant design was not more prone to crestal bone loss or apical punching stresses than nontapered implant designs.[28]

Marginal bone stability around an immediately loaded, freestanding implant is an important area of clinical interest, but seldom adequately reported in the dental literature. This may be partially due to the fact that crestal bone loss can be caused by many different factors independent of implant design, such as surgical trauma,[29] peri-implantitis,[29] occlusal overloading,[29] and inadequate residual facial plate thickness.[30] Several implant manufacturers have introduced new design changes to mitigate crestal bone loss, but other researchers have clinically challenged their efficacy, such as the addition of cervical microthreads on implants[31] and the necessity of excluding the implant-abutment microgap from the biologic width.[32] Further research is needed, however, before adequate data are available to support evidence-based treatment planning.

The purpose of this study was to document prospective clinical data on the immediate, full-occlusal loading of implant-supported, single tooth restorations in human subjects. Study hypotheses were that the (1) success of implants and (2) secondary peri-implant marginal bone loss would be clinically equivalent between implants subjected to immediate, full-occlusal loading as compared with implants conventionally restored with a delayed loading protocol (historical controls); the null hypotheses were that differences in success rates and marginal bone stability would exist between the study implants and the historical controls.

TABLE 1

Patient selection criteria

Inclusion Criteria
Missing at least 1 single tooth that is between 2 teeth
Adequate vertical bone volume to accommodate an implant 3.7 mm × 10 mm or larger
Adequate bone width to preserve at least 1.0 mm of buccal and lingual plate thickness after osteotomy preparation
Skeletally mature and between 18 and 80 years of age upon signing the informed consent form
Premenopausal, not pregnant, or likely to become pregnant during the course of the study
Able and willing to provide signed informed consent
Willingness to participate for the duration of the study
Exclusion Criteria
History of alcoholism, substance abuse, or mental instability that would hinder study participation
Myocardial infarction within the past 12 months
Uncontrolled or unresolved disease, such as uncontrolled diabetes, HIV disease, or periodontitis
Current use of medication known to cause gingival enlargement, such as cyclosporine A, nifedipine, or phenytoin
Evidence of severe patient parafunctional habits, such as clenching and grinding
History of localized irradiation treatments in or near the proposed implant site
Pregnancy or likelihood of pregnancy during the study
Proposed implant site grafted in nonresorbable material or grafted within 1 year with resorbable material
Tooth extraction from proposed implant site within the past 6 months
Heavy smoker (10 or more cigarettes per day)
Low-density bone (type IV[33])

MATERIALS AND METHODS

In this clinical study, subjects presented with 1 missing tooth between 2 adjacent healthy teeth. Dental implants were placed into the edentulous locations, impressions were made for provisional and definitive restorations, and the implant was then immediately provisionalized with a nonoccluding prosthesis. Two weeks later the implant was definitively restored with a fully occluding ceramometal restoration. Clinical and radiographic data were collected at 3-, 6-, and 12-month follow-up appointments. This clinical study was approved by the Institutional Review Boards of the University of Pittsburgh and University of Washington, and was conducted under the ethical and scientific Good Clinical Practice standards of the International Conference on Harmonization.

Patients

Study candidates were consecutive patients who presented in the Center for Maxillofacial Prosthetic Rehabilitation, University of Pittsburgh, and the Department of Periodontology, University of Washington, with a single missing tooth between 2 remaining teeth and who met the study criteria (Table 1). Preliminary screening included an interview and review of the patient's medical and dental histories. Study requirements and alternative treatment options were discussed with each patient. A total of 73 patients provided signed informed consent and were admitted into the study. A comprehensive diagnostic assessment was performed to thoroughly evaluate each candidate. This included complete oral and radiographic evaluations and fabrication of mounted diagnostic casts. Surgical templates to guide placement of the implants relative to the planned restorations were created from prosthetic wax-ups of the participants. Presurgical intraoral digital images (Nikon D-100 digital camera with a 100-mm macro lens, Nikon Photo Products Inc, Tokyo, Japan) or photographs (Fugichrome Sensica 100 ASA color film, Fuji Photo Film Company Ltd, Tokyo, Japan) were made of the maxillary and mandibular ridges and dentition, and pre- and postoperative instructions were provided orally and in writing to each patient.

Medication regimen

Administration of antibiotics is a parameter of care for implant procedures that is usually left to the clinician's discretion according to the patient's needs and immune status.[34–37] In the present study, each patient was prescribed amoxicillin (Sandoz, a Novartis company, Holzkirchen, Germany; 2 g administered orally 1 hour prior to the surgery followed by 2 additional 500-mg doses that day, and then 500-mg doses 3 times daily for 5 days). Alternatively, clindamycin (Sandoz; 600 mg administered orally 1 hour prior to the surgery followed by 150 mg 3 times that day, and then once daily for 4 days) or azithromycin (Sandoz; 500 mg administered orally 1 hour prior to the surgery, followed by 250 mg once per day for 4 days starting the day after surgery) was prescribed for patients sensitive to amoxicillin (Sandoz). On the day of surgery, each patient also received 800 mg of ibuprofen. Postoperative instructions included rinsing 3 times daily for 2 weeks with 0.12% chlorhexidine gluconate (Peridex, Procter and Gamble, Cincinnati, Ohio). Analgesics were prescribed to control pain and discomfort.

Study device

A self-tapping, tapered implant with a microtextured surface, internal hexagon connection, and triple-lead threads (Tapered Screw-Vent MTX, Zimmer Dental Inc, Carlsbad, Calif) was used in this study. This implant was selected as the study device based on its documented ability to achieve initial stability in various bone densities[38] and to maintain marginal bone integrity[28] under a variety of clinical conditions. Implant diameters (3.7 mm, 4.7 mm, 6.0 mm) and

lengths (10 mm, 13 mm, 16 mm) were selected according to patient need.

Surgical and prosthodontic procedures

Patients were prepared for aseptic surgery and anesthetized according to clinician preference. Mid-crestal and vertical releasing incisions were made in the edentulous areas and full-thickness mucoperiosteal flaps were elevated to expose the underlying alveolar process. Following the manufacturer's protocol, implant osteotomies were prepared according to bone density by sequential cutting with internally irrigated drills, and the implants were placed with a self-tapping technique. To be included in the study, implants were required to achieve a minimum torque level of 30 Ncm during placement and to resist rotation when the same amount of torque was applied at abutment screw tightening.

Implants were placed according to manufacturer specifications. A standardized radiograph was then made utilizing an extension cone paralleling technique (XCP System, Dentsply Rinn, Elgin, Ill) to verify adequate implant placement and to serve as a baseline record of peri-implant marginal bone levels. Immediate impressions were made to fabricate provisional[39] and definitive[40] prostheses according to previously described techniques. The nonoccluding provisional prostheses were delivered and the soft tissues were sutured around them. After 7 to 14 days of soft tissue healing, patients returned for suture removal and delivery of fully occluding, ceramometal, single-tooth restorations. Final occlusal adjustments were made, if needed, hygiene procedures were reviewed, and patients were released until their first postrestoration monitoring appointments.

Postrestoration monitoring

At 3, 6, and 12 months after loading, patients were reappointed for follow-up to assess implant stability, oral hygiene, and peri-implant marginal bone levels. At these appointments, clinical application of manual pressure and percussion, and standardized radiographic assessments (XCP System) were made to rule out the presence of implant mobility or peri-implant radiolucency, and to document any changes in peri-implant marginal bone levels. The radiographs were labeled by the principal investigators (A.S., R.O.) at each clinical site and sent to an independent radiologist (P.N.) for analysis. As a precaution, over-the-counter pregnancy tests were administered to premenopausal women prior to taking radiographs, and patients were asked to complete a satisfaction and concern questionnaire. Hygiene prophylaxis was also performed at annual recall visits.

Statistical analyses

A review of the literature[7–11] on dental implants restored with single-tooth restorations after a delayed loading period indicated a 3-year benchmark success rate of 97%, which served as the historical control for implant success in this study. An experimental implant would be considered "successful" if it met the study criteria of being functional, clinically stable when tested manually, and free of peri-implant radiolucency or irreversible pain/infection. A claim of noninferiority was made if the difference in success rates between the experimental group and the literary control (experimental group success rate −97% historical success rate) was >7%. In other words, since the historical control was 97%, the null hypothesis would be rejected if the success rate of the experimental group was >90%. The Mann-Whitney *U* test was used because of the dichotomous pass/fail standard. Study results were analyzed in 2 separate groups: the intent-to-treat group included all cases with surviving implants without regard to protocol adherence, and the treated-per-protocol group was limited to cases that were fully compliant with the protocol.

Crestal bone analyses were performed using SAS for the personal computer (version 8.02, SAS Institute Inc, Cary, NC) on the Windows XP operating system, and were performed at a type I (alpha) error level of .05; significance levels were not adjusted for multiplicity. A standard bone loss value of 1.5 mm after 12 months of function served as the historical control.[44] Postoperative crestal bone loss was summarized at the radiographic level, implant level (maximum mesial or distal measurement), and at the patient level. Independent summaries were made at postoperative months 3, 6, and 12. Analysis was restricted to 102 independent radiographic assessments (mesial and distal) corresponding to 51 implants (both mesial and distal assessments made from each radiograph per implant) placed in 43 study subjects (there were 32 radiographic assessments made on 16 implants placed in 8 subjects).

Crestal bone loss measurements were derived for each postoperative assessment at 3, 6, and 12 months as the difference between the assessment value and the corresponding assessment taken at restoration as change measures. Crestal bone loss was summarized (1) as proportions of radiographs, implants, or patients with crestal bone loss of greater than 1.5 mm, and (2) in continuous variable summaries (N, mean, median, standard deviation, minimum, and maximum) repre-

TABLE 2

Enrollment summary

	Subjects	Implants
Enrolled	73	N/A
Withdrawn before implant placement	8*	N/A
Received implant(s)	65	76
Withdrawn at implant placement	5†	7
Intent-to-treat group	60	69
Withdrawn for protocol deviations	16‡	18
Treated-per-protocol group	44	51
Failed at delivery of the definitive prosthesis	1	1
Completed the study per protocol	43	50

*Inadequate bone volume (n = 3); personal reasons (n = 3); medical conditions (n = 2).

†Bone graft needed (n = 1); implant not stable at 30 Ncm of torque (n = 4).

‡Definitive prosthesis delivered later than 2 weeks; inadequate residual bone after implant placement; used straight instead of tapered implant.

senting actual crestal bone loss reported at the radiograph, implant, and patient level. Mesial and distal assessments were compared within implant and separately within patient in unpaired subgroup analyses. Comparisons were performed to ensure the lack of dependency in observed bone loss to a specific radiographic assessment of similar bone loss for both mesial and distal assessments. Additional subgroup analyses were performed through stratification on the number of implants as comparisons of bone loss for single (N = 1) and multiple (N = 2) implants.

Unpaired comparisons of the proportions of implants that had crestal bone loss of greater than 1.5 mm between mesial and distal assessments were performed at each time of postoperative follow-up with Fisher exact tests using the FREQ procedure in SAS. Unpaired comparisons of average crestal bone loss were performed at each time of postoperative assessment with Student *t* tests using the TTEST procedure in SAS. The assumption of equal sample variances required by Student *t* tests was assessed with both (folded) F tests using the SAS TTEST procedure, as well as with Bartlett test using the SAS GLM procedure. Continuous variable comparisons were also performed nonparametrically with Wilcoxon rank sum test using the SAS NPAR1WAY procedure. All analyses were performed at a type I (alpha) error level of .05, and significance levels were not adjusted for multiplicity.

RESULTS

Seventy-three subjects provided written consent and were recruited according to the study protocol (Table 2). Eight of these subjects were withdrawn from the study before implant placement: 3 for inadequate bone, 3 for personal reasons, and 2 for previously undetected medical conditions that precluded implant placement. The remaining 65 subjects were treated with 76 implants: 54 subjects received 1 implant each and 11 subjects received 2 nonadjacent implants each. Five of these subjects with 7 implants were withdrawn from the study at implant placement: 1 subject (1 implant) required bone grafting and 4 subjects (6 implants) failed to achieve primary implant stability less than 30 Ncm of torque applied at implant placement.

Results are based on the remaining 60 subjects who met all inclusion/exclusion criteria and were treated with 69 implants (intent-to-treat group; Tables 2 and 3). Sixteen of these patients (18 implants) were subsequently withdrawn from the study for protocol deviations: (1) final restoration not performed within the required 2-week timeframe; (2) insufficient bone remaining after implant placement; and (3) implant placement inadvertently performed using a straight rather than a tapered implant design from the same manufacturer, which was not the designated study device. The remaining treated-per-protocol group thus consisted of 44 subjects with 51 implants. At delivery of the definitive prosthesis, 1 implant in this group unscrewed from the bone when the provisional prosthesis was removed. The implant was withdrawn from the study and listed as a failure. A total of 43 subjects with 50 implants completed the study according to protocol.

Cumulative implant success rates were 98.55% (n = 68/69) for the intent-to-treat group and 98.04% (n = 50/51) for the treated-per-protocol group. A series of supplemental Fisher exact tests were computed to assess implant success rates when bone density types or implant location categories were combined. Implant success rate data within each category are shown in Tables 3 and 4. None of the results achieved statistical significance; however, results should be considered exploratory since such collapsing can potentially increase the strength of the statistical tests by reducing the number of subtypes in a single comparison.

The 44 documented protocol deviations in 33 subjects are summarized in Table 5. Of these, 21 were failure to follow the antibiotic regimen specified in the protocol, or failure to perform follow-up within the time intervals mandated in the protocol, neither of which were grounds for withdrawal from the study. However, there were protocol deviations which involved withdrawing 16 subjects (18 implants) from the study. These deviations included: (1) final restora-

TABLE 3

Intent-to-treat group

Patient Distributions	Sex		Age (years)	
	Male, No. (%)	Female, No. (%)	Mean	Range
	24 (40.0)	36 (60.0)	41	21–69
	Dental History		Oral Hygiene During Study	
	Condition	No. (%)	Condition	No. (%)
	Clenching or bruxing	2 (3.3)	Excellent	26 (43.3)
	Jaw/facial pain	1 (1.7)	Good	32 (53.3)
	Periodontitis	4 (6.7)	Fair	2 (3.3)

Implant Placement Data	Distribution by Jaw Location			
	Maxilla, No. (%)		Mandible, No. (%)	
	Anterior	Posterior	Anterior	Posterior
	12 (17.4)	16 (23.2)	0 (0.0)	41 (59.4)
	Distribution by Bone Density, No. (%)			
	Type 1	Type 2	Type 3	Type 4
	10 (14.5)	32 (46.4)	19 (27.5)	8 (11.6)

Implant Survival Data	Implant Survival by Bone Density and Implant Location			
Bone Density or Location	Survivors (No.)	Failures (No.)	Survival (%)	*P*
Types 1 and 2 combined	42	0	100.0	.391
Types 3 and 4 combined	26	1	96.3	
Type 1, 2, and 3 combined	61	0	100.0	.116
Type 4	7	1	87.5	
Posterior mandible	40	1	97.6	1.000
All other locations combined	28	0	100.0	

TABLE 4

Treated-per-protocol group

Implant Placement Data	Distribution by Jaw Location			
	Maxilla, No. (%)		Mandible, No. (%)	
	Anterior	Posterior	Anterior	Posterior
	7 (13.7)	11 (21.6)	0 (0)	33 (64.7)
	Distribution by Bone Density, No. (%)			
	Type 1	Type 2	Type 3	Type 4
	7 (13.7)	22 (43.1)	15 (29.4)	7 (13.7)

Implant Survival Data	Implant Survival by Bone Density and Implant Location			
Bone Density or Location	Survivors (No.)	Failures (No.)	Survival (%)	*P*
Types 1 and 2 combined	29	0	100.0	.431
Types 3 and 4 combined	21	1	95.5	
Type 1, 2, and 3 combined	44	0	100.0	.137
Type 4	6	1	85.7	
Posterior mandible	32	1	97.0	1.000
All other locations combined	18	0	100.0	

TABLE 5

Protocol deviations

Did Not Result in Withdrawal From the Study*			Resulted in Withdrawal From the Study		
Clinical Site No.	Time of Follow-Up	Antibiotic Use	Late Occlusal Loading†	Inadequate Residual Bone‡	Non-Study Implant Used
1	2	21	6	0	0
2	3	0	0	7	5
Total	5	21	6	7	5

*Treatment occurred outside the parameters specified in the protocol.
†Definitive prosthesis delivered more than 2 weeks post operative procedure.
‡Insufficient bone remaining after implant placement.

tion not performed within the required 2-week timeframe; (2) insufficient bone remaining after implant placement; and (3) implant placement inadvertently performed using an implant that was not the study device.

Thirty-two adverse events were documented in 26 subjects (Table 6). Of these, 7 occurred after the patient had previously been withdrawn from the study because of a protocol deviation and 15 did not have a direct relationship to the study device. No serious adverse events were reported, and none of the reported adverse events were considered to be different from the risks involved with a standard implant procedure. All implants and subjects that were withdrawn as a result of an adverse event are being followed for safety purposes, and none have resulted in implant failure.

Crestal bone loss is summarized in Tables 7 through 10. All crestal bone loss occurred during the first 3 months of loading, and then stabilized through the end of the first-year interval. In overall analyses, there were no statistically significant differences in proportions with crestal bone loss greater than 1.5 mm and in average crestal bone loss when mesial and distal assessments were compared at the radiograph level, at the implant level, and at the patient level; all *P* values were greater than .05. Similarly, there were no statistically significant differences in proportions with crestal bone loss greater than 1.5 mm and in average crestal bone loss when the number of study implants was compared at the radiograph, implant, or patient level; all *P* values were greater than .05. Finally, there were no statistically significant differences in proportions with crestal bone loss greater than 1.5 mm and in average crestal bone loss when quality of the baseline assessment (diffuse baseline compared with nondiffuse baseline) was compared at the radiograph level, at the implant level, and at the patient level; all *P* values were greater than .05. Results indicate that percentages were robust to the study population, and that a diffuse baseline appears to result in a greater prevalence of crestal bone loss beyond 1.5 mm at 1 year than any other level of stratification variable. The single exception was patient-level summaries, where both percent crestal bone loss greater than 1.5 mm and average crestal bone loss were elevated. We attribute this to the small number of patients included within the stratum (N = 8).

TABLE 6

Adverse events

Type of Adverse Event	Time of Adverse Event: Treatment Period*	Time of Adverse Event: Posttreatment Period‡
Implant rotated when torqued	8	0
Surgical complication	3	0
Implant failure	1	0
Medical complication	2	5
Porcelain fracture	0	6
Loose abutment	0	2
Non-study implant complication	0	3
Natural tooth complication	0	1
Bone trauma	0	1
Total	14	18

*Adverse event occurred from the time of implant placement to delivery of the definitive prosthesis.
†Adverse event occurred after delivery of the definitive prosthesis.

TABLE 7

Bone loss results: all radiographs, implant maxima, and patient maxima

Postoperative Assessment	All Patients (N = 43)	All Implants (N = 51)	All Radiographs (N = 102)
3 Month			
>1.5 mm	3 (7%)	3 (6%)	5 (5%)
≤1.5 mm	40 (93%)	48 (94%)	97 (95%)
Mean	0.71	0.66	0.48
Median	0.68	0.60	0.41
SD	0.50	0.49	0.52
(Min, Max)	(0, 1.93)	(−0.13, 1.93)	(−1.05, 1.93)
6 Month			
>1.5 mm	8 (19%)	8 (16%)	12 (12%)
≤1.5 mm	35 (81%)	43 (84%)	90 (88%)
Mean	0.90	0.83	0.67
Median	0.73	0.67	0.60
SD	0.62	0.60	0.53
(Min, Max)	(−0.20, 2.43)	(−0.20, 2.43)	(−1.48, 2.43)
1 Year			
>1.5 mm	10 (23%)	10 (20%)	15 (15%)
≤1.5 mm	33 (77%)	41 (80%)	87 (85%)
Mean	1.05	0.98	0.72
Median	0.92	0.83	0.63
SD	0.70	0.67	0.74
(Min, Max)	(−0.38, 2.69)	(−0.38, 2.69)	(−2.04, 2.69)

TABLE 8

Bone loss results: radiographs without a diffuse baseline

	Mesial	Distal	All
3 Month	(N = 39)	(N = 39)	(N = 78)
>1.5 mm	2 (5%)	1 (3%)	3 (4%)
≤1.5 mm	37 (95%)	38 (97%)	75 (96%)
			$P > .99$
Mean	0.4	0.52	0.46
Median	0.36	0.52	0.4
SD	0.47	0.46	0.47
(Min, Max)	(−0.36, 1.68)	(−0.26, 1.93)	(−0.36, 1.93)
			$P = .29$
6 Month	(N = 40)	(N = 40)	(N = 80)
>1.5 mm	6 (15%)	3 (8%)	9 (11%)
≤1.5 mm	34 (85%)	37 (93%)	71 (89%)
			$P = .48$
Mean	0.55	0.59	0.57
Median	0.45	0.53	0.5
SD	0.71	0.53	0.62
(Min, Max)	(−0.78, 2.09)	(−0.41, 1.89)	(−0.78, 2.09)
			$P = .78$
1 Year	(N = 40)	(N = 40)	(N = 40)
>1.5 mm	5 (13%)	5 (13%)	10 (13%)
≤1.5 mm	35 (88%)	35 (88%)	70 (88%)
			$P > .99$
Mean	0.65	0.72	0.69
Median	0.53	0.65	0.6
SD	0.77	0.59	0.68
(Min, Max)	(−0.71, 2.69)	(−0.61, 2.04)	(−0.71, 2.69)
			$P = .66$

TABLE 9

Bone loss results: single implant radiographs

	Mesial (N = 11)	Distal (N = 11)	All (N = 22)
3 Month			
>1.5 mm	1 (9%)	1 (9%)	2 (9%)
≤1.5 mm	10 (91%)	10 (91%)	20 (91%)
			$P > .99$
Mean	0.53	0.53	0.54
Median	0.41	0.41	0.44
SD	0.52	0.52	0.68
(Min, Max)	(0, 1.84)	(0, 1.84)	(−1.05, 1.89)
			$P = .96$
6 Month			
>1.5 mm	1 (9%)	2 (18%)	3 (14%)
≤1.5 mm	10 (91%)	9 (82%)	19 (86%)
			$P > .99$
Mean	0.71	0.69	0.7
Median	0.63	0.83	0.64
SD	0.61	1	0.81
(Min, Max)	(−0.10, 2.03)	(−1.48, 2.43)	(−1.48, 2.43)
			$P = .96$
1 Year			
>1.5 mm	2 (18%)	3 (27%)	5 (23%)
≤1.5 mm	9 (82%)	8 (73%)	17 (77%)
			$P > .99$
Mean	0.85	0.86	0.85
Median	0.69	1.17	0.86
SD	0.74	1.12	0.93
(Min, Max)	(−0.38, 2.25)	(−2.08, 1.96)	(−2.08, 2.25)
			$P = .97$

TABLE 10

Bone loss results: multiple implant radiographs

	Mesial (N = 39)	Distal (N = 39)	All (N = 78)
3 Month			
>1.5 mm	2 (5%)	1 (3%)	3 (4%)
≤1.5 mm	37 (95%)	38 (97%)	75 (96%)
			$P > .99$
Mean	0.4	0.52	0.46
Median	0.36	0.52	0.4
SD	0.47	0.46	0.47
(Min, Max)	(−0.36, 1.68)	(−0.26, 1.93)	(−0.36, 1.93)
			$P = .29$
6 Month			
>1.5 mm	6 (15%)	3 (8%)	9 (11%)
≤1.5 mm	34 (85%)	37 (93%)	71 (89%)
			$P = .48$
Mean	0.55	0.59	0.57
Median	0.45	0.53	0.5
SD	0.71	0.53	0.62
(Min, Max)	(−0.78, 2.09)	(−0.41, 1.89)	(−0.78, 2.09)
			$P = .78$
1 Year			
>1.5 mm	5 (13%)	5 (13%)	10 (13%)
≤1.5 mm	35 (88%)	35 (88%)	70 (88%)
			$P > .99$
Mean	0.65	0.72	0.69
Median	0.53	0.65	0.6
SD	0.77	0.59	0.68
(Min, Max)	(−0.71, 2.69)	(−0.61, 2.04)	(−0.71, 2.69)
			$P = .66$

At the assessment level (N = 102), crestal bone loss of greater than 1.5 mm was observed in 5% of the study assessments at the 3-month assessment, 12% at the 6-month assessment, and 15% at the 1-year assessment. The corresponding averages were 0.48 mm, 0.60 mm, and 0.72 mm. At the implant level (N = 51), crestal bone loss of greater than 1.5 mm was observed in 6% of the study assessments at the 3-month assessment, 16% at the 6-month assessment, and 20% at the 1-year assessment. The corresponding averages were 0.66 mm, 0.83 mm, and 0.98 mm. At the patient level (N = 43), crestal bone loss of greater than 1.5 mm was observed in 7% of the study assessments at the 3-month assessment, 19% at the 6-month assessment, and 23% at the 1-year assessment. The corresponding averages were 0.71 mm, 0.90 mm, and 1.05 mm.

Subject satisfaction and quality of life were measured posttreatment at all follow-up visits utilizing a patient self-assessment form. Most study subjects were very satisfied with the implant and the procedure (≥90% indicated an "excellent" rating); approximately 50% rated their appearance and mastication to be "greatly improved" after implant placement; and all subjects would have the procedure done again, and would recommend it to others. Results are summarized in Table 11.

TABLE 11

Patient satisfaction and quality of life assessment

		Percentage of Responses			
Implant Satisfaction	Category	Poor	Fair	Good	Excellent
	Overall treatment satisfaction	0.0	0.0	2.7	97.3
	Overall tooth satisfaction	0.0	0.0	8.3	91.7
	Comfort with tooth	0.0	0.0	10.8	89.2
	Stability of tooth	0.0	0.0	2.7	97.3
	Ability to speak	0.0	0.0	2.7	97.3
	Ability to bite and chew	0.0	2.7	8.1	89.2
		Percentage of Responses			
Performance and Appearance	Category	Became Worse	Stayed Same	Improved Slightly	Greatly Improved
	Smile appearance	0.0	28.3	24.5	47.2
	Speech	0.0	84.9	3.8	11.3
	Breath odor	1.9	77.4	9.4	11.3
	Ability to bite and chew	0.0	20.8	20.8	58.5
Overall Outcome	Outcome Questions	Percentage of "Yes" Responses			
	Does the new tooth hurt?	0.0			
	Is the new tooth tight and secure?	100.0			
	Is the bite correct?	98.1			
	Would you have this done again?	100.0			
	Would you recommend this to others?	100.0			

DISCUSSION

One-year interim results equaled or surpassed the outcome of the historical controls, which utilized the traditional 2-stage surgical protocol. All successful implants were placed in types 1, 2, and 3[33] bone (88.4%), while implants removed from the study for lack of primary stability were all placed in type 4[33] bone. The resulting high success rates underscore the importance of selecting patients with good bone quality as a prerequisite for immediate, full-occlusal loading of single-tooth restorations.

Although various criteria for implant success have been proposed over the past 3 decades, none has ever met with widespread acceptance or use in the industry, especially regarding crestal bone loss. For example, success criteria proposed by Albrektsson et al[42] only acknowledged crestal bone loss that occurred after the first year of loading, and stipulated that less than 0.2 mm of vertical bone loss per year was the standard. In contrast, Schwartz-Arad et al[43] analyzed published literature on peri-implant crestal bone loss and identified 4 different bone loss patterns after the first year of function: a low-rate marginal bone loss over the years (Albrektsson's[44] pattern); low-rate marginal bone loss in the first few years followed by a rapid loss of bone support; high-rate marginal bone loss in the first few years followed by almost no bone loss; and continuous high-rate of marginal bone loss leading to a complete loss of bone support. Schwartz-Arad et al[43] concluded that implant success protocols should be revised. Since bone healing is combined with the first year of function in the present study, traditional success criteria based on the delayed loading model do not apply. Nonetheless, mean crestal bone loss in the present study was less than 1 mm after 12 months of healing and loading, which was comparable to other historical studies of immediately loaded implants whether[28,44] or not[3–5,9,19] the same study device was used.

Although the number of deviations for not following the antibiotic regimen outlined in the protocol was high (n = 21), it did not lead to an increased number of adverse events related to infection. In fact, there have been no infections reported in the implant sites during the study to date. Upon further review, it was noted that the current protocol should have been revised early on to allow the investigators more freedom to use their discretion as to what antibiotic protocol would be most appropriate for each subject.

CONCLUSIONS

Immediate full-occlusal loading of single-tooth restorations was safely performed in selected subjects

when good primary implant stability and an appropriate occlusal load were achieved.

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