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CLINICAL SCIENCE

Prospective, 1-year observational study of double-threaded tapered body dental implants with immediate loading

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ABSTRACT

Statement of problem. Unlike conventional loading protocols, the immediate loading of single implants has not been fully investigated.

Purpose. The purpose of this study was to assess the prosthetic and esthetic periimplant mucosal outcomes of immediately restored dental implants during a 1-year follow-up.

Material and methods. Twenty participants meeting the established inclusion criteria received double-threaded, tapered body dental implants (SuperLine; Dentium). Implants were placed and stabilized at a minimum of 35 Ncm of torque and restored immediately after the surgery with interim restorations. These were replaced with definitive restorations 6 months after implant placement. Clinical measurements at each visit included resonance frequency analysis, the evaluation of the participants' oral health (gingival and plaque indices), and the esthetic outcome of the interim or definitive restoration.

Results. Implants placed in this clinical study had a 100% success rate. The oral health and esthetic outcomes were favorable for all participants.

Conclusions. Double-threaded, tapered body dental implants that were placed and immediately restored with fixed interim prostheses and with definitive prostheses after 6 months remained stable and functional after 1 year. (J Prosthet Dent 2015;114:46-51)

Immediate/direct dental implant loading is defined as attaching an interim or definitive prosthetic restoration to the implant within 24 hours of implant placement.[1-3] For many patients, immediate implant loading provides a distinct benefit. Long-term treatment that includes an interim removable prosthesis is unacceptable to many patients. Immediate implant loading has become popular because of shorter treatment time, reduced patient discomfort, less inconvenience and anxiety, increased patient acceptance, and improved function and esthetics.[4-8]

The original osseointegrated implant protocol required a healing time of 3 to 6 months before restoration.[1,9,10] Longer and uninterrupted healing time was considered to be essential to avoid a fibrous tissue encapsulation around the implants that might impede or prevent osseointegration.[1,11] Nevertheless, some clinicians immediately loaded implants and obtained encouraging results.[3,4,7] Recent clinical, radiographic, and histologic findings have confirmed that immediately loaded implants can heal with the presence of mineralized tissues at the interface and retain stability over time, at least in dense quality bone.[12-14]

Bone quality at the implant site is a significant factor in immediate-loading protocols. Type IV quality bone is usually described as poor bone for implants because it is soft and it is difficult to achieve early stability for an implant.[1] Jaffin and Berman[15] showed a high implant failure rate (35%) in Type IV bone. The absence of micromotion is the key issue in obtaining

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Clinical Implications

A single implant could be functional immediately after surgery without adversely affecting its stability for 12 months.

osseointegration and is even more important than the timing of implant loading. A final torque of 30 Ncm and an implant stability quotient greater than 60 is required to securely insert implants suitable for immediate loading.[1,7,11,16]

Primary implant stability is recognized as essential for osseointegration. The stability of an implant can be defined as its capacity to withstand loading forces in axial, lateral, and rotational directions.[1] Sennerby and Roos[17] confirmed that primary implant stability is determined by bone quality, bone quantity, implant design, and surgical technique. To evaluate implant stability, nondestructive intraoral testing methods such as resonance frequency analysis (RFA), the Periotest technique, and insertion torque measurements have been introduced.[18,19] While RFA and Periotest are advocated to evaluate implant stiffness, the insertion torque method assesses circumstances at the time of implant placement. The destructive methods of measuring implant stability, for instance pullout and pushout techniques, are commonly used only for in vitro applications. Factors such as bone density, maxillary versus mandibular bone, abutment length, and supracrestal implant length affect the RFA and Periotest measurements. High RFA and low Periotest values point toward successfully integrated implants. Low or decreasing RFA and high or increasing Periotest values may be signs of loss of osseointegration and/or marginal bone loss.[11,18] Periotest has been reported to have poor resolution, sensitivity, and susceptibility to operator variables.[20,21] In comparison with Periotest, RFA is a more sophisticated method with a simple measuring instrument (Osstell; Integration Diagnostics) that is now commercially available. This instrument uses the piezo effect, and the subsequent response to the applied forces is oscillation, which is amplified, analyzed, and displayed graphically and numerically in implant stability quotient (ISQ) units.[22-24] This value is dependent for the most part on the stiffness of the implant in the neighboring tissue and on the implant height above the crestal bone level.[25] However, the results of studies of implant stability conducted before 2003 were presented in hertz and are therefore not comparable with more recent studies on the same topic in which the results were presented in ISQ values.

The purpose of this study was to document the performance and safety characteristics of the double-threaded, tapered body dental implant system when used for interim restoration with occlusal loading and to evaluate the ability of these implants to be restored in full occlusion immediately after insertion. Therefore, the 2 hypotheses formed were that the survival rate of double-threaded, tapered body dental implants immediately restored with interim restorations would be 100% after 6 months of function and that the survival rate of double-threaded, tapered body dental implants subsequently restored with definitive restorations would be 100% after 1 year of function.

Table 1. Exclusion/inclusion criteria

Exclusion Criteria
Active infection or severe inflammation in areas intended for implant placement
Smoking more than 10 cigarettes/day
Uncontrolled diabetes or metabolic bone disease
History of therapeutic radiation to head and neck
In need of bone grafting at site of intended implant placement
Participants known to be pregnant
Parafunctional habits with evidence of severe bruxing or clenching
Lacking posterior support
Inclusion Criteria
Adults 18 years of age or older
Preexisting decision to use dental implants for treating existing partial edentulism in mandible or maxilla
Physically able to tolerate conventional surgical and restorative procedures
At least 1 mm of bone thickness around inserted implants

MATERIAL AND METHODS

Human subject approval for this study was obtained from the Health Sciences Institutional Review Board, University of Southern California, Los Angeles (HS-08-00258). All participants provided written informed consent before entering the study.

Twenty participants were enrolled in the study based on the criteria in Table 1. During the initial participant screening, interproximal bone levels were evaluated radiographically (Fig. 1), and the participant's oral health was evaluated by scoring gingival inflammation and dental plaque. The gingival index was ranked as follows: 0, normal gingiva; 1, mild inflammation, slight change in color, slight edema, no bleeding on probing; 2, moderate inflammation, redness, edema, glazing, bleeding on probing; 3, severe inflammation, marked redness and edema, ulcerations, tendency toward spontaneous bleeding.[26]

The criteria for plaque index were as follows: 0, no plaque in gingival area; 1, no plaque visible to the naked eye, but visible plaque on the point of the probe after removal of the probe across the surface at the entrance of the gingival crevice; 2, marginal area covered with a thin to moderately thick layer of plaque, deposit visible without magnification; 3, heavy accumulation of soft

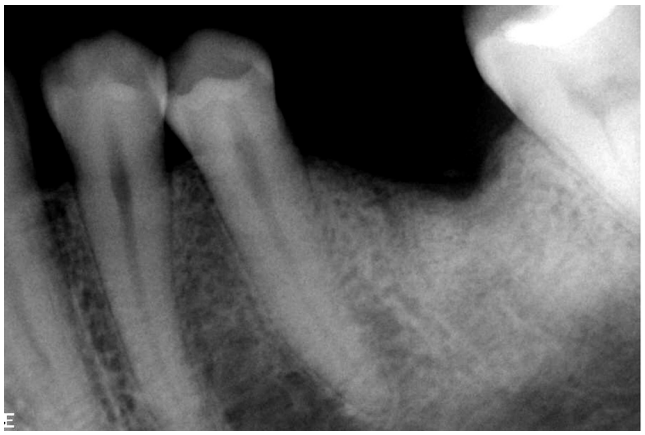

Figure 1. Preoperative radiographic evaluation.

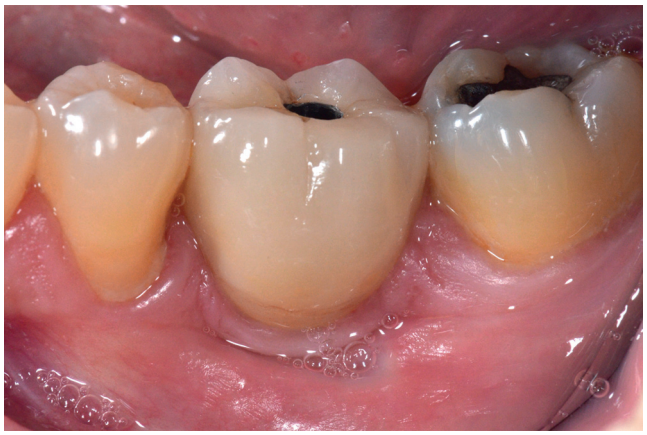

Figure 2. Definitive restoration.

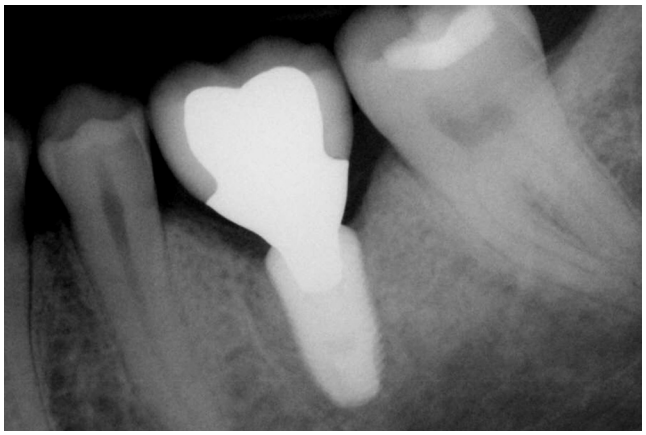

Figure 3. Radiographic evaluation after 6 months.

Table 2. Study protocol

Visit	1	2	3	4	5
	Screening	Surgery Day	3 mo	6 mo	12 mo
Data/history	X				
Implant surgery		X			
Insertion of interim restoration		X			
Radiography	Panoramic	Periapical	Periapical	Periapical	Periapical
Definitive restoration				X	
Clinical evaluation	X	X	X	X	X
Resonance frequency analysis test		X	X	X	X

matter, the thickness of which fills a niche produced by the gingival margin and tooth surface, and interdental area filled with soft debris.[27]

Each participant received 1 single implant. A total of 20 implants were placed and positioned as follows: 4 premolars and 3 anteriors in the maxilla; 1 premolar, 1 anterior, and 11 molars in the mandible.

Surgical guides were fabricated, and shades for the interim restorations were determined. One periodontist (H.N.) performed all of the surgical procedures. The surgical approach and techniques are described as follows: participants were premedicated with 2 g amoxicillin or 600 mg clindamycin 1 hour before the surgical procedure. Participants then rinsed for 1 minute with 1 ounce of 0.12% chlorhexidine gluconate solution and were anesthetized with 2% lidocaine with 1:100 000 concentration of epinephrine. Full-thickness buccal and lingual flaps were reflected. Implants were inserted to a stability of at least 35 Ncm. A surgical guide mimicking the planned restoration as it emerges from the site was used for optimal implant placement. After implant placement, the surgical guides were then used to register temporary cylinders with flowable composite resin. The interim restorations were fabricated with interim acrylic resin and adjusted to have normal contact in the maximal intercuspal position.

RFA (Osstell) was used to measure the stiffness of the implants. Implants were restored with interim crowns immediately after the surgery if the RFA ISQ was 65 or more; this was the case for all participants. Soft tissue flaps were then secured with cytoplast sutures, which were removed at 1-week follow-up appointments. Participants received no specific dieting protocol. Interim restorations were replaced with definitive restorations after 6 months (Figs. 2, 3).

Implants were monitored for 12 months after placement with the protocol given in Table 2. Prostheses evaluation and participants' subjective evaluations were also done at each visit after placement of interim and definitive prostheses. For the prosthesis evaluation, the following variables were examined: prosthesis retention, prosthesis stability, esthetics, phonetics, and pain on mastication. For the subjective evaluation, participants rated the following parameters: comfort, fit, speech, appearance, ability to masticate food, general satisfaction, and pain on mastication. A scale from 1 to 10 was used to rank criteria for the prosthesis and for the participant

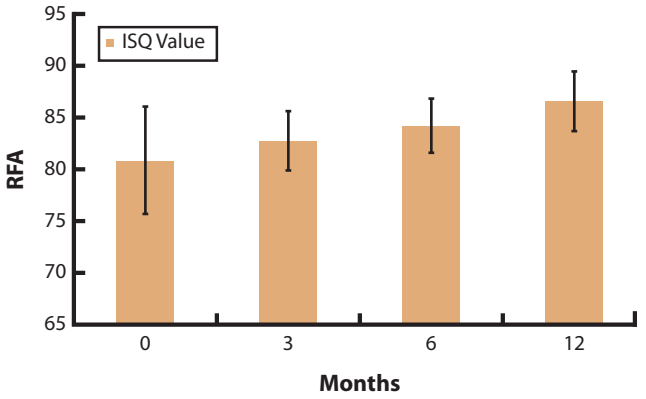

Figure 4. Results of resonance frequency analysis (RFA) measurement.

evaluation, where 10 was equal to the best possible outcome. Gingival and plaque indices, gingival inflammation, gingival suppuration, mobility, periimplant radiolucency, preparation of the immediate provisional prosthesis, implant placement/positioning, implant orientation, attachment of the prosthesis, and final adjustment of occlusal contacts were also evaluated.

RESULTS

All 20 implants (20 participants) were successfully integrated. Prosthesis retention and stability were excellent in all participants after 3 and 6 months in the case of interim restorations and after 12 months in the case of definitive restorations. Esthetic outcomes were documented using a participant evaluation scale of 1 to 10, where 1 is least acceptable and 10 is the best possible appearance. Twenty participant ratings for esthetic outcome were 7 (n=1), 8 (n=6), 9 (n=4), and 10 (n=9) at 3 months; 7 (n=1), 8 (n=2), 9 (n=5), and 10 (n=12) at 6 months; 9 (n=1) and 10 (n=19) at 12 months. At 12 months, 19 participants rated their general satisfaction at 10, and 1 participant rated general satisfaction at 8. Comfort, fit, speech, appearance, and function were evaluated by the principal investigator (T.K.). One participant had some initial speech concerns, but this was resolved when the interim restoration was replaced with the definitive restoration. Results for each tested parameter steadily increased for the duration of the study, with excellent outcomes (90% to 100%, rating of 10) and good to very good outcomes (5% to 10%, ratings of 7 to 9) by 12 months.

Bone status and final drill torque were recorded at the surgical appointment. Fifteen participants had Type II bone, and 5 participants had Type III bone. For 80% of the participants with Type III bone, a 50-Ncm insertion torque was used, and the remaining 20% received a 60 Ncm torque. For 80% of participants with Type II bone, a 50-Ncm final drill torque was used, and the remaining 20% received a 45-Ncm torque.

Table 3. Gingival and plaque indices recorded at each visit

Gingival index	0	1	2	3
Surgery day	90%	10%		
3 mo	90%	10%		
6 mo	100%			
12 mo	90%	5%	5%	
Plaque index				
Surgery day	5%	85%	5%	5%
3 mo	25%	50%	25%	
6 mo	5%	95%		
12 mo	5%	95%		

The results of RFA measurements (Fig. 4) demonstrate an increase in RFA values at follow-up visits. RFA values after implant placement were 80.82 ±5.19; at the 3-month follow up RFA values were 82.71 ±2.86, and after 6 months, 84.21 ±2.61. RFA values measured 12 months after implant placement were 86.57 ±2.91.

The results of gingival and plaque index values are presented in Table 3. Gingival indices were from 0 to 2 and plaque indices from 0 to 3 at various follow-up visits. Indices of 1 were predominant values for both interim and final restorations (12 months). Gingival inflammation, gingival suppuration, mobility of the implant, and periimplant radiolucency were evaluated and were not present for any participants. The evaluation of the preparation of the immediate interim prostheses, implant placement/positioning, implant orientation, attachment of the prosthesis, and definitive adjustment of the occlusal contacts resulted in no adverse findings. There were no surgical complications.

DISCUSSION

Numerous clinical studies on immediately restored dental implants in selected patients have reported success rates comparable with those reported using delayed or late loading protocols.[2,28] Primary implant stability has been recognized as a significant clinical parameter affecting the success of immediate loading.[3,20] The control of an adequate insertion torque has been recommended as an appropriate approach to minimize implant failure related to the inadequate primary stability of immediately loaded implants. Dragoo and Lazara[4] reported that primary implant stability was at least 30 Ncm (insertion torque). Ottoni et al[29] conducted a similar study of single immediately loaded implants, with results and conclusions similar to those of Dragoo and Lazzara.[4] They suggested that an insertion torque greater than 32 Ncm was essential to accomplish osseointegration.[16]

Bone quantity and bone quality are also important parameters influencing immediate loading procedures. Jaffin and Berman[29] conducted implant survival research with different bone types. The results of their study showed that when implants were placed in Type I to III

bone, only 3% failed; while in Type IV bone, 35% failed. In the present study, implants were placed in bone Type II and III. Bone status and final drill torque were evaluated at visit 2. In participants with Type III dental bone, 53.3 Ncm average insertion torque was used; while for participants with Type II dental bone, the average insertion torque was 48.7 Ncm.

Since stability at implant insertion is critical to success, RFA was assessed in this study. Balshi et al[18] showed a decrease in bone implant stability in the first month after implant placement from 70.35 ±0.5 to 66.38 ±0.5, followed by increases in stability in the second and third months (68.01 ±0.5 and 68.82 ±0.49, respectively). Also, they found lower initial stabilities in softer bone types. They concluded that an immediate loading protocol should have an undisturbed period of healing for the first 2 months after implant placement.[18] Valderrama et al[19] concluded in their study that RFA values decreased in the first 1 to 3 weeks after implant placement with small fluctuations in RFA values between 3 and 6 weeks and that significantly increased stability was found from 6 to 12 weeks. RFA measurements in this study (Fig. 4) have increased over the entire observation time period from an average of 80.82 at the time of implant placement to an average of 86.57 after 12 months. This indicates that immediate loading did not adversely affect osseointegration.

To achieve satisfactory primary stability, a screw-implant design is a better choice than press-fit implants because of its higher mechanical retention and greater capability to transfer compressive forces.[8] Also, coated implants seem to have a higher survival rate (94.1%) for immediate implant loading than those with a machined surface (88.8%).[8] In this study, tapered dental implants with SLA surfaces were used. The implants in this study consistently achieved initial intraosseus fixation (100%). Therefore, both hypotheses were accepted.

A 100% survival rate for the immediate loading of single-tooth implants was also shown by Ericsson et al[14] and Cannizzaro and Leone.[5] Henry and Liddelow[6] reported that numerous clinicians support the statement that soft tissue esthetics is improved with immediate loading of dental implants in comparison with a delayed approach. In this study, we conducted a survey to obtain participants' subjective assessments of the interim and definitive restorations. Regardless of the participant assessment, interim restoration retention and stability have resulted in the best possible outcome after 3 and 6 months and after 12 months in the case of definitive restorations. For the esthetic parameter, participant ratings tended to increase during the observation period.

In this prospective cohort study, the treatment of all the participants did not start at the same time. The minimum 12-month follow-up was required for all participants.

CONCLUSION

This study showed a 100% implant success rate during a 12-month observation period. Therefore, immediate implant loading achieved a success rate similar to that reported for traditional, delayed loading protocols. However, careful patient selection, appropriate treatment planning, optimal surgical technique, and interim and definitive restorations should be considered crucial parameters for achieving a high success rate in the immediate loading of dental implants.

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Noteworthy Abstracts of the Current Literature

Comparison of systemic health conditions between African American and Caucasian complete denture patients

Szylkowska E, Kaste LM, Schreiner J, Gordon SC, Lee DJ

J Prosthodont 2014;23:341-6

Purpose. To compare prevalence of systemic health conditions (SHC) between African American and Caucasian edentulous patients presenting for complete dentures (CD) at an urban dental school.

Methods. The study included patients presenting for CD 1/1-12/31/2010, ages 20 to 64 years, and either African American or Caucasian. Covariates included: age group, gender, employment status, Medicaid status, smoking history, and alcohol consumption. SHC included at least one of the following: arthritis, asthma, cancer, diabetes, emphysema, heart attack, heart murmur, heart surgery, hypertension, or stroke.

Results. The group (n = 88) was 44.3% African American, 65.9% ≥50, 45.5% male, 22.7% employed, and 67.0% with at least one SHC. African Americans were older (p = 0.001) and more likely to have one or more SHC (p = 0.011). Patients with at least one SHC were older (p = 0.018) and more likely female (p = 0.012). The total sample logistic regression model assessing SHC yielded only gender as statistically significant (males < OR 0.32, 95% CI 0.11 to 0.92). Caucasian males were less likely to have SHC (OR 0.17, 95% CI 0.04 to 0.77), and Caucasians ≥50 were more likely (OR 5.36, 95% CI 1.19 to 24.08). African Americans yielded no significant associations.

Conclusions. Among selected completely edentulous denture patients at an urban dental school, two out of three patients had at least one SHC. This exploratory study suggests there may be health status differences between African American and Caucasian patients in this setting, calling for further study.