Immediate Provisional Restoration of Osseotite Implants: A Clinical Report of 18-month Results

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Purpose: *The purpose of this study was to assess the survival rates and interproximal bone levels for Osseotite implants that were restored with fixed provisional crowns without occlusion immediately after implant placement.* ***Materials and Methods:*** *Ninety-three implants were placed in 38 partially edentulous patients. All implants were immediately restored with prefabricated abutments and cement-retained provisional crowns without centric or eccentric occlusal contacts. The implants were restored with definitive restorations approximately 8 to 12 weeks after implant placement. All patients included in the study were followed for at least 18 months after implant placement (average 20.3 months).* ***Results:*** *Seventy-seven of the 93 implants satisfied the inclusion criteria. Seventy-five implants became osseointegrated. The overall survival rate was 97.4%. Radiographic bone loss 18 months after implant placement (the mean of both interproximal surfaces) was 0.76 mm. The exact binomial confidence interval was 0.32% to 9.07%. For the exact binomial test with the null hypothesis proportion = .05,* P *was .3334 and was not statistically significant.* ***Discussion:*** *Immediate nonocclusal loading of single-unit dental implants differs from immediate loading of multiple, splinted implants. Unsplinted, restored implants without occlusal loading may still be subject to lateral and occlusal loads secondary to the proximate location of the food bolus. Immediate restoration of dental implants significantly reduces treatment time and may be beneficial in reducing the morbidity associated with loss of teeth, contraction of the alveolus, and loss of interdental papillae associated with the traditional method of treatment following tooth loss.* ***Conclusions:*** *The results of this study suggest that immediate restoration of Osseotite implants can be accomplished with results that are similar to the results obtained with the traditional 1- or 2-stage surgical, unloaded healing protocols.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:534–541

Key words: *dental implants, immediate loading, nonocclusal loading*

Restoration of dental implants is well accepted by the worldwide scientific community.[1–4] Initially, dental implants were used for retention of full-arch prostheses in edentulous patients.[1] Dental implants have become increasingly popular for replacing individual missing teeth.[5,6] Individual and splinted implant restorations have numerous advantages compared to the more traditional method of tooth replacement with fixed partial dentures. Some of the disadvantages associated with conventional fixed prosthodontic treatment include preparation of nonrestored, noncarious abutment teeth, the potential for recurrent dental caries, increased incidence of gingivitis, and average prosthesis life spans of 7 to 10 years.[7]

Success rates ranging from 90% to nearly 100% have been reported for titanium implants.[8–10] Despite the excellent outcomes that have been reported with dental implants, many clinicians and patients still elect treatment involving fixed partial dentures. One of the reasons most often cited in selecting fixed prosthodontics over implant prosthodontics is the amount of time required for implant treatment.[4]

Traditionally, healing periods of 4 and 6 months have been required for implants placed in mandibular and maxillary edentulous sites, respectively.

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Recent evidence suggests that specific types of dental implants may be loaded successfully 2 months after implant placement.[10] The success rates for implants loaded with a 2-month protocol were similar to the success rates of implants loaded with the conventional 4 to 6 months.[4]

However, numerous reports support the use of longer healing times.[11,12] Brunski and colleagues found that fibrous connective tissue encapsulation can occur around implants loaded immediately after placement. They also stated that an unloaded, stress-free healing period encouraged direct bone-implant contact.[11,12]

Other studies have demonstrated that osseointegration can occur when implants are loaded immediately after placement.[13–15] Tarnow and coworkers described a study in which 10 patients with edentulous jaws received multiple implants that were immediately restored with prostheses that provided cross-arch stabilization.[13] At 1 to 5 years postplacement, 67 of the 69 immediately loaded implants were osseointegrated. In a similar study, Cooper and colleagues reported a 100% success rate 18 months after the placement and immediate loading of 54 implants.[14] Ibanez and Jalbot reported on 11 consecutive patients who were treated with 87 Osseotite implants. Four patients' implants were immediately loaded, while 7 patients' implants were loaded 48 hours after implant placement.[15] The patients were followed for at least 2 years. All implants were reported to be osseointegrated. Some of the patients in the studies described received implants immediately after the extraction of teeth. All of the implants were restored with prostheses having cross-arch stabilization.

Chaushu and associates reported an 80% survival rate in situations where hydroxyapatite-coated cylindric implants were placed into fresh extraction sites (FXS) and 100% success when the same type of implants were placed into healed edentulous sites (HES).[16] Several studies have demonstrated that different types of implant surfaces may influence osseointegration.[17–19] Lazzara theorized that implant placement into FXS would be a valid technique for preserving bone at the extraction/implant site.[5] In a similar study, Gelb reported on 35 consecutive patients treated with machined, threaded implants placed immediately into FXS.[20] The implants were placed in a 2-stage protocol that called for 4 to 6 months of unloaded healing. Approximately 4 years later, 49 of the 50 implants were osseointegrated, a survival rate of 98%.

Unsuccessful implants in the studies described may not have achieved primary stability and may therefore have been subjected to micromotion within the osteotomy sites. Micromotion has been defined as a subclinical level of movement between the implant and the osteotomy.[21–24] Micromotion, by definition, is difficult to measure clinically. Several authors have postulated that rough-surfaced implants may tolerate micromotion between 50 and 150 μm[23,24] and that machined-surface implants may tolerate micromotion up to 100 μm.[21,22]

Initial primary implant stability is not developed as the result of any kind of chemical bond.[23,24] Primary implant stability depends on mechanical stability from a precise fit between the osteotomy and the implant surface.[25,26] Kan and colleagues reported on the results of a 1-year prospective study on the efficacy of immediate implant placement and provisionalization of maxillary anterior single-tooth implants.[27] Thirty-five threaded, hydroxyapatite-coated implants were placed in FXS in 35 patients and immediately restored with provisional nonfunctional crowns. The authors reported that all 35 implants were osseointegrated 12 months after extraction and implant placement. They concluded that extraction immediately followed by implant placement and restoration without occlusal loading was a viable technique, with outcomes equivalent to the outcomes associated with the more traditional treatments of extraction, 4 to 12 months of osseous healing following extraction, implant placement with unloaded healing, and definitive restoration 4 to 6 months after implant placement. In a similar study, Petrungaro placed and immediately restored 209 hydroxyapatite-coated, threaded implants and reported that 203 were successful 1 year after implant placement.[28] Other authors have also reported on immediate restoration of implants without occlusal loading.[29–31]

Optimal esthetics for implant restorations in the anterior maxilla may be more difficult to obtain than implant osseointegration. The ability to predictably preserve or reproduce interdental papillae is extremely important in the replacement of maxillary anterior teeth. Bone augmentation procedures at the time of tooth extraction have been shown to contribute to preservation of the alveolus in terms of ridge width, ridge height, and soft tissue contours.[32] Extraction, immediate implant placement, and restoration may be beneficial in maintaining the integrity of extraction sockets and contribute to the maintenance of the interdental papillae around implant restorations.

Several studies have demonstrated a high correlation between interproximal bone height and interproximal contact areas relative to maintenance of the interdental papillae in both natural and implant-restored dentition.[33–35] If the interproximal bone does not resorb after tooth extraction, the prognosis

for maintenance of the interdental papillae should be improved.[33–35]

Cooper and associates proposed that the term *immediate loading* refer to situations where implant placement with primary stability and prosthetic loading of multiple, splinted implants occur at the same clinical appointment.[14] They proposed that *rapid loading* refer to implants placed with primary stability and loaded with a provisional restoration at a subsequent clinical visit prior to achievement of osseointegration. Rapid loading should occur only after approximately 3 weeks of healing.[36] The term *immediate nonocclusal loading* should be used for provisional restorations fabricated and cemented to abutments connected on the day of implant placement. Immediate nonocclusal loaded restorations should not have any centric or eccentric occlusal contacts during healing. Patients should be told to avoid placing any food bolus on or about the provisional restorations and implants. Lazzara and coworkers have defined *early loading* as the occlusal loading of dental implants approximately 8 weeks after implant placement.[10] Lazzara and coworkers proposed that implants not be loaded until osseointegration has occurred.

The purpose of this study was to assess the survival rate for Osseotite implants (3i/Implant Innovations, Palm Beach Gardens, FL) restored with fixed provisional crowns without centric or eccentric occlusal contacts immediately after implant placement. Definitive restorations were fabricated approximately 8 weeks after implant placement. Patients were followed for at least 18 months following the loading of the definitive restorations.

MATERIALS AND METHODS

From June 2000 to June 2002, 38 consecutive patients were treated with 93 implants immediately restored with single-unit, fixed provisional restorations. Seventy-seven of these implants satisfied the minimum follow-up requirement. Fifteen implants were placed in FXS; 62 were placed in HES (at least 1 year from the time teeth were extracted). In 20 cases, there were no teeth distal to the implant.

Patients

The patients ranged in age from 17 to 83 years; the average age was 54.4 years. Twenty patients were male; 18 were female. All patients were in good general health; all were informed of the risks and benefits of the planned procedures. The risks included, but were not limited to, infection, paresthesia, and loss of implants. All signed appropriate consent forms. Heavy smokers (> 10 cigarettes per day), patients with uncontrolled diabetes, and patients with a known bruxism habit were excluded. Both anterior and posterior tooth replacements were permitted. All patients agreed to be available for follow-up clinical visits that were to include postoperative radiographs. Patients who had not been followed up for 18 months by October 2003 were excluded from the study.

Surgical Protocols

Two protocols were used: placement of implants in HES, and placement of implants in FXS. All of the surgeries were performed in outpatient settings with local anesthesia administered by 1 of 2 periodontists or by an oral and maxillofacial surgeon. Patients were premedicated with 2 g penicillin 1 hour prior to surgery. They also received 500 mg penicillin 4 times a day for 7 days postoperatively.[1] Implant sites were prepared according to the standard protocol using low-speed drilling and irrigation with sterile saline. Irrigation was not used during implant placement.

In the HES group, crestal incisions were made in the edentulous spaces. Vertical releasing incisions (in cases where there was at least 1 tooth mesial or distal to the implant site) were frequently necessary to improve surgical access. Hexed Osseotite implants at least 10 mm long and either 3.4, 4, or 5 mm in diameter were placed according to a single-stage surgical protocol. The implants had to achieve placement torque values of at least 30 Ncm. If the implants did not achieve this placement torque, the patients were excluded from the study. The restorative platforms of the implants were placed approximately 2 to 4 mm apical to the cementoenamel junctions (CEJs) of the teeth adjacent to the implants (Fig 1). The abutments were prepared extraorally on a laboratory abutment holder and then placed on the implants. The flaps in the HES group were coronally repositioned around the prefabricated abutments and provisional crowns. They were closed with horizontal mattress and single interrupted sutures.

Patients in the FXS group had implants and provisional restorations placed in extraction sites immediately after the teeth were extracted. Mucoperiosteal flaps were sometimes required for implant placement to avoid tearing the soft tissues in the surgical sites. The sockets were thoroughly debrided and the implants were placed according to the same protocol used for the HES group, modified by the anatomy of the sockets. To obtain adequate primary stability, the implants had to achieve initial torque values of at least 30 Ncm. If implants did not

Fig 1 A radiograph of a 5-mm diameter implant and abutment with a 6-mm emergence profile diameter placed with the implant restorative platform approximately 2 mm apical to the CEJs of the teeth adjacent to the implant.

Fig 2 A GingiHue post in place on laboratory abutment holder for extraoral crown preparation.

achieve this placement torque, the patients were excluded from the study. The restorative platforms of the implants were placed approximately 2 to 4 mm apical to the CEJs of the teeth adjacent to the implants.

Restorative Protocol

The restorative protocol was the same for both groups. Immediately after the implants were placed and requisite placement torque values were obtained, Prep-Tite abutments (Implant Innovations) were connected to the implants. In 70 cases, premachined titanium abutments (GingiHue Posts; Implant Innovations) were used; in 7 cases, premachined zirconia abutments (ZiReal Posts; Implant Innovations) were used. The abutments were selected according the functional and esthetic requirements indicated by the definitive restorations. Generally, the abutments corresponded to the emergence profiles of the teeth that were to be replaced: 5 mm for premolars, 6 mm for canines and maxillary central incisors, and 7.5 mm for molars.

The abutments were initially connected to the implants using square try-in screws (Implant Innovations). The tentative gingival margins were scribed onto the abutments with a dental explorer. The abutments were removed, placed onto laboratory abutment holders with the square try-in screws, and prepared for use as crown preparations (Fig 2). The taper of the axial walls was approximately 6 to 10 degrees. Interocclusal clearance of at least 2 mm was provided to ensure adequate thickness for the restorative material of the provisional crowns. The abutments were transferred back to the implants with gold-coated abutment screws (Gold-Tite square screws; Implant Innovations) torqued to 20 Ncm with Restorative Torque Indicators (Implant Innovations) (Fig 3).

The abutment preparations were refined intraorally with coarse diamond burs in high-speed handpieces under copious water irrigation. The flaps, if present, were closed with resorbable sutures. Radiographs were obtained to verify abutment seating on the implant hexes prior to the delivery of the final torque to the abutment screws. The radiographs were also used to make baseline measurements to compare the locations of the restorative platforms and the interproximal bone heights on the mesial and distal surfaces adjacent to the implants. Measurements were made to the nearest 0.1 mm.

Customized provisional crown restorations (Luxatemp; DMG Products, Hamburg, Germany) were fabricated directly on the abutments (Fig 4). They were contoured for optimal marginal fit, emergence profiles, and interproximal contacts. Occlusal centric and eccentric contacts were not permitted on the provisional restorations. Occlusion was evaluated and modified with the patient seated in both upright and reclined positions. The provisional crowns were cemented to the abutments with temporary cement (Dycal; Dentsply International, Milford, DE).

Postoperative Instructions

Patients were instructed to eat a soft diet and to avoid placing food in the area of the implants and provisional crowns. The provisional crowns served esthetic and phonetic purposes; they replaced the transitional partial dentures that have traditionally been used during implant osseointegration. Patients were instructed to continue with the soft diet for

Fig 3 A full-thickness flap sutured around a prefabricated titanium abutment. The abutment was prepared immediately after implant placement.

Fig 4 A provisional crown cemented onto the prepared abutment on the day of implant placement. Centric and eccentric occlusal contacts were eliminated.

Fig 5 A radiograph of the implant shown in Fig 1 18 months after delivery of the definitive prosthesis demonstrating 0.0 mm bone loss on its mesial and distal surfaces.

the first 8 weeks following implant placement. Oral hygiene was limited to brushing around the implants with a soft toothbrush for the first 2 weeks. Thereafter, conventional brushing and flossing were permitted. Patients were encouraged to rinse with 0.12% chlorhexidine on a daily basis.

Follow-up Appointments

Patients were seen for the first follow-up visit within 7 days of the surgery. Patients were seen again at 1 and 2 months postoperatively. Implant stability, occlusion, gingival margin esthetics, and oral hygiene were evaluated at each follow-up appointment. The provisional restorations and abutments were removed approximately 8 weeks after implant placement. Definitive impressions were made directly to the implants, or the existing abutments were re-prepared to accommodate changes in the peri-implant soft tissues associated with wound healing. The definitive restorations were generally seated approximately 4 weeks after the definitive impressions were made. Radiographs were or will be taken at 12, 18, 24, and 36 months after implant placement (Fig 5). Implants were considered to be osseointegrated if they were clinically stable and showed no signs of infection and if there was less than 1.0 mm of radiographic peri-implant bone loss at the 12-month follow-up appointment.

RESULTS

Of the 93 implants, 77 were followed for at least 18 months postplacement. Two implants from 1 patient were excluded because the patient died before the 1-year follow-up visit was made. Fourteen implants from 10 patients were also excluded because 18 months had not elapsed from the time the implants were loaded with the definitive restorations to the time this article was prepared. Thus, the results of this study are based on the 77 implants that were loaded with definitive restorations and followed for a minimum of 18 months. Fifteen implants (19.5%) were placed in FXS in 4 patients. Sixty-two implants (80.5%) were placed in HES that had been without teeth for at least 1 year. Implants from 11 women and 16 men are included in the results (40.7% and 59.3%, respectively). The average age of the female patients was 53.3 years; the average age of the male patients was 55.1 years. Five patients (17.9%) were smokers (less than 10 cigarettes per day), accounting for 16 (20.8%) of the 77 implants placed into smoking patients.

There were 2 nonintegrated implants; the 18-month implant survival rate was 97.4%. The survival rates of immediate nonocclusal loaded implants placed into intact edentulous ridges were compared to the survival rates of similar implants placed in FXS. The exact binomial confidence interval was from 0.32% to 9.07%. The exact binomial test with the null hypothesis proportion = .05 had a *P* value of .3334 and was not statistically significant.

The preoperative radiographs demonstrated average bone-to-implant restorative platform distances of 0.35 mm on mesial surfaces (range 0.1 to 1.3 mm) and 0.41 mm on distal surfaces (range 0.1 to 1.4 mm). Radiographs obtained at 18 months after implant placement demonstrated bone-to-implant restorative platform distances of 0.67 mm on the mesial surfaces (range 0.3 to 1.2 mm) and 0.85 mm on the distal surfaces (range 0.2 to 1.3 mm).

DISCUSSION

Dental implant components have changed significantly since Brånemark introduced commercially pure titanium implants into North America. The initial unloaded healing protocols for dental implants have also been modified from 4 and 6 months for the mandible and maxillae, respectively, to 2 months for both jaws with Osseotite implants.[10] The results of this study suggest that within certain parameters Osseotite implants that support single-tooth replacements may be placed and restored without occlusal contacts on the same day.

The implants and implant restorations described in this study did not have occlusal contacts when the implants were placed. This concept has been identified as the *immediate nonocclusal loading* of dental implants. Hui and associates described the same-day placement and restoration of single implants.[29] The patients in their study were followed for at least 1 year after implant placement. The implants were placed with primary stability (40 Ncm placement torque). Patients in the study had crowns fabricated with no or minimal contact. Hui and associates described the occlusion as "protected." They reported 100% osseointegration of the dental implants. They pointed out that dental implants immediately restored without occlusal contacts could be loaded with a food bolus in the general vicinity of the implant restoration. However, this type of loading may not be important on a clinical level.

The protocol in the present study was similar to the protocol used by Malo and colleagues.[30] However, the study published by Malo and colleagues was retrospective, 23 of the 54 fixed prostheses in their series were splinted with multiple implants, and the implants were placed with a minimum torque of 32 Ncm. The provisional restorations were seated without occlusal contacts, and the definitive restorations were seated 5 months after the implants were placed as opposed to after 2 months as in the present study. Malo and colleagues reported a 90% implant survival rate at 1 year and also reported that average bone resorption was 0.8 mm 1 year after implant placement. However, radiographic evaluations for bone loss could only be obtained for 35 of the 49 patients. Sullivan and coworkers reported on 147 Osseotite implants that were followed for at least 3 years after implant placement.[37] They reported that 79.7% of the implants had no radiographic bone loss; 11.9% had less than 1 mm; 4.9% had less than 2 mm; 2.8% had less than 3 mm; and 0.7% had bone loss greater than 3 mm. The findings reported in the present study, 0.76 mm average bone loss, corroborate the findings of Sullivan and coworkers.

Immediate nonocclusal loading of dental implants as described in this study is distinctly different from immediate loading of dental implants, which has been described by Tarnow and associates,[34] Cooper and associates,[36] and others.[13–15,29,30,35] Immediate loading of dental implants describes clinical situations where occlusal and nonocclusal loads are transferred directly to the implants immediately after implant placement. Ibanez and Jalbot reported 100% survival rates with splinted, immediately loaded Osseotite implants.[15] They postulated that controlling micromotion was the key to the achievement of osseointegration of immediately loaded implants. They reduced micromotion of the individual implants by placing them with a wide anterior-posterior distribution. The restorations they described also had cross-arch stabilization and were rigidly attached to the implants. Controlling micromotion is key to successful osseointegration with immediate and immediate nonocclusal loading of dental implants.

Ericsson and colleagues[31] reported on immediate loading of Brånemark System single-tooth implants with a protocol similar to the present study. One of their parameters in patient selection involved bilateral occlusal stability in the natural dentition. For instance, if the mandibular right second premolar was being replaced with an immediately restored implant, stable occlusal contacts had to exist in the patient's left posterior quadrants. Out of 14 implants, they reported 2 failed implants (86% survival rate) in the experimental group and no failed implants in the control group (2-stage surgical protocol; implants not immediately loaded). For osseointegration to occur, implants must have primary stability throughout the

healing process. In the study by Ericsson and colleagues, the experimental implants may have been inadvertently loaded during mastication or in eccentric mandibular movements. Single-unit implants subjected to either of these forces would be unlikely to remain stable during healing and thus would fail to integrate. The differences between the findings reported by Ericsson and colleagues and those of the present study may also be attributed to the smaller sample size in the study by Ericsson and colleagues. The current study had a significantly higher level of osseointegration (98%) than was reported by Ericsson and colleagues.

Ericsson and colleagues reported mean bone changes of approximately 0.1 mm 1 year after implant placement. The results of the present study demonstrated slightly higher levels of bone loss when the preplacement and 18-month post–implant placement data were compared. That bone loss in the present study was calculated from measurements made to the nearest 0.1 mm by 2 different examiners may have influenced the results. Sullivan and coworkers reported that 91.6% of the Osseotite implants in their study had less than 1 mm of interproximal bone loss over a 3-year period.[37] However, the implants in their study were placed under a 2-stage surgical protocol and were not immediately loaded. Cooper and associates reported that the mean change in marginal bone levels with their "rapid loading" protocol was 0.4 mm at 12 months.[36] Their protocol was similar to the protocol described in the present study, except that in the Cooper and associates study the temporary restorations were placed approximately 3 weeks after the implants had been placed. Petrungaro did not specifically report bone loss in his study of 400 immediately placed and restored implants.[28]

Given that the parameters in these studies were similar, the major difference between the studies was the type of implants used—machined titanium implants (Nobel Biocare, Yorba Linda, CA) in Cooper and associates and titanium implants with enhanced surfaces used in the present study. Several studies have shown that different implant surfaces can influence osseointegration. Implant surfaces have been modified by blasting them with different materials, including plasma and hydroxyapatite.[17–19] The surface topography of the implants used in this study was changed by thermally acid-etching commercially pure titanium implants with hydrochloric and sulfuric acids in a proprietary process.

In the study of 147 Osseotite implants by Sullivan and colleagues,[3,37] 5 failed implants were identified in the 3-year interim report: 2 failed prior to loading and 3 failed within 6 months of loading. None failed after more than 6 months after loading; thus the cumulative survival rate was 96.6%. Since then, the authors have reported that the cumulative survival rate was still 96.6% after 6 years.[3] The minimization of implant failures occurring after occlusal loading is critical to clinicians because, beyond its importance to patient satisfaction, it minimizes or eliminates the costs associated with the replacement of failed implants and implant-supported restorations.

CONCLUSIONS

The results of this study suggest that immediate nonocclusal loading of Osseotite implants can be accomplished with results that are consistent with the results obtained with traditional 1- or 2-stage surgical, unloaded healing protocols. The treatment protocol described in this study is not amenable to all clinical situations. Parameters identified for the success of this protocol include primary implant stability (ie, implant placement torque values of at least 30 Ncm), elimination of occlusal contacts prior to osseointegration, dietary modifications during the initial healing period (8 weeks postplacement), and the replacement of teeth with implants appropriate to the clinical situation. Further clinical studies are required to obtain additional data regarding the immediate restoration of dental implants. Additional data will provide clinicians and researchers improved foundations for decision making relative to selecting the most appropriate implant treatment protocol for individual patients and clinical situations.

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