CLINICAL RESEARCH

Immediate Occlusal Loading of Osseotite® Implants in Mandibular Edentulous Patients: A Prospective Observational Report with 18-Month Data

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Purpose: **To evaluate the efficacy of treatment consisting of placement and immediate occlusal loading of implants in 27 patients with edentulous mandibles.**

Materials and Methods: **Twenty-seven patients were treated in two private practice settings. One hundred fifty-one implants were placed and immediately occlusally loaded with fixed implant prostheses (15 cement-retained, 12 screw-retained) on the day of implant placement. The implant-retained prostheses were inserted within 5 hours of implant placement. Patients were followed for at least 18 months. The required criteria for immediate occlusal loading was primary implant stability of at least 30 Ncm of insertion torque. The implant prostheses were removed at least 12 months post-placement and the implants were evaluated for primary clinical stability and radiographic bone apposition to implants.**

Results: **At the 12-month follow-up appointments, cumulative survival rates of 98.0% and 100% were recorded for implants and prostheses, respectively. Three implants failed within 3 months. All other implants were clinically successful.**

Conclusions: **Immediate occlusal loading of multiple, splinted mandibular implants is an effective treatment when implants are stable at insertion and are rigidly splinted with implant-retained prostheses.**

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INDEX WORDS: immediate occlusal loading, edentulous mandible

IMPLANT PROTOCOLS in the 1960s included implants placed into immediate occlusal function, a protocol that would now be called immediate occlusal loading. Immediate occlusal loading of endosteal blade implants yielded failure rates of 25% to 50%.[1,2] Branemark developed the concept of osseointegration based on unloaded healing where machined titanium endosteal implants were placed into osteotomies and covered by muco-periosteal flaps.[3] Osseointegration occurred during this unloaded healing period. With this protocol, implant survival rates significantly increased, to approximately 85% in maxillae and 95% in edentulous mandibles;[4] however, this protocol also called for patients to go without their dentures for at least 1 to 2 weeks immediately after implant placement. In addition, these patients had to continue using their removable dentures while the implants osseointegrated (4 to 6 months) and during the time the definitive prostheses were constructed (2 to 4 months).

It is well known that edentulous jaws undergo significant, irreversible resorptive changes after the loss of the natural teeth.[5,6] These resorptive processes may cause significant changes in the anatomy of the edentulous jaws and, in some instances, preclude implant placement.[7] For optimal restoration of function and esthetics in these patients, additional surgeries and technically demanding prosthetic procedures may be required. These additional procedures increase morbidity and may result in a decreased overall success of

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implant treatment. Treatment times and costs will certainly be increased.

Initially, loading of dental implants was governed by a strict protocol.[3,4] Immediate loading of dental implants in the 1960s resulted in fibrous encapsulation of the implants, implant mobility, and loss of implants.[2] In later studies, under certain circumstances, immediate occlusal loading of endosseous implants was found to be effective. Schnitman et al reported on immediate fixed interim prostheses supported by Branemark implants in the treatment of mandibular edentulism.[8] Sixty-three 3.75-mm machined implants (Nobel Biocare, Goteborg, Sweden) of varying lengths were placed into mandibular sites in 10 patients and followed for up to 10 years. Twenty-eight implants were immediately loaded at implant placement with fixed prostheses. Thirty-five adjacent implants in the same patients were allowed to heal unloaded. All 10 prostheses supported by 28 immediately loaded implants were successful during the 3-month healing period. Four of the 28 implants failed, 1 per patient. Of the 24 osseointegrated immediately loaded implants, 23 were incorporated into the definitive prostheses and 22 were in function at the time of the above report (1997). Schnitman et al computed the 10-year cumulative survival rate (CSR) for all of the implants at 93.4%. Life-table analysis of the immediately loaded implants demonstrated a 10-year CSR of 84.7%. The 10-year CSR for the nonloaded implants was 100%. These two sets of data were statistically significant ($p = 0.022$).

Numerous authors have reported on immediate loading of dental implants with somewhat different results. In 1997, Tarnow et al reported 98% CSRs with an immediate occlusal loading protocol 1 to 6 years post-implant treatment.[9] Their report included 4 patients with edentulous maxillae and 6 with edentulous mandibles. In 2000, Cooper et al reported 98% CSRs for mandibular implants 18 months post-implant treatment;[10] Horiuchi et al reported a CSR of 97.2% for 140 immediately loaded implants during an 8- to 24-month follow-up.[11] In 2001, Grunder reported an overall CSR of 92.3% for 91 implants placed and immediately loaded with fixed prostheses.[12] Testori et al reported one failure in a study involving 92 implants that were immediately loaded with fixed prostheses in edentulous mandibles. They reported a CSR of 98.9% with up to 48 months of follow-up.[13] In a second study involving 62 patients and 325 immediately occlusally loaded Osseotite implants, Testori et al reported a CSR of 99.4% for implants followed for 12 to 60 months.[14] The ultimate goal of immediate loading of dental implants was to reduce the number of surgical procedures and the amount of time required for insertion of definitive implant prostheses, but without decreasing the success rates associated with implant treatment and the unloaded healing protocol.

A key element in immediate occlusal loading protocols involves eliminating micromovement between implants and osteotomies. This has been quantified by achieving insertional torque values of immediate implants at the time of implant placement of at least 30 Ncm.[15]

The purpose of this study was to evaluate the efficacy of treatment that consisted of multiple rigidly splinted implants and insertion of a fixed, cross-arched stabilized prosthesis on the same day. Patients were followed for at least 18 months postoperatively. Cumulative implant and prosthesis survival rates were recorded.

Materials and Methods

The study was performed in two private practices with three surgeons and two prosthodontists. All the investigators followed the same clinical protocol for immediate occlusal loading of implants placed into edentulous mandibles. Twenty-seven consecutive patients were treated with at least five mandibular endosseous implants (Osseotite®, Implant Innovations, Inc., Palm Beach Gardens, FL) from February 2002 to August 2003. Twenty patients were edentulous on the day of surgery; 7 patients had their teeth extracted in conjunction with the implant surgery. A total of 151 implants were placed. Twenty patients were treated in the first author's office (CD); 7 were treated in the second author's office (RL). The patients ranged in age from 41 to 75 years; average age was 62.4 years. Six patients were male; 21 were female.

Patients were selected according to the following inclusion criteria: good general health and ability to tolerate the surgical procedures, ability to provide informed consent, and willingness to accept a fixed mandibular prosthesis stabilized by implants. All prostheses were inserted and loaded with full functional occlusion within 5 hours after implant placement. All patients signed appropriate consent forms and agreed to be available for follow-up clinical visits to include postoperative radiographs.

The following exclusion criteria were used for patients in this study: heavy smokers (>ten cigarettes per day), uncontrolled diabetics, known bruxers, active

infections in the surgical sites, pregnancy, and need for bone augmentation in the surgical sites.

All patients had at least five implants placed. The patients presented with either edentulous mandibles (n = 20) or Type III–IV periodontitis (n = 7). The 7 patients who presented with periodontitis consented to extraction of the remaining teeth and alveolectomies to remove alveolar bone to approximately the apical 1/3 of the extraction sites prior to implant placement at the same surgical appointment. All patients were restored with fixed implant prostheses on the day of surgery.

Diagnostic work-ups consisted of physical and radiographic examinations, diagnostic casts, surgical guides, and fabrication of immediate dentures.

Success Criteria

The following criteria were established for implants to be considered successful at the 12-month recall appointments: no macroscopic implant mobility when tested with opposing metallic instrument handles, absence of peri-implant radiolucencies on panoramic radiographs, no peri-implant infections, absence of pain and/or paresthesias.

Surgical Protocols

Two protocols were used: placement of implants into edentulous mandibles, and placement of implants into mandibular bone immediately after tooth extraction and alveolectomy. All surgeries were performed in outpatient settings, with local anesthesia. Patients were premedicated with 2 g of amoxicillin 1 hour prior to surgery, and they also received 500 mg of amoxicillin four times a day for 7 days postoperatively. Implant sites were prepared according to the standard protocol using low-speed drilling and irrigation with sterile saline. Irrigation was not used during actual implant placements. The surgical protocol mandated crestal implant placement.[16]

For the edentulous patients, implants of at least 10 mm lengths for 4-mm diameter implants and at least 8.5 mm lengths for 5-mm diameter implants (n = 2, both distal to the mental foramen) were placed according to a single-stage surgical protocol (Table 1). The implants had to achieve insertional torque values of at least 30 Ncm measured on the drilling units. If the 4.1-mm diameter implants did not achieve this insertional torque, the 5-mm diameter implants were placed. All 5-mm diameter implants achieved primary stability.

For those patients who presented with Type IV periodontitis, their remaining mandibular teeth were extracted and alveolectomies were performed with rongeurs and carbide burs so that the implants would be placed into basal bone. Implants of at least 10 mm lengths and 4 and 5 mm diameters were placed according to a single-stage surgical protocol. The implants had to achieve insertional torque values of at least 30 Ncm as measured on the drilling units. If the 4.1-mm diameter implants did not achieve this insertional torque, the 5-mm diameter implants were placed. All 5-mm diameter implants achieved primary stability.

Table 1. Characteristics of 151 Immediately Loaded Implants

	Diameter (mm)		
Length (mm)	*4.1*	*5*	*Total*
8.5	0	2	2
10	18	4	22
11.5	52	31	83
13	16	15	31
15	5	0	5
18	8	0	8
Total	99	52	151

Panoramic radiographs were taken at the surgical appointments after implant placement, abutment connection, and prosthesis insertion.

Restorative Protocols

Immediate mandibular dentures were constructed in conventional fashion including: preliminary and definitive impressions, jaw relation records, and wax try-in appointments. The dentures were made with heat-cured acrylic resin (Lucitone 199, Dentsply, York, PA).

The treatment objective was to deliver the cross-arch splinted, fixed restorations within 5 hours of implant placement. Fifteen patients were treated with cement-retained prostheses (Figs 1 through 3); 12 patients were treated with screw-retained prostheses (Figs 4 through 6). Prosthetic designs were decided upon through collaborative efforts among the patients, surgeon, restorative dentists, and laboratory technicians. The goal was to have fixed implant-retained prostheses that provided

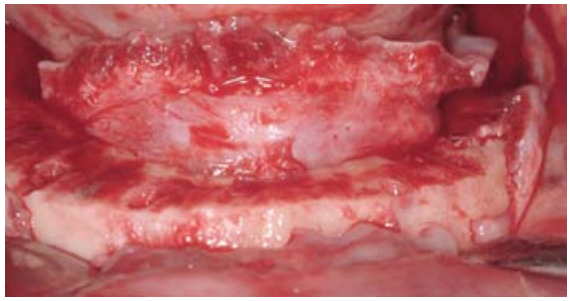

Figure 1. Clinical photograph of patient immediately after the teeth were extracted and alveoloplasty performed to levels at or near the apices of the extracted teeth.

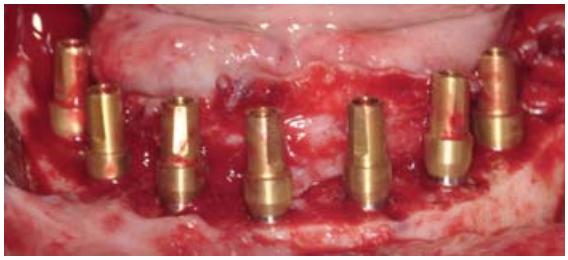

Figure 2. For the cement-retained prostheses, the surgeon placed these stock titanium abutments onto the implants with try-in screws. The abutments were adjusted extraorally until the dentures could be seated around them at the predetermined vertical dimension of occlusion.

cross-arch stabilization and minimized micromotion of the implants during osseointegration.

Cement-retained and screw-retained prostheses differed in the actual manner in which they were fabricated; however, the materials and principles were consistent with both treatment modalities. For both procedures, the implant components were manufactured by Implant Innovations, Inc. For the cement-retained prostheses, the surgeons, prior to wound closure, placed prefabricated titanium alloy abutments. These abutments were available in either straight cylinders or 15° preangled configurations. In order to ensure that the abutments were within the borders of the dentures, straight abutments were generally used in the anterior mandibular segments and preangled abutments were generally used in the posterior segments. The abutment screws were hand-tightened by the surgeons at the time of abutment connection, and the patients were discharged to the prosthodontists for the prosthetic portions of treatment.

Abutment preparation for both axial inclination and interocclusal clearance was accomplished outside of the mouth. In three instances, alginate impressions were made at the time of abutment placement, and

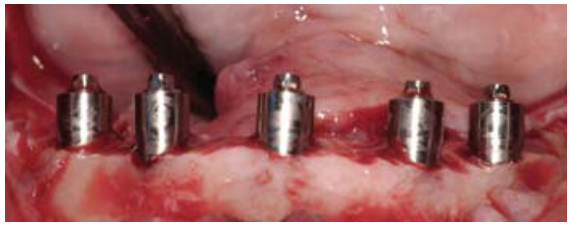

Figure 4. For the screw-retained prostheses, the surgeon placed these screw-retained abutments onto the implants with abutment screws.

diagnostic casts were fabricated and placed on a dental surveyor to assess parallelism of the abutments. The nonparallel abutments were prepared as needed to achieve an appropriate path of insertion/withdrawal. Once the abutments allowed for a path of insertion without undercuts, the abutment screws were torqued to 20 Ncm with a torque device.

The location of the abutments was transferred to the intaglio surfaces of the dentures by identifying the occlusal aspects of the abutments with indelible pencil (Dr. Thompson's Sanitary Color Transfer Applicators, Great Plains Dental Products Co., Inc., Kingman, KS). The dentures were adjusted until they could be seated with the patients in centric occlusion at the predetermined vertical dimension of occlusion. The screw access openings were blocked out with cotton and restored with light-cured composite resin.

A rubber dam was cut and fit around the abutments. The rubber dam served to isolate the surgical field from the prosthetic materials being used to reline the dentures. Autopolymerizing denture acrylic resin (Bosworth Original Truliner, Bosworth Co., Skokie, IL) was mixed to a creamy consistency. Some of the resin was loaded into a 12-cc syringe and injected around the cervical aspects of the abutments; the remainder was loaded into the intaglio surface of the dentures.

The dentures were seated onto the abutments and the patients were guided into centric occlusion at the

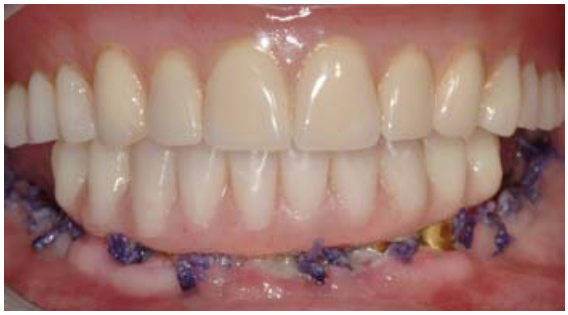

Figure 3. Mandibular cement-retained prosthesis in place just prior to the patient leaving the office on the day of surgery.

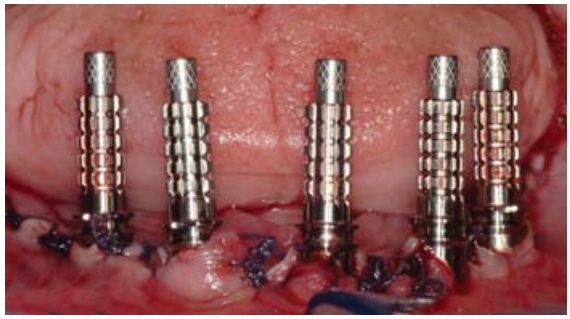

Figure 5. Temporary cylinders were fitted to these abutments and picked up inside the dentures with autopolymerizing acrylic resin.

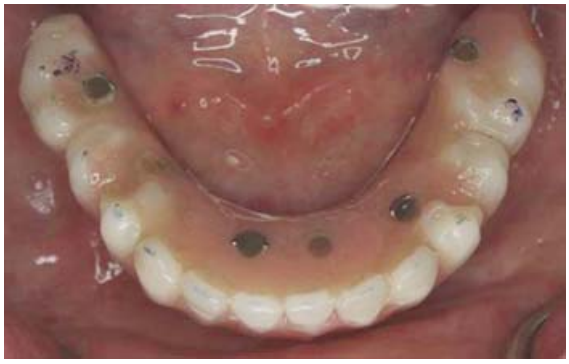

Figure 6. Occlusal view of screw-retained prosthesis in place just prior to the patient leaving the office on the day of surgery.

preestablished vertical dimension of occlusion. The resin was allowed to reach its initial set, and the dentures were removed. The final set occurred with 120° water in a pressure pot at 15 psi, for 10 minutes. The dentures were contoured, finished, and polished (Fig 7). They were reinserted onto the abutments and checked for fit relative to the soft tissues and occlusion. These dentures were cemented to the abutments with glass ionomer cement (GC Fuji Plus, GC Corp., Tokyo, Japan).

The procedures for the screw-retained prostheses were similar to the procedures described above. The surgeons placed the screw-retained abutments (IOL Abutments) prior to wound closure. Generally, 3- and 4-mm abutments were selected so that the margins would be supra-gingival. The abutment cylinders (IOL Abutment Cylinders) were connected to the abutments with 15-mm-long laboratory screws (WSK15). The occlusal aspects of the cylinders were identified with indelible pencil and the dentures were seated. Adjustments were made in the dentures until they could be seated around

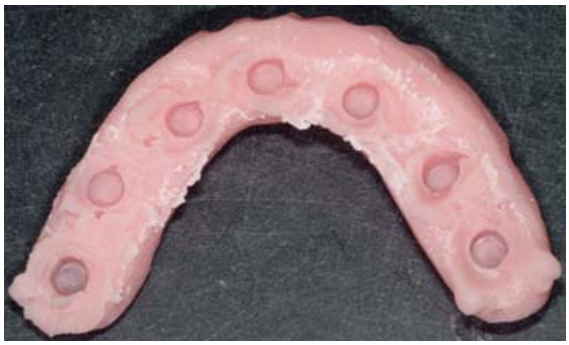

Figure 7. Intaglio surface of cement-retained dentures; the resin was polymerized before finishing, and polishing procedures were completed.

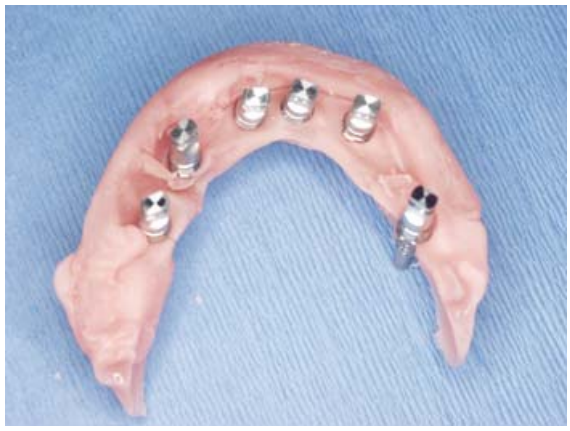

Figure 8. Intaglio surface of screw-retained prosthesis with laboratory analogs in place.

the cylinders without interference and the patients could achieve centric occlusion. Since these prostheses were screw-retained, holes were made in the dentures corresponding to the implants and abutments. Rubber dams were placed around the cylinders and acrylic resin was mixed and placed as described for the cement-retained prostheses. The resin polymerized with the patients in centric occlusion at the predetermined vertical dimension of occlusion.

After the resin had reached its initial set, the prostheses were unscrewed and removed. The rubber dam remained attached to the cylinders imbedded inside the dentures. Laboratory abutment analogs, acting as polishing protectors, were placed onto the cylinders and additional resin was added as needed to fill in any voids (Fig 8). The dentures were placed into the pressure pot and cured. The prostheses were finished and polished in conventional fashion. The intaglio surfaces of both types of prostheses were convex bucco-lingually and did not exert any pressure on the soft tissues (Figs 9 and 10). All the prostheses were totally implant-supported.

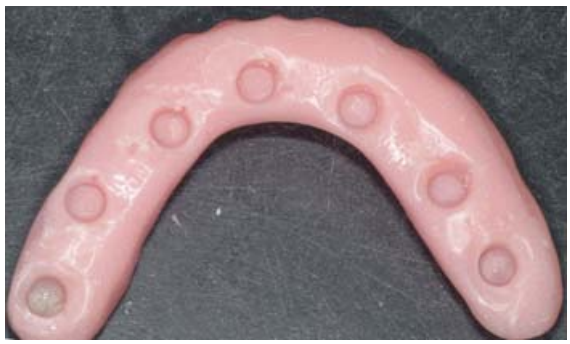

Figure 9. Cement-retained prosthesis prior to insertion.

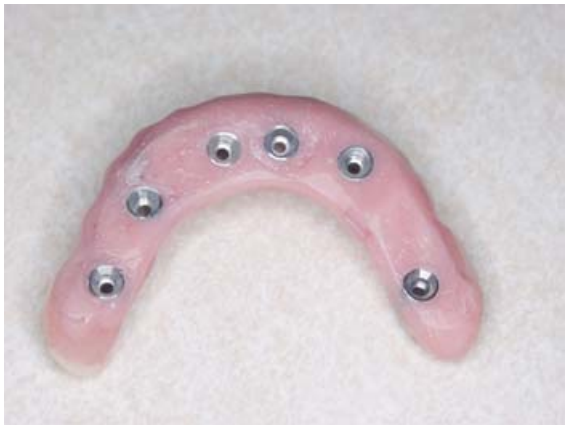

Figure 10. Screw-retained prosthesis prior to insertion.

The abutment screws were torqued to 20 Ncm and the retaining screws were torqued to 10 Ncm with a torque instrument. The screw access openings were blocked out with cotton and sealed with light-cured composite resin.

For all patients, occlusions were adjusted to have even contacts throughout the prostheses. In Class II malocclusions, the anterior teeth were out of contact. Patients were discharged with postoperative instructions for warm salt-water rinses and soft diets. Patients were seen on the first postoperative day and at 2, 4, and 8 weeks postoperatively. Patients were advised to maintain a soft diet for the first several weeks postoperatively. Regular diets were initiated 6 weeks post-implant/prosthesis placement. Patients were also seen at 3, 6, 12, and 18 months. Postoperative radiographs were taken at the 12-month visits to verify bone apposition to the implants. The prostheses were removed at the 12-month recall appointments. Once the prostheses were removed, the individual implants and abutments were evaluated for stability and the abutment screws were tested at 20 Ncm of torque. All the patients continued to wear the original acrylic resin prostheses for the duration of the study.

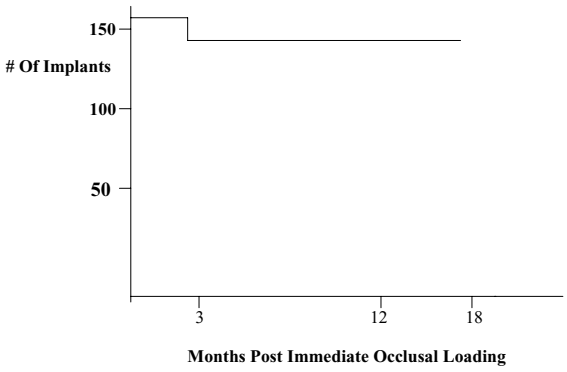

Figure 11. Life-table analysis of implants.

Results

All the prostheses (n = 27) were intact at the 12-month follow-up appointments. A total of 151 implants were placed and restored with immediate occlusal function (Table 1). There were 130 implants placed between the mental foramen; 21 implants were placed distal to the mental foramen. Three patients each lost one implant within the first 3 months (n = 3) (Fig 11). All the failed implants (two 4.1 mm diameters; one 5 mm diameter) were distal to the mental foramen. These patients reported localized pain and had soft tissue swelling around the abutments. The prostheses were removed at these appointments, and the loose, nonintegrated implants were removed. The prostheses were modified and reattached to the remaining abutments.

For this study, 148 implants in 27 patients were followed for at least 18 months after implant placement and occlusal loading. The implant CSR was 98.0%. The prostheses' CSR was 100%. None of the implant failures compromised prosthetic function.

At the 12-month follow-up appointments, panoramic radiographs were taken prior to removal of the prostheses. All abutments were tested by applying 20 Ncm torque to the abutment screws with a torque instrument. None of the implants were mobile, judging by placing two metallic instrument handles onto the abutments and applying force buccally/lingually and mesially/distally. All abutments were clinically stable, and the implants were judged to be osseointegrated. There was no pain with application of torque to the abutment screws of any of the implants.

All patients were available for the recall appointments. Patients were also recalled 18 months post-implant placement. Follow-up visits will be scheduled for 24, 36, and 48 months post-implant placement, when the prostheses will be removed again for clinical evaluation of the implants.

Discussion

There is a growing trend in implant dentistry to decrease the treatment times associated with

implant therapy.[6,8-14,17] One way this can be accomplished is with an immediate occlusal loading protocol.[8-14,17] The immediate occlusal loading protocol demonstrated in this report is technique-sensitive and is indicated for fewer patients than traditional loading protocols. Clinicians must be comfortable with using autopolymerizing acrylic resin intraorally in terms of using appropriate amounts and removing the prostheses at the appropriate time during the polymerization process. Insertional torque values of at least 30 Ncm may not be sensitive enough to validate immediate occlusal loading of dental implants. Other factors may need to be considered to determine if implants are candidates for immediate occlusal loading. For example, stresses may be developed and transferred to the implants secondary to the manner in which the prostheses are constructed with autopolymerizing acrylic resin at the time of implant placement. Occlusal forces generated on the implants during the healing period, in terms of how much force and when the forces are generated, may also impact osseointegration of immediately loaded implants.

The results of this study agree with the results of similar studies showing high success rates for immediate occlusal loading in edentulous mandibles with fixed prostheses.[9-14] The results of this study also demonstrate CSRs that are consistent with CSRs that have been reported in studies involving endosseous implants with traditional protocols and unloaded healing.[3,4]

This study shares several significant characteristics with the above immediate loading studies: all the implants achieved primary stability (at least 30 Ncm) at the time of implant placement; all the implants were splinted together with fixed prostheses at the time of implant placement; all implants were placed into edentulous mandibles. The implants placed immediately post tooth extractions achieved the same levels of primary stability in bone apical to the extraction sockets of the missing teeth, as did the implants placed into long-term edentulous mandibles.

Standard 4.1-mm diameter implants obtained primary stability 66% of the time (99/151). Implants of 5 mm diameter obtained primary stability in the remaining instances. The authors never had to use 6-mm diameter implants during the course of this study. Wide diameter implants (6 mm) may not be appropriate for immediate occlusal loading because of the potential for fenestration of the osteotomies. The use of standard sized implants allowed the authors more opportunities to complete the immediate occlusal loading protocol as described in this study, as opposed to abandoning implant sites that did not provide primary stability secondary to lack of bone.

Clinically, the screw-retained prostheses were more amenable to removal at the 12-month follow-up appointments when compared with the cement-retained prostheses. Initially, the cement-retained prostheses were quicker and slightly less cumbersome to fabricate, but much more difficult to remove at the appropriate recall appointments. All the cement-retained prostheses were stable at the 12-month recall appointments. There were no problems noted relative to acrylic resin fracture, color change, or odor.

Bone levels in this study were not quantified due to difficulties in making radiographs in a consistent, reproducible fashion in the two clinical settings.[13] Radiographs were taken to identify bone apposition onto the implant surfaces and also to verify the absence of radiolucencies. All the implant failures (n = 3) occurred within the first 3 months after immediate occlusal loading, and all the implant failures were distal to the mental foramen. The surgeons did not quantify bone quality at the time of implant placement. No other implants failed. This is consistent with other reports involving this implant surface.[9,13,14]

Conclusions

Within the limitations of this prospective observational study, complete fixed implant-retained prosthetic replacement of all mandibular teeth can be predictably accomplished on the day of implant placement. Implants placed according to this protocol had CSRs similar to the original nonloaded healing protocols with commercially pure, machined, titanium implants. For immediate occlusal loading of dental implants to be viable, implants must obtain insertional torque values of at least 30 Ncm and be rigidly splinted together. The CSR for the acrylic resin prostheses was 100% and demonstrated that acrylic resin prostheses were adequate for immediate occlusal loading for the length of this study.

Further prospective studies with longer follow-ups are warranted to address the above conclusions and limitations of this study.

Acknowledgments

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