Immediate loading of hydroxyapatite-coated implants in the maxillary premolar area: Three-year results of a pilot study

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Statement of the problem. Although immediate loading of implants in the edentulous mandible has been described in the literature, there is limited information regarding immediate loading of single implants.

Purpose. This prospective clinical study evaluated the clinical parameters of immediately loaded single-threaded hydroxyapatite-coated (HA) root form implants.

Material and methods. Ten human subjects were included in this report. In all situations, a screw-retained provisional acrylic resin crown was placed in the maxillary premolar area immediately after implant surgery. Definitive screw-retained metal-ceramic prostheses were placed 6 months after surgery. Standardized periapical radiographs were made before implant surgery, immediately after surgery, and 1, 3, 6, 12, and 36 months after implant surgery. Mobility (measured with the Perio-Test), distance from implant platform to the gingival crevice, distance from the implant platform to the depth of the sulcus, peri-implant probing depth, and bleeding on probing index were recorded at 3, 6, 12, and 36 months after implant placement. For clinical measurements, a 5-mm healing abutment was placed.

Results. All implants appeared clinically osseointegrated. Standardized radiographs demonstrated mean marginal bone loss of 0.6, 0.7, 0.8, 0.9, and 1.0 mm at 1, 3, 6, 12, and 36 months after implant surgery, respectively. Mean implant mobility was −3.3 at the day of surgery and −3.8, −3.4, −3.6, and −4.2 at 3, 6, 12, and 36 months, respectively. The distance from implant platform to the gingival crevice was 2.8, 2.4, 2.4, and 3.1 mm at 3, 6, 12, and 36 months, respectively. The distance from the implant platform to the depth of the sulcus was 0.8, 0.9, 0.9, and 1.1 mm at 3, 6, 12, and 36 months, respectively. The peri-implant probing depth was 3.6, 3.3, 3.2, and 4.3 mm at 3, 6, 12, and 36 months, respectively. The bleeding on probing index was 0.4, 0.4, 0.4, and 0.1 at 3, 6, 12, and 36 months, respectively.

Conclusion. The results of this prospective pilot study provide initial evidence that single root form implants may be immediately loaded when placed at the maxillary premolar area. (J Prosthet Dent 2004;91:228-33.)

CLINICAL IMPLICATIONS

The results of this pilot study indicate that patients who are partially edentulous in the maxillary premolar area may receive a provisional screw-retained crown at the time of implant surgery. Increased sample size is needed before these results can be generalized.

Dental implants have become a predictable treatment option for the completely[1,2] or partially[3,4] edentulous patient. A 3- to 6-month healing period is usually recommended to achieve osseointegration before loading implants with a prosthesis.[5]

Immediate loading of endosseous root form implants has been described in the literature for eliminating the 3- to 6-month healing period. The technique has been described in combination with mandibular bar-retained overdentures,[6-8] complete arch implant-supported prostheses,[9-13] and partial edentulism.[14] However, several authors have reported that micromotion resulting from early implant loading can result in fibrous encapsulation of the implant.[15-21] Whereas most clinical studies have retrospectively examined implant survival rate after immediate loading, a few initial studies of immediate implant loading[22,23] have shown clinical results similar to the conventional 2-stage loading protocol.[24-28] Histologic evaluation from human beings regarding implants that received immediate loading has shown evidence of osseointegration.[29-31] Histologic evaluation in animals has demonstrated osseointegration when implants were immediately loaded.[32-34] Placement of a provisional prosthesis during[35,36] or after[37,38] second-stage surgery offers the potential for ideal soft tissue contours. Similarly, placement of a provisional prosthesis during implant surgery may create soft tissue contours that resemble

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Table I. Patient distribution

Subject	Age	Sex	Recipient site (maxilla)	Implant dimension (diameter × length) in mm	Bone quality[40]
1	62	F	Right first premolar	4.3×13	III
2	61	F	Left first premolar	4.3×13	II
3	65	M	Right first premolar	4.3×13	II
4	37	F	Right first premolar	3.5×13	III
5	40	F	Right first premolar	4.3×13	II
6	77	F	Left first premolar	4.3×13	II
7	62	M	Right first premolar	4.3×13	II
8	51	M	Right first premolar	4.3×13	II
9	69	M	Left first premolar	4.3×13	III
10	47	M	Right first premolar	5.0×13	II
Mean	57.1	N/A	N/A	N/A	N/A
Range	37–77				II–III

normal gingival architecture before placement of the definitive prosthesis.[23] The purpose of this study was to evaluate the clinical parameters of immediate loading single, hydroxyapatite-coated (HA) root form implants in the maxillary premolar region.

MATERIAL AND METHODS

In this study, human subjects were recruited on the basis of their need to restore a single missing maxillary first or second premolar. Ten consecutively treated human subjects, who completed a 36-month re-evaluation, were included in this report (Table I). All subjects were treated at the Center of Prosthodontics and Implant Dentistry at Loma Linda University School of Dentistry and signed the appropriate informed consent form approved by the Institutional Review Board. Inclusion criteria included an existing single partially edentulous space in the maxillary premolar region, presence of natural teeth mesially and distally to the edentulous space, as well as opposing occlusion (natural teeth or removable prosthesis), good oral hygiene, and willingness to return for follow-up examinations as outlined by the investigators. Patients were required to be at least 18 years old and able to read and sign the corresponding informed consent. Exclusion criteria included habits of cigarette smoking,[39] general health-compromising prognosis prohibiting implant surgery, such as stroke, recent infarction, severe bleeding disorders, diabetes, osteoporosis, and cancer, history of bruxism, or surgical site consisting of Type IV bone[40] as assessed during surgery by the surgeon. Diagnostic impressions were made with irreversible hydrocolloid (Jeltrate; Dentsply International, York, Pa). Impressions were poured with Type III dental stone (Microstone; Whip Mix Corp, Louisville, Ky). A wax pattern was formed in the area of the missing tooth. Periapical and panoramic radiographs were made before surgery for all patients.

At the time of implant placement, patients were given a choice of local anesthetic (LA) only, LA with oral sedation (Halcion 0.25mg), or LA with intravenous sedation. HA-coated threaded root form implants (Replace; Nobel Biocare, Yorba Linda, Calif) were placed in the maxillary premolar area for patients by 4 graduate students. Each surgeon had at least 1 year of surgical experience (having placed >35 implants). Full-thickness limited flap design was performed for implant placement (Fig. 1).[41]

In all patients, a screw-retained implant-supported provisional prosthesis was placed immediately after stage I surgery according to a previously described technique.[42] Briefly, a transfer impression of the implant was made using autopolymerizing acrylic resin (Pattern Resin; GC Corp, Tokyo, Japan) to connect an impression coping to the acrylic resin template (Triad; Dentsply International) that was fabricated before the surgery. The screw-retained provisional prosthesis was fabricated in the laboratory with autopolymerizing acrylic resin (Jet acrylic; Lang Dental Mfg Co, Wheeling, Ill) using a vacuum-formed matrix derived from the diagnostic wax-up made before surgery.

The provisional crown was hand-tightened (Fig. 2). Cotton pellets were placed into the access opening, and provisional restorative material (Cavit; 3M ESPE, St. Paul, Minn) was used to cover the opening. Interproximal contacts were evaluated with the use of a shim stock (Artus Co, Englewood, NJ), 10 μm in thickness. The shim stock had to pass through the mesial and distal contact points without being torn. The occlusion was also evaluated with the use of shim stock. Four layers of shim stock were required to pass between the provisional screw-retained crown and the opposing tooth when the subject was in the maximum intercuspation position. Antibiotics were prescribed (amoxycillin 500 mg, 1 every 6 hours for 10 days) and patients were asked to rinse with chlorexidine (Peridex; Zila

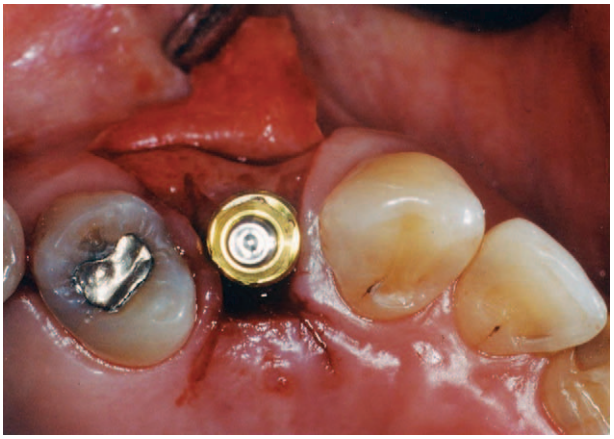

Fig. 1. Limited flap design used during implant placement.

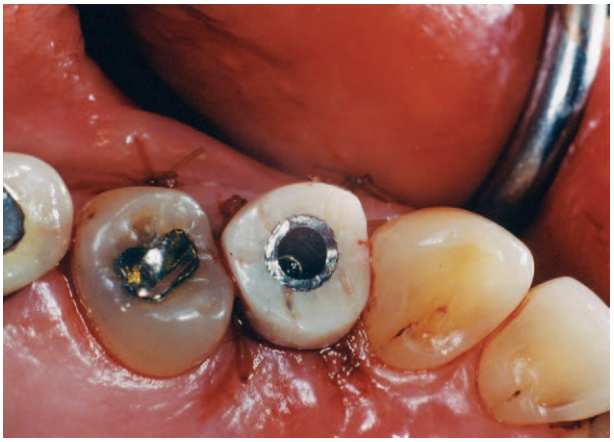

Fig. 2. Provisional crown placed on day of surgery.

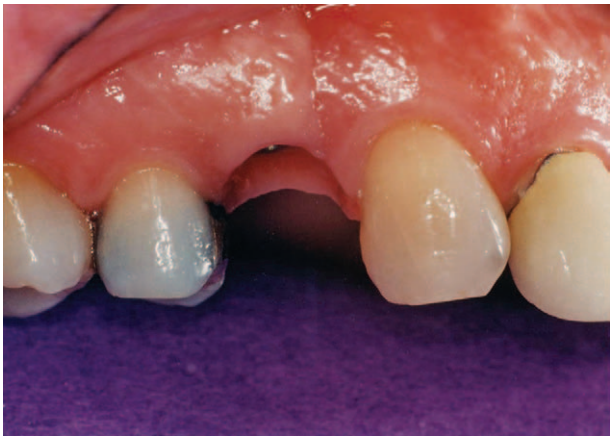

Fig. 3. Six months after implant surgery, soft tissue architecture created with use of provisional crown.

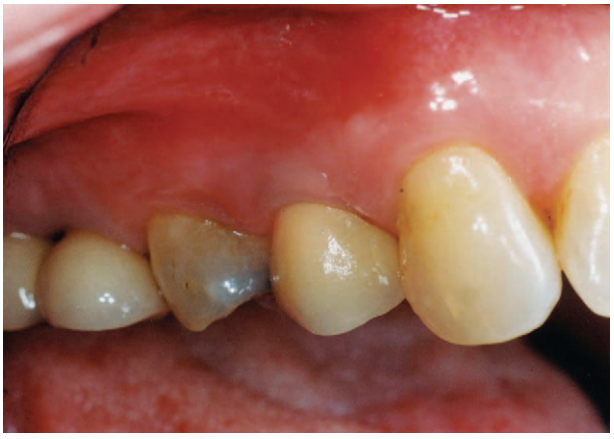

Fig. 4. Definitive metal-ceramic screw-retained crown.

Pharmaceuticals Inc, Phoenix, Ariz) twice each day for at least 2 weeks after the surgery.

Standardized periapical radiographs were made after implant placement with the long cone paralleling technique.[43] An occlusal index made of vinyl polysiloxane (Exabite; GC America Inc, Alsip, Ill) was attached to the film holder as previously described.[22] Vinyl polysiloxane was applied on the film holder, and the patient was asked to occlude on the holder until the impression material polymerized. Excess impression material was trimmed. The index was fabricated intraorally at the time of the provisional prosthesis placement and was used as an aid in standardizing the angulation and position of the film in relation to the beam. A similar film type (Kodak Ultra-speed DF-58; Eastman Kodak Co, Rochester, NY) was used for all patients; radiographs were made at 70 kV(p), 10 mA for 0.5 seconds, and then developed in an automatic radiograph film processor (810 Plus; Velopex International Inc, St. Cloud, Fla).

Implant mobility was evaluated using the Perio-Test device (Perio-Test; Siemens, Bensheim, Germany).[44,45] Implant mobility was recorded immediately after surgery with a 5-mm–long healing abutment in place. The tip of the device was placed at a 90-degree angle to the long axis of the implant, and at the top of the healing abutment. Patients were asked to remain on a soft diet for 1 month after surgery and to return in 2 weeks for suture removal.

At 1, 3, and 6 months after implant surgery, standardized radiographs were made with the provisional crown in place. At 3 and 6 months after implant surgery, the provisional screw-retained acrylic resin crown was removed. The following parameters were recorded after removing the provisional crown: (1) Periimplant probing depth (PPD) at accuracy of 1 mm, (2) bleeding index (BI),[46] (3) distance from the implant platform to the depth of the sulcus (PDS), and (4) distance from the implant platform to the gingival crest (PGC). Four measurements were recorded for each implant: Midbuccal, midmesial, midpalatal, and

Table II. Clinical parameters; mean (SD)

Time (Months)	MBL (mm)	Mobility	PGC (mm)	PDS (mm)	PPD (mm)	BI
0*	N/A	−3.3 (1.7)	N/A	N/A	N/A	N/A
1	0.6 (0.20)	N/A	N/A	N/A	N/A	N/A
3	0.7 (0.23)	−3.8 (1.24)	2.8 (0.93)	0.8 (0.44)	3.6 (1.02)	0.4 (0.36)
6	0.8 (0.30)	−3.4 (1.0)	2.4 (0.73)	0.9 (0.46)	3.3 (0.57)	0.4 (0.32)
12	0.90 (0.32)	−3.6 (1.2)	2.4 (0.46)	0.9 (0.37)	3.2 (0.45)	0.4 (0.42)
36	1.0 (0.26)	−4.2 (0.7)	3.1 (0.84)	1.1 (0.33)	4.3 (0.75)	0.1 (0.18)

MBL, Mean bond loss; *PGC,* distance from the implant platform to the gingival crest; *PDS,* distance from the implant platform to the depth of the sulcus; *PPD,* peri-implant probing depth; *BI,* bleeding index.
*Day of surgery.

middistal. The 4 measurements were averaged, and the mean corresponded to each parameter.

A 5-mm–long healing abutment was then placed and hand-tightened. With the healing abutment in place, the mobility of the implant was recorded with the Perio-Test device. Two investigators performed all data collection and clinical measurements. A calibration process was performed before collecting the data. Measurements were made in 7 patients by both examiners. Interexaminer and intraexaminer reproducibility were measured and appeared to be high. Intraexaminer reproducibility had a 0.93 intraclass correlation coefficient, and interexaminer reproducibility had a 0.90 intraclass correlation coefficient.

The impression for the definitive screw-retained metal-ceramic restoration was made 6 months after implant surgery. A retentive screw was placed through the provisional crown according to the open tray technique.[23] The definitive impression was made and the provisional crown was transferred with the impression. The anatomy of the peri-implant soft tissue was preserved through the provisional crown (Fig. 3). The impression was poured with Type III dental stone (Microstone; Whip Mix Corp), and the cast was fabricated using pink-colored vinyl polysiloxane (Gi-Mask; Coltène/Whaledent Inc, Cuyahoga Falls, Ohio) to simulate the soft tissue.[47] The peri-implant soft tissue architecture was duplicated in the cast. The definitive screw-retained metal-ceramic crown was inserted 2 weeks later (Fig. 4).

Standardized radiographs, mobility, and PPD, PDS, PGC, and BI measurements were made and recorded 12 and 36 months after implant surgery. The definitive prosthesis was removed, and all data were collected as at the 3- and 6-month re-evaluation periods. The results were evaluated according to the implant success criteria as defined by Smith and Zarb.[48] The data collected represent descriptive measurements of the clinical parameters recorded.

RESULTS

For all patients, implants healed uneventfully with no complications. Radiographic examination revealed 0.6 mm of marginal bone loss (MBL) at 1 month after surgery as compared with the radiograph made immediately after surgery. The corresponding marginal bone loss in 3, 6, 12, and 36 months was 0.7, 0.8, 0.9, and 1.0 mm, respectively (Table II).

Examination with the Perio-Test unit revealed −3.3 mobility on the day of surgery, whereas mobility was recorded as −3.8, −3.4, −3.6, and −4.2 at 3, 6, 12, and 36 months after surgery (Table II). Perio-Test values were rounded to 1 decimal and represent the average of Perio-Test values obtained that are integers. PGC was 2.8 mm 3 months after surgery, and 2.4, 2.4, and 3.1 mm at 6, 12, and 36 months after surgery (Table II). PDS revealed a distance of 0.8 mm 3 months after operation, whereas the corresponding numbers for the 6, 12, and 36 months postoperative measurements were 0.9, 0.9, and 1.1 mm, respectively (Table II). PPD was 3.6, 3.3, 3.2, and 4.3 mm at 3, 6, 12, and 36 months, respectively (Table II). BI was measured to be 0.4, 0.4, 0.4, and 0.1 at 3, 6, 12, and 36 months after surgery (Table II).

DISCUSSION

The results of this short-term clinical study demonstrated that HA-coated root form implants placed at the maxillary premolar area may be immediately loaded. The success rate was 100% after 3 years post-loading. The peri-implant soft tissue parameters (bleeding on probing, probing depth, peri-implant soft tissue level), mobility, and marginal bone level appeared to be in agreement with findings of previous retrospective studies regarding conventional 2-stage loading protocol.[24-27]

McGlumphy et al[28] performed a prospective study using HA-coated implants placed with the conventional 2-stage protocol. In that study it was found that implants exhibited average values of 1.1 mm of bone loss in the posterior maxilla, −4.89 Perio-Test Value, and 0.09 gingival bleeding index 5 years after implant placement. In an immediate loading protocol, Rungcharassaeng et al[22] demonstrated similar results using HA-coated implants placed in the anterior mandibular area. This study demonstrated bone loss of

1.16 mm, probing depth of 1.96 mm, and a −5.85 Perio-Test value 1 year after implant placement.

The present study demonstrates the use of single implants for an immediately loading protocol. Immediate loading of dental implants has been primarily described for the completely edentulous mandible using either a bar-retained overdenture[6-8] or a complete arch implant-supported fixed prosthesis.[9-12] It has been maintained that splinting of dental implants is required when immediate loading is planned.[12] In addition, it has been shown that early micromotion of implants can lead to differentiation of cells into fibroblasts.[15-18] It may be hypothesized that cross-arch stabilization in the reported completely edentulous situations may have provided the necessary stability. In the present study, the interproximal contacts have potentially provided this type of stability. Szmukler-Moncler et al[19] stated that there is a range of micromovement within which implants can still achieve osseointegration. Beyond a certain level of micromovement, ''deleterious micromovement,''[20] fibrous tissue will surround the implant, and osseointegration will not occur. This has also been supported by histologic evidence in humans from immediately loaded retrieved implants where a high degree of osseointegration was observed after long-term function.[29-31] Further research is needed to assess the potential of dental implants to achieve and maintain osseointegration when immediately loaded.

Animal studies provide histologic assessment of bone to implant contact when treatment is performed under a standardized protocol. Romanos et al,[32] in a primate study, demonstrated that implants treated with air-borne-particle abrasion can achieve osseointegration when immediately loaded. Piattelli et al,[34] in a primate study, reported that immediately loaded implants had significantly more bone-to-implant contact as compared with implants placed using the conventional 2-stage protocol.

Placement of a provisional restoration on the day of implant surgery offers esthetic, psychological, and functional advantages as compared with the use of a provisional removable prosthesis. It also eliminates second-stage surgery, reducing the patient's discomfort and additional procedural cost. In addition, the length of the treatment is reduced because soft tissue heals simultaneously with hard tissue. It has been maintained that ideal soft tissue contours can be achieved if a provisional restoration is placed during[35,36] or after[37,38] the second-stage surgery. Provisional restorations in partially edentulous patients help confirm esthetics, contours, accessibility for oral hygiene, and duplicate the results to the definitive restoration.[38] A provisional restoration allows for communication between the patient, dentist, and technician. The soft tissue around the implants can heal according the contours of the provisional restoration. However, if the provisional restoration is placed after the implant becomes osseointegrated, an additional 3- to 6-month healing period is needed for soft tissue healing.[35-38] The protocol followed in this study eliminated the period necessary for soft tissue healing and contouring, because healing occurred concurrently with the implant osseointegration. Definitive restoration and soft tissue contouring of the maxillary premolars in this study was feasible 6 months after implant placement.

It should be noted that the results of this pilot study are derived from a sample of 10 patients. These results should be cautiously evaluated before immediate loading of single implants can be applied on a routine basis. A larger sample size and long-term follow-up are needed before definitive conclusions can be made.

CONCLUSIONS

The results of this pilot study demonstrated that HA-coated implants placed in the maxillary premolar region may be immediately loaded by placing a screw-retained acrylic resin crown the day of implant surgery. The 3-year post-loading implant success rate was 100%. Bone loss around implants was 1.0 ($\pm$0.26) mm 3 years after implant placement and loading.

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