Immediate Restoration of Single-Tooth Implants in Mandibular Molar Sites: A 12-month Preliminary Report

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Purpose: *The aim of this prospective clinical study was to evaluate the survival rates at 12 months of transmucosal implants placed in the posterior mandible and immediately restored with single crowns.* ***Materials and Methods:*** *Thirty ITI dental implants with sandblasted, acid-etched surfaces were placed in 30 patients missing at least 1 mandibular molar and immediately restored if acceptable primary stability was attained. Primary stability was measured with resonance frequency analysis (RFA) using the Osstell device, and only implants with a stability quotient greater than 62 were included in the study. RFA measurement and radiographic assessment were made at baseline and 6 months after implant placement. Plaque Index, Bleeding Index, probing depth, attachment level, and width of keratinized tissue were measured at the 12 month follow-up examination.* ***Results:*** *At 12 months, only 1 implant had been lost; it was removed because of acute infection. Radiographic as well as clinical examination confirmed osseointegration of all implants, with a survival rate of 96.7%.* ***Discussion:*** *Interestingly, implant stability as measured using RFA did not increase significantly from baseline to 12 months (P > .05).* ***Conclusion:*** *The present study showed that immediate restoration of transmucosal implants placed in the mandibular area with good primary stability can be a safe and successful procedure. However, larger, long-term clinical trials are needed to confirm the present results.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:855–860

Key words: *dental implants, immediate loading, single-tooth implants*

Osseointegrated titanium dental implants have been successfully used to restore completely and partially edentulous patients.[1–6] The original surgical protocol proposed by Adell and associates[7] and Brånemark and coworkers[8] considered a healing period of 3 to 6 months free from functional loading as optimal to obtain osseointegration of titanium dental implants. Over the years, several studies have reported a high percentage of success with both submerged and nonsubmerged healing.[9,10]

In the last 3 decades, advances in biomaterial technology and continuous clinical research have provided clinicians with improved protocols to provide more advanced treatment options. Some of the original prerequisites of osseointegration have been reassessed to satisfy continuously increasing patient expectations of reduced treatment time, improved esthetics, and increased comfort.

The long-term success of immediately loaded implants has been investigated in animal[11–14] and human studies[15–17] with encouraging results. Most of the studies have reported on implants placed in the anterior segment of the mandible, where bone of good quality is often present and proper initial implant stability can be easily achieved. The aim of

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the present prospective clinical study was to evaluate the implant survival and success rates at 12 months for 30 single implants placed in the posterior mandible and immediately restored.

MATERIALS AND METHODS

Study Sample

Thirty patients (12 females and 18 males) ranging in age from 27 to 59 years (mean age 47.5 years) were enrolled in this study. All patients were recruited based on their need for the restoration of a single missing mandibular molar. The patients declined the option of wearing a temporary removable prosthesis and were informed of the option of immediately restoring their implants. Natural teeth adjacent to the edentulous space were required to have an intact occlusal surface and be free from infection. Additional criteria for entering the study included sufficient bone quantity (ie, sufficient bone height and width) to allow the placement of implants with a minimum diameter of 4.1 mm and minimum length of 10 mm; an occlusal pattern that allowed for bilateral stability; willingness to follow the study protocol; and the provision of informed consent.

Exclusion criteria from the study were compromised general health conditions that would jeopardize the bone healing process (eg, diabetes, osteoporosis, blood disorders, allergies to titanium); severe maxillomandibular space discrepancies; severe parafunctional habits (bruxism or clenching); drug or alcohol abuse; poor oral hygiene, and the need for tissue augmentation procedures during surgery.

All the patients were referred to a restorative clinician for a complete presurgical evaluation, including a diagnostic waxup to determine final tooth position and the fabrication of a surgical template. Diagnostic casts of each patient's maxillomandibular relationship were evaluated. Periapical radiographs, panoramic radiographs, and computerized tomograms were also obtained if necessary.

Surgical Protocol

The implants were placed with a sterile surgical technique as described by Buser and colleagues.[18] All surgical procedures were performed with the aid of a custom-made template. ITI solid implants with a sandblasted, acid-etched surface (Straumann Institute, Waldenburg, Switzerland) were placed according to the manufacturer's indications. Medications prescribed to all patients included 1 g amoxicillin (Amoxicillina; Merck Pharma, Milan, Italy) twice daily for 5 days; 200 mg ipubrofen (Buscopan; Boehringer Ingelheim Italia, Milan, Italy) as needed; and a chlorhexidine mouthwash (PlakOut, BYK Gulden, Cormano, Italy) twice daily for 2 weeks following placement. The sutures were removed 7 to 10 days after surgery.

All implants were clinically stable at the time of placement, and the implant stability was confirmed with resonance frequency analysis (RFA) measurements (Osstell, Integration Diagnostics, Göteborg, Sweden). The Osstell device was used according to the recommendations provided by the designer.[19–21] If implant stability quotient (ISQ) values obtained from the Osstell measurements exceeded 62, the implants were included in the study. Thirty implants qualified for the study.

Prosthetic Protocol

The initial restorative treatment was started immediately following implant placement, while the patient was still under anesthesia. A screw-retained transfer coping was connected to the implant (Fig 1a). Wound closure was then achieved by suture (Fig 1b). Subsequently, an impression was made using a polyether rubber material with a customized impression tray. A 3-mm healing cap was then placed on the implant. Within 24 hours after implant placement, a temporary screw-retained resin restoration was fabricated and connected to the implant (Fig 1c). Following incorporation of the provisional restoration, a periapical radiograph was obtained in a standardized manner, using a silicone impression material as baseline reference (Fig 1d). The occlusal contacts were restored with the provisional crowns.

Follow-up Evaluation

All patients were placed on a strict follow-up regimen until soft tissue healing was completed. Clinical parameters measured at the time of implant restoration were width of keratinized mucosa, which measured in millimeters at the midbuccal aspects; stability of the implants ie, the ISQ obtained with the Osstell machine; and bone level, ie, the distance from the implant shoulder to the first bone-implant contact (DIB) mesially and distally to the implant, which was measured using periapical radiographs taken in a standardized manner.[10,22]

At 6 and 12 months postplacement, all the patients underwent clinical and radiographic examinations, which included evaluation of the following parameters:

- Modified Plaque Index on the mesial, distal, buccal, and lingual-palatal surfaces of the implants[23]
- Modified Bleeding Index on the mesial, distal, buccal and lingual-palatal surfaces of the implants[23]

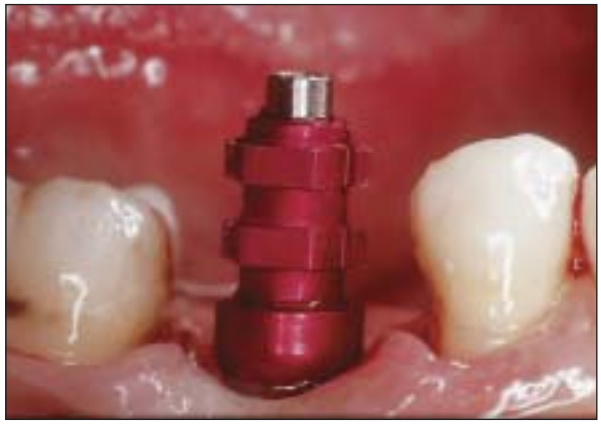

Fig 1a A screw-retained transfer coping is connected to the implant for impression making.

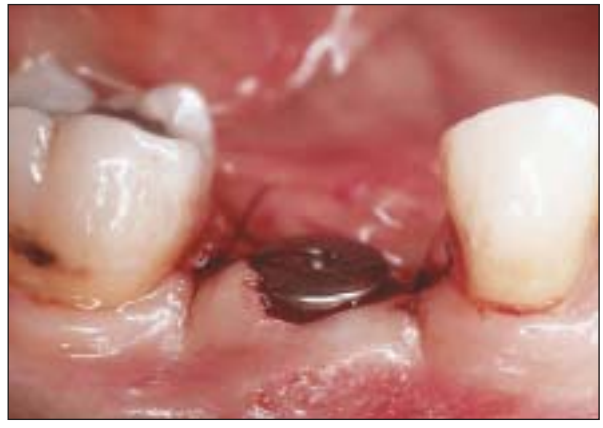

Fig 1b Sutures around a healing cap.

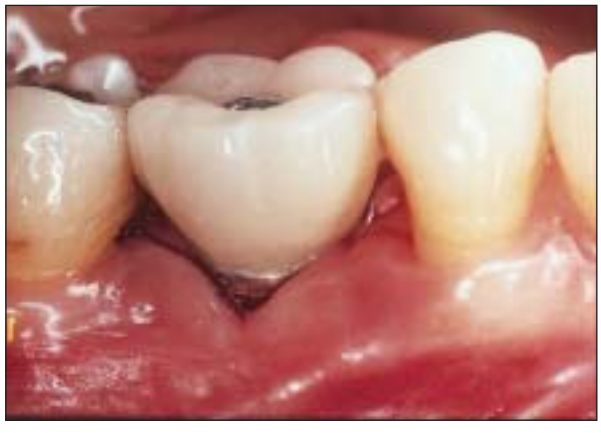

Fig 1c A temporary screw-retained resin restoration is connected to the implant after 24 hours.

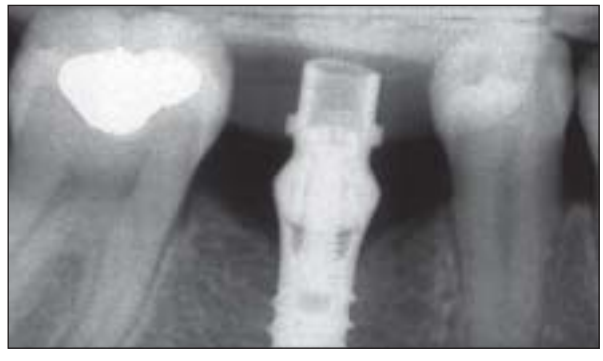

Fig 1d A periapical radiograph taken in a standardized manner.

- The presence or absence of suppuration
- Probing depth, measured to the nearest millimeter with a Hu-Friedy PGF-GFS periodontal probe (Hu-Friedy, Chicago, IL) at the mesial, distal, buccal and lingual-palatal sides of the implants
- The distance between the implant shoulder and the mucosal margin (DIM), measured to the nearest millimeter. If the implant shoulder was subgingivally located, the measurement was recorded as a negative value. Measurements were taken at 4 sites per implant.
- Attachment level, computed for each site by adding the PD to the DIM
- Width of keratinized mucosa, measured in millimeters at the midbuccal aspect
- Implant stability, which was evaluated using the ISQ value obtained with the Osstell machine
- DIB mesially and distally to the implant, which was measured using periapical radiographs obtained in a standardized manner[10,22]

Data Analysis

Clinical measurements for the 30 implants were made for each patient by averaging the readings for each clinical parameter for each patient, since the within-subject variation was much lower than the among subject-variation. Subsequently, the means and medians were calculated for the means per patient at baseline and at the 6-month follow-up examination. The comparison between the baseline and 6-month data was performed with the Student *t* test for paired data (the results of which were considered statistically significant at the level $P \leq .05$).

RESULTS

Thirty immediately restored implants in 30 patients were included in this study. The implant positions and dimensions are reported in Table 1. During the 12-month follow-up period, 1 implant was removed

Table 1 Implant Position and Dimension in 29 Sites

Implant size (w × l) (mm)	Implant position*		
	30 (46)	19 (36)	Total
4.1 × 12	6	7	13
4.8 × 10	5	6	11
4.8 × 12	2	3	5

*Tooth number.

Table 2 Implant Stability Quotient, Width of Keratinized Mucosa, and DIB for 29 Immediately Loaded Implants

Parameters	Baseline	6-month visit	
	Mean (SD)	Mean (SD)	*P*
Implant stability quotient	70.6 (5.8)	71.7 (6.2)	NS
Keratinized mucosa (mm)	3.1 (0.5)	2.9 (0.5)	NS
DIB	1.9 (0.4)	2.3 (0.4)	NS

DIB = distance from the implant shoulder to the first bone-implant contact; NS = not statistically significant.

Table 3 Clinical Measurements at the 12-Month Visit for 29 Immediately Loaded Implants

Clinical parameters	Mean	SD	Range
DIM (mm)	0.8	0.4	0.6 to 1.4
Probing depth (mm)	1.6	0.8	0.2 to 2.7
Attachment level (mm)	0.8	0.3	0.2 to 1.1
mPI	0.5	0.4	0 to 2
mBI	0.4	0.5	0 to 2

DIM = distance between the implant shoulder and the mucosal margin; mPI = modified Plaque Index; mBI = modified Bleeding Index.

4 weeks after placement because of acute infection in the implant site. The remaining 29 implants demonstrated a complication-free healing period and were stable during the entire follow-up period of 12 months. The mean ISQ value (± SD) was 70.6 ± 5.8 at baseline; it was 76.7 ± 7.0 at the 12-month examination. The mean width of keratinized mucosa, which was measured at the midbuccal point of each implant, was 3.1 ± 0.5 mm at baseline and 3.1 ± 0.5 mm at the 6-month follow-up. The periapical radiographs, which were obtained in a standardized manner, revealed a 0.22-mm increase in DIB; however, this mean marginal bone loss was not statistically significant (Table 2). At the 12-month follow-up, plaque was observed at 32.8% (n = 25) of the sites examined; no calculus deposits were found. As consequence of the plaque presence, there was a slight bleeding tendency upon light probing at 35.5% (n = 27) of the sites examined. The clinical parameters evaluated at the 12-month visit are reported in Table 3. All patients reported that the provisional restorations were esthetically acceptable. No mechanical complications, such as screw loosening, resin fracture, or pain during function, were registered during the first 12 months.

DISCUSSION

The preliminary results of the present prospective study indicate that immediate restoration of nonsplinted implants in mandibular molar sites can be a safe and predictable procedure. Only 1 implant was lost during the study period, whereas 29 of 30 implants were clinically functional. This resulted in a survival rate of 96.7% after 12 months of follow-up. These results are in accordance with prospective studies on immediately loaded implants in completely edentulous patients.[24–26]

For single-tooth replacement, the immediate restoration is not yet well documented, and some studies have reported higher failure rates. Ericsson and associates published the results of a pilot study in which they compared the success rate and bone loss of 14 Brånemark System implants restored immediately with single-crown restorations with those of 8 implants loaded following the standard protocol.[27] They reported survival rates of 86% in the immediate loading group and 100% in the standard restoration group. Both groups showed a marginal bone loss of 0.1 mm at 18 months.

Calandriello and coworkers reported the results of a prospective clinical multicenter study with 50 restored single-tooth implants placed in mandibular molar sites, restored immediately, and followed for 6 months.[28] No failures were reported.

Glauser and colleagues placed 127 implants in 41 patients, including smokers, and loaded them immediately.[29] The clinical conditions included single-tooth, partial-arch, and full-arch situations in healed ridges and extraction sockets. Patients with a habit of bruxism and those with imperfect alveolar ridges were not excluded. Restorations were usually placed the day of surgery and were fabricated in centric occlusal contact without excursive contact. After 1 year, the general survival rate was 82.7%; 34% of 41 implants in the maxillary posterior area failed, while only 9% of the other 86 implants in all other areas failed. Furthermore, the authors noted that implants placed in immediate extraction sockets were more successful (88%) than those placed in healed sites (78%).

In a multicenter study, Malò and associates placed 116 machined Brånemark implants in esthetic areas and immediately restored them.[30] They used the surgical technique of underpreparation of the apical

osteotomies to increase initial stability. The occlusion was adjusted to eliminate direct contact with the provisional prostheses. Twenty-four patients in the study sample smoked more than 10 cigarettes per day. After 1 year, they reported a general survival rate of 96.5% for all implants. The survival rate was 100% when considering only implants placed in fresh extraction sockets. None of the smokers lost implants, leading the authors to conclude that initial implant stability was more important than smoking for implant survival and normal healing with this group.

Glauser and colleagues performed a study on 104 Brånemark System Mk IV TiUnite implants placed in 38 patients and immediately loaded.[31] The implants supported 20 single-tooth restorations, 30 fixed partial dentures, and 1 complete fixed mandibular restoration. They reported a cumulative implant survival rate of 97.1% after 1 year of prosthetic loading. The mean marginal bone resorption (± SD) after 1 year of loading was 1.2 ± 0.9 mm.

The results of the studies reviewed, although encouraging, should be interpreted with caution, since great variability exists among the studies regarding inclusion and exclusion criteria for patient selection, area of implant placement (maxilla versus mandible), and loading protocol. Most of the studies have reported on implants placed in the anterior segment of the mandible, where bone of good quality is often present and proper initial implant stability can be achieved.

In the present study, all implants were placed in the posterior area of the mandible. To evaluate the primary stability of the implants, the RFA was measured with the Osstell device. This noninvasive, objective, reliable method allows the clinician to measure the primary stability of implants at the time of placement and to meaure implant stability during the various stages of healing.[19–21] It has been demonstrated that RFA values are consistent with other means of measuring primary stability such as the manual assessment[19] and "true cutting resistance."[20] The present study confirmed that, at least at 6 months, the immediate restoration of transmucosal dental implants with good primary stability can be a safe and successful procedure. Furthermore, it was found that when implants are placed in bone of good quality, primary stability, as measured with RFA, does not significantly increase during the osseointegration period.[21] Further clinical trials with larger sample sizes and longer follow-up periods are needed to demonstrate the long-term success of this procedure.

CONCLUSIONS

The 12-month results of the present study revealed that, thus far, immediate restoration of transmucosal dental implants placed in the posterior area of the mandible appears to be a successful treatment procedure that greatly simplifies and shortens the time of prosthetic rehabilitation of dental implants in this patient population.

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