Immediate Occlusal Loading of Osseotite Implants in the Completely Edentulous Mandible

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Purpose: *This article reports the preliminary data from a clinical study of immediately loaded, full-arch, screw-retained prosthesis with distal extensions (hybrid prosthesis) supported by Osseotite implants placed in the edentulous mandible.* ***Materials and Methods:*** *Fifteen patients who received 103 implants were enrolled in this study. The first 2 patients received both immediately loaded and submerged implants, while the remaining patients had all implants immediately loaded. The first 9 patients received a temporary prosthesis within 4 hours of surgery, and the hybrid prosthesis, made of a titanium framework and acrylic resin teeth, was placed after 6 months. The last 6 patients received the same type of hybrid prosthesis within 36 hours of surgery. Marginal bone loss was monitored via periapical radiographs by a computerized technique.* ***Results:*** *One failure (out of the 92 immediately loaded implants) occurred after 3 weeks of function because of infection. A cumulative success rate of 98.9% was achieved for up to 48 months of follow-up, while the prosthetic cumulative success rate for the same period was 100%. Marginal bone loss at the immediately loaded implants was within the generally accepted conventional limits for standard delayed loading protocols.* ***Discussion:*** *This technique can reduce treatment time but should be applied with caution.* ***Conclusion:*** *The preliminary results of this study suggest that rehabilitation of the edentulous mandible by an immediately loaded hybrid prosthesis supported by 5 to 6 implants may represent a viable alternative treatment to the classical delayed loading protocols.* (Int J Oral Maxillofac Implants 2003;18:544–551)

Key words: *acid etching, dental implants, edentulous jaw, immediate loading, mandible*

The widespread therapeutic use of dental implants in the last 20 years has led to the revision of several aspects[1] of the original 2-stage Brånemark protocol that was developed in the early 1970s.[2,3] After recognition of the single-stage approach as a valid treatment procedure,[4,5] one of the most dramatic changes in implant dentistry has been the increased acceptance of immediate loading protocols as a viable treatment alternative under certain circumstances.[6–14] The ultimate goal of an immediate loading protocol is to predictably reduce surgical interventions and to shorten the time frame between surgery and prosthesis completion. This will ultimately lessen patient reservations and result in increased acceptance of implant therapy. Prior to being embraced as a useful innovative step and becoming part of routine treatment, immediate loading protocols need to be validated with a significant number of clinical cases, extended follow-ups, and clear definition of limitations.

Since implant surface configuration and texture[15] as well as loading mode[16] play a crucial role during the healing phase, it is important to clearly identify the type of implant and the type of rehabilitation when documenting immediate loading cases. The purpose of this article was to present preliminary data of a clinical study on the rehabilitation of the edentulous mandible by an immediately loaded (IL), full-arch, screw-retained prosthesis with distal

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extensions (a hybrid prosthesis) supported by Osseotite implants (3i/Implant Innovations, West Palm Beach, FL).

MATERIALS AND METHODS

Demographics

Between February 1997 and April 2001, 15 patients (8 men and 7 women) were rehabilitated with a hybrid prosthesis supported by IL screw-type implants. Three of them smoked 10 cigarettes per day; the average age at surgery was 59.9 ± 9.1 years (range, 45 to 76 years).

Inclusion and Exclusion Criteria

Patients were included in the study according to the following criteria: *(1)* they were completely edentulous in the mandible; *(2)* rehabilitation with oral implants was considered elective; *(3)* they were physically able to tolerate conventional surgical and restorative procedures; *(4)* they agreed to give signed informed consent; *(5)* they had normal/good bone quality in the mandible; *(6)* all implants could be seated with a torque ≥ 30 Ncm and had initial primary stability.

Exclusion criteria were: *(1)* presence of active infection or inflammation in the areas intended for implant placement; *(2)* more than 10 cigarettes/day smoking habit; *(3)* systemic diseases such as diabetes (all types, regardless of control); *(4)* treatment with therapeutic radiation to the head within the past 12 months; *(5)* need for bone augmentation at the intended implant site; *(6)* presence of previous unresorbed allograft at implant site (detected on radiographs); *(7)* habit of severe bruxism or clenching; *(8)* pregnancy.

Success Criteria

Implants were considered successful if the following conditions were met at the time of evaluation: *(1)* no clinically detectable mobility when tested with opposing instrument pressure; *(2)* no evidence of peri-implant radiolucency; *(3)* no recurrent or persistent peri-implant infection; *(4)* no complaint of pain; *(5)* no complaint of neuropathies or paresthesia; *(6)* no crestal bone loss exceeding 1.5 mm by the end of the first year of functional loading, and no bone loss exceeding 0.2 mm/year in subsequent years.[17]

Surgical Procedures

The first 2 patients received both submerged and IL implants, following a protocol suggested by Schnitman and coworkers.[6] The rationale was that in case all IL implants failed, a sufficient number of submerged implants were left to support the definitive prosthesis. Both the submerged and IL implants were placed with the hex above the bony ridge, in a supracrestal position, as recently described.[18,19] Countersinking was not performed. All implants were placed with insertion torque ≥ 30 Ncm. Bone density was scored as dense, normal, or soft according to the classification proposed by Trisi and Rao.[20] Initial primary stability was assessed prior to removal of the implant mount; implant-bone adaptation was recorded as tight (≥ 30 Ncm), firm (20 to 30 Ncm), or loose (< 20 Ncm).[21] Implants placed in the interforaminal region were > 10 mm long. In the posterior region, additional implants could have a length ≤ 10 mm. Implants of diameter 3.75 or 5 mm were used. Implant characteristics and patient-related parameters are summarized in Tables 1 and 2.

Table 1 Characteristics of the 92 Immediately Loaded Implants

	Diameter		
Length (mm)	3.75 mm	5 mm	Total
≤ 10	8	—	8
11.5	5	3	8
13	56	3	59
15	15	—	15
18	2	—	2
Total	86	6	92

The submerged implants of the first 2 patients received a cover screw, whereas the IL implants received a standard 4-mm-high abutment. The soft tissues were sutured over the submerged implants and around the protruding abutments. Finally, a provisional prosthesis was seated.

The remaining 13 patients received IL implants only, without submerged implants as a backup. They were placed primarily in the interforaminal area; additional implants were placed in the distal area whenever possible. All patients in the present study had normal bone quality in the mandible.

Prosthetic Procedures

For the first 2 patients, a screw-retained provisional prosthesis was placed as soon as 4 hours after implant placement, so that they left the office with a prosthesis. After the surgical procedure, standard abutments were positioned and the flap sutured. Before proceeding with the prosthetic phase, cold-sterilized rubber dam was applied to the standard abutments to isolate the surgical field. A metal-reinforced acrylic resin provisional prosthesis was

Table 2 Patient and Implant Demographics

Patient no.	Age at surgery (y)	Sex	Implants placed (IL/Sub)	Interforaminal/ posterior IL implants	Occlusal antagonist	No. of failures
First group						
1	61	M	6/6	3/3	OD	0
2	52	M	6/5	4/2	ISFP	0
3	45	M	7/–	5/2	ISPP/PFP	0
4	72	F	5/–	4/1	FFP	0
5	76	M	6/–	6/–	FFP	0
6	58	F	5/–	5/–	ISFP	0
7	64	F	6/–	4/2	FFP	0
8	65	F	5/–	4/1	D	0
9	57	F	6/–	6/–	D	0
Second group						
10	51	M	5	5/–	D	0
11	58	F	7	6/1	D	0
12	46	F	6	6/–	PFP/RPP	0
13	57	M	10	6/4	ISFP	0
14	63	M	6	6/–	D	0
15	60	M	6	6/–	FFP	1
Total			92/11	76/16		1

IL = immediately loaded; Sub = submerged; D = full-arch removable prosthesis; FFP = full-arch fixed prosthesis; ISFP = implant-supported fixed full-arch prosthesis; ISPP = implant-supported fixed partial prosthesis; OD = overdenture; PFP = partial fixed prosthesis; RPP = removable partial prosthesis.
First group: IL implants with temporary prosthesis (delivered after 4 hours; definitive prosthesis delivered after 6 months); second group: IL implants with hybrid prosthesis (delivered within 36 hours).

relined over the provisional cylinders and screwed onto the abutments. Finally, the occlusion was carefully checked.

These 2 patients wore their provisional prostheses supported by IL implants. As detailed elsewhere,[22,23] 2 submerged and 1 IL implant were retrieved after 2 months from the first patient, and 2 IL implants were retrieved after 4 months from the second patient for histologic analysis. Before retrieval, the submerged implants were uncovered, and clinical stability of the submerged and IL implants was checked by counter-torque at 20 Ncm.[24] Then the submerged implants received a standard abutment, and the soft tissues were closed around the abutments. At 6 months an impression was made and sent to the laboratory, and a hybrid prosthesis made of a titanium framework and acrylic resin teeth was placed.

Seven more patients received provisional prostheses supported by IL implants 4 hours after completion of the surgery as described above. Submerged implants were not placed in these patients. The temporary prosthesis was left in function for 6 months. At that time, as for the first 2 patients, the provisional prosthesis was unscrewed and implant stability was checked by counter-torque at 20 Ncm. Since all implants were firmly anchored, an impression was made and sent to the laboratory for preparation of the hybrid prosthesis. The latter was screw-retained, and occlusion was checked for final adjustments.

The final group of 6 patients received a distinct immediate loading protocol. Their prosthesis, fabricated of a titanium framework and acrylic resin teeth, was seated within 36 hours of surgery; no provisional prosthesis was provided. At the end of the surgical phase, rubber dam sterilized with a cold solution was used to isolate the surgical and prosthetic fields.[25] Surgical indexing was obtained using a replica of the complete denture of the patient. Wide healing abutments were positioned and removed 36 hours later, when the prosthesis was placed. The surgical indexing, containing all the information needed for fabrication of the prosthesis (vertical dimension of occlusion, centric relation, position of the implants), was sent to the laboratory, and the hybrid prosthesis was completed within 36 hours using the Cresco Ti Precision Method (Lausanne, Switzerland).[26,27] Figures 1a to 1e show the sequence of procedures from the indexing phase to the seating of the prosthesis. Figure 1f shows the x-ray evaluation taken the day after implant placement. The prosthesis was fabricated with resin on the titanium framework. The hybrid prosthesis was

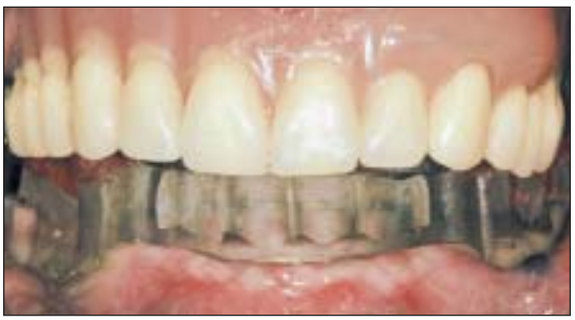


Fig 1a Try-in of the surgical index with the registration of centric occlusion.

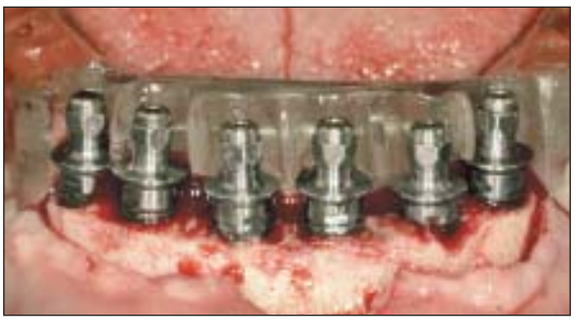


Fig 1b Implants are positioned in the intraforaminal area and the surgical index is in place.

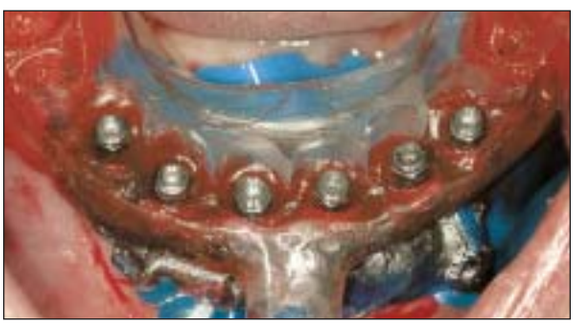


Fig 1c Implant mounts are used as impression copings attached to the surgical index.

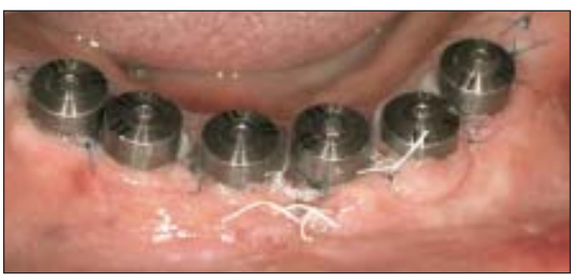


Fig 1d Two-piece wide healing abutments are positioned and 6.0 monofilament sutures are used to close the tissues. At 36 hours postoperative, minimal ecchymosis can be seen in the floor of the mouth and in the vestibule.

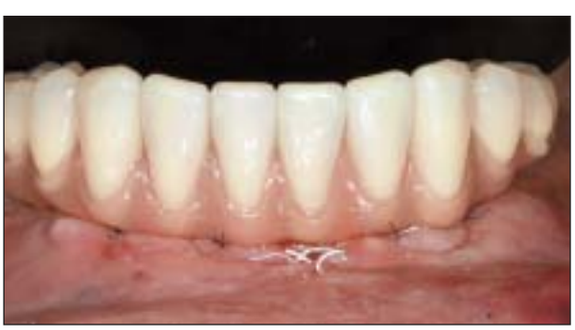


Fig 1e The hybrid prosthesis is seated 36 hours postsurgery.

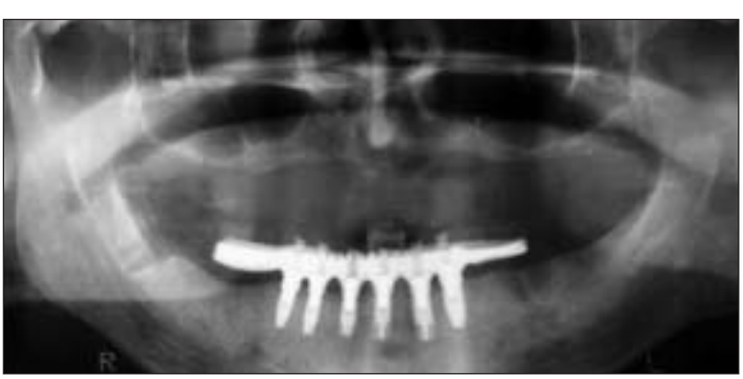


Fig 1f Orthopantomogram of the prosthesis.

Table 3 Life Table Analysis of the 92 Immediately Loaded Implants

Interval time (mo)	No. of patients	No. of implants	No. of failed implants	Success rate (%)	Cumulative success rate (%)
0 to 2	15	92	1	98.91	98.91
2 to 6	15	91	0	100	98.91
6 to 12	15	91	0	100	98.91
12 to 18	13	91	0	100	98.91
18 to 24	13	91	0	100	98.91
24 to 36	12	85	0	100	98.91
36 to 48	10	63	0	100	98.91
> 48	7	39	0	100	98.91

screwed onto the implant platform or on the abutments and occlusion was carefully checked. The patients were asked to limit cleaning procedures to oral rinsing during soft tissue healing until suture removal (10 to 12 days after surgery).

Follow-up

No specific diet was recommended for the patients. The patients were on a recall program during the first 6 months as follows: every week during the first month and then every month until the sixth month. Thereafter, they were followed at 12, 18, and 24 months post-loading and then annually.

Orthopantomograms and periapical radiographs were obtained for image analysis at implant placement. Periapical radiographs were obtained subsequently, after 2, 6, and 12 months of functional loading, and yearly thereafter, at each scheduled follow-up. For the first 2 patients, orthopantomograms were also taken at 12 and 24 months to verify complete bone healing at the biopsy sites.

Radiographic Evaluation

Peri-implant marginal bone change was evaluated by analyzing standard intraoral periapical radiographs with a computerized measuring technique. Radiographs were scanned in a digital format by a scanner (HP Scanjet 3c/t; Hewlett-Packard, Milan, Italy) at a resolution of 600 dpi. Evaluation of the marginal bone level around implants was made with an image analysis software (Scion Image; Scion Corporation, Frederick, MD) that allows measurement of the distance between 2 points. Calibration was performed on each image, using 3 mm as a reference length for 5 consecutive threads along the major implant axis (the distance between 2 consecutive threads is 0.6 mm). The precision of the measurement system was 0.01 mm. To facilitate the measurements, the images were slightly rotated electronically so as to have the major axis in the vertical direction. To improve the visual contrast between bone and implant, an image-processing procedure (sharpening) was performed when necessary (only in barely contrasted images).

The vertical distance between the coronal margin of the implant collar (taken as the reference point) and the most coronal bone-to-implant contact was measured. At each implant, this distance was measured at both the mesial and distal sides. An increase in the vertical distance between the reference point and the most coronal bone-to-implant contact at a given site in consecutive radiographs was considered indicative of peri-implant marginal bone resorption. Bone loss at each follow-up was calculated for each implant with respect to baseline values.

RESULTS

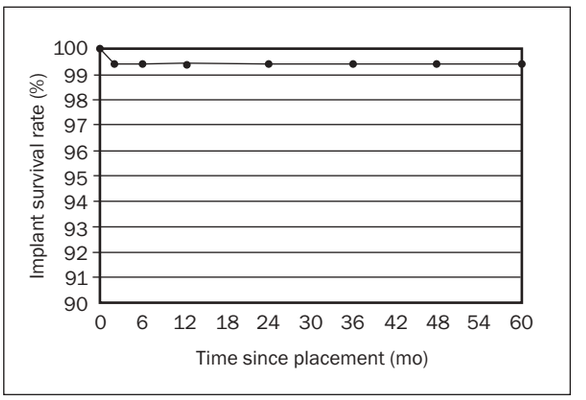
A single failure occurred, as indicated in the life table analysis (Table 3), as a result of peri-implant tissue infection. This implant was removed 20 days after placement; removal did not compromise prosthesis functioning.

All the other implants were clinically stable, and all satisfied the success criteria. The overall implant success rate was 98.9%, while prosthesis survival was 100%. Figure 2 shows the cumulative implant success rate after up to 60 months of follow-up.

No statistically significant difference in marginal bone loss was found between the mesial and distal sides (evaluated by the unpaired Student *t* test) at any time frame; therefore, the mesial and distal evaluations at each implant were pooled and a single bone loss value was assigned to each implant at any given time.

Figure 3a shows the evolution of the mean marginal bone loss. The most pronounced crestal bone loss was observed during the first 6 months; thereafter, it decreased. No specific bone loss that

Fig 2 Diagram illustrating the cumulative implant success rate versus time.



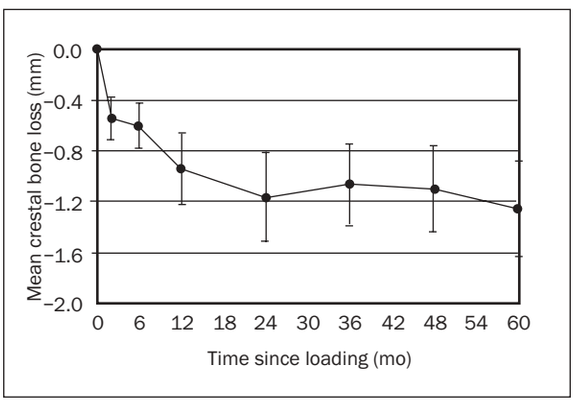


Fig 3a Mean crestal bone loss (mm) around IL implants versus time.

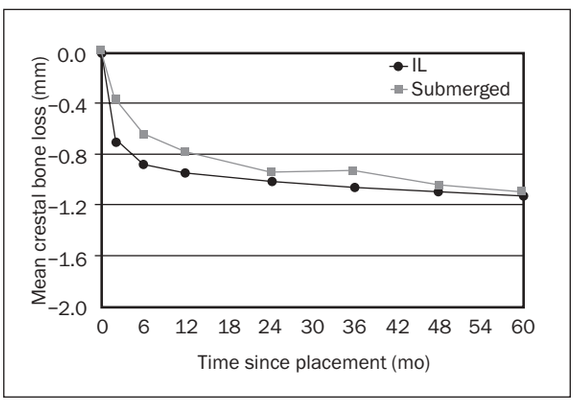


Fig 3b Mean crestal bone loss versus time for the IL and submerged implants in the first 2 patients.

exceeded the values obtained for conventional treatments[17] was recorded. Figure 3b compares the trends of mean marginal bone loss relative to the IL and submerged implants placed in the first 2 patients. No significant differences in marginal bone loss could be detected at any time between the IL and the submerged implants in these patients.

DISCUSSION

There is a trend in implant dentistry to reduce treatment time so as to increase patient acceptance. This might be obtained either by early loading protocols[21,28,29] or by IL procedures.[6–13,22,23,30,31] The key difference between the 2 approaches is that early loading can be applied on a routine basis, even by inexperienced practitioners, and is also suitable for the treatment of unilateral situations. This has been made possible by textured implant surfaces that promote osseointegration.[21,32–40] By contrast, IL procedures can be successful only when the amount of micromotion at the bone-implant interface is kept beneath a certain threshold during the healing phase.[1,16] Several studies have reported higher failure rates for IL implants when compared to delayed loaded ones.[7,12,13,41] This suggests that this procedure, although predictable, is technique-sensitive and should be applied with more caution.

A gradual and progressive approach to IL should be recommended. The authors' procedure for acquiring experience with the use of an IL procedure in the edentulous mandible was to start by adding submerged implants, as first proposed by Schnitman and coworkers.[6] In the present patient pool, this approach was abandoned after 2 patients, because the histologic analysis suggested that all 3 IL implants retrieved from these patients were osseointegrated after 2 months[23] and 4 months[22] of function. Histologic evaluation of the retrieved implants showed high bone-implant contact (64% at 2 months and 78% to 85% at 4 months of loading) and good quality of the newly formed bone around the implants. Moreover, fibrous interposition was not observed in any of the biopsies.[22,23]

The 9 patients of the first group received provisional prostheses as planned, 4 hours after surgery, whereas their definitive rehabilitation was completed

6 months later. However, the last 6 patients received a prosthesis fabricated of a titanium framework and acrylic resin teeth within 36 hours. The reason for this change was related to the success rate and limited bone loss observed in the first group of patients, which increased confidence in the IL protocol. All patients were pleased that they could avoid wearing a removable prosthesis and get their fixed restoration within 4 or 36 hours.

In the present study, the observed marginal bone change around IL implants was within the conventional limits generally accepted for submerged implants.[17] It might be observed that only a few implants have reached 3 years of functional loading. However, it should be stressed that clinical studies involving IL implants have demonstrated that failures occur mostly during the first 6 months of function.[1,6–8,12,13,31,42]

Brånemark and associates[11] described a technique in which a hybrid prosthesis in the mandible can be prepared in 1 day. The technique recommends the use of 3 implants of 5 mm diameter placed with special hardware in the anterior mandible. The authors demonstrated, with 50 patients followed from 3 months to 3 years, that 3 implants were enough to support a hybrid prosthesis. In the present prospective clinical study, the use of standard implants with a diameter of 3.75 mm was preferred, because it offers more flexibility and is less invasive. In addition, the use of more than 3 implants allows a prosthesis to be salvaged in case a single implant fails in the short term or the longer term.[41,42] This was confirmed in the present study, since a patient who lost 1 of 6 implants received the planned prosthesis, showing 100% prosthesis survival.

Finally, the present preliminary data suggest that: *(1)* 5 to 6 IL implants can maintain the amount of micromotion beneath the critical threshold for a hybrid prosthesis, and *(2)* 5 to 6 IL implants can be as predictable as implants placed with a standard delayed loading protocol. Based on this experience, placement of a hybrid prosthesis within 2 days has been introduced in the authors' practice as routine treatment protocol for completely edentulous mandibles.

CONCLUSION

Within the limits of the present data, rehabilitation of the edentulous mandible by an IL hybrid prosthesis supported by 5 to 6 screw-type implants seems to be a viable alternative treatment to the classical delayed loading protocol. A high implant success rate and limited marginal bone loss may be obtained with an IL protocol. Nonetheless, further prospective studies and longer follow-ups are required to obtain better insight into the limitations of this protocol.

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