Immediate occlusal loading of Osseotite implants in the lower edentulous jaw
A multicenter prospective study

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Abstract
Objective: This paper reports the results of a prospective multicenter clinical study on immediately fully occlusally loaded full-arch screw-retained prostheses with distal extensions (hybrid prostheses) supported by Osseotite implants inserted in edentulous lower jaws.

Method and material: Sixty-two patients were enrolled in four clinical centers. Three hundred and twenty-five Osseotite implants were inserted and occlusally loaded according to an immediate loading protocol. The temporary prosthesis was delivered 4 h from surgery. The final prosthesis was delivered after 6 months. Marginal bone loss was monitored from periapical radiographs using a computerized technique.

Results: Two implants failed to integrate within 2 months of occlusal loading. A cumulative implant success rate of 99.4% was achieved for a period of 12–60 months postplacement (mean 28.6 ± 14.1 (SD) months). Crestal bone loss around the immediately loaded implants was similar to that reported for standard delayed loading protocols.

Conclusion: The results of this study suggest that the rehabilitation of the edentulous mandible by an immediate occlusally loaded hybrid prosthesis supported by five to six Osseotite implants represents a viable alternative treatment to classic delayed loading protocols.

The widespread therapeutic use of dental implants over the last 20 years has led to the revision of several aspects [Szmukler-Moncler et al. 2000] of the original two-stage Bränemark protocol, developed in the early 1970s [Bränemark et al. 1977; Bränemark et al. 1985]. After using the single-stage approach as a valid treatment procedure for many years [Ledermann 1979; Schroeder et al. 1983; Babbush et al. 1986; Buser et al. 1997], one of the most dramatic changes in implant dentistry has been the increased acceptance of immediate loading protocols as a viable therapeutic alternative, under certain circumstances [Schnitman et al. 1990; Balshi & Wolfinger 1997; Schnitman et al. 1997; Tamow et al. 1997; Wöhle 1998; Bränemark et al. 1999; Ericsson et al. 2000a; Jaffin et al. 2000; Lozada et al. 2000]. The ultimate goal of an immediate loading protocol is to reduce the number of surgical interventions and shorten the time frame between surgery and prosthetic delivery, all without sacrificing implant success rates. These new protocols will ultimately lessen patients' reservations and result in increased acceptance of implant therapy.
Before embracing the procedure as a routine treatment, the immediate loading technique needs to be validated with a significant number of clinical cases, extended follow-ups and a clear definition of limitations.

Because implant macrogeometry and microgeometry (Szmukler-Moncler et al. 1996) as well as the loading mode (Szmukler-Moncler et al. 1998) play a crucial role during the healing phase, it is important, when documenting immediate loading cases, to identify clearly the type of implant and the type of rehabilitation being used.

In two preliminary investigations, two patients, treated in one of the centers of this study, received both submerged and immediately loaded (IL) implants, according to a protocol adopted by Schnitman et al. (1990). The rationale for the Schnitman et al. (1990) protocol was to provide the patient with a sufficient number of implants should all the IL implants fail. Both the submerged and IL implants were placed with the hex above the bony ridge, in a so-called crestal position (Testori et al. 1999; Darvanapah et al. 2000).

These two initial patients received their provisional prosthesis supported by IL implants 4 h after surgery. Following a surgical prosthetic procedure detailed in previous studies (Testori et al. 2001a, Testori et al. 2002b), two submerged and one IL implants were retrieved after 2 months from one patient and two IL implants were retrieved after 4 months from the second patient for histological analysis. All the retrieved IL implants showed bone-to-implant contact at both time frames, suggesting that immediate loading does not hinder implant osseointegration. Furthermore, no significant differences in crestal bone loss could be detected between the IL and submerged implants at any follow-up evaluation. As a result of these preliminary findings, we were encouraged to apply a similar protocol to a wider range of patients.

This paper presents an interim analysis of a multicenter prospective clinical study on the rehabilitation of the edentulous mandible by an immediate occlusally loaded full-arch screw-retained prosthesis with distal extensions (a hybrid prosthesis).

Material and methods

The study was performed in four clinical centers by six investigators who followed the same clinical protocol for immediate occlusal loading of implants placed in the edentulous mandible.

Inclusion and exclusion criteria

Patients were included in the study according to the following criteria: (1) completely edentulous in the mandible; (2) rehabilitation with oral implants considered the elective treatment; (3) physically able to tolerate conventional surgical and restorative procedures; (4) informed consent signed; (5) implants seated with a torque ≥32 N cm showing good primary stability; and (6) dense/normal bone quality in the interforaminal area. Bone quality was scored according to the classification proposed by Trisi & Rao (1999) as dense (type I according to the classification proposed by Lekholm & Zarb 1985), normal (type II–III) and soft (type IV) bone.

The exclusion criteria were: (1) active infection in the sites intended for implant placement; (2) systemic diseases such as diabetes (all types, regardless of control); (3) treatment with therapeutic radiation to the head within the past 12 months; (4) need for bone augmentation at the intended implant site; (5) radiographic evidence of unresorbed allograft at implant site; (6) severe bruxism; (7) pregnancy; and (8) patients consuming more than 10 cigarettes a day.

Success criteria

The following success criteria were applied in evaluating each implant: (1) no clinically detectable mobility when tested with opposing instrument pressure; (2) no evidence of peri-implant radiolucency on periapical radiographs; (3) no recurrent or persistent peri-implant infection; (4) no complaint of pain at the site of treatment; (5) no complaint of neuropathies or paraesthesia; (6) crestal bone loss not exceeding 1.5 mm by the end of the first year of functional loading, and less than 0.2 mm/year in the following years (Albrektsson et al. 1986).

Surgical procedures

All patients received dual acid-etched cylindrical screw-shaped Osseotite implants (3i, West Palm Beach, FL, USA), whose surface features were 1–3 μm peak-to-peak and 5–10 μm peak-to-valley micropits (Davies 1998). The surgical protocol provided for crestal implant placement as prescribed in the literature (Testori et al. 1999; Darvanapah et al. 2000). All clinicians followed the implant manufacturer’s instructions for implant site preparation and implant insertion procedure. The initial primary stability was assessed by setting the insertion torque of the surgical unit and recorded according to the following classification: ‘tight’ when torque was ≥32 N cm, ‘firm’ between 25 and 32 N cm or ‘loose’ when <25 N cm (Testori et al. 2002a). The length and the diameter of the individual implants could vary from subject to subject, depending upon bone quality and quantity at each surgical site.

Prosthetic procedures

The treatment objective involved delivery of the provisional prosthesis within 4 h of implant placement, by utilizing the prosthetic procedure that best suited the clinical case.

The design of the prosthesis was determined by a collaborative effort between the surgeon, the restorative doctor and the patient, as long as the outcome was consistent with the study’s objectives.

A metal reinforced acrylic provisional bridge was relined over provisional cylinders and immediately screwed onto the abutments. The occlusion was carefully checked.

Follow-up procedures

No specific diet was recommended to the patients. The patients were on a strict recall program during the first 6 months: every week during the first month, and every month between the second and sixth months. Patients were followed thereafter at 12, 18 and 24 months postloading and then on a yearly basis.

Orthopantograms and periapical radiographs were obtained for image analysis at implant insertion. Periapical radiographs were also performed subsequently, after 2, 6 and 12 months of occlusal loading, and yearly thereafter.

Radiographic evaluation

Peri-implant marginal bone change was evaluated utilizing a computerized measuring technique applied to intraoral periapical radiographs.
Radiographs were scanned to provide a digital format (HP Scanjet 3c/t, Hewlett-Packard) at a resolution of 600 dpi. The evaluation of the marginal bone level around implants was carried out using image analysis software (Scion Image, Scion Corporation, Frederick, MD, USA). Each image was calibrated using the known distance between five consecutive threads along the major axis of the implant. This distance is 3 mm because the distance between two consecutive threads on the standard Osseotite implant is equal to 0.6 mm. The precision obtained by the measuring system is accurate to within 0.01 mm. To facilitate the measurements, the images could be slightly rotated by a software function, to fix the major axis in the vertical direction. In order to improve the visual contrast between the bone and implant, an image processing procedure (sharpening) could be performed when necessary.

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 of 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 a peri-implant marginal bone resorption. Bone loss at each follow-up visit was calculated for each implant by determining the difference between baseline values.

## Results

### Enrollment and demographics

Between February 1997 and February 2002, 62 patients (28 males and 34 females) were enrolled in the study. Table 1 shows the distribution of patients among the four centers. The average age at the time of implant surgery was 61.4 ± 11 years [range 33–83 years]. All patients were rehabilitated with a hybrid prosthesis supported by IL Osseotite implants. Six patients were smokers and reported consuming up to 10 cigarettes per day.

A total of 325 implants were inserted. The length and diameter of all the IL implants are summarized in Table 2. Three hundred and one implants (92.6%) were placed in the interforaminal area that scored dense or normal bone quality, utilizing an insertion torque ≥ 32 N cm [tight]. Twenty-four additional implants (7.4%) were inserted into areas distal to the foramen that scored soft bone, utilizing a torque between 25 and 32 N cm [firm].

No deviations from the protocol were reported. Patients' subjective assessment in relation to the type of treatment received was favorable overall. No subjective complaints were reported throughout the follow-up period.

### Radiographic evaluation

All the periapical radiographs of the inserted implants were evaluated for marginal bone change. Assessment of radiographic change in bone level over time showed no statistically significant difference in marginal bone loss between the mesial and distal sides at each time frame. In Table 3, the results of this comparison, performed by paired Student's *t*-test, for all the implants that could be examined are reported. The mesial and distal evaluations at each implant therefore were pooled and a single bone loss value was assigned to each implant at any given evaluation time.

Figure 1 shows the evolution of the mean marginal bone loss over time. The most pronounced crestal bone loss was observed during the first 2 months and decreased thereafter. The observed bone loss was similar to that reported using delayed loading protocols [Albrektsson et al. 1986].

### Discussion

There is a tendency in medicine to reduce the treatment time and simplify the treat-
ment in order to increase patient acceptance and reduce the risk of complications. Treatment simplification for implant dentistry might be obtained either by early [Lazzara et al. 1998; Roynesdal et al. 2001; Testori et al. 2001b; Ericsson et al. 2002b; Testori et al. 2002a] or by immediate loading procedures [Schnitman et al. 1990; Balshi & Wolfinger 1997; Schnitman et al. 1997; Tarnow et al. 1997; Wohlrle 1998; Bränemark et al. 1999; Jaffin et al. 2000; Malo et al. 2000; Chaushu et al. 2001]. The key difference between the two approaches is that early loading can be applied on a routine basis and is also suitable for the treatment of unilateral cases. Early loading has been made possible by using textured surfaces that promote osseointegration [Buser et al. 1991; Klokkevold et al. 1997; Cochran et al. 1998; Davies 1998; Baker et al. 1999; Lazzara et al. 1999; Trisi et al. 1999; Cordioli et al. 2000; Testori et al. 2002a]. By contrast, immediate occlusal loading procedures can be successful only when the amount of micro-motion at the bone-implant interface is kept beneath a certain threshold during the healing phase [Szmukler-Moncler et al. 1998; Szmukler-Moncler et al. 2000]. Several studies have reported higher failure rates for IL implants when compared to delayed-loaded ones [Schnitman et al. 1997; Ericsson et al. 2000; Jaffin et al. 2000; Chaushu et al. 2001]. This shows that this procedure, although predictable, is technique-sensitive and should be applied cautiously. A gradual and progressive approach to immediate loading is therefore recommended. Our original immediate loading procedure in the edentulous mandible began by adding submerged implants as first proposed by Schnitman et al. in 1990. In our case, this approach was abandoned after two preliminary patients because the histological analysis demonstrated that all three IL implants surgically retrieved from patients with trephines were osseointegrated after 2 [Testori et al. 2002b] and 4 months [Testori et al. 2001a] of function. A histological evaluation of the retrieved implants showed a high bone-implant contact [64% at 2 months and 78–85% at 4 months of loading] and evidence of newly formed bone in contact with the implants. Moreover, fibrous interposition was not observed in any of the biopsies [Testori et al. 2001a; Testori et al. 2002b].

In the present study, 68 patients received their provisional prosthesis as planned, within 48 h after surgery, whereas their final rehabilitation was completed 6 months later. All the patients were pleased that they could avoid wearing a removable prosthesis and be fitted with a fixed appliance within 48 h.

In this study, the observed marginal bone change around IL implants was similar to that reported for delayed loading implants [Albrektsson et al. 1986]. However, it should be stressed that the current clinical studies involving IL implants have clearly demonstrated that most failures occur during the first 6 months of function [Babbush et al. 1986; Schnitman et al. 1990; Balshi & Wolfinger 1997; Schnitman et al. 1997; Ericsson et al. 2000a; Jaffin et al. 1999; Testori et al. 2001a; Testori et al. 2002b].

Bränemark et al. [1999] described a technique where a definitive hybrid prosthesis in the mandible can be prepared in 1 day. The technique recommends the use of three implants of diameter of 3 mm inserted with a special hardware in the anterior mandible. The authors demonstrated, with 50 patients followed from 3 months to 3 years, that three implants were enough to support a hybrid prosthesis. In the present prospective clinical study, the use of standard implants with a diameter of 3.75/4 mm was preferred because it offers more prosthetic and surgical flexibility. The technique utilized in this study avoids excessive obligatory osteoplasty. In addition, the use of more than three implants allows the prosthesis to be salvaged in the event of a single implant failure in either the short or the longer term [Babbush et al. 1999].

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**Table 4. Life table analysis of the 325 immediately loaded implants**

<table>
<thead>
<tr>
<th>Interval time (months)</th>
<th>No. of patients</th>
<th>No. of implants</th>
<th>Implant duration (months)</th>
<th>Failed implants</th>
<th>Interval survival rate (%)</th>
<th>Cumulative survival rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–6</td>
<td>62</td>
<td>325</td>
<td>0</td>
<td>2</td>
<td>99.38</td>
<td>99.38</td>
</tr>
<tr>
<td>6–12</td>
<td>62</td>
<td>323</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td>99.38</td>
</tr>
<tr>
<td>12–18</td>
<td>62</td>
<td>323</td>
<td>83</td>
<td>0</td>
<td>100</td>
<td>99.38</td>
</tr>
<tr>
<td>18–24</td>
<td>47</td>
<td>240</td>
<td>94</td>
<td>0</td>
<td>100</td>
<td>99.38</td>
</tr>
<tr>
<td>24–36</td>
<td>28</td>
<td>146</td>
<td>69</td>
<td>0</td>
<td>100</td>
<td>99.38</td>
</tr>
<tr>
<td>36–48</td>
<td>14</td>
<td>77</td>
<td>38</td>
<td>0</td>
<td>100</td>
<td>99.38</td>
</tr>
<tr>
<td>48–60</td>
<td>7</td>
<td>39</td>
<td>23</td>
<td>0</td>
<td>100</td>
<td>99.38</td>
</tr>
<tr>
<td>&gt;60</td>
<td>3</td>
<td>16</td>
<td>16</td>
<td>0</td>
<td>100</td>
<td>99.38</td>
</tr>
</tbody>
</table>

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Fig. 1. Mean crestal bone loss (mm) around immediately loaded implants vs. time. Data are expressed as mean value ± 1 SD.
The advantage of the five to six implant technique was confirmed in the present study when two patients lost one implant out of six installed. These patients were still able to receive their final prosthesis as planned, despite implant loss.

Finally, the present preliminary data suggest that five to six IL implants can provide patients with the same level of success as standard delayed protocols. Based on the results provided by this study, the delivery of provisional hybrid prosthesis within 48 h has been introduced in our practices as a routine treatment protocol for the fully edentulous mandible, as shown in the clinical case (Fig. 3a–f).

Conclusions

Rehabilitation of the edentulous mandible by an immediate occlusally loaded provisional hybrid prosthesis supported by five to six Osseotite implants is a viable alternative treatment to the classical delayed protocols.

Résumé

Cette étude rapporte les résultats d’une étude clinique multicentrique prospective sur la charge occlusale complète immédiate de l’ensemble de la mâchoire sur des prothèses retenues par des implants-vis avec une extension distale supportée par des implants Osseotite insérés dans la mandibule de patients édentés. Soixante-deux patients ont été inclus dans quatre centres cliniques et 325 implants Osseotite ont été insérés et mis en charge occlusale suivant le protocole de charge immédiate. La prothèse temporaire était placée quatre heures après la chirurgie. La prothèse finale était placée après six mois. La perte osseuse marginale était enregistrée à partir de radiographies périapicales via l’utilisation d’une technique informatisée. Deux implants ne se sont pas intégrés dans les deux mois de la mise en charge occlusale. Un taux de succès cumulatif des implants de 99,4% a été atteint pendant une période de douze à soixante mois après le placement (moyenne 28 ± 14,1 mois). La perte osseuse créste autours des implants mis en charge immédiatement était semblable à celle rapportée pour les protocoles de mise en charge retardée. Les résultats de cette étude suggèrent que la réhabilitation de la mandibule chez l’édenté par des prothèses placées sur des implants immédiatement mis en charge placées sur cinq ou six implants Osseotite représente un traitement alternatif au protocole classique avec une mise en charge retardée.

Zusammenfassung


Resultate: Bei zwei Implantaten kam es in den ersten zwei Monaten der okklusalen Sofortbelastung zu Missereignissen. Daraus errechnete sich zwischen dem zwölften und 60. Monat nach Implantation

1986, Chiapasco et al. 1997). The advantage of the five to six implant technique was confirmed in the present study when two patients lost one implant out of six installed. These patients were still able to receive their final prosthesis as planned, despite implant loss.

Finally, the present preliminary data suggest that five to six IL implants can provide patients with the same level of success as standard delayed protocols. Based on the results provided by this study, the delivery of provisional hybrid prosthesis within 48 h has been introduced in our practices as a routine treatment protocol for the fully edentulous mandible, as shown in the clinical case (Fig. 3a–f).
al se suministró a las cuatro horas de la cirugía. La prótesis definitiva se suministró a los seis meses. La pérdida de hueso marginal se monitorizó a través de radiografías periapicales usando una técnica computarizada.

**Resultados:** Dos implantes fracasaron al integrarse dentro de los dos meses de carga oclusal. Se logró un índice de éxito acumulado de 99.4% durante un período de 12 a 60 meses tras el tratamiento (media 28.6 ± 14.1 [SD] meses). La pérdida de hueso crestal alrededor de implantes cargados inmediatamente fue similar a aquellos informados para protocolos de carga diferida estándar.

**Conclusion:** Los resultados de este estudio sugieren que la rehabilitación de la mandíbula edente mediante prótesis híbrida de carga oclusal inmediata soportada por 5–6 implantes Osseotite representa una alternativa viable de tratamiento frente a los protocolos clásicos de carga diferida.

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**References**

Testori et al. A multicenter prospective study on immediate loading


