Prospective multicentre study of immediate occlusal loading of implants in edentulous mandibles

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Abstract

Introduction
This study reports the results of a prospective clinical study on immediate loading of prostheses in full arches of edentulous mandibles supported by osseointegrated implants from different brands.

Materials and methods
The study involved 73 patients. A total of 501 implants were inserted, out of which 420 implants were inserted through immediate occlusal loading. Interim prostheses were placed 4 h after surgery. Final prostheses were placed 6 months after. Marginal bone loss was monitored through linear measurement of the mesial/distal surfaces by means of paralleling (long-cone) periapical X-rays.

Results
Eight implants failed to integrate in 2 months of occlusal loading. The cumulative success rate was 98.06% from 19 July 1999 to 19 October 2012 (the average being 18–84 months). Crest bone loss around immediately loaded implants was found to be similar to that reported in standard protocols for delayed loading.

Conclusion
The findings of this study suggest that edentulous mandible rehabilitation through fixed, immediately loaded, occlusal, interim prostheses supported by four, five or six implants constitutes a viable alternative to traditional treatment protocols for delayed loading.

Introduction
Generalized therapeutic use of implants over the past 20 years has led to revising several aspects of the original, two-stage Brånemark protocol, developed in the early 1970s1,2,3. In the 1990s, one-stage surgical protocols were routine4. One of the most significant changes in dental implantology has been the growing popularity of immediate-loading protocols as a viable therapeutic alternative to be used under specific circumstances and clinical conditions.

The implant-assisted, immediate-loading prosthesis was devised to solve a 3-fold problem—aesthetic, functional and social. Therefore, it is essential to establish protocols to simplify surgical procedure and standardize prostheses for more efficient and lasting results. The main goal of an immediate-loading protocol is to decrease the number of surgical procedures and shorten the time between surgery and prosthesis placement without affecting implant success rates. The new protocols will result in greater patient acceptance of this particular implant technique. Before the procedure becomes routine treatment, the immediate-loading technique must be validated via a considerable number of case reports, extensive follow-ups and a clear definition of its scope and limits. Considering implant-loading techniques, macro- and micro-geometry play a crucial role in healing, it is essential to clearly state implant and rehabilitation type for each case when documenting healing5–11.

In previously published studies, patients treated with this technique have received both types of implants: submerged and immediately loaded, according to the protocol established by Schnitman et al.12,13 and Tarnow et al.14. This protocol was followed in order to provide the patient with a sufficient number of implants in case all immediate-loading implants should fail, thus ensuring restoration success. Both submerged and immediate-loading implant screws were inserted into the bone crest (crestal implant placement)15–17.

No significant difference in crest bone loss was found between immediate-loading and submerged implants at any assessment stage, which was a decisive factor for submitting a larger number of patients to the treatment.

The aim of this study was to report immediate occlusal loading of implants in edentulous mandibles.

Materials and methods
This work conforms to the values laid down in the Declaration of Helsinki (1964). The protocol of this study has been approved by the relevant ethical committee related to our institution in which it was performed. All subjects gave full informed consent to participate in this study.

Four different implant brands were used in the study, following the same protocol for immediate occlusal loading of implants in edentulous mandibles (Tables 1 and 2):

- 3i Osseotite (Implant Innovations Inc.)
- Seven (MIS)
- Biohorizons Internal Hex (Biohorizons)
- Replace Select (Nobel Biocare)

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Surgical procedure
Implant location preparation and implant insertion were carried out as per manufacturers’ instructions. Initial implant primary stability was assessed by setting the insertion torque of the surgical unit and recorded following the categories suggested by Testori et al.:

- Tight: torque ≥32 N cm
- Firm: between 25 and 32 N cm
- Loose: <25 N cm

Implant length and diameter varied from patient to patient, depending on bone quality and the number of prospective implant locations.

Prosthetic procedure
The aim of the treatment was to insert an interim prosthesis within 4 h of implant placement, using the surgical procedure appropriate for each clinical case.

A hybrid, low-complexity, fully screwed-in interim prosthesis was devised to that effect. Occlusion was monitored carefully in compliance with approved follow-up mechanisms.

Follow-up procedure
Patients were given no special diet. For the first 6 months, they followed a strict dentist visit schedule:

- Every week during the first month;
- Every month from the second to the sixth month;
- 12, 18 and 24 months after implant loading;
- Computed tomography scans, panoramic and periapical X-rays were performed to obtain diagnosis;
- Additional periapical X-rays were taken 2, 6 and 12 months after occlusal loading and, afterwards, once a year.

Success criteria
Success criteria applied to each implant:

- Clinically detectable implant immobility;
- Absence of peri-implant radiolucency on periapical X-rays;
- Absence of peri-implant infection;
- No pain, neuropathy or paraesthesia in the treated area;
- Crest bone loss of not >1.5 mm during the first year of functional occlusal loading, and not >0.2 mm per year during the following years, according to the categories established by Albrektsson et al.1 in 1986.

Inclusion and exclusion criteria
Inclusion criteria:
 Patients were selected based on the following criteria:

- Fully edentulous mandible;
- Dental implant rehabilitation being the treatment of choice;
- Physically able to tolerate conventional surgical and restoration procedures;
- Signing an informed consent form;
- Implant insertion torque ≥32 N cm with good primary stability;
- Dense to normal inter- and postforaminal bone quality, bone quality being established based on the categories set either by Trisi and Rao18 or Le-kholm and Zarb19, i.e. Type I (dense), Type II (normal), Type III (soft).

Exclusion criteria:

- Active infection in prospective implant location;
- Systemic disease, such as diabetes (of any kind, regardless of whether or not kept in check);
- Therapeutic head radiation treatment for the previous 12 months;
- Prospective implant location with areas not requiring bone volume increase;
- Severe bruxism;
- Pregnancy;
- Smoking more than 10 cigarettes a day;
- Having received alendronate treatment during the previous year.

Table 1 Quantitative distribution of implants loaded by brand

<table>
<thead>
<tr>
<th>Implant brand</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3i Osseotite (Implant Innovations Inc.)</td>
<td>303</td>
</tr>
<tr>
<td>Replace Select (Nobel Biocare)</td>
<td>20</td>
</tr>
<tr>
<td>Biohorizons Internal Hex (Biohorizons)</td>
<td>20</td>
</tr>
<tr>
<td>Seven (MIS)</td>
<td>77</td>
</tr>
<tr>
<td>Total</td>
<td>420</td>
</tr>
</tbody>
</table>

Table 2 Quantitative distribution of cases, weather, type of temporary prosthesis and final prosthesis

<table>
<thead>
<tr>
<th>Time (time range control)</th>
<th>Temporary prosthesis</th>
<th>Ceramometallic fixed prosthesis</th>
<th>Highly complex hybrid prosthesis in ceramics</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 July 1999 to 19 October 2012</td>
<td>76 low-complexity hybrid prosthesis</td>
<td>17</td>
<td>59</td>
<td>4–6 months</td>
</tr>
</tbody>
</table>

Results

Between 19 July 1999 and 19 October 2012, 76 patients were included in the study (32 males and 44 females). Average age at the time of implant insertion was between 40 and 85 years. All patients were rehabilitated by means of a low-complexity hybrid prosthesis supported by immediately loaded implants; none of them was a smoker.

A total of 501 implants were placed. Out of these, 411 were inserted in an interforaminal region with dense or normal bone quality and 90 in the distal region of the foramen. Of these, 420 were suitable for immediate loading.

The patients’ subjective assessment of the treatment was overall positive. There were no complaints of pain during the follow-up period (Table 3).

X-ray assessment

All periapical X-rays of the inserted implants were assessed to corroborate changes in marginal bone. X-ray assessment of bone level over time did not show a statistically relevant difference in marginal bone loss in the mesial and distal region at any given period.

Crest bone loss was most significant during the first months, decreasing afterwards, this being the case for all implant brands used. Bone loss was found to be similar to that reported in delayed-loading protocols devised by Alberktsson et al. in 1986.

Success rate

None of the patients left the study, although three passed away.

In the first 6 months, eight failures were recorded, as indicated in the Success and Failure Assessment Chart. These implants were removed without jeopardizing final prosthesis design. With the exception of these two cases, there were no complications during the observation period.

All other implants proved to be clinically stable and met the success criteria. The overall implant success rate was 98.06% (Figure 1).

Discussion

In medicine, there is a tendency to shorten the treatment time and to simplify treatment to increase patient acceptance and lower the risk of complications.

In the case of dental implants, the treatment could be simplified by relying on early-loading and immediate-loading procedures.

The fundamental difference between these is that early loading can be used routinely and is appropriate for treating unilateral cases. The use of treated surfaces in early loading fosters osseointegration, as attested by several studies.

In contrast, immediate occlusal loading procedures can only be successful if the micro-motion in the bone–implant interface remains under a specific threshold during the healing stage. Several studies have reported a higher failure rate for immediate-loading implants than for delayed-loading implants. This suggests that technique is a crucial aspect of this procedure, which, although predictable, must be executed with great care.

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Figure 9: Pre-operative appearance.

Figure 10: 3i implant placement 6 osseotite.

Figure 11: Immediate loading. Hybrid prosthesis screwed.

Figure 12: Metal skeleton with porcelain artificial gingiva.

Figure 13: Hybrid prosthesis with ceramic lithium disilicate crowns.

Figure 14: Final restoration.
Therefore, we propose a gradual and progressive implementation of the immediate-loading technique.

Initially, the immediate-loading procedure we used in edentulous mandibles involved submerged implants, as originally proposed by Schnitman et al. We abandoned the procedure in the face of published research containing histological reports that indicated that three immediately loaded implants, removed surgically with a trephine, had become osseointegrated after 2 and 4 months\textsuperscript{27,28}. The studies concluded that the implants removed had a bone-implant contact percentage of 64% at 2 months and 78–85% at 4 months from loading; furthermore, they showed evidence of newly formed bone in contact with the implants\textsuperscript{27,28}.

In our study, all 73 patients received an interim prosthesis within 4 h after surgery, as planned. They completed their rehabilitation in 6 months. Marginal bone change around immediate-loading implants was found to be similar to that reported for delayed-loading implants.

It is worth mentioning that current case reports on this technique have shown that most cases of failure occur during the first 6 months after placement\textsuperscript{4,20,29,30}.

This supports the literature on the subject, which indicates that the micro-motion of four, five or six immediate-loading implants remain under the implant survivorship threshold, thus guaranteeing the same level of success as delayed-loading protocols. Based on these findings, the technique of hybrid, interim prosthesis loading within 4–48 h has become a routine treatment for fully edentulous mandibles at our practice.

**Conclusion**

Edentulous mandible rehabilitation by means of a low-complexity, hybrid, interim, immediately loaded occlusal prosthesis supported by four, five, or six implants constitutes a viable alternative to traditional delayed-loading protocols. Statistical difference was not found between success and failure of implant systems used.

**References**