# Immediate Loading of Two Implants with a Mandibular Implant-Retained Overdenture: A New Treatment Protocol

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### ABSTRACT

*Purpose:* The aim of this study was to present the clinical outcomes of the immediate loading of two bar-splinted implants retaining a mandibular overdenture.

*Materials and Methods:* In a clinical trial, 124 edentulous patients were treated according to a new treatment concept, which involves the immediate loading of two bar-splinted SLActive implants with an implant-retained mandibular overdenture. The new conventional mandibular denture is used as a template for implant positioning and as an impression tray, and for mounting the retention clip by the dental laboratory. At the same day the implants are placed, the conventional denture is converted into an implant-retained overdenture. During the healing and evaluation period, resonance frequency analysis (RFA) was undertaken to assess the effect of loading on implant stability and survival.

*Results:* The survival rate of the implants was 98.8% during the evaluation period (12–40 months). Only 3 of the 248 implants were lost. During the healing (osseointegration) phase, the implant-stability quotient increased significantly (p = .0001). During the evaluation period, four patients (3%) needed a relining of their mandibular overdenture, whereas 13 patients (11%) needed relining of the maxillary denture.

*Conclusions:* Two interconnected implants can be successfully loaded by a mandibular overdenture at the same day of implant placement with a high survival rate of the implants. Only a few patients needed additional relining of the overdenture. Repeated RFA measurements can be useful in gauging implant stability and survival.

KEY WORDS: clinical trial, immediate loading, implant-retained overdentures, SLActive, treatment concept

## INTRODUCTION

Implant-retained overdentures on two implants in the edentulous mandible have proved to be a reliable treatment option.<sup>1–3</sup> By some researchers, it has been called the standard of care for edentulous patients.<sup>4</sup> Several well-designed randomized clinical trials (RCT) have been reported in the literature.<sup>5</sup> An earlier study dealing

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with patient satisfaction<sup>6</sup> and the costs of aftercare<sup>7</sup> for different types of implant-supported overdentures indicate that a bar-supported overdenture on two interconnected implants may be the most efficient system in the long run.

The traditional treatment protocol is based upon the insertion of two or four implants in the interforaminal region of the mandible and the fitting of an overdenture after osseointegration. Although patients are generally satisfied with this mode of treatment,<sup>6</sup> the entire procedure spans a minimum of 3 to 4 months from the time of the initial diagnosis and treatmentplanning to that at which the overdenture is fitted. During the intervening osseointegration phase, the patient experiences discomfort and requires aftercare. It may be possible to curtail this period by the immediate loading of new generation of oral implants with enhanced osseoinductive surface characteristics, of which it is claimed to possess high intrinsic stability, without jeopardizing their survival.<sup>8</sup> Straumann's SLActive

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implant is claimed to remain stable during the initial 1.5 to 3 weeks of the 3 to 4-week period that is required for bony attachment, a phase which is usually associated with transient instability.<sup>9–11</sup>

Immediate loading is defined by the ITI consensus group as a restoration that is placed in occlusion with the opposing dentition within 48 hours of implant placement.<sup>12</sup> Several studies report immediate loading of four or more implants with mandibular overdentures and yield comparable results to those achieved using conventional loading protocols.<sup>13–16</sup>

Immediate loading of only two implants with mandibular overdentures may lead to early implant loss by overloading. This dilemma influenced the study designs of several researchers. Engelke and colleagues<sup>17</sup> inserted two implants into the edentulous mandible, but introduced another two satellite implants for support during the healing phase. Others tried to avoid possible implant loss by overloading with shortening of the healing phase from 6 weeks till 1 week and should be classified as early loading procedures.<sup>18–21</sup>

Marzola and colleagues<sup>22</sup> investigated an immediate loading protocol for two implants with ball-retained overdentures (17 patients), with promising results. According to their procedure, the patients wear the overdenture for the first postoperative week without removing it. Recently, Cannizzaro and colleagues<sup>23</sup> have proposed combining flapless surgery with the immediate loading of two implants bearing bar-retained mandibular overdentures. In a cohort of 60 patients, 30 were subjected to immediate implant loading and the other 30 were subjected to early implant loading. One year after surgery, none of the implants were lost in the immediate loading group and only two in the early loading group. Nineteen postoperative complications occurred in 19 patients during the 1-year follow-up.

Objective prognostic measurement criteria, such as the resonance frequency analysis (RFA) which yields an implant stability quotient (ISQ), can be used to monitor implant stability in patients. Valderrama and colleagues<sup>24</sup> have demonstrated that magnetic devices, such as the Osstell Mentor, yield values that correlate well with those achieved using electronic ones. ISQ values are difficult to interpret, because the measurements are implant design-dependent.<sup>25</sup> Although significantly higher ISQ values are obtained at the time of insertion, for successful implants, the measurements are of low predictive value for implant loss during the loading period.<sup>26</sup> Nedir and colleagues<sup>27</sup> conceive the ISQ to be a suitable gauge of implant stability, but to be of no predictive value for osseointegration. Zix and colleagues<sup>28</sup> have suggested that only when repeated measurements of an implant are made over a prolonged period, the ISQ can be used to assess its current status or to predict its performance.

The aim of this study was to present the clinical outcomes of the immediate loading of two bar-splinted implants retaining a mandibular overdenture.

#### MATERIALS AND METHODS

The cohort of patients consisted of 124 totally edentulous individuals with atrophic mandibles experiencing persistent problems with the retention of complete conventional dentures. The patients were referred by their dentist to the Practice of Implantology and Prosthodontic Dentistry in Rotterdam-Spijkenisse, the Netherlands. Between 2005 and 2007, the patients were fitted with one-stage Straumann SLActive Regular Neck Standard implants (Straumann AG, Basel, Switzerland) and overdentures. Only those patients who were precluded from dental implant treatment by their medical status were excluded from the study. All patients underwent an intraoral examination and X-radiography. The severity of the complaints and the atrophic state of the mandible were recorded.<sup>29</sup>

All patients were informed about the new procedure and about the possible benefits and risks of the treatment. If they agreed to proceed with the proposed treatment, appointments for manufacturing the new complete dentures were scheduled. The study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000, and patients provided informed consent to participate in the study.

The complete dentures were made by a prosthodontist according to a standardized protocol, which yielded optimal fitting and balanced occlusion.<sup>30</sup> The positions of the mandibular anterior teeth accorded with the neutral zone philosophy.<sup>31</sup> At the final appointment before implant insertion, the newly manufactured denture was checked in terms of esthetics, speech, occlusion, and articulation. The patients did not wear this complete denture before the implants were placed.

On the day of implant placement, the location of the implants was established according to the position of the contact point between the mandibular lateral incisor and the canine, at which a perforation was made starting

at the deepest point of the mucosal site of the denture. The guiding sleeves were created in a direction that ran perpendicular to the plane of occlusion of the mandibular denture. Hence, the denture served as a surgical guide. The surgical treatment was planned for the early morning so as to ensure that the dental laboratory had sufficient time to make the bar construction and to mount the clip in the lower denture. After applying a local anesthetic, the mandibular denture is fitted in the mouth of the patient and kept in position by finger pressure of the surgeon and the dental assistant. Two trans-mucosal center points were generated within the bone using a round bur and using the mandibular denture as a surgical guide for positioning the implants. The denture is removed and prepared for the impression. After elevation of a mucoperiostal flap, the implant osteotomies were prepared. Two endosseous implants (SLActive Standard Regular Neck implants) were inserted and tightened with a torque of at least 35 Ncm. If only one of the implants should achieve 35 Ncm or more and the other implant less than 35 Ncm but more than 25 Ncm, then the immediate loading concept was still followed. If both implants should fail to achieve 35 Ncm, then the treatment changed to conventional loading. A SynOcta® 1.5 mm abutment (048.601, Straumann AG) was inserted and tightened with a torque of 25 Ncm. ISQ measurements were made at the levels of the implant and the abutment using an Osstell Mentor device and a Smartpeg (type 4; ref. 100350) (Osstell AB, Göteborg, Sweden). The ISQ measurements were made parallel and perpendicular to the bone crest in the buccolingual direction, and parallel to the bone crest in mesial-distal direction, as advised by Osstell. The mucoperiosteal flaps were sutured in place with Seralon 5/0 thread (Serag-Wiessner KG, Naila, Germany), and an impression was made at the abutment level using the mandibular denture as an impression tray. For this purpose, the holes in the mandibular denture were enlarged on the mucosal side to afford sufficient space for the snap on implant transfers (048.193, Straumann AG) (Figure 1) The impressions were taken using the closed-tray impression technique and using a material of intermediate viscosity (Flexitime Monophase, Heraeus Kulzer, Hanau, Germany).

The patient was administered paracetamol as an analgesic and sent home to return later in the day for the insertion of the bar and the overdenture. In the meantime, the impression was sent to the dental laboratory,



Figure 1 Enlarged holes in mandibular denture to afford sufficient space for the snap on impression posts.

where the egg-shaped Dolder bar (CMST53012P20, Cendres et Métaux SA, Biel, Switzerland) and the SynOcta gold copings (048.204, Straumann AG) were soldered and the retention clip mounted in the lower denture; a rebasing procedure was also performed. The retention clip was activated.

During the first night, the patient was instructed to wear the overdenture, which acted as a pressure bandage for optimal wound healing. For the ensuing 3 weeks, the patient was instructed not to wear the overdenture at night. The patient was permitted to eat with the overdenture in place, but was advised to avoid biting hard food. No further restrictions were imposed.

On the first postoperative day, a control visit was planned to check for possible denture problems and wound healing. The patient was instructed how to remove the overdenture and how to disinfect the mouth, the wound, and the superstructure with 0.12% chlorhexidine (4 times a day for 5 days). The patient was advised to begin brushing the bar twice daily after 3 days. Two weeks after surgery, the sutures were removed and panoramic X-radiography was taken.



**Figure 2** Frequency distribution of patients according to Cawood's classification.<sup>29</sup>

ISQ measurements were made directly after implant placement, and were repeated 1, 2, 4, 8, and 13 weeks later (as recommended by Zix and colleagues<sup>28</sup>). The measurements made at 1, 2, 4, and 8 weeks were performed only at the abutment level to avoid the risk of rotating the implant when dislodging the abutment. A percussion-sounding or implant-sounding test was used as a subjective control. Thirteen weeks after surgery, the ISQ measurements were made at both the implant and the abutment level. The SynOcta abutment was retightened at 35 Ncm. Thereafter, an evaluation was planned for 1 year hence. Prosthodontic aftercare was recorded during the evaluation period.

All numerical data were analyzed by SPSS 14.0 (SPSS Inc., Chicago, IL, USA), using the appropriate descriptives and Wilcoxon's signed ranks test. The level of statistical significance was set at p < .05. The ISQ values at abutment level, which were assumed to follow a Gaussian kernel distribution, were subjected to Loess' curve-fitting analysis, with 95% of the points to fit.

## RESULTS

The patient population included in this study consisted of 57 males and 67 females. Their average age ( $\pm$ SD) was 64.4 ( $\pm$ 9.3) years (range: 45–85 years). The average mandibular height, measured on a lateral headplate and corrected for magnification, was 19.7 ( $\pm$ 4.6) mm (range: 10–31 mm). The average number of edentulous years was 17.8 ( $\pm$ 16.9) (range: 1–57). The average number of dentures that had been worn was 2.4 ( $\pm$ 1.8) (range: 1–9).

Figure 2 depicts the frequency distribution of the patients according to Cawood's classification.

A total of 248 implants were inserted, the diameters and lengths are given in Table 1. All implants had a good primary stability and reached the required insertion torque without any additional bone augmentation. All included patients were treated according to the procedure of the study.

TABLE 1 Diameters and Lengths of the Inserted

Diameter (mm)	Impl			
	10	12	14	Total
3.3	0	27	0	27
4.1	14	206	1	221
Total	14	233	1	248

The average evaluation period was 2.0 years (range: 12–40 months). During the evaluation period, three implants in three patients failed during the first 3 weeks. Each of these patients was fitted with a second implant 10 weeks after implant loss, according with the same procedure and likewise with immediate loading. These second implants healed unproblematically.

At the time of surgery, the average ISQ at the implant level was 75.1 ( $\pm$ 4.9). After 3 months, the value had increased significantly to 78.4 ( $\pm$ 5.1) (p = .0001, Wilcoxon signed ranks test). At the abutment level, the average ISQs at these junctures were approximately 15% lower than at the implant level. The ISQs that were measured at the abutment level are represented as a function of evaluation time in Figure 3. The curve-fitting analysis of these ISQs yielded a line with a low gradient incline. The average ISQ at the abutment level during the first 20 days of evaluation was 64.0 ( $\pm$ 4.5).



**Figure 3** Implant stability quotient measurements at the abutment level, represented as a function of the evaluation time. The values, which were assumed to follow a Gaussian kernel distribution, were subjected to a curve-fitting analysis (according to Loess' method), with 95% of points to fit.

TABLE 2 Prosthodontic Aftercare with Number of Occurred Interventions							
	Month	Months after Implant Insertion					
	0–3	4–12	>12	Total			
Mandibular overdenture							
Relining	0	4	0	4			
Repairs							
Labial fringe	0	3	1	4			
Clip	0	1	2	3			
Teeth/cracks	2	1	1	4			
Total	2	9	4	15			
Maxillary denture							
Relining	7	3	4	14			
Repairs teeth/cracks	0	5	1	6			
Total	7	8	5	20			

During the evaluation period, the prosthodontic aftercare for each patient was registered. All occurred interventions are listed in Table 2.

#### DISCUSSION

Immediate loading of an implant is associated with the risk of micromotion, which can disturb healing<sup>32</sup> and lead to implant loss. This risk can be reduced by splinting the implants with a bar. In this study, the survival rate of such bar-splinted implants was 98.8% after an average evaluation period of 2.0 years. This achieved survival rate is comparable with other studies with traditional early or late loading protocols.<sup>33</sup>

Curve fitting of the ISQ values yielded a line which slope inclined very slightly during the evaluation. Scattering of the values decreased with time after surgery, as the implants became osseointegrated. The fitted line manifested no dip with time, but after 4 weeks, the gradient increased abruptly, albeit slightly.

One case revealed an implant with a decrease in ISQ value, which seemed to have come loose because of overloading. By temporarily removing the bar, the loading of the implant was diminished and possible implant loss was prevented. The ISQ values increased again and reached mean values after 2 weeks. In two other cases, however, an implant was lost, possibly because the patients wore the overdenture day and night and did not follow the surgeon's instructions concerning aftercare. Both patients were smokers. Within 2 weeks of surgery, the ISQ had dropped dramatically, and it was not possible to avert implant loss. Although smoking was not an exclusion criteria in this study, it may be considered to be a risk factor in oral implant treatment.<sup>34,35</sup> The third patient with a non-osseointegrated implant left the country for 8 weeks, thus rendering it impossible to interfere at an appropriate time point by, for instance, removing the bar temporarily.

The ISQ gauging at abutment level was necessary to avoid rotation of the implant when dislodging the abutment. It resulted in approximately 15% lower ISQ values than at implant level caused by lengthening of the lever from the bone to the magnet on top of the Smartpeg. Implants that exhibited diminished resonance frequency values between 30 and 50 became secure again later with time. During this study, patients with ISQ values between 30 and 40 were instructed to avoid hard food for 2 weeks and called back for additional visits to follow the implants. The obtained initial values at implant level were compared with those after 3 months. All secure implants showed ISQ values 75 and up at implant level after 3 months. However, implant stability and osseointegration are two different quantities with a weak correlation.<sup>27,28</sup> The significance of the increased ISQ values at implant level after 3 months is relative, because most of the implants that showed diminished ISQ values also had a tendency to increased ISQ with time, and these implants become secure and osseointegrated.

In this study, RFA proved to be a useful instrument to gauge the clinical success of the individual implants. Lacking a control group with a conventional or early loading procedure, there is an unfulfilled need to compare the RFA values on immediate loading in this study with those with conventional or early loading on SLActive surface or other surfaces with mandibular overdentures by other researchers.

During the evaluation period, the number of interventions of prosthodontic aftercare was registered for each patient. Despite the relining of the mandibular denture at surgical stage, the number of extension of labial fringes and relining of the mandibular denture occurred relatively less and not until 4 months. The mucosa appears to adapt to the denture despite the tendency of swelling in the first days. The prosthodontic aftercare during the first 3 months is limited to seven relinings of maxillary dentures in six patients and two repaired fractured teeth. The relining of the maxillary dentures can be attributed to the patients' perception in the difference between the retention of mandibular and maxillary dentures. The number of prosthodontic interventions contrasts sharply with another study,<sup>23</sup> which reported postoperative complications in 11 out of the 30 patients who had undergone flapless surgery. Moreover, an unspecified number of the patients required a relining of their mandibular overdenture.

With traditional treatment protocols, patients still wear their old dentures during the healing period. During this time, they derive no benefit from the implants and still experience the disadvantages of the old denture. Patients who have been treated according to the new procedure experience immediate benefit, which may favorably dispose them to cope with the new overdenture. However, this postulated psychological benefit needs to be systematically assessed by research including the appropriate control groups.

All patients in this study were treated, and in three cases, retreated, according to this immediate loading protocol despite that there was no selection at bone quality, shape of the mandible, or the width of the restprocessus. Using this new protocol, the total treatment period from the time of the first consultation to that at which the implants and the overdenture are inserted can be reduced. Albeit not examined in this study, it may be suggested that with patients who complain of retention problems and already have a complete denture that complies with treatment standards, this denture could be upgraded to an overdenture within just 1 day. The time required to fabricate the denture is now the bottleneck of the treatment.

## CONCLUSIONS

Two interconnected implants can be successfully loaded by an overdenture at the same day of implant placement with a high survival rate (98.8%) of the implants. Three out of 248 implants were lost. Lacking a control group, literature shows that this survival rate is comparable to that achieved using conventional, delayed-loading protocols. The prosthodontic aftercare included only minor interventions. A few patients (3%) needed additional relining of the overdenture during the evaluation period (12–40 months). Repeated RFA measurements can be useful in gauging implant stability and survival.

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