Immediate Loading of Implants with Mandibular Overdentures: One-Year Clinical Results of a Prospective Study

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> Purpose: The aim of this report is to present the implant and clinical outcomes of an immediate-loading protocol of TiUnite implants with mandibular overdentures in edentulous patients. Materials and Methods: Two groups of edentulous patients were selected. Thirty-five consecutively treated patients received 70 immediately loaded TiUnite implants and 69 Brånemark implants as backup (1 patient received 1 Brånemark implant). The control group was a historical cohort that comprised 42 patients who received 111 Brånemark implants. All overdentures were supported by a resilient bar mechanism. Implant and clinical outcomes, including maintenance events for the first year, were recorded. Results: Implant success rates were in excess of 95% with both protocols. Immediately loaded implants had less bone loss than did implants loaded with the conventional protocol (Mann-Whitney U test; P = .001). Patients in the immediate-loading group required more prosthodontic maintenance, consisting of overdenture remakes and laboratory relining of prostheses (Chi-square test; P < .05). Of note, 74% of patients in the immediate-loading group needed a reline to improve the denture seal around the bar housing (Chi-square test; P < .05). **Conclusion:** The favorable implant and bone level outcomes with immediate loading attest to its biologic success. The prosthetic maintenance encountered in the immediate-loading group does not negate the clinical potential of the treatment but rather suggests that the protocol may benefit from modifications. Int J Prosthodont 2005:18:463-470.

Earlier in the osseointegration experience, it was suggested that an extended implant healing phase prior to occlusal loading was required to achieve predictable outcomes.¹ Eventually, this healing phase of 3 to 6 months was described as empirical,^{2,3} with the suggestion that it be investigated clinically. Indeed, ex-

perimental and clinical evidence suggested that the undisturbed implant healing period could be reduced. A literature review of experimental research indicated that early loading itself was not a contraindication to successful osseointegration; the latter was dependent on maintenance of a load that prevented extensive micromotion at the bone-implant interface. This micromotion was determined experimentally to be between 50 and 150 µm.⁴ Furthermore, clinical evidence supports the notion that Brånemark-type implants can be left exposed during the healing phase without jeopardizing the healing response in both completely edentulous and partially edentulous patients.5-8 This thinking catalyzed in the last decade with the emergence of treatment protocols that relied on a short period of healing time prior to functional loading with both fixed and overdenture prostheses.9-35

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The proposed advantages for protocols with shorter healing times prior to loading are a reduction in the number of surgical and prosthodontic procedures, associated clinical time, healing periods, and treatment costs and an improvement in the quality of life of patients. To date, these advantages have not been scientifically determined. Indeed, the literature is characterized by implant-based treatment outcomes with little regard for patient-related concerns.³⁶ Therefore we embarked on a clinical study investigating the treatment outcomes³⁷ of an immediate-loading protocol of TiUnite implants (Nobel Biocare) with mandibular overdentures. Patient-mediated outcomes will be discussed in another report. It is the aim of this first report to present the clinical outcomes of an immediateloading protocol of TiUnite implants with mandibular overdentures in edentulous patients.

Materials and Methods

Two study groups were selected from patients seeking treatment at the Implant Prosthodontic Unit (IPU), University of Toronto. The Human Ethics Board of the University of Toronto approved both treatment protocols.

Conventional-Loading Protocol

Patients in the conventional-loading group (control group) were recruited from a patient pool treated previously and served as a historical cohort. The patients in this group were matched to the test group (immediate-loading protocol) with respect to medical status, site of implant placement (jawbone and zone), and prosthesis design. The treatment protocol for this group consisted of placement of at least 2 Brånemark dental implants (Nobel Biocare), followed by a healing period of 4 months. During a second surgical intervention, the implants were exposed, and new dentures retained with a resilient ovoid bar/clip system (Cendres Métaux) were fabricated.

Immediate-Loading Protocol

The immediate-loading protocol (test group) was discussed with potential patients and consent obtained. Inclusion criteria were similar to those used in past studies.^{38,39} Prior to implant placement surgery, the prosthodontist and oral surgeon assessed patients with an appropriate combination of medical questionnaires and clinical and radiographic examinations. The latter involved 1 or more periapical, occlusal, panoramic, or lateral cephalometric radiographic views. All patients in the test group first received new complete conventional dentures and were allowed at least 2 months to wear the prostheses prior to implant surgery.

All surgeries were carried out under local anesthesia and antibiotic cover. A crestal incision in the mandible was made between the mental foramina. The mucoperiosteum was elevated and the bone gently drilled to prepare osteotomy sites for the implants. Where appropriate, the crestal jawbone was trimmed to provide an adequate site for implant placement. In the test group, 4 Nobel Biocare implants (2 Brånemark and 2 TiUnite) were placed in the bone. The immediately loaded implants were 2 TiUnite implants, separated by at least 20 mm to allow fabrication of a bar superstructure. During surgery, healing abutments were placed on them at least 2 mm supragingival to the soft tissues. To protect patients in the event that an implant failed, 2 additional Brånemark implants were placed distal to the TiUnite implants and left buried in the bone as sleepers. They were exposed only if 1 of the TiUnite implants failed. The soft tissues were then sutured. Right after surgery, the existing mandibular dentures were hollowed out and relined with a temporary soft liner (Coe-Soft Liner, GC America) that was in direct contact with the healing abutments. Patients were encouraged to wear their prostheses continuously for at least 10 days to allow healing of the soft tissues. They were to remove their prostheses briefly to carry out oral hygiene.

Prosthodontic treatment for the test subjects proceeded 10 days after surgery, with the connection of Multi-unit abutments (Nobel Biocare), as dictated by soft tissue height, on the TiUnite implants and torqued to 20 Ncm with a standardized manual torque. Standardized periapical radiographs were obtained with the long-cone technique and a standardized jig locator at a 10-cm film-to-cone distance.^{40,41} Briefly, a laboratory screw was mounted on the multi-unit abutment. The jig, with holes drilled in the occlusal table and the periapical radiograph held 10 cm away from the cone of the x-ray machine, was then inserted on the laboratory screw and the film exposed. Following confirmation of abutment seating, a pickup impression was made, with the denture serving as a custom tray. It was sent to the dental laboratory and the impression was poured in dental stone. An ovoid bar (Cendres Métaux) was fabricated in gold alloy and returned to the clinic the same day. After passive fit of the bar was confirmed in the patient's mouth, the overdenture was inserted.

Data Collection

The data collected throughout the study were as follows.

Patient demographics. This included gender, marital status, educational level, income, age at implant surgery, and occupation. Furthermore, health and medications, smoking history, oral hygiene at recall visits,

Table 1	Implant Success	Outcomes After 1	Year of Loading
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Group	Implants placed (lost)	Implants loaded	Success rates*	Mean bone loss (± SD, in mm**)
Conventional loading	111 (2)	108	98.2%	1.1 ± 0.5
Immediate loading	139 (2)	70	98.6% ^a	0.4 ± 0.4

All implants were 3.75 mm in diameter, except for 5 implants in the test group that were 4 or 5 mm in diameter.

*Fisher's exact test; P = .646; **Mann-Whitney U test; P = .001.

^aSuccess rate for immediately loaded implants. For all implants loaded (including the backup implant), the success rate was 97.2%.

and years the patient was edentulous prior to implant surgery were recorded.

Implant-related outcomes. This included implant length, platform, and surface (machined [Brånemark] or TiUnite); whether osteotomy site tapping and countersinking were done; presence of bicortical stabilization; bone quality and quantity⁴²; and whether surgical ridge reduction was performed (for the test group only). The latter was defined as "minor" if less than 5 mm of ridge was removed and "major" if more than 5 mm of material was removed. Osseointegration and implant success were determined by testing implants for mobility and pain with a standardized torque wrench set at 20 Ncm. Implants that were mobile or painful while torquing were considered as failures and removed.

At baseline (insertion of the gold bar, ie, 10 days for the immediate-loading group and 4 months for the conventional group) and again during the first annual visit, standardized radiographs were obtained, as described earlier, to perform the bone measurements. The standardized periapical films were scanned into a Dell Inspiron 8000 computer using a Hewlett Packard scanner (Photosmart Scanner S20). They were standardized as to the contrast and scale using the public-domain software NIH Image (version 1.54).43 The image was then assigned a code and saved. Bone loss measurements, as described previously,41,44 were carried out on the patients' periapical radiographs using their baseline films as a basis for comparison. The height was measured from the shoulder of the implant, adjacent to the abutment, to the crest of the lowest plate of bone visible. This was recorded at both the mesial and distal of each implant. All measurements were repeated on 2 separate occasions, and a mean was calculated between the 2 measurements for each site. This measurement was then used for statistical analysis of bone loss. All scanning procedures were carried out in a random fashion with an investigator who was blinded to the patient's information. Similarly, all calculations with respect to bone loss were conducted in a blind fashion. The main investigator was calibrated with an experienced investigator in the department.

Oral hygiene was observed through the study as follows: frameworks and/or abutments with no to minor plaque accumulation were labeled as "good hygiene," and frameworks/implants with heavy plaque and/or calculus buildup on the abutments were labeled as "poor oral hygiene."

Clinical outcomes. The number and nature of the visits were recorded. These included visits for all preoperative consultations, surgeries, prosthodontic treatment, and the visits for prosthodontic maintenance and/or recall visits. The types and number of prosthodontic maintenance or complication issues were collected.

Statistical Methods

The tests were carried out with a SPSS statistical package. The outcomes were implant success, bone levels, maintenance outcomes, and number of visits. The Mann-Whitney U test and Kruskall-Wallis test were used for continuous variables and the Chi-square test was used for analysis of categorical data. Multiple linear regression analyses were performed to identify factors that explained the peri-implant marginal bone loss for both groups. Statistical significance for all the tests was set at P < .05.

Results

Implant-Related Outcomes

No statistically significant differences were observed for the implant success rates; both techniques had similar success rates in excess of 95%. Analysis of bone loss for mesial and distal sites showed no statistical differences (Mann-Whitney U test; P > .05); therefore, sites were combined for the final analysis. Less bone loss was recorded for the test implants when compared to the conventional protocol (Table 1). Statistical signifi-

cance was observed for the following variables: patients in the test group were older at the time of surgery $(64.1 \pm 10.6 \text{ versus } 57.72 \pm 10.47 \text{ years; Mann-Whitney})$ U test; P = .01), and their implants were longer (13.26) \pm 1.73 mm, range 10 to 15 mm, versus 12.59 \pm 3.21 mm, range 7 to 18 mm; Mann-Whitney U test; P = .02). Furthermore, significant differences were observed in the proportional distribution of gender, smoking history, jawbone quality and quantity, and bicortical stabilization of the implants. With respect to the number of years that the patients were edentulous prior to surgery, the control group was edentulous for a mean of 13.74 \pm 9.7 years, while the test group had been edentulous for a mean of 17.75 \pm 17.37 years. The test group could be divided into 2 groups: 26 patients had been edentulous for a long period (22.8 \pm 17 years), and nine patients received immediate dentures following tooth extraction a mean of 6 ± 2 months prior to surgery.

Most of the osteotomy sites in the test group were countersunk, and although the implants used were self-tapping, 40% of the sites were pretapped. Furthermore, 80% of implants in the test group did not have bicortical stabilization (Table 2). With regard to ridge reduction in the test group, 14.3% of patients had major reductions, 28.6% had minor reductions, and 57.1% had no reduction. Multivariate linear regression analyses of the bone loss indicated that more bone loss was observed in female patients, in patients with poor oral hygiene, in sites that had received implants with a machined surface, and in patients with greater bone quantity. The latter can be explained in view of the preponderance of patients with good bone quantity (Table 3).

Clinical Outcomes

Prosthodontic maintenance and number of visits are presented in Table 4. One patient in the test group lost 2 implants (TiUnite and Brånemark implants on same side) and refused further surgery. Therefore, the overdenture retention mechanism was converted to a ball attachment. Implant losses in the conventional group had no adverse impact on the prosthetic plan. Most prosthodontic maintenance issues were related to the acrylic resin superstructure and included fracture of the overdenture, typically in the midline area supporting the bar-clip housing, and fracture of the denture teeth. Furthermore, 4 patients experienced damaged clips following dislodgement of the clips in the acrylic resin. Thus, the problems encountered were not related to the clip itself but more reflective of laboratory technique.

Of note, 26 patients in the test group needed a reline and/or flange addition of their overdenture, typi-

Table 2	Variables for Immediate-Loading (Test) and
Conventio	nal-Loading (Control) Groups

Variable	Test	Control	<i>P</i> value		
Gender					
Female	60.9%	87.1%	.001		
Male	39.1%	12.9%			
Medical history					
Healthy	31.9%	23.5%	.102		
Medically controllec condition Smoking history	68.1%	76.5%			
Smokers	43.5%	20.5%	.001		
Nonsmokers	56.5%	77.1%			
Oral hygiene*					
Good hygiene	69.6%	64.7%	.368		
Poor hygiene	30.4%	35.3%			
Bicortical stabilization	า*				
Yes	20.3%	45.9%	.001		
No	79.7%	54.1%			
Jaw quality*					
Type 2 or 3	81.3%	63.5%	.001		
Type 1 or 4	18.7%	36.5%			
Bone quantity*					
Quantity A or B	48.9%	21.2%	.001		
Quantity C or D	46.0%	67.1%			
Quantity E	5.0%	11.8%			
Years edentulous prior to surgery**	17.75 ± 17.37	13.74 ± 9.77	.400		
Recorded years edentulous*					
0–1 y	20.1%	10.6%	.025		
1–10 y	28.8%	29.4%			
More than 10 y	51.1%	60.0%			

*Chi-square test; **Mann-Whitney U test.

Table 3	Linear Regression for Overall Mean Bone Loss
(in mm/y)	

	Beta	SE	Р
Constant	-0.0287	.285	.920
Recoded age	-0.0316	.034	.358
Oral hygiene (good vs poor)	0.333	.061	.001
Smoking history	0.055	.046	.230
Implant surface (TiUnite vs machined)	0.670	.061	.001
Gender (female vs male)	-0.312	.071	.001
Implant length	0.016	.015	.255
Jawbone quality*	-0.022	.036	.527
Bone quantity*			
Quantity A or B Quantity C or D Quantity E	-0.217	.037	.001

F = 30.55, P = .0001, adjusted $R^2 = 0.503$.

*As classified by Lekholm and Zarb.42

Type of maintenance	G1	G2	G3	G4
Clinical visits after 1 year*				
Presurgical consults	2.51 ± 0.56^{a}	3.21 ± 1.62 ^{c,f}	$2.78 \pm 0.44^{ m h}$	2.42 ± 0.58
Surgeries	1.03 ± 0.17^{a}	$2.00 \pm 0.00^{d,f}$	1.00 ± 0.00^{h}	1.04 ± 0.20
Prosthesis fabrication	5.71 ± 1.43 ^a	$6.50 \pm 0.97^{ m c,f}$	6.22 ± 2.49^{h}	5.54 ± 0.81
Postinsertion adjustments	3.77 ± 1.63 ^b	2.74 ± 1.67 ^{e,g}	4.67 ± 1.50 ^h	3.46 ± 1.58
Total	15.97 ± 3.76^{a}	18.60 ± 3.29 ^{c,f}	17.89 ± 3.10 ⁱ	15.31 ± 3.79
Damaged framework screws**	0	0	0	0
Damaged abutment screws**	0	0	0	0
Fractured denture teeth**	3	0	1	2
Fractured overdenture**	3	0	0	3
Fractured opposing denture**	0	0	0	0
Damaged clip mechanism**	4	2	1	3
Fractured framework (Dolder bar) **	1	1	0	1
Loose framework**	3	0	0	3
Laboratory reline of: **				
Opposing denture only	6 ^b	1 ^{e,g}	4 ^h	2
Overdenture only	26 ^b	4 ^{e,j}	7 ^h	19
Remake of prosthesis**	6 ^b	0 ^{e,g}	2 ^h	4
Remake of new opposing denture**	2	0	0	2

Table 4 No. of Patients Requiring Prosthodontic Maintenance

G1 = Immediate-loading group (n = 35); G2 = conventional-loading group (n = 42); G3 = "immediate denture" group, ie, patients with tooth extractions within 1 year of implant surgery (n = 9); G4 = immediate "healed" group; patients who were completely edentulous prior to implant surgery (n = 26).

*Mann-Whitney U test: a: *P* < .05 G2>G1; b: *P* < .05 G1>G2; c: *P* > .05 G2 to G3; d: *P* < .05 G2>G3, G4; e: *P* < .05 G3>G2; f: *P* < .05 G2>G4; g: *P* > .05 G2 to G4; h: *P* > .05 G3 to G4; i: *P* < .05 G3>G4; j: *P* < .05 G4>G2.

**Chi-square test; pairwise comparisons all nonsignificant unless stated otherwise.

cally in the anterior area related to the surgical site. Changes in the soft tissue at the site resulted in loss of the peripheral seal, and relining was required a mean of 7.8 \pm 3.11 months (range, 4 to 12 months) after insertion of the overdenture prosthesis. Also in the test group, 6 patients also needed relining of the opposing denture to correct a perceived reduction in retention.

New overdentures were fabricated in the test group for the following reasons. Three patients experienced recurrent tooth/denture fracture; 2 other patients were immediate extraction patients, and it was decided that they would benefit from new dentures rather than relining of their prostheses. One patient asked for a new denture owing to esthetic concerns even though she had approved of the denture tooth shade at the prosthetic try-in visit.

Comparison of the 2 groups indicated that the control group required more visits during the first year. However, it should be noted that the extra appointments were related to denture relining during the healing period. In contrast, additional visits required by the test group were related to maintenance issues. No difference between the test subgroups was observed during the surgical and prosthetic phase; however, the immediate-extraction group required more maintenance visits during the first year.

Discussion

Implant-supported overdentures are a predictable and cost-effective means to manage edentulous patients.⁴⁵ It is therefore understandable that studies would explore early loading protocols with overdentures. The mandibular interforaminal area provides the clinician with good bone morphology and concomitant high success rates in excess of 90%, irrespective of the implant design and surface topography, at least in the short term.^{12,13,18,22-28,30} However, in the majority of the papers discussing these protocols, the emphasis was on the osseointegration outcomes per se, without a comprehensive discussion of the surgical protocol itself and, more important, the associated maintenance requirements. It is reasonable to expect a serious and comprehensive investigation of any treatment protocol that proposes to be superior to traditional approaches. This is important to understand if ultimately a protocolin this case an immediate-loading protocol with mandibular overdentures-although biologically successful, can be judged clinically effective as well.

The success rate of immediately loaded TiUnite implants in this study was 98.6% at the 1-year follow-up, and peri-implant bone loss was significantly lower than in patients who underwent conventional loading. The

average bone loss was 0.4 \pm 0.4 mm for the test implants and was within the limits reported in the literature.^{10,12,18,22,24,28} This suggests that immediate loading per se is not a risk factor for early marginal bone loss. Multivariate analysis indicated that the observed bone loss was predicted by gender, poor oral hygiene, bone quantity, and the use of an implant with a machined surface. Interestingly, poor oral hygiene was associated with more bone loss, corroborating previous findings.^{46,47} It remains to be seen what the impact of poor oral hygiene will be around the TiUnite surface. Various authors have also proposed modifications in the surgical protocol to improve the outcomes, including avoidance or reduction of tapping^{11,15,19,23} or tapping of osteotomy sites in dense bone only,31 avoidance or limited countersink in soft bone,^{17,20,21,23,29,31-35} and bicortical stabilization.^{11,12,14,15,17,23,26} Interestingly in our study, none of these modifications affected the shortterm success rates. This suggests that in the anterior mandible, a site that typically has good bone morphology, modification of the surgical protocol does not improve outcomes. However, this does not mean that these surgical modifications are not important in sites with less favorable bone morphology.

All patients in the test group reported an improvement in retention of their conventional dentures during the healing phase. This raises the issue of the necessity on intervening so soon after surgery (including same-day protocols), when soft tissues are still healing. Payne et al²³ noted that after the soft tissues had attained optimal health and a stable position, the ball attachments were noticeably high, and a few patients required relining. This mucosal shrinkage has also been described for overdentures²⁶ and fixed prostheses.9,48 On the other hand, in studies that placed healing abutments during the healing period, only minor complications were reported, such as loosening of the healing abutments or the need for replacement with longer ones.^{10,13,16} Packer et al¹⁶ noted that only half of the definitive abutments were the same length as the healing abutments; this emphasizes how hard it is to predict the eventual form of the soft tissues at the crest of the ridge and floor of the mouth. In fact, in our study, relining of the anterior segment of the prosthesis (that housing the bar assembly) proved to be significantly more common with the immediate-loading patients. This was required to improve the denture seal and highlighted the fact that soft tissues changed over the 1-year observation period. Probably this soft tissue change was not observed with the conventional protocol because of the healing period allowed before prosthetic treatment and because of a much more conservative surgical technique associated with the second-stage surgery. It seems reasonable to assume that when the surgical approach is as conservative as

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stage 2 surgery, little change in the soft tissue will be observed during the prosthetic phase. However, this was not true for our immediate protocol, where the prosthodontic treatment was performed earlier, not allowing adequate time for soft tissue healing. Other prosthetic maintenance issues, such as broken components and dentures, were not significantly higher in the test group. However, it seems that the protocol may have inadvertently weakened the existing mandibular prosthesis, as evidenced by the recurrent tooth and denture fractures that resulted in remakes of a few prostheses. The relatively low frequency (< 10%) of mandibular overdenture fracture, irrespective of attachment mechanisms, has been described in a few studies.49-55 Some investigators have recommended the use of a stellite alloy framework to reinforce the overdenture.55-57 However, a randomized trial limited to a 1-year observation period indicated that there were no differences when the prosthesis was reinforced in this way, suggesting that this procedure (and additional costs) was not justified.58 Indeed, we opted not to reinforce the mandibular denture, an approach justified by the very few fractures observed in the study.

There are clearly no perfect studies, and this study has a number of methodologic weaknesses that should be noted. The study was not randomized, and the control group was a historical cohort. The rationale for using a historical cohort was our previous encouraging experiences with patients treated with the conventional protocol⁵⁹; furthermore, it was hard to recruit an adequate number of edentulous patients for the study. We therefore opted for a historical group, since clinical data was collected regularly for patients treated in the clinic.

Conclusion

To conclude, this study showed over a 1-year observation period that TiUnite dental implants could be immediately loaded with mandibular overdentures. Outcomes comparable to the conventional protocol and favorable bone levels attest to its biologic success. The prosthetic maintenance encountered in the test group does not negate the clinical potential of the treatment but rather suggests that the protocol may benefit from modifications.

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Literature Abstract

Long-term survival of endodontically treated molars without crown coverage: A retrospective cohort study

The purpose of this retrospective, observational study was to determine the survival rate of endodontically treated molars that had not been restored with crowns. A total of 203 subjects (with a total of 220 endodontically treated permanent molars) were identified and recalled for a clinical examination. The dependent variable was defined as a failure if negative findings in the condition of the tooth required a restoration, tooth repair, or extraction. Independent variables included patients' age, gender, location of endodontically treated molars, existence of opposing dentition and adjacent teeth, remaining tooth structure, and types of restorative material. A Kaplan-Meier survival analysis was used to calculate the survival probability, and a log-rank test was used to determine whether significant differences existed for each independent variable and survival outcome. The overall survival rate of molars without crowns at 1, 2, and 5 years were 96%, 88%, and 36% respectively. The survival of the tooth increased with greater amounts of remaining coronal tooth structure. Molars with only occlusal access cavity had a survival rate of 78% at 5 years. Restorations with direct composite (90%) had a better survival rate than amalgam (77%) or reinforced zinc oxide and eugenol with polymethacrylate (60%).

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