# A Prospective Study on Immediate Loading of Implants with Mandibular Overdentures: Patient-Mediated and Economic Outcomes

Nikolai J. Attard, BChD, MSc, PhD<sup>a</sup>/Audrey Laporte, BA, MA, PhD<sup>b</sup>/David Locker, DDS, PhD<sup>c</sup>/ George A. Zarb, BChD, DDS, MS, MS, FRCD(C)<sup>d</sup>

> Purpose: The aims of this report are to present the patient-based outcomes and associated clinical costs of an immediate loading protocol for mandibular overdentures in edentulous patients. Materials and Methods: Two groups of patients were selected. Thirty-five consecutively treated patients received an immediate protocol, while 42 patients treated with a conventional protocol served as a historical control. Patient-based concerns for patients in the immediate group were measured at various stages of treatment with 2 questionnaires: the Denture Satisfaction Scale and the Oral Health Impact Profile. Direct clinical and time costs over a 1-year period were estimated and deflated to 2002 Canadian dollars. Salary rates by occupation, age, and gender were used to evaluate the patients' time costs. Treatment costs were compared between the 2 groups. Additionally, incremental cost-effectiveness ratios for various stages with the immediate protocol were calculated. Results: Significant improvements posttreatment were observed with both the Denture Satisfaction Scale (Wilcoxon signed rank test, P < .05) and the Oral Health Impact Profile (Friedman test, P < .05). The immediate protocol was associated with higher maintenance costs, with resultant higher total costs (Mann-Whitney U test, P < .05). No difference was observed in the time costs associated with the 2 protocols. Within-group analysis of costs at various stages of the immediate protocol suggested that treatment with implant-supported overdentures was more cost-effective than treatment with conventional dentures. Conclusions: This study suggests that implants in 1 jawbone lead to a substantial improvement in perceived oral health status. Furthermore, the immediate loading protocol was not cheaper than a conventional protocol. Int J Prosthodont 2006;19:67-73.

The dental profession has popularized implant treatment protocols that rely on a short period of healing time prior to functional loading (immediate or early protocols) with both fixed and overdenture prostheses. Convincing results supporting these immediate loading protocols have been reported for the edentulous

mandible.<sup>1-17</sup> Their proposed advantages are a reduction in the number of surgical and prosthodontic procedures and in treatment costs. Furthermore, improvement in satisfaction and quality of life (QoL), similar to those reported in patients treated with conventional 2-stage surgical protocols,<sup>18-21</sup> has been proposed. To date, these advantages have not been scientifically determined. These novel protocols can potentially be a very effective approach and as such deserve to be investigated more rigorously so as to ensure their predictability in terms of clinician-related and patient-based outcomes.<sup>22,23</sup> This is particularly relevant in older edentulous patients, whose limited physical and economic resources frequently preclude extensive and expensive treatment. It is apparent that a simple technique is required to accommodate their needs. If it can be demonstrated that immediate load-

67

<sup>&</sup>lt;sup>a</sup>Lecturer, Department of Prosthodontics, Faculty of Dental Surgery, University of Malta, The Medical School, G'Mangia, Malta.

<sup>&</sup>lt;sup>b</sup>Assistant Professor of Health Policy, Management and Evaluation, Faculty of Medicine, University of Toronto, Ontario, Canada.

<sup>&</sup>lt;sup>c</sup>Community Health Services Research Unit, Faculty of Dentistry, University of Toronto, Toronto, Ontario, Canada.

<sup>&</sup>lt;sup>d</sup>Professor and Head of Prosthodontics, Faculty of Dentistry, University of Toronto, Toronto, Ontario, Canada.

**Correspondence to:** Dr Attard, Department of Prosthodontics, Faculty of Dental Surgery, University of Malta, The Medical School, G'Mangia, Malta. E-mail: njattard@maltanet.net

ing with overdentures in the anterior mandible is as safe as the conventional protocol, optimal and relatively inexpensive implant treatment could provide all the inherent merits of the osseointegration technique.<sup>24,25</sup> Therefore we embarked on a clinical study investigating treatment outcomes<sup>26</sup> of an immediate loading protocol with TiUnite implants (Nobel Biocare) with mandibular overdentures. It is the aim of this second report to present the patient-based outcomes and associated clinical costs of the immediate loading protocol.

# **Materials and Methods**

The 2 study groups were selected from patients seeking treatment at the Implant Prosthodontic Unit (IPU), University of Toronto. Both protocols have been described previously.<sup>27</sup> Forty-two patients in the conventional group had been treated previously and served as a historical cohort for comparison of treatment costs only. The treatment protocol for this group consisted of placement of at least 2 Brånemark implants, followed by a healing period of 4 months. The 35 patients in the immediate group first received new complete dentures and were allowed to wear the prostheses for at least 2 months prior to implant surgery. Two TiUnite implants were placed and immediately loaded with a bar superstructure. The data collected throughout the study were as follows.

#### Patient Satisfaction and QoL Outcomes

These data were collected for the patients treated with the immediate protocol only.

**Preoperative data.** The preoperative prosthetic status of the conventional dentures for all patients treated at the IPU was initially investigated with the Denture Satisfaction Scale.<sup>20</sup> The self-reported denture satisfaction scale comprises 12 questions and has a Likert response format ranging from 1 to 5 (1 = totally)satisfied, 2 = very satisfied, 3 = reasonably satisfied, 4 = not very satisfied, and 5 = not at all satisfied). Oral health-related QoL outcomes were measured using the short-form version of the Oral Health Impact Profile questionnaire (OHIP-20),28 which is specifically designed for edentulous patients. The responses were scored on a Likert-type scale with the following answers: 1 = never, 2 = rarely, 3 = occasionally, 4 =often, 5 = very often, and 6 = all of the time (minimum score = 20, highest score = 120). The questionnaires were administered at the preoperative visit (baseline) prior to obtaining informed consent for the study. In both questionnaires, higher scores signified higher levels of patient dissatisfaction or compromised QoL.

**Postoperative data.** The OHIP questionnaire was administered following the fabrication of the conven-

tional complete denture, after implant placement and conversion of the complete denture to a bar-retained overdenture, and again 1 year after surgery. At this stage the Denture Satisfaction Scale questionnaire was also administered. The scores from the Denture Satisfaction Scale were first analyzed globally and then divided into questions related to the individual prostheses and those related to functional status. The OHIP scores were first analyzed globally and divided into function and psychosocial-related questions. Subscale scores were created by summing the responses to the respective questions.

# **Economic Analysis**

Treatment costs, standardized to the base year 2002, were calculated as follows:

- 1. Total costs = (total clinical costs) + (total patient time costs)
- Total clinical costs = (initial treatment costs) + (maintenance costs)
- Maintenance costs = (prosthodontic costs for work other than the first implant-supported prosthesis) + (recall costs)
- Total patient time costs = (salary rate/hour) × (clinical time)

For both groups, the costs for the initial treatment, remakes, and maintenance were collected from the patient's dental charts. Initial treatment costs included fees for surgery, ie, operating room, hardware, and professional fees (surgical and prosthodontic providers). Maintenance included costs for damaged hardware, remakes, relines; costs for professional services by the prosthodontist, surgeon, and laboratory; and costs for the annual recall visit and visits required by patients that were billed.

The clinical time for diverse prosthodontic events was measured directly for the immediate group. However, for the control group, the time was based on averages obtained by measuring prosthodontic events in a group of edentulous patients that received similar overdenture treatment. To estimate patients' time costs, average wages, defined by gender, age, and occupation, were obtained from the Census of Canada.<sup>29-32</sup> Unless stated otherwise in the patient's chart, retirement age for the patients was considered to be 65 years of age. The national average income for Canadians over 65 years of age was obtained from the Income Trends in Canada, Statistics Canada.<sup>33</sup> The income of housewives was considered as the average salary for housekeepers, in an attempt to value the time they spent in the clinic. The study is consistent with the human capital approach, which values patients'

Scale			
Time	Baseline	1 Year	P value*
Maxillary denture	$9.54 \pm 5.00$	$7.11 \pm 2.76$	.001

 $21.00 \pm 2.72$ 

 $5.51 \pm 1.96$ 

 $36.06 \pm 8.39$ 

Mean Scores (± SDs) on the Denture Satisfaction

 $6.63 \pm 2.06$ 

 $2.66 \pm 0.97$ 

 $16.40 \pm 4.83$ 

.001

.001

.001

Best rating = 12; Worst rating = 60.

\*Wilcoxon signed rank test.

Mandibular denture

Functional variables

Table 1

Total

time by quantifying it with the market value of their labor time.<sup>34</sup> In fact, the analysis was conducted from the patient's perspective, because in Ontario, Canada, these clinical procedures are not covered under public health or private insurance. In most cases the patient bears the cost of treatment through direct out-of-pocket payments at the point of service, underscoring the merits for such an approach in our economic analysis.<sup>34</sup>

The costs for every patient in the control group were inflated using the Consumer Price Index (CPI), as described elsewhere.<sup>35</sup> Average wages were adjusted by using the average CPI for Canada.<sup>36</sup> Clinical costs (initial intervention, complications, and recalls) were inflated using the Health CPI.<sup>36</sup>

The economic analysis was twofold. A comparison of treatment costs was first carried out between the 2 groups. Then the immediate group was investigated separately, and a cost-effectiveness ratio was calculated between conventional denture treatment and implantretained overdentures for the postplacement stage and 1-year observation period. Incremental cost-effectiveness ratios were calculated as follows:

$$\frac{\text{Cost}_1 - \text{Cost}_0}{\triangle \text{ OHIP}_1 - \triangle \text{ OHIP}_0}$$

where  $\text{Cost}_1 = \text{cost}$  at implant treatment phase (placement or 1-year follow-up),  $\text{Cost}_0 = \text{cost}$  for denture phase,  $\triangle \text{OHIP}_1 = \text{OHIP}$  score at treatment phase (prosthesis insertion or 1-year follow-up) minus OHIP score at baseline, and  $\triangle \text{OHIP}_0 = \text{OHIP}$  score at denture phase minus OHIP score at baseline.

#### Statistical Methods

The tests were carried out with a SPSS statistical package. The scores from the Denture Satisfaction Questionnaire and the OHIP were compared using the Friedman test and Wilcoxon signed rank tests. Multivariate linear regression analysis was performed to identify factors that explained the change in preoperative versus postoperative OHIP scores. The treatment costs for the immediate and conventional loading groups were compared with the Mann-Whitney U test. Statistical significance was set at P < .05.

#### Results

#### **Denture Satisfaction Questionnaire**

Statistically significant improvements in patient satisfaction scores were observed after treatment with the immediate protocol (Table 1). It can be appreciated that the major change was in the global scores and, more important, for satisfaction with mandibular prostheses. Clinically, this change identified the improvement from a conventional to a mandibular implant-supported prosthetic design

## **Oral Health-Related QoL Outcomes**

The mean overall OHIP and functional and psychosocial subscale scores were statistically significantly different at different intervals versus baseline. The data indicated an improvement both globally and for the functional and psychosocial subscales. No significant change was observed when the scores at implant placement were compared to those obtained at the 1year recall. That is, the improvement in the QoL when the implants were placed (after bar fabrication) was maintained after 1 year of function, irrespective of the various maintenance issues experienced (Fig 1). Linear regression analysis showed that preoperative variables associated with prosthesis satisfaction were predictors of treatment outcomes, as measured with OHIP for the immediate group. Patients with a high score on the Denture Satisfaction Scale for their mandibular conventional prosthesis reported better OHIP outcomes after treatment with implants. Postoperative functional satisfaction with the implant-supported mandibular prosthesis resulted in improved QoL. Furthermore, patients who were housewives or retired were more satisfied with treatment. The model had an adjusted  $R^2$ value of 0.451, explaining 45% of the variance reported (Table 2).

#### Economic Analysis

A cost comparison of the immediate and the conventional protocol was made from the patient's perspective. Recall costs were constant for the 2 groups, since all patients attended their visits during the first year; therefore, the maintenance costs were mainly prostho-

69



**Fig 1a to 1c** Functional OHIP scores (*left*), psychosocial OPHIP scores (*middle*), and global OHIP scores (*right*). Phases: 1 = baseline; 2 = conventional denture insertion; 3 = implant placement; 4 = 1-year recall. Functional scores: Friedman test, chi-square = 80.13; df = 3; P = .01. Psychosocial scores: Friedman test, chi-square = 73.03; df = 3; P = .01. Global scores: Friedman test, chi-square = 85.06; df = 3; P = .01. Wilcoxon signed ranks test: a = baseline > denture insertion stage, implant placement stage, and 1-year recall (P < .001); b = denture insertion stage > implant insertion stage and 1-year recall (P < .001); c = implant placement stage and 1-year recall (P > .05).

 Table 2
 Linear Regression Model for Prediction of Change in OHIP Scores at the 1-year Recall

Factor	Beta	SE	<i>P</i> value	
Constant	30.60	8.29	.000	
Age	-2.79	2.70	.311	
Gender	3.53	2.69	.089	
(0 = female, 1 = male)				
Dummy Nonprofessional	11.27	6.91	.115	
(0 = else, 1 = nonprofessional)				
Dummy Housewife	17.84	7.02	.018	
(0 = else, 1 = housewife)				
Dummy Retired	14.40	5.65	.017	
(0 = else, 1 = retired)				
Years edentulous in mandibular arch prior to	-0.01	0.52	.089	
implant surgery				
Preoperative satisfaction with mandibular prosthesis	-1.48	0.43	.002	
Postoperative functional satisfaction with implant-supported prosthesis	3.59	1.10	.003	

F = 4.10, P = .002, Adjusted  $R^2 = 0.451$ .

dontic in nature. A statistically significant difference was observed for maintenance costs, with resultant higher total clinical costs and total costs for the immediate loading protocol (Table 3). Interestingly, no difference was observed for the time costs for the first year, suggesting that the gain in time associated with the immediate protocol was offset by the maintenance issues observed later on in the study. The average salary rates for the immediate and conventional groups were \$23.5 ± 17.9 and \$20.22 ± 15.8, respectively, and were not statistically significant (Mann-Whitney *U* test, P = .749).

As explained previously, the immediate group included a subgroup that received immediate dentures as part of their treatment. No statistical difference was observed for the 2 subgroups. However, when these 2 groups were compared individually to the conventional group, the same trends discussed previously were obtained: the conventional group had significantly lower maintenance, clinical, and total costs.

# Within-Group Comparison

Since the patients in the immediate loading group were observed throughout the year, the costs associated with an improvement in OHIP scores were calculated. The average cost-effectiveness ratios were calculated for a unit improvement in the patient QoL (unit reduction in OHIP scores) and were as follows: for conventional dentures, \$155.23/10HIP; for implant-supported overdentures after placement of implants, \$112.20/10HIP; and at 1-year follow-up, \$135.00/10HIP. Although one could compare the simple ratios for the 2 arms of treatment and conclude that implant treatment was more cost effective, the correct comparison is that of incremental costs over incremental outcomes. In this case, the incremental cost-effectiveness ratios were \$110.60 and \$135.16 per unit improvement in QoL after implant placement and at the 1-year recall, respectively. That is to say, treatment with implant-supported overdentures was more cost

70

	Immediate protocol	Conventional protocol	P value
Initial costs	2,468.77 ± 311.20	2,431.16 ± 761.85	.774
Total clinical costs	2,813.91 ± 356.91	2,508.27 ± 779.72	.004
Maintenance costs	$345.14 \pm 214.58$	77.61 ± 77.11	.001
Time costs	$301.21 \pm 248.01$	$285.94 \pm 303.88$	.766
Total costs	3,115.13 ± 474.31	$2,794.22 \pm 890.54$	.005

Table 3 Initial Prosthetic and Maintenance Costs in 2002 Canadian Dollars

Mann-Whitney U test.

Fig 2 Average and incremental cost-effectiveness rations.



effective compared to the conventional denture phase. At the 1-year follow-up, the difference between dentures and implant treatment was smaller, owing to maintenance costs observed during the study (Fig 2).

## Discussion

In our study we report an improvement in denture satisfaction and oral health-related QoL following treatment with implants using an immediate loading protocol. Because subjective perceptions of treatment outcomes were measured for the immediate loading protocol only, this precluded direct comparison to a control group; however, the study does have the advantage of having looked longitudinally at the same group of patients at various stages of treatment. In effect, the patients in the immediate group served as their own controls. Our results corroborate other studies that observed that patient satisfaction and oral healthrelated QoL improved significantly if a mandibular denture was supported by implants.18-21

The preoperative status indicated that patients were dissatisfied with a conventional mandibular prosthesis, as evidenced by the high scores reported with the Denture Satisfaction Questionnaire. Satisfaction with existing mandibular complete dentures at baseline was at the extreme end of dissatisfaction, which is clinically rational, since it is a common reason for replacement of complete dentures. In contrast, the scores for the maxillary prosthesis were lower, suggesting that the patients were relatively happy with their status, again reflecting common clinical findings. These differences in scores also point out that patients could discern the problems as related to the respective prostheses, suggesting that the questionnaire was quite useful in understanding the clinical problems. However, the Denture Satisfaction Questionnaire does not measure the patient's QoL, so the positive results cannot be viewed as an enhancement of QoL. The latter was observed through the OHIP questionnaire. An improvement in the QoL was present throughout the different treatment phases, with the most profound difference observed when the new mandibular prostheses were converted to an overdenture. Moreover, this positive change was sustained at the 1-year visit, despite the additional maintenance costs incurred.<sup>37</sup> Of note, the management of oral problems in these patients resulted in an improvement of both functional and psychosocial aspects, underscoring the fact that problems with conventional dentures are not explicitly related to function only and may not be detected by an objective assessment of the clinical situation alone.

The results of the regression analysis corroborated the findings of other researchers.<sup>37</sup> Our study indicated that preoperative denture satisfaction (high scores = poor satisfaction) was a predictor of OHIP scores (low scores = good QoL) following implant treatment. The interpretation of this result is that conventional prostheses, especially mandibular prostheses, caused discomfort, as evidenced by high preoperative denture satisfaction scores. In contrast, once the mandibular prosthesis was implant retained and comfortable, this led to an improvement, as confirmed by a reduction of the postoperative functional satisfaction scores. In the model, a reduction in postoperative denture satisfaction scores was associated with a reduction in OHIP scores, which reflects an improvement in QoL.

The economic analysis showed that, overall, the immediate protocol was not a cheaper alternative. It seems that the prosthodontic phase of the immediate protocol was associated with higher maintenance costs and was not cheaper when compared to the conventional protocol. Obviously, this does not negate the clinical potential of the treatment but rather suggests that the protocol should be modified or the patient should at least be informed of possible maintenance costs. A reasonable alternative should be the fabrication of the new mandibular prosthesis after an adequate soft tissue healing period. This would probably be associated with better prosthetic outcomes with respect to clip dislodgement and tooth fractures and less need for acrylic resin addition/relines. The methodology of measuring clinical time can be criticized, since we used recently measured clinical time for diverse prosthodontic procedures for the historical control group. However, if one had to exclude the time costs from the general conclusions, the results obtained are still valid and do not detract from the fact that the immediate protocol was associated with higher maintenance costs.

Regular observation of the immediate group allowed us to calculate cost-effectiveness ratios for a unit of improvement in the patients' QoL at various stages. Interestingly, although maintenance costs were considerable, treatment with implant-supported prostheses was more cost effective when compared to the conventional denture phase, as attested by the incremental cost-effectiveness ratios for improvement in the patients' QoL. The results suggest that the initial extra costs associated with implant treatment were justified, since it provided a better quality of life. This conclusion is limited, since the amount of change in OHIP units that is clinically relevant is yet to be determined. However, preliminary studies suggest that in a general setting, a 5-point change may be clinically significant.<sup>38</sup>

# Conclusion

Prosthetic maintenance encountered with the immediate group demonstrated that the protocol was not cheaper when compared to the conventional group. The study also suggests that in patients seeking implant-supported mandibular prostheses, the overdenture prosthesis may be more cost effective in improving the patients' QoL when compared to a conventional denture.

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