JPD-18-098

CLINICAL RESEARCH

Clinical outcomes of immediately loaded implant-supported overdentures: Along-term prospective clinical trial

ABSTRACT

Statement of problem. Long-term evidence of immediate loading of dental implants with bar overdentures is lacking.

Purpose. The purpose of this clinical study was to assess the clinical outcomes of immediate and conventional loading protocols of mandibular overdentures supported by 2 dental implants 14 years after initial placement.

Material and methods. Two groups of edentulous patients who received two TiUnite implants were enrolled in this study. In the experimental group (n=35), the implants were loaded immediately. In the control group (n=16), the conventional delayed loading protocol was followed. Both groups of participants were treated with overdentures supported by a standardized resilient bar mechanism. Clinical Oral Health-Related Quality of life (QoL) and patient satisfaction outcomes were recorded for 14 years after initial placement of implants and measured at various stages of treatment.

Results. Significant improvements in all outcomes were observed in both groups compared with baseline, and this improvement was sustained over the duration of the study. No differences were noted in any of the study outcomes between the 2groups.

Conclusions. Both loading approaches provide comparable short- and long-term results. The results of this study confirm that immediate loading of implant-supported overdentures is a

predictable treatment approach. Future studies should focus on assessing long-term clinical outcomes with mandibular overdentures in non-splinted applications.

CLINICAL IMPLICATIONS

Immediate loading of 2-implant-supported bar overdentures in the mandible is a predictable long-term treatment approach.

INTRODUCTION

For over 3 decades, clinicians have restored esthetics and function in edentulous patients with implant-supported prostheses following diverse loading protocols (immediate, early, and delayed). The choice of treatment protocol has biological, time-related, and economic implications for the patient. In this regard, researchers have compared clinical outcomes after immediate versus delayed protocols (the standard treatment) and have shown similarly high levels of success.[1-7]

The rationale for the immediate loading approach is to reduce the number of surgeries, which would lead to a reduction in morbidity. When the bone dimensions are adequate, patient morbidity can be further reduced by using a flapless approach for implant placement.[8,9] To reduce initial treatment cost and complexity, the number of implants supporting an overdenture can be reduced to 2or even one.[10-13]

Furthermore, as patient's expectations of mastication comfort and prosthetic outcome have increased compared with20years ago,[14] loading implants immediately would shorten the timeframe for both surgery and prostheses insertion, which leads to a more rapid achievement of

masticatory functional occlusion and improved esthetics without affecting the high success rates reported forendosseous dental implants.

However, long-term scientific evidence and the implications of immediate loading of dental implants with overdentures are lacking. In addition, little information is available regarding patient-based concerns in relation to treatment outcomes, including such factors as quality of life and overall satisfaction.

Therefore, the objective of this long-term prospective clinical study was to assess clinical and patient-based outcomes after the immediate loading of 2 dental implants with a bar-retained mandibular overdenture. The null hypotheses of this study were that no differences would be found in implant success rates with immediate and conventional protocols; that no difference in patient satisfaction and oral health-related quality of life outcomes would be observed between the immediate loading and conventional loading groups at 14 years of follow-up; and that improvement in patient denture satisfaction scores and oral health-related quality of life observed in edentulous patients treated with an immediate loading protocol would not be maintained over the course of 14 years.

MATERIAL AND METHODS:

The Human Ethics Board of the University of Toronto (Canada) approved the study protocol for a long-term, prospective clinical trial. Data were collected by an experienced, calibrated prosthodontist (SA). Before implant surgery, each patient was examined by an experienced prosthodontist using a combination of medical questionnaires and both clinical and radiographic examinations, which involved the use of one or more periapical, panoramic, and/or computed tomography views.

Implant placement surgery was performed by an experienced oral maxillofacial surgeon under local anesthetic (2% lidocaine, 1:100000 epinephrine) and antibiotic coverage (amoxicillin 2.0 g or clindamycin 600 mg orally 1 hour before surgery). A crestal incision extending approximately 1 cm beyond the mental foramina was made followed by the elevation of the mucoperiosteum. The final twist drill was one size smaller than the implant diameter to achieve primary stability. Two endosseous implants (Branemark TiUnite MK III/ IV;NobelBiocare); diameter: 3.75mm, length: 7 to 18 mm) were placed as parallel to each other as possible. Initial stability was assessed using a torque wrench (torque value ≥35 Ncm).

The participants were instructed to avoid brushing at the surgical sites and to rinse twice a day using 0.12% chlorhexidine mouth wash for 2 weeks. A soft diet for 7 days was recommended. Analgesics (ibuprofen 400 mg) were prescribed to be taken twice a day as needed. Sutures were removed after approximately 2 weeks, and oral hygiene instructions were reinforced.

Based on a pre calculated sample size, 35 participants were assigned to the immediate loading protocol (experimental group) to account for possible drop-out over the years. On the same day of implant-placement surgery, the existing complete dentures were hollowed out and relined with an interim soft reline (COE-Soft Liner; GC America) that was in direct contact with the 2implant healing abutments to ensure the transmission of functional forces to the implants. Ten days after surgery, a resilient ovoid bar/clip system (Dolder resilient bar; Cendres+Métaux SA) was retrofitted to the mandibular overdenture.

The conventional loading protocol (control group) comprised 16 participants who were selected retrospectively and matched with the experimental group in terms of age, implant type, prosthesis type, and the duration of the follow-up period. After implant placement, a healing

period of 3to 4months was allowed. Implant-supported overdentures were then fabricated, and the same resilient bar system used in the experimental group was used as the method of retention. Bilateral balanced articulation was the occlusal scheme provided for the participants in both groups.

Data pertaining to various parameters were collected, including patient demographics, general health, smoking history, and level of oral hygiene. The primary outcome was implant success rate. Criteria for implant success, as suggested in the Toronto Consensus Conference,[15] included testing for stability by tightening implants up to 20 Ncm and evaluating for pain and mobility. If such parameters were identified, the involved implants were categorized as failed and were removed.

The secondary outcomes were patient satisfaction with their dentures and changes in oral health-related QoL. Patient satisfaction was assessed using the Denture Satisfaction Scale.[16] Oral health-related QoL outcomes were measured using the short form version of the Oral Health Impact Profile questionnaire (OHIP-20).[17] The OHIP-20 consists of 20items, which were designed specifically for edentulous patients. Responses are based on a Likert scale format. A score is assigned based on the patient response: never =1, rarely =2, occasionally =3, often =4, very often =5, and all of the time =6 (minimum score 20;highest score 120). In both questionnaires (Denture Satisfaction Scale and OHIP-20), higher scores signified greater levels of patient dissatisfaction or compromised quality of life. In the experimental group, both questionnaires were administered before the fabrication of the new mandibular conventional complete denture (baseline data). The participants were asked to fill out the questionnaires again 1, 5, and 14 years after surgery. The 14-year patient satisfaction and quality of life were compared between the 2groups.

The Denture Satisfaction Scale scores were analyzed globally and analyzed based on only individual prosthesis items and functional status items. The OHIP scores were also analyzed globally and based only on functional-related questions and psychosocial-related questions.

Descriptive characteristics of study participants were summarized using descriptive statistics: mean/standard deviation for numerical variables (such as age, follow-up period) and frequency/percentage for categorical variables (such as sex, marital status). Implant success rates were compared between the control and experimental groups using the Fisher exact test. This test is similar to the chi-square test of independence but robust when dealing with rare events (such as implant failures). Denture Satisfaction and OHIP scores were analyzed using 2statistical tests: the paired samples *t* test (when exploring a change in scores over time within the immediate loading group) and independent samples *t* test (when comparing scores between the conventional loading and immediate loading groups). Paired *t* tests were used for multiple pairwise comparisons (baseline versus 5-year follow-up, baseline versus 14-year follow-up, 5-year versus 14-year follow-up), and to maintain the overall level of statistical significance at α=.05; all pairwise tests were run with Bonferroni correction. Oral health data are categorical; therefore, comparison between groups was performed using the chi-square test for contingency tables.

All inferential analysis was performed with the level of statistical significance as5%. *P* values <.05 were considered to indicate a statistically significant difference, and *P* values between .05 and .10 were considered as approaching significance. Statistical analyses were conducted using statistical software (IBM SPSS Statistics v24; IBM Corp).

RESULTS

Demographic data of the patients in both groups and the average follow-up duration are presented in Table 1. Implant success data for all 35 participants in the experimental group at the 10-year follow-up visit were available. However, 16participantsfrom the same group failed to present for the 14-year recall visit; 4had died, 2had implants that failed, and the other 10participantscould not be located.

As shown in Table 2, the percentage of successful implants at the 10-year follow-up was 94% in the immediate loading group (this is based on all 35 participants enrolled in this group initially) and 100% in the conventional loading group. No significant differences were found between the 2groups in failure rates (Fisher exact test *P*=.43).

The percentage of successful implants at 14 years after loading was 89% in the immediate loading group and 100% in the conventional loading group. No significant differences were found between the 2groups in failure rates (Fisher exact test *P*=.16).

At the 14-year follow-up visit, 2 of 19 participants (89% success rate) had failed implants in the immediate loading group, and none of the patient had failed implants (100% success rate) in the conventional loading group. No significant differences were noted between the 2groups in failure rates (Fisher exact test *P*=.49). At the 10-year follow-up visit, 2 of 35 patients (94% success rate) had failed implants in the immediate loading group, and none of the patients had failed implants (100% success rate) in the conventional loading group; however, the difference between the 2groups in failure rates at the patient level was not significant (Fisher exact test *P*=1.00).

In the immediate loading group, a significant improvement was noted in mandibular, functional, and total scores for denture satisfaction between baseline and 5 years and between baseline and 14 years (Table 3). A significant change as also noted in the total satisfaction score

between the 5- and 14-year follow-up visits (increase from 15.50 to 23.63), indicating lower patients satisfaction at 14-year follow-up.

Comparison between the conventional loading and immediate loading groups at the 14-year follow-up showed significantly more satisfaction for mandibular overdentures (retention, stability, comfort, appearance, and overall satisfaction) (P=.015) and almost significant improvement in functional score (mastication and speaking) (P=.073) for the immediate loading protocol.

The participants in the immediate loading group reported significant improvement in functional (difficulty in mastication, uncomfortable denture, avoiding some foods because of problems with dentures, and meal interruptions because of dentures), psychological (worried by dental problems, self-conscious, upset, feeling of less satisfying life because of problems with dentures), and total mandibular, functional, and total OHIP scores between baseline and 5 years as well as between baseline and 14 years (Table 4). A significant change in OHIP scores was also noted between 5- and 14-year follow-up in all 3categories (functional, psychological, total). However, comparison between conventional loading and immediate loading groups at 14-year follow-up showed no significant difference in functional, psychological, and total OHIP scores indicating a similar level of quality of life.

DISCUSSION

The results of this clinical trial suggested no significant differences in clinical and patient satisfaction between the conventional and immediately loaded implant-supported overdentures. Therefore, the first 2 null hypotheses were accepted. However, the improvement in patient denture satisfaction scores and oral health-related quality of life observed in the immediate

loading group was maintained over the course of 14 years, a finding that led to rejection of the third null hypothesis.

Since both clinical approaches applied in the current study appear to yield almost identical results, decisions regarding the 2treatment approaches must be based on other factors such as patient preference, provider preferences, and provider expertise. Immediate loading provides the patient with a rapid use of implants but is associated with greater treatment complexity and a need for the treatment team to handle the greater difficulty of care.

The lack of randomization of patients to the control and experimental groups is a limitation of the current study. Randomization aims to ensure balance of baseline characteristics between participants in the 2groups so that any possible divergence in outcome between the 2groups can be strongly attributed to a difference in the interventions. Nonetheless, a comparison test for the degree of similarity between the 2groups in terms of demographic characteristics and average follow-up period revealed that the 2groups were similar except for the number of follow-up months at 14 years. This was accounted for in the statistical analysis by performing linear regression analysis controlling for the number of follow-up month at 14 years.

The loss of participants to follow-up that occurred in this study at the 14-year recall examination is common in research involving the elderly, especially over a long duration of study.[1] Nonetheless, the complete data on implant outcomes of all 51 participants at the 10-year period reinforces the validity of the conclusions of the current study.

Future research should focus on reporting of long-term clinical outcomes of 2-implant-supported mandibular overdentures that are not joined by a bar. The use of individual attachments in overdenture applications (versus the use of a bar) simplifies treatment, reduces cost, and has been repeatedly validated in randomized controlled clinical trials. Unfortunately,

much of the current literature on immediate loading of implant-supported mandibular overdentures focuses on treatment methodologies using splinted applications or the use of more than 2 interforaminal implants.[3,6]

CONCLUSIONS

Based on the findings of this prospective clinical trial, the following conclusions were drawn:

1. Both loading approaches provide equivalent short- and long-term results.
2. The results of this study confirm that immediate loading of implant-supported overdentures is a predictable treatment approach.
3. Further studies should focus on assessing long-term clinical outcomes with mandibular overdentures in non-splinted applications.

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TABLES

Table 1. Demographic characteristics of study participants

	Immediate loading group n=35	Conventional loading group n=16	Comparison between groups
Sex			$X^2(1)=.03$, $P=.87$
Male	14 (40%)	6 (37.5%)	
Female	21 (60%)	10 (62.5%)	
Marital status			$X^2(1)=2.28$, $P=.52$
Single	3 (8.6%)	-	
Married	27 (77.1%)	13 (81.3%)	
Divorced	4 (11.4%)	3 (18.7%)	
Widowed	1 (2.9%)	-	
Age at the time of implant installation (years) Mean ±SD (range)	62.41 ±11.25 (36 – 83)	62.99 ±7.86 (50 – 77)	$t(49)=.18$, $P=.86$
Months follow-up at 14-year recall Mean ±SD (range)	170.67 ±3.65 (164 – 178)	152.62 ±14.99 (122 – 176)	$t(16.67)=4.67$, $p< .001$

Note: values reported as N (%) or Mean ±SD

Table 2. Implant success rates

Group	**Implants placed (failed)**	**Success (%)**
Conventional/delayed loading, n=16 (14-year recall)	32 (0)	100%
Immediate loading, n=19 (14-year recall)	38 (4)	89%
Immediate loading, n=35 (10-year average follow-up)	70 (4)	94%

Table 3. Denture satisfaction score

	Denture Satisfaction Score			
	Maxillary	Mandibular	Functional	Total
Conventional loading (CL) group				
14-year follow-up	8.94 ±3.71	11.75 ±4.78	4.19 ±1.94	24.88 ±9.03
Immediate loading (IL) group				
Baseline (BL)	9.54 ±5.00	21.00 ±2.72	5.51 ±1.96	36.06 ±8.39
5-year follow-up	7.10 ±3.77	5.73 ±1.72	2.67 ±1.15	15.50 ±6.06
14-year follow-up	7.63 ±4.40	7.95 ±4.01	3.11 ±1.52	23.63 ±8.41
P-values for comparisons*				
BL versus 5-year follow-up*	.056	<.001	<.001	<.001
BL versus 14-year follow-up*	.956	<.001	.035	.002
5-year versus 14-year follow-up*	.993	.224	.850	.017
IL versus CL group at 14-year	.355	.015	.073	.676
IL versus CL group at 14-year controlling for the months follow-up	.258	.016	.020	.280

*Note: * Bonferroni-adjusted pairwise comparisons; values reported Mean ±SD*

Table 4. Oral Health-Related QoL (OHIP-20) Score

	OHIP Score		
	Functional	Psychological	Total
Conventional loading (CL) group			
14-year follow-up	25.19 ±10.36	16.38 ±7.82	41.56 ±17.92
Immediate loading (IL) group			
Baseline (BL)	42.75 ±13.09	28.09 ±12.04	70.83 ±23.60
5-year follow-up	15.47 ±3.44	10.07 ±1.51	25.53 ±4.43
14-year follow-up	20.89 ±6.83	12.72 ±3.30	33.61 ±9.33
P-values for comparisons*			
BL versus 5-year follow-up*	<.001	<.001	<.001
BL versus 14-year follow-up*	<.001	<.001	<.001
5-year versus 14-year follow-up*	.011	.012	.009
IL versus CL group at 14-year	.158	.080	.109
IL versus CL group at 14-year controlling for the months follow-up	.140	.017	.056

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