A Prospective Randomized Study on the Immediate Loading of Mandibular Overdentures Supported by One or Two Implants; A 3 Year Follow-Up Report

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ABSTRACT

Aim: The objective of the study was to evaluate and compare treatments with mandibular overdentures supported by one or two immediately placed implants 3 years after loading.

Materials and Methods: Thirty-six edentulous subjects were eligible for inclusion. Using a random sampling system, one or two implants were placed in the mandible. Separate ball attachments were connected to the implants, and the denture was relined and delivered the day of surgery with the retentive components incorporated in the denture base. At the follow-up examinations peri-implant bone levels, implant and denture stability/retention, and need for maintenance and adjustments were evaluated. Moreover, the OHIP-EDENT questionnaire was used to measure patient satisfaction.

Results: Nineteen subjects (10 men and 9 women) with a mean age of 56 years were available for the 3-year follow-up examination. The group with 1 implant (Group 1) consisted of 11 subjects (5 women and 6 men) while the remaining 8 (5 women and 3 men) belonged to Group2. Nine subjects had been excluded during the first year due to failing implants, 6 had moved, 1 had died, and 1 reported severe illness. No implant failures between the 12-and 36 month follow-up were observed. The mean peri-implant bone change was .86 mm and the Implant Stability Quotient showed only minor changes with no significant difference between the groups when compared with the 12-month follow-up. Patient satisfaction scores increased significantly when compared with the baseline values and continued to be high for both groups and need for denture maintenance was low.

Conclusion: No significant differences were found between subjects in the two groups with respect to implant survival and peri implant bone loss, and patient satisfaction scores continued to be high for both groups. Need for denture maintenance was low in both groups.

KEY WORDS: bone loss, immediate loading, overdenture

INTRODUCTION

Rehabilitation of the edentulous mandible using osseointegrated dental implants to support a fixed or removable prosthesis is a safe and predictable treatment modality.[1–3] In most countries, overdenture therapy is often used because of lower treatment costs and favorable long term prognosis similar to those reported for fixed implant-supported prostheses.[4] There are many different options when restoring the mandible with an implant overdenture and the number of implants needed to provide satisfactory stability and retention is still a controversy among clinicians.[5,6] A recently

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published study comparing subjects with mandibular overdentures supported by two or four implants reported no significant differences among the groups regarding radiographic and clinical parameters as well as patient satisfaction.[7] There is evidence that a single implant may provide appropriate denture retention and function[8,9] and also when compared with overdentures supported by two implants.[10,11] However, there are no long-term data available to evaluate whether a single implant can be similarly successful and if the immediate loading protocol can be used.

In 2005, a prospective randomized controlled study comparing mandibular overdentures supported by one or two dental titanium implants and using the immediate loading protocol was initiated in the Department of Dental Clinical Sciences at Dalhousie University, Halifax, NS, Canada. The 12-month data have previously been reported[10] and the objective of the present study was to present the 3-year follow-up results.

MATERIALS AND METHODS

Forty edentulous individuals, 19 men and 21 women with a mean age of 53.3 years (range 38–69 years) fulfilled the criteria and were accepted for inclusion in the study. The study was approved by the Dalhousie University Health Sciences Research Ethics Board and all patients gave informed consent for participating in the trial. The criteria for inclusion in the study have been presented elsewhere.[10] The subjects were informed they would have one (Group 1) or two (Group 2) implants placed in the mandible to support a lower denture and that a random procedure (Research Randomizer, JavaScript) was to be used to determine the number of implants placed. All subjects received new upper and lower dentures and were scheduled for implant surgery after they were comfortable with their new dentures. Four subjects, three men and one woman, declined implant surgery, rendering a final study sample of 36 subjects (16 men and 20 women) with a mean age of 53.2 years (range 38–69 years). The surgical procedures were performed by an experienced Oral Maxillofacial Surgeon who placed a total of 55 Branemark System TiUnite implants (Nobel Biocare, Gothenburg, Sweden). A 2.25 mm diameter titanium ball attachment (Nobel Biocare) of suitable height was connected to the implant and secured with 15 Ncm torque. Immediately following the surgical procedure, the denture base was relieved in the areas of the attachments to allow for placement of the female attachment components (OSO o-rings, CA, USA). A reline impression (Aquasil Light Body, Dentsply, York, PA, USA) was made to optimize denture fit and placement of the retentive components in the denture base acrylic. The impression was poured with ball attachment replicas and a reline of the denture base using was done (Heat-cured Lucitone 199, Dentsply). The denture was delivered the day of surgical implant placement, and the subject was instructed to keep the denture seated for 12 hours to minimize postoperative swelling. Follow-up examinations were scheduled 3, 6, and 12 months after surgical implant placement, and thereafter annually for an additional 4 years. The annual clinical examination protocol included:

- Radiographic evaluation of the peri-implant bone level using periapical radiographs. A custom made film holder was used to standardize the radiographs using paralleling technique.
- Evaluation of mucosa using careful probing around the implant abutments
- Evaluation of denture stability and retention
- Evaluation of occlusion and assessment of denture teeth wear
- Recording of implant stability using resonance frequency analysis (RFA, Osstell, Gothenburg, Sweden)
- Recording of technical complications/need for maintenance

Moreover, each patient was asked to complete the OHIP-EDENT questionnaire[12] and return it before the clinical examination was performed. The questionnaire was developed to evaluate quality of life in edentulous subjects and included 19 questions regarding oral function, chewing ability, and problems with dentures related to fit/pain or discomfort. There were also questions related to quality-of-life issues asking if subjects were being upset, embarrassed, and finding life less satisfying because of problems with dentures. Each question had five response alternatives ranging from a negative opinion ("very often") to a positive ("never"). The responses were later coded from 1–5 where a higher value indicated a more affirmative opinion. The questionnaire was used at the baseline examination before new dentures were fabricated and then at 6 months, and annual follow-ups with the intention to evaluate patient satisfaction over time.

TABLE 1 Mean Implant Stability Quotient (ISQ) Values at Baseline and 36-Month Follow-Up

Variable	Group 1	Group 2
Mean ISQ Value BL	73.9 (range 61–85) ($n = 17$)	75.8 (range 63–85) ($n = 19$)
Mean ISQ Value 36-Month	81.9* (range 77–91) ($n = 11$)	83.0* (range 69–90) ($n = 8$)

*Significant difference between baseline and 36-month follow-up ($P < 0.01$).

Statistical Methods

All data were analyzed with descriptive statistics and presented as means with standard deviation, percentage, and distribution among the sample. Student's *t*-test was used to evaluate changes in marginal bone level. Mann–Whitney *U*-test and Wilcoxon signed-rank test were used to analyze differences in outcome between the two groups with respect to gender and number of implants and differences between responses to the OHIP questionnaire. The level of significance was set at 5%. All statistic analyses were performed using statistical software (SPSS 12.0, Chicago, IL, USA).

RESULTS

Of the original 36 subjects, 19 (10 women and 9 men) with a mean age of 56 years (range 41–72 years) were available for the 3-year follow-up. Group 1 included 11 subjects (5 women and 6 men) while the remaining 8 (5 women and 3 men) belonged to Group 2. Twelve subjects had been excluded during the first year, of which nine was due to failing implants and three subjects had withdrawn for personal reasons.

Since the 12-month follow-up, one subject had died, one reported severe illness, and three had moved and could not be reached. No implant failures were observed between the 12- and 36-month follow-up. Mean peri-implant bone level change was .86 mm (range 0.6–4.2 mm) and no significant differences were seen between the groups. The Implant Stability Quotient (ISQ) values showed only minor changes between the groups over time, but significant changes were observed within both groups from baseline to the 36-month follow-up, (Table 1). Patient satisfaction scores as measured by the OHIP-EDENT questionnaire increased significantly from baseline to the 12-month follow-up and continued to be high in both groups at the 36-month examination. No significant differences between the groups were observed (Table 2). Clinical evaluation of denture stability, retention and condition of peri-implant mucosa are presented in Table 3. Most dentures showed good ratings and no evidence of mucosal infections were observed. Need for maintenance was low and the most common procedure was replacement of retentive o-ring. Two complete upper dentures (CUD) needed reline due to poor stability and three metal housings needed to be re-attached to the base acrylic (Table 4). Minor evidence of denture tooth wear were seen among the vast majority but in five subjects, moderate to severe wear including complete loss of occlusal anatomy on bicuspids and molars was observed.

TABLE 2 Responses to OHIP – 19 Questionnaire at Baseline, 12-, and 36-Month Follow-Up

	OHIP Baseline		OHIP 12-Month		OHIP 36-Month	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Valid	17	19	13	11	11	8
Mean	50.8 (range 21–71)	45.4 (range 20–80)	84.8* (range 54–94)	80.7* (range 48–94)	83.2 (range 67–94)	78.6 (range 57–94)
SD	15.8	15.3	10.7	12.7	11.4	15.5

*Significant difference between baseline and 12-month Follow-up, ($P < .0001$).
Max value = 95.

TABLE 3 Clinical Evaluation of Denture Stability, Retention, and Peri-Implant Mucosa

	Ratings					
	Good		Fair		Poor	
Variable	Group 1 ($n = 11$)	Group 2 ($n = 8$)	Group 1 ($n = 11$)	Group 2 ($n = 8$)	Group 1 ($n = 11$)	Group 2 ($n = 8$)
Retention CUD*	9	7	1	1	1	–
Stability CUD*	8	7	2	1	1	–
Retention Mandibular OD**	10	7	1	1	–	–
Stability Mandibular OD**	10	8	1	–	–	
Condition Peri-implant Mucosa	11	8	–	–	–	–

*Complete Upper Denture.
**Overdenture.

DISCUSSION

Loading implants immediately following placement offers major advantages compared with the traditional delayed healing protocol including reduced number of surgical procedures, faster rehabilitation and increased patient comfort/satisfaction. Moreover, a simplified treatment protocol is beneficial especially for edentulous subjects struggling with non-retentive mandibular dentures. However, long-term follow-up studies are important to evaluate clinical outcomes.

In the present study, 19 subjects were available for the 3-year follow-up and no additional implant failures were observed since the 12-month report.[10] It appears that when using the immediate loading protocol risk of implant failure is mainly associated with the initial healing phase and decreases as the intimate implant–bone contact establishes during the osseointegration process. Even if separate ball attachments are beneficial allowing more freedom of denture rotation compared with more rigid stud attachments, force distribution on implants supporting a removable denture is very difficult to predict and loading is less controlled compared with fixed prostheses supported by splinted implants.[13,14] It is likely, however, that factors such as superior initial implant stability together with optimal denture stability and a balanced occlusal scheme to evenly distribute load may reduce unfavorable lateral forces and thereby play an important role for the clinical outcomes. Well-preserved residual ridge anatomy and optimized denture extension are important factor to minimize unfavorable load on implants, especially during the initial healing phase.

TABLE 4 Need for Maintenance among Subjects in the Two Groups between 12- and 36- Months, ($n = 19$)

Procedure	Group 1 ($n = 11$)	Group 2 ($n = 8$)
No. replaced resilient o-rings	6	6
Reline CUD*	1	1
Reline mandibular OD**	–	–
Occlusal adjustment	–	–
Re-attachment of metal housing	1	2
Denture tooth fracture	–	1

*Complete Upper Denture.
**Overdenture.

Significant improvement in patient satisfaction scores as measured by the OHIP-EDENT questionnaire were seen at the 12-month follow-up when compared with baseline values (Table 2). Patient satisfaction scores remained high also at the 36-month follow-up with no difference between the 12-month results and no differences were seen between the one- and two-implant groups. In a similar study comparing mandibular overdentures retained by one or two implants, a dramatic improvement in patient satisfaction was found and no significant differences were seen between subjects with respect to number of implants.[11] In another study on immediate loading of single-implant mandibular overdentures, high satisfaction scores were found and maintenance of high satisfaction level continued through the 36-month recall.[15]

In the present study, two outliers, one in each group were identified and those subjects also expressed major

dissatisfaction with their dentures at baseline. Their negative attitude did not change also after new dentures had been fabricated and connected to the implants although these subjects did not have higher need for denture adjustment or maintenance when compared with the other subjects. However, although lower than average scores at the baseline, both subjects' satisfaction rates more than doubled at the 12-month follow-up and the rates maintained at the same high level at the 3-year follow-up.

Lower costs for components, shorter time for surgery, lower need for maintenance, and equally high patient satisfaction score could be arguments for suggesting that a mandibular overdenture supported by one implant could be a viable alternative to the customary two-implant overdenture.

Mean peri-implant bone change was low and only one subject in group 2 showed bone loss exceeding 1.2 mm for one of his two implants. The results are comparable with findings in similar studies and although some subjects showed plaque accumulations and calculus build up on the ball attachments, no evidence of peri-implant mucosal infections was observed.[16–19] Need for maintenance was low and mainly related to replacement of retentive o-ring (Table 4). All overdentures showed good/fair stability and retention and no fractures or cracks of the base acrylic were observed (Table 3). This is in contrast with findings in another study on mandibular overdentures supported by one or two un-splinted implants where 17 fractures in 13 subjects were recorded.[20]Although there was a higher incidence of fractures among single implant overdentures, no significant differences between the groups could be found.[20]

An interesting finding was the significant increase in ISQ, which indicate improved bone–implant contact over time (Table 1). Other studies on immediate loading of mandibular overdentures report stable or slightly lower ISQ values over time[21–23] so the significant improvement in the present study is surprising. Stephan et al. presented mean ISQ value drop from 74.4 (baseline) to 70.2 at the 2-year follow-up for immediately placed mandibular implants splinted with a bar,[22] and in a study on single implant overdentures, Liddelow et al. reported mean ISQ value drop from of 74.1 (baseline) to 73.1 registered at the 12-month follow-up.[23] No significant differences were seen at the 36-month follow-up.[15] In both those studies, Branemark TiUnite surface implants were used, while in the present study the "groovy" implant design was chosen. It has been suggested that the grooves on the implant thread could trigger implant–bone healing and perhaps this design could explain why ISQ values in the present study exceeded those where conventional threads were used.[24]

In the present study, the first generation Ivoclar BlueLine (Ivoclar Vivadent AG, Schaan, Lichtenstein) denture teeth was used and had been introduced just before the trial started. At the 36-month follow-up, only one of the teeth had fractured, but in five subjects, moderate to severe wear of the denture teeth was observed. The Ivoclar BlueLine denture teeth that were used in the present study were marketed as highly wear resistant due to special double cross-linked material and a special layering technique is used to resemble the natural tooth's esthetics and characteristics. Since none of the subjects were diagnosed with bruxism/clenching habits or presented with any symptoms related to parafunction, the reasons for the extended wear are not fully know. The Blue Line denture teeth were new on the market at the time of the study, and no long term clinical evaluations had been completed. However, no subjects were concerned or uncomfortable with the rough denture tooth surface and no functional or esthetic complaints were presented.

Randomized clinical trials involving a surgical procedure are always at risk of having fewer subjects available for follow-ups, especially when older individuals are included.[25] The fact that several subjects were lost to follow-up has an impact on the generalization of the study results. In the present study, the huge number of lost-to-follow-ups is a weakness, but nevertheless it is still important to present long term follow-up data for those remaining in the study.

Although this was designed as a pilot study, the number of subjects is important for valid statistical analysis of the results. Of the original 36 subjects, 24 attended the 12-month follow-up, and of those, 19 were available for the 3-year follow-up. Of the additional five subjects lost to follow-up at the 3-year follow-up, two (one man and one woman) had a single implant and the remaining three (two women and one man) had two implants. Jemt et al. reported a 26% lost-to follow-up during a 5-year follow-up period among subjects who had implant overdentures in the maxilla or mandible,[26] and similar figures were presented from a 3-year follow-up study on single-implant mandibular overdentures by Liddelow et al.[23]

CONCLUSION

Within the limitations of the present study it can be concluded that patient satisfaction remained high and need for maintenance was low after treatment with immediately loaded mandibular overdentures supported by one or two titanium dental implants. No significant differences were seen between subjects in the two groups indicating that using only one implant to retain a mandibular overdenture could be considered an alternative to the customary two-implant overdenture therapy. Significant increase in mean ISQ for implants in both groups was observed when values at the 36-month follow-up were compared with those from baseline registration.

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