Satisfaction and Clinical Outcomes Among Patients with Immediately Loaded Mandibular Overdentures Supported by One or Two Dental Implants: Results of a 5-Year Prospective Randomized Clinical Trial

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Purpose: *The purpose of this study was to evaluate patient satisfaction and clinical outcomes among subjects with mandibular overdentures supported by one or two immediately placed dental implants 5 years after loading.* ***Materials and Methods:*** *Thirty-six subjects (16 men and 20 women) received one or two dental implants in the anterior mandible, and all implants were loaded the day of surgery. Subjects were scheduled for follow-up 3-, 6-, and 12 months after implant placement and thereafter annually for 4 more years. Patient satisfaction scores were measured with the Oral Health Impact Profile-EDENT (OHIP-EDENT) questionnaire.* ***Results:*** *Seventeen subjects (7 male and 10 female) with a mean age of 59.4 years (range, 44 to 74 years) were available for the 5-year follow-up examination. Nine subjects with 10 failing implants were excluded during the first year and nine subjects were lost to follow-up. No implants failed between the 12- and 60-month follow-up examinations, and the need for denture maintenance was low. Mean peri-implant bone change was 0.92 mm, and the Spearman test failed to show correlation between the insertion torque value and implant stability quotient. Patient satisfaction scores increased significantly when compared with baseline values and continued to be high for both groups, with no significant differences.* ***Conclusion:*** *Ten implants in nine subjects failed early, but no failures were observed after the 12-month examination. No significant differences were found between subjects in the two groups with respect to implant survival rates and peri-implant bone loss, and patient satisfaction scores continued to be high. Although patient satisfaction and implant success were high during the 12- to 60-month period, the results should be interpreted with caution because of the high number of failing implants and patients lost to follow-up. More research is needed to study outcomes of treatment with immediately loaded mandibular implant overdentures.* Int J Oral Maxillofac Implants 2017;32:128–136. doi: 10.11607/jomi.4824

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The two-implant overdenture is a safe and well-documented treatment option that has been used for more than 20 years to restore the edentulous mandible.[1,2] New techniques have been used to develop a rough implant surface, resulting in improved initial stability and higher success rates. Changing implant surface characteristics from smooth to moderately rough with osseoinductive ability appears to increase success rates when using immediate loading protocols.[3–5] Further, the number of implants needed to successfully support fixed and removable prostheses in the edentulous jaw has decreased compared with earlier loading protocols.[6–9] Successful outcomes from studies on immediate loading have been reported, mainly from treatments involving single-tooth and multiunit fixed prostheses.[8,10] Reports are scarce on outcomes from long-term studies on immediate loading of implant overdentures.[11] Although there is evidence that immediate loading of a one- or two-implant overdenture may be successful,[9,12,13] controversy remains among clinicians about whether

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immediate loading can be used as a safe and predictable treatment option. However, evidence exists that a single implant placed in the midline of the mandible may provide appropriate overdenture retention, resulting in improved oral function and patient-reported oral health-related quality of life.[6,7,9,14] Reduced patient cost, treatment time, and need for prosthetic maintenance are also factors to consider.[7] Even though some reports indicate successful results from studies on immediate loading of one- or two-implant–supported overdentures, it is important to evaluate long-term outcomes and the need for prosthodontic maintenance.[11]

In 2005, a prospective, randomized controlled study comparing mandibular overdentures supported by one or two titanium dental implants and using the immediate loading protocol was initiated in the Department of Dental Clinical Sciences at Dalhousie University, Halifax, Nova Scotia, Canada. The 1- and 3-year follow-up data have been reported previously, and the objective of the present study is to present the 5-year follow-up results.[6,9]

MATERIALS AND METHODS

Of the original 40 subjects included in the study sample, 3 men and 1 woman declined implant surgery. The remaining 36 subjects (16 men and 20 women), with a mean age of 53.3 years (range, 38 to 69 years) received mandibular overdentures supported by one or two implants (Brånemark TiUnite). To be included in the study, subjects had to be completely edentulous, have worn maxillary and mandibular dentures for at least 1 year, and be no older than 70 years of age. The subjects' medical history could not have contraindicated surgical implant placement, and patients needed to have enough bone volume between the mental foramina for placement of one or two implants of at least 10 mm in length. The criteria for study inclusion have been presented in detail elsewhere.[6] Subjects were informed that they would have one (group 1) or two (group 2) implants placed in the mandible to support the denture, and that a random procedure (Research Randomizer, JavaScript) was to be used to determine the number of implants placed. All subjects were diagnosed with Angle Class I malocclusion and were provided with new maxillary and mandibular dentures by three experienced prosthodontists. The lingualized occlusal scheme was used exclusively, and no dentures were designed with posterior crossbites. Subjects were seen for follow-ups and adjustments with implant surgery only when they were comfortable with their new dentures. The subject's mandibular denture was duplicated in clear resin (Dentsply) to be used as a surgical guide. An experienced oral and maxillofacial surgeon placed a total of 55 implants (Brånemark System RP TiUnite). Insertion torque value (ITV) and implant stability quotient (ISQ) were recorded for each implant. The ISQ value was recorded with the Osstell device (Osstell). This device quantifies the implant-to-bone stability by analyzing the resonance frequency of a SmartPeg (Osstell) that is temporarily mounted to the implants and can be used at follow-up appointments to evaluate changes in implant stability over time.[15] Bone volume and quality were recorded according to the Lekholm and Zarb index, and the details are presented elsewhere.[6] ITVs for all implants were registered at surgery using the Osseocare motor and manual torque wrench (Nobel Biocare). Immediately after surgical implant placement, a 2.25-mm-diameter ball attachment of desired height was connected to the implant and tightened with the torque recommended by the manufacturer. A vinyl polysiloxane (Aquasil, Dentsply) impression was made, and the denture was sent to the laboratory for hard reline and insertion of the metal housing with the retentive male attachment component. The mandibular denture was delivered the day of surgery. The dentures were carefully evaluated to ensure proper fit (pressure indicator paste, Mizzy), stability, retention, and balanced occlusion. Subjects were given oral hygiene instructions and told not to remove their mandibular overdenture for 24 hours to reduce postoperative swelling. All subjects were instructed to limit their diet to soft foods until they returned for the 1-week follow-up. The follow-up appointment included suture removal, evaluation of soft tissue healing, and denture fit with any necessary adjustments.

Patients were scheduled for follow-up examinations 3, 6, and 12 months after implant placement and thereafter annually for 4 years. The follow-up examinations were performed according to a standard protocol and included evaluation of denture stability and retention, occlusion and wear, implant stability, mucosal condition, and peri-implant bone level. Denture tooth wear was recorded in the following four categories: 1 = insignificant wear; 2 = minor signs of wear/facets; 3 = moderate signs of wear but no loss of vertical dimension; and 4 = significant signs of wear and loss of tooth anatomy and vertical dimension.

Denture stability and retention were recorded and rated "good," "fair," or "poor" depending on the clinical evaluation. Detailed information about the protocol has been presented elsewhere.[6] In addition, all technical complications and need for maintenance were recorded and included factors associated with retention, denture fit, and occlusion. At the 6-month and annual follow-up examinations, subjects were asked to complete the Oral Health Impact Profile-EDENT

Table 1 Distribution of ITV and Initial ISQ Values Among Subjects (n = 36)

ID	Age (y)	Gender	No. of implants	ITV (Ncm)	ISQ (1–100)
1	38	Female	2	40/40	70/68
2	49	Female	2	30/30	78/74
3	54	Female	2	30/30	68/73
4	49	Female	1	30	79[a]
5	56	Female	2	30/30	72/64[a]
6	62	Female	1	30	78
7	67	Male	1	30	78
8	54	Male	2	30/30	77/80
9	63	Male	1	30	69[a]
10	57	Female	2	40/40	74/78
11	45	Male	2	30/30	72/76
12	51	Male	1	30	70[a]
13	67	Female	2	30/30	78/82
14	44	Male	1	30	76
15	51	Female	1	30	74
16	69	Male	2	30/30	79/85
17	58	Female	2	30/30	70[a]/79
18	57	Female	1	35	62
19	57	Male	2	30/30	68[a]/73[a]
20	55	Female	2	30/30	78/84
21	45	Female	2	30/30	79/75
22	59	Female	2	20/40	83/78
23	53	Male	1	30	76
24	43	Male	1	30	78
25	61	Male	1	20	77
26	47	Female	1	30	85
27	51	Female	1	30	66
28	46	Female	2	30/30	72[a]/75
29	50	Male	2	40/40	75[a]/77
30	47	Female	2	20/30	78/76
31	55	Male	2	40/30	71[a]/76
32	64	Female	1	40	71
33	39	Male	1	30	73
34	63	Female	1	30	72
35	47	Male	1	30	73
36	45	Male	2	30/30	80/82

[a]Failing implant.
ITV = insertion torque value; ISQ = implant stability quotient.

(OHIP-EDENT) questionnaire, which contains 19 questions about oral function, chewing ability, and problems related to their dentures. The responses were coded from 1 to 5; a higher value indicates a more affirmative response. The questionnaire has been validated and used in previous studies on oral health–related quality of life,[11] and details have been presented elsewhere.[9] The study was approved by the Health Sciences Human Research Ethics Board at Dalhousie University, Halifax, Nova Scotia, Canada (project 2004-948).

Statistical Methods

Regression methods for complex survey sample designs were used to compare mean values over time and by implant group and gender, accounting for repeated measures over time and producing heteroscedasticity-consistent valid tests.[16,17] All models were adjusted for time, implant group, and gender, and they were assessed for two-way interactions. Regression methods were also used to assess for differences in ordinal rankings over time and by implant group and gender.[18] Life table methods and the log-rank test were used to compare implant survival by implant group.[19] Spearman's ρ test was used to evaluate the correlation between ITV and ISQ values. All analyses were performed using SAS Version 9.3 PROC SurveyReg and LifeTest (SAS Institute).

RESULTS

Table 1 presents the distribution of age, gender, number of implants, ITV, and ISQ values among subjects in the two groups. The vast majority of implants were placed using 30-Ncm insertion torque, including 9 of the 10 failing implants. The mean ITV and ISQ values for group 1 were 30.3 and 74, respectively, and the corresponding values among subjects in group 2 were 31.6 and 76, respectively. Spearman rank test failed to show significant correlation between ITV and ISQ values ($P = .087$).

A total of 10 implants failed early. Three subjects in group 1 lost their single implant, one subject in group 2 lost both implants, and the other five subjects lost one of the two implants (Table 1).

Of the original 36 subjects, 17 (7 male and 10 female), with a mean age of 59.4 years (range, 44 to 74 years), were available for the 5-year follow-up. Nine subjects with failing implants were excluded from the study, one died before the 3-year follow-up, one reported severe illness, and 8 moved and could not be reached. Of the 17 subjects, 11 (6 men and 5 women) were in group 1 and 6 (1 man and 5 women) were in group 2. The 5-year implant survival rate was 82% because no failures were observed/reported between the 12- and 60-month follow-ups.

The ISQ values varied among subjects and within the groups, and mean values over time are presented in Table 2. ISQ values were significantly higher at the 12-, 36-, and 60-month follow-ups than they were at baseline ($P < .01$). However, the values were not significantly

different after the 12-month follow-up. No significant differences were seen according to group or gender.

The mean peri-implant bone loss was 0.92 mm at the 60-month follow-up (range, 0.6 to 3.0 mm), and although the values were slightly higher among subjects in group 2 when compared with those in group 1 (1.3 vs 0.98 mm), no significant difference between the groups was found. However, bone levels varied significantly over time. Significantly less peri-implant bone loss was observed at 12 months than at 36 and 60 months ($P < .0001$), but no difference was seen between the 36- and 60-month follow-up evaluations. When comparing the two groups over time, no significant difference was observed in bone level changes by number of implants or gender.

Table 3 presents subjects' need for prosthodontic maintenance. The most common procedure was replacement of the resilient o-ring.

Denture tooth wear was significantly greater at the 36- and 60-month follow-ups when compared with the 12-month follow-up ($P < .0001$). However, tooth wear between the 36- and 60-month follow-up examinations was not significantly different ($P > .05$), and no differences were seen between the two groups.

Table 4 presents denture stability and retention values. Overall, no significant differences were observed in denture retention for the mandibular overdenture over time. However, when comparing retention and stability between groups, some differences were seen over time. Overdentures in group 2 showed significantly higher retention at 60 months compared with those in group 1 ($P < .0005$, Table 5).

Patient satisfaction scores, as measured with the OHIP-EDENT-19 questionnaire, varied significantly over time (Table 6). The scores were significantly higher at years 1, 3, and 5 compared with baseline ($P < .05$), but they were not significantly different between years 1, 3, and 5 ($P > .05$). Men had significantly higher OHIP ratings than did women (Table 7, mean difference = 10.3, SE = 3.3; $P < .005$; 95% confidence interval, 3.5 to 17.1). No significant two-way interactions (all $P > .33$)—implying the male versus female difference—were observed, and this result was similar at each follow-up time.

Table 2 Distribution of Mean ISQ Values at Baseline and at 12-, 36-, and 60-Month Examinations

Examination	Group 1	Group 2
Baseline	73.9 (range, 61–85) (n = 17)	75.8 (range, 63–85) (n =19)
12 months	83.1* (range, 74–89) (n = 14)	80.8* (range, 74–89) (n = 10)
36 months	81.9 (range, 77–91) (n = 11)	83.0 (range, 69–90) (n = 8)
60 months	83.1 (range, 77–92) (n = 11)	82.4 (range, 75–90) (n = 6)

*Significant difference ($P < .01$).

DISCUSSION

This is the first study, to the authors' knowledge, in which the immediate loading protocol has been used to compare outcomes of a single- versus two-implant mandibular overdenture. In this 5-year report, 17 of the original 36 subjects were available for follow-up. Even though the number of subjects lost to follow-up may be high, it is important to present long-term follow-up data from novel treatment concepts. At the 12-month follow-up,[6] 10 implants in 9 subjects failed early, but no additional implant failures were observed. The results of this study show an overall implant failure rate of almost 20%. Three of the 17 subjects in group 1 lost their only implant, while the other seven failures were observed among 6 subjects in group 2.

These results contrast with findings in a prospective study on immediate loading of a single medium-rough–surface implant supporting a mandibular overdenture in 28 subjects for whom a 100% implant survival rate was reported after 36 months.[14] To be considered for immediate loading in that study, a minimum ITV of 45 Ncm and an ISQ of 60 or higher were required, whereas in the present study, no minimum ITV or ISQ values were included in the protocol. Sato and coworkers[20] included implants with ITVs of 35 Ncm or higher for immediate loading, while another study comparing single- and two-implant overdentures required ISQ values of 60 and above for inclusion.[21] Thus, ITV and ISQ values used in other studies on immediate loading vary and appear to be based on clinical experience rather than on evidence-based research, and the impact on outcomes is not fully understood.[14,20,21]

The force distribution on implants supporting removable prostheses is difficult to predict and estimate, and it seems possible that—although not verified by evidenced-based research—minimum ITV and ISQ values should be considered to allow for immediate loading. When the present study was initiated, there were no recommendations from similar trials regarding minimum ITV or ISQ values for immediate loading of implant overdentures. Furthermore, it is not known what ITV is required to achieve sufficient primary implant stability and successful outcomes. In the present study, nine failing implants had ITVs of 30 Ncm and one had an ITV of 40 Ncm, while the ISQ values ranged between 69 and 79 among subjects with failing implants in group 1 and from 64 to 75 among those in

Table 3 Need for Maintenance Among Subjects in the Two Groups at 12, 36, and 60 Months

Procedure	Group 1			Group 2		
	12 mo (n = 14)	36 mo (n = 11)	60 mo (n = 11)	12 mo (n = 10)	36 mo (n = 8)	60 mo (n = 6)
No. of replaced resilient o-rings	10	6	7	18	6	2
Maxillary denture reline	3	1	–	1	1	–
Mandibular denture reline	2	–	–	1	–	–
Occlusal adjustment	1	–	–	–	–	–
Reattachment of metal housing	–	1	–	–	2	–
Denture tooth fracture	–	–	–	–	1	–

Table 4 Distribution of Denture Stability and Retention Ratings at 12-, 36-, and 60-Month Examinations

Variable	Ratings at 12 mo (n = 24)			Ratings at 36 mo (n = 19)			Ratings at 60 mo (n = 17)		
	Good	Fair	Poor	Good	Fair	Poor	Good	Fair	Poor
Maxillary CD stability[a]	23	1		14	3	2	15	2	
Maxillary CD retention[b]	24			16	2	1	15	2	
Mandibular OD stability[a]	20	4		18	1		17		
Mandibular OD retention[b]	21	3		17	2		10	7	

[a]Good = no mobility when loaded gently on the premolar area; Fair = minor mobility when loaded gently but does not come loose; Poor = denture comes loose when loaded gently.
[b]Good = denture does not come loose when pulled gently in vertical direction; Fair = denture comes loose occasionally when pulled gently in vertical direction; Poor = denture does not stay in place.
CD = complete denture; OD = overdenture.

Table 5 Mandibular Overdenture Retention and Stability with Respect to Number of Implants

Examination	No. of Implants	Retention		Stability	
		Good	Fair	Good	Fair
12 months	Group 1 (n = 14)	11 (78.6%)	3 (21.4%)	10 (71.4%)	4 (28.6%)
	Group 2 (n = 10)	10 (100%)	—	10* (100%)	—
36 months	Group 1 (n = 11)	9 (81.8%)	2 (18.2%)	10 (90.9%)	1 (9.1%)
	Group 2 (n = 8)	8 (100%)	—	8 (100%)	—
60 months	Group 1 (n = 11)	5 (45.5%)	6 (54.5%)	11 (100%)	—
	Group 2 (n = 6)	5** (83.3%)	1 (16.7%)	6 (100%)	—

*$P < .05$.
**$P < .0005$.

Table 6 Responses to OHIP-EDENT-19 Questionnaire[a]

	OHIP Baseline		OHIP 12 mo		OHIP 36 mo		OHIP 60 mo	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Valid	17	19	13	11	11	8	11	6
Mean	50.8	45.4	84.8*	80.7*	83.2	78.6	83.2	67.6

[a]Maximum value: 95.
*$P < .0001$.
OHIP = Oral Health Impact Profile.

group 2. In contrast, three successful implants (two in group 2 and one in group 1) had a low ITV of 20 Ncm and exhibited ISQ values ranging from 77 to 83 (Table 1). Thus, there is no conclusive factor that could be identified to explain the relatively high number of failing implants in this study, but it is reasonable to assume that higher ITVs would be beneficial, and more specific clinical guidelines are needed. However, even if the ITV were relatively low, the ISQ remained above 64 for all implants, indicating an initial good implant-bone contact.

In a review of more than 300 reports on factors contributing to failures of dental implants, Chrcanovic et al[22] found that low insertion torque and poor initial stability were correlated with increased failure rates for immediately loaded implants. However, the same

study concluded that the reasons for implant failures are not easily identified, and although factors such as smoking, surgical technique, short implant length, initial implant stability, and poor bone quality have been mentioned as playing a role, it is unclear how they interact. Variations in the number of subjects and implants, statistical methods, and follow-up periods also make comparisons between studies challenging.[22]

The correlation between ITV and ISQ has been of special interest and is evaluated in a number of recent studies on immediate loading.[23–29] In the present study, the Spearman rank correlation test did not show any significant correlation between the ITV and ISQ values ($P = .087$), but one should use caution when interpreting these results because the present study was not designed to assess for an association between torque and stability. Moreover, there were only three ITVs registered and most were 30 Ncm. Hence, the statistical power is low to demonstrate a correlation between torque and stability.

These study results are in agreement with findings by da Cunha et al[23] with respect to ITV and ISQ values for 24 immediately placed implants. They found no correlation between ITV and ISQ values when comparing machined and moderately rough–surface Brånemark implants.[23] Another study comparing the primary stability of two implant systems found no correlation between ITV and ISQ values in the two systems and concluded that ISQ values from different implant systems are not comparable.[24] However, contrasting results have been reported in several studies. In a study comparing two self-tapping tapered implant systems, a significant correlation of $r = 0.78$ ($P < .001$) was reported,[25] and another study including 158 implants showed a strong correlation of $r = 0.583$. Degidi and coworkers[27] found a weak correlation of $r = 0.218$ between ITV and ISQ values in a study of 4,135 implants. Among subjects with implants of two different designs, a somewhat stronger significant correlation between ITV and ISQ values ($r = 0.427$, $P < .05$) was found.[28]

Both ITV and ISQ have been used to predict risks of implants failing. In an animal study comparing tapered and parallel-sided implants, higher ITVs were seen for tapered implants when compared with parallel-sided implants, while successful implants, regardless of design, showed significantly higher initial ISQ values compared with failing implants.[29] These results are in accordance with the findings in the present study, in which a multivariate model using "implant failure" as the dependent variable found an 11% higher risk of an implant failing per ISQ unit, indicating the lower risk of failure with higher ISQ values.[6]

Results from a number of studies on correlation between ITV and ISQ differ, and concern has been raised about judging implant systems on the basis of those two variables.[29] Thus, it is evident that more research is needed to identify factors of importance and to better understand the association/interaction between ITV and ISQ. Study design and number of implants, as well as variations in surgical technique, drilling protocol, bone density, age, gender, and implant body/thread design and diameter, are factors that have been mentioned as having an impact on variations in outcomes.[25–29]

Table 7 OHIP-EDENT-19 Mean Scores by Time and Gender

Evaluation	Gender	No. of subjects	Mean	SD	Min	Max
12 months	Female	13	79.6	13.7	48.0	94.0
	Male	11	87.9*	5.4	80.0	94.0
36 months	Female	10	74.0	12.8	57.0	92.0
	Male	9	86.7*	9.9	64.0	94.0
60 months	Female	10	71.6	22.2	19.0	92.0
	Male	7	86.4*	4.7	80.0	92.0

Mean difference = 10.3, SE = 3.3.
*$P < .005$.
OHIP = Oral Health Impact Profile.

The ISQ values increased significantly between baseline and the 12-month follow-up, and the values remained basically unchanged at the 36- and 60-month examinations (Table 2). Although data from long-term studies on immediate loading of implant overdentures are lacking, 2- to 3-year results from other similar studies indicate almost unchanged ISQ values over time.[14,30]

The mean peri-implant bone level showed only minor deviations from the 3-year follow-up (0.92 vs 0.86 mm). The results are comparable with those from a study on mandibular overdentures supported by two implants and using a traditional healing/loading protocol.[31] However, contrasting 3-year results regarding peri-implant bone loss were reported from two studies on immediate loading of mandibular two-implant overdentures.[13,32] One study reported more peri-implant bone loss around immediate implants when compared with conventionally loaded[32] implants, while the other study reported values comparable with those for implants loaded according to the delayed protocol.[13] Nevertheless, data are lacking from long-term studies comparing immediate and delayed loading for mandibular two-implant overdentures, and variations in methodology make comparisons between the different protocols difficult.[33,34] In the present study, no significant differences were observed when comparing the groups with respect to implant failure and peri-implant bone loss. This finding indicates that a single implant may be sufficient to retain and stabilize a well-fitting overdenture without

elevated risk of damaging peri-implant bone as a result of occlusal overload.

In the present study, the need for denture maintenance was higher during the first 12 months compared with the 36- and 60-month follow-ups. Only one subject with a single implant experienced denture base fracture, which happened during the first year. No other fractures were observed during the entire follow-up period, and no denture reline was needed after the 36-month examination (Table 3). These findings are in contrast with those of a similar study including 85 subjects with mandibular overdentures supported by one or two implants; in that study, nine subjects with single-implant overdentures experienced 11 fractures, while among those with two implants, 6 fractures were observed.[35] In that study, precision-fitting gold matrices were used to retain the denture, whereas in the present study, resilient silicone rings provided retention. One possible explanation for the lower incidence of fractures in the present study is that a more flexible connection between the ball attachments and the resilient o-rings could have resulted in a more favorable stress distribution in the base acrylic during loading.

A well-fitting, good-quality overdenture distributes chewing forces over the attachments and the edentulous ridge, while forces on the attachments are much higher when the denture has a poor fit, resulting in increased wear of the retentive components and higher risk of denture fracture. In the present study, all dentures were relined and metal housings with retentive o-rings were incorporated in the base acrylic immediately after implant placement to provide optimal quality and fit.

Comparison of different overdenture attachment systems is important when evaluating durability, need for maintenance, and denture retention. In the present study, the resilient o-rings required frequent replacement, particularly during the first years (Table 3). Several subjects in both groups initially reported some problems when seating the denture onto the ball attachment, which may have caused damage to the resilient o-rings, necessitating their replacement. The need to replace the o-rings declined over time as subjects became more comfortable managing insertion and removal of their dentures, and the frequency was similar for both groups (Table 3). The o-rings were easy to replace and are inexpensive for the patient; from a cost perspective, differences existed between the groups. Compared with other common attachment systems on the market, such as the Locator (Zest Anchors), it seems that the ball attachment in combination with a resilient o-ring may be comparable regarding the need for maintenance and cost.

In a study comparing ball and Locator attachments, frequencies of activation and replacement of the matrix as well as denture relines were significantly higher in the ball attachment group when compared with those in the Locator group,[36] whereas another study found a higher number of maintenance events for the Locator attachment system when compared with a ball attachment and plastic matrices system (Southern Implants).[37]

Tooth wear was higher than expected and varied significantly over time ($P < .0001$). A significantly higher degree of tooth wear was seen at 36 and 60 months than at the 12-month examination ($P < .05$). Because the Ivoclar BlueLine denture teeth (Ivoclar Vivadent AG) was not commercially available before the time of the study, no reports from long-term clinical evaluations were available. At the 36-month follow-up, 5 subjects were observed as having moderate or significant denture tooth wear, and the number increased to 10 at the 60-month examination. Of the 10 subjects, 8 were women and 2 were men, which means that the vast majority of the remaining women in the study exhibited moderate or significant denture tooth wear. Studies on masticatory forces among dentate subjects show significantly higher values for men than for women, but no gender differences were found among edentulous subjects.[38,39] The present study's finding that women exhibited more denture tooth wear compared with men is confusing, and there is no clear explanation for this result. It seems possible that at the time of the study, the composition of the new denture tooth material may not have been fully developed or tested, explaining why the batch used in the present study showed more than normal wear. At the screening/initial examination, during the study, and at the follow-up examinations, no subject was diagnosed with parafunctional habits or had any clinical symptoms related to severe tooth clenching or bruxism.

Patient satisfaction scores, as measured by the OHIP-EDENT-19 questionnaire, showed a significant increase between baseline and the 12-month follow-up. The scores remained high and showed no significant differences between the 12-, 36-, and 60-month examinations (Table 6). The results are in agreement with those of Alfadda et al,[11] who reported significant improvement in patient satisfaction with immediately loaded implant overdentures after 5 years.

Men reported significantly higher OHIP satisfaction scores over time compared with women (Table 7). This is in contrast with findings by Walton et al, who did not find any significant differences between men and women at the 12-month follow-up.[7] It is difficult to explain why men were more satisfied, but perhaps having implants to stabilize and retain the mandibular denture was more important to them for improved oral function, while the high incidence of denture tooth wear among women may have had an impact on function and esthetics, resulting in lower satisfaction rates.

In the present study, one outlier in group 2 was identified and expressed major dissatisfaction with her dentures at the 5-year follow-up examination. A common problem with studies involving a small number of subjects is that one subject often ends up having a large influence on the study results. The outlier subject's OHIP scores were comparable with the other subjects' scores during the first years, but a significant decline from 70 to 19 was noted between years 3 and 5. This subject showed moderate tooth wear, which she claimed had resulted in chewing problems. The subject also expressed concern with the esthetics of the maxillary denture, which may explain her low total score (19 of 95). Although her denture stability, fit, and retention scored high, those evaluations were not reflected in the subject's questionnaire responses. It is possible that the dissatisfaction with esthetics and function overshadowed the patient's overall evaluation so that other aspects were not properly considered, resulting in a very low score. With the outlier excluded from the analysis, the mean score for subjects in group 2 increased from 67 to 79 at the 5-year examination (Table 6).

An interesting finding in the present study was that there was no significant difference between groups regarding OHIP-EDENT-19 questionnaire responses, although significantly higher denture retention ($P < .0005$) was recorded for subjects in group 2 (Table 5). However, even if the denture retention in group 2 was higher, it appears that subjects in group 1 were as satisfied and felt that the single implant provided satisfactory denture retention. These results are in accordance with findings of a similar study comparing mandibular overdentures supported by one or two implants placed according to the delayed loading protocol in which no significant difference in the patient satisfaction rate was observed between the groups.[7]

If a single implant can improve chewing ability, oral comfort, and quality of life for the edentulous patient, it can be argued that such treatment should be offered, especially for those who are on a limited fixed income and cannot afford more expensive options. Regardless of loading protocol, it seems likely that an overdenture supported by a single implant could be a viable option for those who cannot afford multiple implants, as it results in lower component costs, reduced treatment times, and lower maintenance costs.[7,14]

CONCLUSIONS

The 5-year results of this randomized clinical trial show 10 early implant failures in 9 subjects, but after the 12-month follow-up, no other failures were identified. Force distributions on unsplinted implants supporting removable prostheses are difficult to assess and predict, and reasons for the failing implants are not clear. However, a lower risk of failure with higher ISQ values has been found. No correlation was found between ITV and ISQ values. However, the statistical power was low, with only three torque values measured. ISQ values for implants in both groups remained significantly higher over time when compared with those recorded at baseline. The need for maintenance was low and patient satisfaction remained high after treatment with immediately loaded mandibular overdentures supported by one or two titanium dental implants. Men reported significantly higher satisfaction scores over time, but no significant differences were seen between the two groups. However, the results of the present study should be interpreted with caution because of the significant number of implants failing during the initial 12 months, numerous patients being lost to follow-up, and the uneven gender distribution in the groups. Further research is needed to investigate whether immediate loading of a one- or two-implant–retained mandibular overdenture is a viable alternative to the customary two-implant overdenture therapy with a delayed healing protocol.

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