Randomized clinical trial comparing the efficacy of mandibular implant-supported overdentures and conventional dentures in diabetic patients. Part III: Comparisons of patient satisfaction

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Statement of problem. There is insufficient evidence to indicate the functional superiority of mandibular implant-supported overdentures to justify their use in edentulous patients.

Purpose. This study compared the benefits perceived by patients who received a new maxillary denture and a mandibular conventional denture (CD) and an implant-supported overdenture (IOD).

Method. New maxillary and mandibular dentures were delivered to 89 diabetic denture wearers with clinically acceptable metabolic control who treated their diabetes either with insulin (IT) or without insulin (NIT). Of the 89 patients, 37 received maxillary and mandibular CDs and 52 received a maxillary CD and an IOD. Two questionnaires with categorical responses were used; the first contained 13 questions to ascertain a patient's absolute assessments of original dentures at entry and study dentures at 6- and 24-months after treatment completion; the second questionnaire had 11 questions that assessed the relative change perceived by patients with study dentures. Of the 78 patients who completed the posttreatment (PT) assessments at 6 months, 68 patients provided longitudinal data for questionnaire I and cross-sectional data for questionnaire II. In addition, 46 patients (18 CD and 28 IOD) also provided PT assessments at 24 months.

Results. Both mean scores and percentage distributions of longitudinal data for questionnaire I showed perceptual improvements with both types of study dentures. Improvements were higher in the IOD than in the CD group. Mean scores failed to show any significant differences between the 2 treatment groups. The only significant difference was found in the change in percentage distributions for perceptual chewing ability in favor of the IOD group. Even this advantage was lost at 24 months. With the comparative questionnaire, a higher percentage of patients in the IOD group than in the CD group perceived improvements with study dentures from their original dentures in chewing ability, chewing comfort, and denture security. However, mean differences were statistically significant in favor of the IOD group only for chewing ability and less difficulty to chew hard foods.

Conclusion. The mandibular implant-supported overdenture offers same advantage in terms of perceived chewing function over the conventional denture. (J Prosthet Dent 1999;82:416-27.)

CLINICAL IMPLICATIONS

The previously reported 15% higher success rates, coupled with a trend of perceived improvements in chewing ability, chewing comfort, and food choices in patients with mandibular implant-supported overdentures, might justify their use in selected patients dissatisfied with clinically acceptable conventional dentures.

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Patient satisfaction is one of the highest goals in the treatment of edentulous patients. Dentists have taken many different approaches to improve chewing function and gain additional stability and retention of complete dentures for achieving patient satisfaction.[1-5] Despite such efforts, treatment may be found unsatisfactory by some patients. Over the past 50 years, a variety of dental implants have been used to gain support for complete dentures, especially in patients with extreme ridge resorption.[6-8] The most encouraging results came with the development and use of osseointegrated endosseous implants for securing complete dentures with screws.[9] High success rates for implants supporting either fixed[10,11] or removable overdentures[12-15] have prompted many dentists to recommend removable implant-supported mandibular overdentures that are costly and require surgical intervention. However, there is insufficient patient-based evidence to demonstrate the superiority of these overdentures for such general use. Almost all patient-based assessments of implant-supported fixed or removable prostheses have been performed on patients who had been dissatisfied with complete dentures.[16-21] Even patient assessments reported from prospective clinical trials were based on dissatisfied denture wearers with extremely resorbed ridges.[22-25]

To our knowledge, this has been the only randomized clinical trial undertaken to compare the efficacies of mandibular implant-supported overdentures (IOD) and mandibular conventional dentures (CD) in a sample of denture wearers with varying degrees of satisfaction with their existing conventional dentures.[26] The study was carried out in controlled diabetic patients because of the common, but unsubstantiated, belief held by dentists that such patients experience more denture problems than those without diabetes. On the basis of prespecified criteria, the 24-month treatment success rate of 56.9% for the CD group was not significantly different ($P>.05$) than 72.1% for the IOD group. Of the 15 treatment failures in the CD group, 10 were due to patient dissatisfaction, chewing discomfort, or infrequent use of dentures for eating, compared with 5 of the 14 failures in the IOD group. The remaining failures in both groups resulted from excessive maintenance care after treatment completion; there was no implant failure. Functional tests failed to show any significant differences in the masticatory performances of the 2 denture groups.[27]

The purpose of this study was to test the hypothesis that denture wearers perceive similar benefits from both mandibular CDs and IODs.

METHODS

The study design, method, and clinical outcomes have been reported previously.[26] A total of 102 patients, whose ages ranged from 48 years to 75 years, qualified for the study (Table I) and signed the consent forms. Patients were stratified into those treating their diabetes with insulin (IT) and without insulin (NIT). From each block of 5 IT or NIT patients, 2 were assigned on a random basis to receive a new set of dentures with a mandibular CD and 3 with an IOD. Three patients from the CD group and 10 from the IOD group withdrew before treatment completion. The remaining 89 patients, 37 in the CD group and 52 in the IOD group, received new maxillary dentures and either mandibular conventional dentures or overdentures.

Table I. Status of patients randomly assigned to 2 treatment groups with respect to treatment completion and patient-based assessments at entry and at 6 months after treatment completion

	Number of patients		
Treatment group	**CD**	**IOD**	**Total**
Randomized	40	62	102
Withdrew before treatment completion	(3)	(10)	(13)
Completed treatment	37	52	89
Missing dentures at entry	(7)	(8)	(15)
Tested with original dentures at entry	**30**	**44**	**74**
Withdrew before 6-mo PT tests with study dentures	5	1	6
Tested with original dentures at entry and study dentures at 6 mo	**25**	**43**	**68**
Tested with study dentures at 6 mo but without tests with original dentures	3	7	5
Tested with study dentures at 6 mo	**28**	**50**	**78**
Tested with original dentures at entry and study dentures at 24 mo	**20**	**26**	**46**

CD = Conventional denture; *IOD* = implant-supported overdentures; *PT* = posttreatment.

The mandibular overdenture had plastic clip retainers for a Hader bar that connected 2 IMZ implants placed in the right and left canine regions. Two clips were used to retain the mandibular denture in 49 patients and 1 or 1½ clips in the other 3 patients. Nonanatomic 0-degree acrylic resin teeth were used to establish a monoplane occlusal plane without any incisal guidance and ramps for occlusal balance in eccentric jaw movements. The study examiner evaluated all new dentures to ensure that they were clinically acceptable before or after making needed alterations, including relines or remakes. The treatment was considered complete 30 days after the insertion of clinically acceptable dentures.

The sample size for pretreatment and posttreatment assessments was as follows. Of the 89 patients who received study dentures (Table I), 74 patients (30 from

Table II. Questionnaire I questions and example of response choices for patient assessment of original denture

Question 1. Do you use your dentures for eating?
(1)_____ I mostly eat with my dentures.
(2)_____ I frequently eat with my dentures.
(3)_____ I occasionally eat with my dentures.
(4)_____ I rarely eat with my dentures.
Question 2. Do you experience any discomfort when you chew with your dentures?
Question 3. How well can you chew with your dentures?
Question 4. Do you enjoy eating with your dentures?
Question 5. Does the denture affect your choice of foods?
Question 6. Do you find food particles getting under the dentures?
Question 7. Do you feel any difference in the taste of food with your dentures?
Question 8. Does the denture affect your speech?
Question 9. Do you experience odor with your dentures?
Question 10. Do you experience difficulty cleaning your dentures?
Question 11. After cleaning, are you satisfied with the cleanliness of your dentures?
Question 12. How secure do you feel with your dentures?
Question 13. How satisfied are you with your dentures?

Table III. Questionnaire II questions and example of response choices for patient assessment of perceived functional changes with modified or new dentures

Question 1. How well can you chew with your present dentures compared with your previous dentures?		
		(Score)
(1)_____	Extremely poorer than before	(–3)
(2)_____	Considerably poorer than before	(–2)
(3)_____	Slightly poorer than before	(–1)
(4)_____	The same as before I got the replacement	(0)
(5)_____	Slightly better than before	(1)
(6)_____	Considerably better than before	(2)
(7)_____	Extremely better than before	(3)
Question 2. Do you feel comfortable when you chew with your present dentures compared with your previous dentures?		
Question 3. What degree of difficulty do you have while eating hard-to-chew foods with your present dentures compared with your previous dentures?		
Question 4. How have your present dentures affected your choice of foods?		
Question 5. How much have your present dentures affected your enjoyment of eating?		
Question 6. How difficult do you find it to clean your present dentures compared with your previous dentures?		
Question 7. How satisfied are you with the cleanliness of your present dentures compared with your previous dentures?		
Question 8. How much odor do you experience from your present dentures compared with your previous dentures?		
Question 9. How often do you experience odor with your present dentures compared with your previous dentures?		
Question 10. How secure do you feel with your present dentures compared with your previous dentures?		
Question 11. How much have your present dentures affected your pronunciation compared with your previous dentures?		

the CD group and 44 from the IOD group) entered the study with a complete set of maxillary and mandibular dentures. They assessed their existing dentures at entry. The remaining 15 patients, 7 in the CD group and 8 in the IOD group, were missing 1 or both dentures.

Five patients from the CD group and 1 from the IOD group failed to keep their posttreatment appointments and refused to return for the 6 months posttreatment (PT) assessment of study dentures. As a result, there were 68 patients (25 in the CD group and 43 in the IOD group) with assessments of original dentures at entry and of study dentures at 6 months. The staggered entry of patients allowed 20 patients in the CD group and 26 patients in the IOD group to complete 24-month PT tests, including assessments of their study dentures before the study termination.

Patients submitted to detailed oromaxillofacial examinations, including clinical ratings of their dentures and denture-bearing tissues and a series of masticatory performance and other oral sensorimotor function tests at entry (baseline) and at 6 months and 24 months posttreatment completion. Two questionnaires, used previously in other outcome studies,[28,29] were used for assessment of dentures by patients. The first instrument with 13 questions rated patients' perceptions of their chewing function, speaking ability, social life, denture hygiene, self-confidence, and overall satisfaction with the original dentures at entry and with the study dentures at 6 and 24 months after treatment completion. The 13 questions and the 4 choices for question 1 are listed in Table II. Four similar choices were available for questions 2 through 12. The 6 responses for question 13 on overall satisfaction included completely, moderately, or slightly satisfied and slightly, moderately, or completely dissatisfied. The second instrument with 11 questions evaluated on a 7-point ordinal scale (+3 to –3) the degree of change perceived by patients with the study dentures at 6 months after treatment completion, compared with the original dentures. The first question with its 7 response choices and the remaining 10 questions for this comparative evaluation are given in Table III. Seven similar response choices were available for all 11 questions. A positive score indicated the degree of improvement and a negative score the degree of deterioration. A zero score was given for no change.

Following a standard approach, a trained interviewer presented the questionnaires to patients. The interviewer provided neither dental care nor served as the clinical examiner for the study. Each question and its choices were printed on individual cards. Patients were given a specific card and the interviewer read each

question and its responses on the card. The response selected by the patient was recorded on the data sheet. Patients were not shown their earlier responses to questions when they assessed the study dentures at the 2 follow-up intervals. The interview approach assures maximal participation with minimal error of misunderstanding.[30]

Data analyses

The percentage distributions of responses, mean scores, and standard deviations for each question were calculated. Comparisons were made between percentage distributions of IT and NIT groups and between percentage distributions of CD and IOD groups for each of the 13 questions. The chi-square test was not applied to compare percentage distributions because the data did not meet the usual requirements for this test.[31] Many cells were empty and 50% of the cells had expected counts of less than 5 for most variables. For this reason, 2-tailed Fisher's exact tests were used to provide exact *P* values for multinomial distributions.

A $2 \times 2 \times 2$ repeated measures analysis of variance (ANOVA) test was performed to compare mean scores of responses for each of the 13 questions between the 2 treatment groups (CD and IOD) and between the NIT and IT at 2 time intervals (entry and 6-months PT). A $2 \times 2 \times 3$ ANOVA test was used to make comparisons of mean scores of 46 patients at 3 time intervals (entry and 6- and 24-months PT). When a significant ANOVA F ratio was found, univariate analyses were used to determine the variables with significant mean differences. Cluster analysis was performed to group questions into clusters on the basis of the assessment scores of original dentures at entry. A multivariate analysis of variance (MANOVA) test was performed for each cluster of related variables for comparisons between groups.

A similar approach was followed for comparisons of the responses to questionnaire II. An alpha level of .05 was used for all comparisons and SAS software[32] for all statistical analyses.

RESULTS

Effects of withdrawals and patients with provisional dentures

In a previous study, the 13 patients who had withdrawn before treatment completion did not differ in terms of general characteristics, medical health, and oromaxillofacial health status from the remaining 89 who received new dentures.[26] Assessments of original dentures by 68 patients with longitudinal data were also compared with those 6 patients who received study dentures but withdrew before the 6-month PT assessments of study dentures. No significant differences were found in either percentage distributions or mean scores of responses for any of the 13 perceptions. This indicates that the final sample of 68 was not influenced by the withdrawal.

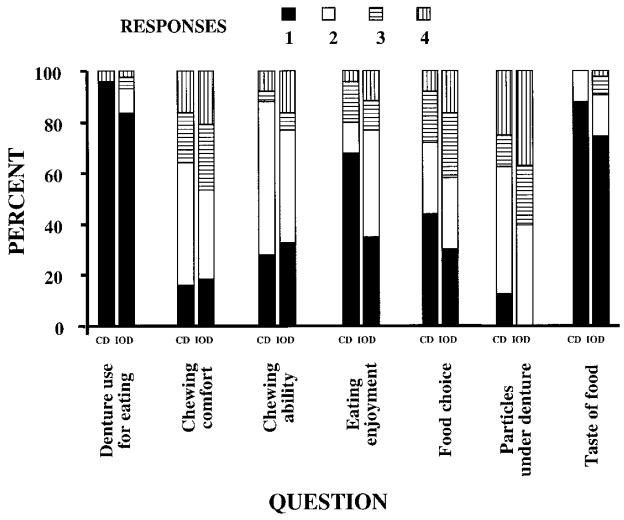

Fig. 1. Percentage distribution of 25 CD and 43 IOD patients by responses to questions related to eating activity in questionnaire I with original dentures.

Percentage distributions of responses to questionnaire I

Comparisons between IT and NIT groups. With original dentures, the only significant difference in percentage distributions (P=.007) was found for satisfaction with denture cleanliness, 84.2% reported full satisfaction in the IT group, compared with 53.3% in the NIT group. Both groups showed significant improvements with study dentures, for 6 perceptions. However, no significant differences in percentage distributions were seen between the 2 diabetic groups for any of the 13 perceptions. Further comparisons were made of the percentage distributions of change scores that resulted with study dentures to evaluate treatment effect. The only significant change was noted for denture cleanliness, with 36.7% additional NIT patients expressing full satisfaction, compared with 0% of IT patients. This improvement in the NIT group increased the percentage of patients completely satisfied with their denture cleanliness to 90% and became comparable to 84.2% in the IT group.

In a previous study, the IT and NIT groups were similar at entry in terms of age, general health characteristics, including clinical quality of original dentures and denture-bearing tissues, functional measures of masticatory performances, oral stereognosis, oral clearance, and whole saliva secretion rates.[26] Approximately 50% of the patients in both treatment groups entered the study with poor dentures. Because patient assessments of their original and study dentures as well as

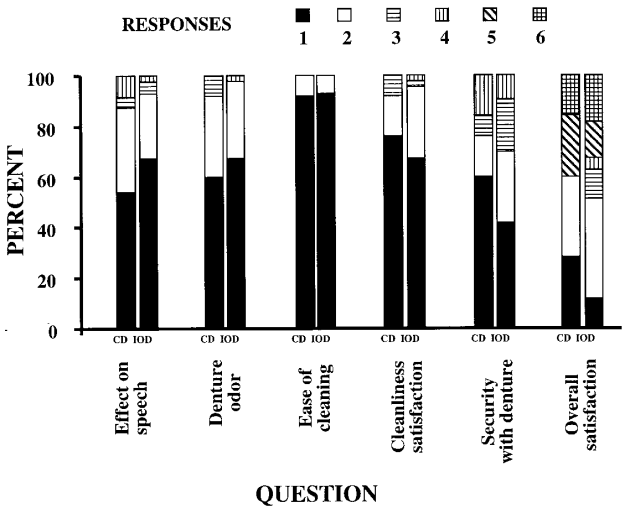

Fig. 2. Percentage distribution of 25 CD and 43 IOD patients by responses to questions related to speech, denture hygiene, security and overall satisfaction in questionnaire I with original dentures.

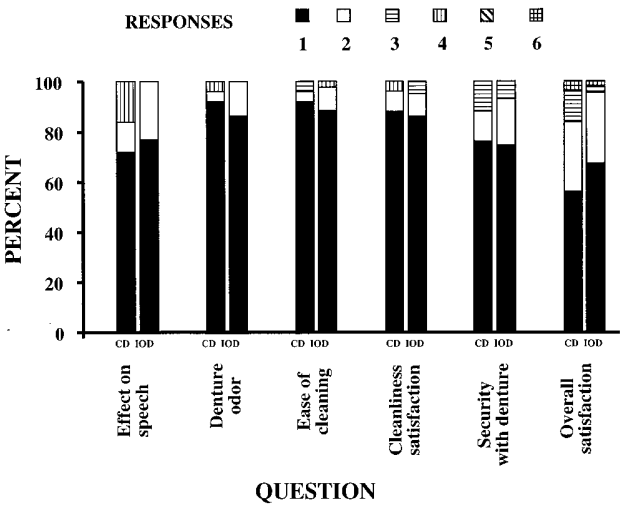

Fig. 4. Percentage distribution of 25 CD and 43 IOD patients by responses to questions related to speech, denture hygiene, security and overall satisfaction in questionnaire I with study dentures.

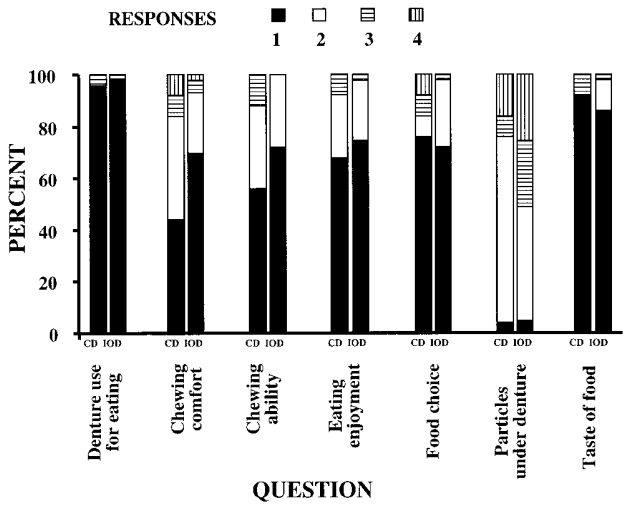

Fig. 3. Percentage distribution of 25 CD and 43 IOD patients by responses to questions related to eating activity in questionnaire I with study dentures.

treatment effects in the NIT and IT groups were quite similar, data were collapsed across these 2 groups to make comparisons between percentage distributions of the CD and IOD groups.

Comparisons between CD and IOD groups. The percentage distributions of responses to 7 questions related to eating with the original dentures at entry are illustrated in Figure 1 and the remaining 6 questions in Figure 2. The only significant difference was found in eating enjoyment (P=.018), with 68% in the CD group who always enjoyed eating with their original dentures, compared with 35% in the IOD group. A marginally significant difference (P=.072) was noted in food particles frequently or always getting under their original dentures. More than 37% of patients in the IOD group experienced this problem, compared with 25% in the CD group. No significant differences were found between the 2 groups in percentage distributions for the remaining 11 assessments at entry.

Percentage distributions of responses with study dentures at 6-month PT are illustrated in Figures 3 and 4. Significant differences were found for 2 items, food selection (P=.044) and speech (P=.021) in favor of the IOD group. In the CD group, 16% of patients reported moderate-to-great restriction in their food selection, compared with only 2.3% in the IOD group. Similarly, 16% were dissatisfied with their speech in the CD group, compared with none in the IOD group.

The positive or negative change from the baseline score (original dentures) with study dentures determined the magnitude of improvement or deterioration. Percentage distributions of change scores for each of the 13 perceptions with the 2 types of study dentures are depicted in Figures 5 and 6. Significant improvements in percentage distributions were noted for 7 perceptions: frequency of denture use (P=.048), chewing comfort (P=.000), chewing ability (P=.000), eating enjoyment (P=.000), food choices (P=.000), feeling of security (P=.001), and overall satisfaction (P=.000) in the IOD group. A marginally significant improvement (P=.051) also appeared for satisfaction with denture cleanliness. Significant improvements in the CD group occurred for denture odor (P=.001) and overall satis-

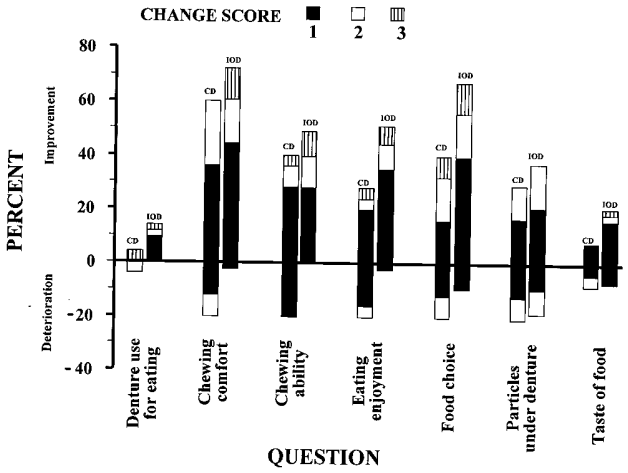

Fig. 5. Percentage distribution of change scores in 25 CD and 43 IOD patients showing magnitude of improvement or deterioration with study dentures in perceptions related to eating activity in questionnaire I.

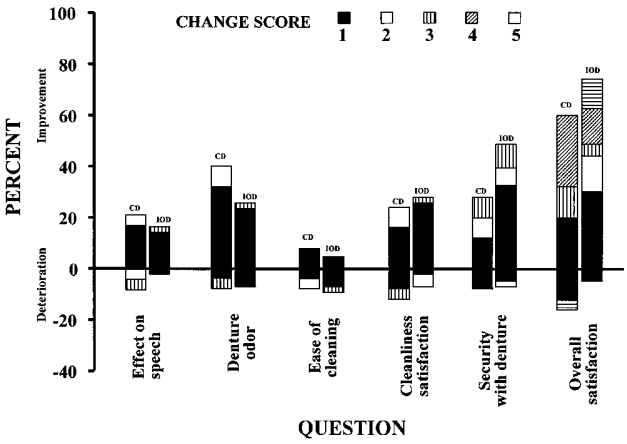

Fig. 6. Percentage distribution of change scores in 25 CD and 43 IOD patients showing magnitude of improvement or deterioration with study dentures in perceptions related to speech, denture hygiene, security, and overall satisfaction in questionnaire I.

Table IV. Comparisons between NIT (n = 30) and IT (n = 38) group mean scores of responses to each of 13 questions about original dentures at entry and study dentures at 6 months after treatment completion

	Mean scores							
	Entry				6-mo after treatment			
	NIT		IT		NIT		IT	
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
Denture use for eating	1.0	0.18	1.3	0.81	1.0	0.00	1.1	0.45
Chewing comfort	2.5	0.90	2.4	1.08	1.4	0.72	1.7	0.85
Chewing ability	2.0	1.00	2.1	0.93	1.3	0.53	1.4	0.60
Eating enjoyment	1.7	0.92	2.0	1.00	1.2	0.43	1.4	0.64
Food choices	2.0	1.03	2.2	1.08	1.4	0.72	1.3	0.71
Particles get under dentures	2.8	0.93	2.8	0.99	2.4	0.82	2.7	0.93
Taste of food	1.2	0.63	1.3	0.62	1.1	0.40	1.2	0.53
Effect on speech	1.5	0.73	1.5	0.84	1.3	0.80	1.4	0.75
Denture odor	1.5	0.78	1.3	0.48	1.1	0.31	1.2	0.56
Ease of cleaning dentures	1.1	0.25	1.1	0.27	1.0	0.18	1.2	0.63
Denture cleanliness satisfaction	1.5	0.63	1.2	0.63	1.1	0.31	1.3	0.69
Security with dentures	2.0	1.07	1.9	1.07	1.4	0.67	1.3	0.62
Overall satisfaction	3.2	1.96	3.2	1.78	1.3	0.55	1.7	1.21

NIT = Without insulin treatment; *IT* = with insulin treatment.
NIT and IT groups at both time intervals represent those patients treated with or without insulin at entry.

faction (P=.001) and a marginally significant improvement for chewing ability (P=.051).

Comparisons of percentage distributions of change scores (study denture score minus original denture score) between the 2 groups showed significant differences (P=.048) for chewing ability (Fig. 5) and a marginally significant difference (P=.058) for overall satisfaction (Fig. 6) in favor of the IOD. The difference in chewing ability resulted primarily from deterioration perceived by 20% of patients in the CD group, compared with none in the IOD group. The percentage distributions of the responses of 18 patients in the CD group and 28 in the IOD group, who completed 24-month PT tests, failed to show any significant differences between the 2 groups, either with original dentures at entry or study dentures at 24 months, or in change scores resulting from study dentures.

Mean scores of responses with original and study dentures for questionnaire I

Mean score comparisons between the IT and NIT groups at entry with original dentures and at 6-month

Table V. Comparisons between CD and IOD group mean scores of responses to each of 13 questions about original dentures at entry and about study dentures at 6 months after treatment completion

	Original dentures				Study dentures			
	CD (n = 25)		IOD (n = 43)		CD (n = 25)		IOD (n = 43)	
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
Denture use for eating	1.1	0.60	1.3	0.66	1.1	0.40	1.0	0.30
Chewing comfort	2.4	0.95	2.5	1.03	1.8	0.91	1.4	0.69
Chewing ability	1.9	0.81	2.1	1.03	1.6	0.71	1.3	0.45
Eating enjoyment	1.6	0.92	2.0	0.98	1.4	0.65	1.3	0.50
Food choices	1.9	1.00	2.3	1.08	1.5	0.96	1.3	0.51
Particles get under dentures	2.5	1.02	3.0	0.89	2.4	0.81	2.7	0.91
Taste of food	1.1	0.33	1.4	0.72	1.2	0.55	1.2	0.43
Effect on speech	1.7	0.92	1.4	0.70	1.6	1.12	1.2	0.43
Denture odor	1.5	0.65	1.4	0.62	1.2	0.62	1.1	0.35
Ease of cleaning dentures	1.1	0.28	1.1	0.26	1.1	0.44	1.2	0.53
Denture cleanliness satisfaction	1.3	0.63	1.4	0.66	1.2	0.65	1.2	0.50
Security with dentures	1.8	1.15	2.0	1.01	1.4	0.70	1.3	0.61
Overall satisfaction	3.1	2.00	3.3	1.77	1.7	1.14	1.4	0.88

CD - Conventional dentures; *IOD* = implant-supported overdentures.

Table VI. Comparisons of mean scores between CD (n = 18) and IOD (n = 28) group mean scores of responses at entry to each of 13 questions about original dentures and about study dentures at 6 months and 24 months after treatment completion

	Mean scores					
	Entry		6-mo after treatment		24-mo after treatment	
	CD	IOD	CD	IOD	CD	IOD
Denture use for eating	1.2	1.4	1.0	1.1	1.0	1.1
Chewing comfort	2.5	2.3	1.9	1.3	1.7	1.4
Chewing ability	2.1	2.1	1.6	1.4	1.5	1.4
Eating enjoyment	1.7	1.9	1.3	1.3	1.4	1.2
Food choices	2.2	2.2	1.4	1.3	1.6	1.3
Particles get under dentures	2.7	2.9	2.5	2.6	2.4	2.4
Taste of food	1.2	1.5	1.1	1.1	1.2	1.3
Effect on speech	1.7	1.3	1.4	1.1	1.2	1.4
Denture odor	1.4	1.3	1.0	1.1	1.0	1.1
Ease of cleaning dentures	1.1	1.1	1.1	1.1	1.1	1.1
Denture cleanliness satisfaction	1.3	1.4	1.1	1.1	1.1	1.1
Security with dentures	2.1	1.9	1.4	1.3	1.2	1.1
Overall satisfaction	3.2	3.1	1.7	1.4	1.6	1.3

CD = Conventional dentures; *IOD* = implant-supported overdentures.

PT with study dentures are shown in Table IV and between CD and IOD groups in Table V. The 3-factor ANOVAs (NIT / IT, CD / IOD, original dentures / study dentures) in 68 patients revealed no significant main effects or interactions for 12 of the 13 variables. A significant interaction between original dentures / study dentures and IT / NIT groups was found for satisfaction with denture cleanliness. Univariate analyses showed a marginally significant difference (P=.059) between the IT and NIT groups with original dentures and a significant difference (P=.021) in mean change scores with study dentures from original dentures. Whereas the mean score with study dentures in the NIT group dropped to 1.1 from 1.5 with original dentures, the mean score increased from 1.24 to 1.26 in the IT group. This improvement in the NIT group helped to overcome the mean score disparity that existed between the 2 groups at entry. A similar change for this perception was noted earlier in comparisons of the percentage distributions of responses for these 2 groups.

Cluster analysis of the entry scores placed 12 of the 13 questions in 3 clusters and frequency of eating with dentures as a separate fourth cluster. The remaining 5 questions related to the eating activity formed the sec-

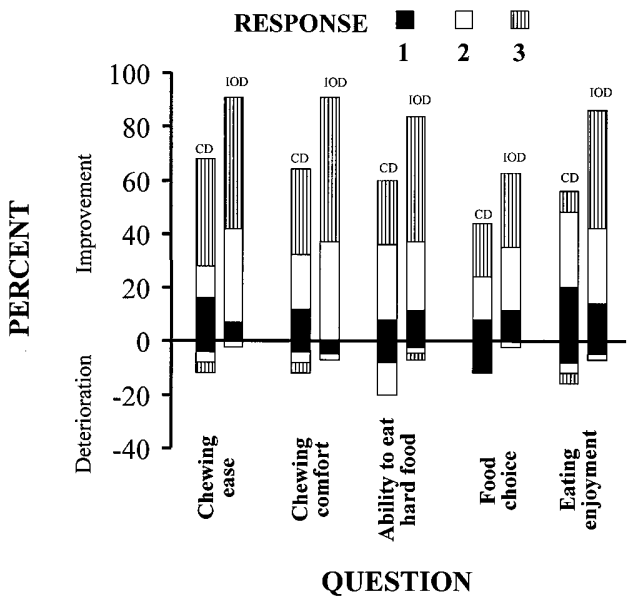

Fig. 7. Percentage distribution of 25 CD and 43 IOD patients by responses for perceived improvement or deterioration with study dentures, compared with original dentures, to questions related to eating activity in questionnaire II.

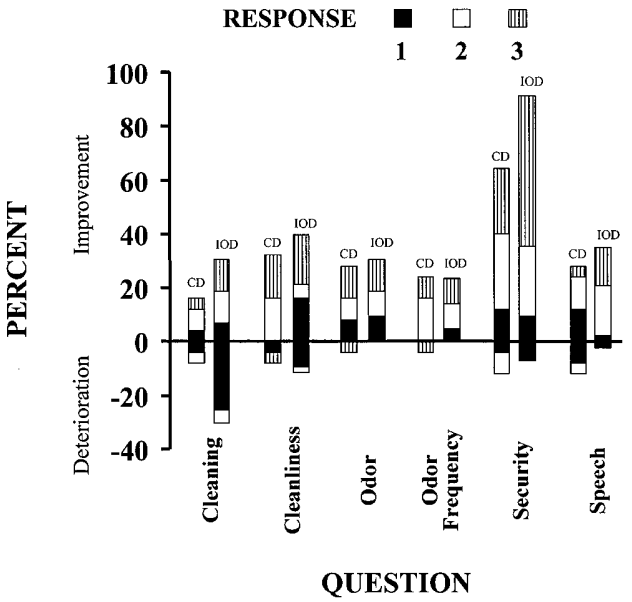

Fig. 8. Percentage distribution of 25 CD and 43 IOD patients by responses for perceived improvement or deterioration with study dentures, compared with original dentures, to questions related to denture hygiene, security, and speech in questionnaire II.

ond cluster. The third cluster included all 4 questions on denture hygiene. Speech, security, and overall satisfaction formed the fourth cluster. The only significant finding in MANOVAs for each of the 4 clusters was an interaction between the 2 denture groups (CD and IOD) and the 2 test intervals for cluster 2. However, no main effect appeared for either denture or diabetic therapy types.

Mean scores of 18 CD and 28 IOD patients at 3 intervals (entry, 6-month PT, and 24-month PT) are presented in Table VI. The $2 \times 2 \times 3$ ANOVAs showed no significant interactions or main effects for any of the 13 variables.

Percentage distributions and mean scores of responses for questionnaire II

Percentage distribution comparisons of responses to questionnaire II for 25 patients in the CD group and 43 patients in the IOD group are illustrated in Figures 7 and 8. Improvements were noted in both groups, but were higher for all 5 perceptions related to eating activity in the IOD group. However, the differences between the 2 groups were statistically significant only for chewing comfort (P=.002), eating enjoyment (P=.008), and denture security (P=.007) and marginally significant for chewing ease (P=.053).

The mean scores and standard deviations of the responses to questionnaire II for IT and NIT groups and CD and IOD groups are presented in Table VII. The 2×2 ANOVAs showed a significant main effect of denture type (CD / IOD) for 5 variables (chewing ease, chewing comfort, difficulty to chew hard foods, eating enjoyment, and denture security). The mean scores for all these 5 variables in the IOD group were significantly higher than those in the CD group. The only main effect for diabetic therapy was found for denture security, with the IT group having a significantly higher mean score than the NIT group. A significant interaction between the IT / NIT and CD / IOD, without any main effect, appeared for satisfaction with denture cleanliness.

The cluster analysis showed 2 clusters, 1 included 5 questions related to eating activity and denture security. Speech and 4 questions about denture hygiene formed the second cluster. MANOVA for the first cluster showed significant main effect for denture type (CD / IOD) with no interaction. Univariate analyses showed the mean differences to be significant in favor of the IOD group for chewing ability (P=.019), chewing comfort (P=.005), ease of chewing hard foods (P=.003), eating enjoyment (P=.001), and denture security (P=.003). No significant main effects or interaction were noted for the second cluster.

DISCUSSION

Because the primary goal of the study was to compare success rates of 2 treatment modalities, 15 (7 CD and 8 IOD) of the 89 patients who received study dentures were allowed to enter without a complete set of dentures. Their exclusion would have not only extended the

Table VII. Comparisons of CD/IOD and NIT/IT group mean scores of responses to 11 questions (Questionnaire II) about changes perceived by patients with study dentures from original dentures at 6 mo after treatment completion

	CD (n = 25)		IOD (n = 43)		NIT (n = 32)		IT (n = 36)	
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
Chewing ability	1.4	1.75	2.2	1.10	2.2	1.11	1.6	1.62
Chewing comfort	1.2	1.71	2.3	1.18	2.2	1.12	1.6	1.69
Ability to eat hard foods	1.0	1.72	1.9	1.47	1.8	1.37	1.3	1.77
Food choices	0.9	1.39	1.4	1.35	1.3	1.29	1.1	1.45
Eating enjoyment	0.7	1.49	1.9	1.30	1.7	1.38	1.3	1.56
Ease of cleaning dentures	0.2	0.96	0.3	1.41	0.2	1.31	0.3	1.22
Denture cleanliness satisfaction	0.6	1.47	0.7	1.34	0.8	1.45	0.6	1.32
Intensity of denture odor	0.5	1.29	0.6	1.07	0.7	1.10	0.5	1.21
Frequency of denture odor	0.4	1.26	0.5	1.01	0.5	1.02	0.4	1.18
Security with dentures	1.2	1.55	2.2	1.17	2.1	1.10	1.6	1.59
Effect on speech	0.3	1.07	0.8	1.21	0.7	1.31	0.6	1.05

CD = Conventional dentures; *IOD* = implant-supported overdentures; *NIT* = diabetes without insulin treatment; *IT* = diabetes with insulin treatment.
NIT and IT groups represent those patients treated with or without insulin at 6 months after treatment.

enrollment of the required sample beyond 54 months but also would have made the sample selective and less representative of the edentulous diabetic population. The 13 withdrawals before treatment completion and 6 after treatment completion, but before the 6-month PT tests, did not bias the remaining sample of 68 patients with assessments of both original and study dentures.

The 2 evaluative questionnaires were designed to detect functional changes perceived by patients after prosthodontic therapy. The questions were based on common complaints expressed by problem patients. They often relate to such perceptions as appearance, eating, speech, sense of security with dentures, and denture odor. Appearance was excluded because the 2 types of study dentures did not directly impact it. Four questions were included on denture hygiene because the 2 types of study dentures differed in that the tissue surface of the implant-supported denture required a deep groove in the anterior region to accommodate the Hader bar and plastic clips. Six questions examined eating problems often cited by problem patients. The other 3 questions assessed speech, denture security, and overall satisfaction. An important requirement for such evaluative instruments is their responsiveness or ability to detect changes.[30] The responsiveness of the 2 instruments was demonstrated previously by functional improvements perceived by patients when their poorly fitting dentures were altered to fit better or replaced with new dentures.[29]

The cluster analysis placed 5 of the 6 variables related to eating activity in 1 cluster, all 4 related to denture hygiene in the second cluster, and the other 3 variables (speech, security and overall satisfaction) in the third cluster. The sixth item related to eating activity, frequency of eating with dentures, formed a separate cluster, as more than 88% of denture wearers in the study always used their original dentures for eating. The 5 other questions on eating activity were partially interrelated (r ranged from 0.40 to 0.60) and were also moderately related (r range, 0.50 to 0.70) to overall satisfaction. Speech and security also showed moderate correlations with overall satisfaction. Similar intercorrelations were reported among these items in an earlier study in patients with poorly fitting dentures.[29]

Behavioral scientists do not recommend the use of parametric statistical analysis for data in an ordinal scale, because the required assumption that the scale intervals be equal may not be true. Comparisons of percentage distributions would be considered a more appropriate measure. Because several previous studies have reported comparisons of mean scores and standard deviations for such data, it was decided to analyze both percentage distributions and mean scores.

A stratified randomization approach was used to assign IT or NIT patients from each block of 5 to the CD and IOD groups, to achieve equal proportions of these 2 types of diabetic patients within these 2 groups. Further NIT and IT groups were found to be comparable in terms of general characteristics and functional measures. Percentage distributions of their responses about their original and study dentures were quite similar. This comparability of the NIT and IT groups permitted collapsing scores across diabetic therapy for comparisons between percentage distributions of responses in CD and IOD groups. The stratified randomization approach also provided comparable CD and IOD groups in terms of general characteristics and 12 of 13 perceptual assessments of their original dentures. The only significant difference was found for eating enjoyment at baseline, with 68% enjoying eating very much with their original dentures in the CD group, compared with 30% in the IOD group.

Although varying degrees of improvements and deterioration (treatment effect) were noted with both

types of study dentures (Figs. 5 and 6), a higher percentage of patients experienced improvements rather than deterioration for 11 perceptions in the CD group and 12 perceptions in the IOD group. These improvements were statistically significant for 3 perceptions (chewing comfort, denture security, and overall satisfaction) in the CD group and highly significant for the same 3 and 4 additional perceptions (frequency of denture use for eating, chewing ability, eating enjoyment, and food choices) in the IOD group.

On the basis of percentage distributions of change scores, no significant differences appeared between the CD and IOD groups with study dentures for 12 perceptions either at 6-month PT or at 24-month PT. This indicates that both treatments produced similar levels of improvements or deterioration. Results for the thirteenth perception were mixed. A significantly greater percentage of patients in the IOD group than in the CD group reported greater improvements and less deterioration in their chewing ability at 6-month PT but not at 24 months. This difference at 6 months resulted primarily from deterioration occurring in 20% of patients with study dentures in the CD group, compared with none in the IOD group (Fig. 5). It appears that 5 of the 25 CD patients required more than 6 months of adjustment after treatment completion with new dentures to achieve the perceived chewing ability than they had with their original dentures.

The difference between the actual percentage distributions of the 2 denture groups for chewing ability at 6-month PT was marginally significant (P=.063). Instead, significant differences in percentage distributions between the CD and IOD groups were noted at 6-month PT with study dentures for food choices and speech in favor of the IOD. However, these differences were not found when comparisons were made of the percentage distributions of change scores. This disparity between the results of PT comparisons of actual percentage distributions for CD and IOD groups and comparisons of distributions of change scores indicates that treatment outcome studies without baseline data can yield misleading results as a result of a lack of equivalence of the 2 treatment groups at baseline.

Despite improvements perceived with both types of study dentures, food getting under dentures remained a major problem. Food always or often getting under their study dentures was reported by 24% of patients in CD group and more than 51% in the IOD group, and less than 5% were free of this problem.

ANOVAs failed to show significant differences between the mean scores of 2 denture groups for any of the 13 variables in questionnaire I. The only significant interaction noted between the IT and NIT groups with original and study dentures was for satisfaction with denture cleanliness. The higher improvement in the NIT with study dentures overcame the disparity that existed in mean scores between these 2 groups at entry with original dentures.

When patients were asked to compare their study dentures with original dentures in questionnaire II, a significantly higher percentage of patients in the IOD group than those in the CD group perceived improvements with study dentures in chewing comfort, eating enjoyment, and denture security. Significant differences between the 2 groups were also noted in mean scores for the same 3 perceptions and for chewing ability and difficulty to chew hard foods in favor of the IOD group. Questionnaire I provided longitudinal data to measure actual perceptual change by asking patients to assess their original dentures at entry and their study dentures at 6 and 24 months. On the other hand, questionnaire II was a comparative questionnaire that required patients to recall their experience with original dentures that they had used 7 to 9 months earlier. It is noted that original dentures in the IOD group were also modified during the implant-healing period.

Although the 2 questionnaires failed to show the same statistically significant differences, the trend was somewhat similar. Both mean scores and percentage distributions showed greater improvements in the IOD group than in CD group with study dentures for chewing ability, chewing comfort, eating enjoyment, and food selections. So, the question remains whether the perceived gains in both groups were due to treatment care / placebo effect and / or improved denture fit, especially in the absence of significant masticatory performance differences between the 2 groups. The significantly higher stability and retention of mandibular overdentures reported earlier might have contributed to these differences in perceptions related to chewing functions.

The results do not support the findings of other investigators who have consistently shown significant improvements in patient satisfaction with implant-supported overdentures. Differences in patient populations and assessment methods are 2 obvious reasons that make it difficult to draw comparisons. To our knowledge, all previous patient-based assessments for implant-supported overdentures were performed on a homogeneous population of dissatisfied denture wearers with extremely resorbed ridges. Most often the patients were referred for treatment with an implant-supported prosthesis as their last resort. One would expect greater improvements after treatment with implant-supported dentures in such a homogeneous population of dissatisfied patients, compared with the mixed sample in this study with a varying degree of satisfaction.

Most previous studies used categorical scales to score a long list of items pertaining to assessments of maxillary and mandibular dentures independently and combined them later to some common measures for treatment comparisons. By contrast, this study consid-

ered a list of outcomes resulting from the functioning of both dentures together. Many previous studies were retrospective and had to depend on recall bias. Others assessed change within a group and did not have a control group. The results of our study question the conclusions drawn from previous retrospective studies or those with posttreatment comparisons without consideration of pretreatment assessments.

CONCLUSIONS

Within the limits of this study, the following conclusions were drawn:

1. With original dentures, a higher percentage of patients in the CD group than in the IOD group reported more eating enjoyment. Improvements with study dentures were seen in 11 perceptions in the CD group and 12 perceptions in the IOD group. Although the net improvements in mean scores were higher for 11 of the 13 items in the IOD group than in the CD group, the differences were not statistically significant. Although a significantly higher percentage of IOD patients (P=.048) noted improvements in chewing ability, the mean score difference between the 2 groups was not significant. The difference in frequency distributions resulted primarily because 20% of patients in the CD group experienced deterioration with study dentures. At 24 months, the difference between the 2 groups disappeared as a result of a higher percentage of patients with improvements in the CD and slight deterioration in the IOD group. In other words, it took longer for some patients to adapt to their new conventional dentures.

2. More than 84% of the patients were fully or moderately satisfied and experienced little or no discomfort with conventional dentures. Earlier, the 2 types of dentures were found to be equally effective in terms of masticatory performances.[27]

3. Limited advantage of the implant-supported dentures in perceived chewing ability, chewing comfort, and food selection, compared with a conventional denture, might indicate their use when patients are dissatisfied and/or experience chronic problems with clinically acceptable conventional dentures.

We express our appreciation to Dr John Beumer, Chairman of Removable Prosthodontics, for providing the dental laboratory and other financial support to complete this study. Appreciation is also extended to Dr John Jow, Chief of Dental Service, and Dr Herbert Engelhardt, Chief of Central Dental Laboratory, West Los Angeles DVA Medical Center for providing support to complete the treatment of veteran patients. The assistance and technical work of Michele Armet, Paul Bui, Tenglang Chen, DDS, Helen Der, Vu Doan, Elif Fanuscu, Ken Hoang, Michelle Kramer, and Roland McFarland are gratefully acknowledged.

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Noteworthy Abstracts of the Current Literature

Immediate functional loading of Brånemark dental implants: An 18-month clinical follow-up study
Randow K, Ericsson I, Nilner K, Petersson A, Glantz PO. *Clin Oral Implants Res 1999;10:8-15.*

Purpose. Endosseous implants that are expected to "osseointegrate" have traditionally been allowed to heal in an undisturbed manner for a specific period of time. This report compared the clinical results of immediately loaded implants placed in the anterior mandible with results of implants placed and restored with the traditional 2-stage protocol.

Material and methods. Sixteen consecutively treated patients were classified as members of the experimental group, whereas patients in the reference group had been treated in a previous study. Exclusion criteria were described. All implants (Mk II, Nobel Biocare AB) were placed in the anterior mandible between the mental foramina. In the experimental group, implants were used to support a fixed prosthesis within 20 days of implant insertion, whereas the reference group received fixed prostheses approximately 4 months after implant placement. Clinical and radiographic assessments were made of all implants during an 18-month follow-up period.

Results. A total of 88 implants were placed in the experimental group and 30 implants were placed in the reference group. No implants were lost in either group during the study. Comparison of radiographs made at prosthesis insertion with those made at the 18-month follow-up revealed an average of 0.4 mm bone loss in the experimental group and 0.8 mm bone loss in the reference group.

Conclusion. On the basis of the results of this study, implants placed in the anterior mandible may be subjected to immediate functional load without serious detrimental effects. *SE Eckert*