A randomized clinical trial comparing the efficacy of mandibular implant-supported overdentures and conventional dentures in diabetic patients. Part II. Comparisons of masticatory performance

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Statement of problem. Convincing evidence is lacking to demonstrate the functional superiority of mandibular implant-supported overdentures over conventional dentures.
Purpose. This randomized clinical trial was conducted to compare masticatory functional effectiveness of mandibular implant-supported overdentures and conventional dentures in diabetic denture wearers with clinically acceptable metabolic control.
Methods. A total of 102 edentulous diabetic patients, treated with or without insulin, were randomized to receive a new maxillary and either a mandibular conventional denture or an implant-supported overdenture. Treatment was completed in 89 patients, 37 with conventional dentures and 52 with Hader bar-clip attachment overdentures supported by two IMZ implants. Besides data from medical and dental histories, oromaxillofacial examinations, and questionnaires, masticatory tests were performed by patients before and at 6 and 24 months after treatment completion. Although 78 patients (28 in the conventional, 50 in the overdenture group) performed tests at 6 months after treatment, 68 (25 in the conventional, 43 in the overdenture) had performance data for both entry and 6-month posttreatment intervals.
Results. The two treatment groups were highly comparable in terms of general characteristics, quality of original dentures, tissue support, and past denture experience. No significant differences were found between patients treated for diabetes with or without insulin. All four masticatory performance scores with original dentures were higher in the conventional denture group than the overdenture group. The posttreatment performance scores for the two treatment groups became similar because of the higher gains in the overdenture group. Patients with low initial performance scores showed greater posttreatment gains with both conventional dentures and overdentures.
Conclusions. The implant-supported overdenture showed no significant advantage over the conventional denture for improving the ability to comminute food in this group of diabetic patients with higher than average initial functional levels observed for other groups of denture wearers in previous studies. (J Prosthet Dent 1998;79:632-40.)

CLINICAL IMPLICATIONS

The use of implant-supported overdentures to improve the ability to comminute food in patients with average and above masticatory performance is not justified.

Presented in part at the annual meeting of the American Association for Dental Research, San Antonio, Texas, March 1995, and the International Association for Dental Research annual meetings, San Francisco, Calif., March 1996, and Orlando, Fla., March 1997.
Supported by National Institute of Dental Research Grant 1R01DE09085 and Department of Veterans Affairs Medical Research.

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Although mandibular implant-supported overdentures are often provided to selected edentulous persons, convincing evidence to demonstrate their functional superiority over conventional dentures is lacking. Subjective reports from patients have indicated improvements in chewing ability after implant-supported denture treatment.[1-3] However, a longitudinal study in a small sample failed to show significant improvements in masticatory performance after the replacement of conventional mandibular dentures with implant-supported mandibular overdentures.[4] The reverse was true in a cross-sectional study of patients with severely resorbed mandibles and persistent denture problems. The performance with the implant-retained overdentures reached the levels observed by the same investigators for satisfied patients with conventional dentures.[5]

The study design, method, and treatment outcomes of a randomized clinical trial that compared the efficacy of mandibular conventional dentures and overdentures supported by two implants and a Hader bar-clip attachment was described previously.[6] The study was conducted in edentulous persons with diabetes mellitus treated either with insulin (IT) or not treated with insulin (NIT). On the basis of the prespecified criteria, the 2-year success rate for the conventional denture (CD) group was 56.9%, compared with 72.1% for the implant-supported overdenture (IOD) group; the difference was not statistically significant. Both types of study dentures significantly reduced the percentage of patients with chewing discomfort and moderate-to-high dissatisfaction experienced with their original dentures. Percentage changes were greater in the IOD group than those in the CD group. Of the 15 treatment failures in the CD group, 8 were due to dissatisfaction or chewing discomfort, and 3 of 14 failures in the IOD group. One patient in the CD group was unable to adjust to his dentures. Two patients in the IOD and 1 in the CD group occasionally ate with their dentures. The remaining failures in both groups were caused by excessive maintenance care.

The purpose of this study was to compare masticatory performances before and after the insertion of the two types of study dentures, mandibular implant-supported overdentures and conventional dentures, in diabetic denture wearers with clinically acceptable metabolic control.

METHODS

The 102 patients enrolled for the study were stratified into IT and NIT groups before they were randomized to receive either a set of new conventional maxillary and mandibular dentures (CD group) or a conventional maxillary and a mandibular implant-supported overdenture (IOD group). Twelve patients withdrew before treatment initiation or completion, and 1 patient was dropped from the study before treatment completion. The remaining 89 patients, 37 in the CD group and 52 in the IOD group, received study dentures. The treatment was considered complete 30 days after insertion of the study dentures.

Patients submitted to a series of examinations, tests, and questionnaires before denture fabrication (entry) and at 6 and 24 months posttreatment (PT) completion. The orofacial examination included clinical evaluation of dentures and their tissue support by methods described previously.[7] A four-point scale was used to rate the retention and stability of the maxillary and mandibular dentures and a three-point scale for the vertical dimension and centric occlusion. A total score of less than 14 indicated the dentures to be poor, 15 to 18 fair, and 19 to 22 good. The size and shape of the mandibular and maxillary ridges was rated on a four-point scale and the peripheral tissue location and tissue resiliency on a three-point scale. The tissue support with a total score of less than 13 was considered as poor, 14 to 17 fair, and 18 to 20 good. Functional assessments required tests of masticatory performance, bite force, masseter muscle electromyographic activity, jaw movements during chewing, resting and stimulated salivary rates, oral stereognosis, food clearance ability, and oral tactile sensitivity. In addition, questionnaires were given to evaluate food preferences and patient perceptions about dentures.

The CD and IOD groups were previously reported to be similar at entry in terms of age, general health characteristics, clinical quality of dentures and denture bearing tissues, method of diabetic control (IT vs. NIT), glycosylated hemoglobin, and creatinine. Comparisons of selected variables are presented in Table I.

Masticatory performance tests

Four masticatory tests, two each with peanuts and raw carrots, were performed by these patients at study entry and at 6 and 24 months after treatment to determine their preferred side (PS) and swallowing threshold (SWT) performances. The reliability and validity of these tests have been established in many previous studies.[8-10]

Patients were asked at entry to identify their preferred chewing side. Patients without a preference were required to choose a side for the PS tests, and the same side was used for PS tests at all subsequent intervals. Three, 3 g portions of peanuts or raw carrots were used for a test. Each portion of peanuts was chewed for 20 strokes and carrots for 40 strokes on the preferred chewing side. For SWT tests, patients were instructed to chew normally each portion of the test food until they were ready to swallow. Neither the side nor number of strokes was specified. The number of strokes and time required to chew each portion of test food until ready to swallow were recorded. The retrieved chewed food was combined for all three portions of a test before ascertaining the volumes of particles finer and coarser than a U.S. standard 12-mesh screen (1.7 mm opening) for peanuts and U.S. standard 5-mesh screen (4.0 mm opening) for car-

Table I. Comparisons of selected entry characteristics between CD and IOD groups

	CD (n = 37)		IOD (n = 52)		T tests
	$\bar{x}$	SD	$\bar{x}$	SD	p value
Age (yrs.)	64.2	(7.4)	65.7	(6.4)	0.34
Height (in.)	67.7	(4.0)	67.1	(3.5)	0.46
Weight (lbs.)	189.5	(35.2)	183.2	(37.4)	0.43
Glycosylated hemoglobin	9.5	(2.0)	9.1	(1.9)	0.32
Max. dent. exp. (yrs.)	17.6	(13.9)	19.5	(13.8)	0.45
Mand. dent. exp. (yrs.)	13.9	(14.3)	16.5	(14.5)	0.46
Tissue support*	14.7	(3.3)	14.4	(3.1)	0.60
Denture quality**	15.0	(3.7)	14.2	(3.8)	0.35
Anterior mand. bone height (mm)	26.9	(6.5)	26.8	(6.5)	0.98

*Combined rating of ridge shape, tissue resiliency, and tissue attachment, range 6 to 20.
**Combined rating of stability, retention, vertical and horizontal interocclusal relationships, range 6 to 22. Seven patients in the CD group entered without dentures and dentures of three of the eight patients with provisional dentures in the IOD group were not rated.

Table II. Number of patients randomly assigned to two treatment groups who performed or failed to perform masticatory tests at entry and/or 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	30	44	74
Withdrew after treatment completion	*(5)*	*(1)*	*(6)*
Tested with study dentures at 6 months	25	43	68
Tested with provisional dentures at entry and with study dentures at 6 months	*0*	*5*	*5*
Tested with original or provisional dentures at entry and study dentures	25	48	73
Tested with study dentures at 6 months but missing data at entry	*3*	*2*	*5*
Total patients tested with study dentures at 6 months	28	50	78

rots. The ratio of the fine particles to the total volume recovered and expressed as a percentage provided the masticatory performance score. Masticatory tests yielded eight scores for each patient, two PS performance scores, two SWT performance scores, and the number of chewing strokes (CS) and chewing time (CT) for SWT tests with peanuts and carrots.

Sample size for pretreatment and posttreatment comparisons of masticatory scores

The missing masticatory performance data either at entry or at 6 months PT completion required a series of comparisons between the two groups with different samples. Distributions by the presence or absence of entry or PT masticatory scores of 89 patients who received study dentures are presented in Table II. Seven patients in the CD group and 8 in the IOD group entered the study without one or both dentures and could not perform masticatory tests at entry. Comparisons were made between the entry performance scores of the remaining 30 patients in the CD group and 44 in the IOD group. Five patients from the CD group withdrew because of treatment dissatisfaction and 1 patient from the IOD group died before the completion of PT tests with study dentures. Separate comparisons were made of the entry and PT performance scores and of changes in scores from entry to PT between the remaining 25 patients in the CD group and 43 in the IOD group. Provisional dentures were made before implant surgery for 8 patients missing one or both original dentures in the IOD group. Six of the patients performed masticatory tests for the entry interval at 6 to 11 weeks after receiving the provisional dentures, but before implant surgery. Five of the patients also completed 6-month PT tests with the study dentures. The entry and PT performance scores as well as their differences were compared for 25 patients in the CD group and 48 patients, including 5 patients with provisional dentures, in the IOD group. Three patients in the CD group and 2 in the IOD group with missing entry data performed PT tests. Thus, a total of 78 patients, 28 patients in the CD group and 50 in the IOD group, performed 6-month PT tests, and their masticatory scores were compared. The final comparison was made between 19 patients in the CD group and 30 in the IOD group who completed their 24-month PT tests.

Data analyses

The SAS package (SAS Institute Inc., Cary, N.C.) was used to perform a series of multivariate analysis of variance (MANOVA) tests for comparisons between the two treatment groups. Separate MANOVAs were calculated for the four performance scores (PS and SWT for peanuts and carrots) and the four effort scores (CS and CT

Table III. Comparisons between entry mean scores of insulin and noninsulin treated persons who submitted to tests with original or provisional dentures

	Noninsulin treated (n = 34) $\bar{x}$	SD	Insulin treated (n = 46) $\bar{x}$	SD
Preferred side				
Peanuts %	36.5	(15.3)	37.1	(15.3)
Carrots %	64.3	(23.3)	63.2	(27.8)
Swallowing threshold				
Peanuts				
Performance %	56.0	(20.9)	53.8	(22.5)
Strokes (n)	39.2	(20.2)	43.3	(16.1)
Time (sec.)	30.4	(17.7)	33.4	(15.8)
Carrots				
Performance %	61.1	(25.8)	69.4	(28.2)
Strokes (n)	43.8	(23.6)	48.9	(17.7)
Time (sec.)	33.0	(20.6)	39.8	(17.5)

MANOVA for preferred and swallowing threshold performances F = 1.21; p = 0.38.
MANOVA for swallowing threshold strokes and time F = 0.91; p = 0.46.

Table IV. Comparisons between mean entry masticatory scores of CD and IOD groups based on 74 denture wearers who submitted to tests with original dentures

	CD group (n = 30) $\bar{x}$	SD	IOD group (n = 44) $\bar{x}$	SD
Preferred side				
Peanuts %	42.1	(16.1)	35.0	(14.3)
Carrots %	69.4	(26.9)	60.2	(25.8)
Swallowing threshold				
Peanuts				
Performance %	59.4	(24.1)	53.1	(20.9)
Strokes (n)	41.5	(14.8)	40.9	(18.1)
Time (sec.)	30.7	(12.7)	32.1	(16.5)
Carrots				
Performance %	69.1	(27.5)	63.8	(28.2)
Strokes (n)	49.0	(21.9)	45.2	(18.0)
Time (sec.)	37.9	(19.8)	35.1	(13.6)

MANOVA comparison of performances F = 1.29; p = 0.28.
MANOVA comparison of strokes and time F = 0.65; p = 0.63.

Table V. Comparisons between mean entry masticatory scores of CD and IOD groups based on 68 patients who submitted to tests with original dentures at entry and with study dentures at 6 months after treatment completion

	CD group (n = 25) $\bar{x}$	SD	IOD group (n = 43) $\bar{x}$	SD
Preferred side				
Peanuts %	41.3	(15.5)	35.7	(13.6)
Carrots %	68.2	(25.8)	61.4	(24.9)
Swallowing threshold				
Peanuts				
Performance %	57.6	(22.9)	53.9	(20.3)
Strokes (n)	40.4	(14.8)	40.9	(18.3)
Time (sec.)	29.9	(12.7)	32.1	(16.7)
Carrots				
Performance %	67.0	(26.7)	65.0	(27.5)
Strokes (n)	49.7	(23.7)	44.7	(17.8)
Time (sec.)	37.6	(20.8)	34.7	(13.6)

MANOVA comparison of performances F = 0.95; p = 0.44.
MANOVA comparison of strokes and time F = 0.78; p = 0.54.

for SWT tests with both foods). When the MANOVA F-ratio was statistically significant, post-hoc F-ratios (Ryan-Elinot-Gabriel-Welsch [REGW]) for individual variables were examined to determine the statistical significance of the mean differences between the two treatment groups. Besides this conservative approach, t tests were conducted to compare the four performance scores independently. A 0.05% level of statistical significance was used for all analyses.

RESULTS

Masticatory performance scores at entry were available for 10 of the 13 patients who withdrew before the completion of treatment. Their mean scores were comparable to 74 patients who received study dentures and performed masticatory tests at entry. Mean age, denture experience, and the quality of dentures and their supporting tissues for these two groups were also similar.

Masticatory scores at entry for IT and NIT groups

Comparisons of the entry masticatory scores of 46 IT and 34 NIT patients are presented in Table III. Six patients with provisional dentures were included in this analysis. Neither mean differences for the four performance scores (MANOVA F = 1.21; p = 0.38) nor mean differences for CT and CS (MANOVA F = 0.91; p = 0.46) between the IT and NIT groups were statistically significant. Because no differences were found, the method of diabetic control was not included as a covariate in further analyses.

Masticatory scores at entry for CD and IOD groups

Three different comparisons were made between the masticatory scores of CD and IOD groups at entry to establish their functional comparability. The first comparison included all 74 patients, 30 in the CD group and 44 in the IOD group, tested with original dentures. The mean scores and their standard deviations are presented in Table IV. All four mean performance scores were higher in the CD group compared with the IOD group. Although MANOVA failed to show these differences to be significant (F = 1.29; p = 0.28), t test comparisons showed the 42.1% PS peanut mean performance of the CD group, compared with 35.0% for the IOD group, to be statistically significant (p = 0.048). The second comparison included 5 patients with provisional dentures in the IOD group and excluded 5 CD patients and 1 IOD patient who withdrew before completion of PT tests at 6 months. The results were similar, except

Table VI. Comparisons between mean posttreatment scores of CD and IOD groups based on 78 patients who submitted to tests with study dentures at 6 months after treatment completion

	CD group (n = 28) $\bar{x}$	SD	IOD group (n = 50) $\bar{x}$	SD
Preferred side				
Peanuts %	39.8	(12.5)	40.2	(14.6)
Carrots %	72.9	(22.6)	76.4	(19.2)
Swallowing threshold				
Peanuts				
Performance %	61.1	(19.4)	61.5	(16.3)
Strokes (n)	41.8	(19.3)	44.1	(23.1)
Time (sec.)	30.1	(14.1)	31.1	(14.5)
Carrots				
Performance %	79.0	(20.1)	78.3	(16.4)
Strokes (n)	46.1	(24.4)	43.0	(19.0)
Time (sec.)	34.2	(23.7)	29.9	(12.1)

MANOVA comparison of performances F = 0.27; p = 0.90.
MANOVA comparison of strokes and time F = 0.88; p = 0.48.

Table VII. Comparisons between mean posttreatment masticatory scores of CD and IOD groups based on 68 patients who submitted to entry tests with original dentures

	CD group (n = 25) $\bar{x}$	SD	IOD group (n = 43) $\bar{x}$	SD
Preferred side				
Peanuts %	39.3	(11.6)	41.2	(15.0)
Carrots %	72.0	(21.9)	78.1	(18.6)
Swallowing threshold				
Peanuts				
Performance %	61.2	(19.3)	63.1	(16.3)
Strokes (n)	43.4	(19.6)	45.2	(24.3)
Time (sec.)	31.0	(14.1)	31.3	(15.6)
Carrots				
Performance %	79.2	(19.9)	79.8	(16.3)
Strokes (n)	48.3	(24.9)	42.8	(18.9)
Time (sec.)	35.6	(24.6)	29.3	(11.9)

MANOVA comparison of performances F = 0.46; p = 0.76.
MANOVA comparison of strokes and time F = 1.24; p = 0.30.

that the mean PS peanut performance difference became marginally significant (p = 0.055).

The third comparison between the two groups was made for 68 patients, 25 in the CD group and 43 in the IOD group, who were also tested with their study dentures at 6 months after completion of treatment (Table V). Again, the mean scores were higher for the CD group than for the IOD group, but none of the eight mean differences, including the PS peanut performance, were statistically significant by either MANOVA or t tests.

Posttreatment masticatory scores at 6 months for CD and IOD groups

Comparisons of the mean masticatory scores of all 78 patients, 28 in the CD group and 50 in the IOD group, who completed PT tests with study dentures at 6 months revealed no significant differences between the two treatment groups for any of the four performance scores (MANOVA F = 0.27; p = 0.90) or strokes and time for SWT tests either by MANOVA or t tests (Table VI). Similar comparisons of the masticatory scores of 68 patients at 6 months with study dentures, 25 in the CD group and 43 in the IOD group, who performed tests at entry with original dentures also did not reveal any significant differences between the two groups for any of the eight measures (Table VII).

Table VIII. Comparisons between mean changes in masticatory scores (6 month minus entry) of CD and IOD groups based on 68 patients who submitted to tests with original dentures and with study dentures at 6 months after treatment completion

	CD group (n = 25) $\bar{x}$	SD	IOD group (n = 43) $\bar{x}$	SD
Preferred side				
Peanuts %	−2.1*	(14.6)	5.5*	(14.7)
Carrots %	5.0	(24.4)	13.2	(28.5)
Swallowing threshold				
Peanuts				
Performance %	3.6	(19.8)	9.2	(17.0)
Strokes (n)	3.0	(21.6)	4.3	(23.5)
Time (sec.)	1.1	(17.1)	−0.8	(18.0)
Carrots				
Performance %	12.2	(22.1)	14.9	(22.2)
Strokes (n)	−1.4	(29.3)	−1.9	(19.9)
Time (sec.)	−2.0	(29.8)	−5.4	(14.4)

MANOVA comparison of performances F = 1.27; p = 0.29.
MANOVA comparison of strokes and time F = 0.46; p = 0.77.
*t test (p = 0.043) REGW (p < 0.05).

Posttreatment changes in masticatory scores

Because there were some differences between the mean performance scores of the IOD and CD groups at entry, change scores (6-month score minus entry score) in 68 patients with both entry and PT scores were calculated to further evaluate treatment effects (Table VIII). All four performance scores in the IOD and three in the CD group were positive, which indicates improvements in performance. Although improvements in all four PT performance scores in the IOD group were statistically significant, the only significant improvement in the CD group occurred in the SWT performance with carrots. In contrast, the CD group experienced a 2.1 decline in the PS mean performance with peanuts, which made the mean change difference of 7.6 between the two groups to be significant by t test (p = 0.043). Although MANOVA (F = 1.27; p = 0.29) revealed the differences to be nonsignificant, REGW also showed the peanut PS performance change to be significantly higher in the IOD group. Differences between the two groups in the four mean change scores for the strokes and time to reach

Table IX. Comparison between performance scores of CD and IOD groups at 24 months after treatment completion

	CD group (n = 19) $\bar{x}$	SD	IOD group (n = 30) $\bar{x}$	SD
Preferred side				
Peanuts %	42.0	(11.2)	40.5	(13.0)
Carrots %	75.8	(16.0)	78.7	(19.2)
Swallowing threshold				
Peanuts				
Performance %	65.3	(13.0)	58.4	(18.2)
Strokes (n)	44.3	(14.7)	39.7	(11.9)
Time (sec.)	28.5	(10.6)	28.0	(9.3)
Carrots				
Performance %	78.5	(14.1)	73.3	(20.0)
Strokes (n)	41.8	(14.3)	36.3	(12.5)
Time (sec.)	27.5	(9.9)	25.0	(9.9)

MANOVA comparison of performances F = 1.92; p = 0.12.
MANOVA comparison of strokes and time F = 1.24; p = 0.31.

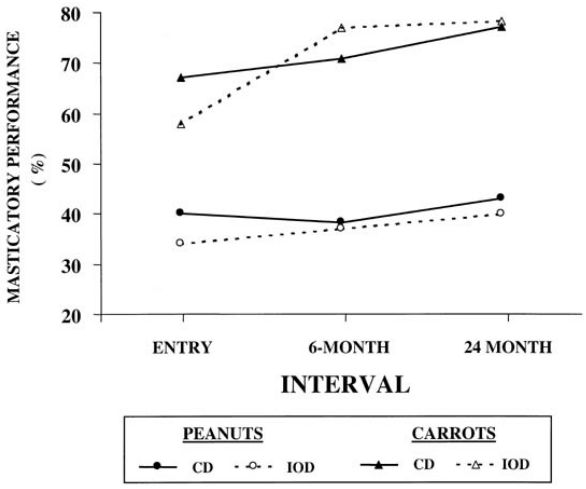

Fig. 1. Preferred side masticatory performance for CD and IOD groups at entry and 6 and 24 months after treatment (n = 46).

the swallowing thresholds were not significant either by MANOVA or t tests.

Posttreatment masticatory scores at 24 months

A total of 19 patients in the CD and 30 patients in the IOD group reached the 24-month PT interval and submitted to tests, and the results showed that none of the differences between the CD and IOD groups for the four performance scores (MANOVA F = 1.92; p = 0.12) or for the four CS and CT scores (MANOVA F = 1.24; p = 0.31) were statistically significant (Table IX). Mean PS masticatory performances at entry, and PT performances at 6 and 24 months are plotted in Figure 1 for the 46 patients completing all three intervals. Entry scores with original dentures for 3 of the 49 patients completing the 24-month tests were not available. Repeated measures ANOVA for PS performance scores with both test foods did not reveal any significant differences between the CD and IOD across the three intervals or within each group over time. Similar results were seen for the swallowing threshold performance scores.

Relationship between entry performance and PT change scores

Correlation matrices were made for the performance scores at entry and the difference scores between 6 months and entry of 68 patients (25 CD and 43 IOD) with data for both intervals. A separate matrix was made for the CD, IOD, and combined groups. Correlations were similar for both CD and IOD groups, and only results for the total sample of 73 are presented. Significant negative correlations ($p < 0.01$) were found between the PS peanuts performance at entry and PT change scores in PS peanuts performance with ($r = -0.57$), in PS carrots performance ($r = -0.32$), in SWT peanuts performance ($r = -0.36$) and in SWT carrots performance ($r = -0.49$).

The relationship between the initial PS peanut performance and improvement in PT masticatory scores was further evaluated by dividing these 73 patients into three subgroups, based on the low, middle, and upper third entry performance scores with peanuts. Mean changes (PT minus entry) in performance scores after treatment are shown by CD and IOD groups for these three performance subgroups in Table X. Whereas increases in all performance scores occurred with new dentures in low and medium performance subgroups, the PS performance scores with both peanuts and carrots declined in the high performance subgroup. MANOVA with two factors, denture type (CD vs. IOD) and performance subgroup (low, medium, high), was used to compare these mean changes. There was neither a statistically significant difference between the two denture groups (MANOVA F = 1.85; p = 0.13) nor an interaction between the denture and performance subgroups (MANOVA F = 0.46; p = 0.88). However, a significant effect of the performance subgroup was found (MANOVA F = 3.37; p = 0.0015). REGW post hoc analyses indicated that the PS change in performance scores with peanuts for the three performance subgroups differed significantly from each other. PS mean differences for carrots among the three performance subgroups were not statistically significant. The low performance subgroup had significantly greater improvement in SWT performance scores with peanuts than the high performance subgroup, but neither the low nor the high performance subgroups differed significantly from the medium group. Both the low and medium performance subgroups showed significantly greater change ($p < 0.05$) in SWT performances with carrots than the high performance subgroup, but did not differ significantly from each other.

Table X. Comparisons between changes in performance scores (6 month minus entry) of CD and IOD subgroups of patients with low, medium, and high preferred side performance with peanuts at entry

	Groups based on entry performance					
	Performance group					
	Low		Medium		High	
	Study denture group		Study denture group		Study denture group	
	CD (n = 6) $\bar{x}$	IOD (n = 18) $\bar{x}$	CD (n = 8) $\bar{x}$	IOD (n = 17) $\bar{x}$	CD (n = 11) $\bar{x}$	IOD (n = 13) $\bar{x}$
Preferred side						
Peanuts	9.8	13.7	−0.5	4.3	−9.6	−1.7
Carrots	5.7	21.0	13.5	14.2	−1.5	−0.4
Swallowing threshold						
Peanuts	11.5	14.1	5.4	9.6	−1.9	3.1
Carrots	15.0	24.5	18.7	14.6	6.0	0.7

MANOVA for treatment factor F = 1.85; p = 0.13.
MANOVA for performance group factor F = 3.37; p = 0.0015.
MANOVA for treatment × performance group interaction F = 0.46; p = 0.88.

DISCUSSION

The random assignment of treatment to patients provided two groups comparable in terms of general characteristics, age, previous denture experience, quality of denture bearing tissues, and their original dentures and 126 other variables related to medical and oromaxillofacial health status. The two groups were also comparable in terms of their whole saliva secretion rates, stereognostic ability, and tactile thresholds. Although the combined four masticatory performance scores or effort at entry for the CD and IOD groups did not differ significantly, all four mean performance scores with the original dentures (entry scores) for the CD group were higher than those for the IOD group. The PS peanut performance score of 42.1 at entry, as an independent measure, was significantly higher for the CD group than 33.7 for the IOD group that included six patients with new provisional dentures. The mean PS peanut performance for these six patients was 24.0 as compared with the mean score of 35.0 for the remaining 44 patients in the IOD group who performed tests with their original dentures. Even after exclusion of these 6 patients with provisional dentures, the PS entry performance remained higher in the CD group, and the mean difference between the two groups became marginally significant (p = 0.055). Thus, patients with provisional dentures were excluded when PT improvements or deterioration in masticatory function with study dentures were assessed at 6 months. Comparisons between the mean PT performance scores of the two treatment groups were made with and without the inclusion of these patients.

Six patients, 5 in the CD group and 1 in the IOD group, withdrew from the study before tests with study dentures at 6 months after completion of treatment. Thus, a total of 68 patients remained, 25 in the CD group and 43 in the IOD group, with both entry and PT masticatory scores. Because the four mean entry performance scores were higher in the CD group than those in the IOD group, the differences between the entry and PT paired scores in these 68 patients were determined to establish improvement or deterioration in masticatory scores with the two types of study dentures. Whereas all four mean PT performance scores in the IOD group showed significant improvements from the entry scores, the only significant improvement in the CD group was noted in the SWT performance score with carrots. Improvements in the PS carrots and SWT peanuts scores in the CD group were not significant. The mean PS performance score in the CD group actually showed a decline of 2.5, which resulted in the only significant mean change difference between the two types of dentures. In a previous study, it was found that, although the carrot performance reached the levels of old dentures at 16 weeks after the insertion of new conventional dentures, the peanut performance failed to do so.[11] The longer adjustment period required to chew peanuts effectively might also explain the low peanut performance scores observed with the provisional dentures that were tested at 6 to 11 weeks after insertion.

Negative correlations between the initial PS peanut performance and PT improvements in performance score indicated that patients with lower initial performance were likely to experience greater improvements in masticatory performances with new dentures, regardless of whether they received mandibular conventional or overdentures. The relatively lower initial performance for the IOD group at entry might explain the higher improvements in performance scores in this group than those in the CD group. This means that the greater gains in the IOD helped only to overcome the initial lower mean scores. For example, the initial mean PS performances for peanuts for the CD group respectively for peanuts and carrots were 41.3% and 68.2% as compared with 35.7% and 61.4% for the IOD group. After treat-

ment, the peanuts and carrots performance scores respectively were 39.3% and 72.0% for the CD group and 41.2% and 78.1% for the IOD group.

Posttreatment masticatory scores for all eight measures for the two types of study dentures failed to show statistically significant differences in these 68 patients. The same was true in the PT scores of all 78 patients (28 CD and 50 IOD), including those with provisional or missing dentures at entry. Patients with both types of study dentures chewed carrots to a finer particle size for swallowing and applied one to two less chewing strokes. Similar PT performance scores in both groups indicated that there was no significant advantage of the implant-supported mandibular denture over the conventional denture in terms of comminuting food. These findings are consistent with the results of a previous longitudinal study in which no significant change in performance was noted after the replacement of conventional mandibular dentures with implant-supported dentures.[4]

Unfortunately, it is difficult to compare the results with a cross-sectional investigation reported by other investigators[5] that showed significantly higher masticatory performances with implant-retained mandibular overdentures than those with conventional dentures. The cross-sectional study differed from this study in three respects. The cross-sectional study (1) was conducted in a selective population of dissatisfied denture wearers with less than 15 mm of mandibular symphyseal jaw bone height, (2) used a synthetic test food (Optocal) and mathematically estimated performance on the basis of median particle size after chewing a specified number of chewing strokes, and (3) did not assess initial performance with original dentures to establish the comparability of the groups treated with conventional and implant-retained dentures.

In contrast, this study accepted all eligible diabetic edentulous patients without regard to their satisfaction with their existing dentures and required sufficient bone height to accommodate implants of 10 mm length in the canine region. The symphyseal jaw bone height ranged from 11 to 39.5 mm with a mean of 26.9 mm. The mean PS performance scores for the study population were substantially higher than those observed for denture wearers in several previous studies.[11-13] This study also determined distributions of particle sizes, ranging from 0.375 to 4.0 mm, of chewed peanuts with 20 strokes. This permitted estimation of the median particle size (X_{50}) in the CD and IOD groups for entry and PT tests. Contrary to the findings of the cross-sectional study, no significant differences were found between the X_{50} scores of the two treatment groups at either test interval.

The conflicting results between these two studies probably stem from the differences in the patient population, especially in their ability to comminute food with conventional dentures. The cross-sectional study was limited to dissatisfied denture wearers with extremely compromised denture tissue support. Because their masticatory performances were not measured at entry, there is no indication how much change in masticatory performance occurred with implant-supported or new conventional dentures. Thus, the functional comparability of the conventional and implant-retained overdenture groups was not established. According to the investigators, the significantly greater ability to comminute test food with mandibular implant-supported dentures than that with the conventional dentures only reached the levels observed for satisfied patients with conventional dentures. Therefore it is possible that implant-supported mandibular overdentures may be functionally more effective than conventional dentures in restoring masticatory performances of denture wearers to the functional level of an average denture wearer. This might also explain the lack of significant difference between the two treatments in this study, where the initial performance levels exceeded the average functional levels. The average functional levels were the same for the two treatment groups, despite significantly higher mean retention and stability of the implant-supported mandibular overdentures, than those of conventional dentures. The lack of effect of added retention and stability further supports the results of several previous studies indicating no significant influence of denture base fit on performance.[7,13,14]

The high initial functional level in this group of diabetic denture wearers is puzzling. One would have expected that peripheral neuropathy associated with the severity and duration of diabetes mellitus would adversely impact the masticatory process. It is possible that these patients are concerned about their dietary intake, paid attention to their chewing, and have learned to achieve high levels of function with their dentures. No differences were seen between the NIT or IT groups for any of the performance scores ($p > 0.05$). Thus, diabetes mellitus and the method of blood sugar control did not appear to affect masticatory function in diabetic denture wearers with clinically acceptable metabolic control.

Although no significant advantage of the IOD was seen in terms of a denture wearer's ability to comminute food, data on patient satisfaction, food selection, and dietary intake are being analyzed to evaluate other potential treatment effect differences between conventional and implant-supported overdentures.

CONCLUSIONS

Although the mean performance gains were somewhat higher in the implant-supported overdenture group than those in the conventional denture group, the gains were enough to overcome the initial low performances observed with the original dentures in the implant-sup-

ported overdenture group. Because all eight posttreatment masticatory scores for the two types of dentures were similar, the mandibular implant-supported overdentures and conventional dentures were considered functionally equivalent in terms of their ability to comminute test foods in this diabetic patient population.

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, Helen Der, Vu Doan, Elif Fanuscu, Ken Hoang, Michelle Kramer, and Roland McFarland are gratefully acknowledged.

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