A randomized clinical trial comparing the efficacy of mandibular implant-supported overdentures and conventional dentures in diabetic patients. Part I: Methodology and clinical outcomes

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Statement of problem. Scientific evidence is lacking to support the general application of implant-supported mandibular overdentures.

Purpose. This randomized clinical trial was undertaken to compare the efficacy of conventional mandibular and implant-supported overdentures in diabetic edentulous patients with clinically acceptable metabolic control.

Method. A total of 102 diabetic patients, treated with or without insulin, were randomized to receive a new maxillary denture and either a conventional or an implant-supported removable mandibular overdenture. Treatment was completed for 89 patients, 37 with the conventional and 52 with implant-supported dentures. Detailed examinations, tests, and questionnaires were given before and at 6- and 24-months after treatment completion. Comparisons between the two treatment groups were made for treatment failures based on prespecifed criteria and the type and amount of maintenance care provided.

Results. The insulin and noninsulin treated groups were collapsed because of the lack of significant differences at entry. The conventional denture and implant-supported overdenture groups were similar in terms of general demographics, medical status, quality of their original dentures and denture support, several functional measures, and patient satisfaction. Treatment was judged to be successful in 56.9% of patients with conventional dentures and 72.1% with overdentures. This difference in success rate was not statistically significant ($p > 0.05$). Patients with treatment failures in both groups required excessive maintenance care. Those with conventional dentures needed frequent denture base adjustments and relines, whereas those with overdentures required frequent clip replacements and repairs. Although significant improvements were seen with both treatment modalities, a higher percentage of patients with implant-supported overdentures than those with conventional dentures reported improvements in chewing comfort and moderate-to-complete overall satisfaction. (J Prosthet Dent 1998;79:555-69.)

CLINICAL IMPLICATIONS

The use of implant-supported mandibular overdentures may be considered when patients continue to experience chronic problems with clinically acceptable conventional dentures.

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The use of osseointegrated dental implants to support a dental prosthesis has become an accepted treatment modality because of the high implant success rates observed by clinicians and researchers.[1-4] The original application of osseointegrated implants was made to support fixed prostheses in edentulous patients who experience problems with complete dentures.[5] Subsequently, their use has been extended to support fixed prostheses for one or more missing teeth in partially edentulous patients[6-9] as well as to provide mechanical attachment for support and retention of removable overdentures.[10,11] A 5-year survival rate of more than 95% has been reported for implants supporting mandibular overdentures.[12,13] A few retrospective studies have also indicated improvements in overall satisfaction of patients and their perception of chewing hard foods.[14,15] Recently, a randomized clinical trial in a selective population of dissatisfied denture wearers has shown the functional superiority of mandibular implant-retained overdentures in terms of patient satisfaction and their ability to comminute test food.[16,17]

Initially, implant-supported overdentures (IODs) were recommended for patients who were dissatisfied with conventional dentures. The high long-term implant success rate and improvements in patient satisfaction have encouraged many clinicians to promote costly IODs for edentulous patients in general. To our knowledge, controlled studies that have shown the superiority of this treatment modality over conventional dentures for such general application are lacking. Thus, this randomized clinical trial was designed in 1989 and undertaken in 1990 to compare the effectiveness of these two types of mandibular dentures in edentulous diabetic patients with acceptable metabolic control.

The study was conducted in diabetic patients because diabetes mellitus and edentulousness are both highly prevalent in the elderly. It is estimated that 15% to 25% of the elderly population in United States suffer from either insulin-dependent diabetes mellitus or noninsulin-dependent diabetes mellitus. Abnormalities in chemotaxis, phagocytosis, and bacterial activity of polymorphoneuclocytes have been shown in poorly controlled diabetics.[18-20] Despite the best efforts to control hyperglycemia, many diabetic patients develop complications, including microvascular and macrovascular disease, retinopathy, renal disease, neuropathic conditions, and foot problems.[21] Evidence exists to indicate that the complications are related to the duration and degree of lack of glycemic control, which is affected by body weight and a patient's compliance with the treatment regimen.[22] However, normal healing occurs in patients with good metabolic control. Although changes in bone and altered collagen metabolism have been shown in experimental diabetics,[23,24] the higher prevalence of osteoporosis in diabetics remains a controversial matter.[25,26] Many studies have shown that periodontal disease is more prevalent and severe in patients with diabetes mellitus than in nondiabetics, but the promoting factors have not been fully understood.[27-32]

Scientific evidence is lacking to support the belief of many dentists that diabetic denture wearers experience more denture problems than do nondiabetics. A recent study in an American Indian population has failed to support a relationship between denture stomatitis and diabetes mellitus or elevated plasma glucose levels.[33] However, a substantial increase in the density of Candida organisms was found in diabetic denture wearers in another investigation.[34] It was believed that this randomized clinical trial in diabetic patients would not only provide comparisons between two treatment modalities but would also shed light on the response of tissues under dentures and around implants in this unique patient population.

The primary purpose of this study was to determine whether an IOD is an effective treatment alternative to a conventional complete denture (CD) in diabetic edentulous patients who are treated with insulin (IT) or not treated with insulin (NIT) but with dietary therapy with and without oral hypoglycemic medications. Treatment effectiveness was based on improvements in treatment success rates, masticatory efficiency, food selection patterns, dietary intake, patient satisfaction, and cost of initial and maintenance care. The study was designed to provide answers for the following six key questions: (1) Is an IOD a significantly superior prosthesis based on prespecified criteria for successful treatment? (2) Does an IOD significantly improve masticatory performance, food selection, dietary intake, and patient satisfaction? (3) Are the performance improvements with the IOD related to changes observed in tactile thresholds, stereognostic ability, oral clearance indices, and maximal biting pressure? (4) Does an IOD alter the chewing stroke dimensions, chewing pattern (unilateral or bilateral), and particle size selectivity? (5) Does an IOD affect the quality and quantity of muscle activity during chewing? (6) Is masticatory performance related to chewing stroke dimensions, unilateral or bilateral muscle activity during chewing, quantity and quality of muscle activity, and particle size selectivity?

MATERIAL AND METHODS

The study plan was to enroll 108 edentulous patients (50 years or older) with an equal number of patients maintaining acceptable metabolic control with or without insulin for their diabetes of 5 years or more duration. Power calculations required 35 patients in each group to detect a difference of 30% in treatment success rates, masticatory performance, number of denture adjustments, or treatment costs between the two treatment groups with at least 95% probability. An additional 7 patients were added to cover a possible loss of 20% of the patients during the study duration. The sample size

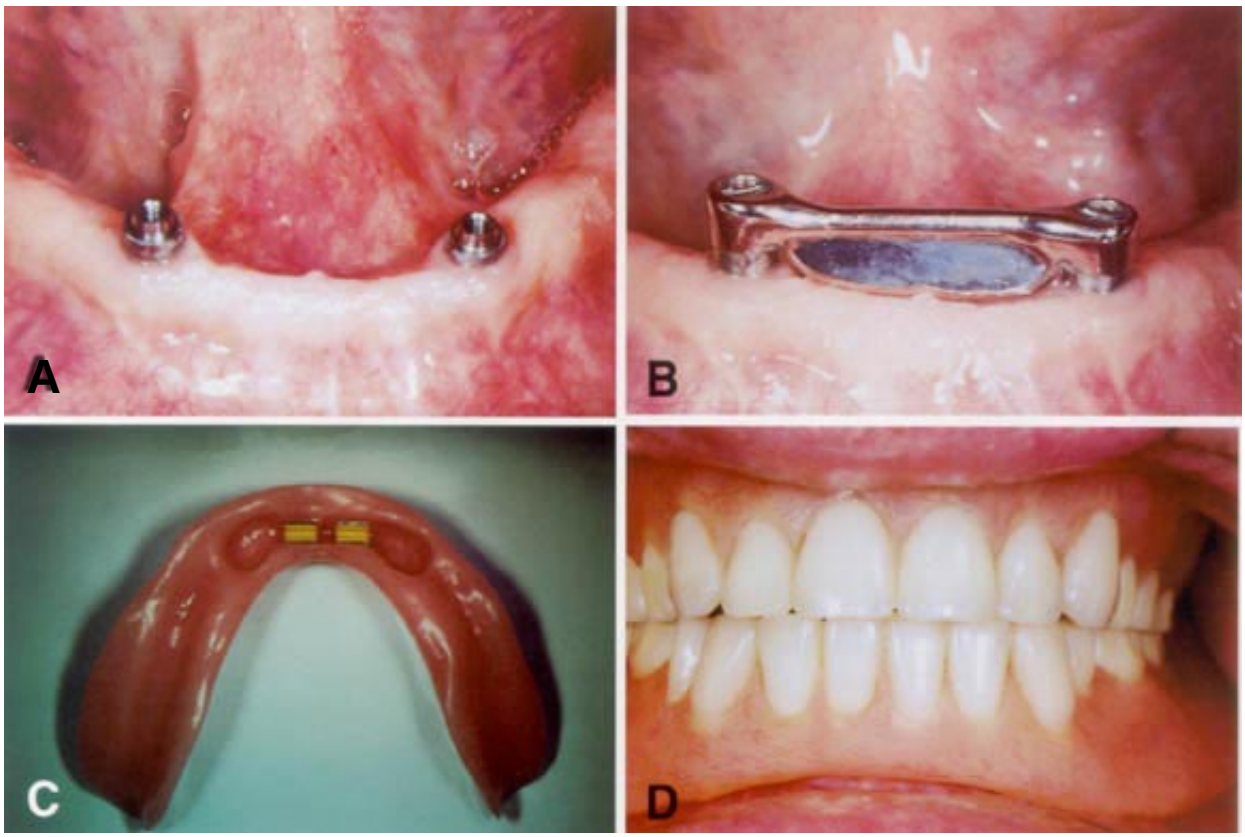

Fig. 1. Right and left implants (**A**), Hader bar attached to implants (**B**), mandibular denture with two plastic clips (**C**), and maxillary and mandibular dentures in place (**D**) in patient with implant-supported mandibular denture.

Table I. List of medical exclusions

Poor metabolic control (glycosylated hemoglobin >13.0% or creatinine >1.7 ml/dl)	Active tuberclosis
Advanced cardiovascular disease, retinopathy, or renal disease	Psychosis
Blood dyscrasias	Osteoporosis
Uncontrolled endocrine disorders	Medical condition with <5-year life expectancy
Connective tissue disorders	Anticoagulant therapy
Liver dysfunction	Anticonvulsant therapy
Auto immune deficiency	Steroid therapy
	Long-term radiation therapy
	Immunosuppressors

in the IOD group was increased to 66 to permit comparisons between IT and NIT subgroups as well as to maintain balanced stratification. Patients were stratified into IT and NIT. From each block of 5 patients in a given stratification category, 3 were randomly assigned to the IOD group and 2 to the CD group by a computer generated schedule. Patients in the CD group received a set of new maxillary and mandibular complete dentures and in the IOD group a new maxillary denture and a mandibular denture with plastic clip retainers for

Table II. Number of insulin treated (IT) and noninsulin treated (NIT) diabetics at randomization and treatment completion

	Patients randomized			Patients completed treatment		
Group	CD	IOD	Total	CD	IOD	Total
NIT	18	29	47	16	23	39
IT	22	33	55	21	29	50
Total	40	62	102	37	52	89

a Hader bar attached to two IMZ implants (Fig. 1). They submitted to a series of examinations, questionnaires, and tests before and after treatment completion.

Of the 108 patients planned, 102 patients meeting certain health requirements were entered. They were prescreened to rule out exclusionary criteria listed in Table I. The final screening required a physician (S.L. and E.F.) to conduct a complete physical examination, including laboratory studies of complete blood cell count, prothrombin, bleeding and clotting times, SMA-12, and urine. Forty patients were assigned to the CD group and 62 to the experimental group. Two patients from the CD group and 8 from the IOD group withdrew before treatment initiation for a variety of reasons, including 3 patients who became apprehensive about implant surgery and 1 patient who refused to ac-

Table III. Patient distribution by implant size

Number of patients	Implant length	Implant diameter	% implants
2	13	3.3	4.3
3	15	3.3	6.5
5	11	4.0	10.8
6	13	4.0	13.0
38	15	4.0	65.4

cept the assigned conventional denture. After randomization, it was found that 1 patient in the CD group was not using his existing clinically satisfactory dentures because of gagging. He was dropped from the study. Two patients from the IOD group withdrew after the placement of implants, one for personal reasons and the other died before the fabrication of dentures. The remaining 37 patients in the CD group and 52 in the IOD group received new dentures. The distributions by IT and NIT of 102 patients who were randomized and 89 who completed the treatment are shown in Table II.

Three patients in the CD group entered the study without dentures and three with maxillary and one with mandibular dentures only. Six patients in the IOD group were without dentures, one with a maxillary denture and one with a mandibular denture. Provisional dentures were made for these eight patients in the IOD group for use during the healing period after implant surgery.

The implants were surgically placed in 27 patients by an experienced oral surgeon (E.F.) and in 27 patients by an experienced periodontist (T.H.). Both operators had extensive experience in implant surgery and essentially followed the standard IMZ protocol with minor differences, such as the location of incision and type of sutures. A full-thickness mucoperiosteal incision was made in the anterior vestibule and reflected lingually to expose the anterior mandible. A clear autopolymerized resin stint prepared from the existing mandibular denture was used to establish the location of the right and left implants in the canine areas. The sites were drilled with consecutively larger twist drills to reach the cortical bone of the inferior border of the mandible. All drilling was performed with copious irrigation. Bacitracin ointment (Barre-National, Inc., Baltimore, Md.) was placed on the threads of the cover screws before inserting into the implants. The surgical site was copiously irrigated and closed with 3-0 chromic gut sutures. Although it was intended to use the longest possible implant of 4 mm diameter, the labiolingual ridge width in 5 patients required placement of 3.3 mm diameter implants. The frequency distribution of patients by implant sizes are given in Table III.

Records were kept on the amount and type of local anesthetic used, total time of operation from incision to soft tissue closure, amount of bleeding, quality of implant seating, implant mobility, any possible or confirmed lingual or buccal cortical plate perforation, and any other complication. One hour before surgery 2 g of penicillin VK were given and prescribed for 7 days after surgery. Erythromycin was substituted for patients who were allergic to penicillin. Besides oral instruction, a postoperative instruction sheet was given to each patient. Patients were given Peridex (Procter and Gamble, Cincinnati, Ohio) to rinse their mouth three times a day for 2 weeks. They were instructed not to use their dentures during the healing period. Patients were seen 24 hours after the operation and thereafter at least once each week. After the tissue had reasonably healed, the existing mandibular denture was adjusted and relined with Viscogel (Dentsply Limited, Weybridge, Surrey, England), a soft tissue conditioning material. The reline was renewed as needed.

The implants were exposed after 16 to 18 weeks. An incision approximately 1 cm that bisected the attached gingiva was made over the crest of the ridge. Releasing incisions of approximately 4 mm from the edges of the cover screw were made as needed on the buccal and/or lingual aspects of the implant. The mucosa was elevated in a split thickness fashion, maintaining the underlying periosteum. The connective tissue and periosteum directly over the implant were excised and the cover screw removed. An abutment sleeve of proper height was positioned and attached with a plastic healing screw. After irrigation with sterile saline, 5-0 chromic sutures were used both at the base of the flap and at the margins to suture the mucosa to the underlying periosteum. Patients were prescribed Peridex for mouth rinse two to three times a day for 2 weeks. After initial healing, the existing mandibular denture was further altered and relined with Viscogel.

Although most patients were treated by two prosthodontists (R.D. and K.K.) at the West Los Angeles Veterans Affairs Medical Center and a prosthodontist at the UCLA School of Dentistry (E.R.), others were treated by senior prosthodontic residents at these two institutions. They all essentially followed the same technical procedures for the fabrication of dentures and Hader bar. Nonanatomic 0° acrylic resin teeth were used to establish a monoplane occlusal plane without any incisal guidance and ramps for eccentric balance. Two plastic clips were used to retain the mandibular denture in 38 patients and one clip in the remaining 14 patients.

Patients were followed for post-insertion adjustments by the treating dentist for 30 days. At that time, the dentures were examined by an experienced prosthodontist (M.H.), who served as the Study Examiner (SE) to assure that the study dentures were clinically acceptable in terms of retention, stability, denture base extension, and occlusal relationship. The treatment of patients with acceptable dentures was considered complete 30 days after denture insertion. Patients with unacceptable den-

tures were referred back to the treating prosthodontists for any needed alterations. One patient from each of the two treatment groups required fabrication of new maxillary and mandibular dentures. Maxillary dentures of three patients in the IOD group and one in the CD group were relined. One patient also required resoldering of the Hader bar to abutments. These patients were again followed for 30 days before their treatments were considered complete.

Posttreatment follow-up care

After treatment completion, patients were seen by the SE for all maintenance care for the duration of the study. Patients were provided a reflectance device and reagent strips and were instructed in their use to monitor their prebreakfast blood glucose level three times a week. They were also instructed to report any dental problems to the clinic and were seen by the SE as soon as possible. The mucosal response and types of denture adjustments made were recorded on a new data sheet at each visit. Patients with implants were seen at 3-month intervals for prophylaxis and assessments of plaque and pocket depth around implants.

The following information was collected after a patient had been accepted for the study and 6 months after treatment completion of study dentures: (1) detailed medical and dental histories; (2) orofacial examination; (3) clinical evaluation of dentures and tissue support; (4) diagnostic casts of maxillary and mandibular arches; (5) 1-week dietary chart; (6) food preference and patient satisfaction questionnaires; (7) masticatory performance tests with electromyographic (EMG) recordings of masseter muscles and kinesiographic recordings of jaw movements; (8) maximum biting and chewing pressures; (9) whole saliva secretion rates; (10) tactile thresholds; and (11) stereognostic and oral clearance performances.

Frontal and sagittal cephalometric radiographs with dentures in centric occlusion position were made at 6 months after treatment completion. Except for the kinesiographic and EMG recordings during chewing, all other tests, examinations, and questionnaires were repeated at 24 months after treatment completion.

Attachment levels and alveolar bone height measurements around implants

The distances from the top of the implant abutment to the gingival margin and to the attachment level (AL) were measured in millimeters at the middle of each of the four implant surfaces with a calibrated periodontal probe. The difference between the two distances provided the pocket depth (PD). The baseline measurements were taken at treatment completion and were repeated at 3-month intervals. Because these measurements were not initially planned, baseline data were not collected in 21 patients.

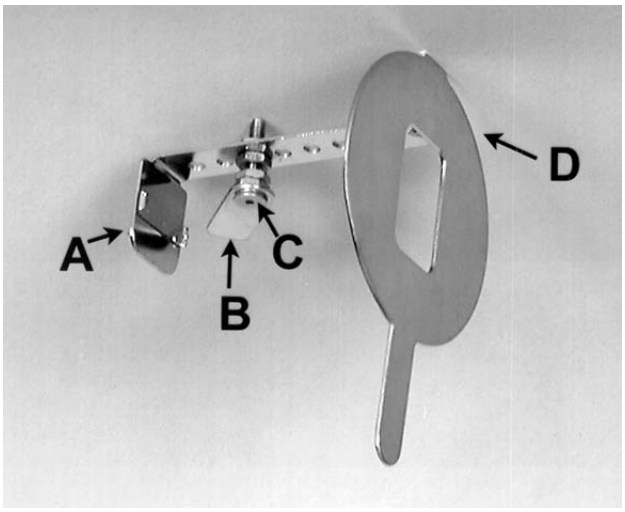

Fig. 2. Special device that was attached to implant to maintain constant position of film holder to implant and x-ray source. Film holder (*A*), reference bar (*B*), sleeve for gold cylinder fastening screw (*C*), and x-ray tube holder (*D*).

A standardized periapical radiograph of each implant was taken to determine mesial and distal bone heights at 6-month intervals. A special device (designed by the SE) was attached to the implant to maintain a constant position of the film holder and the x-ray source (Fig. 2). This method provided radiographs that were found to be clinically superimposable. The periapical radiographs were computer digitized with "Imagelab" software (Image Lab, Werner Frei Associates, Venice, Calif.), and the maximum mesial and distal bone heights of each implant were measured on a blind basis with the NIH Image program (National Institutes of Health, Bethesda, Md.). Repeated images were included for 20 implants without the knowledge of the rater to establish intraexaminer reliability. Correlations of the repeated measures on first and last radiographs of 20 implants were 0.987 for the distal and 0.994 for the mesial ($p < 0.0001$) bone heights. The mean error for the change in mesial and distal bone heights around these 20 implants was 0.076 and 0.104 mm, respectively.

Assessment of general health status

Past and present medical history, including episodes of illness, treatments, and medications, were recorded on specially designed data sheets. The information provided by the patient was verified by a review of the medical records and/or by checking with the patient's private physician.

Assessment of the clinical quality of dentures and tissue support

The methods for determining the clinical quality of dentures and tissue support have been described previously.[35] A 4-point ordinal scale was used to rate the retention and stability of the maxillary and mandibular

Table IV. Comparisons of selected entry characteristics between 50 insulin treated (IT) and 39 noninsulin treated (NIT) diabetics

Items	IT		NIT		
	$\bar{x}$	SD	$\bar{x}$	SD	P-value
Age (yrs.)	65.4	7.0	64.7	6.7	0.649
Height (ins.)	67.9	3.4	66.7	4.0	0.092
Weight (lbs.)	189.6	35.7	180.6	37.5	0.237
Glycosylated hemoglobin	9.8	1.7	8.5	2.1	0.002
Max. denture experience (yrs.)	17.6	14.3	19.5	13.8	0.522
Mand. denture experience (yrs.)	13.9	14.3	16.5	14.5	0.412
Max. ridge shape	3.5	1.0	3.4	0.9	0.608
Max. peripheral tissue location	2.0	0.8	2.4	0.7	0.042
Max. tissue resiliency	2.7	0.6	2.6	0.6	0.495
Mand. ridge shape	2.2	1.2	2.5	1.2	0.298
Mand. peripheral tissue location	1.6	0.8	1.5	0.8	0.672
Mand. tissue resiliency	2.4	0.8	2.4	0.8	0.641
Overall tissue support quality	14.4	3.1	14.7	3.4	0.698
Overall max. and mand. denture quality	14.0	4.2	15.1	2.9	0.210
Lateral mand. bone height (mm)	20.9	5.3	20.1	5.2	0.477
Anterior mand. bone height (mm)	27.1	6.5	26.5	6.5	0.667

Table V. Comparisons of oral functional scores between 50 insulin treated (IT) and 39 noninsulin treated (NIT) diabetics

	IT		NIT		
	$\bar{x}$	SD	$\bar{x}$	SD	P-value
Salivary flow					
Resting (ml/5 min.)	2.3	1.3	2.2	1.2	0.826
Stimulated (ml/5 min.)	5.0	2.7	5.5	2.7	0.379
Stereognosis w/denture					
Correct responses (No.)	14.0	3.7	12.5	3.0	0.059
Time (sec.)	9.8	3.7	11.4	5.6	0.166
Stereognosis w/o denture					
Correct responses (No.)	13.7	3.4	12.7	3.8	0.228
Time (sec.)	10.9	5.7	12.1	7.4	0.417
Oral clearance					
W/tongue sweep (%)	65.5	26.9	62.7	21.6	0.612
W/O tongue sweep (%)	45.8	26.0	38.4	23.5	0.188
Masticatory performance					
Peanuts (%)	37.1	15.3	36.5	15.3	0.878
Carrots (%)	63.2	27.8	64.3	23.3	0.852
Swallowing threshold					
Peanuts (%)	53.8	22.5	56.0	20.9	0.657
Carrots (%)	69.4	28.2	61.1	25.8	0.181

dentures and a 3-point scale for the vertical dimension of occlusion and centric occlusion of the two dentures. A set of dentures with a total score of 14 or less was judged as poor, between 15 to 18 as fair, and 19 to 22 as good. In addition, the previous denture experience and the age of the current dentures since its last relining were obtained from each patient.

The size and shape of maxillary and mandibular ridges were rated on a 4-point scale and the quality of the mucosa and the location of peripheral tissue attachments on a 3-point scale. The total score of 13 or less indicated the tissue support to be poor, between 14 to 17 fair, and 18 to 20 good. In addition, the mandibular bone height was determined from the sagittal cephalometric radiographs at two sites: a midpoint between the gonion and menton, and at the symphysis.

Treatment failure criteria

Treatment in a patient was judged to be a failure for one or more of the following reasons: (1) unable to wear study dentures; (2) dissatisfied with study dentures; (3) never or occasionally used their study dentures for eating; (4) experienced moderate-to-great discomfort during chewing with study dentures; (5) required four or more visits for denture adjustments and/or clip replacements during each 180-days inter-

Table VI. Comparisons of selected entry characteristics between mandibular conventional denture (CD) and implant-supported overdenture (IOD) groups

Items	CD (N = 37) $\bar{x}$	CD (N = 37) SD	IOD (N = 52) $\bar{x}$	IOD (N = 52) SD	P
Age (yrs.)	64.2	7.4	65.7	6.4	0.339
Height (ins.)	67.7	4.0	67.1	3.5	0.457
Weight (lbs.)	189.5	35.2	183.2	37.4	0.426
Glycosylated hemoglobin	9.5	2.0	9.1	1.9	0.324
Max. denture experience (yrs.)	17.6	13.9	19.5	13.8	0.451
Mand. denture experience (yrs.)	13.9	14.3	16.5	14.5	0.459
Max. ridge shape	3.4	1.0	3.4	0.9	0.747
Max. peripheral tissue location	2.3	0.8	2.1	0.8	0.291
Max. tissue resiliency	2.7	0.7	2.6	0.6	0.915
Mand. ridge shape	2.4	1.2	2.3	1.2	0.785
Mand. peripheral tissue location	1.6	0.8	1.5	0.8	0.697
Mand. tissue resiliency	2.5	0.8	2.4	0.8	0.591
Overall tissue support quality*	14.7	3.3	14.4	3.1	0.598
Overall max. and mand. denture quality	15.0	3.7	14.2	3.8	0.351
Lateral mand. bone height (mm)	20.5	5.0	20.6	5.5	0.907
Anterior mand. bone height (mm)	26.9	6.5	26.8	6.5	0.976

*Seven patients in the CD group entered without dentures and three of the eight patients with provisional dentures in the IOD group were not rated.

val after treatment completion; (6) clinically perceptible implant mobility; (7) 30% mesial or distal vertical bone loss around the implant; and, (8) implant removal for any reason. Patients could receive any number of denture adjustments during the first 30 days after the insertion of dentures.

Statistical analysis

The medical and dental histories and the oromaxillofacial examination generated 134 variables defining a patient's general characteristics and medical and oral health status. The tests and questionnaires provided 27 measures of oral functional status at entry. Comparisons were made between IT and NIT diabetics for the total sample of 102 patients randomized, as well as 89 patients whose treatment had been completed. Chi-square analyses or two-tailed Fisher's exact tests were used to determine the statistical differences between percentage distributions and two-tailed *t* tests between mean differences of the two groups. SAS statistical software (SAS Institute Inc., Cary, N.C.) was used to perform multivariate analysis of variance (MANOVA) tests to make comparisons for three variables (quality of denture tissue support, clinical excellence of dentures, and masticatory function) with multiple components. When the MANOVA F-ratio was statistically significant, post hoc Ryan-Einot-Gabriel-Welsch (REGW) multiple F-ratios or univariate analyses were calculated to determine the statistical significance of the mean difference between the two groups for individual variables. Similar statistical tests were made to determine the comparability of the CD and IOD groups for the two samples at entry and after treatment completion.

A life table method[35] was used to determine the success rates for the CD and ID groups at 6-month intervals after treatment completion and chi-square test to compare the success rates of the two groups. An alpha level of 0.05 was used for all statistical analyses.

RESULTS

Comparisons of the success rates of the two treatment modalities and the maintenance care sought by patients in the two groups are presented.

Comparisons between IT and NIT groups

Comparisons were made at entry between the IT and NIT groups for 102 patients randomized as well as 89 patients who received the study dentures. Both comparisons yielded almost similar results. Means and standard deviations for the two groups and comparisons of selected variables for the 89 patients are presented in Table IV. The two groups were similar in terms of educational levels, smoking habits, medical status, medication usage, and orofacial structural integrity, quality of existing dentures, and denture support characteristics. Significant differences between the two groups were noted for only 4 of the 130 variables, glycosylated hemoglobin (ghb), alcohol consumption, bruxism, and mandibular peripheral tissue location. These four differences are fewer than would be expected by chance in such a large number of comparisons. The mean ghb of 9.8% in the IT group was significantly higher ($p = 0.002$) than 8.5% in the NIT group. Among the IT patients, 40.0% consumed alcohol socially and 16.0% reported bruxism as compared with 17.9% and 2.6%, respectively, in the NIT group. Although MANOVA failed to show significant differences in the overall tissue support between the two groups, *t* test showed the mean differ-

Table VII. Percentage distributions of patients by denture quality and tissue support for mandibular conventional denture (CD) and implant-supported overdenture (IOD) groups at entry

	Tissue support		Denture quality	
	CD	IOD	CD	IOD
No. patients	37	52	30*	49**
Poor (%)	40.5	44.2	46.7	55.1
Fair (%)	37.8	36.5	33.3	30.6
Good (%)	21.6	19.2	20.0	14.2
Chi-square *p*-value	>0.90		>0.50	

*Seven patient entered without dentures.
**Missing ratings of provisional dentures in three patients.

ence for the maxillary peripheral tissue location to be significant ($p = 0.042$).

Comparisons of selected functional variables for 89 patients who completed the study treatment are given in Table V. No significant differences were seen between the IT and NIT groups in masticatory performances, oral stereognostic, and oral clearance scores. Except that a higher percentage of patients in the NIT group expressed slight dissatisfaction with the cleanliness of their dentures after cleaning, no significant differences were found between the percentage distributions of responses to the remaining 12 questions related to chewing function, speech, security, and overall satisfaction with dentures.

Comparisons between CD and IOD groups at entry

Because differences between the IT and NIT groups were negligible in the sample of 89 patients, the groups were collapsed to make comparisons between CD and IOD groups. These comparisons were made separately for the 102 patients randomized for the study as well as for the 89 patients with treatment completion. Both sets of comparisons provided similar results. Comparisons of selected variables for general and orofacial health characteristics for 89 patients with treatment completion are presented in Table VI. Patients ranged in age from 48 to 75 years, with a mean age of 64.2 ± 7.4 for the CD group and 65.7 ± 6.4 for the IOD group. No significant differences were noted between the two groups in educational levels, 18 medical conditions including hypertension, smoking habit, use of 14 of the 15 classes of medications or denture experience. The only significant difference was that 43.2% patients in the CD group were using analgesics as compared with 23.0% in the IOD group. MANOVA showed no significant mean differences between the two groups either in the quality of their original dentures ($F = 1.03$; $p = 0.413$) or supporting tissue characteristics ($F = 0.29$; $p = 0.939$).

The percentage distributions of patients by their overall quality of original dentures and their tissue support are given in Table VII. Again, differences between the two groups were not statistically significant.

Comparisons of selected oral functional scores between the CD and ID groups are presented in Table VIII. All four masticatory performances were higher in the CD group than those in the IOD group. MANOVA failed to show these differences to be significant ($F = 1.91$; $p = 0.118$). However, t test comparisons showed significant mean difference ($p < 0.015$) in the preferred side (PS) chewing performance with peanuts. Only marginally significant differences were noted in the percentage distributions of responses to 2 of the 13 questions related to patient satisfaction with their original dentures. A higher percentage of patients ($p = 0.052$) in the IOD group than in the CD group perceived difficulty with food particles getting under their dentures and did not enjoy eating with their original dentures ($p = 0.095$).

Comparisons between withdrawals and patients with treatment completion

The characteristics of 13 patients, 12 who withdrew from the study prior to treatment completion and one who was dropped from the study, were compared with the remaining 89 patients whose treatments were completed. The two groups were essentially comparable. Significant differences appeared in only three of the 128 medical and dental health variables and none of the functional variables. A higher percentage of patients in the withdrawal group did not smoke cigarettes or cigars, controlled their diabetes with oral hypoglycemic agents, and had anatomic posterior teeth in their original dentures than those in the treated group.

Treatment outcome comparisons

The treatment outcome was not determined until the last patient reached the 6-month follow-up interval. On the basis of prespecified criteria, the treatment was judged a failure in 13 CD and 12 IOD patients during the first 6 months. An additional two failures occurred in both groups during the next 18 months. The success rates by life table analysis and 95% confidence intervals for the two groups are presented in Table IX. The 6- and 24-month success rates came to 63.9% and 56.9%, respectively, in the CD group and 76.5% and 72.1% in the IOD group. The difference between the cumulative success rates of the two groups was found to be statistically not significant (chi-square = 1.95, $p = 0.162$).

The reasons for all failures in the two treatment groups are listed separately for IT and NIT patients in Table X. None of the failures occurred because of implant failure. The difference in percentage failures between the IT and NIT patients was not statistically significant in either of the two treatment groups.

Comparisons between quality measures of original and study dentures

The means and standard deviations for the quality measures of original and study dentures are given in

Table VIII. Comparisons of functional scores at entry between mandibular conventional denture (CD) and implant-supported overdenture (IOD) groups

	CD		IOD		
	$\bar{x}$	SD	$\bar{x}$	SD	P-value
Salivary flow					
Resting (ml/5 min.)	2.2	1.4	2.3	1.2	0.876
Stimulated (ml/5 min.)	5.7	2.8	4.8	2.6	0.135
Stereognosis w/denture					
Correct responses (No.)	14.1	3.5	13.0	3.5	0.172
Time (sec.)	10.7	4.9	10.4	4.5	0.776
Stereognosis w/o denture					
Correct responses (No.)	13.8	3.7	12.9	3.5	0.291
Time (sec.)	10.8	5.9	11.9	7.0	0.461
Oral clearance					
W/tongue sweep (%)	65.4	24.0	63.6	25.3	0.749
W/O tongue sweep (%)	47.3	26.2	39.8	24.3	0.201
Masticatory performance					
Peanuts (%)	42.1	16.1	33.7	13.9	0.015
Carrots (%)	69.4	26.9	60.2	24.8	0.123
Swallowing threshold					
Peanuts (%)	59.4	24.1	52.0	20.0	0.143
Carrots (%)	69.1	27.5	63.9	27.4	0.412

Table IX. Treatment success rates by life table method at 180-day intervals from treatment completion to 2 years after completion for mandibular conventional denture (CD) and implant-supported overdenture (IOD) groups

Days after treatment completion	Successful at beginning of interval		Failed during interval		Patients withdrawn successful		% success at end of interval		95% confidence interval	
	CD	IOD	CD	IOD	CD	IOD	CD	IOD	CD	IOD
0-180	37	52	13	12	2	2	63.9	76.5	±15.8	±11.7
181-360	22	38	1	1	4	2	60.7	74.4	±16.2	±12.1
361-540	17	35	1	1	2	7	56.9	72.1	±16.9	±12.6
541-720	14	27	0	0	2	14	56.9	72.1	±16.9	±12.6

Table XI for the 78 patients who completed the 6-month tests. MANOVA for all six measures showed that the mean differences between the CD and IOD groups were not statistically significant for the old dentures but were significant ($p < 0.0001$) for the study dentures. The REGW F-ratios showed that significant mean differences between the two groups existed only for retention and stability scores of the study mandibular dentures. The mean differences for the other four mandibular and all six maxillary denture measures were not statistically significant.

Maintenance care comparisons

The determination of treatment outcome at the termination of the study offered all patients the needed maintenance care (MC) without bias. At a given visit, one or more procedures were performed. However, adjustments made in different locations of a denture base at the same visit were counted as one procedure for the given denture. Similarly, one or both clip replacements were considered as one procedure.

The number of patients available for MC and the number and percentage of patients who sought care during each of the four 180-day intervals after treatment completion were determined for the two treatment groups. These distributions as well as the number of procedures performed in the CD and IOD groups during the first two 180-day intervals are listed separately for those with treatment success or failure in Table XII and for the third and fourth intervals in Table XIII. The staggered entry and patient withdrawals reduced the number of patients eligible for care during the third and fourth intervals. In addition, fewer patients sought care.

Of the 37 patients in the CD group, 23 (62.2%) sought and received MC as compared with 22 of the 52 patients (42.3%) in the IOD group during the first 180 days. A higher percentage of patients with both successful treatment outcome (STO) and failed treatment outcome

Table X. Numbers of insulin-treated (IT) and noninsulin-treated (NIT) diabetics with treatment failures and their reasons in mandibular conventional denture (CD) and implant-supported overdentures (IOD) groups

	Number of patients					
	CD			IOD		
	IT	NIT	TOT	IT	NIT	TOT
Patients treated	21	16	37	29	23	52
Complete dissatisfaction	3	2	5	1	0	1
Moderate to severe chewing discomfort	2	1	3	1	1	2
Unable to wear	1	0	1	0	0	0
Occasionally used for eating	1	0	1	1	1	2
Four or more adjustment visit/180 days	3	2	5	4	5	9
Treatment failure	10	5	15	7	7	14
% treatment failure	47.6	31.3	40.5	24.1	30.4	26.9
Chi-square (*p*-value)		>0.50			>0.90	

Table XI. Comparisons between CD and IOD groups of clinical quality of original and study dentures

	Original dentures		Study dentures		CD/IOD study dentures
	CD $\bar{x}$	IOD $\bar{x}$	CD $\bar{x}$	IOD $\bar{x}$	REGW P-value
Maxillary retention	3.4	2.9	3.7	3.8	>0.05
Maxillary stability	3.5	3.0	3.7	3.8	>0.05
Mandibular retention	1.9	1.8	2.5	4.0	<0.05
Mandibular stability	3.0	3.0	3.6	3.9	<0.05
Centric occlusion	1.8	1.8	2.7	2.9	>0.05
Vertical dimension (VDO)	1.7	1.7	2.7	2.7	>0.05
MANOVA (*P*-value)	0.4229		0.0001		

(FTO) in the CD group sought and received care than did those in the IOD group during the first two intervals. The reverse was true during the third interval, and the percentages for the two treatment groups were similar during the fourth interval. The average number of procedures for STO patients in both the CD and IOD groups was markedly lower than that for the respective subgroup of FTO during all four intervals. For example, the average number of procedures for the STO patients came to 2.1 and for the FTO patients 5.8 in the CD group and 1.4 and 4.2, respectively, for the IOD group during the first 180 days. As can be seen, the major difference between the two treatment groups occurred in the FTO patients. Patients in the CD group required more adjustments to their mandibular denture bases, and patients in the IOD group more replacements of clips and mandibular denture repairs. A total of 45 mandibular denture base adjustments were made in the CD group as compared with 21 in the IOD group during the first interval. Five patients in the CD group were given 23 chairside mandibular relines and one maxillary reline with soft tissue conditioning material and subsequent laboratory relines, one patient a new set of maxillary and mandibular dentures and another a new mandibular denture in the CD group. Patients in IOD group received 75 clip replacements during the four intervals, 47 clips in 11 FTO patients and 28 clips in 10 STO patients.

Patient perceptions

Three of the eight treatment outcome criteria were based on responses by patients to three questions related to the use of dentures for eating, degree of chewing comfort, and overall satisfaction with dentures. The responses for these three items were examined in 25 CD patients and 48 IOD patients with data both at entry and at 6 months. Fisher's exact tests showed no significant differences between the percentage distribution of responses to any of the three questions in the two groups either at entry with the original dentures or with the study dentures at 6 months. However, comparisons of the distributions for the change in responses (6-months minus entry) showed significantly higher percentages of patients with improvements in their overall satisfaction in the IOD group ($P = 0.028$) than those in the CD group. Comparisons were also made after the four-point response scales for eating frequency with dentures and chewing discomfort were collapsed into two and three categories, respectively, and the six-point scale for the overall satisfaction into three categories. The collapsed distributions for the two groups are given in Table XIV. As can be noted, there were substantial improvements in chewing comfort and overall satisfaction in both groups. The number of patients with moderate-to-severe chewing discomfort dropped from 9 (36.0%) to 4 (16.0%) in the CD group and from 21 (3.8%) to

Table XII. Numbers and types of denture adjustments in patients with successful and failed treatment during the first two follow-up intervals

	First 180 days				181-360 days			
	Successful		Failed		Successful		Failed	
Treatment outcome	CD	IOD	CD	IOD	CD	IOD	CD	IOD
Patients qualified for treatment	24	40	13	12	21	37	14	13
Patients sought treatment	11	13	12	9	7	9	10	8
% sought treatment	*45.8*	*32.5*	*92.3*	*75.0*	*33.3*	*24.3*	*71.4*	*61.5*
Procedures								
Occlusion correction	2	2	3	1	2	1	3	0
Mandibular denture								
Base adjustment	15	7	30	14	4	3	23	6
Chairside soft reline	0	0	19	0	0	0	4	0
Laboratory reline	0	0	2	0	0	0	2	0
Repair	0	2	0	0	0	3	0	1
Remake	0	0	1	0	0	0	1	0
Clip replacement	—	3 (5)*	—	8 (13)*	—	3 (6)*	—	7 (12)*
Other procedures	0	0	0	3	0	0	0	2
Maxillary denture								
Base adjustment	4	2	11	12	3	2	4	2
Chairside soft reline	0	0	1	0	0	0	0	0
Laboratory reline	0	0	1	0	0	1	0	0
Repair	2	2	0	0	1	0	0	1
Remake	0	0	1	0	0	0	0	0
Total procedures	23	18	69	38	10	13	37	19
Procedures/patients treated	2.1	1.4	5.8	4.2	1.4	1.4	3.7	2.4

*The value in parentheses represents the total number of clips replaced and the other value the number of visits for clip replacement.

3 (6.3%) in the IOD group. Similarly, the number of patients with moderate-to-high dissatisfaction with their original dentures was reduced to 1 (4.0%) from 10 (40.0%) in the CD group and to 1 (2.1%) from 15 (1.2%) in the IOD group. Although the changes in the percentages of collapsed responses with the original dentures to study dentures were highly significant ($p < 0.001$) for and overall satisfaction within both treatment groups, the difference between the two treatment groups was not significant.

Changes in bone height and attachment levels around implants

The difference in time between the initial and the follow-up radiographs ranged from 6 to 54 months in 48 IOD patients with a mean duration of 20.2 months. During this time, a mean loss of 0.11 mm in mesial and 0.13 mm in distal bone heights occurred around 95 implants. Whereas 25 patients with baseline and 24-month radiographs showed a mean loss of 0.09 mm in mesial and 0.19 mm in distal bone heights, 36 patients with baseline and 12-month radiographs showed a mean loss of 0.21 mm both in mesial and distal bone heights.

The PD and AL measurements were available for 31 patients at baseline and after 6 months and for 19 patients after 12 months. The mean PD change after 6 months ranged from -0.24 to 0.24 mm at the four sites of the right and left implants and from -0.28 to 0.45 mm after 12 months. There was no statistically significant difference in any of the 16 measurements. The change in mean AL ranged from -0.2 to 0.45 mm after 6 months and -0.07 to 0.39 mm after 12 months. The only statistically significant mean change among these 16 measurements was the mean AL loss of 0.45 mm at the distal surface of right implants after 6 months. No clinical mobility was detected in any of the 104 implants in place from 6 months to 54 months.

DISCUSSION

A stratified randomization approach for treatment assignment provided two comparable groups based on their general health, education level, smoking habit, alcohol consumption, present medication use, diabetic status, and oromaxillofacial characteristics. The two groups were also similar in terms of previous denture experience, quality of denture tissue support, clinical excellence of their original dentures, and a variety of oral functional measures. Although the study prohibited the enrollment of patients with substance abuse, two patients with chronic alcohol problems, one in each treatment group, slipped into the study. This was not discovered until after the placement of implants in the IOD group and the time of denture insertion in the CD group. The patient in the IOD group died between Phase II implant surgery and fabrication of dentures, and the treatment of the patient in the CD group was judged a

Table XIII. Numbers and types of denture adjustments in patients with successful and failed treatment during the third and fourth follow-up intervals

	361-540 days				541-720 days			
	Successful		Failed		Successful		Failed	
Treatment outcome	**CD**	**IOD**	**CD**	**IOD**	**CD**	**IOD**	**CD**	**IOD**
Patients qualified for treatment	16	34	15	14	14	27	15	14
Patients sought treatment	3	9	6	9	3	6	3	3
% sought treatment	*18.8*	*26.5*	*40.0*	*64.3*	*21.4*	*22.2*	*20.0*	*21.4*
Procedures								
Occlusion correction	0	0	1	0	0	0	0	0
Mandibular denture								
Base adjustment	2	4	16	7	0	3	6	8
Chairside soft reline	0	0	0	1	0	0	0	0
Laboratory reline	0	0	0	1	0	0	0	1
Repair	0	1	0	2	1	0	0	0
Remake	0	0	0	0	0	0	0	0
Clip replacement	—	5 (8)*	—	10 (16)*	—	5 (9)*	—	4 (6)*
Other procedures	0	0	0	1	0	1	0	0
Maxillary denture								
Base adjustment	0	3	2	4	1	1	0	4
Chairside soft reline	0	0	0	0	0	0	0	0
Laboratory reline	0	0	0	1	0	0	0	1
Repair	1	2	0	0	3	0	0	1
Remake	0	0	0	0	0	0	0	0
Total procedures	3	15	19	27	5	10	6	19
Procedures/patients treated	1.0	1.7	3.2	3.0	1.7	1.7	2.0	6.3

*The value in parentheses represents the total number of clips replaced and the other value the number of visits for clip replacement.

failure because of excessive maintenance care during the second 6-month interval.

To our knowledge, no specific criteria for treatment success or failure have been defined in the literature or used in controlled or uncontrolled studies of complete dentures. Most previous investigations have been devoted to implant survivals, patient satisfaction, and/or functional outcomes.[14-16,37] The failure criteria in this study were based on patient satisfaction, chewing comfort, use of dentures for eating, implant failure, and amount of maintenance care. They are not different from those presumably used by dentists to differentiate between satisfied and problem patients. The only criterion open to debate is four or more MC visits per 180 days and the inclusion of visits for clip replacements. These two arbitrary values were based on two considerations. First, we knew that the study might be terminated after the last patient completed the 6-month follow-up tests and examinations. The staggered entry of patients and additional 6 months required to complete treatment in the IOD group would limit the follow-up to only one or two 6-month intervals for many late entries in this group. Second, we believed that patients needing four or more MC visits after having adjustments during the 30 days after denture insertion were likely to be considered difficult patients by most clinicians. This would also be true of patients requiring frequent clip replacements in the IOD group.

Because the criterion of four MC visits per 6 months was arbitrary, five treatment failures in the CD group and eight in the IOD group that resulted exclusively from this criterion were further examined. Twelve of them expressed moderate-to-high satisfaction and one slight satisfaction with the study dentures. In the CD group, four of the five patients with such treatment failures required more than 10 MC visits and three of them received mandibular laboratory relines during the 24-month period. The fifth patient made 23 MC visits. He experienced temporomandibular joint dysfunction and chronic ridge soreness several weeks after the insertion of study dentures with an increase of about 6 mm in the vertical dimension of occlusion (VDO) from that of the original dentures. This problem occurred despite the fact that the VDO was gradually increased and established on the original dentures without symptoms before making the study dentures. Several visits were made to alter the VDO and reline dentures with tissue conditioning material. On the other hand, only one of the eight such failures in the IOD group required more than 10 MC visits. He made 23 visits, 5 for clip replacements before the bar was remade and mandibular and maxillary dentures relined and 3 additional visits for clip replacements afterward. The remaining 14 visits were made for denture base adjustments and bar remake, and 1 for the removal of a papilloma. Two other patients required seven or more denture adjustments. The remaining five IOD failures

Table XIV. Distributions of responses by patients in the CD and IOD groups about their original and study dentures

	CD (N = 25)				IOD (N = 48)			
	Original dentures		Study dentures		Original dentures		Study dentures	
	No.	%	No.	%	No.	%	No.	%
Always or frequently ate with dentures	24	96.0	24	96.0	44	91.7	47	97.9
Never or occasionally ate with dentures	1	4.0	1	4.0	4	8.3	1	2.1
No chewing discomfort	4	16.0	11	44.0	10	20.8	34	70.8
Slight chewing discomfort	12	48.0	10	40.0	17	35.4	11	22.9
Moderate or severe chewing discomfort	9	36.0	4	16.0	21	43.8	3	6.3
High to moderate overall satisfaction	15	60.0	21	84.0	25	52.1	46	95.8
Slight satisfaction or dissatisfaction	0	0.0	3	12.0	8	16.7	1	2.1
Moderate to high dissatisfaction	10	40.0	1	4.0	15	31.2	1	2.1

required three or less MC visits during the remaining three 6-month intervals before and after the treatment was judged a failure. Most of them were for clip replacements. For example, five of the six adjustment visits made by the only failure in the IOD group during the second interval were related to clip replacements or for tightening the abutment screws. If the replacement of clips was excluded from the visit count for treatment failure, the treatment of these five patients would be judged successful. Such a revision in the criterion would increase the IOD success rates from 76.5% to 84.3% at 6 months and from 72.1% to 80.9% at 24 months and make the difference between the two treatment groups significant (chi-square = 6.18, $p = 0.013$).

It is important to point out that only one visit was counted for multivisit procedures such as denture reline, denture remake, or bar repairs. Similarly, adjustments to a denture base immediately before chairside relines were not counted. In both groups, FTO patients received two to three times the number of mandibular denture base adjustments, 75 in CD and 35 in IOD groups as compared with 21 and 17, respectively, for the STO patients. In addition, the 25 tissue conditioning relines (23 mandibular and 1 maxillary in the CD group and 1 maxillary in the IOD group) were exclusively placed in FTO patients. All three denture remakes (one maxillary and two mandibular) and five relines (four mandibular and one maxillary) in the CD group and four of the five relines (two maxillary and two mandibular) were performed in FTO patients. Likewise, six of the seven other procedures including bar remake, bar resolder, and abutment screw tightening, and 47 of the 75 clip replacements occurred in FTO patients. Obviously, all these procedures were carried out to overcome patient problems and complaints.

The MC varied among STO patients in both groups. Eight such patients in the CD required no MC and 14 received 41 procedures including one to five mandibular base adjustments in 10 patients. In the IOD group, 14 required no MC and 21 received 56 procedures including one to three mandibular base adjustments in 11 patients and one or more clip replacements in 10 patients. All 8 denture repairs (1 mandibular and 7 maxillary) in the CD group and 10 of the 15 denture repairs (6 maxillary and 4 mandibular) were required by STO patients. The need for excessive repairs with overdentures and frequent clip replacements were noted previously in several retrospective studies.[38-41]

The most notable MC differences between the two groups were in mandibular denture base adjustments, relines, remakes, and repairs. The CD group received 96 base adjustments, 4 relines, and 2 new dentures as compared with 52 adjustments and 2 relines in the IOD group. This indicates that tissue trauma was more common in the CD group, especially among the FTO patients. The reverse was true for mandibular denture repairs, 9 in the IOD group and only 1 in the CD group.

Significant improvements in chewing comfort and overall satisfaction were perceived by patients with study dentures in both groups. Among 74 patients with original dentures and 5 with provisional dentures at entry, 31 experienced moderate-to-severe discomfort, 33 slight, and 15 no discomfort during chewing. Whereas 11 of them with moderate-to-severe discomfort were completely dissatisfied, only one with no chewing discomfort and one with slight discomfort expressed this feeling. Of the 73 patients that had data at both entry with original or provisional dentures and with study dentures at 6 months, the percentage able to chew without discomfort increased from 16.0% with original dentures to 44.0% with study dentures in 25 CD patients and from 20.8% to 70.8% in 48 IOD patients. Similarly, the percentage of patients with moderate-to-complete overall satisfaction increased from 60.0% with original dentures to 84.0% in the CD group and from 52.1% to 95.8% in the IOD group. However, the overall moderate-to-complete satisfaction rate dropped to 72.4% in the CD group when 4 patients, who left the study because of dissatisfaction with their study dentures before the 6-month interval, were included ($n = 29$) in the calculation. This change made the difference at 6 months between the two groups statistically significant ($p < 0.003$). However, the difference in the percentages of patients with improved overall satisfaction with their study dentures

in the two treatment groups in Table XIV was statistically nonsignificant.

The higher percentage of patients with overall satisfaction with the mandibular IOD than with mandibular CD are consistent with the previous study that showed wider differences between the two treatment modalities in previously dissatisfied denture wearers with no more than 15 mm of mandibular bony ridge height.[16] Neither patient dissatisfaction with dentures nor the ridge height was considered as the acceptance criteria for the current study. The mandibular ridge height at the symphysis ranged from 11 to 39 mm in this study.

No deterioration in chewing comfort or overall satisfaction was noted in both groups after 2 years of denture insertion. This was contrary to the deterioration observed by another investigator after 1 year of insertion of complete dentures.[42]

It was also interesting to note that 7 patients, 4 in the CD and 3 in the IOD groups, experienced moderate-to-severe discomfort with study dentures. Only 2 of them, 1 in each group, were completely dissatisfied. Four of the remaining 5 were moderately to completely satisfied and one slightly satisfied with their study dentures. In addition, 11 of the 48 IOD patients and 10 of the 25 CD patients experienced slight chewing discomfort with study dentures. Only 2 of them from the CD group expressed slight satisfaction and all others moderate-to-complete satisfaction with their dentures. It appears that the response to the question "How satisfied are you with your dentures" was not based on denture comfort alone by many patients. Perhaps it included the quality of care they received. The high degree of satisfaction even by patients with chewing discomfort further indicates that many denture wearers accept the discomfort associated with dentures and learn and/or resign themselves to function with them. Others have difficulty adjusting to such discomfort. This matter will be further explored in the detailed assessments of the responses to the food selection and two different patient satisfaction questionnaires.

The metabolic diabetic control of the 89 patients with treatment completion varied from good to low as indicated by the ranges of blood glycosylated hemoglobin (ghb) from 5.1% to 12.7% and creatinine from 0.6 to 1.7. There were no major complications or clinically perceptible implant mobility. Slight soft tissue dehiscence was noted around five implants in three patients after Stage I implant surgery and around two implants in two patients after Stage II surgery; one of the latter with localized infection. Three of these five patients had moderate levels of metabolic control with ghb levels of 7.4 to 9.2 and the other two with low metabolic control with ghb of 11.7 and 11.9. All these minor complications were resolved after appropriate therapy. Changes in pocket depth and attachment levels were minimal. The average bone loss was limited to 0.12 mm around 95 implants that were in place from 6 to 54 months. Similar limited changes in bone support and attachment levels have been reported by other investigators for implants supporting overdentures in nondiabetic patients.[43] This indicates that implants can be successfully used to support complete dentures in patients with diabetes mellitus of long duration but with clinically acceptable metabolic control. The quarterly professional cleaning provided to patients in this study may have contributed to the stable periodontal health.

Although the success rate was higher by 15.2% in the IOD group than that in the CD group, it seems unreasonable to recommend the general application of IOD because the treatment was judged a failure in one of four patients. In addition, the treatment was successful in 57% of CD patients and improvements were achieved in overall satisfaction and chewing comfort by both treatments. It would seem more reasonable to consider a mandibular IOD after clinically acceptable existing or new conventional dentures fail to meet a patient's needs. The existing conventional denture could be modified to an implant overdenture without duplicate costs. Further insight will be gained on this issue by the ongoing data analyses of functional outcomes such as masticatory performances, muscle activity, biting forces, and jaw movements during chewing and dietary intakes.

CONCLUSIONS

The study dentures were superior to the original dentures in terms of retention, stability, and occlusion. The better fit considerably reduced the number of patients with moderate-to-severe chewing discomfort and increased the percentage of patients with high overall satisfaction with both types of study dentures. The mandibular IOD denture was found to be clinically more retentive and stable than the CD and caused tissue trauma in fewer patients. A higher percentage of patients in the IOD group perceived improvement in chewing comfort and overall satisfaction than those in the CD group. Six failures in the CD group resulted from complete dissatisfaction as compared with only one in the IOD group. Patients with successful treatment in both groups required few maintenance care visits for simple denture base adjustments and/or clip replacements to correct their problem. Patients with treatment failures in both groups required excessive maintenance care, those in the CD group needed more denture base adjustments or relines, and those in the IOD group required frequent clip replacements and denture repairs.

It is apparent that even with mandibular overdentures, one of four patients experienced problems. However, the higher success rate and higher percentages of patients with improved chewing comfort and overall satisfaction with the IOD treatment indicate that it may be considered for selected patients experiencing chronic irritation and/or chewing discomfort with well-fitting

dentures. It might be possible to convert the existing clinically acceptable mandibular denture to an implant-supported overdenture. The inconvenience and added cost of clip replacements and repairs may be justified to achieve reduced tissue trauma and less chewing discomfort. The absence of any undue complications indicate that implants can be successfully used to support dentures in diabetic patients with even low to moderate levels of metabolic control.

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