CLINICAL TRIALS

Do Implant Overdentures Improve Dietary Intake? A Randomized Clinical Trial

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Abstract: *People wearing mandibular two-implant overdentures (IOD) chew food with less difficulty than those wearing conventional complete dentures (CD). However, there is still controversy over whether or not this results in better dietary intake. In this randomized clinical trials (RCT), the amounts of total dietary fiber (TDF), macronutrients, 9 micronutrients, and energy in diets consumed by persons with IOD and CD were compared. Male and female edentate patients ≥ 65 yrs (n = 255) were randomly divided into 2 groups and assigned to receive a maxillary CD and either a mandibular IOD or a CD. One year following prosthesis delivery, 217 participants (CD = 114, IOD = 103) reported the food and quantities they consumed to a registered dietician through a standard 24-hour dietary recall method. The mean and median values of TDF, macro- and micronutrients, and energy consumed by both groups were calculated and compared analytically. No significant between-group differences were found (ps > .05). Despite quality-of-life benefits from IODs, this adequately powered study reveals no evidence of nutritional advantages for independently living medically healthy edentate elders wearing two-implant mandibular over-dentures over those wearing conventional complete dentures in their dietary intake at one year following prosthesis delivery (International Clinical Trials ISRCTN24273915).*

Key Words: nutrition/nutritional sciences, dental implant(s), edentulous/edentulism, geriatric dentistry, prostheses, removable prosthodontics.

Introduction

A large percentage of our aging population is edentulous (Morais *et al.*, 2003; MacEntee, 2007). Studies have shown that edentate people have poorer nutrition than those with teeth (Sahyoun *et al.,* 2003), as well as being more vulnerable to disease (Lowe *et al.*, 2003). Furthermore, findings from several studies suggest that the number of teeth is a significant, independent risk indicator for mortality and that use of adequate dentures may reduce this risk (Abnet *et al.,* 2005; Padilha *et al.*, 2008). Thus, the importance of a mandibular two-implant overdenture (IOD) cannot be overemphasized in light of the scientific evidence supporting its use as a first-choice standard of care for elderly edentate individuals (Feine *et al.*, 2002; Timmerman *et al.*, 2004; Thomason *et al.,* 2009). A panel of prosthodontic experts from US dental faculties supported treatment with IODs over conventional dentures (CDs) (Das *et al.*, 2012), indicating their agreement with the McGill (Feine *et al.*, 2002) and York Consensus Statements (Thomason *et al.*, 2009), which were based on research demonstrating the superiority of mandibular IODs over CDs for many variables, including oral health–related quality of life (Awad *et al.*, 2000; Jofre *et al.*, 2013), patient satisfaction (Thomason *et al.,* 2003; Heydecke *et al.*, 2008), food avoidance (Gjengedal *et al.*, 2012), chewing ability (de Oliveira and Frigerio, 2004), and food preparation (Awad *et al.*, 2012). Although there is a long list of scientific reports and randomized clinical trials (RCT) on the advantages of IODs over CDs, few studies have investigated the effects of IODs on dietary intake. Those had limitations, such as the use of small sample sizes (Morais *et al.*, 2003; de Oliveira and Frigerio, 2004; Muller *et al.*, 2008; Gjengedal *et al.*, 2012; Moynihan *et al.*, 2012) or having been conducted in individuals with diabetes (Hamada *et al.,* 2001). Thus, it is unknown if edentate individuals wearing mandibular IODs gain better nutrition through diet than

those wearing CDs. Moreover, a look at the possible dietary differences between mandibular IODs and CDs becomes more essential in light of the increase in the elderly population, longer life expectancy, demand for better quality of life for the elderly, and evidence showing a relationship between an increased intake of some macro- and micronutrients and a reduced risk of some illnesses, such as cardiovascular disease, rheumatoid arthritis, pulmonary disease, and certain types of cancer (Hutton *et al.*, 2002; Denny *et al.*, 2003; Lowe *et al.*, 2003; Abnet *et al.*, 2005).

The main objective of this RCT was to assess the effects of mandibular IODs on the nutritional status of edentate elders. The primary hypothesis was that, at 6 and 12 mos post-treatment, patients who received mandibular IODs would have no significant difference in their blood serum concentration of homocysteine [tHcy] than those who received CDs. This was reported in a previous publication (Awad *et al.*, 2012). The secondary objective, and the subject of this report was to determine whether those independently living edentate elders wearing new mandibular IODs and CDs consumed different daily amounts of micro- and macronutrients, as well as total dietary fiber (TDF) and energy. This outcome could indicate whether there was a difference between the groups in dietary intake that had not yet made a difference in blood nutrient values.

The following null hypotheses were tested:

(1) There is no difference between the groups in the intake of TDF one year post-treatment.
(2) There is no difference between the groups in the intake of energy (KCal) one year post-treatment.
(3) There is no difference between the groups in the intake of macronutrients (proteins, fats, and carbohydrates) one year post-treatment.
(4) There is no difference between the groups in the intake of 9 micronutrients (vitamins A, B6, B12, C, and D, as well as thiamin,

riboflavin, folate, and niacin) one year post-treatment.

Materials & Methods

Study Design

Data reported in this paper were gathered from a randomized, controlled, parallel trial comparing the effects of 2 types of mandibular prosthetic treatment (IOD and CD) in independently living edentulous elders in Montreal, Canada. The study was conducted at the MUHC-Royal Victoria Hospital (RVH) Clinical Investigation Unit (Montreal, Canada). The data used in this analysis were obtained at baseline and 12 mos following prosthesis delivery, by a standard 24-hour dietary recall method.

The study protocol and informed consent documents were approved by the institutional review board at McGill University. All study participants gave their written informed consent. Participants were financially compensated for their transportation and parking costs.

Sample Size Estimation

The sample size estimation was carried out to maintain adequate power to assess the primary and secondary outcomes, including those described in this report (Awad *et al.,* 2012). A total of 104 individuals *per* group would be required to ensure a power of 95%, with a two-sided test at a .05 level of significance for the primary outcome. We targeted our sample size for a somewhat higher traditional power than usual, to enhance power for secondary outcomes. In terms of secondary outcomes, this sample size provides 80% power with a type I error of .05 on all parameters, with a two-sided test. We also anticipated 18% loss to follow-up. Accordingly, we adjusted our targeted baseline sample size to 127 *per* group.

Recruitment

Recruitment and treatment allocation steps were described in a previous publication (Awad *et al.,* 2012). In general, potential participants were recruited through French and English advertisements in local papers. Once eligibility and consent were confirmed,

the research assistant obtained treatment assignment from an independent center using a computer-generated permuted block scheme. Various block sizes were used to preserve allocation concealment and reduce potential selection bias.

Participants

The sample population consisted of men and women (≥ 65 yrs) who had been edentate for a minimum of 5 yrs. Other inclusion criteria included adequate understanding of written and spoken English or French, as well as willingness and ability to understand the protocol and to give informed consent. Potential participants completed a medical history with questions about oral condition, general health, and use of medications. They also completed questionnaires on oral function to assess their ability to understand and use the measures to be employed in the study. They were then examined by two calibrated clinicians. Patients were excluded if they had insufficient bone for placement of 2 implants in the anterior mandible, acute or chronic symptoms of TMD, systemic or neurologic disease that contraindicated implant surgery, any neoplasia diagnosed < 5 yrs previously, a body mass index (BMI) < 20 or > 32 kg/m², and/or current usage of dietary supplements, antineoplastic medication, phenytoin, or corticosteroids. Since memory must be intact to provide accurate 24-hour dietary recall information, potential participants were excluded if they scored 24 or less on the Mini-Mental State Evaluation.

The Intervention

Maxilla

Both the treatment and control groups received a maxillary CD fabricated in a standard manner.

Mandible: Treatment Group

Participants randomized to the experimental group received a mandibular IOD on 2 implants with ball attachments (ITI, Straumann-048.242/243, Waldenburg, Switzerland) in the canine region of the anterior mandible. After a three-month healing period, the participants received new mandibular IODs.

Mandible: Control Group

Participants received complete CDs.

Dietary Assessments

Three 24-hour dietary recalls were collected through telephone interviews at baseline and 12 mos after prosthesis delivery. Trained personnel used a structured template to collect information on dietary intake during the previous 24 hrs (Gray-Donald *et al.*, 1995).

The interviews were conducted on 3 separate occasions, twice on weekdays and once on a weekend. Dietary intake values were used to calculate intake of TDF, macronutrients (proteins, fat, and carbohydrates), 9 of the micronutrients (vitamins A, B6, B12, C, and D, thiamin, riboflavin, folate, and niacin), and energy. Individual values were used to calculate mean daily intakes, as well as mean and median intakes of both groups. Participants were trained at baseline on food serving portions and how to calculate their daily food intake. To standardize computations and reduce individual computational errors, we analyzed the collected data using nutrient values from the Canadian Nutrient File with the help of specialized software from the McGill University Faculty of Dietetics and Human Nutrition (CANDAT, Godin London Inc., London, ON, Canada).

Statistical Analysis

Because of the skewed nature of the data, medians were estimated as the measure of central tendency. Wilcoxon rank sum tests were used for bivariate comparisons of the various independent variables, according to treatment received (JMP statistical software version 10; SAS Institute Inc., Cary, NC, USA). Quantile regression models were used to estimate the conditional median of the dependent variables (post-treatment values of the micronutrients) between treatments, adjusted for baseline values and gender, since they require no distribution assumption; these models are more robust to outlying observations of the predictor variables (Stata SE software version 10.1; StataCorp, College Station, TX, USA). Any *p* values ≤ .05 were considered statistically significant.

Figure.

Flow chart of participants' enrolment in the study (up to one year post-treatment).
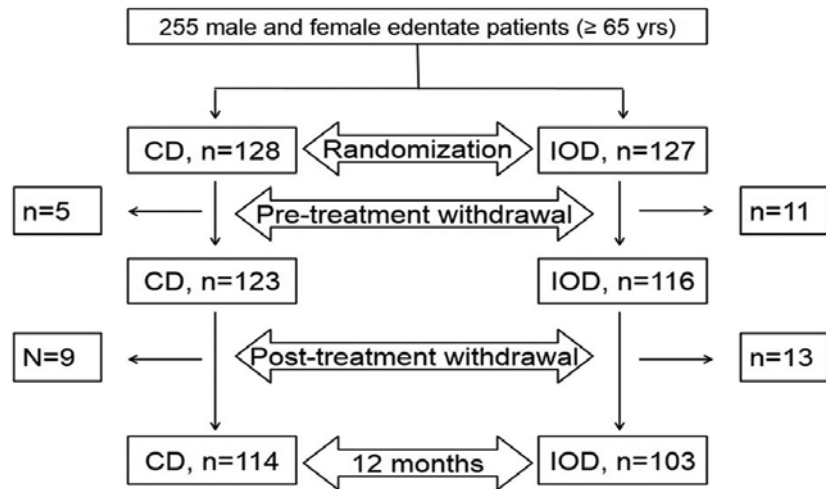
Results

Two hundred fifty-five (255) participants were enrolled and randomly assigned to receive a maxillary CD and either a mandibular CD (n = 128) or an IOD (n = 127). A total of 207 participants (n = 114 CD, n = 103 IOD) provided follow-up data at one year post-treatment and were included in this analysis (Fig.). Reasons for loss to follow-up included illness, fear of surgery, and/or lack of interest. At baseline, the groups were similar in age (CD mean, 69.7 ± SD 4.6; IOD mean, 70.5 ± SD 5.0) and gender distribution [CD, men N = 57 (44.5%), women N = 71 (55.5%); IOD, men N = 57 (44.9%), women N = 70 (55.1%); *p* = .95].

The analysis failed to reject any of 4 null hypotheses (*p* > .36; Table 1), even with gender stratification (*p* > .17; Table 2). No significant inter-group difference was found in intake of TDF (*p* > .36; Table 1), energy (*p* > .58; Table 2), or macronutrients, *i.e.,* proteins, fats, or carbohydrates (*p* > .41; Table 2) at baseline and one year post-treatment. There were also no significant differences between the two groups for any of the 9 examined micronutrients (vitamins A, B6, B12, C, D, and thiamin, riboflavin, folate, and niacin) (*p* > .13; Table 1).

A non-significant correlation was observed for the association between all dependent variables (TDF, energy, macro- and micronutrients) and treatment, adjusted for baseline values and gender (Table 3). However, a tendency for higher median dietary intake values of energy, 3 macronutrients (proteins, fats, and carbohydrates), vitamin D, thiamin, vitamin B6, vitamin B12, and folate among CD wearers was observed. Similarly, there was a tendency for higher median dietary intake values of TDF, vitamin A, vitamin C, riboflavin, and niacin among individuals with IODs. Based on this regression model, women had significantly higher median dietary intakes of thiamin and riboflavin and significantly lower intakes of energy and folate after adjustment for treatment received and baseline values. Moreover, baseline median intakes of energy, protein, thiamin, and riboflavin were significantly higher and baseline values for folate were significantly lower, after adjustment for treatment received and gender.

Discussion

To our knowledge, this is the first RCT with a sample size adequate for the

Table 1.

Intergroup – Baseline and 12-month Average Means and Median Daily Intakes of TDF, Energy, Macronutrients, and 9 Micronutrients for IOD and CD Groups

Variables	Group	Baseline Results				12-month Results			
		Mean (STD)*	Median (Q1, Q3)†	95% CI‡	*p* value§	Mean (STD)*	Median (Q1, Q3)†	95% CI‡	*p* value§
Fiber (TDF) (g)	IOD	16.3 (7.7)	14.7 (11.6, 18.7)			15.9 (7.3)	14.5 (11.1, 19.0)		
	CD	15.7 (7.1)	14.9 (10.9, 19.0)	(-1.3, 1.8)	.81	16.8 (7.7)	15.4 (11.5, 19.9)	(-2.4, 1.0)	.36
Energy (KCal)	IOD	1,540.2 (541.7)	1,432.7 (1,150.7, 1,909.3)			1,474.4 (431.7)	1,469.7 (1,201.3, 1,633.0)		
	CD	1,557.4 (554.2)	1,478 (1,147.5, 1,877.4)	(-160.0, 114.0)	.72	1,505.7 (482.0)	1,403.0 (1,193.7, 1,741.1)	(-123.3, 108.7)	.96
Macronutrients									
PROT (g)	IOD	67.7 (22.3)	66.1 (50.4, 79.4)			64.7 (22.5)	61.8 (49.2, 77.6)		
	CD	67.1 (24.8)	62.8 (52.7, 79.0)	(-4.2, 7.5)	.55	65.0 (22.7)	61.4 (49.7, 78.1)	(-5.7, 5.2)	.94
FAT (g)	IOD	56.8 (23.6)	51.6 (38.9, 70.1)			56.0 (20.0)	54.4 (41.1, 67.5)		
	CD	59.3 (27.4)	53.3 (41.4, 72.3)	(-8.0, 3.9)	.57	55.3 (19.5)	53.0 (41.8, 66.3)	(-4.2, 6.2)	.64
CARB (g)	IOD	189.2 (80.5)	166.7 (135.2, 235.0)			177.1 (59.6)	173.9 (133.6, 198.4)		
	CD	185.6 (69.2)	174.6 (136.3, 233.8)	(-20.4, 16.4)	.84	187.1 (83.5)	174.6 (141.4, 213.0)	(-18.1, 10.0)	.64
Micronutrients									
VIT A (µg)	IOD	675.8 (922.6)	533.3 (342.3, 733.3)			661.1 (672.7)	525.7 (385.7, 769.0)		
	CD	830.5 (1,016.6)	562.2 (371.3, 860.1)	(-118.3, 38.7)	.38	713.4 (717.3)	572.7 (357.9, 797.4)	(-96.7, 52.7)	.63
VIT D (µg)	IOD	4.7 (4.1)	3.1 (2.2, 6.1)			4.1 (3.6)	3.3 (2.0, 5.0)		
	CD	3.8 (3.2)	3.1 (1.9, 4.7)	(-0.1, 1.0)	.13	4.2 (4.9)	3.1 (1.8, 5.0)	(-0.3, 0.7)	.41
VIT C (mg)	IOD	108.5 (75.6)	90.5 (58.2, 141.2)			98.5 (71.7)	91.2 (47.9, 131.0)		
	CD	100.6 (64.8)	86.1 (53.9, 130.8)	(-10.6, 19.9)	.53	104.3 (65.3)	89.0 (61.0, 143.1)	(-22.8, 8.9)	.36
THIA (mg)	IOD	1.4 (0.7)	1.3 (0.9, 1.8)			1.5 (0.7)	1.3 (1.0, 1.8)		
	CD	1.4 (0.5)	1.3 (1.1, 1.8)	(-0.2, 0.1)	.69	1.4 (0.6)	1.3 (1.1, 1.6)	(-0.1, 0.1)	.98
RIBO (mg)	IOD	2.0 (1.6)	1.7 (1.4, 2.2)			1.8 (0.6)	1.7 (1.4, 2.1)		
	CD	1.8 (0.7)	1.7 (1.4, 2.2)	(-0.1, 0.2)	.69	1.9 (1.7)	1.7 (1.4, 2.0)	(-0.1, 0.2)	.68
Niacin (NEs)	IOD	31.2 (10.5)	30.5 (24.1, 38.2)			30.8 (11.8)	28.5 (23.6, 36.8)		
	CD	31.4 (12.0)	28.3 (23.8, 37.6)	(-2.3, 3.1)	.76	30.2 (11.1)	28.6 (23.5, 35.3)	(-2.3, 2.8)	.85
VIT B6 (mg)	IOD	1.5 (0.6)	1.4 (1.1, 1.8)			1.6 (1.1)	1.4 (1.1, 1.7)		
	CD	1.5 (0.6)	1.4 (1.1, 1.8)	(-0.1, 0.2)	.53	1.5 (0.6)	1.4 (1.2, 1.7)	(-0.2, 0.1)	.47
VIT B12 (µg)	IOD	3.9 (2.9)	3.3 (2.3, 4.7)			4.4 (5.6)	2.8 (2.0, 4.1)		

(continued)

Table 1.
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Variables	Group	Baseline Results				12-month Results			
		Mean (STD)*	Median (Q1, Q3)†	95% CI‡	p value§	Mean (STD)*	Median (Q1, Q3)†	95% CI‡	p value§
	CD	5.4 (7.8)	2.8 (2.0, 5.1)	(-0.3, 0.6)	.44	3.8 (3.4)	3.1 (2.2, 4.3)	(-0.5, 0.3)	.66
DFE (Folate) (µg)	IOD	355.4 (148.5)	308.3 (262.0, 442.7)			362.9 (193.3)	340.0 (252.7, 419.0)		
	CD	349.5 (135.2)	326.7 (243.8, 433.1)	(-33.3, 36.0)	.88	340.4 (116.8)	315.2 (255.7, 413.7)	(-21.7, 42.3)	.56

* Mean (Standard Deviation).
† Median and quartiles (25th [Q1] and 75th [Q3]).
‡ 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair by the Wilcoxon method.
§ p values were obtained from the Wilcoxon rank-sum test.

Table 2.
Intergroup – 12-month Average Means and Median Daily Intakes of TDF, Energy, Macronutrients, and 9 Micronutrients after Stratification by Gender for IOD and CD Groups

Variables	Male Results				Female Results			
	CD Group	IOD Group			CD Group	IOD Group		
	Median (Q1, Q3)*	Median (Q1, Q3)*	95% CI†	p value‡	Median (Q1, Q3)*	Median (Q1, Q3)*	95% CI†	p value‡
Fiber (TDF) (g)	16.0 (12.5, 21.4)	16.1 (11.5, 21.1)	(-3.2, 2.1)	.63	14.7 (10.3, 19.7)	13.9 (10.3, 17.9)	(-2.9, 1.4)	.45
Energy (KCal)	1,452.3 (1,220.8, 1,987.7)	1,527.7 (1,339.0, 1,828.3)	(-152.0, 223.0)	.58	1,357.0 (1,105.8, 1,648.7)	1,335.7 (1,080.3, 1,581.6)	(-173.7, 104.3)	.61
Macronutrients								
PROT (g)	64.9 (53.1, 81.3)	66.6 (53.2, 89.9)	(-5.8, 11.8)	.57	57.5 (47.4, 74.9)	59.2 (45.4, 68.0)	(-8.9, 5.1)	.65
FAT (g)	58.2 (42.2, 74.4)	59.0 (47.8, 72.0)	(-7.3, 9.7)	.78	51.4 (39.5, 58.3)	50.4 (37.9, 63.2)	(-5.7, 7.2)	.79
CARB (g)	186.0 (152.0, 222.9)	188.3 (158.7, 226.0)	(-21.8, 26.4)	.82	166.7 (124.3, 188.9)	161.3 (125.0, 182.4)	(-25.6, 9.0)	.41
Micronutrients								
VIT A (µg)	606.0 (359.5, 875.7)	574.0 (388.7, 814.0)	(-131.5, 116.0)	.97	542.5 (357.5, 709.0)	434.2 (369.8, 704.5)	(-138.3, 52.3)	.42
VIT D (µg)	3.3 (2.0, 5.3)	4.0 (2.5, 5.8)	(-0.4, 1.5)	.27	2.8 (1.7, 4.8)	3.1 (1.9, 4.7)	(-0.6, 0.7)	.93
VIT C (mg)	83.9 (62.1, 137.6)	88.0 (42.0, 131.0)	(-26.0, 17.8)	.64	107.3 (59.0, 148.1)	93.1 (49.7, 134.0)	(-33.1, 12.6)	.37
THIA (mg)	1.4 (1.1, 1.7)	1.5 (1.1, 2.3)	(-0.1, 0.4)	.22	1.3 (1.1, 1.5)	1.1 (0.9, 1.6)	(-0.2, 0.1)	.32
RIBO (mg)	1.8 (1.5, 2.1)	1.9 (1.6, 2.3)	(-0.1, 0.3)	.17	1.5 (1.3, 2.0)	1.6 (1.4, 1.8)	(-0.2, 0.1)	.81
Niacin (NEs)	30.4 (24.7, 37.2)	31.0 (25.1, 41.4)	(-2.8, 5.1)	.61	27.2 (21.9, 33.8)	27.3 (20.5, 33.6)	(-3.6, 3.0)	.95
VIT B6 (mg)	1.4 (1.2, 1.8)	1.4 (1.1, 1.9)	(-0.2, 0.2)	.93	1.4 (1.1, 1.7)	1.3 (1.0, 1.6)	(-0.2, 0.1)	.30
VIT B12 (µg)	3.4 (2.3, 4.7)	3.5 (2.3, 5.3)	(-0.7, 0.7)	.94	2.7 (2.0, 3.9)	2.7 (1.8, 3.4)	(-0.7, 0.3)	.59
DFE (Folate) (µg)	337.3 (283.3, 471.7)	378.7 (290.7, 457.7)	(-38.3, 70.3)	.64	309.0 (242.3, 379.2)	316.7 (249.0, 396.6)	(-30.0, 44.3)	.71

* Median and quartiles (25th [Q1] and 75th [Q3]).
† 95% confidence interval for the median difference was obtained by non-parametric comparisons for each pair by the Wilcoxon method.
‡ p values were obtained from Wilcoxon rank-sum test.

Table 3.

Association between Nutrients and Treatment Adjusted for Baseline Values, Gender*

Variable	B†	95% CI
Total Dietary Fiber (TDF) (g)		
Implant	1.0	-0.57, 2.57
Female	-0.2	-1.83, 1.43
Baseline	0.4	0.29, 0.51
Energy (KCal)		
Implant	-46.2	-160.26, 67.8
Female	-132.4	-258.6, -6.2**
Baseline	0.11	0.01, 0.22**
PROT (g)		
Implant	-0.80	-9.0, 7.4
Female	-4.8	-13.6, 3.9
Baseline	0.21	0.01, 0.39**
FAT (g)		
Implant	-1.2	-7.0, 4.5
Female	-6.3	-12.4, -0.22
Baseline	0.08	-0.4, 0.2
CARB (g)		
Implant	-0.16	-11.2, 10.9
Female	-11.9	-24.1, 2.9
Baseline	0.11	0.02, 0.19
VIT A (µg)		
Implant	93.0	-27.3, 213.3
Female	-100.71	-221.3, 19.9
Baseline	0.03	-0.02, 0.08
VIT D (µg)		
Implant	-0.2	-0.85, 0.47
Female	-0.4	-1.07, 0.27
Baseline	0.2	-0.11, 0.3
VIT C (mg)		
Implant	10.67	-12.02, 33.4
Female	11.9	-10.7, 34.6
Baseline	0.3	0.14, 0.46
THIA (mg)		
Implant	-0.05	-0.22, 0.10
Female	-0.22	-0.41, -0.05**
Baseline	1.6	1.13, 2.06**
RIBO (mg)		
Implant	0.004	-0.03, 0.2
Female	1.0	0.30, 1.7**
Baseline	0.003	0.002, 0.07**
Niacin (NEs)		
Implant	0.22	-4.3, 3.92
Female	-2.22	-6.8, 2.3
Baseline	0.11	-0.09, 0.31
VIT B6 (mg)		
Implant	-0.001	-0.91, 0.92
Female	-0.006	-0.94, 0.96
Baseline	0.05	-0.24, 1.25

(continued)

Table 3.
(continued)

Variable	B†	95% CI
VIT B12 (µg)		
Implant	-0.06	-1.83, 0.62
Female	0.03	-1.52, 0.94
Baseline	0.05	-0.06, 0.15
DFE (Folate) (µg)		
Implant	-14.64	-50.6, 21.3
Female	-45.24	83.0, 7.5**
Baseline	0.23	0.10, 0.36**

* Analysis was based on quantile regression.
† Unstandardized regression coefficient.
** $p < .05$.

study of differences in dietary intake between IOD and CD wearers. The results demonstrate that, one year after delivery of new prostheses, dietary intake of medically healthy elders receiving mandibular two-implant overdentures is not statistically different from that of those treated with conventional complete dentures. The two groups had similar intakes of TDF, energy, macronutrients (proteins, fats, and carbohydrates), and 9 micronutrients.

Although our results support findings from previous studies (Sebring *et al.,* 1995; Hamada *et al.*, 2001; Morais *et al.*, 2003; Gjengedal *et al.*, 2012), several limitations of this type of nutritional comparison should be mentioned. The bias due to reporting error inherent in the 24-hour dietary recall method may be greater than the inter-group difference (Subar *et al.*, 1990). Moreover, a self-report of dietary intake could be biased by social desirability (Hebert *et al.*, 1995). However, given the relatively large sample size used in this study and based on the average value of 3 recalls, these 24-hour recall data are likely to be appropriate.

Furthermore, our results also raise a number of questions: First, why are the dietary intakes so similar in both groups, despite the fact that IOD wearers report superiority in their masticatory performance and ability to chew a greater variety foods (de Oliveira and Frigerio, 2004; Van Kampen *et al.*, 2004; Muller *et al.*, 2008)?

The fact that this study revealed similar dietary intake in both groups suggests that either the same foods were eaten, but pre-pared differently, or that different foods with similar nutritional profiles were consumed. We believe that the reported differences in the way in which patients in both groups prepared their foods (Awad *et al.*, 2012) helped to produce similar dietary intake effects, *e.g.*, a person who bites an apple will take in the same nutrients as someone who uses a knife to cut the apple into pieces or drinks pure apple juice. Furthermore, our study participants were medically healthy, independently living elders who demonstrated a good nutritional state at baseline. They also had above-average educational levels and incomes. Thus, they were likely health-conscious and capable of choosing and preparing foods appropriately to compensate for difficulties in chewing. Therefore, the chance of gaining nutritional benefit in this population may be limited.

Second, what are the possible causes of the few significant differences found by the regression model for gender, adjusted for treatment and baseline values, and for baseline values, adjusted for treatment received and gender? Those significant differences by gender are expected, because males and females do differ in nutrition and caloric intake (Baker and Wardle, 2003). Furthermore, significant differences between baseline and post-treatment values are also expected because it is possible that, regardless of treatment received, both groups modified their diets from baseline because of receiving new prostheses.

Third, what are the implications of these similarities, and what could have been done to improve the chance of finding any potential differences? We believe that changing dietary habits, including the types of foods consumed, may be a multifactorial adaptation process that takes much longer than a year for a measurable effect (Schlettwein-Gsell, 1992). Additionally, dietary counseling can improve fruit and vegetable intake in an edentulous individual (Bradbury *et al.*, 2006). Our study participants were not given specific individual dietary counseling before or during the study and, consequently, could have needed more time to adapt their eating habits to the new treatment. Thus, an RCT in which participants are followed for a longer period of time and in which they are given specific individual dietary counseling might maximize the possibility of dietary improvement (Moynihan *et al.*, 2012).

In conclusion, although there is much evidence supporting the adoption of two-implant mandibular overdenture (IOD) treatment as the standard of care for edentate patients, this evidence does not include an improvement in dietary intake at one year for medically healthy independent edentate elders when given no specific dietary counseling.

Acknowledgments

References

Abnet CC, Qiao YL, Dawsey SM, Dong ZW, Taylor PR, Mark SD (2005). Tooth loss is associated with increased risk of total death and death from upper gastrointestinal cancer, heart disease, and stroke in a Chinese population-based cohort. *Int J Epidemiol* 34:467-474.

Awad MA, Locker D, Korner-Bitensky N, Feine J (2000). Measuring the effect of intra-oral implant rehabilitation on health-related quality of life in a randomized controlled clinical trial. *J Dent Res* 79:1659-1663.

Awad MA, Morais JA, Wollin S, Khalil A, Gray-Donald K, Feine JS (2012). Implant overdentures and nutrition: a randomized controlled trial. *J Dent Res* 91:39-46.

Baker AH, Wardle J (2003). Sex differences in fruit and vegetable intake in older adults. *Appetite* 40:269-275.

Bradbury J, Thomason J, Jepson N, Walls A, Allen P, Moynihan P (2006). Nutrition counseling increases fruit and vegetable intake in the edentulous. *J Dent Res* 85:463-468.

Das KP, Jahangiri L, Katz RV (2012). The first-choice standard of care for an edentulous mandible: a Delphi method survey of academic prosthodontists in the United States. *J Am Dent Assoc* 143:881-889.

de Oliveira TR, Frigerio ML (2004). Association between nutrition and the prosthetic condition in edentulous elderly. *Gerodontology* 21:205-208.

Denny SI, Thompson RL, Margetts BM (2003). Dietary factors in the pathogenesis of asthma and chronic obstructive pulmonary disease. *Curr Allergy Asthma Rep* 3:130-136.

Feine JS, Carlsson GE, Awad MA, Chehade A, Duncan WJ, Gizani S, *et al.* (2002). The McGill consensus statement on overdentures. Mandibular two-implant overdentures as first choice standard of care for edentulous patients. Montreal, Quebec, May 24-25, 2002. *Int J Oral Maxillofac Implants* 17:601-602.

Gjengedal H, Dahl L, Lavik A, Trovik TA, Berg E, Boe OE, *et al.* (2012). Randomized clinical trial comparing dietary intake in patients with implant-retained overdentures and conventionally relined denture. *Int J Prosthodont* 25:340-347.

Gray-Donald K, Payette H, Boutier V (1995). Randomized clinical trial of nutritional supplementation shows little effect on functional status among free-living frail elderly. *J Nutr* 125:2965-2971.

Hamada MO, Garrett NR, Roumanas ED, Kapur KK, Freymiller E, Han T, *et al.* (2001). A randomized clinical trial comparing the efficacy of mandibular implant-supported overdentures and conventional dentures in diabetic patients. Part IV: Comparisons of dietary intake. *J Prosthet Dent* 85:53-60.

Hebert JR, Clemow L, Pbert L, Ockene IS, Ockene JK (1995). Social desirability bias in dietary self-report may compromise the validity of dietary intake measures. *Int J Epidemiol* 24:389-398.

Heydecke G, Thomason JM, Awad MA, Lund JP, Feine JS (2008). Do mandibular implant overdentures and conventional complete dentures meet the expectations of edentulous patients? *Quintessence Int* 39:803-809.

Hutton B, Feine J, Morais J (2002). Is there an association between edentulism and nutritional state? *J Can Dent Assoc* 68:182-187.

Jofre J, Castiglioni X, Lobos CA (2013). Influence of minimally invasive implant-retained overdenture on patients' quality of life: a randomized clinical trial. *Clin Oral Implants Res* 24:1173-1177.

Lowe G, Woodward M, Rumley A, Morrison C, Tunstall-Pedoe H, Stephen K (2003). Total tooth loss and prevalent cardiovascular disease in men and women: possible roles of citrus fruit consumption, vitamin C, and inflammatory and thrombotic variables. *J Clin Epidemiol* 56:694-700.

MacEntee MI (2007). The prevalence of edentulism and diseases related to dentures—a literature review. *J Oral Rehabil* 12:195-207.

Morais J, Heydecke G, Pawliuk J, Lund J, Feine JS (2003). The effects of mandibular two-implant overdentures on nutrition in elderly edentulous individuals. *J Dent Res* 82:53-58.

Moynihan PJ, Elfeky A, Ellis JS, Seal CJ, Hyland RM, Thomason JM (2012). Do implant-supported dentures facilitate efficacy of eating more healthily? *J Dent* 40:843-850.

Muller K, Morais J, Feine J (2008). Nutritional and anthropometric analysis of edentulous patients wearing implant overdentures or conventional dentures. *Braz Dent J* 19:145-150.

Padilha DM, Hilgert JB, Hugo FN, Bós AJ, Ferrucci L (2008). Number of teeth and mortality risk in the Baltimore Longitudinal Study of Aging. *J Gerontol A Biol Sci Med Sci* 63:739-744.

Sahyoun NR, Lin CL, Krall E (2003). Nutritional status of the older adult is associated with dentition status. *J Am Diet Assoc* 103:61-66.

Schlettwein-Gsell D (1992). Nutrition and the quality of life: a measure for the outcome of nutritional intervention. *Am J Clin Nutr* 55(6 Suppl):1263S-1266S.

Sebring NG, Guckes AD, Li SH, McCarthy GR (1995). Nutritional adequacy of reported intake of edentulous subjects treated with new conventional or implant-supported mandibular dentures. *J Prosthet Dent* 74:358-363.

Subar AF, Harlan LC, Mattson ME (1990). Food and nutrient intake differences between smokers and non-smokers in the US. *Am J Public Health* 80:1323-1329.

Thomason JM, Lund JP, Chehade A, Feine JS (2003). Patient satisfaction with mandibular implant overdentures and conventional dentures 6 months after delivery. *Int J Prosthodont* 16:467-473.

Thomason JM, Feine J, Exley C, Moynihan P, Müller F, Naert I, *et al.* (2009). Mandibular two implant-supported overdentures as the first choice standard of care for edentulous patients—the York Consensus Statement. *Br Dent J* 207:185-186.

Timmerman R, Stoker G, Wismeijer D, Oosterveld P, Vermeeren J, Van Waas M (2004). An eight-year follow-up to a randomized clinical trial of participant satisfaction with three types of mandibular implant-retained overdentures. *J Dent Res* 83:630-633.

Van Kampen F, Van Der Bilt A, Cune M, Fontijn-Tekamp F, Bosman F (2004). Masticatory function with implant-supported overdentures. *J Dent Res* 83:708-711.