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ABSTRACT

It is unclear whether mandibular implant overdentures improve the nutritional state of edentulous patients better than conventional dentures. In a randomized clinical trial, we tested for post-treatment differences in nutritional status between patients with mandibular two-implant retained overdentures and those with conventional complete dentures. Edentulous subjects (ages 65-75 yrs) received two-implant mandibular overdentures (IOD, $n = 30$) or conventional dentures (CD, $n = 30$). Measures of nutritional state were gathered before and 6 mos after treatment. Significant improvements in anthropometric parameters were detected in the IOD but not in the CD group, for percent body fat ($p = 0.011$) and skin-fold thickness at the biceps, subscapularis, and abdomen ($p < 0.05$), with significant decreases in waist circumference ($p < 0.0001$) and waist-hip ratio ($p = 0.001$). Significant increases were seen in concentrations of serum albumin ($p = 0.015$), hemoglobin ($p = 0.01$), and B12 ($p = 0.01$). No significant between-group differences were found. These results suggest that low-cost IOD treatment may improve the nutritional state of edentulous people.

KEY WORDS: nutrition, elderly, mandible, edentulous, dental prosthesis, dental implants.

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INTRODUCTION

Millions of people throughout the world have lost all of their teeth, and prevalence increases with age. In the United States, prevalence of edentulism in seniors (aged 65 yrs and over) ranges from 13.9% in Hawaii and 16.2% in California to 44.0% in Kentucky and 47.9% in West Virginia (US Department of Health and Human Services, 2000). In Europe, the prevalence of edentulism ranges from 12.8% in Italy to at least 60% in Denmark, the Netherlands (65.4%), and Iceland (69.6%; Bourgeois *et al.*, 1998).

The elderly edentulous avoid many types of foods, particularly raw vegetables and other hard and tough foods, because they cannot chew these with conventional dentures (Hartsook, 1974; Wayler and Chauncey, 1983; Chauncey *et al.*, 1984). As a result, such individuals consume significantly less protein and other key nutrients—including fiber, calcium, non-heme iron, and some vitamins—than do individuals with teeth (Sheiham *et al.*, 2001). This may explain why elderly institutionalized Japanese with no teeth have poorer general health and higher mortality rates than those with teeth (Shimazaki *et al.*, 2001).

Several studies have shown that the ability of edentulous patients to chew most foods improves significantly when the mandibular denture is fully or partly supported by endosseous implants (Feine *et al.*, 1994; Geertman *et al.*, 1999). We have recently shown that a simple overdenture with ball attachments on 2 implants in the anterior mandible provides significantly greater satisfaction, masticatory function, and oral-health-related quality of life (OHRQoL) than new conventional dentures (Awad *et al.*, 2000). In a second randomized clinical trial (RCT) (seniors aged 65-75 yrs), the group with overdentures (IOD Group) had a greater ability to chew tough meat and raw fruits and vegetables than the conventional denture group (CD Group; Awad *et al.*, in press). In this paper, we report the results of anthropometric and nutritional analyses that were carried out during the trial. We tested the hypothesis that there is no difference in nutritional status between patients with mandibular two-implant retained overdentures and those with conventional dentures at 6 mos post-treatment.

MATERIALS & METHODS

Sixty older independently living male and female adults (aged 65-75 yrs) were enrolled in this RCT, which was approved by the McGill University Institutional Review Board. The subjects were recruited from a pool of respondents to newspaper advertisements. Inclusion criteria included a history of edentulism for at least 5 yrs. For further inclusion and exclusion criteria, see Table 1. Informed written consent was obtained from all subjects. A sample size of 26 subjects *per* group had been calculated according to standard statistical criteria ($\alpha = 0.05$, $\beta = 0.20$) for the primary outcome of the study, general satisfaction measured on

Table 1. Inclusion and Exclusion Criteria for the Study Subjects

Inclusion Criteria	Exclusion Criteria
• Males and females	• Insufficient bone to place 2 implants in the anterior mandible
• Age 65-75 years	• Acute or chronic symptoms of temporomandibular disorders
• Complete edentulism for ≥ 5 years	• Systemic or neurologic disease that contraindicates implant surgery
• Patient wants replacement of existing complete denture	• Other health conditions: alcoholism, smoking of ≥ 1 pack of cigarettes/day, obesity
• Ability to understand and respond to the scales used in the study	• Psychologic or psychiatric conditions that could influence a subject's reaction to treatment
• Willingness to accept and give informed consent	

visual analog scales. Subjects were randomly assigned to each of the 2 treatments in blocks of 10.

Subjects received either mandibular overdentures ($n = 30$) retained by ball attachments on 2 transmucosal implants (ITI

arrive in a fasting state at the Clinical Investigation Unit (CIU) of the Royal Victoria Hospital. Data were gathered by a research dietitian and a trained nurse, who were blind to treatment assignment.

On a digital scale (ScaleTronix 5002, White Plains, NY, US),

we measured, to the nearest 100 g, patients' body weight after voiding and with patients wearing light clothing and without shoes. Height was measured by means of a stadiometer; waist and hip circumferences were measured with a non-elastic tape. From height and weight, the Body Mass Index was calculated. A Lange caliper (Beta Technology, Inc., Santa Cruz, NM, US) was used for skin-fold thickness (SFT) measurements (Lohman *et al.*, 1988), which were repeated at least twice on the dominant side of the body in the biceps, triceps, and subscapular and supra-iliac areas. Only the 2 closest measurements within 1 mm were averaged. The sum of the skin-fold thickness measurements from the 4 areas was used to estimate % body fat (Durnin and Womersley, 1974). Lean Body Mass (LBM) was calculated from % body fat and weight; the results were compared with those from a bio-electrical impedance analysis (BIA; BIA-101A, RJL Systems, Detroit, MI, US) (Lukaski *et al.*, 1985; Roubenoff *et al.*, 1997). Handgrip strength was recorded 3x with a Jamar dynamometer (Jamar-Sammons Preston, Bolingbroke, GA, USA); the

Table 2. Anthropometric Data, Blood Nutrient Concentrations, and Dietary Assessment

	Conventional				Implant			
	Post-treatment Mean	Mean Difference	95%CI Lower Upper		Post-treatment Mean	Mean Difference	95% CI Lower Upper	
Patient characteristics								
Age	70.1	0.48	0.23	0.70	69.6	0.50	0.02	0.90
Weight (kg)	72.5	0.92	-0.24	2.08	77.7	-0.40	-1.32	0.52
Height (cm)	162.1	-0.01	-0.24	0.22	165.4	-0.17	-0.45	0.11
Anthropometric data								
BMI (kg/m ²)	27.5	0.37	-0.07	0.81	28.3	-0.04	-0.38	0.30
LBM (kg)	45.4	-0.30	-1.06	0.46	47.5	-0.97^a	-1.58	-0.36
% Fat (SFT)	36.6	0.33	-0.84	1.49	35.7	1.10	0.38	1.82
% Fat (BIA)	37.1	1.30	0.03	2.57	38.1	1.10	0.27	1.93
Biceps SFT (mm)	13.0	1.81	0.74	2.87	12.5	1.36	0.202	.52
Triceps SFT (mm)	23.5	-0.42	-2.50	1.66	22.3	0.23	-1.23	1.69
Subscap. SFT (mm)	21.9	0.48	-0.90	1.85	21.2	1.82	0.42	3.23
Supra-alv. SFT (mm)	23.1	0.56	-0.98	2.09	22.7	1.40	.43	3.22
Abdom. SFT (mm)	29.4	1.30	-0.73	3.32	32.1	3.28	1.10	5.45
Waist circumference (cm)	92.7	-0.59	-1.93	0.75	93.2	-2.97	-4.44	-1.50
Hip circumference (cm)	103.8	-0.01	-1.04	1.02	106.2	-0.42	-1.34	0.49
Waist/hip ratio	0.9	0.00	-0.02	0.01	0.9	-0.02	-0.04	-0.01
Handgrip strength (kg)	27.3	-0.26	-1.33	0.81	28.9	-0.01	-1.05	1.02
Blood parameters								
RBC ($\times 10^{12}$)	4.6	-0.01	-0.09	0.06	4.7	0.10	-0.21	0.41
Hgb (g/L)	141.9	2.33	-0.16	4.83	144.4	3.21	0.85	5.58
Total lymph ($\times 10^9$)	1.6	0.04	-0.07	0.15	1.6	0.08	-0.06	0.22
Albumin (g/L)	42.9	0.85	-0.27	1.97	43.8	1.14	0.24	2.03
Pre-albumin (g/L)	0.3	-0.01	-0.02	0.00	0.2	-0.01	-0.03	0.01
Carotene ($\mu\text{mol/L}$)	2.8	-0.01	-0.29	0.27	3.1	0.38	-0.04	0.79
B12 (pmol/L)	291.8	22.07	-6.89	51.04	269.3	27.62	7.30	47.94
Ser. folate (nmol/L)	35.2	1.44	-3.21	6.10	33.5	1.34	-1.61	4.30
RBC folate (nmol/L)	888.1	-49.85	-181.20	81.50	829.0	37.83	-101.65	177.31
Serum Fe ($\mu\text{mol/L}$)	16.8	-0.97	-3.01	1.06	18.4	-0.83	-2.99	1.33

^a Significant within-group differences are in bold (paired *t* test, $p \leq 0.05$). No significant between-group differences were found.

maximum value was used in the analysis. Forty-mL venous blood samples were drawn for blood-cell-counting and measurements of the concentrations of several nutritional parameters and nutrients, including albumin, pre-albumin, carotene, plasma cobalamin (B12), serum and erythrocyte folate, and serum Fe. Analyses of the nutrients from the food diaries were conducted with the use of Genesis R&D software (V 5.09, ESHA Research, Salem, OR, USA).

Additional secondary outcomes were patients' assessments of gastrointestinal symptoms, including ratings of heartburn, difficulty swallowing, digestive problems, use of laxatives, difficulty chewing different types of meats, vegetables, and fruits (for a complete list, see Appendix Table A2, www.dentalresearch.org), and self-reported measures of dietary habits. For these items, the severity and frequency of impact were scored on five-point category scales.

For parametric data, between-group comparisons were made with independent *t* tests; univariate ANOVA was used for variables that required adjustment for gender (weight, height, LBM, SFT). For within-group data, paired *t* tests were performed. For categorical data, we used Mann-Whitney U tests to test between-group differences, and Wilcoxon signed-rank tests for within-group comparisons.

RESULTS

Sixty patients were initially randomized into the study. Fifty-six patients attended the six-month follow-up appointment. Four female subjects did not attend the six-month session because of general dissatisfaction (n = 1), general health problems (n = 1), or because they could not be found (n = 2; see Fig.).

No significant between-group differences were found for any of the measurements at baseline.

Anthropometric Data and Blood Nutrients

Significant increases were detected at 6 mos in the IOD group for percent body fat (p = 0.011) and skin-fold thickness at the biceps (p = 0.023), subscapularis (p = 0.013), and abdomen (p = 0.005), with significant decreases in waist circumference (p < 0.0001) and waist-hip ratio (p = 0.001). Increases in % body fat based on SFT measurements (p = 0.003) and BIA (p = 0.011) and a decrease in LBM (p = 0.003) were also significant. In the conventional group, significant increases were found only for % body fat according to the BIA (p = 0.045) method and biceps SFT (p = 0.002).

Table 3. Problems with Chewing, Biting, and Swallowing (bold-face fields indicate significance)

	Median ^a				p		Post-treatment (between groups ^e)
	Conventional		Implant		Within-group ^d (pre-/post-treatment)		
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Conventional	Implant	
Food choice limited ^b	2.0	2.0	2.0	1.0	0.206	0.009	0.041
Difficulty biting whole apple ^c	3.0	4.0	1.5	3.0	0.227	0.021	1.000
Difficulty biting pieces of apple ^b	1.0	1.0	1.0	1.0	0.341	0.018	0.142
Difficulty biting pieces of carrot ^b	3.0	3.0	3.5	1.0	0.280	0.166	0.040
Difficulty chewing with dentures ^b	4.0	2.0	3.0	2.0	0.013	0.000	0.347
Difficulty chewing pieces of beef ^c	5.0	5.0	4.0	5.0	0.171	0.001	0.304
Difficulty chewing raw vegetables ^c	3.0	3.0	3.0	5.0	0.051	0.003	0.109
Difficulty chewing whole fruit ^c	3.0	4.0	3.0	4.5	0.049	0.001	0.047
Difficulty chewing pieces of fruit ^c	4.0	5.0	4.0	5.0	0.034	0.001	0.006
Difficulty chewing fruit with peel ^c	4.0	4.0	4.0	4.5	0.022	0.014	0.234
Difficulty chewing bread with crust ^c	5.0	4.0	4.0	5.0	0.066	0.018	0.587
Difficulty chewing nuts ^c	4.0	5.0	3.0	5.0	0.089	0.004	0.105
Difficulty chewing pieces of chicken ^b	4.0	4.0	3.0	3.0	0.197	0.847	0.009
Difficulty swallowing ^b	5.0	5.0	5.0	5.0	1.000	0.157	0.057
Drink to ease swallowing ^b	2.0	2.0	2.0	1.0	0.514	0.008	0.068
Add sauce to ease swallowing ^b	1.0	1.0	2.0	1.0	0.156	0.009	0.523
Frequency of constipation ^c	5.0	5.0	4.0	5.0	0.629	0.071	0.364

- ^a Minimum score = 1, maximum = 5.
- ^b Lower scores represent improvement.
- ^c Higher scores represent improvement.
- ^d Wilcoxon signed-ranks test, p ≤ 0.05.
- ^e Mann-Whitney U Test, p ≤ 0.05.

For IOD subjects, significant increases were also seen in the concentrations of serum albumin (p = 0.015), hemoglobin (p = 0.01), and serum B12 (p = 0.01), with a tendency for increases in carotene (p = 0.072; see Table 2). Within-group differences for the remaining parameters were not significant.

No significant between-group differences were found.

Dietary Habits

Both groups showed significant improvement 6 mos after treatment in their responses to 4 questions regarding difficulty in chewing with dentures, and chewing pieces of fruit and fruit with peel (Table 3). Scores of the IOD group were significantly

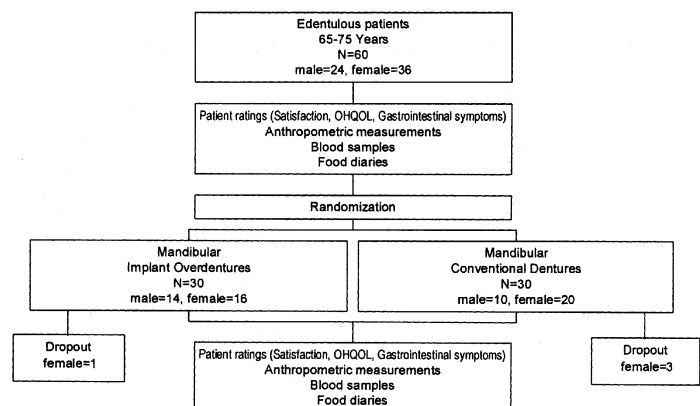


Figure. Trial profile. Participant flow and follow-up.

improved for 9 other questions: They were less limited in their choice of food ($p = 0.009$), and perceived less need to drink in order to swallow ($p = 0.008$). There was a tendency toward significance for having less constipation ($p = 0.07$). IOD subjects also reported significantly less difficulty chewing pieces of meat ($p = 0.001$) and whole, hard vegetables and fruits ($p < 0.05$; Table 3).

Between the two groups, significant differences in responses to 5 questions were found in favor of the implant group, whose members reported less difficulty chewing whole ($p = 0.047$) and cut-up fruit ($p = 0.006$) and pieces of carrot ($p = 0.040$) and chicken ($p = 0.009$). Implant subjects also reported less difficulty swallowing, for which there was a tendency toward significance ($p = 0.057$; Table 3). No significant differences were found for the remaining variables (see Appendix Table A1, www.dentalresearch.org).

The evaluation of nutrient intake by means of food diaries yielded no significant between-group differences. A significant post-treatment decrease of Vitamin E intake was found in the CD group ($p = 0.038$; see Appendix Table A1, www.dentalresearch.org).

DISCUSSION

Analysis of the data presented in this report of an RCT suggests that replacing a mandibular conventional denture by a very simple implant-retained mandibular prosthesis allows patients to modify their diet. This leads to improvements in selected important nutritional variables 6 mos later. Some of these improvements are greater than those which follow the provision of a new conventional mandibular denture.

Implant subjects had significant increases in the biceps, subscapular, and abdominal skin-fold thickness measurements, whereas the only significant increase in the CD group was in the biceps. Together with the significant reduction in waist circumference and waist/hip ratio, this indicates not only a higher caloric intake, but also a healthier distribution of adipose tissue in the implant group. A deep abdominal fat deposit around the visceral organs is detrimental, but elsewhere it becomes protective. Indeed, the best survival curves in the elderly are seen with BMI between 24 and 29 kg/m², which is much higher than those in younger populations (BMI 20-25 kg/m²; (Grabowski and Ellis, 2001). We observed a healthier distribution of fat deposition, since, despite increases in the % total body fat, the abdominal indices of fat, waist circumference, and waist/hip-ratio decreased.

Our findings confirm that hard and coarse foods such as fruits, vegetables, and meats, which are typically major sources of vitamins, minerals, proteins, and fiber, are difficult to chew with conventional dentures. Furthermore, the addition of liquid is sometimes required to aid swallowing. Depending on the degree of impairment, chewing difficulty may result in a shift in food selection patterns (Wayler and Chauncey, 1983). There is good evidence that people adapt to tooth loss by altering their dietary intake to compensate for the increased difficulty of eating certain foods, even if masticatory function is restored with conventional dentures (Wayler and Chauncey, 1983; Chauncey *et al.*, 1984; Fontijn-Tekamp *et al.*, 1996). In a non-randomized prospective study (Allen and McMillan, 2002), edentulous patients were provided with conventional and two-implant overdentures for the mandible. There was no change in the group receiving the conventional dentures. However, a

significant number of those who received the implant overdentures reported that they had increased their intake of cheese, raw carrot, raw apple, nuts, and bacon (Allen and McMillan, 2002). Our findings confirm that the provision of mandibular dentures supported by 2 implants increases food choice for individuals accustomed to wearing conventional dentures. They find it easier to consume hard, tough, and crisp foods, such as raw vegetables and fruits, as well as different types of meats.

Altered eating habits are reflected in the results from the comparisons of blood parameters. Serum albumin concentration increased significantly in the implant group, by 1.7 g/L, a difference similar to that attained when dietary supplements were given to an elderly population (de Jong *et al.*, 1999). In the absence of inflammation or significant trauma, this is a stable value that reflects long-term nutritional habits (Doweiko and Nopleggi, 1991). Serum albumin is recognized as an indicator of general good health and nutritional status. Lower serum albumin levels are associated with a higher prevalence of cancer, cardiovascular disease, and mortality (Phillips *et al.*, 1989). For example, the NHANES I epidemiologic follow-up study showed that low serum albumin values are associated with increased stroke risk (Gillum *et al.*, 1994), while another study conducted in three different elderly communities in the USA showed that serum albumin combined with physical disability predicts mortality (Corti *et al.*, 1994). Although the baseline and post-therapy levels of albumin are in the normal range, higher values have been associated with improved survival in the elderly (Klonoff-Cohen *et al.*, 1992). For example, people with a serum albumin concentration above 44 g/L had half the incidence of stroke, after adjustment for other risk variables, compared with those having levels below 42 g/L (Gillum *et al.*, 1994).

There is an increased prevalence of vitamin B12 or cobalamin deficiency with age in 15% of the elderly (Pennypacker *et al.*, 1992). B12 deficiency is associated with both hematological (*e.g.*, megaloblastic anemia, bone marrow suppression) and neurological diseases (*e.g.*, peripheral neuropathy; Stabler, 1995). Although vitamin B12 absorption mechanisms depend on many factors (stomach pH, intrinsic factor production, bowel bacteria), the recent Framingham Offspring Study showed that plasma vitamin B12 levels are associated with vitamin B12 intake (Tucker *et al.*, 2000). Dietary intake of vitamin B12 comes mainly from animal sources (milk, meat, and entrails) and, to a lesser extent, from fish.

The significant increase in serum B12 concentration in the IOD group, combined with the increases in albumin and hemoglobin (iron), may be linked to the decreased difficulty in chewing meat. There were no significant changes in the blood parameters of the conventional group, and between-group differences were not significant, probably because the sample size was too small.

However, the dietary changes were not reflected in the nutritional intake calculated from the food diaries. We found only one significant difference in the conventional group (reduced post-treatment Vitamin E intake), which may be an artifact. While few studies of the effects of implant prostheses on dietary intake are available, they presented similarly ambiguous results from food diary data. In a randomized clinical trial, Hamada *et al.* (2001) studied a diabetic male

population (n = 58, US veterans) aged 50+ yrs. The nutritional state of both groups deteriorated during the study. There was less deterioration in the implant group in food energy (-5.4% conventional dentures vs. -1.4% implant) and in many nutrients, but none of the differences was significant. Sandström and Lindquist (1987) used a four-day food diary with an even smaller sample of subjects (n = 23), who first wore conventional dentures, then received mandibular implant prostheses. There was no significant effect of treatment. Since the "hard" blood nutrient data in our study showed significant differences and the food diaries did not, this may indicate that the food diaries were insensitive, partly because of the small sample size.

In this trial, we tested multiple hypotheses. Adjustment for multiple testing has been an issue of debate. Several authors in the medical and dental field have argued that if results are interpreted with caution and in relationship to their plausibility, such adjustments may not be necessary (Perneger *et al.*, 1998; Stevenson *et al.*, 1999). Although one must bear in mind the increased likelihood of finding significance by chance (which is the reasoning behind Bonferroni adjustments), one should also consider carefully the plausibility of the findings. In our study, it is unlikely that the differences between the groups and between sampling periods arose by chance alone, since they were all in the predicted direction (IOD > CD; post-treatment > baseline).

These results suggest that providing edentulous patients with low-cost mandibular two-implant prostheses improves their dietary intake and nutritional state. However, these findings must be confirmed. A larger randomized clinical trial has begun, in which the sample size has been increased for adequate power for the nutritional outcomes.

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