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Dental Diet System™

A Behavior Modification Tool to Reduce Food Intake

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Abstract

Objective:

A behavioral recommendation for weight loss is reduction of size of bites of food. This "proof of concept" study tested the efficacy of a new patented behavior modification tool, the Dental Diet System™ (DDS™) for reducing food intake. This removable tool (fitted for an individual) is inserted into the upper palate of the mouth, reducing the size/space of the oral cavity, thereby potentially reducing bite size.

Research Methods and Procedures:

Thirty-two adults (18-65 yrs) with BMI between 27 and 40 were randomly assigned to the control or experimental conditions. Participants ate all meals, and stayed between meals, at a research center. Day 1 served as baseline for both groups. On Day 2, experimental participants utilized the DDS™ tool during each meal. Changes in subjective hunger and satiety were measured using Visual Analog Scales (VAS) before and after each meal.

Results:

Food intake difference scores were calculated for each participant (Day 2 minus Day 1). Analysis of co-variance on the difference scores, using baseline as a covariate, showed that the experimental group ate significantly less ($p < .05$) on the second day (M = -659.2 kcal/day) compared to the control group (M = -125.9 kcal/day). Multivariate analysis of co-variance for VAS pre- and post-meal ratings showed no consistent differences in hunger or satiety between groups on either day for any meal.

Discussion:

These findings suggest that use of this tool during meals significantly reduced food intake. This reduction did not influence ratings of hunger or satiety during a single day of testing.

Key Words: weight loss aid, bite-size, weight management, food intake

Dental Diet System™:

A Behavior Modification Tool to Reduce Food Intake

Over the past 30 years, the worldwide prevalence of overweight and obesity has increased, resulting in an "obesity epidemic". In the United States, using a nationally representative sample of the US population, the prevalence of overweight has increased to 64.5 percent and the prevalence of obesity has increased to 30.5 percent compared to 55.9 and 22.9 percent respectively in 1998 (1). The epidemic of obesity causes great concern because obesity is associated with numerous negative health conditions, including type 2 diabetes, cardiovascular disease, and premature death and is associated with negative psychosocial outcomes, including decreased quality of life, low self-esteem, body dissatisfaction, ridicule, discrimination, and prejudice (2; 3).

Many research studies have tested the efficacy of numerous weight loss strategies. Previous studies have tested the efficacy of behavior modification (4; 5), pharmacotherapy (6), meal replacements (7; 8; 9), gastric bypass surgery (10), gastric balloon (11), and jaw wiring (12). Though these weight loss methods utilize different techniques, they share the aim of reducing energy intake to promote a negative energy balance that results in weight loss. According to an energy balance model (13), obesity results from caloric intake exceeding caloric expenditure (positive energy balance), and the excess calories produce weight gain because they are stored as fat. Therefore, one primary target of treatment is food consumption, since this is the primary source of caloric intake. Because eating can be conditioned, eating behaviors can, in principle, be modified by environmental manipulation (3). One of the usual recommendations of behavior modification is to reduce bite size (5; 14). This treatment strategy assumes that reduced bite size results in decreased food intake, and implicitly assumes that levels of hunger and

satiety will be unaffected after consuming less food. Behavioral theory hypothesizes that the learned behavior of taking smaller bites should result in reduced food intake and should promote weight loss (14). This hypothesis has seldom been the subject of empirical studies of eating behavior.

There have been few tests of the effects of bite size reduction on food intake, hunger, or satiety despite the fact that it was described as one of the components of behavior modification for obesity over 30 years ago (15). To our knowledge, Spiegel, Kaplan, Tomassini, and Stellar (16) conducted one of the few studies that directly tested the relationship between bite size and food intake. They manipulated bite size (5, 10, or 15 g) and found that participants presented with larger bite sizes ate at a faster rate, but did not consume more food compared to the other groups. Another study reported by Orlet-Fisher, Rolls, and Birch (17) investigated whether large portion sizes influenced children's eating behavior (including total energy intake and bite size). They found that by increasing the portions to double the age-appropriate size, the children consumed approximately 25% more of an entrée and increased total energy intake by approximately 15%. They stated that these changes were attributable to increases in the average size of the children's bites when eating large portion sizes.

The present study tested if use of a patented behavior modification tool, called the Dental Diet System™ (DDS™) was associated with decreased food intake. The DDS™ was developed based upon the hypothesis that smaller bite size results in less food consumption, with hunger and satiety unaffected. The DDS™ fits into the upper palate of the mouth and limits oral capacity, resulting in smaller bite size. In this study, the efficacy of the DDS™ was tested in the laboratory. It was hypothesized that use of the DDS™ would result in reduced food consumption, without decreasing satiety or increasing hunger over the course of a day. Thus, we hypothesized that people using the behavior modification tool would eat less, yet report being as satiated and full as participants in a control group who did not use the DDS™. Food intake and subjective ratings of satiety and hunger before and after meals were measured to test this hypothesis. The study utilized a between-group experimental design whereby participants were randomly assigned to either the experimental (DDS™) or control condition (no DDS™). Two test days were

scheduled. The first day served as a baseline assessment of food intake. On the second day, the experimental group ate with the DDS™ secure in their mouth.

Methods

Participants

Thirty-two adults with an average age of 39.7 years (±3.0) for females and 34.9 years (±3.4) for males were recruited for this study. They were randomly assigned to either the experimental (n = 16: DDS™) or control arm (n = 16), and were stratified by gender to equalize men and women in each treatment arm. A total of five males and eleven females were assigned to each arm of the study. Participants were recruited from the community and university using advertisements. All participants met the following eligibility criteria: 1) adult males or pre- or post-menopausal females, 2) between the ages of 18 and 65, 3) a body mass index $\geq$ 27 kg/m^2 and $\leq$ 40 kg/m^2, 4) no other significant health problems, and 5) completion of both test days of the experiment. Pre-menopausal females conducted the food intake tests during the luteal phase of their menstrual cycle. Testing in one phase of the menstrual cycle limits the confounding effects of the menstrual cycle on energy intake (18). A nurse in conjunction with a physician evaluated the health status of potential participants to exclude persons with a history of diabetes, significant cardiovascular illness or other health problems that may have interfered with the person's ability to participate in the study.

Screening Methods

The screening process included measures of individual subject characteristics that might be associated with differential responses to the Dental Diet System™ such as food preferences, eating disorders and depression. A questionnaire was specifically designed for this study, which assessed preferences for the foods that were to be consumed during test days. Volunteers who showed a strong dislike for the foods to be consumed were excluded from the study during screening. Participants were also screened for the presence of eating disorder pathology and depression using the Multiaxial Assessment of Eating Disorder Symptoms (MAEDS; 20) and Beck Depression Inventory II (BDI-II; 19).

Participants who scored greater than 20 on the BDI-II or scored greater than 70 (standardized *t* score) on any scale of the MAEDS were excluded from the study. No participants were excluded based upon these test scores.

Assessment Measures

Visual analogue scales (VAS). Food intake motivation was assessed with the use of visual analog scales (VAS's) completed on a laptop computer by using the mouse or the left/right arrow keys to position a blinking cursor where desired on a 100mm line. The scales assessed: 1) *Hunger:* How hungry do you feel at this moment?; 2) *Desire to eat:* How strong is your desire to eat at this moment?; 3) *Fullness:* How full does your stomach feel at this moment?; 4) *Motivation to eat:* How much food do you think you could eat at this moment? These VAS ratings have been determined to be valid and reliable indicators of hunger and satiety (21).

Beck Depression Inventory II (BDI-II; 19). The BDI-II is a 21 item self-report inventory that measures symptoms of depression. The BDI-II has been found to be a sensitive tool for a variety of clinical studies, including studies on obesity (22; 23).

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS; 20). The MAEDS is a self-report inventory designed to evaluate symptoms associated with eating disorders and treatment outcomes for eating disorders. This inventory can be used to discriminate between individuals with and without eating disorder symptomotology and was used for this study as a screening device to prevent enrollment of people with eating disorder characteristics.

Test meals. Participants completed two consecutive test days, where breakfast, lunch, and dinner were served and consumed at the Pennington Center. Identical foods were used in the test meals of both days. Food consumption between meals was prohibited and an experimenter remained with participants at all times to ensure that participants only consumed foods during test meals. The test meals were administered in individual cubicles to ensure privacy. In order to simulate a "normal meal", participants were provided with meals comprised of foods that constitute a standard diet. The use of hot foods is

contraindicated because of evaporation of water in foods over time, which contributes to error variance in measuring food intake over time. The meal, for both test days, consisted of the foods shown in Table 1.

Procedure

Prior to scheduling of test days, participants who had been randomly assigned to the DDS™ group were sent to a dentist (consultant to the project) for an impression of their mouth, which was to be used for the development of a DDS™ designed specifically for them. Once their DDS™ arrived (usually within one-two weeks of the visit for the impression), the participants were asked to put the DDS™ in their mouth for any needed adjustments and inspection for correct fitting by the dental consultant, who then made final adjustments to secure a good fit.

Test days were consecutive, and participants in the same treatment group completed the study on the same day to prevent the two groups from conversing with each other, particularly on the second day when the experimental group wore the behavior modification tool while eating. One to five volunteers, with a median number of two, participated in the study on any given day. Changes in appetite were measured using VAS ratings. Participants rated hunger, satiety, fullness, and desire to eat on a 100 mm line that was presented by computer before and after each meal. Once presented with the meal, participants were asked to consume as much of the food as they liked. Meal duration was not limited in any way, participants were told to "take as much time as they liked". Pre- and post- weights of each meal item were recorded to measure food intake (pre-meal grams minus post-meal grams) at each meal.

On the second test day, experimental participants were given their DDS™ and asked to insert it into their mouth. After ensuring the Dental Diet System™ was fitted properly, they were told to leave the DDS™ in their mouth for the entire time they were eating, and not to remove it until a researcher returned following their indication that they were done with the meal. These instructions were presented orally before each of the three meals consumed on the second day. There were no indications throughout the study that a participant failed to abide by these instructions. When a participant had finished eating, they were re-administered the VAS for ratings of hunger and satiety. When participants completed their meal,

they were taken to a different room in which they remained until the following meal. Between meals, the participants were free to read, work on tasks they brought with them, or watch general-audience movies made available by the research team. Each meal was presented in the same manner, on the following schedule: breakfast--8am, lunch--noon, and dinner--5pm. Participants were not allowed to consume food or beverages between meals.

Participants received a $200 stipend for their contribution to the research following completion of the second day of the study. Any participant who did not complete the full two-days was given $75. There was one participant who attended only the first day of the study and this person was excluded from the data analysis. Participants provided consent to participate in this study by signing consent forms. The Institutional Review Board of the Pennington Biomedical Research Center approved the protocol.

Results

The weight, gender, and other demographic characteristics of the two treatment groups are summarized in Table 2.

Primary outcome measures were total food intake and changes in VAS ratings before and after each meal. Changes in food intake from Day 1 to Day 2 were defined using changes in food intake (defined as pre-meal grams minus post-meal grams) across days (Day 2 minus Day 1). Difference scores were used since day 1 served as the baseline day for both groups. To examine the differences between groups in food intake from baseline, a two- way analysis of co-variance (ANCOVA) was performed using treatment group and gender as the two factors, and food intake on Day 1 as a covariate. The dependent variable was food intake (grams). The total food intake difference (Day 2 - Day 1) between groups was statistically significant, F (1, 28) = 7.49, $p < .05$. Gender was not associated with differences in food intake and did not interact with group to influence food intake. The DDS™ group significantly reduced food intake from Day 1 to Day 2 ($p < .01$), while the control group did not significantly reduce food intake ($p > .05$). The mean differences on food intake between the groups are summarized in Table 3. From this table, it can be seen that the DDS™ group consumed an average of 331.87 grams less on Day 2

than on Day 1, while those in the control condition consumed 32.13 grams less on Day 2 than Day 1. Food intake was converted to kilocalories to illustrate results in caloric terms. Differences in calorie intake between the two groups are depicted in Table 4. A 2 (Treatment: DDS™, control) by 2 (Gender: male, female) by 3 (Meal: breakfast, lunch, dinner) multi-variate analysis of variance was conducted to determine if food intake (in grams) differed by treatment, gender or meal type. Results revealed no significant differences between groups or genders across the three meals, F (2, 56) = 1.41, $p > .05$.

Changes in hunger and satiety, based upon VAS ratings, were tested using multivariate analysis of co-variance. Participants rated four subjective states for each of the three meals on both test days. Therefore, twelve comparisons were performed to determine if the rating change scores from pre- to post-meal differed between the two groups of participants. The Bonferroni correction procedure was used to adjust the alpha to $p < .004$. No differences as a function of group were found.

Discussion

These findings support the hypotheses that a tool to reduce bite size (the DDS™ behavior modification tool) during meals reduced food intake, without affecting satiety or hunger. As seen in Table 3, the experimental group reduced their intake of food (in grams) by 25.85% (659.2 kcals) on the test day. The control group reduced their food intake (in grams) by only 3% (125.9 kcals). The findings from this study suggest that use of the Dental Diet System™ could significantly reduce food intake, which could promote weight loss if this behavior change was maintained over time. Analyses of VAS ratings indicated that the two groups did not differ in feelings of hunger or satiety across meals consumed in a single day. This finding leads to the conclusion that although the experimental group did not consume as many grams of food on the test day as they did during baseline, greater feelings of hunger and less feelings of satiety were not evident. In conclusion, the hypothesis that reduced bite size was associated with reduced food intake, without side effects of feeling hungrier or less satiated, was supported.

To our knowledge, this is the first study to directly test if reduced bite size results in less food intake, a central assumption of behavior therapy for weight loss. These findings provide support for one of the assumptions of behavior therapy for weight loss.

Limitations of this study include the failure to collect data on amount of time for completion of meals. These data could have allowed us to determine whether the DDS™ tool actually slowed the rate of eating, potentially allowing satiety signals to be recognized before excessive calories have been consumed. A study designed to test this hypothesis would strengthen our understanding of appetite mechanisms that might account for the differences in food intake observed in this study.

Further research on the efficacy of the DDS™ behavior modification tool is warranted given the positive findings from this preliminary "proof of concept" study. Future research might include a clinical trial that tests if long-term use of the DDS™ behavior modification tool results in significant weight loss. This type of research might address compliance with continued use of the DDS™, the effect of use of the DDS™ behavior modification tool on weight loss, and consumer satisfaction with this approach to weight management. The DDS™ behavior modification tool might also be especially useful for individuals who often lose control while eating, resulting in binge eating or overeating (24). This tool also might be especially helpful to people who recognize that rapid eating is a habit that results in excessive consumption of food.

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Table 1. Test meals, by item, amount, and kcal/gram, used for both test days.

Meal	Grams Pre-meal*	Kcal/Gram
Breakfast		
“Mini” Blueberry Muffins	170	3.96
Mixed Fruit	375	0.66
Yogurt	340	0.83
Lunch		
Subway® Sandwich	350	1.26
Mayonnaise	60	7.14
Mustard	50	0.66
Subway® Cookies	90	4.67
Dinner		
Grilled Chicken Lettuce Salad		
Lettuce	200	0.17
Chicken	85	1.31
Croutons	15	4.28
Dressing	100	3.79
Cheese Slices	110	3.93
Crackers	50	5.00
Chocolate Iced Brownies	250	3.41

*Grams pre-meal are approximate values; grams per item varied slightly with each meal.

Table 2. Gender and mean demographic characteristics of participants in the two groups*.

Parameter	DDS (*n*=16)	Control (*n*=16)
Sex		
Women	11	11
Men	5	5
Mean Age (years)		
Women	38.18 (3.61)	41.18 (4.92)
Men	31.80 (6.25)	38.00 (2.81)
Mean Weight [kg]		
Women	90.45 (2.27)	85.20 (3.57)
Men	94.84 (5.54)	96.04 (3.47)
Mean Height [cm]		
Women	164.74 (1.35)	161.53 (1.64)
Men	177.06 (4.34)	178.56 (2.06)
Mean BMI (kg/m^2)		
Women	33.36 (.86)	32.59 (1.12)
Men	30.20 (.98)	30.12 (1.03)

*Standard errors are shown in parentheses. The two groups did not differ on any variable ($p > .05$).

Table 3. Mean Food Intake Differences from Day 1 (Day 2 - Day 1), in grams

	DDS			Control		
	n	**Mean(*SE*)**	**%Change**	***n***	**Mean(*SE*)**	**%Change**
Gender						
Males	5	-270.20 (63.33)		5	13.11 (84.55)	
Females	11	-359.90 (107.97)		11	-52.69 (59.81)	
Total	16	-331.87* (76.11)	25.85	16	-32.13* (47.93)	3.0

*Total food intake difference between groups are significantly different, F (1, 28)=7.49, $p<.05$

Table 4. Mean Caloric (kcal) Intake* Per Group, Per Meal, and Per Day.

	Day 1	**Day 2**	**Difference (Day2 - Day1)**
DDS			
Breakfast	694.2	494.2	-200
Lunch	894.3	737.6	-156.7
Dinner	1294.9	992.5	-302.4
Total	2883.4	2224.2	-659.2
Control			
Breakfast	622.5	617.7	-4.8
Lunch	774.4	763.0	-11.4
Dinner	1075.9	966.3	-109.6
Total	2472.8	2346.9	-125.9

*Caloric intake is dependant on the type of food given and the food choices made by each participant, therefore this data is for informational purposes only and should not be used for comparison with other studies.