

## Preliminary study on the effects of a calcium-rich whey protein supplement (OsoLean™ powder) on weight loss, waist circumference, and appetite in overweight subjects

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### INTRODUCTION

The World Health Organization estimates that over 1 billion people worldwide are classified as overweight [1]. Currently, about two-thirds of American adults are overweight [2], and it has been predicted that over 85% of Americans will be overweight by the year 2030 [3]. Authorities are attempting to address this problem via population-wide measures to improve dietary choices and increase physical exercise. With several weight-loss supplements on the market, it is difficult to fully assess and rely on their proposed safety and efficacies. Different versions and amounts of whey protein supplementation used in studies have shown effects on anthropometric indices and other measures, although results have been equivocal. The current study examined the effects of a specialized whey protein supplement (OsoLean™ powder), rich in bioactive peptides and calcium, on weight, waist circumference, and appetite in healthy, overweight adults.

### METHODS

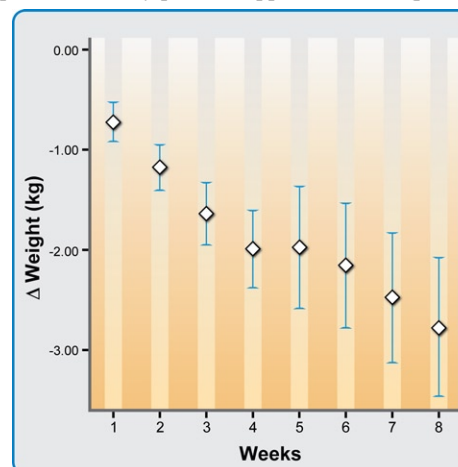
This is a preliminary, open-label study of 112 overweight subjects (80 female, 32 male) who were instructed to add one serving (12.2 g) of OsoLean™ powder to 8 fluid oz (237 mL) of liquid and drink once in the morning, 20 minutes before breakfast, and again in the evening, 20 minutes before dinner, for a total of 24.4 g/day for 8 weeks. The specialized whey protein supplement provided 45 calories and contained 10 g of protein and 244 mg of calcium per serving. The subjects completed a quality of life questionnaire at baseline and at the end of week 8. They were provided a tracking log in which they were asked to record their height, daily supplement consumption, and self-measurements of weight, waist circumference, and estimated daily caloric intake. Body Mass Index (BMI) was calculated by the study coordinator. Body weight, BMI, and waist circumference were analyzed using a two-tailed paired t-test to compare the primary outcomes at specific time periods vs. baseline values. Data from the quality of life questionnaire was analyzed using the McNemar's chi-

square test to detect if there were significant changes in subject responses. Significance was set at a  $p < 0.05$ .

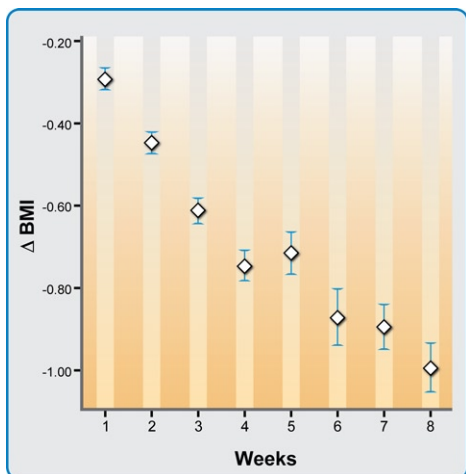
### RESULTS

The average body weights reported at the end of each week decreased and the subjects reported an average  $\pm$  standard error weight loss of  $2.8 \pm 0.3$  kg by week 8 ( $p < 0.0001$ ) (Figure 1). The average BMI decreased compared to baseline values by the end of the first week and remained significant throughout the completion of the study with a decrease of  $1.0 \pm 0.1$  points at week 8 ( $p < 0.0001$ ) (Figure 2). Average waist circumferences, reported at the end of each week, were significantly reduced compared to baseline measurements by a difference of  $7.1 \pm 0.7$  cm at week 8 ( $p < 0.0001$ ) (Figure 3). The results from the Quality of Life questionnaire revealed statistically significant improvements in appetite control and energy levels, as well as overall health, reduced pain interference, and the ability to sleep well by the end of week 8 ( $p < 0.05$ ) (Table 1). The supplement was well-tolerated by the participants in this study. There were no adverse events that required a physician's care.

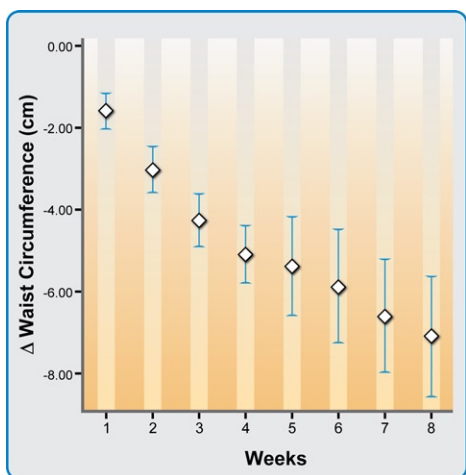
**Figure 1.** Reduction in body weight (kg) during 8 weeks of specialized whey protein supplementation. ( $p < 0.0001$ )



**Figure 2.** Decrease in average Body Mass Index (BMI) during 8 weeks of specialized whey protein supplementation. ( $p < 0.0001$ )



**Figure 3.** Reduction in waist circumference (cm) during 8 weeks of specialized whey protein supplementation. ( $p < 0.0001$ )



**Table 1.** Quality of life survey data

Characteristic	Day 1†	Week 8†
Overall health	60.71	76.12*
Moderate activity performance	79.49	86.57
Work activity performance	90.18	97.06
Energy level	66.08	88.24*
Stress coping abilities	86.49	91.18
Relaxation/calmness	66.07	74.63
Personal relationships	79.47	92.54
Ability to sleep	69.64	80.60*
Appetite control	42.85	70.15*
Little to no pain interference	75.89	86.15*

† Percentages of subjects that reported positive levels during self-assessment. Percentages were significantly different from those at baseline 1: \* $p < 0.05$ .

## DISCUSSION

Supplementation with 24.4 g/day of this specialized whey protein for 8 weeks resulted in a steady loss of body weight, decrease in BMI, and decrease in waist circumference in overweight individuals. Subjects also reported better appetite control and energy levels over the study period. We suggest that the effects on weight loss, waist circumference reduction, and appetite control were likely due to an increased daily intake of calcium and consumption of specialized bioactive peptides found in whey protein, as both changes have been associated with positive impacts on weight and body composition.

Evidence suggests that consumption of an additional 300 mg calcium (~1 dairy serving) per day may result in decreased weight gain, or greater weight loss during dieting, in the range of 0.24-0.35 lbs (0.11-0.16 kg) per year [4]. Increasing calcium intake, via supplementation or dairy consumption, to an amount of 1200 mg/day for 6 months has been shown to enhance weight and fat loss during caloric reduction, with more fat lost from the abdominal region when compared to low calcium diets (500 mg/day) [5]. Animal and human studies have shown that increasing dietary calcium can reduce calcitrophic hormone levels and increase fecal fatty acid excretion, mechanisms that may be responsible for the observed fat loss seen with increased dietary calcium consumption in humans [6].

In a 12-week, placebo-controlled, randomized clinical trial of overweight subjects adhering to a 500 calorie-reduced diet, daily consumption of a flavored, sweetened beverage including 24.4 g of intact and hydrolyzed whey protein, peptides, calcium, and other milk minerals significantly increased fat loss and retained lean muscle mass when compared to non-supplemented controls [7]. In addition, whey protein preloads (>45 g) consumed 1-4 hours before a meal have been shown to significantly increase satiety when compared to preloads containing carbohydrates or other protein sources, such as casein [8, 9]. Dairy proteins, such as whey, contain a high proportion of bioactive compounds, such as angiotensin converting enzyme (ACE) inhibitors and branched chain amino acids, which can act synergistically with calcium to enhance fat loss and maintain lean muscle mass [6].

## CONCLUSION

This preliminary study demonstrated that daily consumption of a specialized whey protein supplement, containing 20 g whey protein and 488 mg calcium, significantly

decreased weight, BMI, and waist circumference in healthy, overweight adults over an 8 week period. Also noted by the subjects was better appetite control and improved energy levels. The whey protein supplement was demonstrated to be safe to consume over this time period. The ability to draw definitive conclusions is limited because of this study's uncontrolled, open-label methodology. However, the results are very encouraging and should be explored further using a randomized, double-blind, placebo-controlled trial.

### ACKNOWLEDGEMENT

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### REFERENCE LIST

- [1] Obesity and overweight. World Health Organization [updated 2006 Sep; cited 2008 Nov 11]; Available from: <http://www.who.int/mediacentre/factsheets/fs311/en/print.html>
- [2] Pastor PN, Makuc DM, Ruben C, Xia H. Chartbook on Trends in the Health of Americans. Health, United States, 2002. Hyattville, Maryland: National Center for Health Statistics. 2002.
- [3] Wang Y, Beydoun MA, Liang L, Caballero B, Kumanyika SK. Will all Americans become overweight or obese? Estimating the progression and cost of the US obesity epidemic. *Obesity* 2008.
- [4] Heaney RP, Davies KM, Barger-Lux MJ. Calcium and weight: clinical studies. *J Am Coll Nutr* 2002; 21(2):152S-5S.
- [5] Zemel MB, Thompson W, Milstead A, Morris K, Campbell P. Calcium and dairy acceleration of weight and fat loss during energy restriction in obese adults. *Obes Res* 2004; 12(4):582-90.
- [6] Zemel MB. The role of dairy foods in weight management. *J Am Coll Nutr* 2005; 24(6 Suppl):537S-46S.
- [7] Frestedt JL, Zenk JL, Kuskowski MA, Ward LS, Bastian ED. A whey-protein supplement increases fat loss and spares lean muscle in obese subjects: a randomized human clinical study. *Nutr Metab (Lond)* 2008; 5:8.
- [8] Araya H, Hills J, Alvina M, Vera G. Short-term satiety in preschool children: a comparison between high protein meal and a high complex carbohydrate meal. *Int J Food Sci Nutr* 2000; 51:119-24.
- [9] Hall WL, Millward DJ, Long SJ, Morgan LM. Casein and whey exert different effects on plasma amino acid profiles, gastrointestinal hormone secretion and appetite. *Br J Nutr* 2003; 89:239-48.