



Technical Literature

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A 20 Week Open-Label Clinical Study Shows Slendesta™ Potato Protein Extract is Effective for Weight Loss and Improved Body Measurements

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Key Conclusions

- **Slendesta Potato Protein Extract taken daily prior to meals resulted in statistically significant weight loss from baseline ($p < 0.001$).**
- **Slendesta Potato Protein Extract users experienced statistically significant decreases in waist and hip measurements ($p < 0.001$), and changes in their waist-to-hip ratios ($p < 0.001$).**
- **No serious side effects were observed in this 20-week study.**

Introduction

Overweight and obesity are now a global epidemic. In the United States, approximately 61% of the adult population is affected by this condition, while more than one billion adults are overweight and over 300 million are obese worldwide (1-3). Obesity is associated with an increased risk for cardiovascular disease, metabolic syndrome, hypertension, stroke, diabetes, osteoarthritis, sleep apnea, depression, gallbladder disease, and several cancers (4). The scientific literature reports that even modest gains in weight during adult life are associated with important increases in risk of coronary heart disease. In a cross-sectional analysis of middle-aged men and women, almost all overweight persons of both genders, those with a body-mass index (BMI) of 25 kg/m² or more, experienced adverse effects of blood pressure, glucose control, or lipid metabolism (5). Waist-to-hip ratio is a recognized measure of obesity related risk for cardiovascular disease and a stronger indicator of heart attack risk than BMI (7). It has been

determined that death rates due to coronary heart disease increase when the waist-to-hip ratio was >0.80 in women or >0.90 in men (6).

Increased awareness of associations between chronic diseases and excess body weight has motivated consumers to seek weight loss and management aids that are safe and effective without side effects. An essential component of weight management is appetite control and one way of controlling appetite is to maintain a feeling of satiety. Enhanced satiety with feelings of fullness for longer periods can result in less food consumed at meals and reduced snacking between meals, thereby promoting weight loss. Pharmacological agents and over-the-counter supplements designed to suppress hunger have had limited success and are often accompanied by numerous side effects (8, 9). Because of this, there is a large and continuously growing market for other safe ingestible approaches for appetite control.

Slendesta™ Potato Protein Extract (Slendesta) is a satiety aid ingredient introduced by Kemin Health that has been shown to induce satiety, the feeling of fullness, in humans. Slendesta is standardized to its active constituent, potato proteinase inhibitors (PI2). The presence of PI2 in the intestine results in increases in the level of cholecystokinin (CCK) (10), a satiety hormone naturally released in response to a meal (11). Consumption of PI2, supplied by Slendesta, before a meal has been shown to be safe (12-15). PI2 at a 1.5 g dose before a meal has been shown to reduce energy intake in healthy subjects (12,13). An average 2-kg weight loss has been demonstrated in overweight women when PI2 was taken daily prior to lunch and dinner for four weeks (16). Furthermore, oral administration of 15-30 mg PI2 (300-600 mg Slendesta Potato Protein Extract 5% Powder*) was able to significantly decrease hunger ratings in overweight and healthy subjects (17,18).

An open-label non-randomized clinical study conducted by Kemin Health demonstrated statistically significant reductions from baseline in weight and body dimensions over a 12-week period (19) of 15-30 mg PI2 treatment (300-600 mg Slendesta Potato Protein Extract 5% Powder*). To confirm that ongoing use of Slendesta would continue to result in weight loss, the initial 12 weeks of the study (Phase 1) was extended an additional eight weeks (Phase 2) to a total of 20 weeks, testing the effectiveness of Slendesta in promoting satiety and weight loss in overweight to obese healthy adults who elected to continue their participation in the study. The results of this study support that PI2 supplied by Slendesta offers a useful approach for satiety, managing hunger naturally, and can be an effective tool for promoting weight loss, weight maintenance, and improved body measurements in motivated individuals. Notably, the Food and Drug Administration has accepted open-label studies to support efficacy for certain pharmaceuticals, in addition to well-designed placebo-controlled blinded studies, based on the recognition that such studies reflect the real-life conditions under which patients may use certain drugs (20).

Study Design

The study was a non-randomized open label study. The research study was conducted by Heartland Vascular Medicine & Surgery with Alan R. Koslow, M.D., F.A.C.S. as Principal Investigator. Fifteen male and female healthy adults ranging in age from 22 to 59 years were enrolled in the extended study (Phase 2, **Figure 1**). These individuals were overweight to obese with initial BMI between 25 and 35 kg/m², had completed the Phase 1 study (12 weeks), and continued to meet the eligibility criteria.

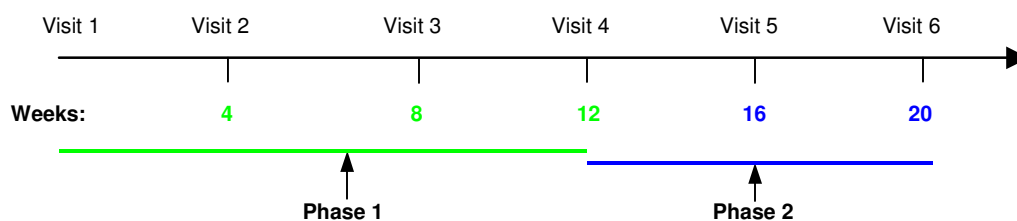


Figure 1. Study Timeline: Phase 1 included 4 visits over a 12 week period. Phase 2 included two more visits and extended for an additional 8 weeks, for a total study duration of 20 weeks.

* 300-600 mg Slendesta Potato Protein Extract 5% Powder in capsule form (Satise®) provided 15-30 mg PI2.

At Visit 4 of Phase 1, signed informed consent and release forms were obtained before continuation in Phase 2. Updates of medical history, body weight, BMI (calculated), waist, and hip measurements were recorded. Photographs of subjects were taken by a professional photographer. Subjects were instructed to continue taking the product according to the same regimen of 15-30 mg PI2 (300-600 mg Slendesta Potato Protein Extract 5% Powder*) 60 minutes before each of the two major meals of the day and were given a sufficient supply to last until the next visit.

Subjects were instructed about the general benefits of nutritious eating and exercise as part of weight management, but no specific diet or exercise program was provided. Subjects were given study product use diaries to complete daily with the number of capsules taken, the actual time taken, and the subsequent time of meal consumption. These diaries, all study capsules, and empty capsule containers were collected at each clinic visit. Compliance with treatment regimen was determined by capsule count and product use diary review.

At monthly Visits 5 and 6 that were scheduled at equal intervals, vital signs, body measurements, and changes in medical history were recorded. Supplies and new diaries sufficient to last until the next visit were again given to subjects. Any adverse events occurring during the study were recorded. Final photographs were taken at Visit 6. A consulting statistician analyzed study results for subjects who participated in Phase 2, as well as for all available subjects over all monthly measurement periods of Phase 1 and 2.

Results

Body weight changes. The amount of weight lost from baseline was statistically significant at all time points of the study ($p=0.0016$ at 4 weeks, $p<0.001$ at 8, 12, 16, and 20 weeks). Subjects lost an average of 4.8 kg (10.7 lbs) by sixteen weeks and 5.3 kg (11.7 lbs) by twenty weeks (**Figure 2**). The percentage of subjects losing $\geq 5\%$ of body weight was 13% by week four, 30% by week eight, and 53% by week twelve through the end of the study.

The maximum amount of weight loss experienced by subjects during the study was 11.5 (25.4 lbs) at week 12, 13.3kg (29.3 lbs) by week 16 and 15.6 kg (34.4 lbs) by twenty weeks. These results are consistent with those of a previously conducted open-label study using Slendesta with diet and exercise (21). Overall, 87% of subjects who extended their participation beyond 12 weeks either maintained or increased their weight loss through study completion at 20 weeks.

Most diet programs show a decrease in the rate of weight loss, resulting in a plateau with which many dieters struggle. Slendesta continues to result in weight loss over time, albeit more gradual. The apparent rate of weight reduction (0.27 kg/week or 0.60 lbs/week) over 20 weeks is in accordance with the FDA guidelines for healthy gradual weight loss of approximately 1 lb per week with diet and exercise (22).

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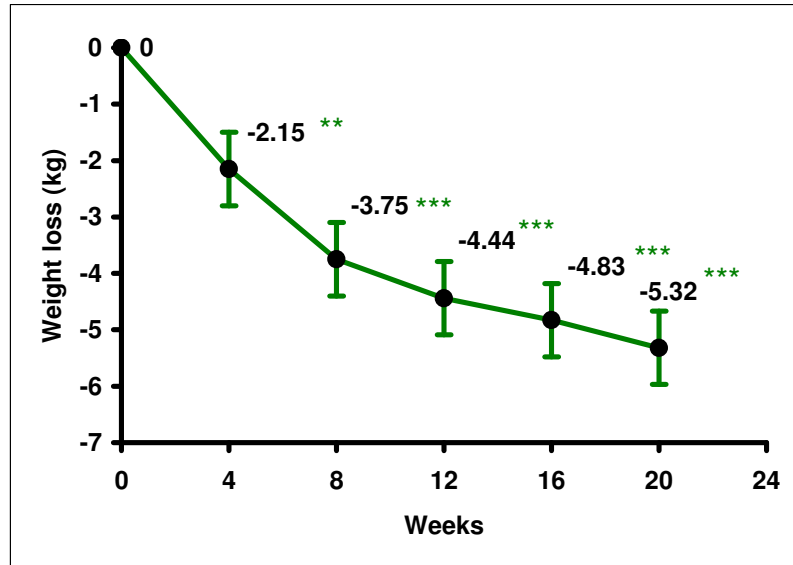


Figure 2. Mean change in body weight from baseline for Phase 2 subjects. Amount of weight lost was a statistically significant change from baseline (**p=0.0016, ***p<0.001).

Subjects reported in a study questionnaire that the study product with Slendesta made them feel full sooner (100%) and longer (93%), made it easier to eat less (93%), and helped reduce between-meal snacking (87%) throughout the study. At the end of the 20-week period, 80% of subjects were satisfied with the weight loss achieved and 87% were satisfied with the effect of this product on appetite control. No serious side effects were associated with product use.

Changes in waist and hip dimensions. As continued weight loss became more gradual over the study period, waist and hip dimensions declined at an increasing rate for a total waistline reduction of 16 cm (6.4 in) and a total hip reduction of 10 cm (4 in) by 20 weeks (**Figure 3**). Overall, subjects experienced decreases of 16% in waistline and 9% in hip dimensions at 20 weeks. Reductions in waist and hip circumference were statistically significant (hips at 4 weeks, p=0.0048, waist and hips at all other time points, p<0.001). In addition to its usefulness for weight loss, Slendesta appears likely to be useful for weight management by helping achieve and maintain target weight and target waist and hip circumference.

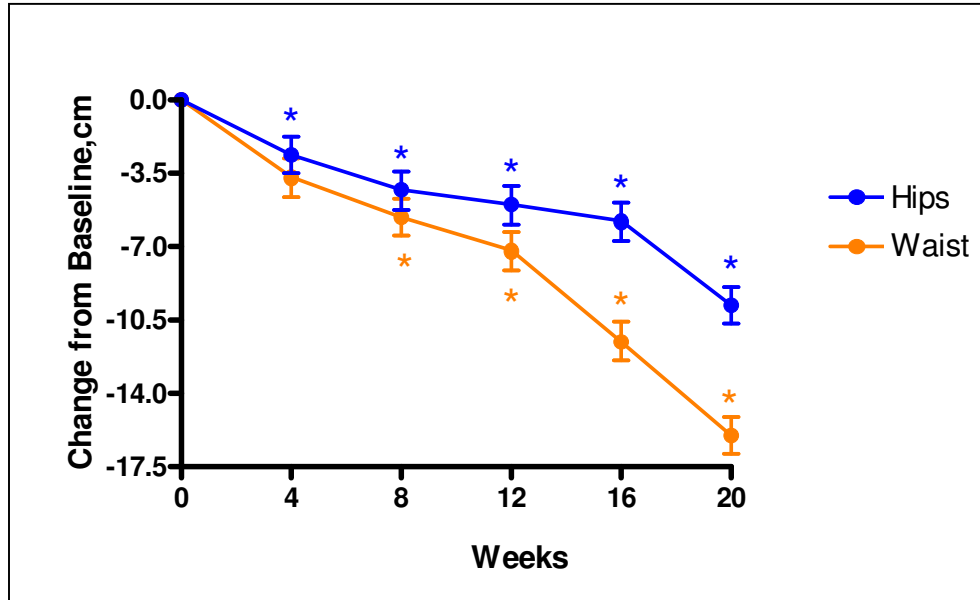


Figure 16. Mean changes in hip and waist circumference. Values are reported as LSMean ± standard error. Changes from baseline were statistically significant for hips at 4 weeks ($p=0.0048$) and at all other time points for waist and hips ($p<0.001$).

Changes in waist-to-hip ratio. Also important was a statistically significant reduction in waist-to-hip ratio. Subjects' average baseline 0.87 waist-to-hip ratio gradually decreased to 0.85 ($p=0.0197$) by 12 weeks, 0.81 ($p<0.001$) by 16 weeks, and 0.80 ($p<0.001$) by 20 weeks. This reduction suggests an improvement in the risk of cardiovascular disease for these individuals. Furthermore, these results raise the possibility that Slendesta may aid in the reduction of belly fat thereby promoting improvement in the overall health of Slendesta users.

Conclusions

According to the results of this open label study, using 15 to 30 mg of PI2 (300 to 600 mg Slendesta Potato Protein Extract 5% Powder*) as directed before meals, daily, results in statistically significant gradual healthy weight loss, and reductions in waist and hip measurements as early as four weeks and continuing up to 20 weeks. Statistically significant beneficial changes in waist-to-hip ratios resulted. The weight loss and body changes observed in this study were achieved without side effects that can be associated over-the-counter products and prescription medications. The results of this study indicate that Slendesta offers a useful approach to satiety and can be a safe and effective tool for weight loss, and for maintaining weight loss, as part of a weight management program.

* 300-600 mg Slendesta Potato Protein Extract 5% Powder in capsule form (Satise®) provided 15-30 mg PI2.

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