

Pro-Stat® and Pro-Stat® AWC Publications

Lee SK, Posthauer ME, Dorner B, et al. Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomized controlled trial. *Adv Skin Wound Care*. 2006;19:92-6.

Objective:

Observational studies have indicated that pressure ulcers will heal better with a high protein supplement. However, no clinical studies have examined the effect of a collagen protein supplement on pressure ulcer healing. This study aimed to evaluate the effect of a concentrated, fortified, collagen protein hydrolysate supplement on stage II, III, and IV pressure ulcers healing rates.

Methods:

This double-blind, placebo-controlled, randomized, multicenter study included eighty-nine residents of long term care facilities with stage II, III, and IV pressure ulcers. Residents were randomized to receive standard care with either a placebo supplement or standard care with a concentrated, fortified, collagen protein hydrolysate supplement three times daily for eight weeks. The placebo was a non-caloric liquid product that was indistinguishable from the study product in terms of color, taste, and texture. The Pressure Ulcer Scale for Healing (PUSH) tool was used to measure and provide numeric scores for wound parameters of exudate, wound surface area, and tissue type. The main outcome measured was the change in PUSH tool score in each group at baseline compared to the end of eight weeks. PUSH scores were compared through analysis of variance with repeated measures.

Results:

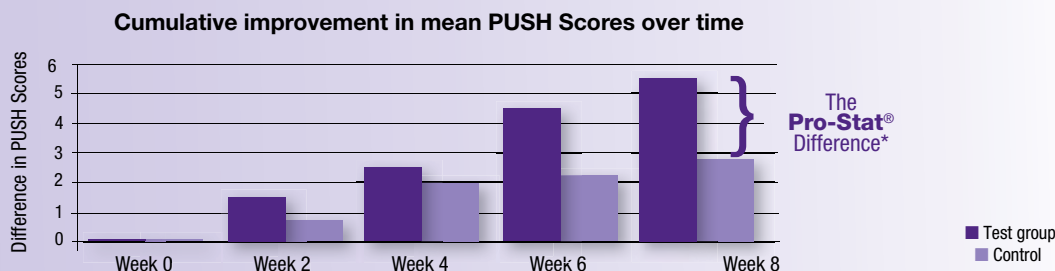
Thirty-three residents were provided standard care plus placebo and fifty-six residents were provided standard care plus the concentrated, fortified, collagen protein hydrolysate supplement. PUSH tool scores decreased for all residents at the end of the eight weeks compared to baseline. However, the group that received the collagen protein supplement had approximately twice the rate of pressure ulcer healing compared to the group who only received standard care plus the placebo (control group PUSH tool scores 3.22 ± 4.11 versus test group PUSH tool scores 3.55 ± 4.66 ($p < .05$)).

Conclusion:

Along with standard care, a concentrated, fortified, collagen protein hydrolysate supplement may provide improved healing for residents with stage II, III, or IV pressure ulcers in long term care facilities.

Residents who received Pro-Stat had statistically significant improved PUSH tool scores compared with those receiving the placebo.

Pro-Stat® showed 96% greater pressure ulcer healing in 71 residents in a double-blind, placebo controlled clinical trial



*Significantly different from Control at $p = .05$

Lee SK, Posthauer ME, Dorner B, et al. Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomized controlled trial. *Adv Skin Wound Care*. 2006;19:92-6.

Adapted from the publicly available abstract: <http://www.ncbi.nlm.nih.gov/pubmed/16557055>

Pro-Stat® and Pro-Stat® AWC Publications

Sundell MB, Cavanaugh KL, Wu P, et al. Oral protein supplementation alone improves anabolism in a dose-dependent manner in chronic hemodialysis patients. *J Ren Nutr.* 2009;19:412-21.

Objective:

Previous studies have shown that patients on chronic hemodialysis who received parenteral and oral nutritional supplementation provided during hemodialysis showed an anabolic response. However, there are limited studies that have demonstrated the efficacy and feasibility of providing a protein supplementation to patients on chronic hemodialysis. This study aimed to examine the protein anabolic effects of a high nitrogen-containing, enzyme-hydrolyzed, tryptophan-fortified, collagen protein supplement provided to patients during hemodialysis.

Methods:

The study was a randomized, prospective, crossover design that included six chronic hemodialysis patients who were randomly assigned to the three following groups; 1) a single serving of Pro-Stat® (30 mL; 15 g protein) thirty minutes before dialysis and Pro-Stat (30 mL; 15 g protein) thirty minutes after initiation of dialysis, 2) Pro-Stat (60 mL; 30 g protein) thirty minutes before dialysis and Pro-Stat (60 mL; 30 g protein) thirty minutes after initiation of dialysis, and 3) a control group that did not receive Pro-Stat or any other nutritional supplementation. All patients participated in each study group with at least four weeks between each group. Blood samples were collected to quantify blood chemistries, plasma amino acids, forearm amino-acid uptake, and whole-body protein metabolism.

Results:

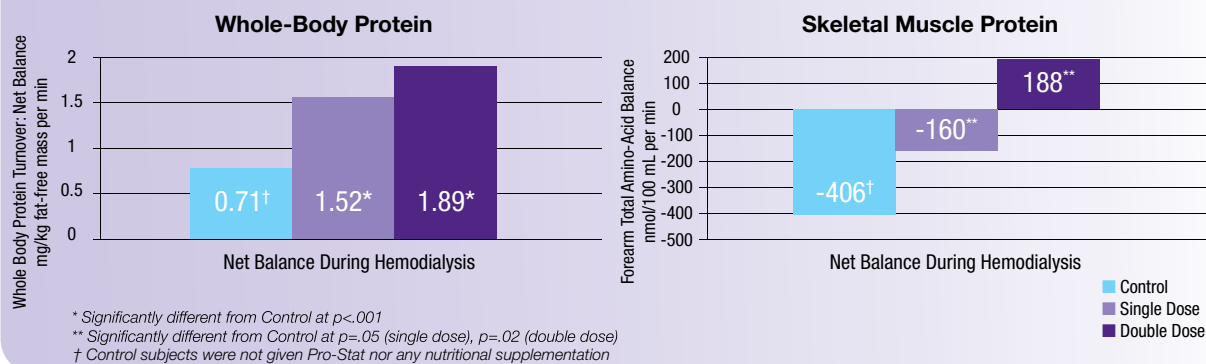
Compared with the control group, plasma nonessential amino acid and total amino acid concentrations were significantly higher and dose dependent during and post-hemodialysis when patients consumed Pro-Stat. Both 30g and 60g protein servings of Pro-Stat showed statistically significant forearm amino acid uptake for essential, nonessential, and total amino acids compared with the control group. The nonessential amino acid uptake was only significantly better after the 60g of protein serving of Pro-Stat. A positive dose-dependent effect was demonstrated in whole-body protein metabolism representing a statistically significant improvement during hemodialysis with the 60g protein serving of Pro-Stat compared to both the 30g protein serving of Pro-Stat and the control group (0g protein).

Conclusion:

A high nitrogen-containing, enzyme-hydrolyzed, tryptophan-fortified, collagen protein supplement provided to patients during and after hemodialysis can improve whole-body and skeletal muscle protein anabolism in patients on chronic hemodialysis.

Pro-Stat supplementation alone improved whole-body and skeletal muscle protein anabolism in chronic hemodialysis patients.

Pro-Stat® improved whole-body & muscle anabolism in one clinical trial of six chronic hemodialysis patients



Sundell MB, Cavanaugh KL, Wu P, et al. Oral protein supplementation alone improves anabolism in a dose-dependent manner in chronic hemodialysis patients. *J Ren Nutr.* 2009;19:412-21.

Adapted from the publicly available abstract: <http://www.ncbi.nlm.nih.gov/pubmed/19500999>

Pro-Stat® and Pro-Stat® AWC Publications

Hays NP, Kim H, Wells AM, et al. Effects of whey and fortified collagen hydrolysate protein supplements on nitrogen balance and body composition in older women. J Am Diet Assoc. 2009;109:1082-7.

Objective:

Elderly people need adequate protein to maintain lean body mass and provide adequate amounts of amino acids for protein synthesis. Often, elderly people do not consume enough protein and may benefit from a high quality, low-fat protein supplement. It has been hypothesized that a supplement of whey protein would result in a similar nitrogen balance compared to a collagen-based hydrolysate supplement. The aim of this study was to compare a concentrated source of 100% whey protein isolate supplement (Beneprotein®) to a concentrated, enzyme-hydrolyzed collagen protein fortified with L-tryptophan supplement (Pro-Stat®) with the nitrogen balance and body composition changes in older women.

Methods:

The study was a double-blind, crossover design that included eleven older women (65 – 85 years old) who were randomly assigned to the two following groups in an outpatient setting; 1) 100% whey protein isolate in addition to diet (total protein = 0.8g/kg body weight/day) and 2) concentrated, enzyme-hydrolyzed collagen protein fortified with L-tryptophan in addition to diet (total protein = 0.8g/kg body weight/day) for fifteen days. Approximately, half of the protein was provided as a supplement and the other half of the protein was provided as diet. Nine subjects completed each study group with at least seven days between each group. Body composition assessment was measured by the BOD POD® body composition system. Resting energy metabolism was assessed over a thirty minute indirect calorimetry measurement. The Harris-Benedict equation for women was used to determine daily total energy requirements. Nitrogen balance was determined from both the food samples and twenty-four hour urine samples obtained during days 6 to 10 and 11 to 14 of each trial. Paired t tests (two-tailed) were used to compare nitrogen balance within each trial (days 6 to 10 vs. 11 to 14) and between periods (days 6 to 14). Analysis of variance with repeated measures was used to examine the differences between protein supplements.

Results:

Body weight decreased significantly ($p = 0.02$) at the end of the whey protein isolate supplement study phase, but neither body fat nor resting metabolism changed significantly. No changes in body weight or body composition occurred during the concentrated, enzyme-hydrolyzed collagen protein fortified with L-tryptophan supplement study phase of the study. Nitrogen excretion was higher during the whey protein isolate supplement study phase compared to the concentrated, enzyme-hydrolyzed collagen protein fortified with L-tryptophan ($p = 0.047$), but there were no statistically significant differences in nitrogen balance between the two study phases. In addition, there were no differences in urinary nitrogen excretion from days 6 to 10 to days 11 to 14 for either study phase.

Conclusion:

Energy intake was adequate in all subjects and the nitrogen balance did not show any statistical differences between the two protein supplements demonstrating protein equivalence between the 100% whey protein isolate supplement and the concentrated, enzyme-hydrolyzed collagen protein fortified with L-tryptophan supplement. To maintain nitrogen balance and preserve lean body mass in older women, a concentrated, enzyme-hydrolyzed collagen protein fortified with L-tryptophan supplement may provide benefits to older women who are consuming a low protein diet.

After 15 days of consumption, Pro-Stat maintained nitrogen balance and preserved lean body mass in patients consuming a relatively low-protein diet.

Adapted from the publicly available abstract: <http://www.ncbi.nlm.nih.gov/pubmed/19465192>