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The Effects of Supplementing Ingredient Optimized Whey Protein Isolate (ioProtein) Versus Whey Protein Comparator Following High Intensity Exercise for 8-Weeks

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Abstract

It is common practice for many athletes and active adults to use protein supplements to enhance gains in lean muscle mass, and whey protein, in particular, is ideal due to its high levels of essential amino acids. Whey protein isolates, one of the most common forms of protein, are considered one of the best sources of protein available. To date, no studies have examined the relative performance of whey protein that has undergone the patent-pending Ingredient Optimized process in order to enhance its effects on muscle protein synthesis and lean muscle anabolism. As such, the primary aim of this study was to examine the relative benefit of this ioProtein whey protein isolate, in combination with resistance exercise, on several measures of body composition among a sample of athletes in comparison with those associated with an untreated whey protein isolate. Twenty healthy male and female adults, between the ages of 18 and 37 years, were recruited. Results indicated that individuals who supplemented with the Ingredient Optimized whey protein saw a significant improvement in fat-free mass ($p<0.5$) compared to those taking non-optimized, non-treated whey protein. Moreover, individuals supplementing with Ingredient Optimized whey protein also experienced significantly enhanced performance on bench press ($p<0.5$), squat ($p<0.5$), recovery time ($p<0.5$), and stomach discomfort ($p<0.5$), which was not reported from individuals taking the non-optimized control whey protein.

Keywords: Whey protein; Whey protein isolate; Exercise; Protein supplements; Lean muscle mass

Introduction

The purpose of the study is to examine the potential benefits of a patent-pending food technology, Ingredient Optimization, on whey protein and the effects of Ingredient Optimized® (io) whey protein (referred to as ioProtein®) on body composition and various markers of performance and strength. The rationale for studying this investigational supplement is based on Ingredient Optimization's ability to incite functional changes in the protein peptide. These changes have been shown to positively affect the main outcomes of this study: free fat mass, fat mass and participant strength before and after the experimental regimen. This study is intended to confirm the presence and extent of these effects on these variables.

The use of protein supplements among athletes and recreationally active adults is incredibly prevalent [1]. Current Dietary reference intake guidelines recommend a protein intake of 0.8 g/kg/day; however, research suggests that a protein intake of up to 2.8 g/kg/day can be safe and effective for individuals attempting to maintain or increase fat-free mass (FFM). Protein supplementation is a common choice for individuals seeking to increase their daily protein intake for the purpose of lean muscle enhancement. Due to a number of digestion-related factors, including rapid clearance of the small intestine, it is suggested that an average of only 15 g of dietary protein may actually be absorbed, even at higher intake levels. At these levels, the remaining protein is disregarded as waste, leading to possible stomach discomfort, and reducing the overall physical benefits of this dietary intervention. That said, it is well understood that adding protein supplementation to an exercise regime can increase muscle mass gains, and also improve an athlete's overall physical performance [1,2]. To date, two meta-analyses have been conducted to understand the impact of protein supplement use on direct measures of muscle mass and strength [3,4]. One reviewed the results from 22 randomized controlled trials, published between 1995 and 2010, in order to define the benefit of protein supplementation in terms of the adaptive response of skeletal muscle to resistance-type exercise more clearly [3]. Findings from this meta-analysis provided strong evidence that protein supplements significantly augmented gains in FFM and performance when compared resistance exercises without dietary protein supplementation.

Whey protein, a protein source derived from the cheese-manufacturing process, is one of the primary bovine-milk protein groups [5,6]. Whey protein is highly regarded for being rich in essential vitamins and minerals, and high levels of essential amino acids. Whey protein is available in a number of varieties, including whey concentrate, whey powder, and whey isolate. Table 1 compares the composition of each whey protein variety [7]. Of these three varieties, whey protein isolates are considered the purest source of protein available, containing protein concentrations of more than 90% and

Supplements	Whey concentrate	Whey powder	Whey isolate
Protein	25%-89%	11%-14.5%	90+%
Lactose	10%-55%	63%-75%	0.5%
Milk Fat	2%-10%	1%-1.5%	0.5%
*Adapted from Geiser [7].			

Table 1: Comparative compositions of whey concentrate, powder, and isolate*.

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only about 0.5% of lactose or milk fat [5]. In addition, whey protein isolates are rapidly absorbed into the body, allowing the protein to reach muscles faster, which can enhance muscle recovery, muscle mass gains, and transient increases in total body protein synthesis [8].

There have been no studies to date that have investigated whey protein that has undergone a structural change such as the patent pending ioProtein ingredient optimization process, which is believed to enhance the performance of the ingredients. As such, the primary aim of this study was to examine the relative benefit of this ioProtein whey protein isolate on several measures of body composition among a sample of athletes in comparison with those associated with an untreated whey protein isolate. This experimental condition will also be combined with a strenuous exercise routine.

Recruitment and subjects

Twenty (N=20) healthy male and female subjects with an average age of approximately 18 to 35 years of age were recruited. Assuming the same variation for both groups, it was determined that a minimum of 6 participants were needed in each group. However, 10 participants per group were recruited as a contingency for drop-outs (which were projected at >30% of the group due to the rigorous dietary and workout protocol). Volunteers for the study were recruited from a single exercise facility. Adult athletes who were over the age of eighteen (18) years of age at the time of the study were eligible to enrol. Eligible participants were those who had reported that they exercised regularly (defined as training at a minimum of four (4) days per week).

Exclusion criteria

Participants were not allowed to participate in this study if they had any known metabolic disorder including heart disease; arrhythmias; diabetes; thyroid disease or hypogonadism. Ineligible candidates also had a history of pulmonary disease; hypertension; hepatorenal disease; musculoskeletal disorders; neuromuscular/neurological diseases; autoimmune disease; cancer; peptic ulcers or anaemia. In addition, individuals taking any medications to treat any condition as above, or who took androgenic medications, were also ineligible for this study. In addition, individuals who had taken ergogenic levels of nutritional supplements that may affect muscle mass or aerobic capacity (e.g., creatine, HMB, or anabolic/catabolic steroid hormone analogues (e.g., androstenedione, DHEA, etc.) within six months prior to the start of the study were ineligible. People who had reported any unusual adverse events associated with this study that in consultation with the supervising physician were also advised to drop out from the study.

At the initiation of the study, twenty (20) adult athletes were recruited to participate. Participants were randomized into two groups: the experimental group (n=10) and the control group (n=10). Due to attrition, only fourteen (14) of the initial participant pool successfully completed all requirements before the study concluded and, thus, were included in the final analyses. The reasons for dropout included sustaining an injury during training and violating specific protocol directives, such as deviating from the outlined exercise schedule or dietary restrictions. The age of those included in the final sample ranged from 18 to 37 years of age (M=28.43, SD=6.43) and there were somewhat fewer females (n=5; 35.71%) than males (n=9; 64.29%). Table 2 details complete results of initial study participant measures.

Methods

This study utilized a single-blind, randomized clinical trial design, with two parallel intervention groups (i.e., the experimental group, receiving ioProtein®, and a control group, receiving a comparator non-optimized whey isolate protein) and two assessment points (i.e., pre-test and post-test). Each study participant was provided instruction to consume one serving of either the ioProtein® or the comparator whey protein, depending on their randomization group, each day following their exercise session. A serving was defined as one scoop of the provided whey protein, which provided 28 g of protein per serving across both groups. Participants were instructed to maintain their current diet; however, inclusion in the study required that they discontinue the use of any additional supplements besides those provided for the duration of the study. While enrolled, the dietary habits of all participants were closely monitored for compliance with study protocol. Individuals who deviated from the outlined diet restrictions were excluded from the final analyses. Participants were expected to remain engaged in the study for eight (8) weeks.

Variables	Experimental Group (ioProtein)	Control Group (Comparative Whey Protein)
Total (n)	8	6
Age range (Years)	18-37	25-36
Mean age (SD in parentheses)	26.75 (7.13)	30.67 (5.09)
Mean height (SD in parentheses)	69.5” (3.59)	67.5” (3.56)
SD: Standard Deviation.		

Table 2: Initial participant measurements by experimental group.

Safety and ethical considerations

Whey protein is regarded as probably safe for the majority of adults when consumed orally in an appropriate manner. There has been some suggestion that high doses of whey protein can cause side effects, such as nausea; bloating; abdominal cramps; more frequent bowel movements; thirst; reduced appetite; fatigue and headaches. The study was single-blinded as a safety-measure to address the exposure of lactose-intolerant subjects to lactose, so as to gather data on the purported ability of Ingredient Optimization technology to reduce protein-related stomach discomfort. Given that stomach discomfort can be a by-product of both lactose exposure and the fermentation of undigested protein in the gut, it was determined that the inclusion of lactose intolerant subjects would provide insight for the direction of future studies.

Informed consent

All individuals included in the study provided written informed consent for their participation and completed medical history questionnaires along with general information screening instruments. Participants also signed a written non-disclosure agreement, indicating that they would not discuss the study or their current progress with anyone else, including fellow participants. This study was approved and conducted in compliance with Institutional Review Board guidelines.

Study monitoring, data gathering and validity

The lead investigator was to be the sole investigator in the study, and as such the only person capable of monitoring for any significant adverse reaction. In order to overcome any potential bias resulting from a single-blinded study design, all analysis and data interpretation was conducted by a second blinded party. Participants were instructed that they would be administered a supply of whey protein and a directives sheet, specifying the amount of whey protein to consume and the frequency of the dosage. Participants remained blind to their randomization group and were not provided information on whether they received the Ingredient Optimized whey isolate or the comparator whey protein.

Measures

All anthropometric measurements were gathered using a medical Body Composition Analyzer (seca mBCA 514; seca North America, Chino, CA), which employs an 8-point bioelectrical impedance analysis that apportions weight into medically-relevant components [9]. The two measurements of interest to the current study were fat mass and FFM. Each participant's height was gathered using a mobile stadiometer (seca 213; seca North America, Chino, CA). Every effort was made to ensure that all measurements were gathered at the same time and on the same day of the week for both the pre-test and the post-test for each study participant. This was done to establish consistency in both the measurement equipment and the unique state of the participant, as well as to minimize the impact of variability from extraneous variables [10-12].

Body mass index (BMI): Each participant's Body Mass Index (BMI) was calculated for this study using measurements of height and weight. For purposes of this study, calculations of BMI were used as an added indicator of any increase or decrease in body composition (particularly body weight) from pre-test to post-test.

Fat-free mass (FFM): Global measures of body weight can provide an indication of changes in overall body composition from pre-test to post-test; however, these measures are inadequate in determining whether these changes occurred in terms of muscle mass, fat, or water. Thus, one of the critical factors measured in this study is the measure of muscle mass, which comprises the majority of Fat-Free Mass (FFM) [13-15]. It has been suggested that greater absolute FFM is related to higher daily energy expenditure, which leads to improved performance and a decrease in percentage of body fat (PBF) [16,17]. An increased metabolic rate and activity level contributes to more calories being burned during physical activity and, thus, added support in terms of losing or maintaining FFM [18].

Fat mass (FM): Fat mass (FM) can be grossly estimated as the difference in FFM from the individual total body weight. Thus, as noted above, an inverse relationship exists between FFM and FM: as FFM increases, FM decreases [16,17,19,20]. Athletes may be able to decrease FM through weight training and exercise while increasing their FFM. As this occurs, performance gains are expected to be apparent.

Percentage of body fat (PBF): An individual's percentage of body fat (PBF) is estimated as the total FM divided by total body mass. Calculations of PBF can be used as a general measure of fitness, given that it determines an individual's relative body composition without regard to their height or weight measurements. As such, PBF was used in the current study as an indicator of potential changes in body composition from pre-test to post-test.

Strength: Measures of each athlete's maximum ability in bench presses and squats (per repetition) were gathered at pre- and post-test time points.

Stomach discomfort and digestion: Psychometric measures of the protein's taste, impact on stomach distress, and post-training recovery time following ingestion of the protein supplement were gathered during the trial.

Results

The statistical analysis used to evaluate for changes in the study variables from pre-test to post-test was an independent samples t-test using IBM SPSS Statistics Package for Mac, Version 19 (IBM Corp., Armonk, NY). Differences were examined using a 95% confidence interval. Findings were considered statistically significant provided that they achieved a p-value of less than 0.05. Both within-group and between-group differences were explored. Preliminary analyses were conducted to eliminate potential pre-existing group differences. An independent samples t-test was performed, and results indicated that there were no significant differences in terms of mean group age ($p=0.44$), height ($p=0.39$), and BMI ($p=0.30$) across both the experimental and the control group conditions.

Results from independent samples t-tests examining for both within-group and between-group differences in pre-test versus post-test BMI, weight, percentage body fat, and fat mass did not reveal significant findings. Within the experimental group, significant differences in lean body mass were noted when comparing pre-test ($M=140.75$) scores to post-test ($M=142.55$) scores ($p<0.05$) (Figure 1). In terms of the objective measures of strength, post-test ($M=198.33$) ratings of maximum bench press ability were significantly increased compared to pre-test measures ($M=188.33$) within the experimental group only ($p<0.05$) (Figure 2). Similarly, reported ratings of maximum squat ability was significantly increased post-test ($M=237.50$) compared to pre-test ($M=224.38$) within the experimental group alone ($p=0.004$) (Figure 3). In terms of psychometric measures of stomach discomfort and digestibility, the reported rate of recovery was significantly faster for the experimental group compared to the control group (Figure 4). Additionally, those in the experimental group saw a significant reduction in stomach discomfort after taking the investigational whey protein supplement relative to those in the control group (Figure 5). Two (2) participants in the experimental group and zero (0) in the control group were reported to be lactose-intolerant. Only one (1) participant in the experimental group reported experiencing an adverse event (flatulence) after taking the supplement, while two (2) reported this in the control group.

Figure 1: Comparison of total lean body mass increase (lbs) of experimental protein group and control protein group change 0- week 8.

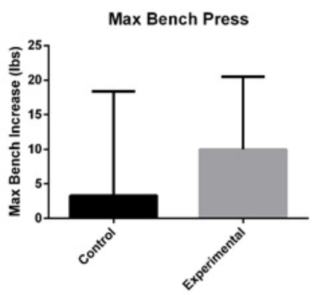

Figure 2: Comparison of 1 repetition bench press increase (lbs) of experimental protein group and control protein group change 0- week 8.

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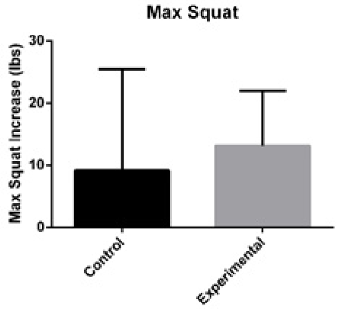

Figure 3: Comparison of 1 repetition max squat increase (lbs) of experimental protein group and control protein group change 0- week 8.

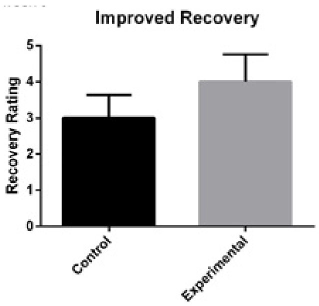

Figure 4: Comparison of psychometric recovery rating of experimental protein group and control protein group.

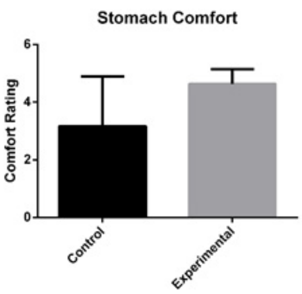

Figure 5: Comparison of psychometric reduction in stomach discomfort rating of experimental protein group and control protein group.

Ingredient optimization and the resulting ioProtein® appear to be safe and effective when the high safety profile of both the technology and protein, combined with the total absence of adverse effects observed during and after the trial among participants using ioProtein, is taken into consideration. The process appears to have, the potential to enhance the already high safety profile of whey protein.

Discussion

Results from this trial indicated that FFM increased as a result of the trial's regimen for the experimental group alone. This indicates a confirmation of the existing literature suggesting that whey protein supplementation provides benefits for FFM when taken in conjunction with strenuous exercise. Moreover, the increase in FFM occurred only in the investigational group provides evidence for the relative benefit of ingredient optimization technology on whey protein when compared to a non-optimized, non-treated whey protein.

The importance of the significant difference between objective FFM is further bolstered by findings from the strength and psychometric results. More specifically, individuals in the experimental group, though blinded to the intervention, reported that their performance in both the bench press and squat was enhanced from pre-test to post-test. This was not observed among those in the control group. Moreover, individuals in the experimental group reported the Ingredient Optimized-whey protein isolate produced reduced stomach discomfort and that they were able to recover faster following the eight-week supplementation regimen, whereas the control group did not demonstrate these notable differences. It is generally regarded that bioavailability is related to a number of key human physiological outcomes including improved lean muscle mass. This is related to enhanced muscle protein synthesis, and a reduction in stomach discomfort produced by more complete protein digestibility [21,22]. It is proposed that one of the key mechanisms for improved physiological response to Ingredient Optimized protein (ioProtein) is improved protein bioavailability through ingredient optimization technology. Given this hypothesis, the increase in FFM and the reduced stomach discomfort among subjects taking ioProtein is in accordance with our expectations. Further studies could explore the specific improvements ingredient optimization has on measures of protein bioavailability, including measures related to the absorption of specific amino acids.

Conclusion

In sum, findings from this study suggest that consumption of patent pending, ingredient optimized whey isolate (ioProtein®) not only provides a significantly increased benefit in lean muscle mass and strength but may also allow athletes to recover faster from exercise and be easier on the stomach to digest than comparison whey protein supplements on the market.

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