Minnesota Applied Research Center
18894 Lake Drive East, Chanhassen, MN 55317
Ph: 952-974-4370, Fax: 952-937-7667

FINAL REPORT

A Prospective, Randomized, Double Blind Study to Evaluate the Effect of Lean Source™ on Body Composition in Overweight Adult Men and Women

Sponsors: **Life Time Fitness, Inc.**
6442 City West Parkway
Eden Prairie, MN 55344

Principal Investigator: **John L. Zenk, MD**
Minnesota Applied Research Center
18894 Lake Drive East-Suite 180
Chanhassen, MN 55317

Investigator: **Sandra A. Leikam, RN**
Minnesota Applied Research Center
18894 Lake Drive East-Suite 180
Chanhassen, MN 55317

Statistician: **Michael A. Kuskowski, PhD**
Geriatric Research Education and Clinical Center
Veterans Administration Medical Center
One Veterans Drive
Minneapolis, MN 55417

Pertinent Dates:
Submitted to IRB-02/19/03
Accepted by IRB-03/05/03
Recruitment Ads-03/29/03
Patient Screening-03/31/03
Study Initiation-04/21/03
Study Completion-06/27/03
Statistical Analysis Completion-08/22/03

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18894 Lake Drive East, Chanhassen, MN 55317
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Abstract

Objective: This study evaluated the effect of a formula containing 7-oxo-DHEA, conjugated linoleic acid, chromium picolinate, bitter orange extract and green tea extract (Lean Source™) on body weight, body composition, body mass index (BMI) and basal metabolic rate (BMR) in overweight patients on a reduced calorie diet and exercise regimen.

Methods: In this prospective, randomized, double-blind, placebo-controlled trial, healthy, overweight adults were given two gelcaps of Lean Source twice daily or an identical placebo and followed a calorie restricted diet and an exercise program for eight weeks. Body weight, BMI, BMR, waist and hip circumference, and body composition by dual energy x-ray absorptiometry (DEXA) were measured at baseline and week 8.

Results: Of 65 adults enrolled, 54 completed the study (38 women, 16 men; age 25-45 years) with a mean BMI of 32.2 kg/m². Patients taking Lean Source had a significant ($p=0.046$) decrease in percent body weight losing 2.94 ± 1.91% (2.9 ± 1.9 kg) compared to a decrease of 1.68 ± 2.82% (1.5 ± 2.6 kg) in the placebo group. There were no other statistically significant differences in any of the other primary or secondary outcome variables. Lean Source was well tolerated and there were no serious adverse events

Conclusion: The results of this study reveal that when combined with a reduced calorie diet and a moderate exercise program, Lean Source was more effective at reducing body weight than exercise and diet alone.

Keywords: 7-oxo DHEA, weight loss, obesity, conjugated linoleic acid, chromium.

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18894 Lake Drive East, Chanhassen, MN 55317
Ph: 952-974-4370, Fax: 952-937-7667

Study Description

Objective: To evaluate the effect of LeanSource™ vs. Placebo administration on weight loss, body composition, and basal metabolic rate in overweight patients on a calorie restricted diet and exercise regimen.

Hypothesis:

1. Patients taking LeanSource and following a program of exercise and calorie restriction will have a significantly greater decrease in body weight, waist and hip circumference and body fat over eight weeks, as compared to those taking placebo and following the same program.
2. Patients in the LeanSource treatment group will have significantly less reduction in basal metabolic rate associated with weight loss, as measured by indirect calorimetry.
3. Patients in the LeanSource treatment group will have an incidence of adverse events that is not significantly different from the placebo group.

Patients: Healthy adults aged 25 to 45 years with a BMI ≥ 27 and ≤ 40 kg/m^2 were eligible for the study. Individuals with hepatic or renal disease, diabetes, unstable cardiovascular disease, uncontrolled hypertension, eating disorder, active cancer, human immunodeficiency virus infection, AIDS or surgery for weight loss were excluded from the study. Patients were also excluded if they were using medications for weight loss or were pregnant or lactating. This study was approved by the Quorum Review, Inc. An Institutional Review Board – Seattle, WA. All participants gave their written informed consent.

Study Design and Duration: This was a prospective, randomized, double blind, placebo controlled trial. The study duration was eight weeks. Patients were randomized to receive LeanSource orally twice daily or an identical placebo (soy bean oil). Baseline medical history, vital signs, height, waist and hip circumference, chemistry profile and complete blood count, basal metabolic rate (by indirect calorimetry, Delta Track II Metabolic Monitor, Sensor Medics), body composition (by bioelectric impedance, Quantum II BIA, RJL Systems and dual energy x-ray absorptiometry, DEXA) and health assessment measurement (12-Item Short Form Health Survey version 2, SF-12v2™) were obtained at the initial visit and then at 4 and 8 weeks, except for the laboratory work and DEXA which were done at baseline and at the completion of the study and height which is measured only at Week 0.

At the initial visit, all patients were interviewed by a registered dietician and prescribed a reduced calorie diet. The basal metabolic rate (BMR) of each patient was determined, and the total daily energy expenditure was estimated by multiplying BMR X 1.2. Daily caloric intake was set at approximately 600 kcal less than the estimated energy requirement, to achieve a weight loss of approximately 1-1.5 pounds per week. The composition of the diet was 45% of calories as carbohydrate, 25% as protein, and 30% as fat. The exercise program consisted of cardiovascular exercise for 30 minutes, 3 times per week and resistance training 3 times per week for 30 minutes per session. The exercise protocol was completed at a local health club facility and personal training staff were assigned to each patient for orientation and programming on all equipment and were available for questions or concerns regarding the study exercise protocol. Patients were asked to complete a diary, recording each exercise session, and a daily food diary on designated days.

Patients were monitored with monthly clinic visits to assess compliance with the study supplement, diet and exercise. Compliance with the study supplement was assessed by pill count and diet and exercise by review of the exercise diary and the two-day food intake diary. Patients were also contacted by telephone between clinic visits to review diet and exercise compliance.

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Study Description (Continued)

Measurements: The parameters necessary to evaluate the primary and secondary end-points were obtained utilizing the following standard techniques.

1. Body Weight – Patients were weighed in a paper exam gown after disrobing using a Tanita TBF-300 digital scale (Tanita Corp, Arlington Heights, Illinois).
2. Body Mass Index and Total Body Water – BMI and total body water were assessed using a Quantum II Bioelectric Impedance Analysis Instrument (RJL Systems, Clinton Township, Michigan).
3. Body Composition – Body composition was assessed using a Dual-Energy X-ray Absorptiometry (DEXA) Scan, Lunar DPX-IQ Pencil Beam Instrument.
4. Basal Metabolic Rate – BMR was determined by indirect calorimetry using a Deltatrac II Metabolic Monitor (Sensor Medics Corp, Yorba Linda, California).
5. Vital Signs – digital automated instruments. Included were blood pressure, pulse, temperature and height.
6. Waist and Hip circumference – Waist and hip circumference measurements were performed with the patients in an exam gown using a Tech-Med, model #4414 measuring tape according the following technique: waist circumference obtained at the midpoint between the level of lowest rib and the top of the anterior iliac crest and hip circumference obtained at the level of largest diameter below the anterior iliac crest.
7. Laboratory studies – Blood specimens were obtained using standard technique by the investigators. Specimens were analyzed by Quest Diagnostics Laboratory in Minneapolis, Minnesota. Included were a Chemistry Profile and a Complete Blood Count (CBC).
8. Health Assessment Measurement Tool – 12-Item Short Form Health Survey, (SF-12v2™)

Statistical Analysis: Baseline characteristics were compared between groups using Mann-Whitney tests except Chi-Square test for gender. The computed change from baseline was compared for all measured variables and expressed as the mean, with variability expressed as the standard deviation (SD) except for body weight, BMI, body fat percentage, waist and hip circumference and SF-12v2 mental health subset score which were expressed as the mean percentage change, with variability expressed as the SD to account for the differences between the groups at baseline for this variable. All data analyses were conducted on patients who completed the study. Eleven patients (5 in the Lean Source group and 6 in the placebo group) dropped out of the study on or before week 4. Considering the large percentage of patients not completing the study protocol, an intent-to-treat analysis was performed with last observation carried forward and this analysis revealed similar results to the analysis of the study completers. Statistical significance was set at $p<0.05$.

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Study Results

Study Population: Sixty-five patients (45 women, 20 men) enrolled in the study. The mean age of the participants was 37.7 years (range, 25-45 years), mean body weight was 95.6 kg, and mean BMI was 32.5 kg/m^2 (range, 27.0 –39.7). Of the 65 patients randomized, 54 completed the study-27 in the Lean Source treatment group (19 women and 8 men) and 27 in the placebo group (19 women and 8 men). (Table 1). There were no significant differences in baseline characteristics between the 2 treatment groups, except for body weight, BMI, body fat percentage, waist and hip circumference; the Lean Source group had higher values in each of these variables than the placebo group. Of the eleven study non-completers, 6 withdrew from the placebo treatment group (3 women, 3 men); 3 patients had personal scheduling conflicts which precluded further visits to the research center, 2 patients were lost to follow-up and 1 patient moved out of state. 5 patients withdrew from the Lean Source treatment group (4 women, 1 man); 1 patient had personal scheduling conflicts which precluded further visits to the research center, 2 patients were lost to follow-up, 1 patient was called to jury duty and 1 patient developed bacterial pneumonia. Throughout the study, there were no significant differences in dietary compliance (the amount of carbohydrate, protein, fat, and total kilocalories consumed), exercise compliance, or medication compliance between the 2 groups.

Table 1: Baseline Characteristics

Variable	Lean Source* (n = 27)	Placebo (n = 27)	p ‡
Sex, no. Male Female	 8 19	 8 19	 0.99
Age, y†	38.8 ± 5.9	37.8 ± 6.0	0.56
BMI, kg/m^2†	33.6 ± 2.1	30.7 ± 3.3	0.001
BMR, kcal/d†	2254.8 ± 452.3	2021.5 ± 252.3	0.09
Body Weight, kg†	99.7 ± 11.8	89.3 ± 12.7	0.002
Height, cm†	171.9 ± 8.9	169.7 ± 7.5	0.54
Body Fat, kg†	42.6 ± 6.5	36.1 ± 9.1	0.002
Body Lean Tissue, kg†	52.7 ± 5.8	55.6 ± 7.4	0.19
SBP, mmHg†	133.3 ± 9.2	133.8 ± 12.8	0.70
DBP, mmHg†	77.8 ± 9.5	78.5 ± 8.3	0.86
Heart Rate, bpm†	77.7 ± 11.7	74.6 ± 8.8	0.42
Total Body Water, L†	46.3 ± 10.2	42.5 ± 8.1	0.12
Waist circumference, cm†	104.6 ± 9.8	97.1 ± 10.7	0.01
Hip circumference, cm†	120.5 ± 8.6	113.4 ± 8.8	0.005

BMI= body mass index, BMR=basal metabolic rate, SBP=systolic blood pressure, DBP=diastolic blood pressure
**Trademark: LifeTime Fitness, Inc. – Eden Prairie, MN*
†*Mean ± SD*
‡*p value (Mann-Whitney Test except Chi-Square for gender)*

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Study Results (Continued)

Between Group Differences in Primary Outcome Variables
Table 2 lists the mean change ± SD from baseline to week 8 for each of the primary outcome variables in each treatment group. Analysis of these data with the Mann-Whitney test revealed that the percentage weight change was significantly different (p=0.046) between the two groups with the Lean Source group losing a higher percentage of body weight than the placebo group. (Note: In tables 2-3, a positive mean change indicates a decrease or loss and a negative mean change indicates an increase or gain in that variable)

Table 2: Changes in Primary Outcome Variables From Baseline to Week 8.

Variable	Lean Source™ (n = 27)	Placebo (n = 27)	p‡
BMI, kg/m^2¥	2.97 ± 1.95	1.73 ± 2.81	0.061
BMR, kcal/d†	132.22 ± 285.34	112.3 ± 199.85	0.68
Body Weight, %¥	2.94 ± 1.91	1.68 ± 2.82	0.046
Body Fat, %¥	5.85 ± 4.15	5.10 ± 6.17	0.74
Lean Tissue, %¥	-3.02 ± 2.85	-2.19 ± 3.11	0.26
Waist circumference, cm¥	3.50 ± 2.13	3.66 ± 2.81	0.64
Hip circumference, cm¥	2.61 ± 1.84	2.10 ± 1.91	0.57

†Mean ± SD change from baseline to week 8.
¥Percent ± SD change from baseline to week 8
**Trademark: LifeTime Fitness, Inc. – Eden Prairie, MN*
‡p value (Mann-Whitney Test)

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Study Results (Continued)

Between Group Differences in Secondary Outcome Variables
There were no significant between-group differences in any of the other measured variables. Specifically, there were no between group differences in the following measured variables: heart rate, temperature, systolic blood pressure, diastolic blood pressure, carbohydrate intake, protein intake, fat intake, total kcal intake, total body water, medication compliance, exercise compliance or adverse events. See Table 3.

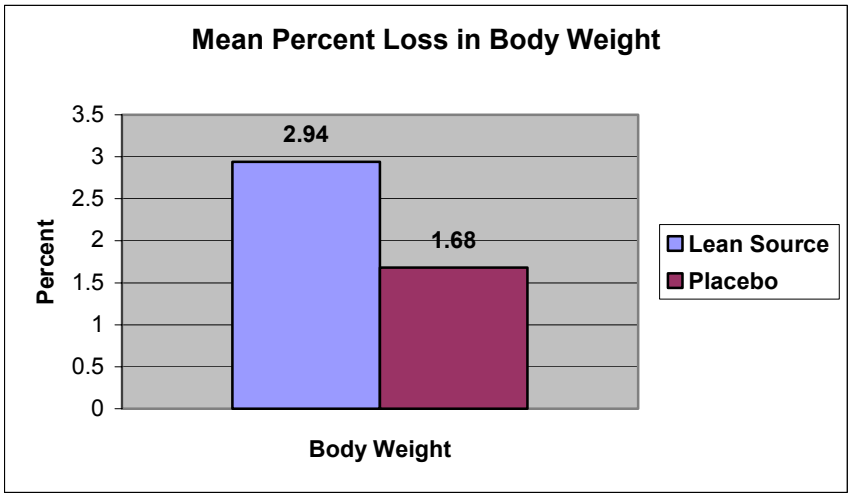
Table 3: Mean Changes from Baseline in the Secondary Outcome Variables.

Variable	Lean Source™* (n = 27)	Placebo (n = 27)	p‡
Heart Rate, bpm†	5.96 ± 13.64	5.30 ± 10.68	0.84
Temperature, °C†	-0.02 ± 0.81	0.14 ± 0.59	0.40
SBP, mmHg†	-1.67 ± 9.45	2.67 ± 12.00	0.15
DBP, mmHg†	0.26 ± 10.12	2.66 ± 8.01	0.34
Carbohydrate Intake, g†	27.22 ± 81.89	55.96 ± 80.62	0.20
Protein Intake, g†	-5.30 ± 37.65	-7.15 ± 34.61	0.85
Fat Intake, g†	24.26 ± 49.80	13.63 ± 38.60	0.39
Total kcal Intake, kcal†	306.04 ± 706.13	317.93 ± 705.54	0.95
Total Body Water, %†	-0.39 ± 1.92	-1.21 ± 1.91	0.12
Capsule Discrepancy, #	-4.15 ± 5.68	-9.81 ± 16.74	0.10
Exercise Noncompliance, #	7-cardio 7-resistance	6-cardio 6-resistance	0.80 0.80
Adverse Events, #	4	5	0.99

†Mean ± SD change from baseline to week 8.
**Trademark: LifeTime Fitness, Inc. – Eden Prairie, MN*
‡p value (Mann-Whitney Test)

Figures 1 through 8 illustrate the mean change from baseline for each of the primary outcome variables in each of the treatment groups.

Figure 1: Mean Percent Change in Body Weight



Study Results (Continued)

Figure 2: Mean Change in Body Weight

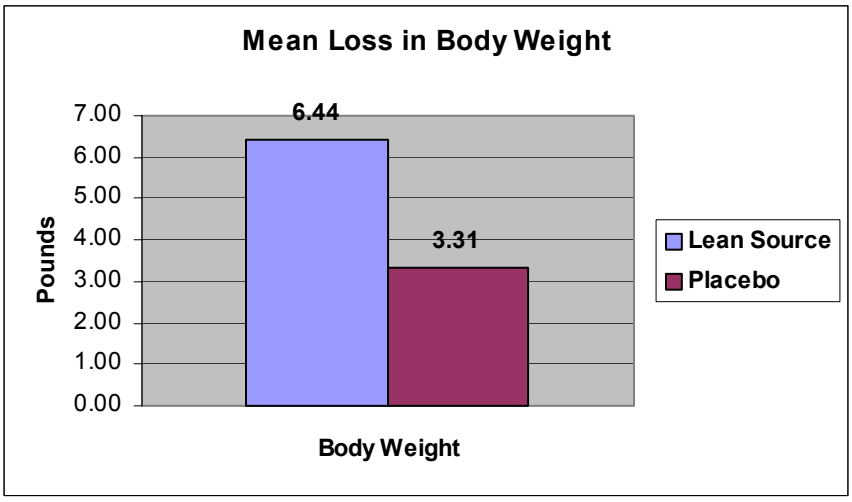
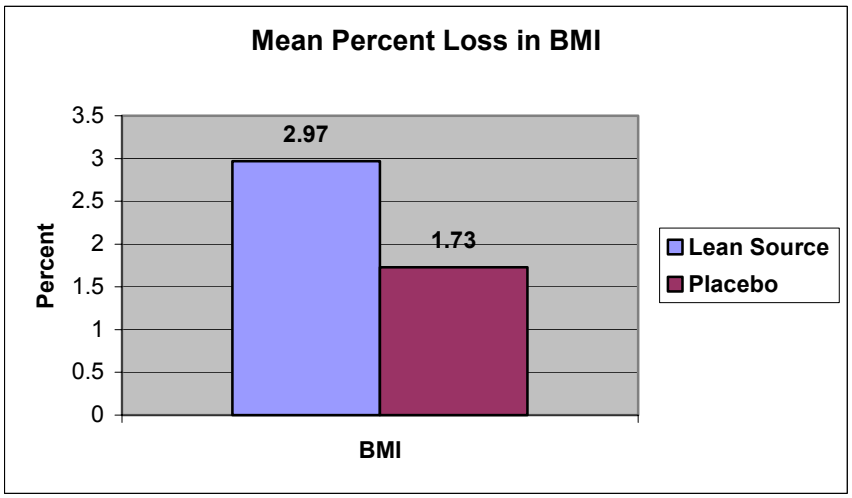


Figure 3: Mean Percent Change in BMI



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Study Results (Continued)

Figure 4: Mean Change in BMR

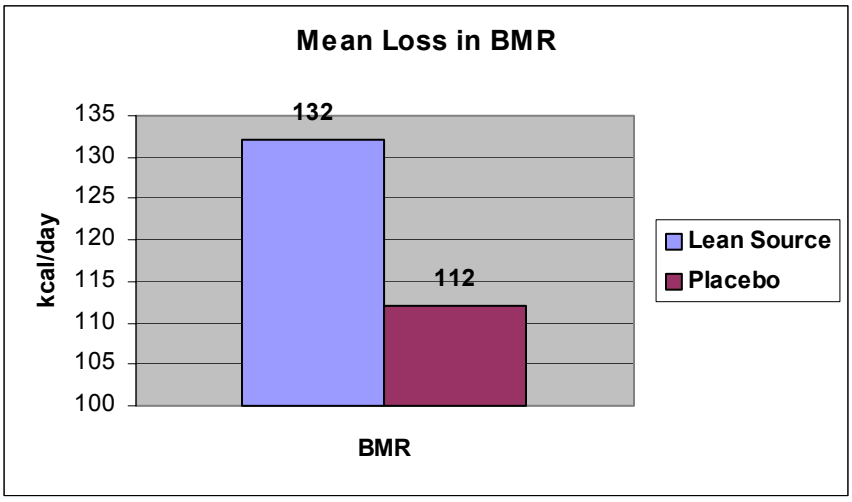
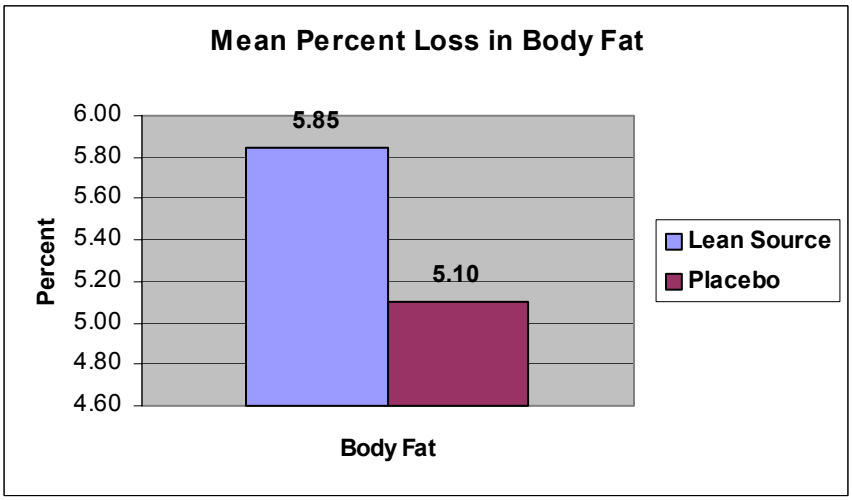


Figure 5: Mean Percent Change in Body Fat



Study Results (Continued)

Figure 6: Mean percent Change in Lean Tissue

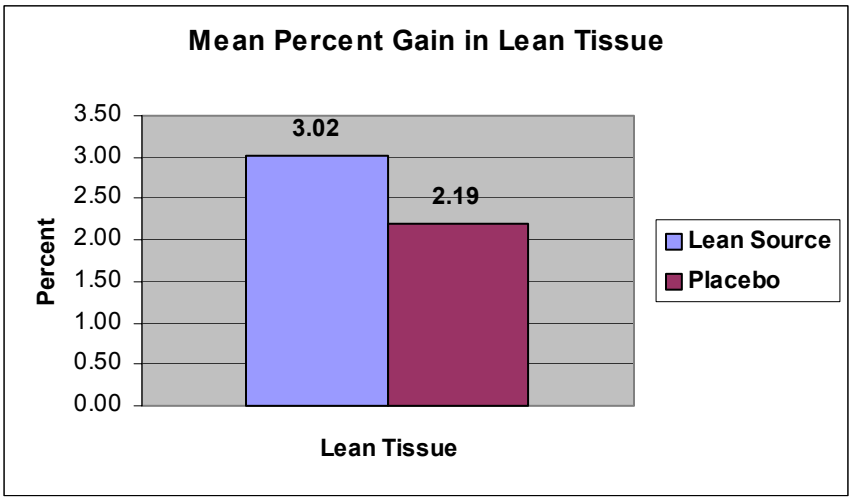
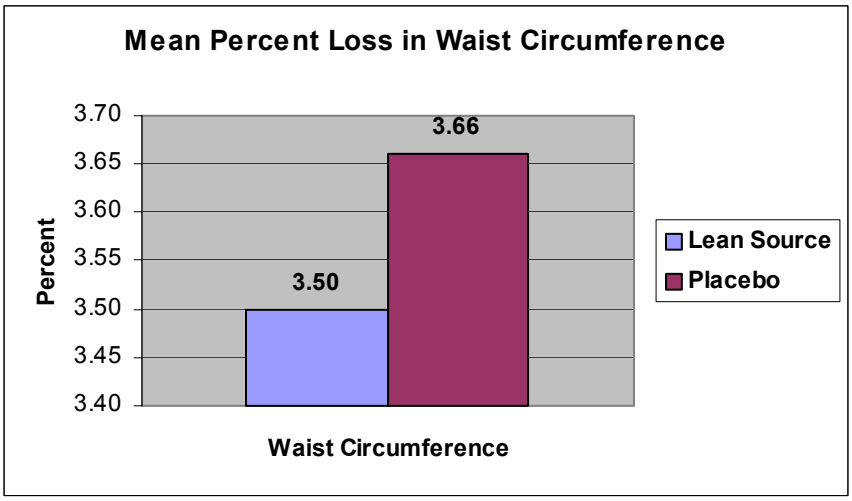


Figure 7: Mean Percent Change in Waist Circumference Measurement



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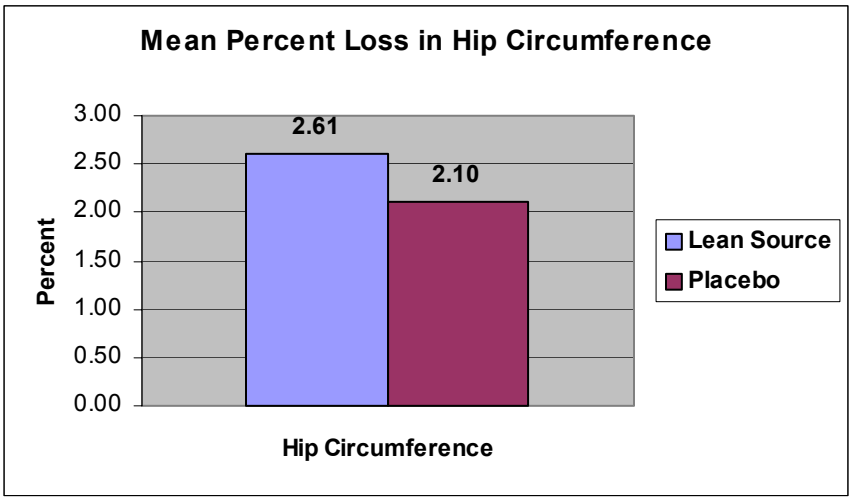
Study Results (Continued)

Figure 8: **Mean Percent Change in Hip Circumference Measurement**



Results of SF-12v2™ General Health Survey
The SF-12v2 has 8 subset scores and two composite scores that were examined as separate measured variables. They include: PF-physical functioning, RP-role physical, BP-bodily pain, GH-general health, VT-vitality, SF-social functioning, FE-role emotional, MH-mental health, MCS-mental component score and PCS-physical component score. MCS and PCS are composite scores. The raw SF-12v2 scores are converted via a scoring algorithm to norm-based scores. In norm-based scores, the general population norm is built into the scoring algorithm so that scores above or below 50 can be interpreted as being above or below the general population norm.

Table 4 lists the norm-based scores for each of the 8 subset scores and two composite scores for each treatment group and Table 5 lists the mean change in each score from baseline to week 8. A comparison of the baseline scores of each of the SF-12v2 measured variables in the Lean Source group and the placebo group revealed significant differences in the MH subset score (p=0.04) and the PCS and MCS composite scores (p=0.04 and 0.03, respectively). A comparison of the mean change scores between the two treatment groups reveals that the percent change in the MH subset score was significantly different (p=0.008) with the placebo group having a significant improvement in their mental health status during the study period.

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Study Results (Continued)

Table 4: Norm-Based SF-12v2 Scores for each Treatment Group at Baseline and Week 8 with Baseline Score Analysis Between the Groups.

Variable	Week	Lean Source™* n=27	Placebo n=27	P‡
PF†	0	51.37 ± 6.42	51.70 ± 6.88	0.71
	8	52.97 ± 5.46	53.61 ± 5.33	-
RP†	0	51.04 ± 6.26	51.55 ± 7.60	0.52
	8	52.40 ± 5.34	54.45 ± 4.65	-
BP†	0	53.67 ± 5.76	54.42 ± 6.20	0.45
	8	53.29 ± 5.83	53.29 ± 6.48	-
GH†	0	43.13 ± 5.40	51.21 ± 6.95	0.12
	8	50.17 ± 5.87	53.20 ± 5.38	-
VT†	0	49.61 ± 7.40	48.50 ± 8.79	0.60
	8	54.08 ± 5.68	52.97 ± 8.07	-
SF†	0	53.58 ± 6.75	51.70 ± 6.49	0.15
	8	53.95 ± 5.31	52.46 ± 7.55	-
RE†	0	52.97 ± 4.74	49.66 ± 7.86	0.14
	8	51.93 ± 6.12	50.49 ± 6.39	-
MH†	0	52.58 ± 6.44	48.26 ± 8.91	0.04
	8	52.58 ± 6.21	51.90 ± 8.44	-
PCS†	0	50.72 ± 4.46	53.36 ± 6.43	0.04
	8	52.33 ± 5.14	54.49 ± 5.81	-
MCS†	0	52.62 ± 5.33	48.08 ± 9.23	0.03
	8	52.81 ± 5.49	50.74 ± 9.19	-

†Mean ± SD
**Trademark: LifeTime Fitness, Inc. – Eden Prairie, MN*
‡p value (Mann-Whitney Test)

Minnesota Applied Research Center
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Study Results (Continued)

Table 4.2: Mean Change in Norm-Based SF-12v2 Scores for Each Treatment Group

Variable	Lean Source™* n=27	Placebo n=27	p‡
PF†	1.59 ± 5.85	1.91 ± 6.45	0.69
RP†	1.36 ± 7.21	2.90 ± 5.14	0.33
BP†	-0.38 ± 6.62	-1.13 ± 7.11	0.91
GH†	1.01 ± 7.36	2.00 ± 6.66	0.88
VT†	4.47 ± 6.44	4.47 ± 11.28	0.94
SF†	0.37 ± 4.41	0.75 ± 9.67	0.59
RE†	-1.04 ± 4.40	0.83 ± 7.06	0.13
MH¥	0.01 ± 0.15	0.11 ± 0.23	0.008
PCS†	1.62 ± 5.55	1.13 ± 4.98	0.99
MCS†	0.19 ± 4.98	2.66 ± 10.66	0.12

†Mean ± SD change from baseline to week 8.
¥Percent ± SD change from baseline to week 8.
**Trademark: LifeTime Fitness, Inc. – Eden Prairie, MN*
‡p value (Mann-Whitney Test)

Safety and Tolerability
There were no significant between-group differences in vital signs (systolic and/or diastolic blood pressure, heart rate and temperature). There were also no significant differences in the chemistry profile and complete blood count between the two groups. Furthermore, there were no between group differences in the number of adverse events experienced by patients in either group. With regard to adverse events, the Lean Source group reported 4 adverse events; 2 patients reported constipation that was considered possibly related to treatment. The placebo group reported 5 adverse events. No serious adverse events were reported. The incidence of all adverse events, regardless of whether they were thought to be related to the study supplement, is listed in Table 5.

Table 5: Number of Patients Reporting each Adverse Event

Adverse Event	Lean Source™* (n = 27)	Placebo (n = 27)
Nausea	-	1
Constipation	2	-
Headache	-	1
Peripheral Neuropathy	-	1
Skin Rash	-	1
Memory Deficit	-	1
Back Pain	1	-
Pneumonia	1	-

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Discussion

In this study the treatment group taking Lean Source experienced a significantly greater reduction in body weight than did the group taking placebo over an 8 week period. Patients taking Lean Source had a significant (p=0.046) decrease in percent body weight losing 2.94 ± 1.91% (2.9 ± 1.9 kg) compared to a decrease of 1.68 ± 2.82% (1.5 ± 2.6 kg) in the placebo group. There were no statistically significant differences in the amount of carbohydrate, protein, fat or in total kilocalories consumed between the 2 groups, nor was there a significant difference in total body water, exercise compliance or medication compliance. Therefore, the difference in body weight is attributable to Lean Source and not a lack of compliance in the placebo group.

In regard to the baseline characteristics of the patients in this study, the patients were carefully screened in regard the study inclusion and exclusion criteria. All 65 patients enrolled qualified with a BMI of 27-39.7 (mean = 32.5 kg/m^2) and were 69.1% female and 30.1% male. These 65 patients were then blindly randomized to one of two treatment groups. The 54 patients who completed the study had a mean BMI of 32.2 kg/m^2 and were 70.4% female and 29.6% male with equal numbers of men and women in each treatment group. Despite this prudent preparation a greater percentage of patients with a BMI > 32.0 kg/m^2 became randomized to the Lean Source treatment group. The Lean Source group had 63% of its patients with a BMI > 32.0 kg/m^2 as compared to the Placebo group who had only 33% of its patients with a BMI > 32.0 kg/m^2. This inequity in randomization resulted in a statistical difference in 5 of the 14 primary outcome variables; body weight, BMI, body fat %, waist circumference and hip circumference. It is clear to see that the difference in these particular variables is directly proportional to the higher BMI's of the patients in the Lean Source group. As stated in the statistical analysis section in this report, this difference in the baseline characteristics between the two treatment groups required an analysis of the percentage change in these primary outcome variables to recognize the baseline differences in these particular variables.

Although not statistically significant, the trend demonstrated by the Lean Source treatment group in regard to the change body fat percentage and lean tissue percentage is worthy of note. The Lean Source treatment group lost a higher percentage (5.85% vs. 5.10%) of body fat and gained a higher percentage (3.02% vs. 2.19%) of lean tissue than the placebo group. Of these two variables, the increase in lean tissue percentage by the Lean Source group was more statistically relevant (p=0.26) than the loss in body fat percentage (p=0.74).

The SF-12v2 is a general health survey measurement instrument and the results of this study reveal that general health parameters in each group did not differ from each other except for the mental health subset score which revealed that the placebo group had an 11% improvement versus no change in the Lean Source group. A significant change in the SF-12v2 was not expected and was included in this study to rule out any adverse effects on general health functioning in either of the treatment groups. The results reveal that neither the Lean Source group nor the placebo group suffered any decline in measured general health parameters throughout the study period.

It should also be noted that there were no significant changes in vital signs, laboratory work or adverse events between the two treatment groups. This convincingly demonstrates that oral administration of Lean Source is safe and has a side effect profile that is no different than placebo. This is particularly important considering that Lean Source is a unique new formula with a combination of ingredients that have never been studied previously.

There was one adverse event noted in the Lean Source group that could be possibly related to Lean Source administration. Two patients experienced mild constipation approximately two weeks after starting Lean Source capsules. These symptoms did not persist and were not serious but bear monitoring in future studies.

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Conclusion

The results of this study reveal that when combined with a reduced calorie diet and a moderate exercise program, Lean Source was more effective at reducing body weight over an 8-week period than exercise and diet alone. Lean Source was well tolerated, and there were no serious adverse events.

Proposed Lean Source™ Claims Based on the Results of this Clinical Study*:

1. Lean Source™ when combined with a program of reduced calorie diet and modest exercise will result in two times or 100% faster weight loss than diet and exercise alone
2. 100% Faster Weight Loss Than Diet and Exercise Alone.
3. Two (2) Times More Weight Loss Than Diet and Exercise Alone.
4. Clinically Proven Formula for Accelerating Weight Loss.
5. Clinically Proven Safe, When Used as Directed.
6. Clinically Proven to Have No Stimulant Side Effects.

** Claims are based on the statistically significant findings of this clinical study and have not been subject to legal review for advertising purposes.*

Respectfully Submitted,

John L. Zenk, MD
Principal Investigator