Summary of Body Composition Changes During the UltraMeal Challenge 2003

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ABSTRACT

The UltraMeal Challenge 2003 was a contest conducted in the U.S. between January 1, 2003 and May 31, 2003 by Metagenics, Inc. A criterion for participation in the UltraMeal Challenge was assessment of body composition by the participant's clinician using a standardized Bioelectrical Impedance Analysis (BIA) machine. We have performed a retrospective analysis on the complete data sets obtained during the UltraMeal Challenge for all participants who completed a 12-week, practitioner-supervised UltraMeal Body Composition Program within the contest timeframe. The data analyzed for 112 women showed a significant decrease in body fat of 1.99% ($p < 0.005$) with a corresponding increase in lean mass of 2.75% ($p << 0.0001$). Likewise, the data sets from 20 men participating in the Challenge also showed a significant 2.38% decrease in body fat ($p < 0.05$) and an increase of 4.2% lean mass ($p < 0.005$). Body Mass Index (BMI) also improved significantly in both women and men, resulting in a decrease of 1.8 kg/m^2 ($p << 0.0001$) and 2.5 kg/m^2 ($p < 0.0001$), respectively. The greatest improvement in body composition was observed in those who initially had the highest body fat. For example, the 99 women starting the Challenge with 30% or more body fat reported an average decrease of 3.1% body fat, and the 18 men beginning the program with body fat above 20% showed an average decrease of 3.8% body fat after the Challenge. Both systolic and diastolic blood pressure (BP) readings showed significant decreases in men and women as well. These data support the published studies with UltraMeal, which show that this soy-based medical food promotes healthy body composition by an increase in relative lean mass during loss of fat mass.

INTRODUCTION

Body composition is determined by the amount of fat mass compared to fat-free (lean) mass. Maintaining healthy body composition during aging has been linked to lower risk of cardiovascular disease (CVD), metabolic syndrome (or syndrome X), and development of type 2 diabetes.[1-3] Therefore, much research and clinical emphasis has been focused on how to establish and maintain healthy body composition.

Historically, total weight, body mass index (BMI), and skin-fold thickness have been used as measures of body composition. However, research over the past decade has established that bioelectrical impedance analysis (BIA) is a more reliable measurement of body composition than are other clinical measures.[4,5] Studies have shown that the estimation of body composition with BIA is reliable and comparable to more rigorous research approaches to body composition assessment, such as dual-photon absorptiometry.[6] Easy-to-use, inexpensive equipment has made BIA a useful clinical tool for monitoring body composition.

An analysis of 5225 healthy subjects between 15 and 98 years was performed using BIA to determine the optimal body composition values. In this study, the greatest lean mass for men was found in the 35 to 44 year old group, in which the top 50% of the men had between 11.0% and 19.5% fat mass. The greatest lean mass for women was found in the 45 to 54 year old group, in which the top 50% of the women had 18.0% to 27.9% fat mass.[7]

UltraMeal is an isoflavone- and soy protein-based medical food designed to nutritionally support the management of conditions associated with altered body composition, such as dyslipidemia, hypertension, metabolic syndrome, and estrogen imbalance. The UltraMeal Body Composition Program, which includes

a dietary plan and regular exercise, is also designed to help reduce the risk to CVD and diabetes. Clinical studies with UltraMeal have shown that it promotes healthy body composition by the retention of lean mass during loss of fat mass.[8-10] The UltraMeal Challenge 2003 was developed as a national contest by Metagenics, Inc. to promote healthy body composition with UltraMeal.

As part of the UltraMeal Challenge, the clinicians overseeing the participants in the Challenge provided original copies of BIA data to Metagenics, Inc. We have reviewed the data obtained during the UltraMeal Challenge 2003 and have performed a retrospective analysis on the complete data sets that were provided. We report our observations in this clinical summary.

METHODS

Participants and Description

The UltraMeal Challenge was conducted in the U.S. Participants in the UltraMeal Challenge were required to be 21 years or older and to follow the UltraMeal Body Composition Program[11] for 12 weeks under the supervision of a physician or other licensed healthcare practitioner. Pregnant women and nursing mothers were excluded from participation.

Data were collected and analyzed retrospectively from the participants entered into the UltraMeal Challenge. The participants were self-selected, but all complete data sets that were obtained at Metagenics were used for this analysis. A complete data set was defined as a completed, qualified, signed and dated entry form, a dated final form, a participant letter, a clinician statement, complete original copies of all BIA data (initial and final) with dates of analysis occurring within the Challenge limits, and signed consents.

Body Composition

Body composition was assessed as percent body fat using a BIA machine. Only measurements taken on standardized BIA machines were accepted for this retrospective analysis. Data were obtained at the initial time and completion of the Challenge. Timing and quality of the data were assessed by review of copies of data print-outs per each participant. Blood pressure, weight, and BMI were not required and, therefore, were not available for all subjects in this analysis.

Data Analysis and Statistical Methods

Data were analyzed using standard statistical procedures on MS Excel software (Microsoft®) and JMP Statistical Package (SAS Institute, Cary, NC). Data are presented as mean ± standard deviation (± sd) unless otherwise indicated. Significance was determined using a one-tailed, paired t-test; HO:pre-body fat > post body fat.

RESULTS

Women on the UltraMeal Challenge

Data from 112 women (average age 45 ± 11; range 22 to 73 years) qualified for the body composition analysis and are summarized in Table 1. A significant decrease in % body fat, weight, and BMI was observed with a corresponding significant increase in % lean mass. Overall, body composition improved from 47.01 ± 5.46% body fat to 45.02 ± 5.17% body fat ($p < 0.005$), with the range of fat loss from 0.1% to 17.9%. Lean mass increased from 62.12 ± 8.08% to 64.87 ± 8.24%.

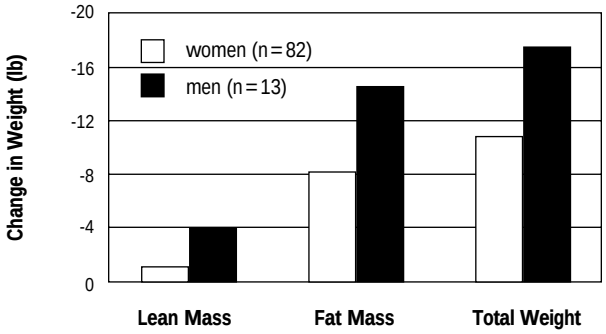
Table 1. **Average change (± sd) in body composition for the women on the UltraMeal Challenge.**

	Initial	Final	Significance* (p)
Weight (lb; n = 111)	186 ± 44	176 ± 41	$p << 0.0001$
BMI (kg/m^2; n = 111)	31.4 ± 7.1	29.6 ± 6.8	$p << 0.0001$
Body Fat (%; n = 112)	47.01 ± 5.46	45.02 ± 5.17	$p < 0.005$
Lean Mass (%; n = 84)	62.12 ± 8.08	64.87 ± 8.24	$p << 0.0001$
Body Water (L; n = 100)	37.41 ± 6.00	37.01 ± 6.24	ns†
Phase Angle (n = 100)	6.36 ± 0.75	6.31 ± 0.69	ns†

*paired, two-tailed t-test; †ns = not significant

The improvement in lean mass, from 62.12 ± 8.08% to 64.87 ± 8.24%, was highly significant ($p << 0.0001$). Analysis of actual lean mass showed a loss of 1.2 ± 5.6 lb; however, fat loss was far greater at 8.3 ± 7.8 lb (n = 82) indicating the vast majority of weight loss was due to fat loss, resulting in improved body composition (Figure 1).

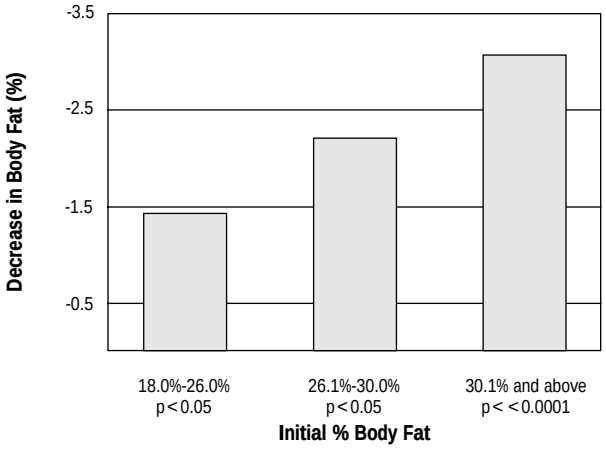
Figure 1. **Loss of lean, fat, and total weight during the UltraMeal Challenge.**



Ninety-three women reported an overall loss of weight of between 1.0 and 46 lb. While the change overall was positive, 12 of the women reported no loss in percent body fat, and 18 reported no weight loss.

The greatest change in body fat was observed in those who initially had the highest body fat. The 99 women starting the challenge with 30% or more body fat reported an average decrease of 3.1% body fat, from 41.8 ± 6.6% body fat initially to 38.7 ± 7.3% body fat after the UltraMeal Challenge (Figure 2).

Figure 2. **Decrease in % body fat in women after the UltraMeal Challenge.**



Men on the UltraMeal Challenge

Data from 20 men (average age 47 ± 13; range 28 to 75 years) qualified for the analysis, and are summarized in Table 2. Men also showed a significant decrease in percent body fat, BMI, and weight, with a corresponding increase in percent lean mass. In the men, body composition improved significantly from 32.56 ± 4.27% body fat to 30.19 ± 4.31% body fat ($p < 0.05$), with the range of fat loss from 0.7% to 15.4%.

Table 2. **Average change (± sd) in body composition for the men on the UltraMeal Challenge.**

	Initial	Final	Significance* (p)
Weight (lb; n=18)	236 ± 43	219 ± 41	$p < 0.0001$
BMI (kg/m^2; n=18)	33.4 ± 7.0	30.8 ± 6.2	$p < 0.0001$
Body Fat (%; n=20)	32.56 ± 4.27	30.19 ± 4.31	$p < 0.05$
Lean Mass (%; n=13)	70.30 ± 5.41	74.50 ± 6.75	$p < 0.005$
Body Water (L; n=19)	56.07 ± 11.73	55.71 ± 8.12	ns†
Phase Angle (n=19)	7.07 ± 0.98	7.04 ± 0.97	ns†

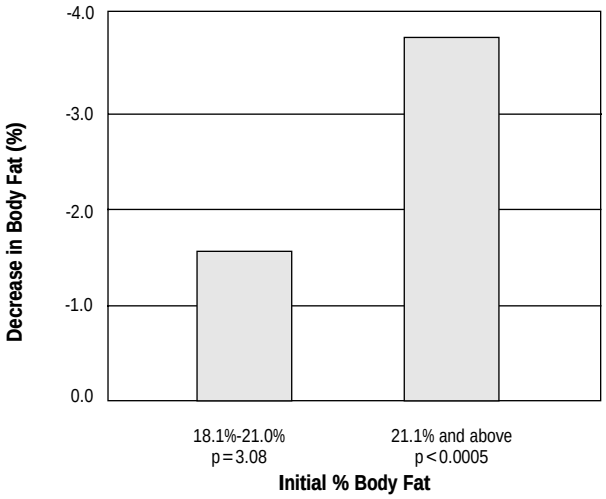
*paired, two-tailed t-test; †ns=not significant

The lean mass improved significantly ($p < 0.005$), from 70.30 ± 5.41% to 74.50 ± 6.75% lean mass. Analysis of actual lean mass showed a loss of 4.0 ± 9.0 lb; however, as seen with the women, fat loss was far greater at 14.7 ± 12.8 lb (n=13) indicating the vast majority of weight loss and was due to fat loss, resulting in improved body composition (Figure 1).

All men for whom weight was reported showed a loss in actual weight, ranging from 2.0 lb to 35 lb, with an average weight loss of 17.5 ± 10.2 lb. Only 1 of the 20 men showed no loss of fat during the Challenge.

Similar to the women, the 18 men beginning the program with body fat above 20% showed a greater change in body fat, from 29.1 ± 5.0% body fat to 25.3 ± 5.9% body fat for an average decrease of 3.8% body fat after the Challenge (Figure 3).

Figure 2. **Decrease in % body fat in men after the UltraMeal Challenge.**



Change in Blood Pressure

Pre- and post-Challenge data for blood pressure were reported for 82 women and 13 men (Table 3). A significant change in blood pressure was observed for the women from 126/81 to 120/77 ($p < 0.05$) and the men from 138/87 to 124/76 ($p < 0.001$).

Table 3. **Average change (± sd) in BP after the UltraMeal Challenge.**

	Pre-Challenge BP (mmHg)		Post-Challenge BP (mmHg)	
	Systolic	Diastolic	Systolic	Diastolic
Women (n=82)	126 ± 17	81 ± 12	120* ± 15	77* ± 13
Men (n=13)	138 ± 19	87 ± 10	124* ± 13	76† ± 6

*Significance $p < 0.05$; paired t, two-tails test.
†Significance $p = 0.001$; paired t, two tails test.

SUMMARY

The UltraMeal Challenge 2003 was a voluntary, national health promotion. Body composition, weight, BMI, and blood pressure were analyzed for those participants providing complete sets of data during the Challenge.

In this analysis, 89% of women showed a decrease in % body fat. The overall decrease in body fat was highly significant and was accompanied by an increase in relative lean mass. Weight data showed that 84% of women reported an overall weight loss and the vast majority of the weight was lost as fat mass, with little actual lean mass decrease. These data indicate the UltraMeal Challenge resulted in an improvement in body composition by a decrease in fat mass with an increase in percent lean mass.

Complete data sets were obtained for 20 men and similar results were observed. That is, significant improvements in percent body fat and percent lean mass were observed. Of the weight loss reported by the men, the majority of decrease in weight occurred as a loss of fat mass.

Several factors can promote a healthy body composition, retention of lean mass, and management of fat mass. In animals studies, soy protein and soy isoflavones have been shown to support maintenance of lean mass and effect expression of genes that promote lean mass and decrease fat.[12,13] Clinical studies with UltraMeal have shown that it promotes a healthy body composition in humans by supporting retention of lean mass and loss of fat mass.[8-10]

Low dietary calcium has been associated with high central adiposity and increased CVD risk.[14] Calcium and magnesium have been shown to play a role in maintenance of healthy blood pressure.[15] Fiber and olive oil are also known to be beneficial in lowering risk factors to CVD and diabetes.[16,17]

Much has been reported on the beneficial effects of soy protein on the risk to CVD. So substantial is the data that the FDA has approved a health claim for soy protein-containing foods, which states that "diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease."[18] Soy protein with isoflavones has been shown to improve blood lipids levels and endothelial function.[19-21] Soy protein has also been reported to have an effect on improvement in blood pressure.[22]

In the present analysis, blood lipids were not obtained. Blood pressure was reported voluntarily on most participants and a significant, positive change was observed in both men and women. The beneficial effects seen on blood pressure could be due to the soy protein or to the overall positive changes in body composition. High body fat, in particular visceral fat, is known to associate with increased blood pressure.[23]

The analysis summarized in this report was performed on the complete data sets obtained from the UltraMeal Challenge 2003. As such, the participants were self-selected and compliance to the program during the

Challenge was not assessed. In addition, several factors can influence BIA measurements, including hydration, fasting, and severe obesity.[24-26] However, the observation that some of the participants did not show decrease in body fat, weight, or BMI suggested that the data are representative of patients on a program for improvement in body composition.

In summary, this analysis of the clinical observations from the UltraMeal Challenge 2003 supports previous clinical studies with the UltraMeal Body Composition Program showing promotion of healthy body composition by supporting a decrease in fat mass with maintenance of lean mass in both men and women.

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