

## **Investigation of a Mesunique Protocol: Pilot Study**

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### **Background:**

The natural ingredients with mesunique make the fat cell membrane more permeable so that it can release the fat. After fat is released, it is utilized in the muscle for energy-burned through normal metabolism, exercise-or processed and removed from the body by the liver. The final option is for the fat to be reabsorbed by the body. Exercise will burn the fat and prohibit reabsorb ion. Liposuction has its place; it can be a very safe and effective procedure when placed in the right hands. But every surgical procedure comes with its own set of risks. Mesotherapy continues to gain respect and acceptability because of its success vs. risk ratio. Mesotherapy in general is a much safer, more patient friendly procedure than liposuction. The next generation of spot fat reduction is applied directly to the skin.

One day while applying another cream I use transdemally(absorbed through the skin), I thought to myself, "There must be a way to apply special ingredients in the same manner that would help in fat metabolism ." Obviously they could observe positive effects all over because it would be absorbed and transported to other areas of the body also, but it would be especially effective at the site of application.

The next questions were, "Could I develop a formula of natural substances similar to what we use in Mesotherapy injections? I knew that many medications were being developed employing transdermal patches and creams, so the possibility was certainly there. While I was giving a seminar in Phoenix on Mesotherapy, I ran into friend of mine who happens to own a pharmaceutical company. I brought up my idea about this new topical form of Mesotherapy, he said he had just recently developed a unique system that could do just what I was thinking of, and he had a patent on it. I told him what formula would be necessary for it to be effective, and he said he would see what he could do. Within a few short months, he had it, and was ready for me to try. He had added a few more ingredients to make it work better absorbing into the skin. He asked me to look it over, and if I liked it, he would put it in a bottle that would dispense even doses every time. After a few weeks of going back and forth with discussions on the final product, I asked him to manufacture a batch and I would test it on myself, and if I liked it, I would ask some patients to try it.

I did a clinical study in my office with six patients who used the cream along with weight loss and exercise. Five of the patients loved the cream while one decided not to use it any longer and just do diet and exercise. All six of the patients lost weight and inches, but the five who did both the cream and weight loss had much more noticeable results. Needless to say, the sixth patient is back using the cream and much happier. Since then, more patients have used the cream, with very impressive results. Patients are saying that they can see changes in the skin tone in as early as two weeks.

The cream was developed for those people who cannot find a specialist in the area, those who cannot afford the treatment, and for those who are scared of needles. I believe people can now experience the same amazing results as Mesotherapy.

**Primary Objective:**

To evaluate Mesunique efficacy and safety on spot reduction adipose tissue (inches lost), weight loss, and BMI in conjunction with diet and exercise program as compared to diet and exercise alone.

**Study Design:**

Prospective, open label, multi-center, two arm study.

**Treatment Groups:**

Arm A; Diet and Exercise

Arm B; Diet, Exercise, Mesunique and Accelerator

General Diet Guidelines include avoid sugars, starches, Trans and saturated fats.  
General Exercise Guidelines include 30 minute walk, six days weekly.

For Diet and Exercise Details see attachment A

**Number of Subjects and Centers:**

2 centers, 22 totaled enrolled. 22 evaluated. 12 patients at center one (Dr. Parker) and 10 patients at center two (Chris Sotelo)

**Target Population:**

Inclusion

1. Age 18.

2. Patients of understanding the purpose and risks of the study.
3. BMI 15
4. Normal EKG

Exclusion:

1. Age 18
2. Patients unable to understand the purpose and risks of the study.
3. Pregnant Women
4. Patients unable to walk at least 30 minutes a day.
5. Patients on liquid diet or special diet related to chronic disease process including cancer, diabetes or gastric bypass.
6. Patients with severe diarrhea or other gastrointestinal disorders that might prevent their ability to absorb their food properly.
7. Patients participating in other clinical trails.
8. Patients with excessively high blood pressure or EKG abnormalities.
9. Any other conditions that the physician may feel uncomfortable with.
10. Any lab findings the physician feels should exclude the patient from the study.

**Concomitant Medications:**

Medications required to treat patients underlying or concurrent diseases should be administered as needed.

**Study Treatments:**

Apply 30 mg to predetermined adipose area twice daily taking accelerator three times daily by mouth, diet and exercise plan.

**Labeling:**

See attached B

**Packaging:**

Mesunique pre-dosed dispenser, a 30 day supply.  
Accelerator-90 Capsules, a 30 day supply.

**Assessment:**

Baseline measured pre-treatment and after maximum length of study 30 days with assessment measurements, weight and photos at 30 days.

**Safety Issues:**

Upon conclusion of study, no adverse events were witnessed or reported for any patients or participants in the study.

### **Ethical Aspects:**

It is the responsibility of all the investigator, or a person designated by the investigator, to obtain written , informed consent for each patient participating in this study, after adequate explanation of methods, anticipated benefits, and potential risks of the study.

### **References:**

Dissolve Fat and Eliminate Cellulite, Parker, Gerald.

### **Pilot Study Data & Results:**

#### DATA ANALYSIS AND RESEARCH DESIGN

The 22 participants recruited for this pilot study were assigned to the two study conditions (Arm A: Diet and Exercise or Arm B: Diet, Exercise, Mesunique and Accelerator). Ten participants were enrolled in the Arm A treatment condition (Diet and Exercise) and twelve participants were enrolled in the Arm B treatment condition (Diet, Exercise, Mesunique and Accelerator).

#### *Examining Pretreatment Group Differences*

Descriptive and frequency statistics were reported for the treatment groups on the demographic variables and assessment measures. An Analysis of Variance (ANOVA) was conducted to assess the differences between the two treatment groups on the pretreatment scores of Body Mass Index (BMI), weight (lbs.) and waist (inches).

#### *Treatment Outcome*

Paired-Sample T-Tests were conducted to measure the treatment outcome of participants in Arm B (Diet, Exercise, Mesunique and Accelerator) alone. Participants' scores on the measures of Body Mass Index (BMI), weight (lbs.), waist (inches) and hips (inches) were used to assess treatment outcome for this analysis. An Analysis of

Covariance (ANCOVA) was conducted to measure treatment outcome for participants as a function of Arm A (Diet and Exercise) or Arm B (Diet, Exercise, Mesunique and Accelerator) group assignment. Participants' scores on the measures of Body Mass Index (BMI), weight (lbs.) and waist (inches) were used to assess treatment outcome for this analysis. Participant pretest scores were used as a covariate in the analysis.

## RESULTS

### *Descriptive Statistics*

The Arm A treatment condition (Diet and Exercise) was comprised of 10 participants. The mean BMI of these participants was 19.89 (SD = 5.91) ranging from 10.80-30.00. The mean weight of these participants was 162.80 pounds (SD = 37.09) ranging from 110-235 pounds. The mean pretreatment waist in inches for the Diet and Exercise Only treatment group (Arm A) was 33.07 inches (SD = 6.96) ranging from 24 to 46 inches.

The Arm B treatment condition (Diet, Exercise, Mesunique and Accelerator) was comprised of 12 participants. The mean BMI of these participants was 30.29 (SD = 7.70) ranging from 21.00-43.00. The mean weight of these participants was 189.54 pounds (SD = 65.62) ranging from 120-312.90 pounds. The mean pretreatment waist in inches for the Diet, Exercise, Mesunique and Accelerator treatment group (Arm B) was 38.35 inches (SD = 8.53) ranging from 28 to 54 inches.

### *Pretreatment Group Differences*

A one-way Analysis of Variance (ANOVA) was conducted to assess the differences between Arm A (Diet and Exercise) and Arm B (Diet, Exercise, Mesunique and Accelerator) on Body Mass Index (BMI), weight (lbs.) and waist (inches) (see Table 1). There were no significant differences between the two groups' pretreatment scores of weight and waist (Weight:  $F = 1.30$ ,  $p > .05$ ; Waist:  $F = 2.45$ ,  $p > .05$ ). However, there was a statistically significant difference between the groups on the pretreatment BMI scores ( $F = .12.19$ ,  $p < .01$ ) with the Arm B treatment group exhibiting a greater mean BMI (30.29.) than the Arm A treatment group (19.89).

#### *Treatment Outcomes*

Paired-Sample T-Tests were conducted to measure treatment outcomes for participants in the Arm B treatment group (Diet, Exercise, Mesunique and Accelerator) alone. Participants' scores on the measures of Body Mass Index (BMI), weight (lbs.), waist (inches) and hips (inches) at pretreatment and 30 days (posttreatment) were used to assess treatment outcome for this analysis (see Table 2). The Arm B treatment condition was associated with significant pre-post treatment differences in BMI score ( $t = 6.60$ ,  $p < .01$ ), weight ( $t = 4.28$ ,  $p < .001$ ), waist ( $t = 9.07$ ,  $p < .001$ ), and hips ( $t = 5.35$ ,  $p < .001$ ). More specifically, the Arm B treatment group demonstrated statistically significant reductions in BMI, weight, waist and hips from pretreatment to 30 days post-treatment (see Table 3).

Analysis of Covariance (ANCOVA) was conducted to measure treatment outcomes for participants as a function of Arm A (Diet and Exercise) or Arm B (Diet, Exercise, Mesunique and Accelerator) group assignment. Table 4 presents a series of three univariate ANCOVAs that were conducted for the examination of BMI, weight

(lbs.) and waist (inches) outcomes as a function of treatment group (Arm A vs. Arm B).

Patient pretest scores were used as covariates in the analysis, thus all posttreatment scores reported in the table use adjusted marginal means.

A statistically significant treatment group difference was identified for the measurement of waist from pretreatment to 30 days, ( $F = 5.683$ ,  $p = .028$ ). More specifically, the Arm B treatment group exhibited greater waist reduction (Adjusted Mean = 32.92) than the Arm A treatment group (Adjusted Mean = 34.60) from pre to posttreatment. No significant treatment group differences were identified for BMI ( $F = 3.86$ ,  $p = .064$ ) or weight ( $F = 3.50$ ,  $p = .077$ ).

### *Conclusions*

This study examined the effect of two treatments (Arm A: Diet and Exercise or Arm B: Diet, Exercise, Mesunique and Accelerator) on BMI, weight (lbs.), waist (inches) and hips (inches). Pretreatment group differences were found between Arm A (Diet & Exercise) and Arm B (Diet, Exercise, Mesunique and Accelerator) on BMI. More specifically, Arm B subjects demonstrated statistically significant higher pretreatment BMI scores than Arm A subjects. However, no significant pretreatment differences were found between Arm A and Arm B on weight or waist size.

When change in the outcome measures from pretreatment to posttreatment was analyzed for the Arm B (Diet, Exercise, Mesunique and Accelerator) treatment group only, statistically significant changes were found. In fact, the Arm B treatment group demonstrated statistically significant reductions in all outcome areas including BMI, weight, waist and hips from pretreatment to 30 days. These results suggest that the

combination of Diet, Exercise, Mesunique and Accelerator is effective for decreasing BMI, weight, and hips and waist size over a 30 day period.

Finally, statistically significant differences were found between the Arm A and Arm B treatment groups on the measurement of Waist from pretreatment to 30 days. While both treatment groups demonstrated a reduction in waist size at posttreatment, the Arm B treatment group demonstrated greater waist reduction than the Arm A treatment group. This finding was promising and suggests that the treatment received in Arm B was more successful in reducing waist size than the combination of diet and exercise administered to Arm A. However, no statistically significant differences were found for BMI or weight when comparing the Arm A and Arm B treatment groups. It is possible that the pretreatment group differences for BMI may be responsible for this lack of difference; Arm B had significantly greater BMI at pretreatment than Arm A.

In summary, in the present study, Arm B showed improvement in BMI, weight, and waist and hip size over time. Thus, the present study demonstrates that the combination of Diet, Exercise, Mesunique and Accelerator can improve these outcomes over time, as well as reduce waist size significantly more than the combination of diet and exercise alone. These results are very promising and additional research is warranted to confirm these early findings. Future studies should include a larger number of participants to increase statistical power and additional measures to confirm these preliminary findings.

Table 1

One-Way Analysis of Variance of Pretreatment BMI, Weight (lbs) and Waist (inches) by Treatment Group

	<u>SS</u>	<u>df</u>	<u>MS</u>	<u>F</u>	<u>p</u>
Pretreatment BMI					
Between group	590.15	1	590.15	12.19	.002*
Within group	968.09	20	48.40		
Total	1558.25	21			
Pretreatment Weight					
Between group	3900.63	1	3900.63	1.30	.267
Within group	59755.52	20	2987.77		
Total	63656.16	21			
Pretreatment Waist					
Between group	152.01	1	152.01	2.45	.13
Within group	1238.06	20	61.90		
Total	1390.08	21			

Note: \*p < .01.

Table 2

Means and Standard Deviations for BMI, Weight, Waist and Hips at Pre and Posttreatment for Arm B Only (Diet, Exercise, Mesunique and Accelerator)

Measure	Pretreatment		Post-Treatment	
	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>
BMI	30.29	7.70	27.91	6.65
Weight	189.54	65.62	177.10	56.61
Waist	38.35	8.53	35.25	8.44
Hips	43.35	5.11	40.72	4.32

Table 3

Paired-Samples T-Tests Comparing Arm B Pre and Posttreatment Differences on BMI, Weight, Waist and Hips

Variable Pair	Paired Differences			
	<u>M</u>	<u>SD</u>	<u>t</u>	<u>p</u>
Pair 1: Pretreatment BMI– Post-treatment BMI	2.37	1.24	6.60	.000***
Pair 2: Pretreatment weight– post weight	12.43	10.04	4.28	.001***
Pair 3: Pretreatment waist– Post-treatment waist	3.10	1.18	9.07	.000***
Pair 4: Pretreatment hips– Post-treatment hips	2.62	1.55	5.35	.000***

Note: \*\*\*p < .001.

Table 4

Comparison of Pre- and Posttreatment Outcome Measures for Arm A (n = 10) vs. Arm B (n = 12) Treatment

Variable	Pretreatment				Posttreatment			
	Arm A		Arm B		Arm A		Arm B	
	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>
BMI	19.89	5.91	30.29	7.70	17.57 (22.69)	5.94	27.91 (23.64)	6.65
Weight	162.80	37.09	189.54	65.62	157.60 (170.48)	36.20	177.10 (166.37)	56.61
Waist	33.07	6.96	38.35	8.53	31.81 (34.60)	6.86	35.25 (32.92)	8.44

Note: Adjusted means in parenthesis were used for the group by treatment interaction analysis. Adjusted

the covariates of pretreatment BMI, weight and waist scores. \* $p < .05$

## MEATS

## VEGETABLES

If you have a favorite diet of your own, just follow it. But be sure to avoid sugar, starches, trans fats and saturated fats. Avoid salt and soda as well.

If you would like to follow our preferred diet, use the following menu as a guide. Remember that you should never begin a weight loss or workout program without first consulting your physician.

BREAKFAST	
1. 8 oz. skim milk OR 1 cup of low-fat yogurt	
2. Choose one of the following:	
1 apple	1 medium size wedge of watermelon
1 poached egg	1 medium size wedge of cataloupe
1 peach	1 pear
1 nectarine - 13 -	1 unripe banana (limit 2 per week)
1/2 grapefruit	1 orange
1 cup of melon cubes	
2 medium size wedges of honeydew	

MID-MORNING SNACK
1/2 piece of fruit from list above
3-4 nuts: Brazil nuts, peanuts, walnuts or almonds

LUNCH
4 oz. meat AND 2 cups of
cooked vegetables ( <a href="#">Vegetables List</a> )
An unlimited amount of uncooked vegetables from
vegetables list can be eaten

MID-AFTERNOON SNACK
1/2 piece of fruit from list above
3-4 nuts: Brazil nuts, peanuts, walnuts or almonds

<b>SUPPER</b>
6 oz. meat ( <a href="#">Meats List</a> ) AND
2 cups of uncooked vegetables ( <a href="#">Vegetables List</a> )
An unlimited amount of uncooked vegetables from vegetable list can be eaten

<b>MID-EVENING SNACK</b>
1/2 piece of fruit from list above
3-4 nuts: Brazil nuts, peanuts, walnuts or almonds

<b>VEGETABLES</b>
When uncooked the following vegetables may be eaten in unlimited amounts.
When cooked, 2 cups at lunch and 2 cups at supper.

green beans	green bell peppers	garlic
broccoli	lettuce	spinach
cabbage	asparagus	tomatoes
celery	Brussels sprouts	radish
cucumbers	okra	

<b>MEATS</b>
The following meats may be eaten in these proportions:
4 oz. at lunch *** 6 oz. at supper.

extra lean	turkey	sirloin steak
ground beef	salmon	T-bone steak
pot roast	tuna	round steak
beef hearts	cod	filet mignon
liver or kidney	bass	2 eggs
lamb kidney	flounder	
chicken	haddock	

### **Regular Exercise**

Get regular exercise. Dr Parker states, those who can participate daily in an activity that gets the heart rate up and keeps it up for at least 30 minutes steady, will get better results. Reference Chapters 8 and 14 in Dr. Parkers book for more specific information. This activity may include swimming, bicycling, walking and / or running. it is not the exercise alone that helps burn the fat, but also the increased metabolism that results from the exercise for up to eight hours afterwards. For best results, you should do this morning and evening. Of course, consult your personal physician before beginning any exercise program.



# mèsunique™

One full press pump dispenses enough cream to treat a 6x6 inch area of the skin. Each pump (about 1.35 grams) provides a 60 mg dose of the key ingredients.

### **Suggested Use:**

As an aid to lipid metabolism (fat emulsifier), apply to desired areas such as abdomen, thighs, love handles, hips, arms, buttocks, chin or any other areas needing treatment.

Apply one (1) pump twice daily. AM / PM.

### **Caution**

Discontinue use if irritation occurs. Contact physician before re-using.

### **Ingredients**

Purified Water, Deoxycholic Acid – 5% concentration, Glycerine, Isopropyl Palmitate, Shea Butter, Capric/Caprylic Triglycerides, Phosphatidyl Choline, Glyceryl Stearate, Stearic Acid, Sodium Hyaluronate (HA), Allantoin, Sodium PCA, Cetearyl Alcohol & Ceteareth-20, Soda Ash, Citric Acid, Carbomer, Methyl Paraben, Propyl Paraben, Disodium EDTA, Retinyl Palmitate (Vitamin A), Ascorbyl Palmitate (Vitamin C) and Tocopheryl Acetate (Vitamin E).

These statements have not been evaluated by the Food & Drug Admin. The product and the statements are not intended to diagnose, treat, cure or prevent a disease.

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