The Effect of a Slimming System with a Lipolytic Cream on Body weight, Girth and Whole Body and Regional Fat Loss

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ABSTRACT

A slimming system consisting of a garment, a lipolytic cream, and brief exercise was tested for either the tummy or the legs to see how they can alter body composition and girth. There were 151 female subjects in this single blinded randomized study divided into six groups and participated for 6 weeks. There were three lifestyle groups (LS).

These were:
• Group 1: No change in diet and exercise (LS control)
• Group 2: Here subjects applied a lipolytic cream only to their tummy area and only performed abdominal exercises from an exercise DVD (LS tummy)
• Group 3: this group applied lipolytic cream only to their thighs and only performed leg exercises from an exercise DVD (LS thighs).

The last three groups were diet and exercise groups (DE).

• Group 4: these subjects performed exercise 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and ate a healthy diet (DE control)
• Group 5: The subjects exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and ate a healthy diet. Also, they applied the lipolytic cream only to their tummy area and performed abdominal exercises from an exercise DVD (DE tummy)
• Group 6: these subjects exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and ate a healthy diet. Also, they applied the lipolytic cream only to their thighs and performed leg exercises from an exercise DVD (DE thighs).

The results of the study showed that the slimming system caused a significant reduction in subcutaneous body fat and girth.
which was associated with the area that the cream and short exercise was applied.

**INTRODUCTION**

Obesity is a major problem both in United States and in the world. For this reason, there has been an increased emphasis on dietary programs with diets ranging from high carbohydrate to high lipid to high protein diets. However, diets in themselves suffer from two problems. First, people generally stay on the diet for the first few days. Without changing lifestyle, many diets result in weight loss and immediate weight gain. Another problem with dieting alone is that basal metabolism is reduced during many types of diets thus making it harder to lose weight. Further, without exercise, weight loss results in flabbiness in the skin as fat is lost from the subcutaneous tissue and actually reduces body image especially in women. Exercise is effective for weight loss and toning. Spot reduction in fat has been a problem in the cosmetic industry.

Therefore, a more effective means of losing weight is to combine exercise with dieting. Exercise in itself tones muscle. Further, the energy expenditure associated with exercise also helps promote post exercise energy expenditure causing additional weight loss greater than that which could be achieved by dieting alone. This shift in metabolism associated with exercise and diet together have been shown to be beneficial in preventing pathology such as diabetes.

One problem with dieting and exercise is that it is hard to target where the fat loss occurs. Depending on race and genetics, fat loss can occur in any area of the body. If fat loss is to be targeted at specific areas, one solution is a lipolytic agent applied to the skin. Compounds such as aminophylline and caffeine liberate subcutaneous fat, thinning the fat layer and also reducing cellulite. Exercise in specific areas of the body has been in some cases, shown to alter body composition in subcutaneous areas and remove uneven fat deposits called cellulite. One successful cream is aminophylline. It is marketed under many names, and has been shown to liberate subcutaneous fat. Even as far back as 20 years ago, this compound was reviewed as being safe and mobilizing abdominal fat. It seems to have no side effects and mobilizes fat under the cream. Even some 20 years later, this over the counter cream has been shown to work but not have side effects.

In the present investigation, weight loss, girth, and subcutaneous fat in the abdominal and thigh area were assessed under conditions of not changing lifestyle or when combined with diet and exercise. In some subjects, a slimming system was used involving a lipolytic cream, a garment, and exercise was used to see if it alters spot fat loss. Girth, body tone, and cardiovascular markers were used to assess the efficacy of this combined program.

**SUBJECTS**

One hundred fifty one female subjects in the age range of 20 to 50 years old participated in the study. Subjects were recruited over a wide range of body masses. Subjects were free of cardiovascular disease or neurological injury at the time of the experiment. Subjects were allocated into one of six groups randomly. Groups 1-6 participated for 6 weeks. Groups 1, 2, and 3 were the lifestyle groups where exercise and diet were not changed. Groups 4, 5, and 6 were the diet and exercise groups, which followed the same diet and exercise program.

- **Group 1**: No change in their diet and exercise program. This group is control subjects. (LS control)
- **Group 2**: Applied lipolytic cream only to their tummy area, and only performed abdominal exercises from an exercise DVD only with no additional changes in diet and exercise (LS tummy).
- **Group 3**: Applied lipolytic cream only to their thighs area and only perform leg exercises from exercise DVD only with no additional changes in diet and exercise (LS thigh).
- **Group 4**: Exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc) and ate a
Group 5: Exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and ate a healthy diet. Also, applied lipolytic cream only to their tummy area and performed abdominal exercises from exercise DVD (DE tummy).

Group 6: Exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and ate a healthy diet. Also, applied lipolytic cream only to their thighs area and performed leg exercises from exercise DVD (DE thigh).

All subjects signed a consent form and all procedures were approved by Solutions Institutional Review Board. The demographics of the subjects are listed in Table 1. There was no statistical difference between the characteristics of the 6 groups of subjects.

There were 30 subjects in group 1, 25 subjects in group 2, 25 subjects in group 3, 21 subjects in group 4, 27 subjects in group 5, and 23 subjects in group 6.

METHODS

Compliance

Subjects were asked to complete log sheets on a daily basis for compliance for both the diet and exercise programs and log any food that they ate that were not on the diet and that date.

The diet compliance scale used was as follows:
The subjects were to subjectively state on a daily percentage score on if they have eaten with the proper dietary guidelines. For example, if they ate ¾ of their meals in a healthy manner, they would mark 75% for that day.

For the exercise, the compliance scale was:
The subjects were to subjectively state on a daily percentage score on if they exercised as per the guidelines. For example, if they did ¾ of the exercise, they would mark 75% for that day.

The following groups exercised:

- Group 2: (LS tummy) performed 3 minutes twice per day of abdominal exercises from an exercise DVD, but did not add any other exercise.
- Group 3: (LS thigh) performed 3 minutes twice per day of leg exercises from an exercise DVD, but did not add any other exercise.
- Group 4: (DE controls) Exercised 180 minutes per week at a moderate intensity

<table>
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<th>group</th>
<th>age (mean ± sd)</th>
<th>height (mean ± sd)</th>
<th>weight (mean ± sd)</th>
<th>BMI (mean ± sd)</th>
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<tbody>
<tr>
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<td>81.3 ± 15.1</td>
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<td>165.3 ± 6.6</td>
<td>76.5 ± 11.8</td>
<td>28.2 ± 5.4</td>
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<td>162.7 ± 3.7</td>
<td>76.6 ± 16.3</td>
<td>28.9 ± 5.8</td>
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<td>group 5</td>
<td>39.6 ± 12.2</td>
<td>161.7 ± 6.0</td>
<td>82.2 ± 19.7</td>
<td>31.5 ± 7.5</td>
</tr>
<tr>
<td>group 6</td>
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<td>161.6 ± 4.4</td>
<td>80.5 ± 14.4</td>
<td>30.7 ± 4.7</td>
</tr>
</tbody>
</table>
level (jogging, bicycling, swimming, etc.).

- Group 5: (DE tummy) Exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and performed 3 minutes of abdominal exercise twice per day from an exercise DVD.

- Group 6: (DE thigh) Exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and performed 3 minutes of leg exercise twice per day from an exercise DVD.

The exercise DVD had two parts: exercises for the abs and exercises for the legs. The leg exercises consisted of 3 minutes of doing squats and lunges. The abdominal exercises consisted of doing floor crunches for 3 minutes or standing isometric crunches. The subjects did either of these exercises twice a day (once in the morning and once in the evening) for a duration of 3 minutes each time after applying cream to their respective target areas and donning the garment. The instructions for performing the 180 minutes of exercise were the same for groups 4, 5, and 6. Subjects were instructed to accumulate 180 minutes of exercise a week of moderate intensity. Exercise was to keep heart rate between 50-85% of maximum heart rate. Subjects could select from a variety of exercises including treadmill, jogging, bicycling, aerobic dance, etc.

**Diet:**

The Diet was as follows. Groups 4, 5, 6, ate a healthy diet. The instructions for the diet were the same for groups 4, 5, and 6.

The diet consisted of healthy foods (ie, lean proteins, more complex carbohydrates, high fiber, and lower calorie dense foods). This diet was not set on a calorie restriction method. It was based on a behavioral strategy based approach. An accelerated diet was used for the first week, with a set dietary plan, and consisted of pre-determined meals consisting of low fat and higher protein foods, with a daily calorie restriction of 1,300 calories maximum, and the food was provided.

**Blood Pressure:**

Blood pressure was measured by auscultation of the left arm. An automatic blood pressure cuff was used on the wrist (Omron Hem 621, Bannockburn).

**Heart Rate:**

Heart rate was determined by counting the radial pulse over a 15 second period and multiplying by 4.

**Body Fat Determination**

Body fat percentage was determined by electrical impedance using Omron Body Composition Monitor with Scale, model BF108, (Omron Inc. Netherlands), which measured resistance and reactance with 1 ohm of resolution. Four electrodes were used on the body, two source electrodes and two recording electrodes, each on the hands and feet. The BF108 uses 8 measures on the arms and legs to calculate body fat.

**Girth Measurement**

Girth measurements were made by a measuring tape with a tensionometer that applies 3 grams of force during the measurements. The locations were: girth of the waist at the umbilicus, and the hips and thighs at half of the distance between the hip and knee. The same clinician made all of the measurements throughout the study. In addition, with the subject standing evenly on both legs, a measurement was made from the floor to the lowest point of the buttocks.

**Ultrasound**

Subcutaneous fat thickness and cellulite level were assessed with a Mindray M7 Ultrasound. The probe used was a linear probe with 512 elements in the probe, which could measure the thickness of skin and subcutaneous fat to a resolution of 0.1 mm. It was used at a base frequency of 10 MHz. Five measurements were made on the abdominal area and thigh, and from these measured the mean subcutaneous fat and the coefficient of variation was calculated. The coefficient of variation was used as a normalized measure of the extent of cellulite.

**Lipolytic Thermal Accelerator Cream**

The lipolytic cream is a proprietary for-
mulation containing mainly two lipolytic compounds, caffeine and aminophylline. Subjects rubbed the lipolytic cream on twice daily applied as per below.

- Group 2: Applied lipolytic cream only to their tummy area
- Group 3: Applied lipolytic cream only to their thigh area
- Group 5: applied lipolytic cream only to their tummy area
- Group 6: applied lipolytic cream only to their thigh area

The hip area was the cross over point and the tummy groups were not to rub cream below their hips and the thigh people were not to rub cream above their hips.

Garment
An elastic garment was given to each subject to wear over their thighs and abdominal area for 10 minutes each morning and evening after the cream was applied. For the exercise groups (5 and 6), they were instructed that they did not have to wear the garment during the 180 minutes of exercise and could perform their exercise anytime during the day.

Subject Instructions
People received written instructions at the start of the study. The lifestyle groups were instructed not to change their diet or activity level. The Diet and exercise groups were given diet and exercise instructions. The compliance for the diet and exercise and use of the cream was logged each day and assessed at the end of the study. The lifestyle groups were interviewed at the end of the study for their compliance with instructions and for not changing lifestyle.

PROCEDURES
This study was a single blinded randomized design. The subjects were randomly assigned to the six groups and the technicians were blinded so they did not know who was in each group. At the onset of the study, demographic data was obtained for each subject including age, height, weight, BMI, resting heart rate, blood pressure, and total body fat by impedance. Girth of the waist (at the umbilicus) and thighs (half of the distance between the hip and knee) and hips was measured as described in the methods section. There were a total of six groups of subjects who participated as follows:

For the six groups, the measurements taken were height, weight, circumferences (at belly button, hips, and left and right thighs), blood pressure, subcutaneous fat thickness, heart rate, and the height of the gluteals. These were taken on day 0 for control data. Weight and girths were repeated at 1, 2, 4, and 6 weeks. Ultrasound images for fat thickness (at tummy and thighs) and for the level of cellulite on the thighs, the height of the gluteals, heart rate, and blood pressure were only measured at the beginning and end of the study (weeks 0 and 6).

The six groups consisted of:

Lifestyle groups (no change in diet or exercise)
- Group 1: (LS control) No change in their diet and exercise program. This group is control subjects.
- Group 2: (LS tummy) Applied lipolytic cream only to their tummy area and only performed abdominal exercises from an exercise DVD.
- Group 3: (LS thigh) Applied lipolytic cream only to their thighs area and only performed leg exercises from exercise DVD.

Diet and exercise groups
- Group 4: (DE control) Exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and ate a healthy diet.
- Group 5: (DE tummy) Exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and ate a healthy diet. Also, applied lipolytic cream only to their tummy area and performed abdominal exercises from exercise DVD.
- Group 6: (DE thigh) Exercised 180 minutes per week at a moderate intensity level (jogging, bicycling, swimming, etc.) and ate a healthy diet. Also, applied lipo-
lytic cream only to their thighs area and performed leg exercises from exercise DVD.

RESULTS
The results of the experiments are listed in Figures 1-9.

Weight Loss-
The weight loss for the 6 groups of subjects is shown in Figure 1.
As shown in Figure 1, the LS control subjects had no significant change in their weight over the 6-week period (p>0.05). All other groups lost weight. There was a small but significant loss in weight in the lifestyle cream groups, but it was only about 1kg. The most significant weight losses were in the DE exercise groups, while the LS cream groups also had a significant weight loss but much smaller in magnitude. The weight loss of the LS cream groups was significant (p<0.01) as were the DE exercise groups (p<0.01) and, the LS cream vs the DE exercise groups were significantly different from each other (p<0.01). The lifestyle cream groups were significantly different than the lifestyle control group. There was no significant difference between the 3 DE exercise groups at the end of the first week of the study and by the end of the study the diet and exercise thigh group lost significantly more weight than the other two diet and exercise groups (p<0.05).

Girth at the waist-
The girth change at the waist for the six groups of subjects is shown in Figure 2. As shown in Figure 2, the greatest loss in abdominal girth was in the diet and exercise tummy group (p<0.01), and this was significantly different than the DE controls (p<0.01). Likewise, the lifestyle tummy group (lifestyle, no exercise) lost considerable abdominal circumference (p<0.01), which was significant compared to the lifestyle control groups (p<0.05). There was no significant difference in the girth loss between the lifestyle cream tummy and the DE control and DE thigh groups (p>0.05), but all showed significant girth loss through the study (p<0.01). The lifestyle cream
tummy and DE groups had significant girth loss in the first week (p<0.05). The lifestyle cream thigh group had no loss in girth in the abdominals showing the specificity of the cream targeting fat loss in the area that the cream is applied to. The fact that there was nearly as much loss in abdominal girth in the lifestyle tummy group where there was little weight loss also shows good targeting by the cream on the area it is applied to.

**Girth at hips**

The girth change at the hips for the 6 groups is shown in Figure 3.

The lifestyle control group had no change in girth at the hips (p>0.05). There was a significant loss in circumference in all of the other 5 groups of subjects (p<0.01). The greatest loss was in the diet and exercise tummy group compared to the other groups (p<0.01). The girth loss at the hips in the lifestyle tummy and lifestyle thigh groups is due to the fact that the hip area was the crossover point and they rubbed the cream over part of the hips in both groups. Therefore, the girth loss was also enhanced in this area.

**Girth at thighs**

The girth change at the thighs for the six groups of subjects is shown in Figure 4.

As shown in Figure 4, the greatest loss in girth in the thigh was the diet and exercise and lifestyle thigh groups. The lifestyle cream thigh group still lost considerably more girth on the thigh (p<0.01), which was significant compared to the lifestyle control group (p<0.05), and even more than the diet and exercise control group (p<0.01). The DE control and DE tummy lost girth, but there was no significant difference between the 2 (p>0.05). In the first week of the study, the girth loss in the LS thigh and DE thigh was significant (p<0.01). The DE thigh group was significantly greater than the DE control group throughout the study (p<0.01). At the end of the study, the difference was about 2.2 times greater than the DE controls.

**Body Fat changes**

The change in body fat in each of the groups is shown in Figure 5.
As shown in Figure 5, the lifestyle control group had no significant change in the percent body fat from the beginning to the end of the study (p>0.05). However, the lifestyle cream groups did have a significant but small drop in total body fat (p<0.05). The three exercise groups had similar reductions in total body fat, which were significant (p<0.01). Based on the loss in body weight, this loss in weight was all body fat and not lean body mass. The diet and exercise cream tummy group had significantly more fat loss than the diet and exercise control and diet and exercise thigh group (p<0.05).

**Change in gluteal height**-

The change in gluteal height is shown in Figure 6. As shown in Figure 6, the exercise groups averaged over a centimeter increase in the height of the gluteal. This increase was significant (p<0.01). The greatest increase was in the thigh cream exercise group, which was significantly higher and double the other exercise groups (p<0.01). The lifestyle cream tummy and lifestyle control group had no significant change, but the lifestyle cream thigh group did (p<0.05) and this was significant compared to the lifestyle controls (p<0.05).

**Subcutaneous Fat (Ultrasound)** –

The loss in thickness of the subcutaneous fat for the thigh is shown in Figure 7. As shown in Figure 7, the greatest subcutaneous fat loss was in the thigh cream exercise group, where the fat loss was significantly higher than the other groups (p<0.01). There was no change in the control lifestyle or lifestyle tummy group. The lifestyle thigh group change was significant (p<0.05) and was significant compared to the lifestyle controls (p<0.05). There was a significant change in the DE control and DE tummy from the beginning to the end of the study but there was no significant difference in subcutaneous fat between the DE control and DE tummy group. The coefficient of variation for the Lifestyle thigh group was reduced by 39.3% showing a smoother skin and fat layer after the 6 weeks of the study. As shown in Figure 8, the lifestyle cream group had a significant but small drop in total body fat (p<0.05) and this was significant compared to the lifestyle controls (p<0.05).
on thigh did as well as the diet and exercise control and the diet and exercise tummy cream groups in smoothing skin and subcutaneous fat (p>0.05), and the lifestyle cream thigh was significant compared to the lifestyle controls (p<0.05). All three groups had a significant improvement in skin smoothing (p<0.01). The diet and exercise cream group on the thigh did significantly better than any of the other groups (p<0.01). The DE thigh group showed a 54.3+/-7.9% reduction in the coefficient of variation. There was no significant difference for the lifestyle control and lifestyle cream tummy groups (p>0.05). The lifestyle cream tummy group was significant vs the lifestyle controls (p<0.05), and showed the same subcutaneous fat loss as the diet exercise control group. The diet exercise tummy group was approximately twice the subcutaneous fat loss as the diet exercise control group (p<0.01).

**Compliance**

Exercise compliance was above 80% for all groups. Diet compliance was lower than exercise compliance and ranged from 60-76%. Cream use compliance was over 80% in all groups using cream. Compliance with the instructions in the lifestyle groups for not changing their diet and exercise was 100%.

**Blood Pressure and heart rate**

There were no significant differences in heart rate and blood pressure through the study, but there was a strong trend in the exercise groups for a reduction in heart rate and blood pressure (systolic).

**DISCUSSION**

Obesity is a major problem in the United States and around the world.5-8 With increasing diets consisting of fats and carbohydrates, obesity is even a problem in Asia,31-33 a population that always ate well.
Some studies call the increase in obesity “Coca-cola-ization” of Mc Donaldsization.34 But in all reality, it is a changing diet and people leaving agrarian societies and moving to office jobs in the cities, fast food, and little exercise.35 The increase in body fat also causes a loss of self-image that people want to correct.36

In the present investigation, we examined a slimming system with a lipolytic cream to evaluate if there could be spot loss in fat with and without exercise and dieting. Using cream alone caused a very small weight loss over a 6-week period. However, the diet and exercise program did cause appreciable weight loss over this same period with, and without the cream applied to either the abdominals or the thighs. The girth loss in the areas targeted by the slimming system was significantly higher than the other areas of the body compared to the control groups.

For example, when the cream was used on the abdominal area, as shown in Figure 2, the greatest loss in girth was in the abdominal area. Even when the cream was used without exercise and diet, there was still as much girth loss as in the exercise and diet control group. Thus, the cream was very effective in causing spot loss in fat. In fact, the loss in girth and fat loss was approximately 2 times greater in the DE targeted groups than the DE control group. The girth loss for the DE tummy was about 1.6 times the girth loss in the DE controls and the DE thigh loss was about 2.2 times the loss in girth as the DE controls. Similarly the subcutaneous fat loss was 1.8 times greater on the DE tummy and 2.6 times greater on the DE thigh in the respected targeted areas compared to the DE controls. This is also seen in Figure 4, where the greatest loss in girth at the thighs was in the DE thigh cream group, while diet and exercise alone causes less of a change in girth at the thighs. When subcutaneous fat was measured by ultrasound, the greatest loss in subcutaneous fat was in the thigh with thigh cream and exercise and on the tummy with tummy cream and exercise. The lifestyle groups also showed significant subcutaneous fat loss in the areas targeted by the slimming system. These areas also saw the greatest smoothing in the skin and subcutaneous fat layer.

The coefficient of variation provided a statistical measure of the improvement in cellulite by measuring a change in the variation in the skin and subcutaneous fat. Ultrasound has been successfully used to measure cellulite by variability in the thickness of subcutaneous fat.21 Subcutaneous fat variability under ultrasound imaging has been correlated to the degree of cellulite. In other words, less variability measured by ultrasound means a smoother appearance of the skin. This statistical analysis here used a similar technique and showed a significant reduction in cellulite.

Diet and exercise alone showed a good reduction in cellulite by 38.8 %, and was very comparable to the lifestyle cream group which was a 39.3% improvement in skin smoothness (p<0.01). Diet and exercise thigh showed a significant improvement in skin smoothness above the diet and exercise
controls (p<0.01). Improvement in cellulite is consistent with diet and exercise\textsuperscript{28} and with lipolytic cream.\textsuperscript{29} Additionally, the protocol for applying the cream involves a gentle upward massaging technique comparable to lymph edema drainage massage. Poor lymphatic flow has been implicated as a potential contributor to cellulite, and recently various forms of upward massage techniques have demonstrated positive effects on cellulite.\textsuperscript{37}

Finally, when the height of the gluteals was measured, it responded best to exercise and thigh cream. Here there was a large increase in height, giving better sculpting of the body. Diet and exercise alone improved the height of the gluteals, since diet and exercise tones and reduces body fat. But the lifestyle thigh group, while losing only a modest amount of weight and not exercising, saw the same improvement in the height of the gluteals as did the exercise and diet control group. The height increase in the gluteals in the DE thigh group was 2 times that of the DE control group.

In conclusion, the overall results of the study showed consistent fat and girth loss in the areas targeted by the slimming system under the no change in lifestyle and exercise conditions. For the lifestyle conditions, fat and girth loss only occurred in the targeted areas. At the hips, there was some cream applied in the tummy and thigh groups due to the close position of the hips to the tummy and thighs, the cross over point on the skin between the two groups. This resulted in fat loss at the hips in both of these groups. The lifestyle controls showed no statistical change in any parameter.

Similarly for the diet and exercise condition, fat and girth loss was statistically higher in the targeted areas than the diet and exercise control group and was on the average 2 times higher. For the lifestyle groups there was some weight loss so fat was not just removed from the target areas but removed from the body. The elastic garment obviously provides a slimming effect due to its elastic nature similar to other slimming garments. However, unlike other garments, the system provides actual girth and fat loss in the areas treated.

Thus people receive the instant slimming effect from the garment while actual girth and fat are being reduced by the system. There were no adverse events reported from the study participants such as skin sensitivity to the cream. The results of the study are consistent with other studies using an aminophylline and caffeine cream for targeted fat reduction.

REFERENCES


