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## Clinical Efficacy of Mannatech LIFT™ Skin Care Products

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### OBJECTIVES

A usage study was performed to test the efficacy and safety of the Mannatech LIFT skin care system over the course of 12 weeks. A kinetic study was performed to evaluate the immediate effect (one hour after use) of the Multiphase Serum on the face and the hydration effects of the Body Lotion, Day Moisturizer and Night Repair Crème over an 8-hour period.

### METHODOLOGY

#### Study Participants

A subject sample of females were included based on the following criteria: self-perceived dry skin on the face and body; clinically determined mild to moderate fine lines and coarse wrinkles in the periorcular area; use of razors to remove hair from the legs. Of the subject sample, subjects with mild to moderate dryness on the lower legs at Baseline were eligible for participation in the kinetic study.

From a sample of 46 subjects who enrolled to participate, 44 subjects completed the usage study; 30 subjects completed the kinetic study. Two subjects voluntarily withdrew from the usage study due to personal reasons not related to the test materials. Subject demographic information is presented in Table 1.

**Table 1: Subject Demographics**

		All Subjects (n=44)
Age (Years)	Mean ± Standard Deviation	49.42 ± 6.78
	Minimum	36.43
	Maximum	63.49
Ethnicity	African American	5 (11.4%)
	Asian	5 (11.4%)
	Caucasian	22 (50.0%)
	Hispanic	11 (25.0%)
	Caucasian/Hispanic	1 (2.3%)

#### Study Design

Prior to study enrollment, subjects completed an Eligibility and Health Questionnaire, and read and signed an Informed Consent Agreement, a Confidentiality Agreement, a HIPAA Agreement and a Photography Release Form.

For the usage study, efficacy and safety of the Mannatech LIFT skin care system were assessed via visual grading and photography at baseline and after 8 and 12 weeks of product usage. Self-Assessment Questionnaires were completed after 8 and 12 weeks of usage.

Visual Grading Scales:

- Firm appearance (0=toned/resilient, 9=loose/lax)

- Radiance (0=dull/matte appearance, 9=radiant, luminous appearance)
- Lift (0=well-defined contouring, 9=loss of contouring due to sagging)
- Pore size (0=small, 9=large)
- Overall dyschromia (0=none, 9=severe)
- Overall photodamage (0=none, 9=severe)
- Skin laxity on the left temple (0=tight/firm, 9=loose)
- Tactile roughness (0=smooth, 9=rough)
- Fine lines (0=none, 9=severe)
- Coarse wrinkles (0=none, 9=severe)

For the kinetic study, four test sites (25 cm<sup>2</sup> each) were demarcated on the lower lateral side of the right and left legs. Three sites were assigned to receive product application (one test site per product); the fourth site was assigned to remain untreated to serve as a negative control. Visual grading was performed at baseline and after one and eight hours of product application. Cutometer measurements were performed at baseline and after one hour of product application. Corneometer measurements were performed at baseline and after eight hours of product application. Self-Assessment Questionnaires were completed after one hour of product application.

Additional Visual Grading Scales:

- Scaling (0=none, 8=obvious large scales)
- Fissuring (0=none, 8=obvious cracking and small breaks in skin)
- Overall skin condition (0=good, 9=poor)

## Products

Exfoliating Facial Cleanser #34-105  
Multiphase Serum #34-155  
Day Moisturizer #34-109  
Night Repair Crème #34-117  
Body Lotion #34-125

## Product Usage

Upon completion of the baseline procedures, subjects in the kinetic regression portion of the study applied the Multiphase Serum to the face. A clinician pipetted 100 microliters of Hydrating Body Lotion, Day Moisturizer and Night Repair Crème onto the test sites (one product per test site).

During the course of the usage study, subjects applied products to the face in the morning (Exfoliating Facial Cleanser, Multiphase Serum and Day Moisturizer) and evening (Exfoliating Facial Cleanser and Night Repair Crème). The Body Lotion was applied twice per day to the lower legs.

## Statistical Methods

For the usage study, mean scores at each post-baseline time point were statistically compared to mean baseline scores using a paired t-test. For the kinetic study, comparisons between time points were conducted using analysis of variance (ANOVA) with pair-wise comparisons (Fisher's LSD).

The Self-Assessment Questionnaires, completed at the conclusion of the usage and kinetic studies, were tabulated, and a top-box analysis was performed.

## RESULTS

### Usage Study

A total of 44 subjects completed the usage portion of the study. Results of the visual grading showed that the appearance of radiance, lift, pore size, overall dyschromia, overall photodamage, skin firmness, skin

laxity and tactile roughness were significantly improved on the face; fine lines and coarse wrinkles were significantly improved on the right face, left face and facial average after 8 weeks and 12 weeks of facial regimen usage, when compared to baseline. The average percent changes from baseline and percentages of subjects showing improvements at both 8 and 12 weeks are presented in Table 2. Scaling, fissuring and overall skin condition were significantly improved on the right leg, left leg and leg average after 8 weeks of Body Lotion usage. There were no significant negative effects on irritation grading (erythema, edema, scaling, burning, stinging, itching, tightness and tingling) during the usage study.

**Table 2: Facial Grading**

	8 weeks		12 weeks	
	Change from baseline	Subjects improved	Change from baseline	Subjects improved
Firm Appearance	-10.10%	43.10%	-18.80%	70.40%
Radiance	9.40%	86.30%	10.80%	93.10%
Lift	-12.10%	45.40%	-20.50%	65.90%
Pore Size	-3.50%	34.00%	-4.90%	38.60%
Overall Dyschromia	-13.30%	54.50%	-23.90%	81.80%
Overall Photodamage	-22.60%	97.70%	-36.20%	97.70%
Skin Laxity	-15.80%	79.50%	-22.10%	90.90%
Tactile Roughness	-95.00%	100.00%	-100.00%	100.00%
Fine Lines - Right Face	-15.70%	72.70%	-24.10%	90.90%
Coarse Wrinkles - Right Face	-23.30%	79.50%	-37.70%	88.60%
Fine Lines - Left Face	-16.30%	63.60%	-25.30%	86.30%
Coarse Wrinkles - Left Face	-20.20%	68.10%	-31.10%	90.90%
Fine Lines - Facial Average	-16.00%	88.60%	-24.70%	95.40%
Coarse Wrinkles - Facial Average	-21.70%	88.60%	-34.20%	95.40%

Yellow highlighting indicates significant change from baseline (paired t-test; p<0.05)

Results of the top-box/bottom-box analysis of the Self-Assessment Questionnaires showed that a greater proportion of subjects responded favorably rather than unfavorably for all parameters after 8 and 12 weeks of test material usage. The top-box analysis of the questionnaire results is presented in Table 3.

**Table 3: 12-week Self-Assessment Questionnaire**

	Favorable response
Overall liking of entire regimen	90.90%
Exfoliates the skin	100.00%
Leaves skin feeling smooth	93.10%
Leaves skin feeling healthy	90.90%
Leaves skin radiant/luminous	86.30%
Leaves skin refined	90.90%
Hydrates/moisturizes the skin	90.90%
Reduces fine lines in the eye and facial area	93.10%
Reduces wrinkles in the eye and facial area	90.90%
Reduces skin discolorations	72.70%
Evens skin tone	75.00%
Leaves pores less noticeable	75.00%
Leaves skin more resilient/elastic	86.30%
Leaves skin looking and feeling younger	90.90%
Leaves skin feeling clean	88.30%
Is gentle enough for everyday use	88.30%

Yellow highlighting indicates a significantly greater proportion of subjects responded favorably rather than unfavorably (top-box analysis;  $p \leq 0.0005$ )

### Kinetic Study

A total of 30 subjects completed the kinetic portion of the study. Results of the visual grading showed that radiance, skin laxity and tactile roughness were significantly improved on the face; fine lines and coarse wrinkles were significantly improved one hour after application of the Multiphase Serum, when compared to baseline. Results of the cutometer measurements showed that pure elasticity and biological elasticity were significantly decreased one hour after application of the Multiphase Serum, when compared to baseline. Additionally, the Day Moisturizer, Night Repair Crème and Body Lotion significantly improved scaling, fissuring and overall skin condition on the legs after eight hours, when compared to baseline. Results of the corneometer measurements showed improvements in skin hydration on the legs for the Day Moisturizer and Night Repair Crème after eight hours, when compared to baseline. The average percent changes from baseline and percentages of subjects showing improvements during the kinetic study are presented in Tables 4 and 5.

**Table 4: One-Hour Kinetic Study – Multiphase Serum**

	Change from baseline	Subjects improved
Firm Appearance	-0.60%	3.30%
Radiance	8.00%	86.60%
Lift	0.00%	0.00%
Pore Size	0.00%	0.00%
Overall Dyschromia	0.00%	0.00%
Overall Photodamage	-1.70%	10.00%
Skin Laxity	-2.00%	13.30%
Tactile Roughness	-84.90%	100.00%
Fine Lines - Right Face	-3.60%	30.00%
Coarse Wrinkles - Right Face	-6.30%	33.30%
Fine Lines - Left Face	-6.50%	33.30%
Coarse Wrinkles - Left Face	-6.90%	36.60%
Fine Lines - Facial Average	-5.10%	53.30%
Coarse Wrinkles - Facial Average	-6.60%	50.00%
Cutometer - Extensibility	0.50%	66.60%
Cutometer - Resiliency	-3.80%	46.60%
Cutometer - Pure Elasticity	-10.40%	26.60%
Cutometer - Biological Elasticity	-7.90%	30.00%

Yellow highlighting indicates significant change from baseline (paired t-test;  $p \leq 0.05$ )

**Table 5: Eight-Hour Kinetic Study**

		Change from baseline	Subjects improved
<b>DAY MOISTURIZER</b>	Scaling	-92.70%	93.30%
	Fissuring	-87.50%	56.60%
	Overall Skin Condition	-89.30%	90.00%
	Corneometer (Hydration)	20.40%	90.00%
<b>NIGHT REPAIR CRÈME</b>	Scaling	-88.70%	93.30%
	Fissuring	-72.00%	66.60%
	Overall Skin Condition	-86.50%	93.30%
	Corneometer (Hydration)	15.10%	93.30%
<b>BODY LOTION</b>	Scaling	-65.90%	90.00%
	Fissuring	-68.00%	53.30%
	Overall Skin Condition	-70.20%	90.00%
	Corneometer (Hydration)	1.90%	53.30%

Yellow highlighting indicates significant change from baseline (paired t-test; p≤0.05)

**CONCLUSIONS**

Clinical grading results showed the Mannatech LIFT skin care system to be well-tolerated and significantly effective in improving all efficacy parameters after 8 weeks and 12 weeks of product usage. In addition, the Body Lotion was significantly effective in improving leg skin scaling, fissuring and overall skin condition after eight weeks of usage.

During the kinetic portion of the study, the Multiphase Serum significantly improved skin radiance, skin laxity, tactile roughness, fine lines and coarse wrinkles after one hour of product application. The cutometer results showed that pure elasticity and biological elasticity were significantly lowered, suggesting that the skin became firmer. Furthermore, the Day Moisturizer, Night Repair Crème and Body Lotion significantly improved scaling, fissuring and overall skin condition on the legs after eight hours, while the corneometer measurements showed improvements in skin hydration on the legs for the Day Moisturizer and Night Repair Crème.

Self-Assessment Questionnaires were overwhelmingly positive for all of the Sponsor’s regimen products.

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