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EVALUATION OF INTERX COSMETOLOGY THERAPY IN IMPROVING THE CONDITION OF FACIAL PHOTOAGING

Pilot + Standard Study

Prepared For:

Neuro Resource Group

Thomas C. Thompson

Thomas J. Stephens & Associates, Inc.

Stephens Study Number: C06-D099
Sponsor Study Number: CS0601002

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PURPOSE

This single-center, controlled usage study was conducted for Neuro Resource Group to assess the efficacy of InterX Cosmetology Therapy, an interactive neural stimulation device, in improving photodamage when used by men and women on the face. Product efficacy was measured using digital photography, clinical grading of digital images, silicone replicas, staining and grading of full-thickness skin biopsies, and subject self-assessment questionnaires.

GENERAL INFORMATION

Stephens Study Number:	C06-D099
Neuro Resource Group Study Number:	CS0601002
Test:	Evaluation of InterX Cosmetology Therapy in Improving the Condition of Facial Photoaging
Test Material:	InterX 5000
Investigator/Study Physician:	Peter D. Hino, M.D., Board Certified Dermatologist
Sub-Investigator:	Monya L. Sigler, Ph.D.
Sub-Investigator:	Thomas J. Stephens, Ph.D.
Clinic Manager:	Barbara Hammond, B.S.
Biostatistics Manager:	Paul Kavanaugh, M.S.
Quality Assurance Manager:	Colleen Banas
Testing and Administrative Facility:	Thomas J. Stephens & Associates, Inc. 3310 Keller Springs Road, Suite 130 Carrollton, Texas 75006
Sponsor:	Neuro Resource Group 1100 Jupiter Road, Suite 190 Plano, Texas 75074
Sponsor Representative:	Thomas C. Thompson
Experiment Start Date:	May 12, 2006
Experiment End Date:	October 3, 2006

SUMMARY

This single-center, controlled usage pilot study was conducted for Neuro Resource Group to assess the efficacy of InterX Cosmetology Therapy, an interactive neural stimulation device, in improving photodamage when used by men and women on the face. Product efficacy was measured using digital photography, clinical grading of digital images, silicone replicas, staining and grading of full-thickness skin biopsies, and subject self-assessment questionnaires.

Five subjects (001, 002, 004, 005, 007) participated in a pilot study, which was conducted to determine the best methodology to capture potential product benefit. The results of the pilot study are incorporated into this report (see Appendix XII for a copy of the Pilot Study report). As a result of the pilot study, Ultrasound measurements were not performed during the standard portion of the study and are not addressed in this report.

A total of 29 subjects completed participation in the pilot or standard portion of the study. Subjects qualified for study participation according to the following criteria:

- Fitzpatrick Skin Classification Type I, II, III or IV
- Modified Glogau Classification of Category II (Moderate) or Category III (Advanced)
- Presence of mild to moderate lines and wrinkles in the crow's foot and/or under eye area

Ten facial treatments were performed in the clinic over the course of two weeks at Visits 1 through 10. Facial treatments using the Sponsor's InterX Cosmetology Therapy device were performed by the Sponsor's personnel for approximately 15 to 20 minutes.

Subjects participated in clinical assessments at Baseline (prior to the first treatment) and at two weeks and six weeks after Baseline. The following procedures were performed at the indicated time points:

- Digital Photography (Baseline, Week 2, Week 6)
  One full-face, visible-light digital photograph was taken of either the right side, left side, or frontal face (as determined by the expert grader) using the NikonD1 or D100 digital camera.

- Expert Clinical Grading (Baseline, Week 2, Week 6)
  The digital photographs were evaluated by an expert clinical grader and graded for the following efficacy and safety parameters: fine lines/wrinkles, evenness of skin tone, clarity, lifting, overall facial appearance, erythema, and dryness/scaling.

- Silicone Replicas (Baseline, Week 2)
  A silicone replica (negative cast) was taken of the right or left crow's foot area (same side selected for photographs/grading) by the Sponsor's personnel.

- Skin Biopsies (Baseline, Week 2)
  The Study Physician collected a full-thickness 2-millimeter punch biopsy of facial skin from the right or left cheek (as determined by a randomization design). Tissue samples were forwarded to ProPath laboratories for processing and grading of specific parameters.

SUMMARY (Continued)

- Self-Assessment Questionnaires (Week 2, Week 6)
  Subjects completed a self-assessment questionnaire regarding improvements in skin condition.

Results of this study showed the following:

- After 10 days of treatment (Week 20 and after an additional four weeks of post treatment follow up (Week 6), all clinical parameters showed a significant improvement over baseline except for evenness of skin tone. Dryness/scaling showed no changes for the duration of the study and erythema showed a significant decrease four weeks after treatments were completed.
- Analysis of full thickness skin biopsy samples showed significant improvements for epidermal/dermal glycosaminoglycan and collagen formation.
- Top box analysis of questionnaire responses were overwhelmingly positive with a significantly greater number of subjects answering positively than negatively for all 11 questions regarding facial improvements and experience with the treatment.

Overall, results of blinded clinical grading and subject self assessment questionnaires show that 10 treatments with the Sponsor's device over a two week period was effective in improving the appearance of photodamaged facial skin, and that the benefit persists for at least four weeks after treatment. Analysis of full thickness skin biopsies taken at baseline and after 10 treatments suggests that deposition of glycosaminoglycans and collagen may underlie these visual improvements.

STORAGE, HANDLING, AND DOCUMENTATION OF TEST MATERIALS

The receipt of test materials by Thomas J. Stephens & Associates, Inc. was documented in a logbook, which serves as a permanent record of the receipt, storage, and return of all study materials. All study materials were kept in a locked product storage room accessible to clinical staff members only. The Sponsor's treatment device remained at the testing facility or was brought to the testing facility by the Sponsor on the days of treatment. At the conclusion of the clinical study, remaining test materials were returned to the Sponsor.

INFORMED CONSENT

Written informed consent conforming to 21 CFR 50.25 was obtained from each subject prior to enrollment in the study. An original signed copy for each subject participating in the study will be retained in the study file. Each subject received a copy of the agreement. Please see Appendix V for a sample form.

INSTITUTIONAL REVIEW BOARD

The protocol and informed consent agreement for this study were reviewed and approved by IntegReview Institutional Review Board (IRB) on 05/02/06. Please see Appendix IV for copies of the IRB approval letters.

RECORD OF SPONSOR MONITORING VISITS

During the course of the pilot and standard study, the following Sponsor representatives visited the testing facility to provide training, perform subject treatments, and monitor study procedures on the indicated dates:

	Sponsor Representative(s)	Dates of Visits
Pilot Study	Sarah Magee	05/12/06, 05/16/06, 05/17/06, 05/18/06, 05/19/06, 05/22/06, 05/23/06, 05/24/06, 05/25/06, 05/26/06.
Standard Study	Sarah Magee	08/17/06
	Tommy Thompson, Gretchen Wild, Sarah Magee	08/18/06
	Sarah Magee, Zunia Frost	08/21/06, 08/22/06, 08/23/06, 08/24/06, 08/25/06, 08/28/06, 08/29/06, 08/30/06, 08/31/06, 09/01/06
	Paul Magee	08/31/06, 09/01/06

ATTRITION

A total of 29 subjects completed the pilot or standard portion of the study. Thirty-four (34) subjects enrolled in the study and five subjects were discontinued due to the following reasons:

- Disqualified from the study: 003, 006
- Voluntarily discontinued participation: 014
- Failed to attend scheduled visits: 032
- Enrolled in the pilot group: 016

Please see Appendix VI for a copy of the Attrition Form.

ADVERSE EVENTS

During the course of the study, two subjects experienced adverse events which were determined to be not related to the test material or study procedures. Subjects 013 and 022 experienced bruising on the face after sustaining minor injuries. Please see Appendix VIII for complete copies of the Adverse Event Forms.

SUBJECT DEMOGRAPHICS

Twenty-nine (29) subjects completed the study. Table 1 presents each subject's ethnicity, gender, and date of birth. Ethnicity information was obtained from each subject's Eligibility and Health Questionnaire.

TABLE 1
SUBJECT DEMOGRAPHICS

Subject Number	Ethnicity	Gender	Date of Birth
001	Caucasian	Female	10/02/60
002	Caucasian	Female	12/17/57
004	Caucasian	Female	12/29/49
005	Caucasian	Female	04/13/59
007	Caucasian	Female	12/05/42
008	Asian	Male	04/26/52
009	Caucasian	Female	07/20/60
010	Caucasian	Female	12/26/48
011	Caucasian	Female	09/01/45
012	Caucasian	Female	02/03/59
013	Caucasian	Female	11/22/42
015	Caucasian	Female	06/20/47
017	Caucasian	Female	01/04/61
018	Hispanic	Male	11/29/54
019	African American	Male	12/22/45
020	Asian	Male	05/08/47
021	Caucasian	Female	10/09/64
022	Caucasian	Female	09/23/49
023	Caucasian	Female	03/02/49
024	Asian	Female	06/26/65
025	Caucasian	Female	08/07/53
026	Hispanic	Female	08/09/47
027	Caucasian	Female	03/16/58
028	Caucasian	Female	04/06/59
029	Caucasian	Female	11/24/53
030	Caucasian	Female	10/11/64
031	Caucasian	Female	09/30/57
033	Caucasian	Female	03/06/50
034	Caucasian	Female	01/16/66

PROTOCOL AMENDMENTS

Affected Section of Protocol:	**CONDUCT OF STUDY**, Schedule of Procedures/Procedures
Deleted Procedures:	Ultrasound scans were not performed at any time point during the standard study.
Reason for Change:	Sponsor request

Affected Section of Protocol:	**CONDUCT OF STUDY**, Procedures, Visit 1: Baseline, *Expert Clinical Grading*
Original Wording:	• Evenness of Skin Tone (0 = very blotchy uneven color, 9 = no blotchiness, smooth even color)
	• Clarity (0 = dull, matte finish; 9 = bright, radiant finish)
	• Overall Facial Appearance (0 = unhealthy, dull, aged appearance, 9 = bright, healthy, youthful appearance)
Revised Wording:	• Evenness of Skin Tone (0 = no blotchiness, smooth even color, 9 = very blotchy uneven color)
	• Clarity (0 = dull, matte finish; 9 = bright, radiant finish)
	• Overall Facial Appearance (0 = bright, healthy, youthful appearance 9 = unhealthy, dull, aged appearance)
Reason for Change:	Investigator request

PROCEDURES AND METHODS

Five subjects (001, 002, 004, 005, 007) participated in a pilot study, which was conducted to determine the best methodology to capture potential product benefit. The results of the pilot study are incorporated into this report (see Appendix XII for a copy of the Pilot Study report). As a result of the pilot study, Ultrasound measurements were not performed during the standard portion of the study and are not addressed in this report.

Prior to the start of the study, prospective subjects participated in a 1 to 3 day washout period, during which moisturizing products were not used on the face. At the Baseline Visit (Visit 1), prospective subjects signed an Informed Consent Agreement and were evaluated on the face for the following eligibility criteria:

- Fitzpatrick Skin Classification (Types I, II, III and IV qualify)
  The Fitzpatrick Skin Classification is based on the skin's unprotected response to the first 30-45 minutes of sun exposure after a winter season without sun exposure:
  - I Always burns easily; never tans.
  - II Always burns easily; tans minimally
  - III Burns moderately; tans gradually
  - IV Burns minimally; always tans well
  - V Rarely burns; tans profusely
  - VI Never burns; deeply pigmented

- Modified Glogau Classification (Categories II and III qualify)
  - I Mild: no keratoses or scarring; little wrinkling
  - II Moderate: early actinic keratoses - slight yellow skin; discoloration; early wrinkling - parallel smile line
  - III Advanced: actinic keratoses - obvious yellow skin; discoloration with telangiectasia; wrinkling - present at rest
  - IV Severe: actinic keratoses; skin cancers have occurred; wrinkling - much cutis laxa of actinic, gravitational, and dynamic origin

- Presence of mild to moderate lines and wrinkles in the crow's foot and/or under eye area (score of 3 to 7 on a scale where 0 = none and 9 = numerous, extensive wrinkling).

PROCEDURES AND METHODS (Continued)

Subjects completed an Eligibility and Health Questionnaire and signed a Confidentiality Agreement and a Photography Release Form. Qualified subjects participated in the following clinical grading and instrumentation procedures:

- Digital Photography
  One full-face, visible-light digital photograph was taken of either the right side, left side, or frontal face (as determined by the expert grader) using the NikonD1 or D100 digital camera.

- Expert Clinical Grading
  The digital photographs were evaluated by an expert clinical grader and graded for the following efficacy and safety parameters using a 0 to 9 scale (scale anchors are listed in parentheses):

  Efficacy Parameters
  - Fine Lines/Wrinkles (0 = none, 9 = numerous, extensive wrinkling)
  - Evenness of Skin Tone (0 = no blotchiness, smooth even color, 9= very blotchy uneven color)
  - Clarity (0 = bright, radiant finish, 9 = dull, matte finish)
  - Lifting (0 = well defined tight skin, 9 = sagging skin)
  - Overall Facial Appearance (0 = bright, healthy, youthful appearance, 9 = unhealthy, dull, aged appearance)

  Safety Parameters
  - Erythema (0 = none, 9 = angry redness over most of face)
  - Dryness/Scaling (0 = none, 9 = large visible lifting scales over most of face)

- Silicone Replicas
  A silicone replica (negative cast) was taken of the right or left crow's foot area (same side selected for photographs/grading) by the Sponsor's personnel.

- Skin Biopsies
  The Study Physician collected a full-thickness 2-millimeter punch biopsy of facial skin from the right or left cheek (as determined by a randomization design). An injection of lidocaine or other anesthetic was given prior to biopsy collection and sites were sutured at the physician's discretion. Tissue samples were fixed in 10% buffered formalin and forwarded to ProPath laboratories (Dallas, Texas) for processing and grading of collagen, hyaluronic acid, epidermal thickness, corneal and granular layer compaction, and glycosaminoglycans.

Subjects were provided with a calendar of study visits and subject instructions.

Ten facial treatments were performed in the clinic over the course of two weeks at Visits 1 through 10. Facial treatments using the Sponsor's InterX Cosmetology Therapy device were performed by the Sponsor's personnel for approximately 15 to 20 minutes.

Subjects returned to the clinic approximately two weeks after Baseline (Visit 11: Week 2 assessments). Subjects participated in digital photography, clinical grading of photographs, silicone replicas, and skin biopsies as described for Baseline. Subjects also completed a self-assessment questionnaire regarding improvements in skin condition.

Subjects returned to the clinic approximately six weeks after Baseline (Visit 12: Week 6 assessments). Subjects participated in digital photography, clinical grading of photographs, and self-assessment questionnaires.

BIOSTATISTICS AND DATA MANAGEMENT

Mean values for clinical grading parameters (from photographic images) at Week 2 and Week 6 were statistically compared to mean Baseline values using a paired t-test at the $p \leq 0.05$ significance level. Mean percent change from Baseline and incidence of positive responders were calculated for all attributes. Please see Appendix I for complete statistical calculations.

Self-assessment questionnaires completed by subjects at Week 2 and Week 6 were tabulated and a top box analysis was performed. Please see Appendix II for questionnaire tabulations.

Biopsy samples were forwarded to ProPath laboratories for processing and grading of specific parameters. Silicone replicas were collected and maintained by Sponsor personnel.

MAINTENANCE OF RECORDS

All original records (including the study protocol, observation records, medical histories, informed consent agreements, attrition form, and any other records or forms used in this study) and a copy of the final report will be retained on file in the Thomas J. Stephens & Associates, Inc. archives for two years from the date of study completion. When the archive time has expired, the study files will be either destroyed or sent to the Sponsor at the Sponsor's expense.

RESULTS

Photographic images taken of each subject at Baseline, Week 2, and Week 6 were clinically graded for efficacy and safety parameters. Table 2 presents the results of the digital photograph clinical grading. Mean values at Week 2 and Week 6 are statistically compared to mean Baseline values for significant differences. Additionally, the following information is listed: Delta (average change from Baseline); % Change (average percent change from Baseline); and % Improved (the percentage of subjects showing improvement). Shaded cells indicate that the parameter could not be calculated.

Note that the images were graded by Ronald L. Rizer, Ph.D. of the Thomas J. Stephens & Associates, Inc. Colorado Research Center.

TABLE 2
MEAN VALUES FOR CLINICAL GRADING OF EFFICACY AND SAFETY PARAMETERS FROM PHOTOGRAPHIC IMAGES (n=29)

	Baseline	Week 2				Week 6			
	Mean	Mean	Delta	% Change	% Improved	Mean	Delta	% Change	% Improved
EFFICACY PARAMETERS									
Fine Lines/Wrinkles	4.11	3.79 ⇩	-0.32	-7.4%	39.3%	3.71 ⇩	-0.39	-9.4%	53.6%
Evenness of Skin Tone	3.30	3.11	-0.20	-4.4%	35.7%	3.13	-0.18	-4.8%	35.7%
Clarity	3.66	3.41 ⇩	-0.25	-6.0%	28.6%	3.45 ⇩	-0.21	-5.1%	25.0%
Lifting	3.59	3.50 ⇩	-0.09	-2.7%	17.9%	3.46 ⇩	-0.13	-3.8%	17.9%
Overall Facial Appearance	3.86	3.59 ⇩	-0.27	-7.1%	50.0%	3.48 ⇩	-0.38	-10.2%	60.7%
SAFETY PARAMETERS									
Erythema	2.09	1.89	-0.20	5.3%	46.4%	1.64 ⇩	-0.45	-14.4%	50.0%
Dryness/Scaling	0.00	0.00				0.00			

⇩ Indicates a statistically significant ($p \leq 0.05$) decrease (*improvement*) compared to Baseline

RESULTS (Continued)

At Visit 1 and Visit 11 biopsy samples were collected from naïve sites on the subjects' right or left cheek (as determined by a randomization design). The biopsy samples were fixed in 10% buffered formalin and forwarded to ProPath Laboratories for analysis and grading of collagen, hyaluronic acid, epidermal thickness, corneal and granular layer compaction, and glycosaminoglycans. Table 3 presents the results of the biopsy analysis results. Please see Appendix XI. for a signed copy of the report from ProPath Laboratories and a description of the grading scales used.

TABLE 3
RESULTS OF BIOPSY SAMPLE ANALYSES

	Baseline		Week 6		
	n-value	Mean Values	Mean Values	Mean Delta	p-value
Maximum Epidermal Thickness (measured in microns)	28	74.22	78.00	3.93	0.2627
Corneal Layer Compaction	28	0.41	0.37	-0.07	0.6259
Maximum Granular Layer Thickness (measured in microns)	28	6.16	6.33	0.22	0.5782
Epidermal/Dermal Glycosaminoglycans	29	0.90	1.30	0.45	0.0069
Hyaluropnic Acid (Using HABP)	29	0.43	0.37	-0.07	0.6626
Collagen Pattern (Trichrome)	29	1.47	2.00	0.55	0.0180
Reticulin Staining	29	0.63	0.70	0.07	0.6455

RESULTS (Continued)

Subjects completed a self-assessment questionnaire regarding improvements in skin condition at Week 2 and Week 6. Table 4 presents the top box/bottom box analysis (positive versus negative responses) of the self-assessment questionnaires. The number of subjects with the specific response is listed, followed by the percentage of the total subject population in parentheses. An asterisk (*) indicates that the proportion of subjects responding positively for a given statement is statistically greater than the proportion of subjects responding negatively.

TABLE 4
RESULTS OF TOP BOX ANALYSIS FOR SELF-ASSESSMENT QUESTIONNAIRES (n=29)

		Very Good, Good	Very Poor, Poor
Improves skin texture and tone (firm feel)	Week 2	* 29 (100.0%)	0 (0.0%)
	Week 6	* 27 (93.1%)	2 (6.9%)
Reduces the appearance of surface wrinkles	Week 2	* 28 (96.6%)	1 (3.4%)
	Week 6	* 26 (89.7%)	3 (10.3%)
Increases skin brightness/radiance	Week 2	* 29 (100.0%)	0 (0.0%)
	Week 6	* 29 (100.0%)	0 (0.0%)
Evens the skin tone / color	Week 2	* 27 (93.1%)	2 (6.9%)
	Week 6	* 26 (89.7%)	3 (10.3%)
Improves elasticity	Week 2	* 28 (96.6%)	1 (3.4%)
	Week 6	* 26 (89.7%)	3 (10.3%)
Reduces pore size	Week 2	* 26 (89.7%)	3 (10.3%)
	Week 6	* 26 (89.7%)	3 (10.3%)
Improves smooth feel	Week 2	* 29 (100.0%)	0 (0.0%)
	Week 6	* 27 (93.1%)	2 (6.9%)
Overall improvement	Week 2	* 28 (96.6%)	1 (3.4%)
	Week 6	* 27 (93.1%)	2 (6.9%)

		Strongly Agree, Agree	Strongly Disagree, Disagree
Treatment with the interactive stimulation device was comfortable	Week 2	* 29 (100.0%)	0 (0.0%)
	Week 6	* 29 (100.0%)	0 (0.0%)
The device would be easy for me to use at home	Week 2	* 29 (100.0%)	0 (0.0%)
	Week 6	* 29 (100.0%)	0 (0.0%)
My overall experience with the device was good	Week 2	* 29 (100.0%)	0 (0.0%)
	Week 6	* 28 (96.6%)	1 (3.4%)

DISCUSSION AND CONCLUSIONS

This single-center, controlled usage pilot study was conducted for Neuro Resource Group to assess the efficacy of InterX Cosmetology Therapy, an interactive neural stimulation device, in improving photodamage when used by men and women on the face. Product efficacy was measured using digital photography, clinical grading of digital images, silicone replicas, staining and grading of full-thickness skin biopsies, and subject self-assessment questionnaires.

Five subjects (001, 002, 004, 005, 007) participated in a pilot study, which was conducted to determine the best methodology to capture potential product benefit. The results of the pilot study are incorporated into this report (see Appendix XII for a copy of the Pilot Study report).

A total of 29 subjects completed the pilot or standard portion of this study. Subjects qualified for study participation according to the following criteria:

- Fitzpatrick Skin Classification Type I, II, III or IV
- Modified Glogau Classification of Category II (Moderate) or Category III (Advanced)
- Presence of mild to moderate lines and wrinkles in the crow's foot and/or under eye area

Ten facial treatments were performed in the clinic over the course of two weeks at Visits 1 through 10. Facial treatments using the Sponsor's InterX Cosmetology Therapy device were performed by the Sponsor's personnel for approximately 15 to 20 minutes.

Clinical Grading of Photographic Images

At Baseline, Week 2, and Week 6, one full-face, visible-light digital photograph was taken of either the right side, left side, or frontal face (as determined by the expert grader). These photographs were evaluated by an expert clinical grader (Ronald L. Rizer, Ph.D.) and graded for the following efficacy and safety parameters: fine lines/wrinkles, evenness of skin tone, clarity, lifting, overall facial appearance, erythema, and dryness/scaling. There was a statistically significant ($p \leq 0.05$) decrease (improvement) in the following parameters compared to mean Baseline values at the indicated time points:

- Fine Lines/Wrinkles: Week 2, Week 6
- Clarity: Week 2, Week 6
- Lifting: Week 2, Week 6
- Overall Facial Appearance: Week 2, Week 6
- Erythema: Week 6

Biopsy Sample Analyses

At Visit 1 and Visit 11 biopsy samples were collected from naïve sites on the subjects' right or left cheek (as determined by a randomization design). The biopsy samples were fixed in 10% buffered formalin and forwarded to ProPath Laboratories for analysis and grading of collagen, hyaluronic acid, epidermal thickness, corneal and granular layer compaction, and glycosaminoglycans. Results of the biopsy analyses showed a statistically significant increase in Collagen Pattern (Trichrome) at Week 6 compared to mean Baseline values.

Self-Assessment Questionnaires

At Week 2 and Week 6, subjects completed a self-assessment questionnaire regarding improvements in skin condition. Top box analysis showed that a significantly greater proportion of subjects responded positively than negatively for all questions at both time points:

- Improves skin texture and tone (firm feel)
- Reduces the appearance of surface wrinkles
- Increases skin brightness/radiance
- Evens the skin tone / color
- Improves elasticity
- Reduces pore size
- Improves smooth feel
- Overall improvement
- Treatment with the interactive stimulation device was comfortable
- The device would be easy for me to use at home
- My overall experience with the device was good

DISCUSSION AND CONCLUSIONS (Continued)

Overall Conclusions

Results of this study showed the following:

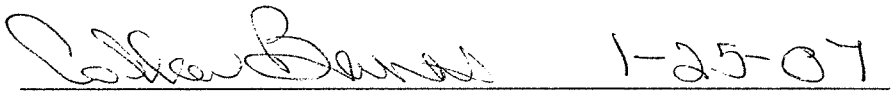
- After 10 days of treatment (Week 20 and after an additional four weeks of post treatment follow up (Week 6), all clinical parameters showed a significant improvement over baseline except for evenness of skin tone. Dryness/scaling showed no changes for the duration of the study and erythema showed a significant decrease four weeks after treatments were completed.
- Analysis of full thickness skin biopsy samples showed significant improvements for epidermal/dermal glycosaminoglycan and collagen formation.
- Top box analysis of questionnaire responses were overwhelmingly positive with a significantly greater number of subjects answering positively than negatively for all 11 questions regarding facial improvements and experience with the treatment.

Overall, results of blinded clinical grading and subject self assessment questionnaires show that 10 treatments with the Sponsor's device over a two week period was effective in improving the appearance of photodamaged facial skin, and that the benefit persists for at least four weeks after treatment. Analysis of full thickness skin biopsies taken at baseline and after 10 treatments suggests that deposition of glycosaminoglycans and collagen may underlie these visual improvements.

STATEMENT OF QUALITY ASSURANCE

All data and supporting documentation for this study have been audited by the Thomas J. Stephens & Associates, Inc., Quality Assurance Department and found to be accurate, complete, and in compliance with the requirements of the protocol and Stephens & Associates' Standard Operating Procedures. This report has been reviewed and accurately reflects all aspects of the conduct of the study.

All clinical research studies that are performed by Thomas J. Stephens & Associates, Inc. are in accordance with federal regulations and Good Clinical Practice guidelines.



Colleen Banas — Date
Quality Assurance Manager

REPORT APPROVAL

Report approved by:

THOMAS J. STEPHENS & ASSOCIATES, INC.

JAN 23 2007

Peter D. Hino, M.D., Board Certified Dermatologist — Date
Investigator/Study Physician

1/24/07

Monya L. Sigler, Ph.D. — Date
Sub-Investigator

APPENDICES

I. **Biostatistics**

II. **Questionnaire Tabulations**

III. **Protocol: Evaluation of InterX Cosmetology Therapy in Improving the Condition of Facial Photoaging**

IV. **Copies of IRB Approval Letters**

V. **Sample Forms**
- Eligibility and Health Questionnaire
- Informed Consent Agreement
- Confidentiality Agreement
- Photography Release Forms
- Observation Records
- Self-Assessment Questionnaires

VI. **Copy of Attrition Form**

VII. **Copy of Randomization Form**

VIII. **Copies of Adverse Event Forms**

IX. **Copies of Observation Records**

X. **Copies of Questionnaires**

XI. **Copy of Biopsy Sample Analysis from ProPath Laboratories**

XII. **Copy of Pilot Study Report from Thomas J. Stephens & Associates, Inc.**