Research Report S07-54

Confidential Material

5 Day Anti-Inflammatory Test Using Skin Trauma After Razor Shaving Bioassay

Sponsor: AkPharma, Inc.
6840 Old Egg Harbor Road
Pleasantville, NJ 08232
Charles L. Bove, ACRP, BA
Telephone No: 609-645-5100

Respectfully submitted by:

Gary Lee Grove, Ph.D. Date
Principal Investigator

Charles Zerweck, Ph.D. Date
Director of Clinical Studies

Danielle Fendrick Date
Director of Operations

Lawrence Park Industrial Park
700 Parkway Drive
Broomall, PA 19008

Phone: 610-325-0112
Fax: 610-325-0881
Email: cyberDERM@comcast.net

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I. OBJECTIVE

This study was designed to assess the anti-inflammatory and barrier effects of three test formulations by using the skin trauma after razor shaving bioassay as the substrate for applying each test product.

II. EXPERIMENTAL DESIGN

A. General Considerations

This study was conducted under the supervision of Gary Grove, Ph.D. and Charles Zerweck, Ph.D., at cyberDERM Clinical Studies in Broomall, Pennsylvania. A copy of each of their curriculum vitae is on file with the Sponsor.

In conducting this study, we followed current Good Clinical Practices (cGCP) and current Good Laboratory Practices (cGLP) guidelines as well as the COLIPA Efficacy Testing Guidelines.

This study was conducted from June 25-29, 2007. A calendar of events outlining the schedule of treatments and evaluative procedures that were followed during this trial is attached as **Appendix A**.

Briefly, panelists reported on Day 1 to the test facility for Baseline assessments of each of the test sites. There were four volar forearm test sites, with two sites being on each arm. An Expert Grader assessed each site for dryness and erythema. Water loss measurements were taken with a cyberDERM Research Grade Evaporimeter, skin surface conductance measurements were taken with an IBS Skicon-200 Conductance Meter and skin surface color measurements were taken with a Cortex Technology DSM II Color Meter. The integrity of the stratum corneum was pre-challenged by dry shaving of the skin surface with a disposable razor. The result was significantly elevated transepidermal water loss and eventual erythema associated with razor “chafed” skin. Thirty minutes after the challenge, the sites were re-evaluated to determine post-trauma values. The panelists had products applied to 3 of the 4 test sites by a trained technician (1 site was left as a damaged non-treated control).

Panelists returned to the lab on Days 2, 3 and 4 and had the test sites re-evaluated and the test products applied to the same sites. The final evaluations were made on Day 5.

B. Panelist Selection

Seven volunteers were recruited from a pool of healthy suburban Caucasian men and women who met the inclusion/exclusion criteria. Briefly, they were within the range from 18 to 55 years of age with a Fitzpatrick Skin Type of I-III. Each candidate was interviewed to make certain that they had no medical problems and were not using concomitant medications that might interfere with the study results. They were also screened to make sure that they had no known allergies to tapes or adhesives, cosmetics, soaps or fragrances. Women who were either pregnant or breast-feeding were excluded from participating in this study.

1. Inclusion Criteria

a. Is Caucasian male or female, 18-55 years of age
b. Is Fitzpatrick Skin Type I-III
c. Is In good general health as determined by interview
d. Has volar forearms clear of any irritation, scars, moles or other blemishes that may interfere with the study
e. Is willing to discontinue use of topical products including moisturizers on the volar forearms for the 3 days prior to start of study (Day 1)
f. Is willing to refrain from exercising prior to each visit
g. Is not currently taking any anti-histamine, anti-allergy, or anti-inflammatory medication and is willing to not take any anti-histamine, anti-allergy, or anti-inflammatory mediation within 48 hours of their Day 1 visit and willing not to take any until after the final study assessments on Day 5
h. Is willing and able to follow all study directions
i. Is able to read, understand and sign the consent form

2. Exclusion Criteria

a. Is pregnant or nursing female, as determined by interview
b. Is diabetic
c. Is currently going through menopause (i.e., experiencing hot flashes)
d. Has known allergies or sensitivities to cosmetics, soaps or fragrances
e. Is currently taking anti-histamine, anti-allergy, or anti-inflammatory medication (Aspirin, Advil/Motrin, Aleve, arthritis meds, etc.) or topical medication that may interfere with study results
f. Has systemic or cutaneous disease that may interfere with study results
g. Has presence of irritation on the volar forearms at the beginning of the study

All volunteers signed a consent form after being informed as to their obligations and risks that they might encounter as a participant in this study. A copy of the consent form is provided as **Appendix B**. Each candidate was instructed to stop the use of all moisturizing products on their arms during a 3 day pre-conditioning period prior to testing.

Upon being selected into the study, the panelists were reminded of the general nature and purpose of the study and were also instructed not to apply any other products nor tamper with their arms in any way during the remaining study period.

During the study, the following restrictions were imposed:

- Panelists may not apply any moisturizing products to the arms 3 days prior to study start and for the duration of the study.
- Panelists may not take any anti-histamine, anti-allergy, or anti-inflammatory medication within 48 hours of their Day 1 visit and not take any until after the final study assessments on Day 5.
- Panelists may not have scars, moles or other blemishes on the arms that would obscure measuring of the test sites.
- Panelists may not be diabetic.
- Panelists may not carry small children during study as this will affect the measurements.
- Panelists must wear short-sleeves or loose sleeves that can be pulled up to elbows to each visit.
- Panelists may not apply any other products to the arms, including intentional washing or scrubbing sites with any kind of cleanser for the duration of the study
- Panelists may not exercise prior to any visit as this will affect the measurements.
- Panelists must not be going through menopause (i.e., experiencing hot flashes).
- Panelists may shower in mornings or evenings but may not shower within 6 hours of any previous product application.

C. Treatments & Procedures

The selected panelists reported to the test facility and their arrivals were staggered. Assignment of panelist number was in order of their arrival at cyberDERM Clinical Studies. Each panelist reported to Charles Zerweck, Ph.D. who logged in each panelist and outlined four 5 cm x 5 cm sites (2 sites on each arm).

All water loss measurements were taken following a 25-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at 68 ± 2° F.

1. Expert Grader Evaluations

Charles Zerweck, Ph.D. served as the Expert Grader for this study. He assessed the amount of dryness and erythema on each of the volar forearm test sites. Assessments were made at Baseline (Day 1) pre-trauma, 30 minutes post-trauma (immediately prior to product application) and again on Days 2, 3, 4 and 5. The data for each session was manually recorded by the Expert Grader on a worksheet. The Expert Grader was not permitted to review the grades that he had given in any previous session.

The following grading scales were used:

Dryness	
0	None
2	Slight flaking
4	Moderate flaking/scaling
6	Marked scaling, slight fissuring
8	Severe scaling, fissuring

Erythema	
0	None
2	Mild, slight erythema
4	Moderate, confluent erythema
6	Marked erythema, slight edema
8	Marked erythema, edema, possible erosion

Intermediate grades were allowed so that finer distinctions could be made. The ties were broken by forcing the Expert Grader to add 0.1 to that site which he thought might be worse, except at Baseline and 30 minutes post trauma (pre-treatment). To maintain the Expert Grader's blindness to products, visual assessments were conducted in a separate area.

2. Cortex Technology DSM II Color Meter

The new DSM II Color Meter offers a new and innovative approach to color measurement. Its fully handheld and lightweight design takes advantage of the latest development in color sensing technology, and the cable connected color sensing probe offers the highest degree of freedom and flexibility in operation. Further, a special lens arrangement focuses on the target area and highly reduces

the influence of ambient light. The key component is an RGB Photodiode Array that corresponds to the 3 types of cones in the human retina. A specially designed white LED powered by a constant current source ensures that brightness and spectral characteristics of the illuminator do not change over time. The emitter/detector geometry is the standard 45°/0° optical train and is housed within a lightweight probe that allows the operator to directly view the target area. Alternate illuminants can be readily incorporated into the design.

The output of the device appears on an LCD display and can be sent to an interfaced PC where it can be parsed into 3 channels respectively representing the R, G, and B values of the target area in real time. Companion software routines provide several different outputs including those based on the tri-chromatic CIE L* a*and b* system as well as the Erythema and Melanin Indices derived from Farr & Diffy's 2-wavelength method.

The color meter was calibrated prior to use on each time point using a standard white tile.

Three sets of Erythema Index readings were taken by Mr. Jonn Damia with the assistance of Ms. Diana Pearce from each of the four volar forearm test sites. Measurements were taken at Baseline (Day 1) pre-trauma, 30 minutes post-trauma (immediately prior to product application) and again on Days 2, 3, 4 and 5.

3. Water Loss Measurements with the cyberDERM, inc. Evaporimeter

At Baseline (Day 1), evaporative water loss measurements were taken from each of the test sites as described below. Any individuals with water loss values outside the normal range (>10.0 gms/m^2hr) were excluded at this time.

Evaporative water loss measurements provide an instrumental assessment of skin barrier function. These measurements were made using recently calibrated cyberDERM RG1 Evaporimeter Systems [Unit P5 and Unit 5-020] (Broomall, PA) with TEWL Probes [#688 & #690 and #233 & #296 respectively] that were manufactured by Cortex Technology (Hadsund, Denmark) and available in the US through cyberDERM, inc. (Broomall, PA).

This instrument is based on the vapor pressure gradient estimation method as designed by Nilsson and initially utilized by the Servo Med Evaporimeter. There are slight dimensional differences and the sensor technology is greatly improved in the DermaLab® TEWL probe but the underlying principles of the measurement remain the same. Both probes contain two sensors that measure the temperature and relative humidity at two fixed points along the axis normal to the skin surface. This arrangement is such that the device can electronically derive a value that corresponds to evaporative water loss expressed in gm/m^2hr. Evaporimetry with TEWL Probe is more fully described in two publications by Grove et al:

Grove, G.L., M.J. Grove, C. Zerweck and E. Pierce: Comparative metrology of the evaporimeter and the DermaLab® TEWL probe. Skin Res. & Tech. 5:1-8, 1999.

Grove, G.L., M.J. Grove, C. Zerweck and E. Pierce: Computerized evaporimetry using the DermaLab® TEWL probe. Skin Res. & Tech. 5:9-13, 1999.

The guidelines established for using the Servo Med Evaporimeter as described by Pinnagoda [Pinnagoda, J., R.A. Tupker, T. Anger and J. Serup. Guidelines for transepidermal water loss (TEWL) measurement. In: Contact Dermatitis 1990: 22:164-178] are quite appropriate for the DermaLab® TEWL Probe as well.

The cyberDERM RG1 Evaporimeter System is completely computerized and continuously communicates with its PC through a USB port and associated cyberDERM, inc. software for the Evaporimeters. We used the application program entitled x1WL2M that captures the water loss data from the attached evaporimeter at a sampling rate of 8 inputs/second. These inputs were graphed as a real time display on the computer monitor. The extracted value refers to the average evaporative water loss rate collected over a twenty-second interval once steady state conditions had been achieved. These were directly transferred to an Excel file using a DDE link.

Dr. Zerweck and Mr. Jonn Damia served as the water loss technicians for this study. Measurements were taken at Baseline (Day 1) prior to razor trauma, 30 minutes post-trauma (immediately prior to product application) and again on Days 2, 3, 4 and 5. Duplicate water loss readings were taken from each volar forearm site and electronically recorded using a spreadsheet format based on Excel software that computes the average value for each test site. These values were also manually recorded on a worksheet that served as a back up in case of possible computer malfunction.

Such measures provide a noninvasive method for determining the barrier function of the stratum corneum. Damage leads to a disruption of the barrier that is accompanied by elevated water loss rates.

4. IBS Skicon-200 Conductance Meter

As has been shown, most notably by Obata and Tagami [Obata, M. and Tagami, H. A rapid *in vitro* test to assess skin moisturizers. In: J. Soc. Cosmet. Chem., 41, 235-241 (July/August, 1990)], the ability of an alternating current to flow through the stratum corneum is an indirect measure of its water content. The value recorded which is expressed in units of micromho (microsiemens) represents the AC

conductance 2-3 seconds after placing the spring-loaded probe tip to the sample site. This timing interval is sufficiently long enough for the electronic circuits to stabilize in response to this change in conductance but short enough not to be influenced by an increased hydration at the probe tip due to its being occlusive and acting as a hindrance to the normal water loss at the test site.

In this study, we employed an IBS Skicon-200 Conductance Meter (unit 2283) equipped with a Measurement Technologies probe (probe A red) to further enhance its ability to measure changes in skin surface hydration. It was anticipated that moisturizers would lead to increased conductance values over time. This tendency will, however, be superimposed over the skin response to the dry shave challenge which is expected to be an immediate elevation in conductance due to trauma followed by a gradual drying out and diminished conductance values.

Five conductance measurements were taken from each of the four test sites by Ms. Pearce at Baseline (Day 1) prior to razor trauma, 30 minutes post-trauma (immediately prior to product application) and again on Days 2, 3, 4 and 5. The average value was computed for each site after each measurement session.

5. Skin Trauma After Razor Shaving Bioassay

After the Day 1 Baseline measurements were completed, the stratum corneum barrier was challenged by dry shaving of the skin surface of the volar forearms with a disposable razor. The result was significantly elevated transepidermal water loss and the eventual development of erythema associated with razor “chafed” skin.

Using this technique we created razor chafed sites along each volar forearm. Our experience has been that normal Baseline TEWL values of 4-10 gm/m^2/hr could be easily elevated by 10-20 gm/m^2/hr.

6. Self-Assessment of Stinging

After the post-trauma assessments were completed, the panelists reported to Mrs. Carol Cesari, who served as the treatment technician. Prior to the first application of each product, Mrs. Cesari asked the panelists to rate the amount of burning/stinging on a 0-10 scale (0 = No sensation to 10 = Severe stinging/burning). The panelists were also asked to rate the amount of stinging following each treatment on Days 1-4.

7. Test Products and Treatment Procedures

Three test products were supplied by the Sponsor as follows:

cyberDERM Code	Sponsor Code	Description
A	070605B	Squeeze bottles with clear gel
B	0092105A	Squeeze tubes with white cream
C	100506A	Squeeze tubes with clear gel, tubes labeled by Sponsor with small green dot

The test products will be returned to the Sponsor (if desired) after the final report for this study has been issued.

Approximately 0.35 cc of test product was dispensed by Mrs. Cesari using a metered syringe onto the designated test site. Mrs. Cesari used a clean finger cot to evenly spread the product over the test area. Panelists were instructed not to shower or wash off the test products for at least 6 hours following application.

Treatment of each test material to the designated razor chafed site was done according to the randomization schedule (**Appendix C**). Three sites were treated and one site was left non-treated but razor chafed to serve as a control.

The test products were reapplied by Mrs. Cesari to the same sites following completion of all assessments and measurements on Days 2, 3 and 4.

The instrument operators and Expert Grader were not involved in any treatment aspects of this study so that their assessments and instrument readings were done in a blind fashion and recorded in the same sequence as assessed.

D. Statistical Analyses

Dr. Grove was responsible for devising a sorting template based on Excel 2003 spreadsheet software and implemented on the IBM clone desktop computer. The sorted data for each parameter was tabulated and arranged in order of panelist number for every point of evaluation. In creating these tables, column averages were computed in each case, but only to give a preliminary look at the findings.

Dr. Grove was also responsible for statistical analysis of the findings using appropriate software programs. The sorted data tables were converted into ASCII files for use in these applications. Descriptive statistics were run on each data set and compared to the column averages to insure that all imported files were correct.

Due to the small sample size, a full statistical analysis was not warranted. However, cyberDERM calculated the average value for each test site for each panelist at each time point. For all panelists, the average and standard deviations were computed for each test product and the non-treated control at each time point.

A summary of the values observed at the follow-up sessions were provided graphically for each assessment.

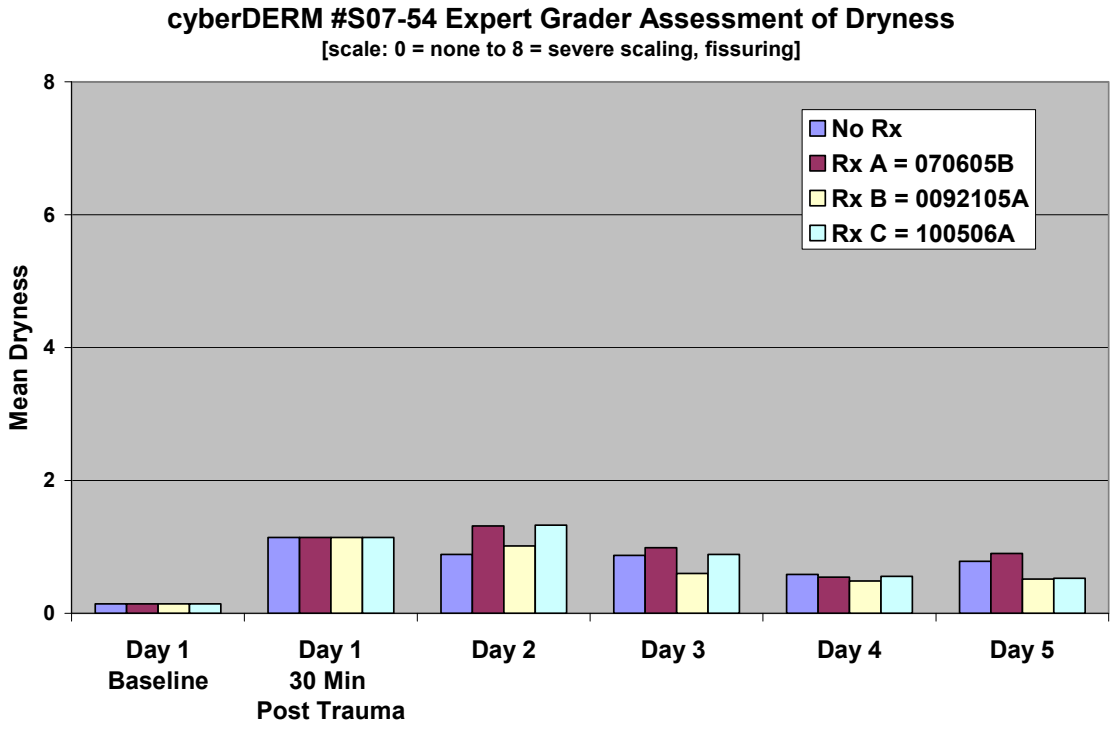
III. RESULTS

A. Panelist Accountability

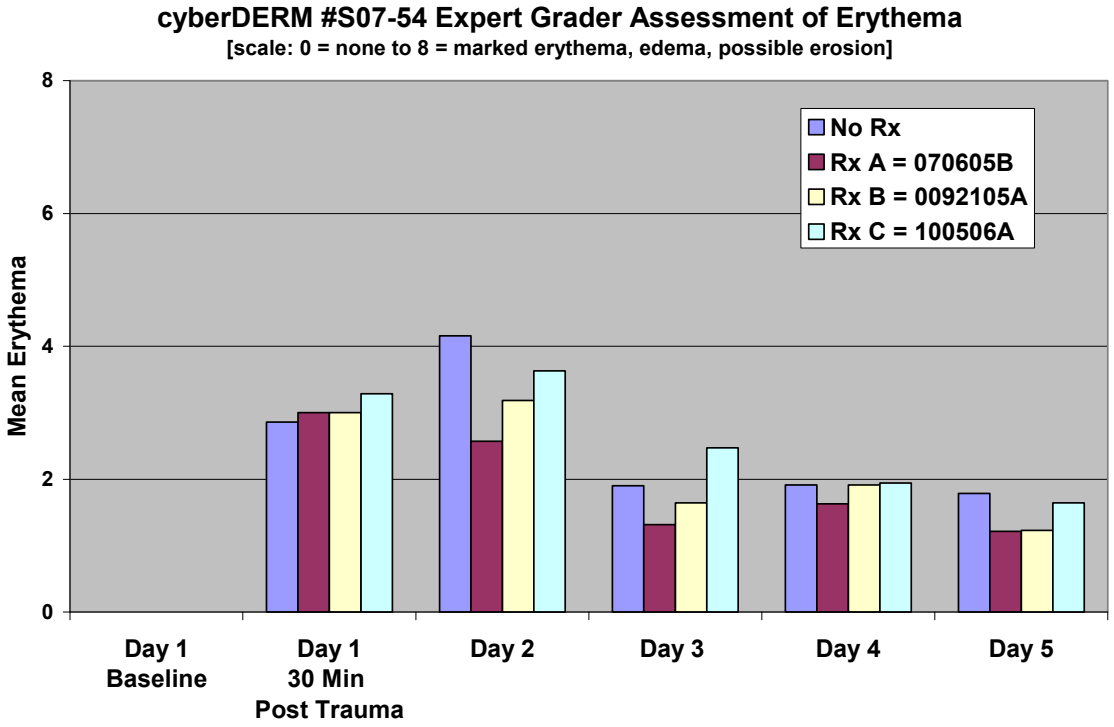
Seven panelists reported to the test facility for Baseline measurements, all of whom qualified for inclusion on the study panel. **Appendix D** contains a listing of each panelist's age and sex. All panelists were able to successfully complete the entire course of the study. We have no reason to believe that these panelists were not fully compliant with the requirements of this study.

B. Expert Grader Assessments of Dryness & Erythema

The decoded and sorted Expert Grader dryness and erythema data from each time point are attached as **Appendix E**. These results are also graphically summarized in the figures below:



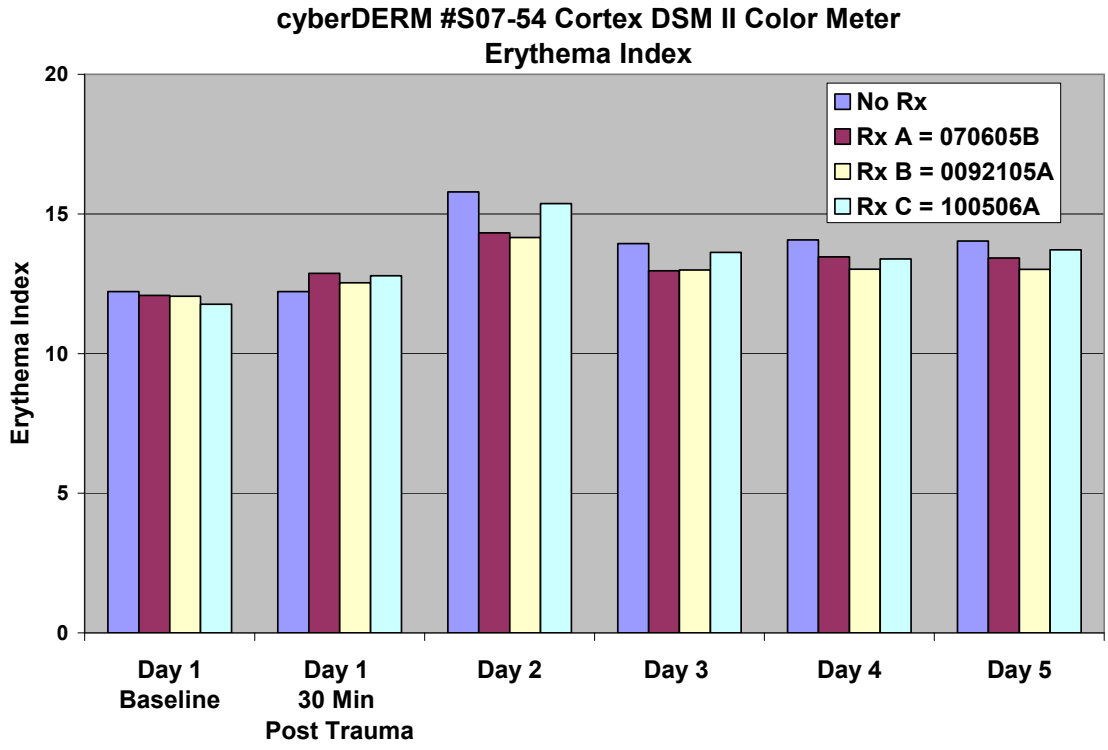
Expert Grader visual assessment of skin dryness found a very mild increase in visual dryness immediately following the razor challenge to the volar forearm skin. This visual dryness subsided toward baseline levels over the subsequent 4 days. There was no apparent difference between treatments or between treated and non-treated sites in this regard.



Expert Grader assessment of erythema found a mild to moderate increase immediately following the razor challenge to the volar forearm skin. Within the next 24 hours erythema progressed to moderate levels on non-treated skin sites but not on any of the treated sites. Of the three treatments, it appears that Rx A offers the most promise in reducing redness during the first two days post trauma compared to no treatment or to treatments Rx B or Rx C. Product treatment Rx B was also generally associated with less post trauma erythema compared to no treatment. There did not appear to be any benefit to treatment with product Rx C following Day 2 in terms of reduced erythema.

C. Cortex DSM II Color Meter Measurements

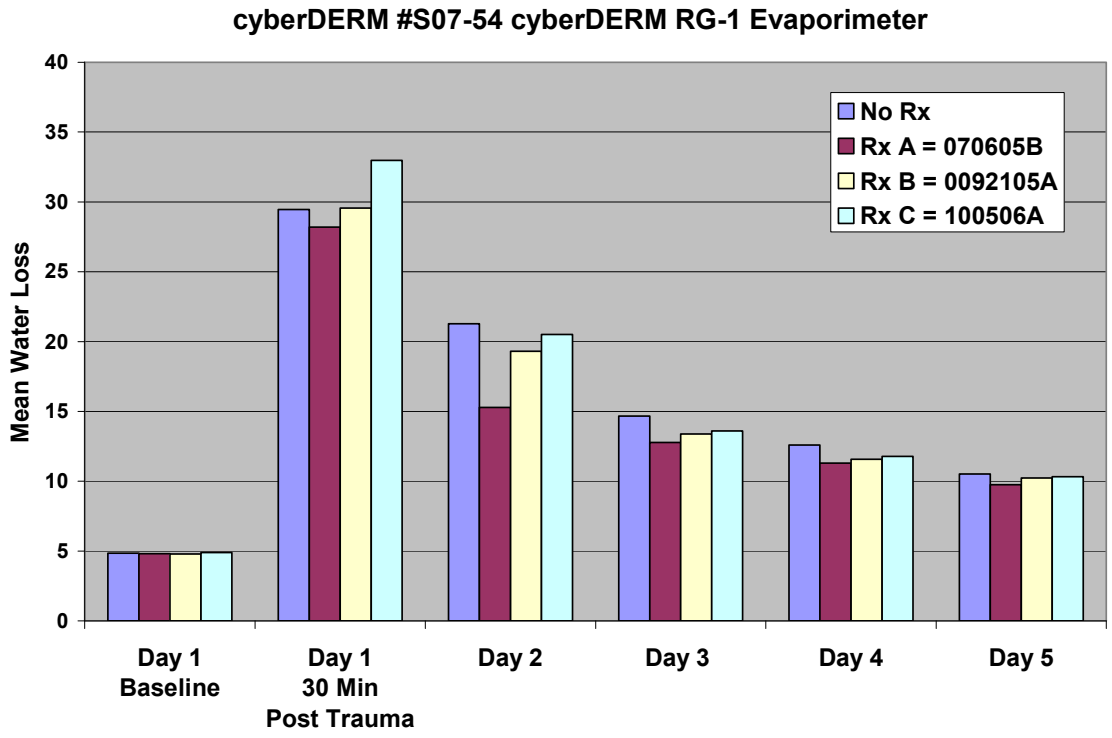
The decoded and sorted Color Meter Erythema Index values from each time point are attached as **Appendix F**. These results are also graphically summarized in the figure below:



DSM II Color Meter results indicated that a mild increase in erythema index occurred within 30 minutes post razor trauma. Erythema continued to develop toward moderate levels by Day 2. There is a tendency on Days 2 and 3 for treatments Rx A and Rx B to be associated with reduced levels of erythema compared to either no treatment or treatment with Rx C. Treatment Rx B continues to demonstrate the least erythema through Day 5.

D. cyberDERM RG-1 Water Loss Measurements

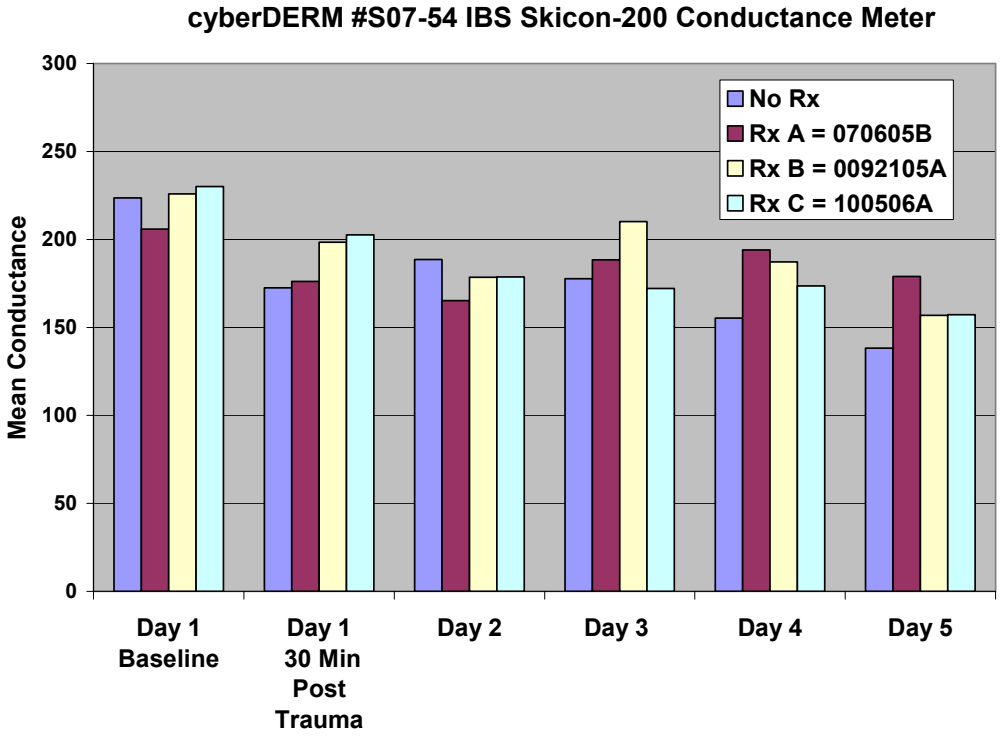
The decoded and sorted water loss data from each time point are attached as **Appendix G.** These results are also graphically summarized in the figure below:



Results of evaporative water loss measurements reveal a marked increase 30 minutes post trauma. The water loss values on Day 2 are most noticeably reduced by treatment with Rx A compared to any other treatments or no treatment. On Days 3 through 5 there is little or no difference between treated groups and only a small and diminishing improvement over no treatment.

E. IBS Skicon-200 Conductance Measurements

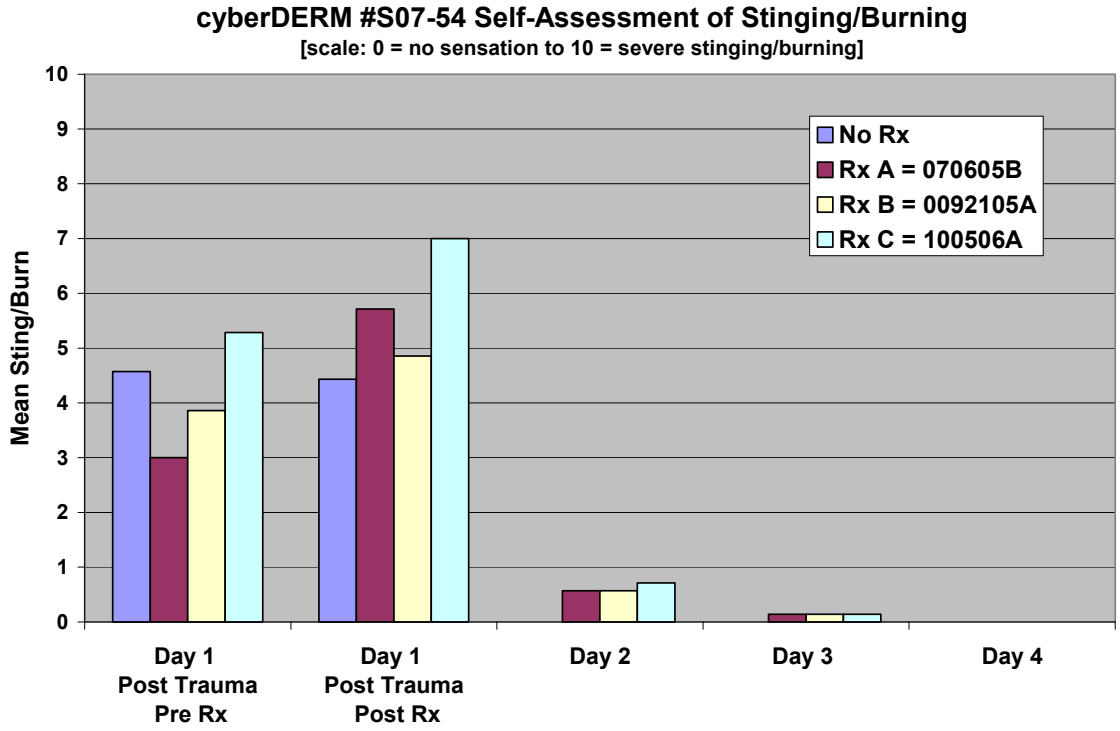
The decoded and sorted conductance data from each time point are attached as **Appendix H.** These results are also graphically summarized in the figure below:



The results of electrical conductance measurements show a fall in apparent skin surface hydration 30 minutes post trauma. Surface hydration measured on non-treatment sites diminishes progressively from Days 2 through 5. Although somewhat variable, the results for each of the treatment groups fail to show a similar decline in hydration.

F. Self-Assessments

The decoded and sorted self-assessment data from each time point are attached as **Appendix I.** These results are also graphically summarized in the figure below:



Self-assessment results indicate a moderate perception of stinging immediately after razor trauma and prior to treatment. A heightened perception of stinging was experienced immediately after treatment on Day 1 with each of the three treatments. Perception of stinging was greatly diminished on Day 2 and completely absent by Day 4 for all treatments.

IV. CONCLUSIONS

Based on the trends observed as a result of this pilot study it is reasonable to conclude that further study would confirm similar results. Treatment with either formulation Rx A or Rx B following razor chafe trauma appears to reduce the subsequent development of erythema. Rx A also shows some promise as a barrier in diminishing the water loss resulting post razor trauma. Although all treatment formulations demonstrated some increase in sensation of stinging following the initial application, this perception was greatly reduced or entirely absent on follow-up treatments.

V. RECORD RETENTION

Please be advised that the records for this study will remain on file at cyberDERM, Inc. (or a remote storage site) for a period of 1 year from the issue date of the final report and then destroyed unless we are notified otherwise by the Sponsor using the form accompanying the final report. It is the duty of the Sponsor to ensure that the completed form is promptly returned to cyberDERM.

VI. PROPRIETARY REPORT AND NON-ENDORSEMENT POLICY

This research report is considered to be proprietary and confidential by cyberDERM, inc. It is not to be shared with any third party except appropriate government regulatory agencies without written consent of an officer of cyberDERM Clinical Studies or cyberDERM, inc. The name of cyberDERM, inc., cyberDERM Clinical Studies, any officer, employee or collaborating scientist are not to be used for any advertising, promotional or sales purposes without the written consent of cyberDERM, inc. or cyberDERM Clinical Studies. If there are any questions regarding this policy, please contact Dr. Gary Grove.

Appendix A: Calendar of Events

cyberDERM #S07-54: 5 DAY ANTI-INFLAMMATORY TEST USING SKIN TRAUMA AFTER RAZOR SHAVING BIOASSAY

	DAY 1	DAY 1 Post-trauma	DAY 2	DAY 3	DAY 4	DAY 5
Expert Grader Dryness & Erythema	X	X	X	X	X	X
TEWL measurements	X	X	X	X	X	X
Cortex DSM II Erythema	X	X	X	X	X	X
IBS Skicon-200 Conductance Meter	X	X	X	X	X	X
Razor Challenge	X					
Wait 30 minutes	X					
Treatment at lab		X	X	X	X	
Self-Assessment of Stinging		X	X	X	X	

PRE-TRIAL CONDITIONING:
Panelists will stop the use of all moisturizing products on the arms 3 days prior to study start.

PANEL:
N=6-7; Caucasian male or female panelists, ages 18 to 55.

TEST SITES:
Volar forearms (2 sites on each arm)

RAZOR CHALLENGE:
All four volar forearm test sites will be dry shaved with a disposable razor to disrupt the stratum corneum barrier.

CLINICAL ASSESSMENTS:
Expert Grader assessments of dryness and erythema of the 4 volar forearm test sites at Baseline, 30 minutes post-chafing immediately prior to product application, and on Days 2, 3 and 4 prior to treatment and again on Day 5.

SELF-ASSESSMENTS:
The panelists will be asked to rate the amount of burning/stinging on each site prior to the first set of treatments and immediately after each treatment on Days 1-4.

cyberDERM #S07-54: 5 DAY ANTI-INFLAMMATORY TEST USING SKIN TRAUMA AFTER RAZOR SHAVING BIOASSAY (continued)

INSTRUMENTAL ASSESSMENTS:
The following assessments will be taken from each of the 4 sites at Baseline (pre-trauma), 30 minutes post trauma and on Days 2, 3 and 4 prior to treatment and again on Day 5:

- Duplicate transepidermal water loss measurements will be obtained with a cyberDERM RG-1 Evaporimeter.
- Cortex DSM II erythema measurements of skin surface redness will be taken in triplicate.
- Five IBS Skicon-200 Conductance Meter measurements will be taken.

TEST PRODUCTS:
3 Test products supplied by Sponsor. Product will be applied by a technician to 3 of the 4 test sites using a clean finger cot according to the randomization schedule. Product will be applied by a technician on Days 1-4.

Appendix B: Sample Consent Form

Subject Number: _____ Subject ID:_____

SUBJECT INFORMATION AND CONSENT FORM

TITLE: 5 Day Anti-Inflammatory Test Using Skin Trauma After Razor Shaving Bioassay

PROTOCOL NO.: cyberDERM #S07-54

INVESTIGATOR: Gary L. Grove, Ph.D.
Telephone: 610-325-0112 (Day)
610-358-2381 (Night)

CO-INVESTIGATOR: Charles R. Zerweck, Ph.D.
Telephone: 610-325-0112 (Day)
610-627-9236 (Night)

STUDY SITE(S): cyberDERM Clinical Studies
Lawrence Park Industrial Park
700 Parkway Drive
Broomall, PA 19008
Telephone: 610-325-0112

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

INTRODUCTION

Before agreeing to enroll in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from this study at any time. No guarantees or assurances can be made as to the results of the study.

This study is being conducted for a consumer product company. cyberDERM Clinical Studies is being paid by the study sponsor to conduct this study.

BACKGROUND AND PURPOSE OF STUDY

The objective of this study is to determine the anti-inflammatory and barrier properties of three test products using a razor induced chafed skin model to create mild damage to the skin prior to product application.

Approximately 7 volunteers will enroll in this study.

This study is under the direction of Drs. Gary L. Grove and Charles R. Zerweck.

LENGTH OF STUDY AND PROCEDURES USED
This study will last approximately 8 days (3 days of pre-trial conditioning and 5 days of testing). This study will require a total of five (5) visits to the laboratory.

-3 Days:
Approximately 7 panelists will stop the use of all moisturizing products on their arms for the 3 days prior to the study start.

Day 1, start of testing (Visit 1):
Please wear a short-sleeved shirt.

- At your appointment, your volar forearms (inner forearms) will be divided into an upper section and a lower section. You will have 2 test sites (2 inches by 2 inches in size) mapped onto each arm with a skin-marking pen by a technician.
- You will then sit quietly and acclimate to the conditions of the test lab for approximately 25-30 minutes.
- You will have the test sites visually graded and instrumentally measured by technicians. The following instruments will be used:
    - A cyberDERM RG-1 measures Transepidermal Water Loss (referred to as TEWL or TWL) which is the amount of water evaporating from the skin. A probe is gently placed against the skin for 1 minute while non-invasive measurements are taken.
    - A DSM II Color Meter will be used to measure the color of each site. A probe is gently placed against the skin for up to 10 seconds while non-invasive measurements are taken.
    - An IBS Skicon-200 Conductance Meter will be used to measure how dry or moist the skin is. A probe is gently placed against the skin for a few seconds while non-invasive measurements are taken.

If your measurements are in the anticipated range, you will be accepted onto the final panel.

- Following measurements, your skin on the palm side of your lower arms (volar forearms) will be intentionally damaged. This will be done by gently but repeatedly dry shaving your volar forearms with a disposable razor. The damage will be similar to chapping and redness from a brush-burn.
- You will wait 30 minutes and then the sites will be graded and measured again.
- After the second set of measurements is completed, a technician will treat 3 of the 4 sites on your arms. One site will not be treated. The technician will ask you to rate any burning/stinging you may feel prior to and after each test product is applied.
- After the treatments are completed, you may then leave the lab until

your appointment the next day. During this time you must not tamper with, or intentionally wash or scrub the test sites.

Day 2 – (Visit 2), Day 3 – (Visit 3), Day 4 – (Visit 4):

- You will sit quietly and accommodate to the conditions of the test lab for approximately 25-30 minutes.
- The sites will be graded and measured.
- The test products will be applied to the same three sites. You will be asked to rate any burning/stinging sensations you feel immediately following each treatment.

Day 5 – (Visit 5):

- You will sit quietly and accommodate to the conditions of the test lab for approximately 25-30 minutes.
- The sites will be graded and measured.
- Your participation in this study will end.

STUDY REQUIREMENTS & RESTRICTIONS

- Panelists may not be pregnant or nursing
- Panelists may not apply any moisturizing products to the arms 3 days prior to study start and for the duration of the study.
- Panelists may not take any anti-histamine, anti-allergy, or anti-inflammatory medication within 48 hours of their Day 1 visit and not take any until after the final study assessments on Day 5.
- Panelists may not have scars, moles or other blemishes on the arms that would obscure measuring of the test sites.
- Panelists may not be diabetic.
- Panelists may not carry small children during study as this will affect the measurements.
- Panelists must wear short-sleeves or loose sleeves that can be pulled up to elbows to each visit.
- Panelists may not apply any other products to the arms, including intentional washing or scrubbing sites with any kind of cleanser for the duration of the study
- Panelists may not exercise prior to any visit as this will affect the measurements.
- Panelists must not be going through menopause (i.e., experiencing hot flashes).
- Panelists may shower in mornings or evenings but may not shower within 6 hours of any previous product application.

Report for all scheduled appointments; should not use any other treatments, apply any other products, or otherwise tamper with the test sites.

LIST OF MATERIALS
Three coded products, cyberDERM RG-1 Evaporimeter, IBS Skicon-200 Conductance Meter, Cortex DSM II Color Meter, Sharpie marker, latex finger cots

ANTICIPATED RISKS AND POSSIBLE SIDE EFFECTS
The therapy and procedures to be followed in this study may involve the following foreseeable risks and discomforts. The dry shaving procedure will damage your skin. You may have possible lightening or darkening of the skin, skin irritation including, but not limited to, redness, dryness, itching, burning/stinging. This is usually temporary but could persist for a long time (even permanent). Your participation in this study may involve risks that are currently unforeseeable or unknown.

You may experience momentary discomfort with the test material (e.g. a mild to moderate stinging on application), a reddening of the skin, bumps or other changes in skin condition. These are usually temporary and may be caused by chemical irritation or mechanical trauma. These skin conditions should dissipate within one to two days after the materials are removed.

If it is determined that an allergic reaction has occurred, you can expect an allergic reaction to the material if you encounter it at a later date. Whenever possible, you will be told the name of the product that caused the allergic reaction in order that you may avoid contact with it in the future.

You should report any unusual symptoms or signs you may notice during the study, even if you consider such symptoms or signs to be minor or unrelated to the study.

BENEFITS
There are no known direct benefits to you as a participant in this investigational study. The findings or results, however, will permit the sponsor to determine the effects of these products.

ALTERNATIVE TREATMENT
As this study is for research purposes only, an alternative would be to not participate in this study.

SUBJECT COMPENSATION
You will be paid $_____ to compensate you for your time and participation. If you do not complete the study, either by choice (such as not attending a visit) or as instructed by the study doctor for any reason, you will be paid on a pro-rated basis, depending on the procedures you completed. Your payment will be provided after the end of the study.

CONFIDENTIALITY
Records of your participation in this study will be held confidential so far as permitted by law. However, the investigator, the sponsor, and under certain circumstances, the Food and Drug Administration will be able to inspect and have access to confidential data which identifies you by name. Any publication of the data will not identify you. By signing this consent form, you authorize the investigator to release your medical records to the sponsor and the FDA.

COMPENSATION FOR STUDY-RELATED INJURY
In the event that you develop an adverse reaction, side effect, or complication as a result of your participation in this study, emergency medical treatment will be provided by a physician at cyberDERM Clinical Studies, at no cost to you. No additional compensation is available. You will not lose any of your legal rights as a research subject by signing this consent form.

EMERGENCY CONTACT
If you have questions about this study, or in the event of a research-related injury or illness, you should call:

Gary L. Grove, Ph.D.	Charles R. Zerweck, Ph.D.
Investigator	Co-Investigator
Telephone: 610-325-0112 (Day)	610-325-0112 (Day)
610-358-2381 (Night)	610-627-9236 (Night)

Project Coordinator: Danielle Fendrick
Telephone: cyberDERM Clinical Studies - 610-325-0112 (Day)

VOLUNTARY PARTICIPATION/WITHDRAWAL
The investigator can end your participation in this study at any time without your consent for the following reasons: the occurrence of serious side effects, any change in your medical condition that may interfere with the study, pregnancy, failure to attend study visits, failure to follow the treatment regimen or other instructions, or cancellation of the study, or for administrative reasons.

Your participation in this study is entirely voluntary. If you withdraw from the research study, you should notify the technician and/or investigator of your intention to do so and you will be compensated up to the time of withdrawal. You can refuse to participate in the study or quit at any time without loss of any rights or benefits to which you would be entitled. If you quit or are withdrawn from the study, you may be asked to have study ending tests and procedures for your safety.

ADDITIONAL COSTS THAT MAY RESULT FROM PARTICIPATION IN THE RESEARCH STUDY
You should incur no costs for participating in this research study. If you fully understand the details and possible risks of this study as outlined above and you still

wish to participate, please read the section below carefully. This is important for your protection.

CONSENT

I have read and understand this informed subject consent and hereby consent to take part in the clinical research study. This study may involve some discomfort and there is a potential for adverse experiences. This and my part in the research study have been clearly explained to me, and I have had complete freedom to ask any questions about this study. All of my questions have been answered. I will be given a signed copy of this consent form to keep. I authorize the release of my study-related medical records to the sponsor and the FDA.

Certain products in the study are highly proprietary to the Sponsor. Therefore, I agree to keep confidential the products and all information pertaining thereto. I understand that some individuals with health problems have a higher risk of developing adverse reactions to the test products. I have provided truthful information about my health status to the investigator's staff. I am not pregnant or breast feeding.

IF I DO NOT REPORT OR CALL IN, MY PARTICIPATION IN THIS STUDY MAY BE DISCONTINUED.

I CERTIFY I AM NOT PREGNANT OR NURSING AND DO NOT PLAN A PREGNANCY DURING THIS STUDY. _____ (initials)

I HAVE NO CHANGES TO MY MEDICAL HISTORY CARD: _____ (initials)

I CERTIFY THAT I AM NOT CURRENTLY PARTICIPATING IN AND WILL NOT PARTICIPATE IN ANOTHER STUDY ON MY VOLAR FOREARMS FOR THE DURATION OF THIS STUDY: _____ (initials)

Please sign both copies of this informed consent and return one to the study investigator. You should keep the other copy.

_____	_____	_____
Signature of Volunteer	Printed Name of Volunteer	Date

_____
Person conducting consent discussion

Appendix C: Randomization Schedule

cyberDERM S07-54

Randomization

#	ID	RU	RL	LU	LL
1	D082	A	B	C	No Rx
2	T018	B	C	No Rx	A
3	L016	B	A	No Rx	C
4	N009	C	B	A	No Rx
5	A038	No Rx	A	B	C
6	H080	C	No Rx	A	B
7	D059	A	No Rx	C	B

Rx A = 070605B
Rx B = 092105A
Rx C = 100506A

Appendix D: Demographic Data

Demographic Data

#	ID	AGE	SEX
1	D082	40	F
2	T018	52	F
3	L016	48	F
4	N009	50	F
5	A038	43	F
6	H080	44	F
7	D059	24	F

Appendix E: Expert Grader Data

Decoded & Sorted Data **cyberDERM #S07-54**

Expert Grader Assessment of Dryness

[scale: 0 = none to 8 = severe scaling, fissuring]

Day 1 / Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	0	0	0
2	T018	0	0	0	0
3	L016	1	1	1	1
4	N009	0	0	0	0
5	A038	0	0	0	0
6	H080	0	0	0	0
7	D059	0	0	0	0
	Mean	**0.14**	**0.14**	**0.14**	**0.14**
	SD	**0.38**	**0.38**	**0.38**	**0.38**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Dryness

[scale: 0 = none to 8 = severe scaling, fissuring]

Day 1 / 30 Minutes Post Trauma (pre-treatment)

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	1	1	1	1
2	T018	1	1	1	1
3	L016	3	3	3	3
4	N009	1	1	1	1
5	A038	1	1	1	1
6	H080	0	0	0	0
7	D059	1	1	1	1
	Mean	**1.14**	**1.14**	**1.14**	**1.14**
	SD	**0.90**	**0.90**	**0.90**	**0.90**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Dryness

[scale: 0 = none to 8 = severe scaling, fissuring]

Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	2.1	2	1
2	T018	1.1	1	0	2
3	L016	1	3	2.1	2
4	N009	2	1	0	0.1
5	A038	0	1	2	2.1
6	H080	2	1.1	0	1
7	D059	0.1	0	1	1.1
	Mean	**0.89**	**1.31**	**1.01**	**1.33**
	SD	**0.89**	**0.96**	**1.02**	**0.74**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Dryness

[scale: 0 = none to 8 = severe scaling, fissuring]

Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	1.1	0.1	0	1
2	T018	2	2.1	1	0
3	L016	2	4	1	3
4	N009	1	0.2	0.1	0
5	A038	0	0.1	1	1.1
6	H080	0	0.2	1	0.1
7	D059	0	0.2	0.1	1
	Mean	**0.87**	**0.99**	**0.60**	**0.89**
	SD	**0.90**	**1.51**	**0.50**	**1.06**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Dryness

[scale: 0 = none to 8 = severe scaling, fissuring]

Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	0.3	0.1	0.2
2	T018	2	0	1	0.1
3	L016	1.1	2	0	1
4	N009	0	0.2	0.1	0.3
5	A038	1	0	1.1	1.2
6	H080	0	1.1	1	0.1
7	D059	0	0.2	0.1	1
	Mean	**0.59**	**0.54**	**0.49**	**0.56**
	SD	**0.80**	**0.74**	**0.51**	**0.49**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Dryness

[scale: 0 = none to 8 = severe scaling, fissuring]

Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	2	1	0.1
2	T018	1.2	1.1	1	0
3	L016	3	2	0	2.1
4	N009	1	1.1	0	0.1
5	A038	0	0.1	1	1.1
6	H080	0.2	0	0.3	0.1
7	D059	0.1	0	0.3	0.2
	Mean	**0.79**	**0.90**	**0.51**	**0.53**
	SD	**1.09**	**0.89**	**0.47**	**0.79**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Erythema

[scale: 0 = none to 8 = marked erythema, edema, possible erosion]

Day 1 / Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	0	0	0
2	T018	0	0	0	0
3	L016	0	0	0	0
4	N009	0	0	0	0
5	A038	0	0	0	0
6	H080	0	0	0	0
7	D059	0	0	0	0
	Mean	**0.00**	**0.00**	**0.00**	**0.00**
	SD	**0.00**	**0.00**	**0.00**	**0.00**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Erythema

[scale: 0 = none to 8 = marked erythema, edema, possible erosion]

Day 1 / 30 Minutes Post Trauma (pre-treatment)

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	3	3	3	3
2	T018	1	1	1	1
3	L016	3	4	3	4
4	N009	5	5	5	5
5	A038	3	3	3	4
6	H080	4	4	4	4
7	D059	1	1	2	2
	Mean	**2.86**	**3.00**	**3.00**	**3.29**
	SD	**1.46**	**1.53**	**1.29**	**1.38**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Erythema

[scale: 0 = none to 8 = marked erythema, edema, possible erosion]

Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	3	1	2	3.1
2	T018	5	3	4	4.1
3	L016	5	4	4.1	5.1
4	N009	4	3	3.1	2
5	A038	5.1	4	5	6
6	H080	5	3	4	4.1
7	D059	2	0	0.1	1
	Mean	**4.16**	**2.57**	**3.19**	**3.63**
	SD	**1.23**	**1.51**	**1.65**	**1.74**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Erythema

[scale: 0 = none to 8 = marked erythema, edema, possible erosion]

Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	2.1	1.1	1	2
2	T018	1	0	2	2.1
3	L016	2	1.1	1	2.1
4	N009	3	2	2.2	2.1
5	A038	3.1	3	3.2	4
6	H080	2.1	1	2	3
7	D059	0	1	0.1	2
	Mean	**1.90**	**1.31**	**1.64**	**2.47**
	SD	**1.09**	**0.94**	**1.02**	**0.76**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Erythema

[scale: 0 = none to 8 = marked erythema, edema, possible erosion]

Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	1.1	0.1	1
2	T018	2.2	1	2.1	2
3	L016	2	3.1	3	2.1
4	N009	3	2	3.1	2.1
5	A038	3.2	3.1	3	4
6	H080	1	0	1.1	1.2
7	D059	2	1.1	1	1.2
	Mean	**1.91**	**1.63**	**1.91**	**1.94**
	SD	**1.11**	**1.16**	**1.20**	**1.02**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Expert Grader Assessment of Erythema

[scale: 0 = none to 8 = marked erythema, edema, possible erosion]

Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	1.1	1.2	1.3	1
2	T018	2	0	1	1.1
3	L016	2	3	2.1	2.2
4	N009	3	1	2	2.1
5	A038	3	2.1	2	4
6	H080	1.1	1.2	0	1
7	D059	0.3	0	0.2	0.1
	Mean	**1.79**	**1.21**	**1.23**	**1.64**
	SD	**1.02**	**1.08**	**0.87**	**1.26**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Appendix F: Cortex DSM II Color Meter Data

Decoded & Sorted Data **cyberDERM #S07-54**

Cortex DSM II Color Meter
Erythema Index

Day 1 / Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	10.5	11.3	11.4	10.5
2	T018	13.3	12.4	12.1	11.8
3	L016	14.1	14.0	14.7	13.8
4	N009	12.2	10.0	10.5	9.6
5	A038	11.5	11.5	11.6	11.2
6	H080	14.3	14.9	13.4	14.5
7	D059	9.5	10.5	10.8	10.8
	Mean	**12.21**	**12.08**	**12.05**	**11.76**
	SD	**1.80**	**1.81**	**1.50**	**1.79**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Day 1 / 30 Minutes Post Trauma (pre-treatment)

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	8.8	9.7	9.3	9.9
2	T018	12.6	11.5	11.3	11.4
3	L016	13.2	14.8	14.5	12.8
4	N009	13.9	15.3	14.9	13.4
5	A038	11.6	12.0	11.4	12.9
6	H080	16.4	16.4	15.9	18.4
7	D059	9.1	10.4	10.4	10.6
	Mean	**12.21**	**12.87**	**12.53**	**12.78**
	SD	**2.67**	**2.61**	**2.54**	**2.79**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Net Change from Baseline @
Day 1 / 30 Minutes Post Trauma (pre-treatment)

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	-1.7	-1.7	-2.1	-0.6
2	T018	-0.7	-0.9	-0.8	-0.4
3	L016	-0.9	0.8	-0.2	-1.0
4	N009	1.6	5.3	4.5	3.7
5	A038	0.0	0.5	-0.2	1.7
6	H080	2.1	1.4	2.5	3.9
7	D059	-0.5	-0.1	-0.4	-0.2
	Mean	**0.00**	**0.78**	**0.48**	**1.02**
	SD	**1.37**	**2.26**	**2.23**	**2.10**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	11.6	12.7	10.8	11.9
2	T018	17.2	13.9	14.6	16.9
3	L016	17.1	16.9	16.9	16.8
4	N009	15.6	13.3	12.6	12.4
5	A038	18.4	15.4	16.3	17.4
6	H080	19.8	17.8	17.3	20.7
7	D059	10.8	10.3	10.6	11.4
	Mean	**15.79**	**14.32**	**14.16**	**15.36**
	SD	**3.40**	**2.56**	**2.83**	**3.52**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Net Change from Baseline @ Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	1.1	1.4	-0.5	1.4
2	T018	3.9	1.5	2.6	5.1
3	L016	3.1	2.9	2.2	3.0
4	N009	3.4	3.4	2.1	2.8
5	A038	6.8	3.9	4.7	6.2
6	H080	5.5	2.8	3.9	6.2
7	D059	1.3	-0.2	-0.2	0.5
	Mean	**3.57**	**2.24**	**2.11**	**3.60**
	SD	**2.10**	**1.41**	**1.95**	**2.28**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	11.3	12.5	10.4	10.1
2	T018	14.0	13.1	12.7	13.5
3	L016	15.8	15.0	15.8	15.6
4	N009	13.8	11.7	12.0	11.2
5	A038	14.9	12.1	13.6	14.7
6	H080	18.4	17.5	16.7	19.9
7	D059	9.3	8.7	9.6	10.5
	Mean	**13.94**	**12.96**	**12.99**	**13.62**
	SD	**2.97**	**2.76**	**2.62**	**3.47**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Net Change from Baseline @ Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0.8	1.2	-0.9	-0.4
2	T018	0.7	0.8	0.7	1.6
3	L016	1.8	1.0	1.1	1.8
4	N009	1.5	1.8	1.5	1.5
5	A038	3.4	0.6	2.1	3.5
6	H080	4.1	2.6	3.3	5.4
7	D059	-0.2	-1.8	-1.2	-0.4
	Mean	**1.73**	**0.88**	**0.94**	**1.86**
	SD	**1.54**	**1.37**	**1.59**	**2.04**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	11.8	12.4	10.1	10.9
2	T018	15.3	12.6	13.2	13.8
3	L016	16.0	16.3	16.8	15.5
4	N009	14.1	12.3	11.0	11.2
5	A038	14.1	13.3	13.5	13.7
6	H080	16.1	17.1	16.2	17.4
7	D059	10.9	10.2	10.2	11.2
	Mean	**14.07**	**13.46**	**13.02**	**13.39**
	SD	**2.02**	**2.44**	**2.75**	**2.49**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Net Change from Baseline @ Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	1.3	1.1	-1.2	0.4
2	T018	2.0	0.3	1.2	2.0
3	L016	1.9	2.3	2.1	1.7
4	N009	1.9	2.4	0.6	1.5
5	A038	2.6	1.8	2.0	2.5
6	H080	1.8	2.2	2.8	2.9
7	D059	1.4	-0.4	-0.6	0.3
	Mean	**1.85**	**1.38**	**0.97**	**1.62**
	SD	**0.43**	**1.08**	**1.49**	**0.98**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	D081	12.0	12.4	10.4	11.3
2	T018	14.8	13.0	13.6	14.7
3	L016	16.2	16.6	16.8	15.0
4	N009	14.5	12.1	12.1	10.9
5	A038	14.7	14.1	13.4	16.4
6	H080	16.3	16.4	14.6	17.2
7	D059	9.7	9.4	10.2	10.4
	Mean	**14.03**	**13.42**	**13.01**	**13.71**
	SD	**2.36**	**2.53**	**2.32**	**2.80**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Cortex DSM II Color Meter
Erythema Index

Net Change from Baseline @ Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	D081	1.5	1.1	-1.0	0.8
2	T018	1.5	0.6	1.5	2.9
3	L016	2.1	2.6	2.1	1.2
4	N009	2.2	2.2	1.6	1.3
5	A038	3.2	2.6	1.9	5.2
6	H080	2.0	1.4	1.2	2.7
7	D059	0.2	-1.2	-0.6	-0.4
	Mean	**1.82**	**1.34**	**0.96**	**1.95**
	SD	**0.92**	**1.33**	**1.22**	**1.84**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Appendix G: cyberDERM RG-1 TEWL Data

Decoded & Sorted Data **cyberDERM #S07-54**

cyberDERM RG-1 Evaporimeter

Day 1 / Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0.6	1.5	0.7	0.9
2	T018	2.8	3.3	3.2	3.5
3	L016	2.9	3.3	3.5	3.3
4	N009	9.6	9.3	9.6	9.2
5	A038	4.9	5.3	5.2	5.4
6	H080	7.8	5.9	6.7	7.4
7	D059	5.3	5.1	4.7	4.5
	Mean	**4.84**	**4.82**	**4.79**	**4.89**
	SD	**3.10**	**2.50**	**2.83**	**2.78**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Day 1 / 30 Minutes Post Trauma

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	14.8	11.6	10.2	17.5
2	T018	29.4	18.9	23.9	28.1
3	L016	25.2	29.3	27.3	24.6
4	N009	37.9	55.2	52.4	58.1
5	A038	36.5	30.8	33.3	34.6
6	H080	36.5	36.1	40.4	44.2
7	D059	25.8	15.4	19.4	23.7
	Mean	**29.46**	**28.19**	**29.56**	**32.98**
	SD	**8.33**	**14.85**	**13.95**	**14.03**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Net Change from Baseline @ Day 1 / 30 Minutes Post Trauma

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	14.2	10.2	9.5	16.6
2	T018	26.7	15.6	20.8	24.6
3	L016	22.3	26.0	23.8	21.3
4	N009	28.3	45.9	42.8	48.9
5	A038	31.6	25.5	28.1	29.2
6	H080	28.7	30.2	33.7	36.8
7	D059	20.6	10.3	14.7	19.2
	Mean	**24.62**	**23.37**	**24.77**	**28.08**
	SD	**5.96**	**12.71**	**11.32**	**11.40**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	11.1	9.0	10.2	12.1
2	T018	20.3	14.5	17.6	18.9
3	L016	13.3	11.8	14.3	14.8
4	N009	22.5	20.2	24.1	21.3
5	A038	38.2	26.1	26.5	30.5
6	H080	28.3	14.1	27.4	30.3
7	D059	15.3	11.3	15.1	15.8
	Mean	**21.28**	**15.28**	**19.30**	**20.51**
	SD	**9.49**	**5.91**	**6.68**	**7.36**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Net Change from Baseline @ Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	10.5	7.5	9.5	11.2
2	T018	17.5	11.2	14.4	15.4
3	L016	10.4	8.5	10.8	11.5
4	N009	12.9	10.9	14.5	12.1
5	A038	33.2	20.8	21.3	25.0
6	H080	20.5	8.2	20.7	22.9
7	D059	10.0	6.2	10.4	11.2
	Mean	**16.44**	**10.46**	**14.51**	**15.61**
	SD	**8.42**	**4.89**	**4.84**	**5.90**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	9.8	8.5	9.5	9.9
2	T018	14.5	11.7	12.1	13.4
3	L016	11.4	11.3	11.5	11.6
4	N009	19.0	18.2	18.2	17.5
5	A038	19.7	16.3	14.6	16.2
6	H080	16.5	13.6	16.5	16.5
7	D059	11.7	9.8	11.3	10.2
	Mean	**14.66**	**12.77**	**13.38**	**13.60**
	SD	**3.89**	**3.47**	**3.14**	**3.15**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Net Change from Baseline @ Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	9.2	7.0	8.8	9.0
2	T018	11.8	8.4	8.9	9.9
3	L016	8.5	8.0	8.0	8.3
4	N009	9.4	8.9	8.6	8.3
5	A038	14.7	11.0	9.4	10.7
6	H080	8.7	7.7	9.8	9.0
7	D059	6.4	4.7	6.6	5.7
	Mean	**9.82**	**7.95**	**8.59**	**8.70**
	SD	**2.69**	**1.90**	**1.06**	**1.58**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	8.8	8.5	8.6	8.5
2	T018	11.4	10.9	9.7	10.5
3	L016	9.5	9.4	9.2	10.3
4	N009	17.4	16.3	17.1	15.8
5	A038	16.6	14.6	13.1	13.2
6	H080	14.3	10.8	13.6	14.5
7	D059	10.1	8.6	9.6	9.6
	Mean	**12.59**	**11.30**	**11.57**	**11.78**
	SD	**3.51**	**3.01**	**3.13**	**2.72**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Net Change from Baseline @ Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	8.2	7.0	7.9	7.7
2	T018	8.7	7.6	6.6	7.0
3	L016	6.6	6.1	5.7	7.0
4	N009	7.8	7.0	7.5	6.6
5	A038	11.7	9.3	8.0	7.8
6	H080	6.5	4.9	7.0	7.1
7	D059	4.8	3.5	4.9	5.1
	Mean	**7.75**	**6.49**	**6.78**	**6.89**
	SD	**2.14**	**1.88**	**1.15**	**0.90**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	6.3	7.3	7.2	6.6
2	T018	10.0	9.1	8.7	10.3
3	L016	7.0	6.8	8.3	7.9
4	N009	16.3	15.6	15.4	14.7
5	A038	13.1	11.0	10.6	11.3
6	H080	12.2	10.8	12.0	12.6
7	D059	8.8	7.7	9.4	8.8
	Mean	**10.52**	**9.75**	**10.23**	**10.32**
	SD	**3.55**	**3.06**	**2.77**	**2.79**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

cyberDERM RG-1 Evaporimeter

Net Change from Baseline @ Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	5.7	5.8	6.5	5.8
2	T018	7.2	5.8	5.6	6.8
3	L016	4.1	3.5	4.8	4.6
4	N009	6.6	6.3	5.8	5.4
5	A038	8.2	5.8	5.5	5.8
6	H080	4.4	4.9	5.3	5.2
7	D059	3.5	2.6	4.7	4.3
	Mean	**5.68**	**4.94**	**5.44**	**5.42**
	SD	**1.75**	**1.38**	**0.63**	**0.83**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Appendix H: IBS Skicon-200 Conductance Data

Decoded & Sorted Data **cyberDERM #S07-54**

IBS Skicon-200 Conductance Meter

Day 1 / Baseline

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	327.8	309.8	294.6	336.4
2	T018	304.4	264.2	302.8	291.4
3	L016	110.0	108.0	145.4	89.4
4	N009	94.6	145.6	98.4	119.6
5	A038	244.6	193.4	238.4	232.2
6	H080	247.0	225.2	237.6	283.8
7	D059	237.0	194.8	263.6	257.8
	Mean	**223.63**	**205.86**	**225.83**	**230.09**
	SD	**89.54**	**68.39**	**76.47**	**91.94**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Day 1 / 30 Minutes Post Trauma (pre-treatment)

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	131.6	153.2	131.2	167.4
2	T018	249.4	204.2	278.0	271.4
3	L016	91.0	86.8	99.6	78.8
4	N009	101.8	149.0	110.8	120.6
5	A038	211.8	200.4	253.4	242.0
6	H080	233.6	255.8	254.0	317.0
7	D059	188.4	183.4	261.8	220.8
	Mean	**172.51**	**176.11**	**198.40**	**202.57**
	SD	**64.24**	**53.26**	**80.02**	**84.65**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Net Change from Baseline @ Day 1 / 30 Minutes Post Trauma (pre-treatment)

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	-196.2	-156.6	-163.4	-169.0
2	T018	-55.0	-60.0	-24.8	-20.0
3	L016	-19.0	-21.2	-45.8	-10.6
4	N009	7.2	3.4	12.4	1.0
5	A038	-32.8	7.0	15.0	9.8
6	H080	-13.4	30.6	16.4	33.2
7	D059	-48.6	-11.4	-1.8	-37.0
	Mean	**-51.11**	**-29.74**	**-27.43**	**-27.51**
	SD	**67.41**	**62.59**	**64.29**	**66.26**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	286.2	133.4	181.2	243.2
2	T018	231.6	249.4	272.4	204.8
3	L016	120.0	64.8	84.6	93.0
4	N009	84.8	121.4	89.8	114.8
5	A038	204.0	132.4	206.6	118.0
6	H080	161.2	195.6	158.2	178.6
7	D059	232.2	259.6	256.8	298.6
	Mean	**188.57**	**165.23**	**178.51**	**178.71**
	SD	**70.41**	**71.89**	**73.98**	**75.64**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Net Change from Baseline @ Day 2

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	-41.6	-176.4	-113.4	-93.2
2	T018	-72.8	-14.8	-30.4	-86.6
3	L016	10.0	-43.2	-60.8	3.6
4	N009	-9.8	-24.2	-8.6	-4.8
5	A038	-40.6	-61.0	-31.8	-114.2
6	H080	-85.8	-29.6	-79.4	-105.2
7	D059	-4.8	64.8	-6.8	40.8
	Mean	**-35.06**	**-40.63**	**-47.31**	**-51.37**
	SD	**35.72**	**71.91**	**39.25**	**62.61**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	381.6	365.8	385.0	313.2
2	T018	166.6	236.0	247.2	180.2
3	L016	117.2	72.6	105.8	84.4
4	N009	101.8	120.4	91.4	105.2
5	A038	158.0	121.6	256.8	119.8
6	H080	145.0	225.6	153.4	163.4
7	D059	173.6	176.8	231.4	238.6
	Mean	**177.69**	**188.40**	**210.14**	**172.11**
	SD	**93.62**	**98.11**	**102.29**	**81.01**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Net Change from Baseline @ Day 3

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	53.8	56.0	90.4	-23.2
2	T018	-137.8	-28.2	-55.6	-111.2
3	L016	7.2	-35.4	-39.6	-5.0
4	N009	7.2	-25.2	-7.0	-14.4
5	A038	-86.6	-71.8	18.4	-112.4
6	H080	-102.0	0.4	-84.2	-120.4
7	D059	-63.4	-18.0	-32.2	-19.2
	Mean	**-45.94**	**-17.46**	**-15.69**	**-57.97**
	SD	**69.68**	**39.08**	**57.19**	**53.40**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	297.2	299.2	328.0	273.6
2	T018	178.0	226.8	265.0	220.4
3	L016	66.2	85.8	109.6	72.6
4	N009	99.4	142.6	108.6	107.2
5	A038	176.2	168.4	215.4	220.0
6	H080	149.8	262.0	128.0	156.2
7	D059	120.6	173.0	155.4	165.4
	Mean	**155.34**	**193.97**	**187.14**	**173.63**
	SD	**74.59**	**73.27**	**85.04**	**69.91**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Net Change from Baseline @ Day 4

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	-30.6	-10.6	33.4	-62.8
2	T018	-126.4	-37.4	-37.8	-71.0
3	L016	-43.8	-22.2	-35.8	-16.8
4	N009	4.8	-3.0	10.2	-12.4
5	A038	-68.4	-25.0	-23.0	-12.2
6	H080	-97.2	36.8	-109.6	-127.6
7	D059	-116.4	-21.8	-108.2	-92.4
	Mean	**-68.29**	**-11.89**	**-38.69**	**-56.46**
	SD	**48.11**	**24.08**	**54.32**	**44.87**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	D081	299.4	277.4	230.2	254.6
2	T018	128.0	166.8	213.8	152.4
3	L016	76.0	93.4	89.2	91.8
4	N009	67.4	112.8	86.0	110.8
5	A038	149.6	182.6	227.4	190.0
6	H080	128.8	230.0	116.6	134.4
7	D059	118.2	189.8	134.6	166.2
	Mean	**138.20**	**178.97**	**156.83**	**157.17**
	SD	**77.02**	**63.60**	**64.95**	**54.19**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

IBS Skicon-200 Conductance Meter

Net Change from Baseline @ Day 5

#	ID	No Rx	Rx A	Rx B	Rx C
1	D081	-28.4	-32.4	-64.4	-81.8
2	T018	-176.4	-97.4	-89.0	-139.0
3	L016	-34.0	-14.6	-56.2	2.4
4	N009	-27.2	-32.8	-12.4	-8.8
5	A038	-95.0	-10.8	-11.0	-42.2
6	H080	-118.2	4.8	-121.0	-149.4
7	D059	-118.8	-5.0	-129.0	-91.6
	Mean	**-85.43**	**-26.89**	**-69.00**	**-72.91**
	SD	**57.51**	**33.99**	**47.36**	**59.68**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Appendix I: Self-Assessment Data

Decoded & Sorted Data **cyberDERM #S07-54**

Self-Assessment of Stinging/Burning

[scale: 0 = no sensation to 10 = severe stinging/burning]

Day 1 / 30 Minutes Post Trauma
Pre-Treatment

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	5	1	1	5
2	T018	0	0	0	0
3	L016	5	3	3	7
4	N009	8	8	8	8
5	A038	1	2	3	5
6	H080	6	1	5	5
7	D059	7	6	7	7
	Mean	**4.57**	**3.00**	**3.86**	**5.29**
	SD	**2.99**	**2.94**	**2.97**	**2.63**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Self-Assessment of Stinging/Burning

[scale: 0 = no sensation to 10 = severe stinging/burning]

Day 1 / 30 Minutes Post Trauma
Post Treatment

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	5	2	2	7
2	T018	0	3	0	3
3	L016	5	8	7	8
4	N009	8	7	9	9
5	A038	1	6	7	8
6	H080	7	7	4	6
7	D059	5	7	5	8
	Mean	**4.43**	**5.71**	**4.86**	**7.00**
	SD	**2.94**	**2.29**	**3.13**	**2.00**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Self-Assessment of Stinging/Burning

[scale: 0 = no sensation to 10 = severe stinging/burning]

Day 1 / 30 Minutes Post Trauma

Net Change from Pre-Treatment @ Post Treatment

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	1	1	2
2	T018	0	3	0	3
3	L016	0	5	4	1
4	N009	0	-1	1	1
5	A038	0	4	4	3
6	H080	1	6	-1	1
7	D059	-2	1	-2	1
	Mean	**-0.14**	**2.71**	**1.00**	**1.71**
	SD	**0.90**	**2.50**	**2.31**	**0.95**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Self-Assessment of Stinging/Burning

[scale: 0 = no sensation to 10 = severe stinging/burning]

Day 2
Post Treatment

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	0	0	0
2	T018	0	2	0	2
3	L016	0	1	1	1
4	N009	0	0	0	0
5	A038	0	0	0	0
6	H080	0	0	2	2
7	D059	0	1	1	0
	Mean	**0.00**	**0.57**	**0.57**	**0.71**
	SD	**0.00**	**0.79**	**0.79**	**0.95**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Self-Assessment of Stinging/Burning

[scale: 0 = no sensation to 10 = severe stinging/burning]

Day 3
Post Treatment

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	0	0	0
2	T018	0	0	0	0
3	L016	0	0	0	0
4	N009	0	0	0	0
5	A038	0	0	0	0
6	H080	0	0	0	0
7	D059	0	1	1	1
	Mean	**0.00**	**0.14**	**0.14**	**0.14**
	SD	**0.00**	**0.38**	**0.38**	**0.38**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A

Self-Assessment of Stinging/Burning

[scale: 0 = no sensation to 10 = severe stinging/burning]

Day 4
Post Treatment

#	ID	No Rx	Rx A	Rx B	Rx C
1	D082	0	0	0	0
2	T018	0	0	0	0
3	L016	0	0	0	0
4	N009	0	0	0	0
5	A038	0	0	0	0
6	H080	0	0	0	0
7	D059	0	0	0	0
	Mean	**0.00**	**0.00**	**0.00**	**0.00**
	SD	**0.00**	**0.00**	**0.00**	**0.00**

Rx A = 070605B
Rx B = 0092105A
Rx C = 100506A