Research Report S06-15

Confidential Material

A Randomized, Controlled Pilot Study Assessing Topical Calcium Glycerophosphate as a Potential Agent for Minimizing Damage due to Adhesive Dressings

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I. OBJECTIVES

This pilot study was designed to determine if a test formulation reduces redness, stratum corneum disruption and pain/discomfort associated with adhesive tape trauma to the skin. This was done using Expert Grader assessments of erythema, instrumental measurements of transepidermal water loss, skin surface hydration, skin surface redness, and self-assessments of pain/discomfort.

II. EXPERIMENTAL DESIGN

A. General Considerations

This pilot study was conducted under the supervision Gary Grove, Ph.D. and Charles Zerweck, Ph.D., at cyberDERM Clinical Studies in Broomall, Pennsylvania on Feb. 21, 2006. A copy of both Drs. Grove's and Zerweck's curriculum vitae are 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.

A calendar of events outlining the schedule of treatments and evaluative procedures that were followed during this study is attached as **Appendix A**.

This was a randomized, controlled study. Panelists were evaluated by the Expert Grader for suitability for inclusion on this study. Baseline instrumental measurements were taken prior to the product applications and tape trauma procedure. The test product was then applied to 2 of the 4 test sites on the back and allowed to dry. One piece of adhesive tape (5cm x 5cm) was then applied to each of the 4 test sites and then removed. The panelists were asked to rate the difference in pain/discomfort between the sites immediately after the tapes were removed. The test product was reapplied to the same 2 sites, allowed to dry and new adhesive tape strips were applied to all 4 sites and removed. This procedure of applying the test product, allowing it to dry, applying new adhesive tape strips and removing them was repeated for a total of 10 times for all 4 test sites. The degree of damage to the stratum corneum barrier that resulted from repetitive stripping of the skin surface was evaluated by an Expert Grader and by measuring elevated transepidermal water loss and erythema associated with adhesive tape trauma. Changes in TEWL rates were obtained using a cyberDERM Research Grade Evaporimeter while skin surface redness measurements were obtained using a Minolta Chromameter. Additional measurements with the DermaLab® Skin Sensor which is a novel device for measuring skin properties were also obtained. Digital photographs were taken of the test sites at the end of the study.

B. Panelist Selection

Volunteers for this project were recruited from a pool of healthy suburban Caucasian women who were willing to comply with the requirements of this experimental design. They were within the age range from 18 to 55 years and were interviewed to ascertain that they were not pregnant or nursing, had no medical problems, no known allergies to soaps, fragrances or adhesives, and were not using concomitant medications that might interfere with the study results. The inclusion/exclusion criteria were as follows:

1. Inclusion Criteria

a. Female, 18-55 years of age, and in good general health.
b. Agrees to discontinue use of all products except for cleansers on the back for 3 days prior to start of study (Day 1).
c. Willing and able to follow all study directions and to commit to all follow-up visits for the duration of the study.
d. Must be willing to lie on stomach for time necessary to perform assessments.
e. Has read and completed the informed consent process.

2. Exclusion Criteria

a. Is pregnant or nursing.
b. Is taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
c. Has irritation, scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
d. Has any allergy or sensitivity to tapes or adhesives.
e. Systemic or cutaneous disease that may interfere with study results.
f. Is diabetic.

All volunteers signed a consent form (**Appendix B**) after being informed as to their obligations and risks that they might encounter as a participant in this study. The selected panelists were advised of the general nature of this study and instructed not to "tamper" with the sites in any way. Each candidate was also instructed to stop the use of any products other than cleansers on their back during a 3 day pre-conditioning period prior to testing.

<u>During the study, the following restrictions were imposed:</u>

- Panelists were asked to wear a tank bathing suit or a type of top that has a low back (halter). They were also asked to bring a button-down shirt to wear over the front of them to keep warm and covered up.
- Panelists must not have had any allergies or sensitivity to tapes or adhesives.

- Panelists may not have scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
- Panelists may not be diabetic.
- Panelists may not be taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
- Panelists must be willing to lie on stomach for time necessary to perform assessments.
- Panelists may not exercise before your visit as this will affect the measurements

Prior to testing, all candidates were assessed by Charles Zerweck, Ph.D., for suitability to be included on the panel. Any individuals with scars, moles, or other blemishes on the back that would obscure grading or measuring of the test sites were excluded at that time. Qualified panelists were then assigned a panelist number in the order of their admittance to the study panel. Dr. Zerweck logged each panelist in and outlined four 5 centimeter by 5 centimeter test sites on the left and right sides of the back (two on each side) using a standard template.

C. Expert Grader Evaluations

Charles Zerweck, Ph.D., served as the Expert Grader for this study. At Baseline (prior to product applications and tape trauma) and again approximately 30 minutes after the tenth and final repetition of product application/tape stripping had been completed, Dr. Zerweck was responsible for assessing the amount of erythema on the 4 test sites located on the back based on the following nine point grading scale:

Erythema	
0 =	None
2 =	Mild, erythema
4 =	Moderate, confluent erythema
6 =	Marked erythema with some edema
8 =	Intense erythema, edema, flare, possible erosion

Intermediate grade increments were used to denote intermediate levels of severity. 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.

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

All water loss measurements were taken following a 15-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at 70 $\pm$ 2°F.

At Baseline, 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 a recently calibrated cyberDERM RG1 Evaporimeter System (Broomall, PA) with TEWL Probes 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. Evaporimetery 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 RG-1 Evaporimeter. We use an application program that captures the water loss data from the attached evaporimeter at a

sampling rate of 8 inputs/second. These inputs are 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 are directly transferred to an Excel file using a DDE link.

At each session, duplicate water loss readings were taken from each 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 serves as a back up in case there are problems with the computerized records.

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.

Measurements were taken by Ms. Jennifer Damia from all 4 sites at Baseline prior to the product applications and tape trauma and again approximately 30 minutes after the last of the 10 repetitions of product application/tape strippings.

E. Minolta Chromameter a* Measurements

Skin surface color was measured instrumentally using reflectance techniques based on the standardized tristimulus system recommended by CIE. The specific model employed for such measurements was the Minolta CR-200 Chromameter that has an 8mm measuring area using the illuminant conditions of D_{65} which most closely approximates normal daylight conditions. This is a hand held device that is gently placed against the surface to be color characterized. When triggered, a pulsed xenon light source flashes and this light is reflected off the surface and measured back into the device. Within the device, there are 6 silicon photocells that are filtered to detect primary stimulus values for red, green and blue wavelengths of light. For color readings, the values are translated into the L*a*b* coordinates whose spacing correlates closely with color changes perceived by the human eye. This is an internationally recognized convention for numerically expressing color differences established by the C.I.E. (Commission International de L'Eclairage). The L* value represents the density value from black to white. The a* and b* values represent the color axes ranging from green to red and from blue to yellow, respectively. Higher a* values along the red-green axis are an indication that a treatment site is more irritated. [Babulak, S.W., Rhein, L.D., Scala, D.D., Simion, A.F. and Grove, G.L., Quantitation of Erythema in a Soap Chamber Test Using the Minolta Chroma (Reflectance) Meter: Comparison of Instrumental Results with Visual Assessments, J. Soc. Cosmet. Chem. 37:475-479, 1986.]

Three sets of a* readings were taken by Dr. Zerweck from each of the test sites at Baseline prior to the product applications and tape trauma and again approximately 30 minutes after the 10 repetitions of product application/tape strippings and the average value computed for each site.

F. DermaLab® Skin Sensor

The DermaLab® Skin Sensor is a novel device that is based on a patent issued to Procter & Gamble (Cincinnati, OH) that is now being produced by Cortex Technology and commercially available though cyberDERM, inc. who serves as their North American agent. The device consists of a multi-electrode sensing pad which is placed onto the skin surface. The circuitry is such that a DC voltage can be applied across the skin and the resulting current monitored in real time while the DC voltage is ramped up at a constant rate from 0 to a maximum of 80 volts. By plotting the resulting current as a function of the applied DC voltage, several parameters which are related to the basic conductance properties of the stratum corneum can be derived. These include the onset voltage at which current first begins to raise, the maximum voltage which is required to have the current reach a value of 2 microamps and the total charge under the curve. Preliminary studies have suggested that the onset voltage is related to skin surface hydration levels while maximum voltage and charge are more a measure of the barrier properties of the stratum corneum.

Three sets readings were taken by Mr. Jonn Damia from each of the test sites at Baseline prior to the product applications and tape trauma and again approximately 30 minutes after the 10 repetitions of product application/tape strippings and the average value computed for each site.

G. Test Product and Treatment Procedures

The test product used in this study was supplied by Sponsor in individual squeeze bottles and labeled:

Cellerity Code 070605B
Investigational Use Only
Lab Control: 11/22/05

Two of the four test sites on the back were randomly assigned to the test product while two sites served as non-treated controls. The randomization was a balanced block design and is included in **Appendix C**.

After completing the visual grades and instrument measurements at Baseline, Mrs. Trish Alfano applied the test product using a clean finger cot to two of the four sites prior to each of the ten tape strips being applied and removed. The other two sites remained non-treated to serve as controls.

Initially, the test product was to be applied at a dose of 0.15 cc and allowed to dry for 3 minutes before the tapes are applied. During the course of treating the 1st 3 panelists, we discovered that this was an excessive product amount that would not dry in the allotted time. Thus we first adjusted the dry time to 4 minutes and then the decision was made to adjust both the dose (reduced to 0.10 cc) and the product drying time (increased to 5 minutes). **Appendix D** includes a chart that shows when the adjustments were made during this pilot study.

H. Repetitive Tape Strip Trauma

After the Baseline measurements were completed and the product had been applied and allowed to dry, 3M Blenderm™ adhesive tape (5cm x 5cm) was firmly applied by Dr. Zerweck to 4 test sites on the back (2 on each side) and removed. We had originally planned to remove the tape immediately after being placed on the skin but we became concerned that sufficient time had not elapsed to ensure optimal adhesion to the skin. Thus, as indicated on the chart in **Appendix D,** we increased the wear time to 5 minutes before the adhesive tape strips were removed.

This process of applying the test product, allowing it to dry 5 minutes, applying new tape samples and removing them 5 minutes later was repeated for a total of 10 times for the remainder of the study.

I. Panelist Self-Assessment of Discomfort/Pain

Immediately after removing the adhesive tape strips, Ms. Damia or Mrs. Alfano asked the panelists to rate if there was any difference in **discomfort/pain** between the sites when each set of tapes were removed. During the assessments, the panelists first compared the removal of the 2 tapes from the upper sites and then compared the removal of the 2 tapes from the lower sites. The following scale was used for these assessments:

0	No difference
1	Slightly more discomfort/pain
2	Moderately more discomfort/pain
3	Dramatically more discomfort/pain
MUST FORCE CHOICE FOR FINAL (if tied)	

The panelists were asked to make a forced choice between each pair of sites after the 10th set of tapes was removed if any sites were rated equal.

J. Digital Macrophotography

Standardized images were captured by Dr. Zerweck using a Canon EOS 10D digital camera with a 90 mm macro lens. Images were taken 30 minutes after the 10 repetitions of product application and tape stripping for all panelists.

This camera apparatus was configured by Faraghan Medical Camera systems. The design incorporates a pair of Twin Lite MT 24 EX strobes at fixed positions and inclinations.

All images were reviewed, stored and retrieved using Canon Utilities Zoom Browser EX software. This was done to photodocument the test results and no attempts were made to analyze these images. The images were provided to the Sponsor.

K. Termination of a Site

All tape stripped sites were evaluated by the Expert Grader. If any site was deemed to be substantially worsened during the course of treatment, that site would have been discontinued and no further treatments with the study materials would have been made. It was not necessary to discontinue any treatment or control site during this study.

L. Adverse Reactions

Definition
An adverse event (AE) is any undesirable event occurring to a subject during a clinical trial, whether or not considered related to the trial product. This includes events not seen at baseline.

All AE's are classified as either: Serious Adverse Events (SAE)
Non-Serious Adverse Events (AE)

Serious Adverse Event
A serious adverse event is any experience that suggests a medically significant hazard including any event that:

> is fatal, is life threatening, is permanently disabling, requires in patient hospitalization (requiring overnight admission), prolongs hospitalization, causes a congenital abnormality, is diagnosed as cancer, is an over-dose or under-dose and results in inpatient hospitalization.
>
> Pre-planned elective procedures are not to be reported as serious

adverse events.

Reporting of SAE

The investigator/designate must report SAE to the Sponsor within 24 hours of knowledge of the event. The information must be provided by phone or fax to the Sponsor.

Non-Serious Adverse Event

All adverse events not classified as serious will be reported and non-serious adverse events. At each visit all adverse events observed by the investigator/designate or reported by subject spontaneously must be evaluated and recorded on the standard adverse event form. A non-serious adverse event is further classified with respect to severity and relationship to the trial product:

Severity:

Mild:	Transient symptoms, easily tolerated, no interference with subjects daily activities.
Moderate:	Marked symptoms, moderate interference with subjects daily activities and tolerable.
Marked:	Considerable interference with subject's daily activities, not tolerable.
Note:	Pre-planned elective procedures should be reported as non-serious adverse events.

Relationship to trial product:

All serious adverse events and non-serious adverse events must be evaluated by the investigator with respect to its relationship to the trial product as follows:

Probable:	Good reasons and sufficient documentation to assume causal relationship
Possible:	Causal relationship is likely and cannot be excluded.
Unlikely:	The event is most likely related to an etiology other than the trial treatment.
Unknown:	Unable to assess due to insufficient evidence, conflicting data or poor documentation.

M. Statistical Analysis

Dr. Grove was responsible for devising a sorting template that is 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 every case, but only to give a preliminary look at the findings. A paired t-test was used to compare the net change in the tabulated results. This was a pilot study and employed only 6 panelists and thus extreme caution must be placed on the interpretation of these findings.

III. RESULTS

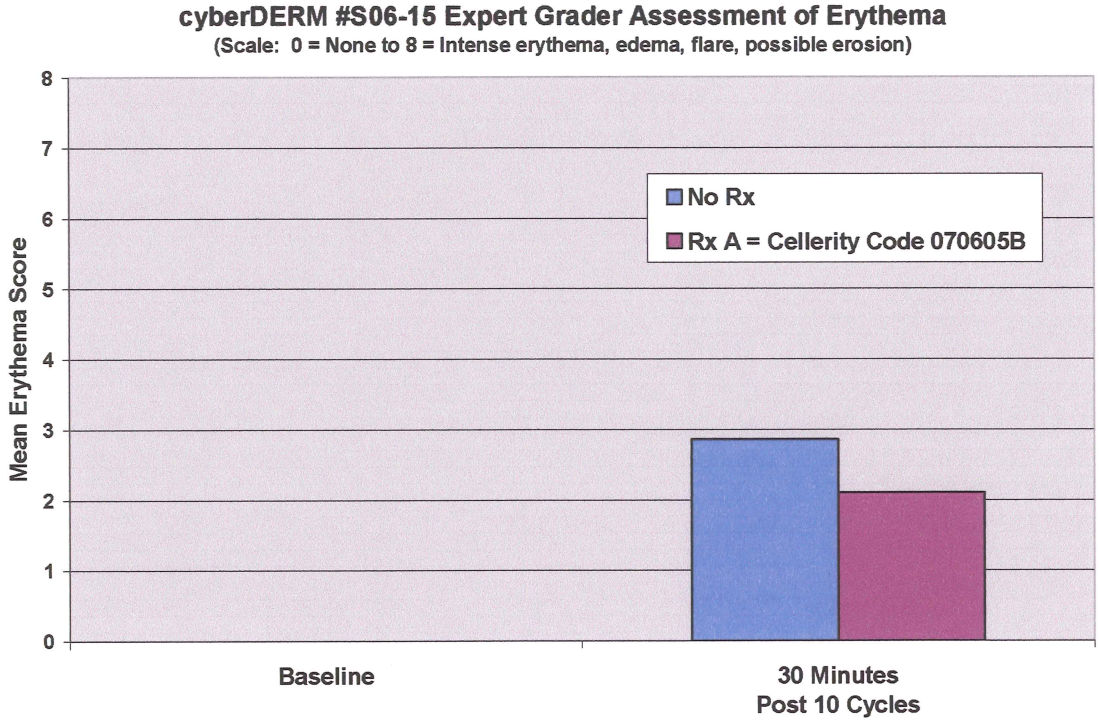
A. Panelist Accountability

Seven panelists reported to the test facility for Baseline measurements, 6 of whom qualified for inclusion on the study panel. One panelist (#4 C051) was disqualified during the Baseline measurement session due to high water loss values. **Appendix E** contains a listing of each panelist's age and sex.

All 6 of the qualified 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 Evaluations

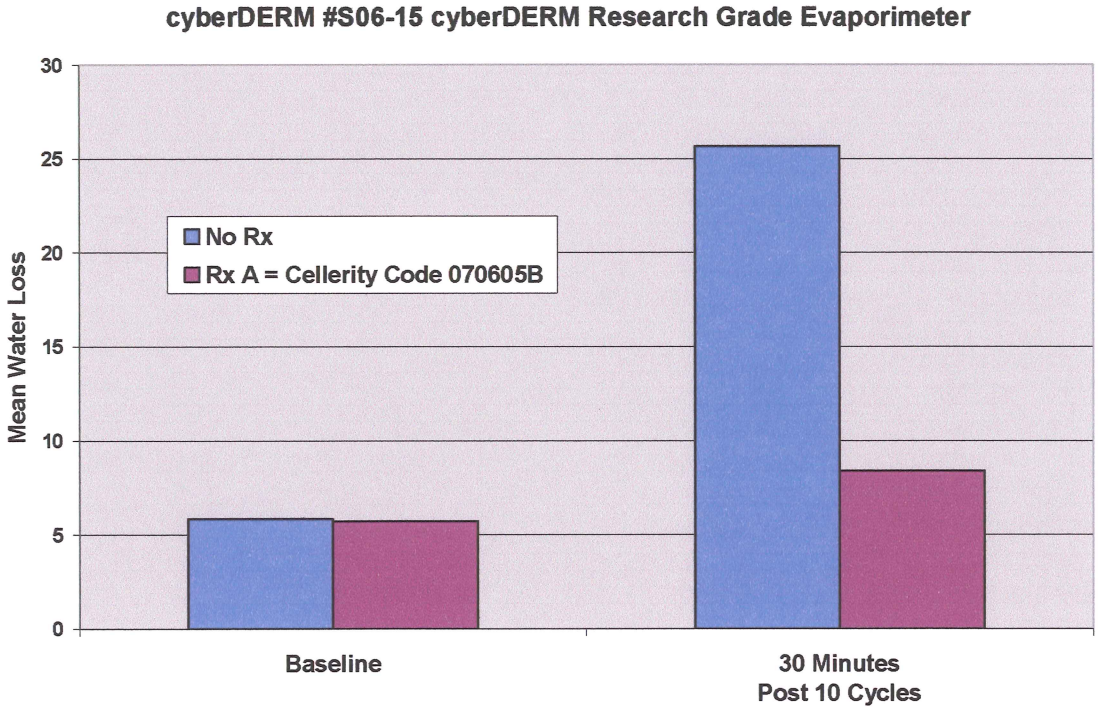
The decoded and sorted Expert Grader erythema data from the sessions at Baseline and 30 minutes post removal of the final treatment/tape application cycle are attached as **Appendix F**. These results are also graphically summarized in the figure below:



Although there seemed to be a trend for the pooled erythema scores for the treated sites to be lower than the non-treated following tape stripping, this did not prove to be statistically significant.

C. Water Loss Measurements – cyberDERM, inc. Evaporimeter

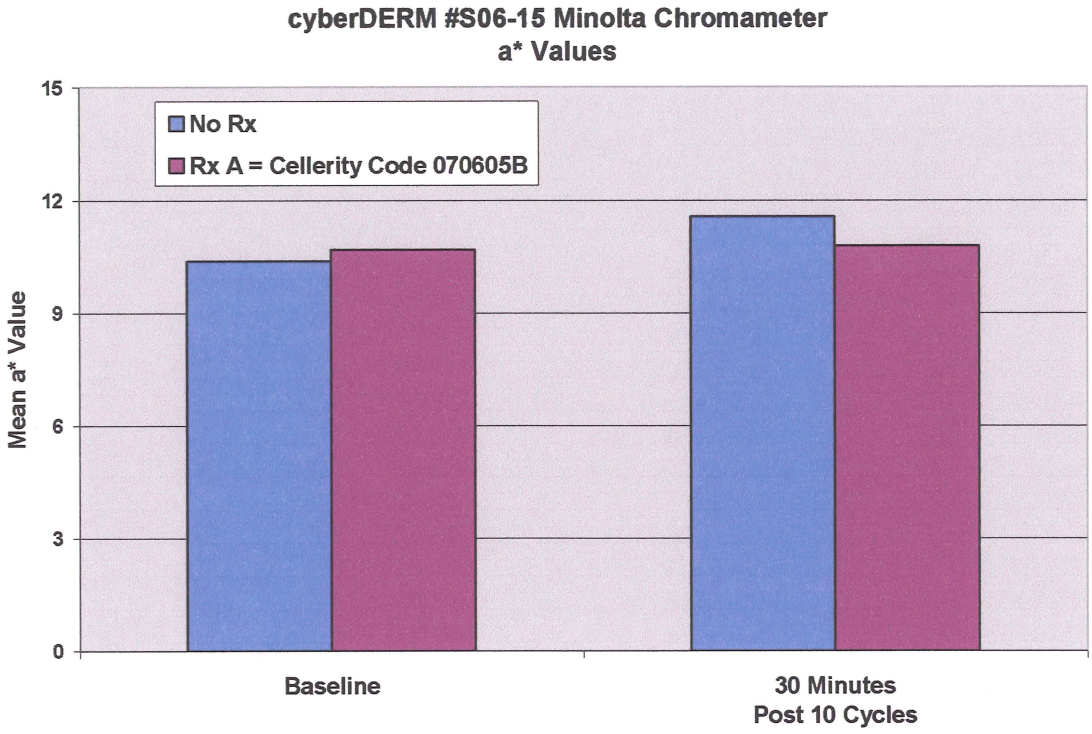
The decoded and sorted water loss measurement data from the sessions at Baseline and 30 minutes post removal of the final treatment/tape application cycle are attached as **Appendix G**. These results are also graphically summarized in the figure below.



In contrast to the Expert Grader erythema results, there were dramatic differences in evaporative water loss measurements between treated and non-treated sites. Water loss values for treated sites remained largely within the normal "uncompromised" range, while non-treated sites exhibited markedly elevated values when compared either to Baseline or treatment ($p < 0.01$).

D. Minolta Chromameter a* Measurements

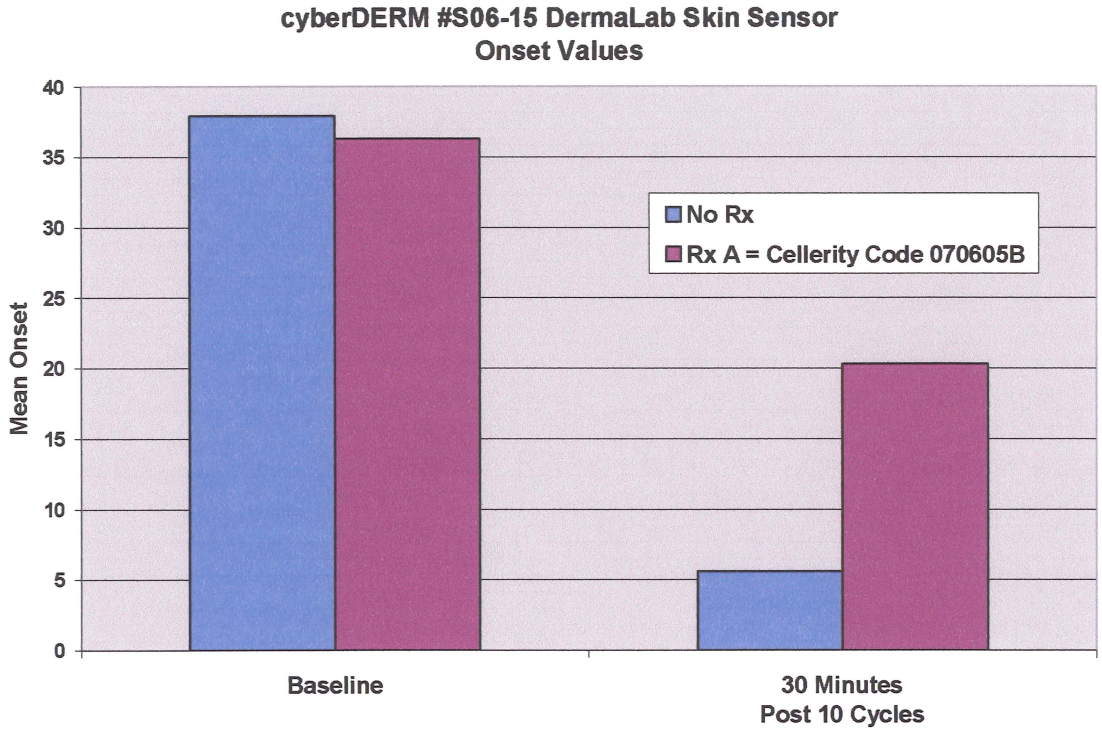
The decoded and sorted Chromameter a* data from the sessions at Baseline and 30 minutes post removal of the final treatment/tape application cycle are attached as **Appendix H.** These results are also graphically summarized in the figure below:



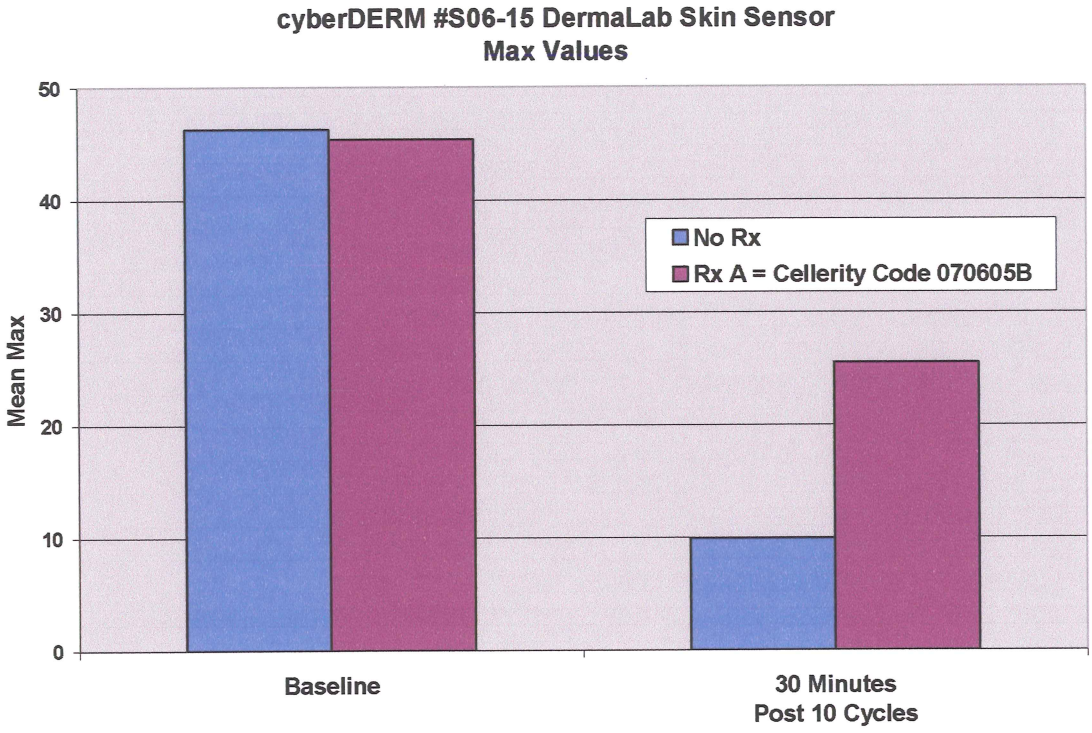
As with the Expert Grader scores for erythema, the Minolta Chromameter results appeared to indicate a greater net increase in redness associated with non-treated sites. However, once again, there did not prove to be a statistically significant difference between treated and non-treated groups

E. DermaLab® Skin Sensor Measurements

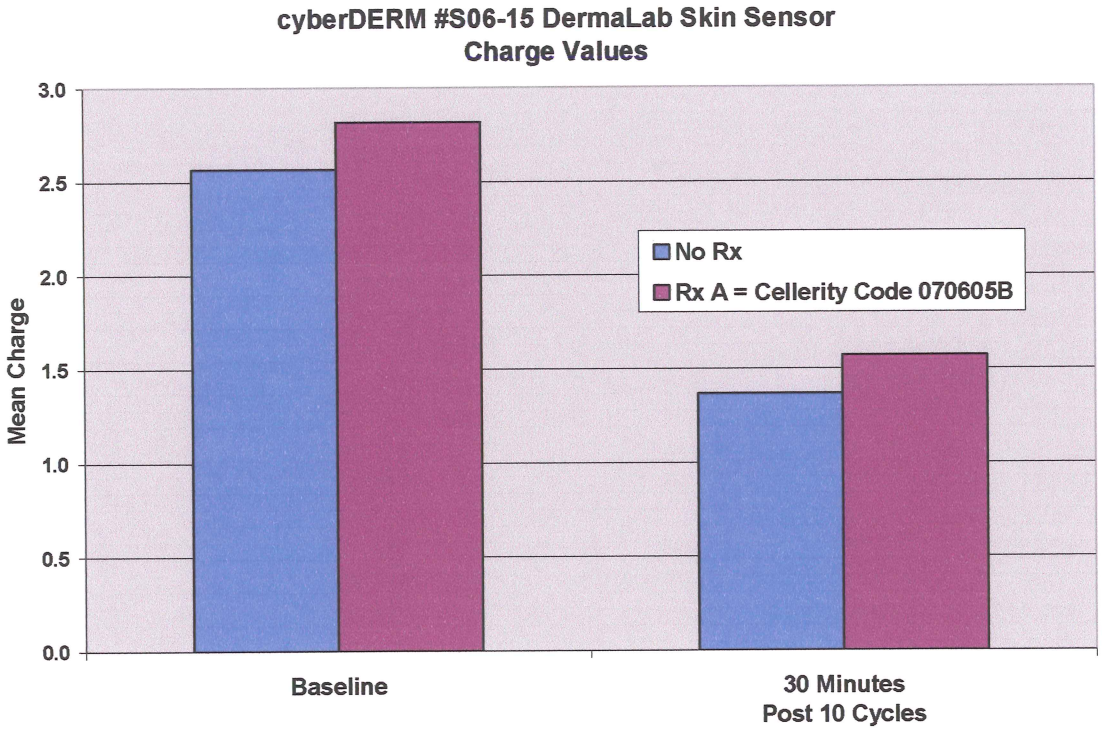
The decoded and sorted Skin Sensor measurement data from the sessions at Baseline and 30 minutes post removal of the final treatment/tape application cycle are attached as **Appendix I.** These results are also graphically summarized in the figures below:



Post tape stripping values for Sensor Onset are reduced for both treatment and non-treatment groups compared to Baseline values. Treated sites exhibit significantly ($p < 0.005$) higher Onset values and smaller net change from Baseline than the non-treated sites.



Post tape stripping values for Sensor Max are reduced for both treatment and non-treatment groups compared to Baseline values. Treated sites exhibit significantly ($p < 0.005$) less net change from Baseline than the non-treated sites.



Post tape stripping values for Sensor Charge are reduced for both treatment and non-treatment groups compared to Baseline values. However, there was no significant difference in net change from Baseline between treated and non-treated groups.

F. Self-Assessment of Discomfort/Pain upon Tape Removal

The decoded and sorted Self-Assessment data from after each of the 10 cycles comparing the discomfort upon tape removal are attached as **Appendix J**.

It does not appear that the panelists could distinguish between treated and non-treated sites in terms of a difference in Discomfort/Pain during any of the ten cycles in which tapes were stripped from their backs. It should be noted that the panelists were only comparing the amount of discomfort/pain but were not indicating the presence or absence of discomfort/pain upon removal.

IV. CONCLUSIONS

Based on the instrumental results of this small pilot study it is reasonable to conclude that application of this test product prior to an adhesive tape dressing serves to reduce the damage caused by adhesive stripping. Both evaporative water loss and various DC voltage measurements with the Skin Sensor indicate that sites treated with the test product show significantly less compromised stratum corneum and better skin barrier function following adhesive stripping. Although these pilot results are based on a small sample size, they were dramatic and warrant further study.

It is of certain interest that there was not a good correlation between the extent of redness (erythema) and the assessed disruption to the stratum corneum as measured by evaporative water loss following the treatment / tape stripping regimen. This disconnect in an often assumed parallel between increased erythema and water loss values may in this instance be in part due to mechanical stimulation of local blood flow associated with the somewhat aggressive nature of the tape stripping regimen.

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.

Appendix A: Calendar of Events

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CLINICAL STUDIES

cyberDERM #S06-15 CALENDAR OF EVENTS
A RANDOMIZED, CONTROLLED PILOT STUDY ASSESSING TOPICAL CALCIUM GLYCEROPHOSPHATE AS A POTENTIAL AGENT FOR MINIMIZING DAMAGE DUE TO ADHESIVE DRESSINGS

BASELINE ASSESSMENTS	PRODUCT APPLICATION AND TAPE STRIPPING PROCEDURE	ASSESSMENTS POST 10 STRIPS APPLIED & REMOVED
Expert Grader Erythema assessments	Product applied to 2 of 4 sites on back (randomized)	Expert Grader Erythema assessments
Minolta Chromameter a* measurements	Wait 3 minutes for product to dry	Minolta Chromameter a* measurements
cyberDERM Research Grade Evaporimeter measurements	Tape stripping of 4 sites on back, 1 strip of tape applied and removed from each site	cyberDERM Research Grade Evaporimeter measurements
DermaLab® Skin Sensor measurements	Self-Assessment of discomfort/pain	DermaLab® Skin Sensor measurements
	Repeat treatment procedure, tape stripping procedure and self-assessment 9 additional times	Digital Photography
	Wait 30 minutes	

CONDUCTION DATE: Tuesday, February 21, 2006

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

PANEL:
N=6 female panelists, ages 18 to 55

TEST SITES:
Four 5 x 5 cm test sites will be located on the back (2 on each side). Two of the four sites will be treated and two will remain non-treated to serve as controls using a balanced block randomization. All four sites will be tape stripped.

cyberDERM #S06-15 CALENDAR OF EVENTS
A RANDOMIZED, CONTROLLED PILOT STUDY USING TOPICAL CALCIUM GLYCEROPHOSPHATE AS AN ADHESIVE DAMAGE BARRIER (continued)

TEST PRODUCT:
The test product to be used in this study was supplied by Sponsor in individual squeeze bottles and labeled:

Cellerity Code 070605B
Investigational Use Only
Lab Control: 11/22/05

Approximately 0.15 cc of product will be applied by a technician using a clean finger cot to two of the four sites prior to each of the ten tape strips being applied. The product will be allowed to dry for 3 minutes before the tapes are applied. The randomization will be a balanced block design.

TAPE STRIPPING PROCEDURE:
Following each of the ten product applications, one piece of 3M Blenderm™ adhesive tape, which will be approximately 5 x 5 cm in size, will be applied firmly to each of the four test sites on the back (2 on each side) and removed.

CLINICAL ASSESSMENTS:
Expert Grader assessments of erythema will be made of the 4 test sites prior to the first product application and again approximately 30 minutes after 10 repetitions of product application/tape stripping have been done on each site. Ties will be broken by forcing the Expert Grader to add 0.1 to the site he thinks is worse, except at Baseline.

INSTRUMENTAL ASSESSMENTS:
The following measurements will be taken of the 4 test sites prior to the first product application and again approximately 30 minutes after 10 repetitions of product application/tape stripping:

- Measurements of skin surface redness using the Minolta Chromameter (a* values)
- Transepidermal water loss measurements using a cyberDERM Research Grade Evaporimeter
- Measurements using the DermaLab® Skin Sensor

cyberDERM
CLINICAL STUDIES

cyberDERM #S06-15 CALENDAR OF EVENTS
A RANDOMIZED, CONTROLLED PILOT STUDY USING TOPICAL CALCIUM GLYCEROPHOSPHATE AS AN ADHESIVE DAMAGE BARRIER (continued)

SELF-ASSESSMENTS:
The Treatment Technician will ask the panelists to rate if there is any difference in **discomfort/pain** between the sites when pulling off each set of tapes. The following scale will be used:

0	No difference
1	Slightly more discomfort/pain
2	Moderately more discomfort/pain
3	Dramatically more discomfort/pain
MUST FORCE CHOICE FOR FINAL (if tied)	

The panelists will be asked to make a forced choice between the sites after the 10th set of tapes are removed if any sites are rated equal.

DIGITAL MACROPHOTOGRAPHY:
Digital images will be obtained of the 4 test sites on each panelist after the 10 repetitions of product application/tape stripping.

DATA ANALYSIS & REPORT:
A full statistical analysis is not warranted due to the small sample size; however, a Paired T-Test will be used to ascertain any trends in the data which would warrant further study. For all analyses, a two tailed $p < 0.05$ will be taken as the level of significance. A final report will be completed by cyberDERM Clinical Studies.

PANELIST RESTRICTIONS:
- Must not have any allergies or sensitivity to tapes or adhesives.
- May not have scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
- May not be diabetic.
- May not be taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
- The panelists may not exercise before their visit as this will affect the measurements.

Appendix B: Consent Form

Subject Number: _____ CCS ID:_____

SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Randomized, Controlled Pilot Study Assessing Topical Calcium Glycerophosphate as a Potential Agent for Minimizing Damage due to Adhesive Dressings

PROTOCOL NO.: cyberDERM #S06-15

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: cyberDERM Clinical Studies
700 Parkway Drive
Broomall, Pennsylvania 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

In this study, the test formulation will be applied to 2 of 4 sites on your back and allowed to dry. Each site will be approximately 5 centimeters by 5 centimeters. One piece of

tape will be applied to each site and removed. This study is designed to determine the effectiveness of a test formulation in reducing redness and working as a protective agent against adhesive tape damage to the skin, as well as relieving any pain/discomfort associated with adhesive tape damage. The process of applying the product, letting it dry, applying a piece of tape and removing it will be repeated 10 times. This will intentionally damage the non-treated sites and treated sites. The damage will be similar to a removing an aggressive adhesive bandage. We will use the measurement of transepidermal water loss to assess the changes to the skin's barrier. Changes in skin redness will be assessed visually by and Expert Grader and instrumentally using the Minolta Chromameter. Digital images will also be taken of the test sites to capture any changes or differences in the test sites.

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

Approximately 6 volunteers will enroll in this study.

LENGTH OF STUDY AND PROCEDURES USED

Your participation in this study will last 1 day and involves 1 study visit. You will be asked to report to the testing facility at a specific time for the study. It is important that you report at the designated time. Your visit will last approximately 3 ½ to 4 hours. If you agree to participate, the following steps will occur:

Saturday, 3 Days prior to testing start:

- You will begin a 3-day washout period. During this time, you must not use topical products (including moisturizing skin care products) on your back.

On Sunday through Monday (The 2 days prior to testing start):

- Continue washout.

Tuesday, Day of testing:

- You will have 4 test sites mapped onto your back (2 on each side) with a skin-marking pen by the treatment technician. Each test site will be approximately 5 centimeters by 5 centimeters in size.
- You will then sit quietly and accommodate to the conditions of the test lab for approximately 15-20 minutes. During the accommodation and evaluations, your back must remain exposed to the air.
- You will have the test sites visually graded and instrumentally measured by technicians.
    - One instrument measures Transepidermal Water Loss (referred to as "TEWL" or "TWL"), which is the amount of water evaporating from your skin. A probe is gently placed repeatedly against the skin for up to 1 minute while each non-invasive measurement is taken. You will lie face down on a padded exam table during the measurements.
    - Skin redness will be measured using the Minolta Chromameter. This

will be done by gently placing the probe on each site for a few seconds. Three readings will be taken from each site.
    - Measurements will also be taken using the DermaLab® Skin Sensor which measures the skin's hydration and barrier properties. The probe will be gently placed on each site for up to 1 minute while measurements are being taken.
- If the measurements are in the desired range and you are accepted onto the panel, you will then have the test formulation applied to 2 of the 4 sites. The product will be allowed to dry for 3 minutes.
- One piece of tape will be applied to each of the 4 sites on your back and removed to intentionally damage the skin surface.
- You will be asked to rate any difference in discomfort/pain between the sites when the tapes were pulled off of the sites.
- The test formulation will be applied to the same sites and allowed to dry. One piece of tape will be applied to each site and removed. You will be asked to rate the difference in discomfort/pain again.
- This procedure of applying the test product to 2 sites, allowing it to dry, applying a piece of tape to each site and removing it and assess the difference in discomfort/pain will be repeated for a total of 10 times. The damage will be similar to a very mild brush-burn.
- After the 10^{th} tape is removed from the last site, you will wait 30 minutes.
- The same assessments and measurements taken at baseline will be repeated.
- Digital photographs will also be taken of the 4 test sites.
- Your participation in this study will end.

STUDY REQUIREMENTS AND RESTRICTIONS

- You must not have any allergies or sensitivity to tapes or adhesives.
- You may not have scars, moles, other blemishes on the back that would obscure grading or measuring of the test sites.
- You may not be diabetic.
- You may not be taking anti-inflammatories (Advil, Aleve, arthritis medications, etc.) except for acetaminophen (e.g. Tylenol).
- You must be willing to lie on stomach for an extended period of time.
- You may not exercise before your visit as this will affect the measurements.

RISKS OR DISCOMFORTS

- The therapy and procedures to be followed in this study may involve the following foreseeable risks and discomforts. The tape stripping procedure will cause slight temporary 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 one or more of the test materials (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.
- Your risk may be increased in some situations. You should not participate in this study if you have an active skin infection, psoriasis, active dermatitis or are diabetic. You should also not participate in this study if you are sensitive to cosmetics, toiletries or any other skin care products.

If any of these should occur, the condition of your skin will be closely monitored until it returns to normal. Consultation with a physician will be made, if necessary.

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.

NEW FINDINGS
Significant new findings that develop during the course of this study that may relate to your willingness to continue participation will be provided to you.

BENEFITS TO YOU OR TO OTHERS THAT MAY RESULT FROM THE RESEARCH STUDY
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 $65.00 to compensate you for your time and participation if you complete the entire study. If you do not complete the study, either by choice (such as not attending a visit) or as instructed by the study investigator 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 (FDA) 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.

The telephone number listed below is a currently working number I can be reached. If I cannot be reached by telephone, I will be removed from the panel list. I must report to cyberDERM Clinical Studies for study visits as required. IF I DO NOT REPORT OR CALL IN, MY PARTICIPATION IN THIS STUDY MAY BE DISCONTINUED.

I will receive a signed and dated copy of the consent form for my files.

_____ _____

Printed Name of Volunteer Date

_____ _____

Signature of Volunteer Date

_____ _____ _____ _____

Telephone Number Birth date Age Sex

_____ _____

Person conducting consent discussion Date

Appendix C: Randomization

cyberDERM #S06-15

Randomized Treatment Map

#	ID	Left Back		Right Back	
		Upper	Lower	Upper	Lower
1	X015	A	No Rx	No Rx	A
2	S041	A	No Rx	No Rx	A
3	M125	No Rx	A	A	No Rx
4	C051	A	No Rx	No Rx	A
5	H047	No Rx	A	A	No Rx
6	B070	No Rx	A	A	No Rx
7	H010	A	No Rx	No Rx	A

A = Cellerity Code 070605B

Appendix D: Chart of Adjustments to Dosing & Timing

cyberDERM #S06-15

Chart of Adjustments to Dosing and Timing during Pilot Study

		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10
Dosing:											
1	X015	0.15 cc	0.15 cc	0.15 cc	0.15 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc
2	S041	0.15 cc	0.15 cc	0.15 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc
3	M125	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc
5	H047	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc
6	B070	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc
7	H010	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc	0.10 cc
Dry time:											
1	X015	3 min.	3 min.	4 min.	4 min.	4 min.	4 min.	4 min.	4 min.	5 min.	5 min.
2	S041	3 min.	3 min.	4 min.	4 min.	4 min.	4 min.	4 min.	5 min.	5 min.	5 min.
3	M125	4 min.	4 min.	4 min.	4 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.
5	H047	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.
6	B070	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.
7	H010	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.
Dwell time:											
1	X015	0	0	0	0	0	0	0	0	5 min.	5 min.
2	S041	0	0	0	0	0	0	0	5 min.	5 min.	5 min.
3	M125	0	0	0	0	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.
5	H047	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.
6	B070	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.
7	H010	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.	5 min.

Appendix E: Demographic Data

cyberDERM #S06-15

Demographic Data

#	ID	AGE	SEX
1	X015	23	F
2	S041	33	F
3	M125	31	F
4	C051	44	F
5	H047	42	F
6	B070	26	F
7	H010	50	F

Appendix F: Expert Grader Data

Decoded & Sorted Data

cyberDERM S06-15

Expert Grader Assessment of Erythema

[Scale: 0 = none to 8 = Intense erythema]

Baseline

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	0	0	0	0	0	0
2	S041	0	0	0	0	0	0
3	M125	0	0	0	0	0	0
4	C051						
5	H047	0	0	0	0	0	0
6	B070	0	0	0	0	0	0
7	H010	0	0	0	0	0	0
					Mean	0	0
					SD	0	0
					paired t	1.0000	

A = Cellerity Code 070605B

Expert Grader Assessment of Erythema

[Scale: 0 = none to 8 = Intense erythema]

End Point

(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	3.1	0	3	2	1.55	2.5
2	S041	4	0	3	2	2	2.5
3	M125	1.1	1	3	1.2	1.05	2.1
4	C051						
5	H047	2	4.1	5	4	3.05	4.5
6	B070	3	2	1.1	1	2.5	1.05
7	H010	3	2	4	5	2.5	4.5
					Mean	2.11	2.86
					SD	0.73	1.38
					paired t	0.1834	

A = Cellerity Code 070605B

Appendix G: Water Loss Data

Decoded & Sorted Data — cyberDERM S06-15

cyberDERM RG-1 Evaporimeter

Baseline

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	5.00	3.90	4.05	4.45	4.45	4.25
2	S041	5.35	5.25	5.80	5.95	5.30	5.88
3	M125	4.45	4.30	5.35	4.25	4.38	4.80
4	C051						
5	H047	6.95	5.85	5.45	7.00	6.40	6.23
6	B070	6.45	8.15	6.45	7.00	7.30	6.73
7	H010	4.90	8.30	7.70	6.85	6.60	7.28
					Mean	5.74	5.86
					SD	1.21	1.15
					paired t	0.5840	

A = Cellerity Code 070605B

cyberDERM RG-1 Evaporimeter

End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	5.50	6.20	14.60	15.10	5.85	14.85
2	S041	11.20	10.60	17.05	48.05	10.90	32.55
3	M125	7.20	7.15	34.05	23.90	7.18	28.98
4	C051						
5	H047	10.40	9.75	44.00	41.30	10.08	42.65
6	B070	6.35	8.90	8.80	13.25	7.63	11.03
7	H010	7.25	10.45	25.75	22.20	8.85	23.98
					Mean	8.41	25.67
					SD	1.89	11.67
					paired t	0.0096	

A = Cellerity Code 070605B

cyberDERM RG-1 Evaporimeter

Net Change from Baseline @ End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	0.50	2.30	10.55	10.65	1.40	10.60
2	S041	5.85	5.35	11.25	42.10	5.60	26.68
3	M125	2.75	2.85	28.70	19.65	2.80	24.18
4	C051						
5	H047	3.45	3.90	38.55	34.30	3.68	36.43
6	B070	-0.10	0.75	2.35	6.25	0.33	4.30
7	H010	2.35	2.15	18.05	15.35	2.25	16.70
					Mean	2.68	19.81
					SD	1.84	11.64
					paired t	0.0092	

A = Cellerity Code 070605B

Appendix H: Chromameter a* Data

Decoded & Sorted Data

cyberDERM S06-15

Minolta Chromameter a* Values

Baseline

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	13.4	13.5	13.4	13.5	13.42	13.45
2	S041	8.5	7.6	8.2	7.5	8.02	7.88
3	M125	7.5	8.3	9.5	6.5	7.90	8.02
4	C051						
5	H047	11.2	12.6	11.5	9.4	11.88	10.42
6	B070	9.9	11.2	10.2	9.9	10.57	10.07
7	H010	13.3	11.3	11.9	13.0	12.33	12.45
					Mean	**10.69**	**10.38**
					SD	**2.30**	**2.26**
					paired t	**0.2774**	

A = Cellerity Code 070605B

Minolta Chromameter a* Values

End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	13.0	12.0	12.0	12.9	12.53	12.45
2	S041	11.8	8.0	9.7	9.0	9.90	9.37
3	M125	7.8	8.5	10.2	7.1	8.13	8.67
4	C051						
5	H047	11.5	13.3	16.1	13.7	12.37	14.90
6	B070	11.6	9.1	10.6	8.5	10.37	9.58
7	H010	12.6	10.3	13.9	15.0	11.45	14.43
					Mean	10.79	11.57
					SD	1.67	2.73
					paired t	0.2905	

A = Cellerity Code 070605B

Decoded & Sorted Data

cyberDERM S06-15

Minolta Chromameter a* Values

Net Change from Baseline @ End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	-0.3	-1.4	-1.4	-0.6	-0.88	-1.00
2	S041	3.4	0.4	1.5	1.5	1.88	1.48
3	M125	0.2	0.2	0.7	0.6	0.23	0.65
4	C051						
5	H047	0.3	0.7	4.7	4.3	0.48	4.48
6	B070	1.7	-2.1	0.4	-1.4	-0.20	-0.48
7	H010	-0.7	-1.0	2.0	2.0	-0.88	1.98
					Mean	0.11	1.19
					SD	1.04	1.97
					paired t	0.2178	

A = Cellerity Code 070605B

Appendix I: DermaLab® Skin Sensor Data

Decoded & Sorted Data

cyberDERM S06-15

DermaLab® Skin Sensor
Onset

Baseline

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	57.17	58.57	48.40	51.23	57.87	49.82
2	S041	34.15	42.57	42.73	31.03	38.36	36.88
3	M125	20.12	30.04	22.61	28.19	25.08	25.40
4	C051						
5	H047	21.23	24.27	33.06	25.90	22.75	29.48
6	B070	39.06	28.33	56.56	47.27	33.70	51.91
7	H010	43.95	36.1	31.58	36.69	40.03	34.13
					Mean	36.30	37.94
					SD	12.65	10.78
					paired t	0.6933	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Onset

End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	31.61	34.83	6.15	7.90	33.22	7.03
2	S041	6.20	15.21	3.07	1.50	10.70	2.29
3	M125	18.92	19.19	2.17	6.67	19.05	4.42
4	C051						
5	H047	11.45	11.55	2.24	2.00	11.50	2.12
6	B070	21.67	21.00	11.67	13.97	21.33	12.82
7	H010	27.27	24.87	5.47	4.50	26.07	4.98
					Mean	**20.31**	**5.61**
					SD	**8.63**	**3.97**
					paired t	**0.0048**	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Onset

Net Change from Baseline @ End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	-25.56	-23.73	-42.25	-43.33	-24.65	-42.79
2	S041	-27.95	-27.36	-39.66	-29.53	-27.66	-34.60
3	M125	-1.20	-10.85	-20.45	-21.52	-6.03	-20.98
4	C051						
5	H047	-9.78	-12.72	-30.82	-23.90	-11.25	-27.36
6	B070	-17.39	-7.33	-44.89	-33.30	-12.36	-39.10
7	H010	-16.69	-11.23	-26.11	-32.19	-13.96	-29.15
					Mean	-15.98	-32.33
					SD	8.37	8.05
					paired t	0.0015	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Max

Baseline

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	61.43	66.40	55.47	58.56	63.92	57.02
2	S041	38.17	50.03	48.33	37.90	44.10	43.12
3	M125	34.29	42.37	30.52	39.23	38.33	34.87
4	C051						
5	H047	36.74	29.58	41.67	35.35	33.16	38.51
6	B070	48.53	34.41	65.04	59.74	41.47	62.39
7	H010	55.42	47.58	40.37	43.17	51.50	41.77
					Mean	**45.41**	**46.28**
					SD	**10.93**	**10.91**
					paired t	**0.8560**	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Max

End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	37.00	41.52	9.69	13.94	39.26	11.82
2	S041	11.47	20.74	7.43	5.29	16.11	6.36
3	M125	23.81	25.08	6.11	9.75	24.44	7.93
4	C051						
5	H047	17.01	15.27	6.63	6.32	16.14	6.48
6	B070	27.91	25.21	16.15	17.07	26.56	16.61
7	H010	31.32	30.00	10.25	10.61	30.66	10.43
					Mean	**25.53**	**9.94**
					SD	**8.88**	**3.93**
					paired t	**0.0033**	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Max

Net Change from Baseline @ End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	-24.43	-24.88	-45.78	-44.62	-24.66	-45.20
2	S041	-26.69	-29.29	-40.90	-32.61	-27.99	-36.76
3	M125	-10.49	-17.29	-24.41	-29.48	-13.89	-26.94
4	C051						
5	H047	-19.73	-14.31	-35.03	-29.03	-17.02	-32.03
6	B070	-20.63	-9.19	-48.89	-42.66	-14.91	-45.78
7	H010	-24.10	-17.58	-30.13	-32.57	-20.84	-31.35
					Mean	-19.89	-36.34
					SD	5.63	7.74
					paired t	0.0043	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Charge

Baseline

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	1.84	2.13	2.16	2.07	1.99	2.12
2	S041	1.40	2.35	1.83	2.17	1.88	2.00
3	M125	4.49	4.17	2.41	3.69	4.33	3.05
4	C051						
5	H047	4.64	1.91	2.73	2.52	3.28	2.63
6	B070	2.55	2.01	3.04	3.54	2.28	3.29
7	H010	2.897	3.437	2.633	2.02	3.17	2.33
					Mean	2.82	2.57
					SD	0.95	0.52
					paired t	0.4893	

A = Cellerity Code 070605B

DermaLab® Skin Sensor Charge

End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	1.16	2.12	1.17	1.84	1.64	1.51
2	S041	1.69	1.69	1.29	1.18	1.69	1.24
3	M125	1.31	1.52	1.29	1.09	1.41	1.19
4	C051						
5	H047	1.91	1.38	1.26	1.33	1.65	1.29
6	B070	1.98	1.40	1.46	0.86	1.69	1.16
7	H010	0.94	1.76	1.57	2.06	1.35	1.82
					Mean	1.57	1.37
					SD	0.15	0.25
					paired t	0.2205	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Charge

Net Change from Baseline @ End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	-0.68	0.00	-0.99	-0.23	-0.34	-0.61
2	S041	0.28	-0.66	-0.53	-0.99	-0.19	-0.76
3	M125	-3.18	-2.65	-1.12	-2.60	-2.92	-1.86
4	C051						
5	H047	-2.74	-0.53	-1.47	-1.19	-1.63	-1.33
6	B070	-0.57	-0.62	-1.58	-2.67	-0.59	-2.13
7	H010	-1.95	-1.68	-1.07	0.04	-1.82	-0.51
					Mean	-1.25	-1.20
					SD	1.06	0.68
					paired t	0.9171	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Max minus Onset

Baseline

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	4.27	7.83	7.07	7.33	6.05	7.20
2	S041	4.01	7.47	5.60	6.87	5.74	6.23
3	M125	14.17	12.33	7.91	11.03	13.25	9.47
4	C051						
5	H047	15.51	5.31	8.61	9.45	10.41	9.03
6	B070	9.47	6.07	8.48	12.47	7.77	10.48
7	H010	11.47	11.48	8.793	6.487	11.47	7.64
					Mean	9.12	8.34
					SD	3.06	1.58
					paired t	0.5117	

A = Cellerity Code 070605B

DermaLab® Skin Sensor
Max minus Onset

End Point
(30 Minutes Post 10 cycles)

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	5.39	6.69	3.54	6.04	6.04	4.79
2	S041	5.27	5.53	4.36	3.79	5.40	4.08
3	M125	4.89	5.89	3.95	3.07	5.39	3.51
4	C051						
5	H047	5.55	3.72	4.39	4.32	4.64	4.36
6	B070	6.24	4.21	4.48	3.11	5.23	3.79
7	H010	4.05	5.13	4.78	6.11	4.59	5.44
					Mean	**5.22**	**4.33**
					SD	**0.54**	**0.70**
					paired t	**0.0818**	

A = Cellerity Code 070605B

Appendix J: Self-Assessment Data

Decoded & Sorted Data **cyberDERM S06-15**

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 1

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	1	0	0	1	0.5	0.5
2	S041	0	0	0	1	0	0.5
3	M125	0	2	1	0	1	0.5
4	C051						
5	H047	0	0	0	1	0	0.5
6	B070	0	1	0	0	0.5	0
7	H010	1	1	0	0	1	0
					Mean	0.50	0.33
					SD	0.45	0.26
					paired t	0.5301	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 2

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	1	0	0	1	0.5	0.5
2	S041	3	0	0	0	1.5	0
3	M125	0	1	0	0	0.5	0
4	C051						
5	H047	1	0	0	0	0.5	0
6	B070	0	1	1	0	0.5	0.5
7	H010	1	0	0	1	0.5	0.5
					Mean	0.67	0.25
					SD	0.41	0.27
					paired t	0.1412	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 3

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	0	1	1	0	0.5	0.5
2	S041	0	1	1	0	0.5	0.5
3	M125	1	0	0	0	0.5	0
4	C051						
5	H047	2	1	0	0	1.5	0
6	B070	0	1	0	0	0.5	0
7	H010	0	0	0	0	0	0
					Mean	0.58	0.17
					SD	0.49	0.26
					paired t	0.1412	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 4

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	0	0	0	1	0	0.5
2	S041	0	0	0	1	0	0.5
3	M125	0	0	1	1	0	1
4	C051						
5	H047	1	0	0	1	0.5	0.5
6	B070	0	2	1	0	1	0.5
7	H010	0	1	0	0	0.5	0
					Mean	0.33	0.50
					SD	0.41	0.32
					paired t	0.5301	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 5

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	1	0	0	0	0.5	0
2	S041	0	0	0	1	0	0.5
3	M125	0	0	2	0	0	1
4	C051						
5	H047	1	0	0	1	0.5	0.5
6	B070	0	1	1	0	0.5	0.5
7	H010	0	1	0	0	0.5	0
					Mean	0.33	0.42
					SD	0.26	0.38
					paired t	0.7412	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 6

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	1	0	0	1	0.5	0.5
2	S041	1	0	0	1	0.5	0.5
3	M125	0	0	2	0	0	1
4	C051						
5	H047	1	0	0	1	0.5	0.5
6	B070	1	1	0	0	1	0
7	H010	1	0	0	0	0.5	0
					Mean	0.50	0.42
					SD	0.32	0.38
					paired t	0.7711	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 7

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	1	0	0	1	0.5	0.5
2	S041	1	0	0	1	0.5	0.5
3	M125	0	0	2	1	0	1.5
4	C051						
5	H047	0	0	0	0	0	0
6	B070	1	2	0	0	1.5	0
7	H010	1	0	0	0	0.5	0
					Mean	0.50	0.42
					SD	0.55	0.58
					paired t	0.8417	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 8

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	1	0	0	1	0.5	0.5
2	S041	1	0	0	1	0.5	0.5
3	M125	0	0	2	1	0	1.5
4	C051						
5	H047	1	0	0	0	0.5	0
6	B070	0	2	0	0	1	0
7	H010	1	0	0	0	0.5	0
					Mean	0.50	0.42
					SD	0.32	0.58
					paired t	0.8220	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 9

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	3	0	0	1	1.5	0.5
2	S041	0	0	1	0	0	0.5
3	M125	0	0	0	2	0	1
4	C051						
5	H047	0	0	0	0	0	0
6	B070	0	1	1	0	0.5	0.5
7	H010	0	0	1	0	0	0.5
					Mean	0.33	0.50
					SD	0.61	0.32
					paired t	0.5761	

A = Cellerity Code 070605B

SELF-ASSESSMENT OF DISCOMFORT/PAIN

[Scale: 0 = No difference to 3 = Dramatically more discomfort/pain]

After Tape # 10

		Rx A		No Rx		Pooled	
#	ID	Left	Right	Left	Right	Rx A	No Rx
1	X015	0	0	1	1	0	1
2	S041	2	1	0	0	1.5	0
3	M125	0	0	1	2	0	1.5
4	C051						
5	H047	0	0	1	1	0	1
6	B070	1	1	0	0	1	0
7	H010	0	0	1	1	0	1
					Mean	0.42	0.75
					SD	0.66	0.61
					paired t	0.5430	

A = Cellerity Code 070605B