

Essex Testing Clinic, Inc.



DRAFT REPORT

**CLINICAL EVALUATION OF AN ANTI-ACNE TEST SYSTEM OF
GLUTATHIONE PATCHES AND LIFEWAVE HOMEOPATHIC SPRAY**

**Homeopathic Spray
Glutathione Patches**

Sponsor

**LifeWave Products, LLC
1020 Prospect Street
Suite 200
La Jolla, CA 92037**

Sponsor Representatives

David Schmidt, CEO

**Dr. Steve Hattiwanger
Science Director**

Clinical Testing Facility

**Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044**

**Sponsor Code: L51
ETC Panel No.: 09219
ETC Entry Nos.: 17360.01-.02**

Date of Draft Report

1-15-10

SIGNATURE PAGE

**CLINICAL EVALUATION OF AN ANTI-ACNE TEST SYSTEM OF
GLUTATHIONE PATCHES AND LIFEWAVE HOMEOPATHIC SPRAY**

Homeopathic Spray
Glutathione Patches

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Essex Testing Clinic, Inc. _____

QUALITY ASSURANCE STATEMENT

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in CFR Title 21, Parts 50, 56 and 312 and/or the Declaration of Helsinki, as appropriate.

For purposes of this clinical study:

Informed Consent was obtained.

Informed Consent was not obtained.

An IRB review was not required.

An IRB review was conducted and approval to conduct the proposed clinical research was granted.

This study report has been reviewed to assure that it correctly describes the methods of testing and that the reported results accurately reflect the data obtained during the clinical study (ETC Panel No.: 09219; ETC Entry Nos.: 17360.01-.02).

Sherri L. Sayles, MS
Manager, Quality Assurance

Date

Essex Testing Clinic, Inc. _____

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CLINICAL EVALUATION OF AN ANTI-ACNE TEST SYSTEM OF GLUTATHIONE PATCHES AND LIFEWAVE HOMEOPATHIC SPRAY

Homeopathic Spray Glutathione Patches

1.0 OBJECTIVE

The objective of this study was to determine if the use of a test system (a non-transdermal glutathione patch and homeopathic spray) improved (reduced the appearance of) acne after 1, 2, 3, 4 and 6 weeks of use in a study of 40 volunteers, aged 13-35 years. All panelists were to have mild to moderate acne, as qualified by a Board-Certified Dermatologist, according Cook's scale.

2.0 SPONSOR

LifeWave Products, LLC
1020 Prospect Street, Suite 200
La Jolla, CA 92037

2.1 Sponsor Representatives

David Schmidt, CEO

Dr. Steve Hattiwanger
Science Director

3.0 CLINICAL INVESTIGATORS

Study Coordinator:	Nicole DeNisco
Study Director:	Annemarie E. Hollenback, BA
Principal Investigator:	Toni F. Miller, PhD, DABT, BCFE
Medical Investigator:	John A. Erianne, MD, Board-Certified Dermatologist

4.0 CLINICAL TESTING FACILITY

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

5.0 STUDY DATES

Baseline Visit:	September 23, 2009
1-Week Visit:	September 30, 2009
2-Week Visit:	October 7, 2009
3-Week Visit:	October 14, 2009
4-Week Visit:	October 21, 2009
6-Week Visit:	November 4, 2009

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6.0 ETHICS

6.1 Ethical Conduct of the Study

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures (SOPs).

6.2 Subject Information and Consent

This study was conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study. A copy of the Informed Consent was provided to each subject.

6.3 Institutional Review Board (IRB)

This study (and any modification) and appropriate consent procedures, were reviewed and approved by an independent Institutional Review Board (IRB). A letter or certificate of approval was sent by the Investigator/Study Director to the Sponsor prior to study initiation.

7.0 TEST MATERIALS

The test articles used in this study were provided by:

LifeWave Products, LLC
1020 Prospect Street, Suite 200
La Jolla, CA 92037

The test articles were received on July 14, 2009 and identified as follows:

<u>ETC Entry No.</u>	<u>Qty. Rec'd</u>	<u>Test Article</u>	<u>Description</u>
17360.01	50 Pump Bottles	Homeopathic Spray	Clear Liquid
17360.02	90 Packets	Glutathione Patches	White Circular Patches

8.0 TEST SUBJECTS

A sufficient number of male and female subjects ranging in age from 12 to 35 years were to be empanelled for the home-use test procedure to ensure that 40 would complete the study.

Each panelist was to read, understand and sign a written Informed Consent Form and complete a brief Medical History Form.

9.0 STUDY DESIGN

9.1 Subject Selection

A sufficient number of individuals, between 12 and 35 years of age (inclusive) and in general good health, were to be empanelled so that at least 40 would finish. To be enrolled, all subjects had to have mild to moderate acne, as graded by the trained technician (who was an expert grader) according to the Cook's scale and moderate redness on the face. All subjects were required to read, understand and sign a written Informed Consent and complete a brief demographic Medical History Form. Subjects under the age of 18 had to have a parent/legal guardian sign the Informed Consent Form. Subjects were evaluated at baseline and after 1, 2, 3, 4 and 6 weeks of product use.

9.1.1 Inclusion Criteria

1. Male and female individuals between the ages of 13 and 35 years (inclusive) in general good health (no physical required).
2. Individuals with an acne score of 1 - 3 according to the Cook's Acne Grading Scale but were otherwise free of any dermatologic condition that might have interfered with the purpose, conduct or integrity of the study.
3. Individuals who indicated their willingness to participate in the study, follow directions and to stay on the study for the full 6 weeks.
4. Individuals who signed a photograph release (subjects' identities were not released with the photographs).
5. Individuals who were not on any OTC treatment programs for acne within 4 weeks prior to the initiation of the study.
6. Individuals who could read, understand and sign the Informed Consent Form.

9.0 STUDY DESIGN (CONT'D)

9.1.2 Exclusion Criteria

1. Any individual who did not meet the inclusion criteria.
2. Women who were pregnant, planning a pregnancy, or lactating and/or nursing a child.
3. Individuals with a known sensitivity to cosmetics or personal care products.
4. Individuals using an OTC acne treatment within 4 weeks to study initiation, systemic or topical anti-inflammatory agents with the exception of OTC acetaminophen (eg, Tylenol), ibuprofen (eg, Advil), or aspirin for 5 days prior to the start of testing.
5. Individuals who had been on prescription treatment for acne (eg, Accutane, Retin-A, antibiotics) within the past 6 months.
6. Individuals who could not agree not to use acne treatment, systemic or topical anti-inflammatory agents, with the exception of OTC acetaminophen (eg Tylenol), ibuprofen (eg, Advil) or aspirin during the course of the study.
7. Individuals with any systemic or dermatologic disorder including a known history of allergies which in the opinion of the Investigator might have interfered with the conduct of the study, interpretation of results or increased the risks of an adverse reaction.
8. Individuals taking other medications that might have interfered with the test results.
9. Individual who had participated on another facial study within 2 weeks.
10. Individuals with a Cook's Acne grade score or greater than 3 or less than 1.

9.2 Test Procedure

Prior to study enrollment, potential panelists completed an Informed Consent Form, a Medical History form and a photo release form. Individuals who appeared to meet the study criteria based on Medical History review were evaluated by the Board-Certified Dermatologist to determine the grade of acne, according to Cook's scale. In order to qualify, the Cook's grade had to be a "1", "2" or "3". The Dermatologist also identified and counted the number of acne lesions on the cheeks, chin and forehead (each type of lesion was recorded). Subjects meeting the inclusion/exclusion criteria were empanelled. Enrolled subjects had photographs taken by a trained technician with the Visa CR® Digital Imaging System (Canfield Scientific, Fairfield, NJ). Subjects were given the test products to take home, use instructions and a daily diary.

9.0 STUDY DESIGN (CONT'D)

9.2 Test Procedure (Cont'd)

Follow-up digital photographs were taken by a trained technician after 1, 2, 3 and 4 weeks of product use and at the 6-week (final) visit a Board-Certified Dermatologist performed all evaluations and a trained technician took digital photographs. All evaluations were conducted in according to the procedures outlined in Section 9.3.

No facial makeup was permitted to be worn at the study visits, and had been removed at least 30 minutes before each visit to the Testing Facility. Additionally, all facial area products normally used by the subjects (soaps, creams, etc.) were noted on the Medical History forms.

9.2.1 Baseline Evaluations

Subjects reported to the Testing Facility for the baseline visit. The trained technician graded the presence of acne on the face of each subject using the Cook's Acne Scale and counted the lesions present on the face of each subject. In order to qualify, the Cook's Scale had to be a score of "1", "2" or "3". If the subject met all qualification requirements and was enrolled, digital photographs were taken of the face of each subject using the Visia CR® Digital Imaging System. Subjects received the test product and a daily diary containing use instructions and a place to record product use and any pertinent comments.

INSTRUCTIONS: Dates and times of use must be included in this diary:

1. Record each time (a.m. and p.m.) that the test regimen was used.
2. Do not use any acne products other than the ones that are provided.
3. Female subjects only: If you have your menstrual period at any time during the test procedure, please record it on the space provided on the diary.
4. If you are going to be in the sun for a period longer than 30 minutes, please apply the provided sunscreen.
5. Record any comments you may have (if any) in the space provided below.

DIRECTIONS:

GLUTATHIONE PATCH: *Remove the patch from the package. The liner is removed from the adhesive backing and the patch is applied adhesive side to the skin on the designated site. (Follow instructions and diagram.)* You will wear the patch for five (5) consecutive days starting on Monday until Friday. You will wear the patch on either the abdomen or on the chest (breast bone) each day, rotating the position daily. You will not wear the patch on Saturday or Sunday. You will receive written instructions and a diagram that will explain proper placement of the test article. You will apply a new patch each day. The patch is to be applied in the morning and removed at night. You should wear the patch for 12 hours daily, but no longer than that. Following the written instructions and diagrams that are provided to you, you will alternate the patch everyday between the abdomen and the breast bone. (It is important that you change the site every night to reduce irritation from the patch.)

9.0 TEST PROCEDURE (CONT'D)

9.2 Test Procedure (CONT'D)

9.2.1 Baseline Evaluations

DIRECTIONS:

HOMEOPATHIC SPRAY: The spray is to be used daily by squirting 3 sprays into the mouth three (3) times daily. You will use this spray Monday through Friday. You will not use it on Saturday or Sunday.

NOTES: You are permitted to use your regular cosmetics (non-oily based only) and your regular facial cleanser. You must refrain from applying any facial cosmetics prior to ALL study visit. **It is important that you stay properly hydrated while on the study. It is critical for optimal performance of LifeWave Glutathione patch.** Keep the patches and the sprays at room temperature. These research products should not be left in a hot car or car trunk. Exposure to high temperature can affect the products' ability to work.

All evaluations were conducted in accordance with the scales and procedures outlined in Section 9.3.

Evaluations of efficacy were based upon a comparison of baseline vs. each observation period.

9.2.2. One-, Two-, Three-, Four- and Six-Week Evaluations

Subjects were instructed to return after 1, 2, 3, 4 and 6 weeks of product use. At the 1, 2, 3 and 4-week visits, all evaluations and digital photographs were performed by a trained technician. At the final (6-week) evaluations, dermatologist performed all lesions counts and the trained technician took digital photographs.

9.0 TEST PROCEDURE (CONT'D)

9.3 Clinical Evaluation Procedures

All evaluations were conducted in accordance with the following scales and procedures.

9.3.1 Acne Evaluation (Cook's Acne Grading Scale)

The following scale was used to grade the level of acne at all visits. In order to be enrolled, the baseline score had to be a 1, 2 or 3.

Modified Cook's Acne Grading Scale¹:

- 0 = Facial skin need not be perfectly clear. A few scattered comedones or papules may be present, but these should be visible only on close examination.
- 1 = Comedones and small papules are present and noticeable from a distance of 1-3 feet away.
- 2 = About one fourth (25%) of facial area is involved, with small papules (about 6 to 12) and comedones (a few pustules or large prominent papules may be present).
- 3 = Approximately 30% (26-49%) of facial area is involved with small papules (13 to 20) and small comedones (a few pustules or large prominent papules may be present).
- ⁶4 = Approximately half (50%) of facial area is involved, with small papules and large or small comedones. A few pustules or large prominent papules are usually present. (If lesions are generally large, subject may have a grade "4" severity, although less than half of facial area is involved.)
- 5 = More than half (51-74%) of facial area is involved with large and small papules and comedones (less facial area of involvement is permissible if inflammatory lesions are large). A moderate number of pustules are usually present, some of which may be large.
- 6 = Approximately three fourths (75%) of facial area is involved, with papules and/or large open comedones. (Less facial area of involvement is permissible if inflammatory lesions are large.) Numerous pustules are usually present; some of which may be large.
- 7 = Greater than 75% but less than 85% of facial area is involved with lesions with the majority being papules and large open comedones. Pustules may be large and prominent.

¹Cook, CH, Centner, RL, Michaels, SE. An acne grading method using photographic standards. Arch. Dermatol. 1979;115:571-575.

9.0 STUDY DESIGN (CONT'D)

9.3.2 Lesion Evaluation

At each visit, the following scale was used to identify and count the number of lesions present on the face of each subject.

Assessment Scale for Lesions

Open comedones = blackheads
Closed comedones = whiteheads
Papules = raised circular areas without pus
Pustules = small, inflammatory lesions with pus
Nodules = large inflamed lesions

9.3.3 Irritation Evaluation

At each visit, the following scale was used to assess irritation on the face of each subject. This evaluation was for safety purposes only and was not used in determining efficacy.

Assessment Scale for Irritation

0 = No evidence of any effect
+ = Barely perceptible irritation present
1 = Mild irritation present
2 = Moderate irritation present
3 = Marked irritation present
4 = Severe irritation present

9.3.4 Visia CR® Complexion Analysis

At all visits, digital images of the face of each subject were taken using the Visia CR® Imaging System. Photographs were taken from the front, right and left views. In order to ensure consistency between the photographs, each subject was draped with a black cloth around the shoulders in order to eliminate the appearance of clothing in the pictures and each subject wore a black headband to pull hair off of and away from the face. The images were NOT analyzed. Subjects were required to sign a photograph release form, giving LifeWave Products, LLC., permission to use the images.

10.0 RESULTS AND DISCUSSION

Forty-four (44) subjects, 18 males and 26 females ranging in age from 13 to 34 years, were enrolled for the home-use testing procedure. A total of 40 (40/44) subjects successfully completed the test procedure. Four (4/44) test panelists (Subject Nos. 11, 12, 13 and 29) were discontinued for personal reasons unrelated to the conduct of the study. Subject demographics are presented in Appendix 1.

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10.0 RESULTS AND DISCUSSION (CONT'D)

10.1 Daily Diary Comments

Subjects were given a daily diary to record and any pertinent comments. Daily diary comments entered by the subjects are presented in Appendix 2.

10.2 Acne Grade

At each visit, the Board-Certified Dermatologist or a trained technician evaluated the face of each subject for acne. Individual acne grade scores and statistical analyses are presented in Appendix 3.

**Mean Acne Grade
(% Change from Baseline)**

	Mean	p-Value
Baseline	1.4	-
Week 1	1.4 (0.0%)	1.000
Week 2	1.3 (-7.1%)	0.289
Week 3	1.1* (-21.4%)	0.012
Week 4	1.0* (-28.6%)	<0.001
Week 6	1.4 (0.0%)	0.680

*Statistically significant difference from baseline ($p \leq 0.05$)

When acne grade score taken after 1, 2, 3, 4 and 6 weeks of product use were compared with baseline, there was no change after 1 week of product use. There was a 7.1%, 21.4% and 28.6% decrease (improvement) in the acne grade after 2, 3 and 4 weeks of product use, respectively. At 6 weeks, there was no change from baseline.

The improvements observed after 3 and 4 weeks of product use were statistically significant when compared with baseline.

10.0 RESULT AND DISCUSSION (CONT'D)

10.3 Lesion Counts

At each visit, the Board-Certified Dermatologist or a trained technician evaluated and counted the lesions on the face of each subject. Individual lesion count scores and statistical analyses are presented in Appendix 4.

**Mean Lesion Counts
 (% Change from Baseline)**

	Open Comedones	Closed Comedones	Papules	Pustules	Nodules
Baseline	1.3	3.0	0.1	0.2	0.0
Week 1	1.1 (-5.4%)	3.0 (0.0%)	0.2 (100%)	0.2 (0.0%)	0.0 (0.0%)
p-Value	0.375	1.000	0.500	1.000	1.000
Week 2	0.4* (-69.2%)	0.5* (-83.3%)	2.8* (2700%)	0.6 (200%)	0.0 (0.0%)
p-value	0.003	<0.001	<0.001	0.012	1.000
Week 3	0.2* (-84.6%)	0.7* (-76.7%)	3.1* (3000%)	0.2 (0.0%)	0.0 (0.1)
p-Value	0.001	<0.001	<0.001	0.217	1.000
Week 4	0.1* (-92.3%)	0.2* (-93.3%)	3.4* (3300%)	0.3 (50.0%)	0.0 (0.0%)
p-Value	0.001	<0.001	<0.001	0.398	1.000
Week 6	0.7 (-46.2%)	1.0* (-66.7%)	1.8* (1700%)	0.5* (150%)	0.0 (0.0%)
p-Value	0.151	<0.001	<0.001	0.012	1.000

*Statistically significant difference from baseline ($p \leq 0.05$)

When lesion counts taken after 1, 2, 3, 4 and 6 weeks of product use were compared with baseline, there was:

- a decrease (improvement) in open comedones at every evaluation. The greatest improvement occurred after 4 weeks of product use (92.3%). The improvements observed after 2, 3 and 4 weeks of product use were statistically significant when compared with baseline;
- a decrease (improvement) in closed comedones after 2, 3, 4 and 6 weeks of product use. The greatest improvement occurred after 4 weeks of product use (93.3%). The improvements observed after 2, 3, 4 and 6 weeks of product use were statistically significant when compared with baseline;
- an increase (worsening) in papules at every evaluation. The increases at 2, 3, 4 and 6 weeks were statistically significant compared with baseline;
- an increase (worsening) in pustules after 2, 4 and 6 weeks of product use. The increases observed after 2 and 6 weeks of product use were statistically significant when compared with baseline; and
- no change in nodules during the course of the study.

10.0 RESULT AND DISCUSSION (CONT'D)

10.4 Skin Irritation

At each visit, the Board-Certified Dermatologist or a trained technician evaluated the face of each subject for irritation. Individual irritation scores and statistical analyses are presented in Appendix 5.

**Mean Irritation Scores
(% Change from Baseline)**

	Mean
Baseline	0.0
Week 1	0.0 (0.0%)
Week 2	0.0 (0.0%)
Week 3	0.0 (0.0%)
Week 4	0.0 (0.0%)
Week 6	0.0 (0.0%)

There was no irritation observed on any subject during the course of the study.

11.0 CONCLUSIONS

A clinical efficacy study was conducted with 40 subjects to determine if Test Articles: Homeopathic Spray and Glutathione Patches helped to decrease the appearance of lesions on the face.

Open Comedones were significantly improved after 2, 3 and 4 weeks of product use. There were 69.2%, 84.6%, 92.3% and 46.2% improvements after 2, 3, 4 and 6 weeks of product use, respectively.

Closed Comedones were significantly improved after 2, 3, 4 and 6 weeks of product use. There was an 83.3% improvement after 2 and 3 weeks and 93.3% and 66.7% improvements after 4 and 6 weeks, respectively.

Mean Acne Grade was significantly improved after 3 and 4 weeks of product use. There was a 7.1%, 21.4% and 28.6% improvement after 2, 3 and 4 weeks of product use, respectively.

There was no irritation observed during the course of the study.

APPENDIX 1

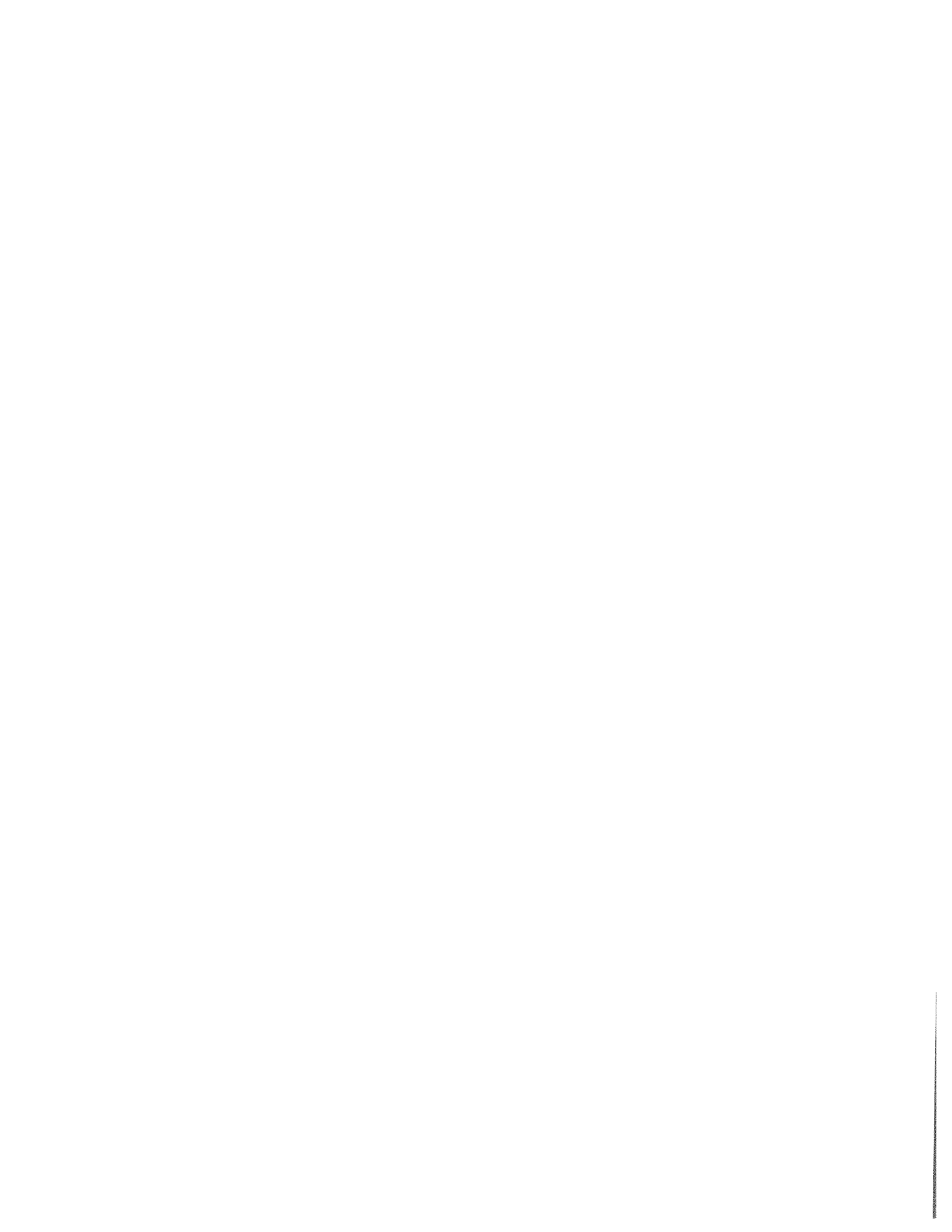
SUBJECT DEMOGRAPHICS

**Test Article: Homeopathic Spray
 Glutathione Patches**

Subject No.	Initials	Age	Sex	Race
1	MIS	18	F	CA
2	J-A	28	F	HS
3	E-C	28	F	CA
4	CLB	22	M	HS
5	KRA	16	F	CA
6	REP	22	M	CA
7	A-A	17	M	HS
8	RRH	14	F	CA
9	CMM	14	M	CA
10	C-S	16	F	HS
11	D-B	32	F	CA
12	M-C	24	M	HS
13	M-S	20	F	CA
14	EMT	17	F	CA
15	RNP	20	F	HS
16	MJG	14	F	CA
17	JAC	22	M	HS
18	K-L	14	F	CA
19	K-C	14	M	CA
20	J-S	13	F	CA
21	D-G	34	F	BA
22	K-G	13	M	BA
23	B-F	22	F	HS
24	TLC	14	F	CA
25	KAB	17	M	CA
26	A-Y	13	F	HS
27	M-D	18	M	CA
28	CJG	16	M	CA
29	A-A	15	F	CA
30	M-A	15	M	CA
31	M-B	14	M	CA
32	L-P	14	F	CA
33	N-A	30	F	CA
34	J-C	13	M	CA
35	C-S	13	F	CA
36	A-V	14	F	CA
37	M-H	14	F	BA
38	M-H	13	M	BA
39	V-Z	15	M	CA
40	S-Z	13	M	CA
41	KTB	17	M	BA
42	DBM	13	F	BA
43	N-K	34	F	CA
44	SAM	24	F	CA

BA = Black/African-American
 CA = Caucasian
 HS = Hispanic

Shaded area = Discontinued subject

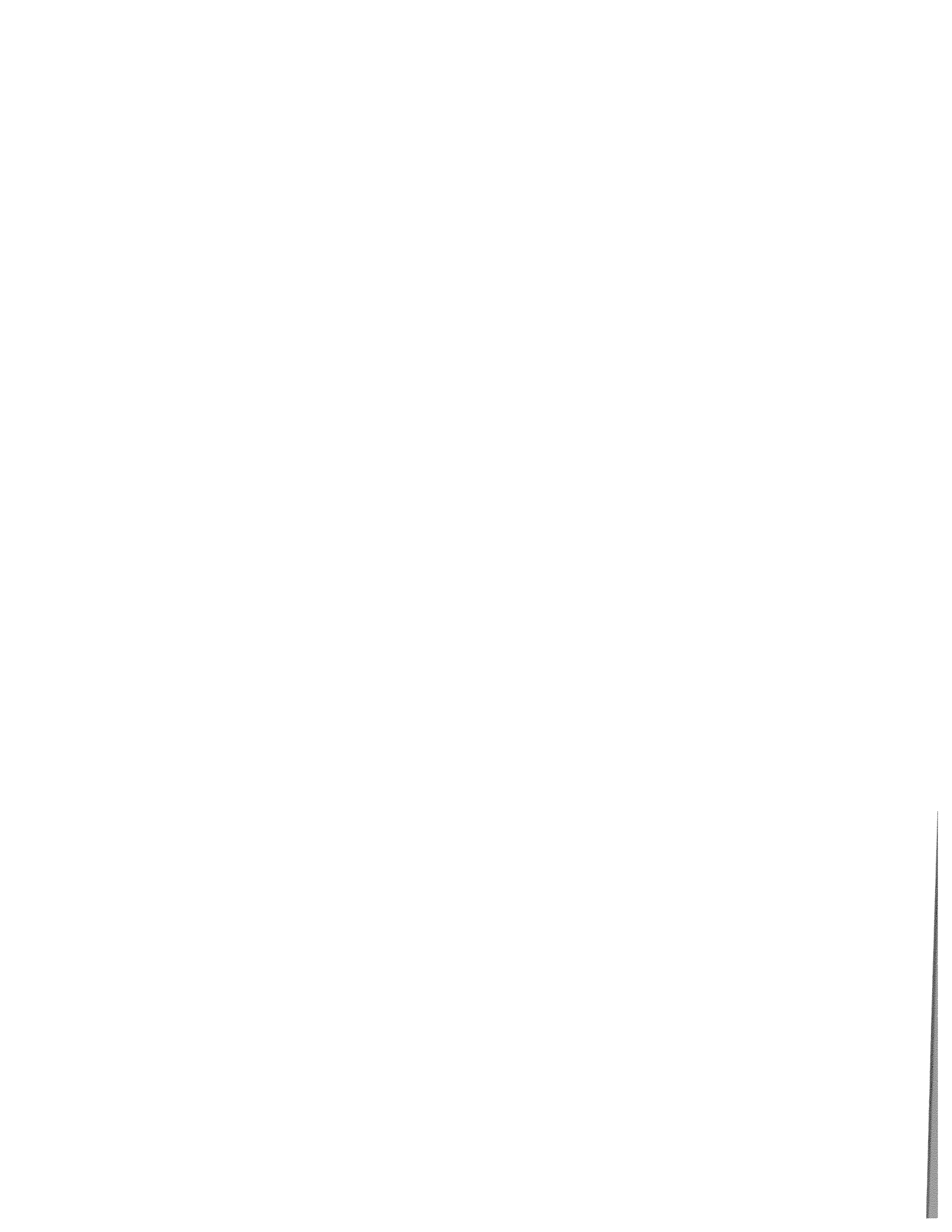


APPENDIX 2

DAILY DIARY COMMENTS

**Test Articles: Homeopathic Spray
Glutathione Patches**

Subject No.	Comments
2	Still have pimples.
6	It worked well.
10	Some days the patch was making me itchy where is was placed by the chest.
14	Hurt to peel off stomach.
20	The patch didn't work at all and sometimes it got itchy.
23	The patch bothered me a little on my chest. I noticed I broke out more using the patches and spray.
26	Dry mouth (spray). Itchy, itchy (patch).
42	Acne got worse in the beginning then, later on in the study it cleared up.
44	The glue was sticky and turned that part of my skin pink/red. The spray had a funny taste otherwise nothing bad.



APPENDIX 3

IRRITATION EVALUATION

Test Articles: Homeopathic Spray

Glutathione Patches

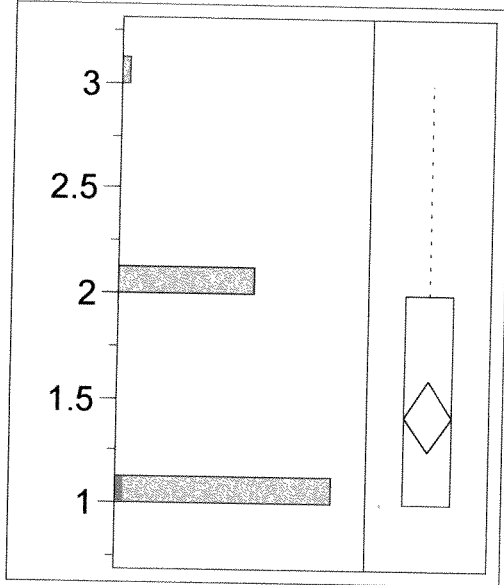
Subject No.	Dermatologist Evaluation Baseline	Technician Evaluation 1 Week	Technician Evaluation 2 Weeks	Technician Evaluation 3 Weeks	Technician Evaluation 4 Weeks	Dermatologist Evaluation 6 Weeks
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	0	0	0	0	0	0
7	0	0	0	0	0	0
8	0	0	0	0	0	0
9	0	0	0	0	0	0
10	0	0	0	0	0	0
11	0	0	0	0	0	0
12	0	Discontinued				
13	0	Discontinued				
14	0	Discontinued				
15	0	0	0	0	0	0
16	0	0	0	0	0	0
17	0	0	0	0	0	0
18	0	0	0	0	0	0
19	0	0	0	0	0	0
20	0	0	0	0	0	0
21	0	0	0	0	0	0
22	0	0	0	0	0	0
23	0	0	0	0	0	0
24	0	0	0	0	0	0
25	0	0	0	0	0	0
26	0	0	0	0	0	0
27	0	0	0	0	0	0
28	0	0	0	0	0	0
29	0	0	0	Discontinued		
30	0	0	0	0	0	0
31	0	0	0	0	0	0
32	0	0	0	0	0	0
33	0	0	0	0	0	0
34	0	0	0	0	0	0
35	0	0	0	0	0	0
36	0	0	0	0	0	0
37	0	0	0	0	0	0
38	0	0	0	0	0	0
39	0	0	0	0	0	0
40	0	0	0	0	0	0
41	0	0	0	0	0	0
42	0	0	0	0	0	0
43	0	0	0	0	0	0
44	0	0	0	0	0	0
MEAN	0.0	0.0	0.0	0.0	0.0	0.0

Irritation Grading Scale:

- 0 = No evidence of any effect
- + = Barely perceptible irritation present
- 1 = Mild irritation present
- 2 = Moderate irritation present
- 3 = Marked irritation present
- 4 = Severe irritation present

Descriptive Statistics
Baseline

Distributions
 acne grade base



Quantiles

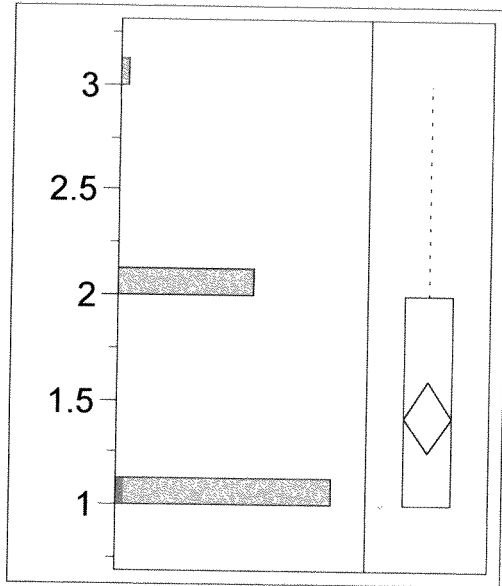
100.0%	maximum	3.0000
99.5%		3.0000
97.5%		2.9750
90.0%		2.0000
75.0%	quartile	2.0000
50.0%	median	1.0000
25.0%	quartile	1.0000
10.0%		1.0000
2.5%		1.0000
0.5%		1.0000
0.0%	minimum	1.0000

Moments

Mean	1.425
Std Dev	0.5494753
Std Err Mean	0.0868797
upper 95% Mean	1.6007307
lower 95% Mean	1.2492693
N	40

Descriptive Statistics
Week 1

acne grade w1



Quantiles

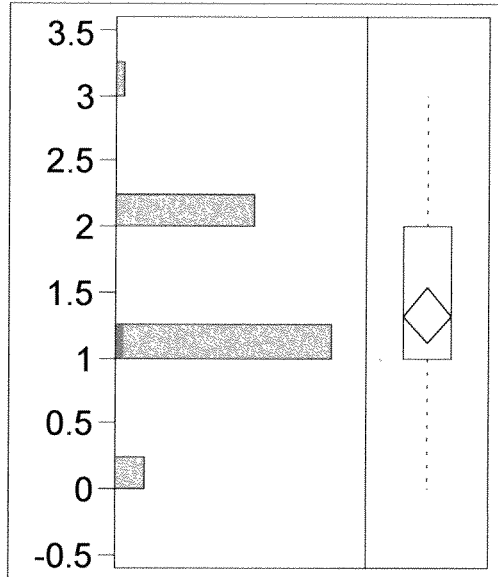
100.0%	maximum	3.0000
99.5%		3.0000
97.5%		2.9750
90.0%		2.0000
75.0%	quartile	2.0000
50.0%	median	1.0000
25.0%	quartile	1.0000
10.0%		1.0000
2.5%		1.0000
0.5%		1.0000
0.0%	minimum	1.0000

Moments

Mean	1.425
Std Dev	0.5494753
Std Err Mean	0.0868797
upper 95% Mean	1.6007307
lower 95% Mean	1.2492693
N	40

Descriptive Statistics
Week 2

acne grade w2



Quantiles

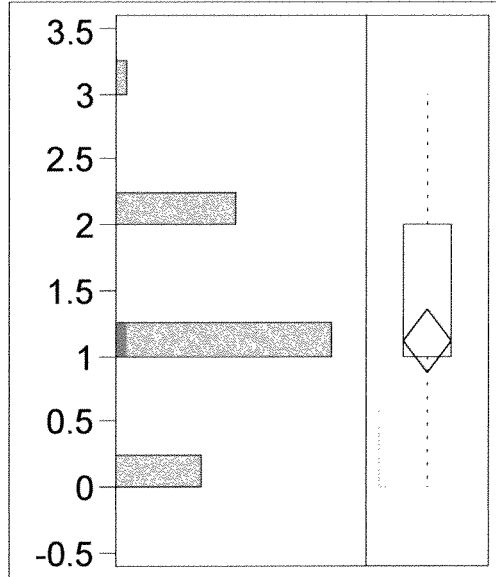
100.0%	maximum	3.0000
99.5%		3.0000
97.5%		2.9750
90.0%		2.0000
75.0%	quartile	2.0000
50.0%	median	1.0000
25.0%	quartile	1.0000
10.0%		1.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	1.325
Std Dev	0.6558416
Std Err Mean	0.1036977
upper 95% Mean	1.5347483
lower 95% Mean	1.1152517
N	40

Descriptive Statistics
Week 3

acne grade w3



Quantiles

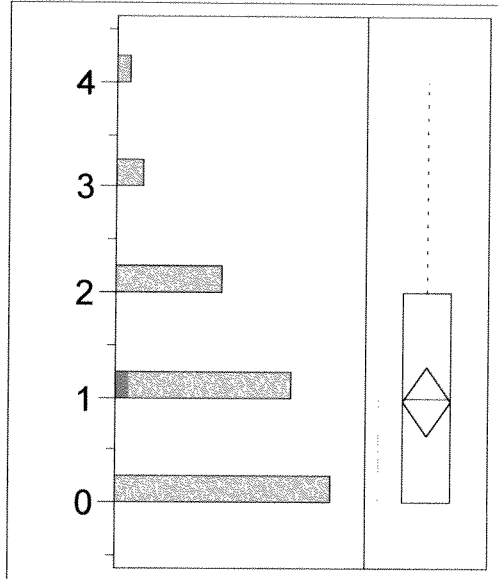
100.0%	maximum	3.0000
99.5%		3.0000
97.5%		2.9750
90.0%		2.0000
75.0%	quartile	2.0000
50.0%	median	1.0000
25.0%	quartile	1.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	1.125
Std Dev	0.7574417
Std Err Mean	0.1197621
upper 95% Mean	1.3672416
lower 95% Mean	0.8827584
N	40

Descriptive Statistics
Week 4

acne grade w4



Quantiles

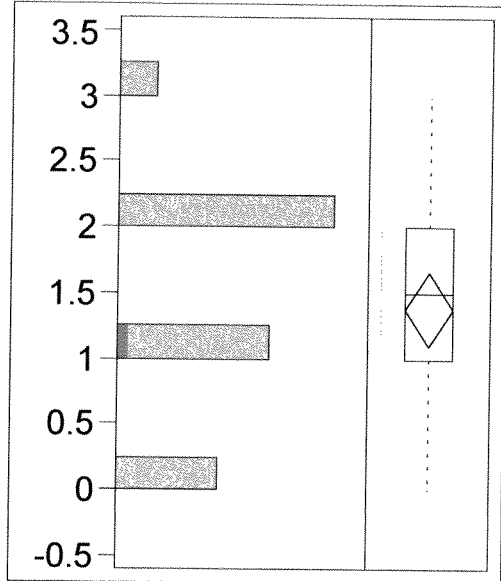
100.0%	maximum	4.0000
99.5%		4.0000
97.5%		3.9750
90.0%		2.0000
75.0%	quartile	2.0000
50.0%	median	1.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.975
Std Dev	1.0250078
Std Err Mean	0.162068
upper 95% Mean	1.3028134
lower 95% Mean	0.6471866
N	40

Descriptive Statistics
 Week 6

acne grade w6



Quantiles

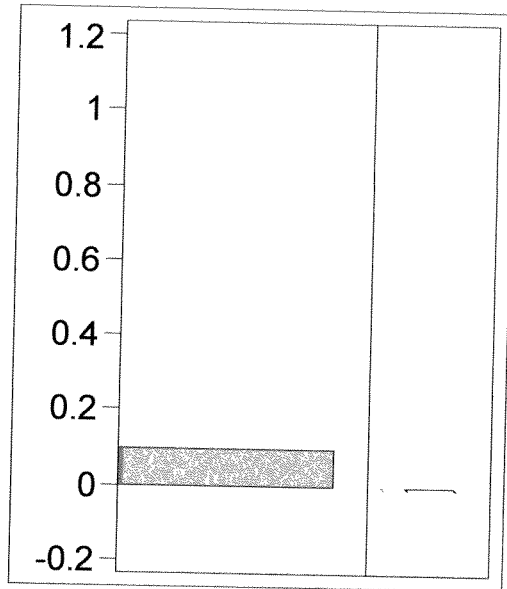
100.0%	maximum	3.0000
99.5%		3.0000
97.5%		3.0000
90.0%		2.0000
75.0%	quartile	2.0000
50.0%	median	1.5000
25.0%	quartile	1.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	1.375
Std Dev	0.8969321
Std Err Mean	0.1418174
upper 95% Mean	1.6618528
lower 95% Mean	1.0881472
N	40

Change from Baseline
Week 1

w1-base



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

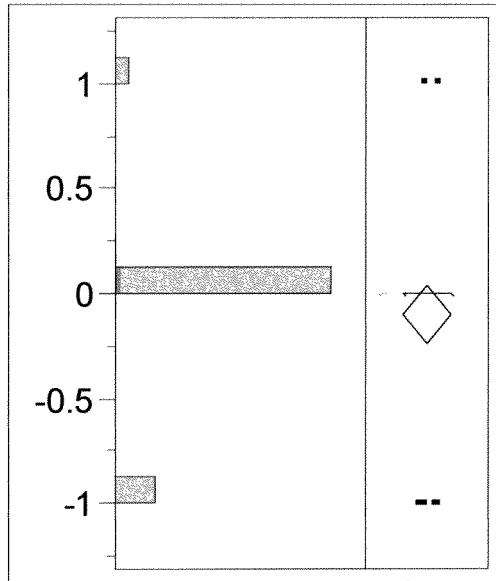
Test Mean=value

Hypothesized Value	0
Actual Estimate	0
df	39
Std Dev	0

Test Statistic	t Test	Signed-Rank
Prob > t	.	0.000
Prob > t	.	1.000
Prob < t	.	0.500

**Change from Baseline
 Week 2**

w2-base



Quantiles

100.0%	maximum	1.000
99.5%		1.000
97.5%		1.000
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	0.000
10.0%		-1.000
2.5%		-1.000
0.5%		-1.000
0.0%	minimum	-1.000

Moments

Mean	-0.1
Std Dev	0.4414429
Std Err Mean	0.0697982
upper 95% Mean	0.0411803
lower 95% Mean	-0.24118
N	40

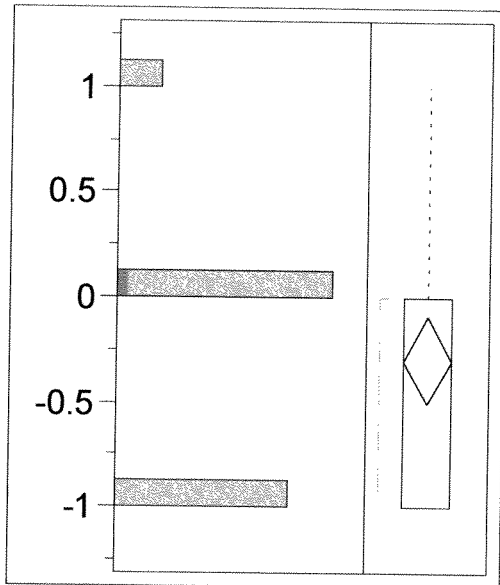
Test Mean=value

Hypothesized Value	0
Actual Estimate	-0.1
df	39
Std Dev	0.44144

	t Test	Signed-Rank
Test Statistic	-1.4327	-9.000
Prob > t	0.1599	0.289
Prob > t	0.9200	0.855
Prob < t	0.0800	0.145

**Change from Baseline
 Week 3**

w3-base



Quantiles

100.0%	maximum	1.000
99.5%		1.000
97.5%		1.000
90.0%		0.900
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	-1.000
10.0%		-1.000
2.5%		-1.000
0.5%		-1.000
0.0%	minimum	-1.000

Moments

Mean	-0.3
Std Dev	0.6484696
Std Err Mean	0.102532
upper 95% Mean	-0.092609
lower 95% Mean	-0.507391
N	40

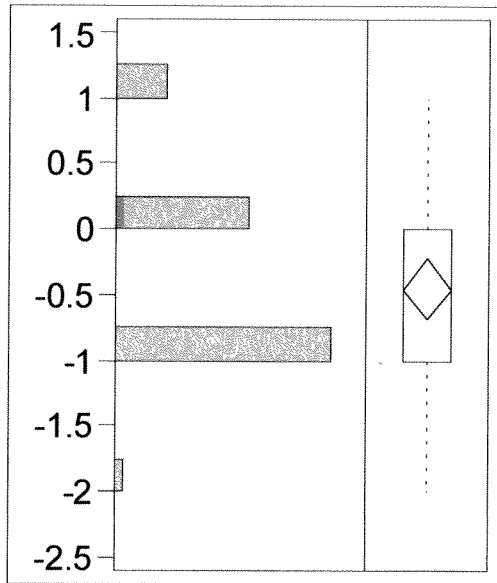
Test Mean=value

Hypothesized Value	0
Actual Estimate	-0.3
df	39
Std Dev	0.64847

	t Test	Signed-Rank
Test Statistic	-2.9259	-63.000
Prob > t	0.0057	0.012
Prob > t	0.9971	0.994
Prob < t	0.0029	0.006

**Change from Baseline
 Week 4**

w4-base



Quantiles

100.0%	maximum	1.000
99.5%		1.000
97.5%		1.000
90.0%		1.000
75.0%	quartile	0.000
50.0%	median	-1.000
25.0%	quartile	-1.000
10.0%		-1.000
2.5%		-1.975
0.5%		-2.000
0.0%	minimum	-2.000

Moments

Mean	-0.45
Std Dev	0.7493587
Std Err Mean	0.118484
upper 95% Mean	-0.210343
lower 95% Mean	-0.689657
N	40

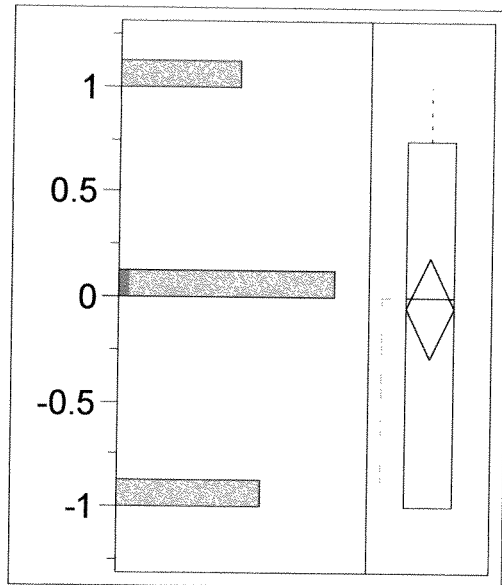
Test Mean=value

Hypothesized Value	0
Actual Estimate	-0.45
df	39
Std Dev	0.74936

	t Test	Signed-Rank
Test Statistic	-3.7980	-121.5
Prob > t	0.0005	0.000
Prob > t	0.9998	1.000
Prob < t	0.0002	0.000

Change from Baseline
 Week 6

w6-base



Quantiles

100.0%	maximum	1.000
99.5%		1.000
97.5%		1.000
90.0%		1.000
75.0%	quartile	0.750
50.0%	median	0.000
25.0%	quartile	-1.000
10.0%		-1.000
2.5%		-1.000
0.5%		-1.000
0.0%	minimum	-1.000

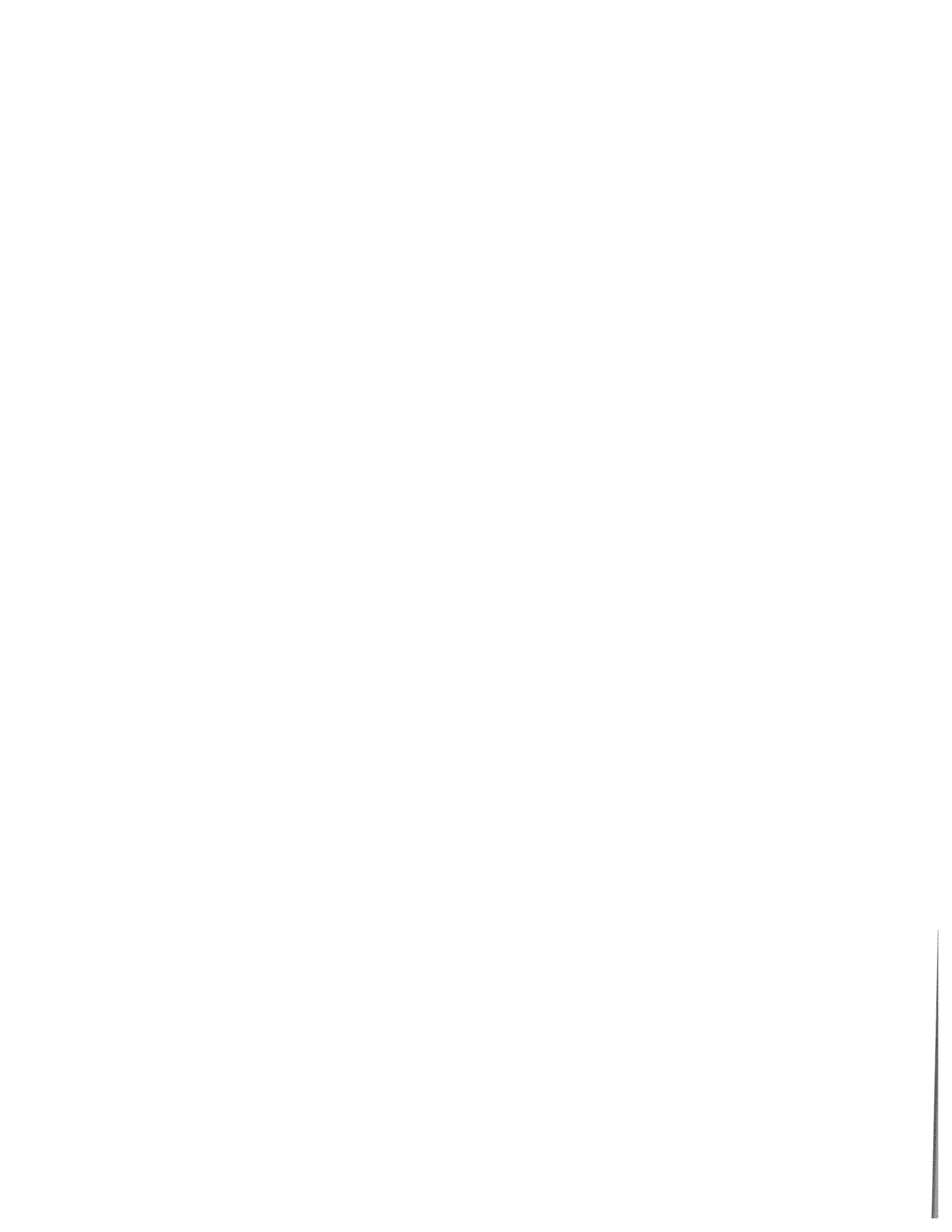
Moments

Mean	-0.05
Std Dev	0.7493587
Std Err Mean	0.118484
upper 95% Mean	0.1896565
lower 95% Mean	-0.289657
N	40

Test Mean=value

Hypothesized Value	0
Actual Estimate	-0.05
df	39
Std Dev	0.74936

	t Test	Signed-Rank
Test Statistic	-0.4220	-11.500
Prob > t	0.6753	0.680
Prob > t	0.6623	0.660
Prob < t	0.3377	0.340



APPENDIX 4

LESION COUNTS

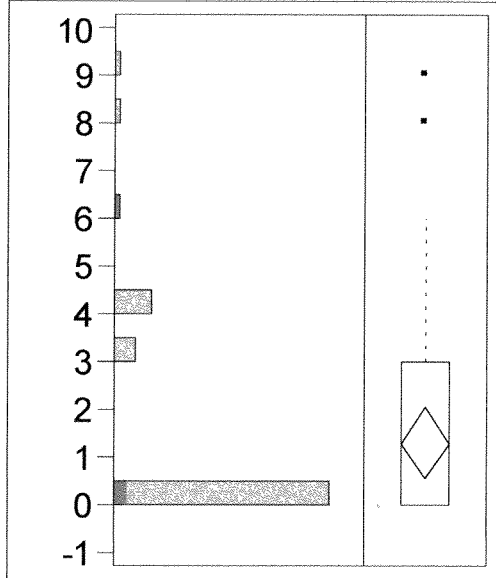
Test Article: Homeopathic Spray
Glutathione Patches

Sub No.	Dermatologist Evaluation Baseline				Technician Evaluation 1 Week				Technician Evaluation 2 Weeks				Technician Evaluation 3 Weeks				Technician Evaluation 4 Weeks				Dermatologist Evaluation 6 Weeks															
	OC	CC	PA	PU	NO	Total	OC	CC	PA	PU	NO	Total	OC	CC	PA	PU	NO	Total	OC	CC	PA	PU	NO	Total	OC	CC	PA	PU	NO	Total						
1	3	0	0	0	0	4	4	0	0	1	0	5	0	0	8	0	0	0	0	8	0	0	0	0	8	0	0	0	0	4	0	0	4			
2	0	3	0	0	0	3	0	0	6	0	0	6	0	3	2	1	0	6	0	0	3	0	0	3	0	0	0	0	4	0	0	4				
3	8	2	0	0	0	10	8	2	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4			
4	3	0	0	0	0	3	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4			
5	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2			
6	0	4	0	0	0	4	0	4	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2			
7	6	0	0	0	0	6	0	5	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2		
8	0	5	1	0	0	6	0	5	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	
9	0	5	0	0	0	5	0	5	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	
10	0	4	0	0	0	4	0	1	4	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	
11	0	5	0	0	0	5	0	1	4	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	
12	0	4	0	0	0	4	0	5	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
13	0	5	0	0	0	5	0	5	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
14	0	2	0	0	0	2	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
15	0	4	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
16	0	5	0	0	0	5	0	5	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
17	0	4	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
18	0	4	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
19	4	1	0	0	0	5	4	1	0	0	0	5	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
20	0	7	0	0	0	7	0	0	7	0	0	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7
21	9	0	0	0	0	9	6	0	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9	
22	4	0	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
23	0	3	0	0	0	3	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
24	0	5	0	0	0	5	0	5	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
25	0	7	0	0	0	7	0	6	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7
26	0	3	0	0	0	3	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
27	0	4	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
28	0	0	1	6	0	7	0	0	1	6	0	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7
29	3	2	2	0	0	7	2	2	0	0	0	3	0	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
30	0	5	0	0	0	5	0	5	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
31	0	4	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
32	0	4	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
33	0	3	0	0	0	3	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
34	0	4	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
35	0	2	0	0	0	2	0	2	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
36	0	6	0	0	0	6	0	6	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6
37	0	3	0	0	0	3	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
38	4	0	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
39	4	3	0	0	0	7	3	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7
40	4	0	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
41	0	3	0	0	0	3	0	2	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
42	0	3	0	0	0	3	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
43	3	0	0	0	0	3	0	3	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
44	0	4	0	0	0	4	0	4	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
MEAN	1.3	3.1	0.1	0.2	0.0	4.6	1.0	3.1	0.2	0.2	0.0	4.4	0.3	0.7	2.8	0.5	0.0	4.3	0.2	0.7	3.1	0.2	0.0	4.2	0.1	0.2	3.4	0.3	0.0	4.1	0.7	1.0	0.0	4.2		

Open Comedones = blackheads
Closed comedones = whiteheads
Papules = raised circular areas without pus
Pustules = small inflammatory lesions with pus
Nodules = large inflamed lesions

Descriptive Statistics
Open Comedones
Baseline

Distributions
B OC



Quantiles

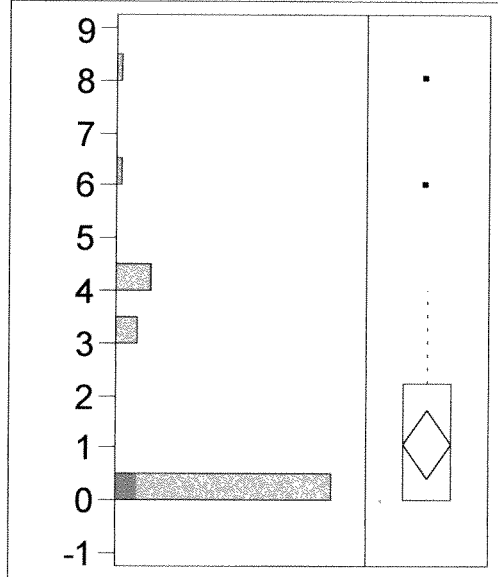
100.0%	maximum	9.0000
99.5%		9.0000
97.5%		8.9750
90.0%		4.0000
75.0%	quartile	3.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	1.3
Std Dev	2.3772425
Std Err Mean	0.375875
upper 95% Mean	2.060279
lower 95% Mean	0.539721
N	40

Descriptive Statistics
Open Comedones
Week 1

w1OC



Quantiles

100.0%	maximum	8.0000
99.5%		8.0000
97.5%		7.9500
90.0%		4.0000
75.0%	quartile	2.2500
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

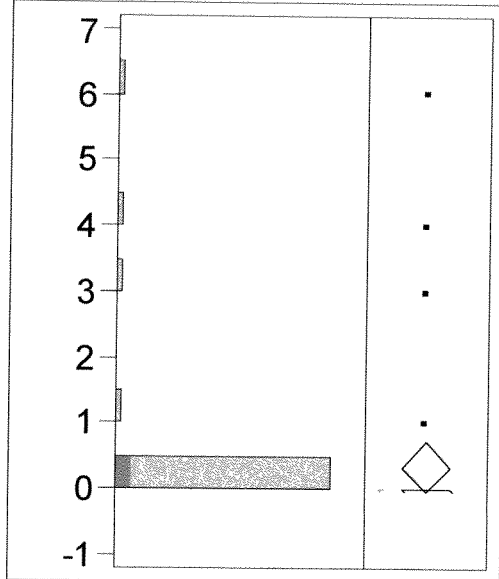
Moments

Mean	1.075
Std Dev	2.0303783
Std Err Mean	0.321031
upper 95% Mean	1.7243465
lower 95% Mean	0.4256535
N	40

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Descriptive Statistics
Open Comedones
Week 2

wk2 OC



Quantiles

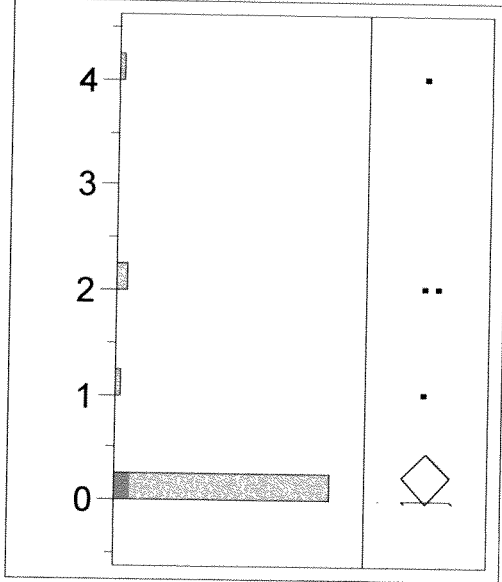
100.0%	maximum	6.0000
99.5%		6.0000
97.5%		5.9500
90.0%		0.9000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.35
Std Dev	1.2100011
Std Err Mean	0.191318
upper 95% Mean	0.7369771
lower 95% Mean	-0.036977
N	40

Descriptive Statistics
Open Comedones
Week 3

w3OC



Quantiles

100.0%	maximum	4.0000
99.5%		4.0000
97.5%		3.9500
90.0%		0.9000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

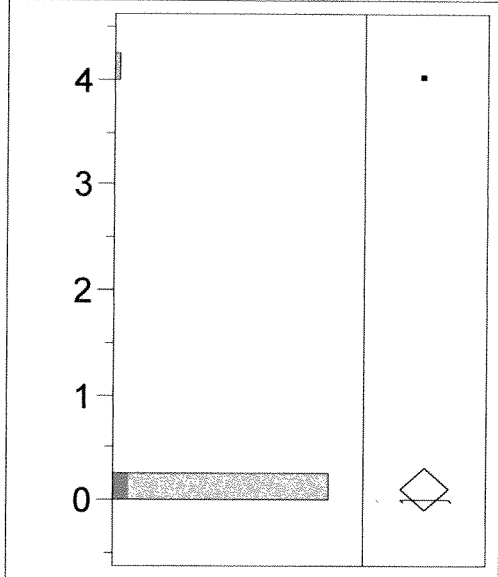
Moments

Mean	0.225
Std Dev	0.7675302
Std Err Mean	0.1213572
upper 95% Mean	0.4704681
lower 95% Mean	-0.020468
N	40

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Descriptive Statistics
Open Comedones
Week 4

wk4OC



Quantiles

100.0%	maximum	4.0000
99.5%		4.0000
97.5%		3.9000
90.0%		0.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

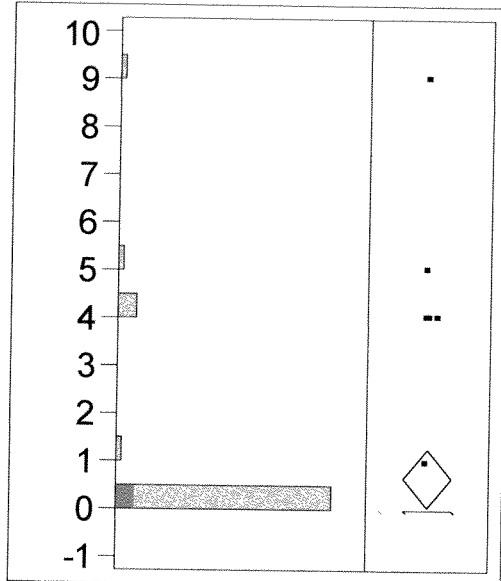
Moments

Mean		0.1
Std Dev		0.6324555
Std Err Mean		0.1
upper 95% Mean		0.3022691
lower 95% Mean		-0.102269
N		40

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Descriptive Statistics
Open Comedones
Week 6

wk6OC



Quantiles

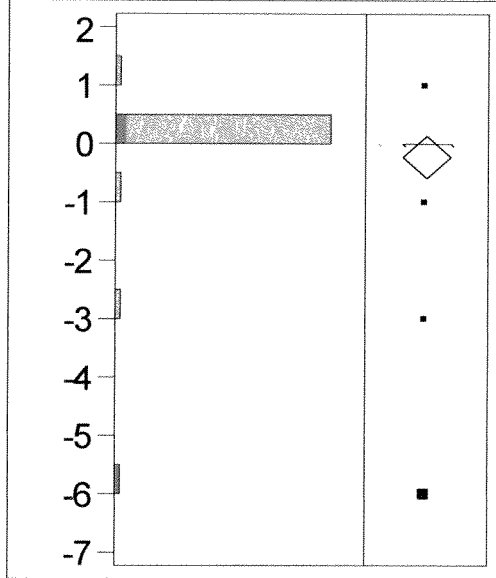
100.0%	maximum	9.0000
99.5%		9.0000
97.5%		8.9000
90.0%		4.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.675
Std Dev	1.8727123
Std Err Mean	0.2961018
upper 95% Mean	1.2739224
lower 95% Mean	0.0760776
N	40

Open Comedones
Change from Baseline
Week 1

w1 OC-B



Quantiles

100.0%	maximum	1.000
99.5%		1.000
97.5%		0.975
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	0.000
10.0%		0.000
2.5%		-5.925
0.5%		-6.000
0.0%	minimum	-6.000

Moments

Mean	-0.225
Std Dev	1.0738739
Std Err Mean	0.1697944
upper 95% Mean	0.1184415
lower 95% Mean	-0.568442
N	40

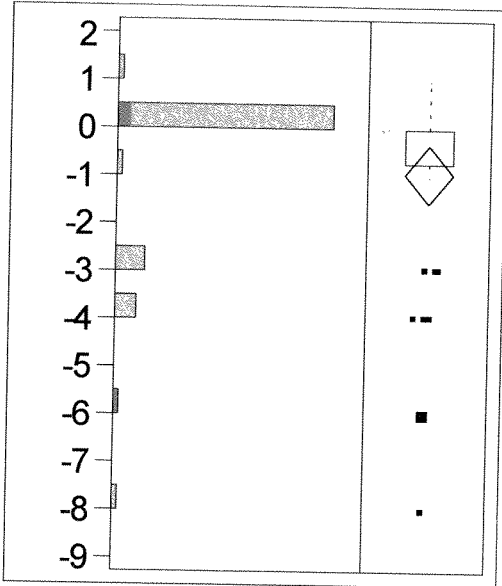
Test Mean=value

Hypothesized Value	0
Actual Estimate	-0.225
df	39
Std Dev	1.07387

	t Test	Signed-Rank
Test Statistic	-1.3251	-3.500
Prob > t	0.1928	0.375
Prob > t	0.9036	0.813
Prob < t	0.0964	0.188

Open Comedones
Change from Baseline
Week 2

w2OC-B



Quantiles

100.0%	maximum	1.000
99.5%		1.000
97.5%		0.975
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	-0.750
10.0%		-4.000
2.5%		-7.950
0.5%		-8.000
0.0%	minimum	-8.000

Moments

Mean	-0.95
Std Dev	1.9605075
Std Err Mean	0.3099835
upper 95% Mean	-0.322999
lower 95% Mean	-1.577001
N	40

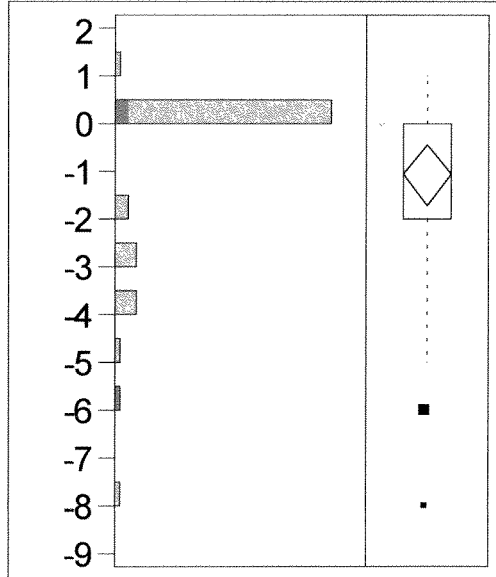
Test Mean=value

Hypothesized Value	0
Actual Estimate	-0.95
df	39
Std Dev	1.96051

	t Test	Signed-Rank
Test Statistic	-3.0647	-31.500
Prob > t	0.0039	0.003
Prob > t	0.9980	0.999
Prob < t	0.0020	0.001

Open Comedones
Change from Baseline
Week 3

w3OC-b



Quantiles

100.0%	maximum	1.000
99.5%		1.000
97.5%		0.975
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	-2.000
10.0%		-4.000
2.5%		-7.950
0.5%		-8.000
0.0%	minimum	-8.000

Moments

Mean	-1.075
Std Dev	2.0429679
Std Err Mean	0.3230216
upper 95% Mean	-0.421627
lower 95% Mean	-1.728373
N	40

Test Mean=value

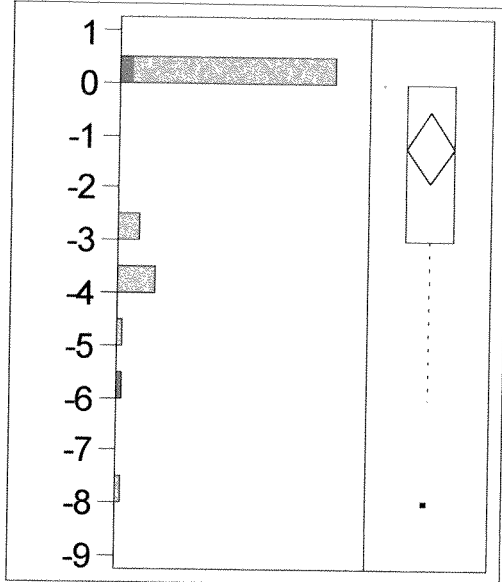
Hypothesized Value	0
Actual Estimate	-1.075
df	39
Std Dev	2.04297

	t Test	Signed-Rank
Test Statistic	-3.3280	-38.000
Prob > t	0.0019	0.001
Prob > t	0.9990	1.000
Prob < t	0.0010	0.000

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Open Comedones
Change from Baseline
Week 4

OC 4-b



Quantiles

100.0%	maximum	0.000
99.5%		0.000
97.5%		0.000
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	-3.000
10.0%		-4.000
2.5%		-7.950
0.5%		-8.000
0.0%	minimum	-8.000

Moments

Mean	-1.2
Std Dev	2.1146619
Std Err Mean	0.3343574
upper 95% Mean	-0.523698
lower 95% Mean	-1.876302
N	40

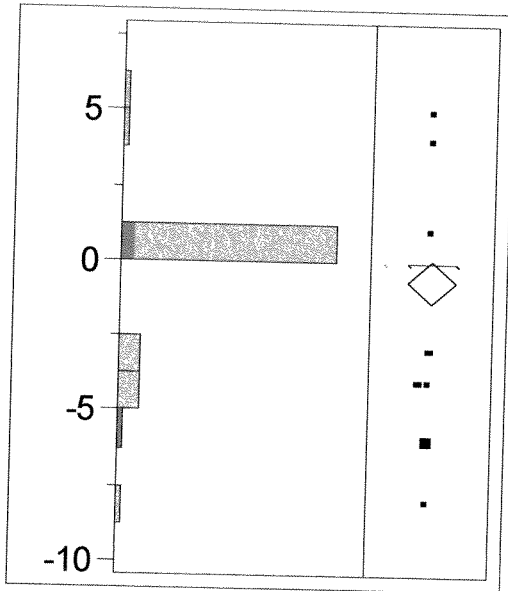
Test Mean=value

Hypothesized Value	0
Actual Estimate	-1.2
df	39
Std Dev	2.11466

	t Test	Signed-Rank
Test Statistic	-3.5890	-33.000
Prob > t	0.0009	0.001
Prob > t	0.9995	1.000
Prob < t	0.0005	0.000

Open Comedones
 Change from Baseline
 Week 6

OC 6-b



Quantiles

100.0%	maximum	5.000
99.5%		5.000
97.5%		4.975
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	0.000
10.0%		-4.000
2.5%		-7.950
0.5%		-8.000
0.0%	minimum	-8.000

Moments

Mean	-0.625
Std Dev	2.2723251
Std Err Mean	0.3592862
upper 95% Mean	0.1017248
lower 95% Mean	-1.351725
N	40

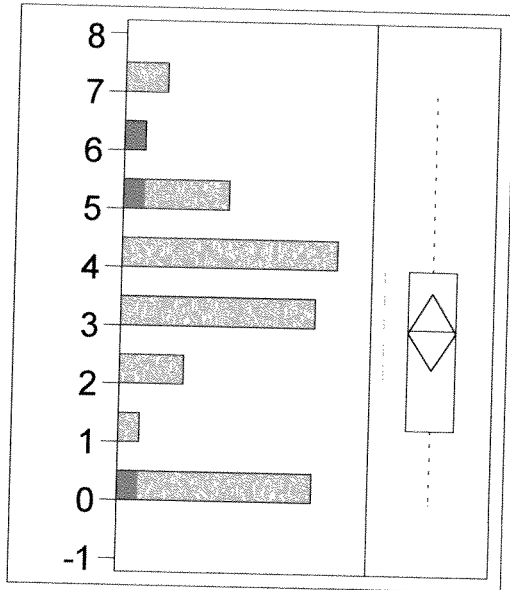
Test Mean=value

Hypothesized Value	0
Actual Estimate	-0.625
df	39
Std Dev	2.27233

Test Statistic	t Test	Signed-Rank
	-1.7396	-16.500
Prob > t	0.0898	0.151
Prob > t	0.9551	0.924
Prob < t	0.0449	0.076

Descriptive Statistics
Closed Comedones
Baseline

B C C



Quantiles

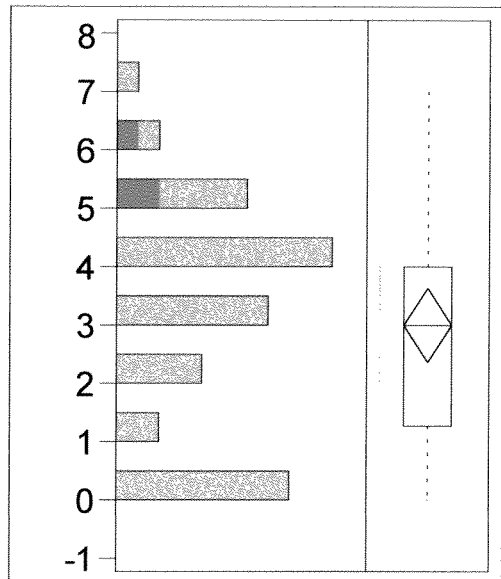
100.0%	maximum	7.0000
99.5%		7.0000
97.5%		7.0000
90.0%		5.0000
75.0%	quartile	4.0000
50.0%	median	3.0000
25.0%	quartile	1.2500
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	2.975
Std Dev	2.0189804
Std Err Mean	0.3192288
upper 95% Mean	3.6207013
lower 95% Mean	2.3292987
N	40

Descriptive Statistics
Closed Comedones
Week 1

w1CC



Quantiles

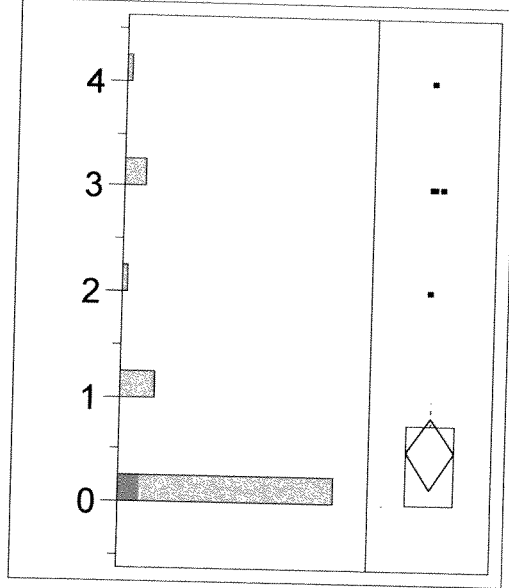
100.0%	maximum	7.0000
99.5%		7.0000
97.5%		6.9750
90.0%		5.0000
75.0%	quartile	4.0000
50.0%	median	3.0000
25.0%	quartile	1.2500
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	3
Std Dev	1.9741925
Std Err Mean	0.3121472
upper 95% Mean	3.6313774
lower 95% Mean	2.3686226
N	40

Descriptive Statistics
Closed Comedones
Week 2

wk2 CC



Quantiles

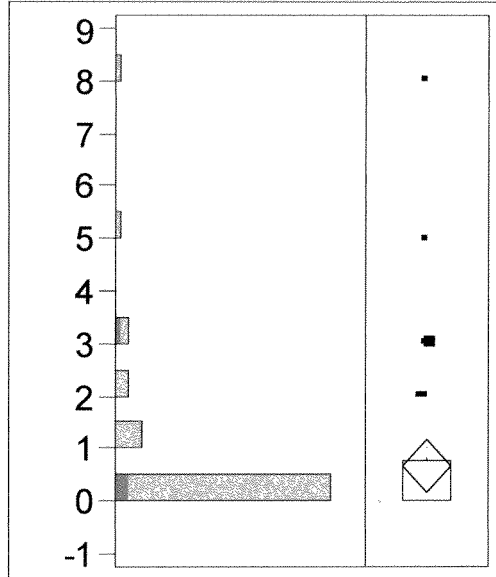
100.0%	maximum	4.0000
99.5%		4.0000
97.5%		3.9750
90.0%		2.9000
75.0%	quartile	0.7500
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.5
Std Dev	1.037749
Std Err Mean	0.1640825
upper 95% Mean	0.8318882
lower 95% Mean	0.1681118
N	40

Descriptive Statistics
Closed Comedones
Week 3

w3CC



Quantiles

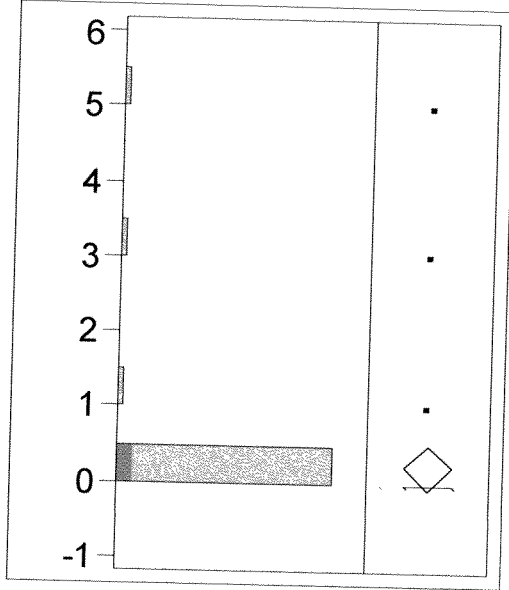
100.0%	maximum	8.0000
99.5%		8.0000
97.5%		7.9250
90.0%		2.9000
75.0%	quartile	0.7500
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.675
Std Dev	1.6074745
Std Err Mean	0.254164
upper 95% Mean	1.1890953
lower 95% Mean	0.1609047
N	40

Descriptive Statistics
Closed Comedones
Week 4

w4CC



Quantiles

100.0%	maximum	5.0000
99.5%		5.0000
97.5%		4.9500
90.0%		0.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

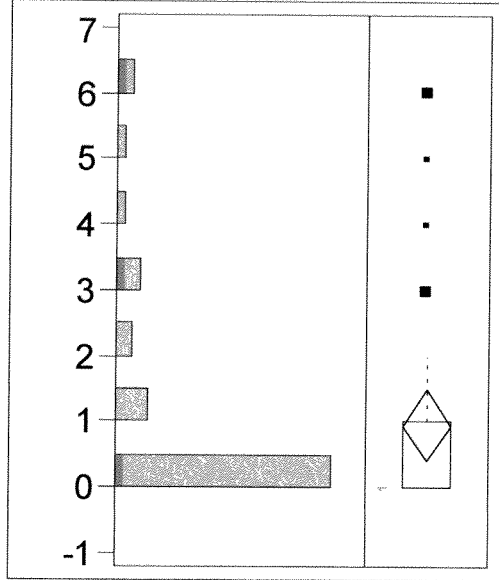
Moments

Mean	0.225
Std Dev	0.9195177
Std Err Mean	0.1453885
upper 95% Mean	0.519076
lower 95% Mean	-0.069076
N	40

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Descriptive Statistics
Closed Comedones
Week 6

wk6CC



Quantiles

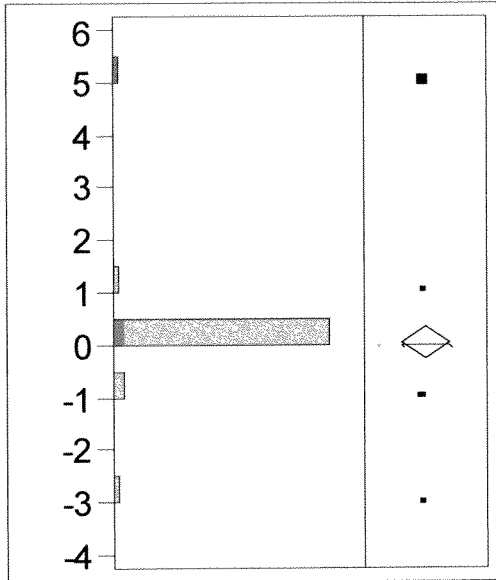
100.0%	maximum	6.0000
99.5%		6.0000
97.5%		6.0000
90.0%		3.9000
75.0%	quartile	1.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.95
Std Dev	1.7238895
Std Err Mean	0.2725709
upper 95% Mean	1.5013266
lower 95% Mean	0.3986734
N	40

Closed Comedones
Change from Baseline
Week 1

w1 CC-B



Quantiles

100.0%	maximum	5.000
99.5%		5.000
97.5%		4.900
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	0.000
10.0%		0.000
2.5%		-2.950
0.5%		-3.000
0.0%	minimum	-3.000

Moments

Mean	0.025
Std Dev	0.9736924
Std Err Mean	0.1539543
upper 95% Mean	0.3364019
lower 95% Mean	-0.286402
N	40

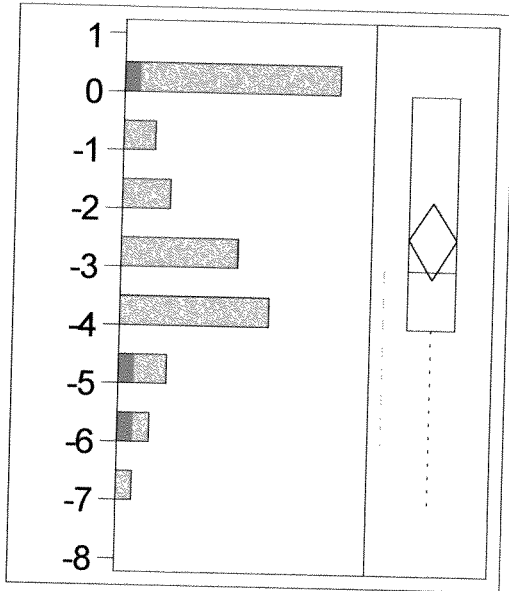
Test Mean=value

Hypothesized Value	0
Actual Estimate	0.025
df	39
Std Dev	0.97369

	t Test	Signed-Rank
Test Statistic	0.1624	-0.500
Prob > t	0.8718	1.000
Prob > t	0.4359	0.500
Prob < t	0.5641	0.500

Closed Comedones
Change from Baseline
Week 2

wk2CC-B



Quantiles

100.0%	maximum	0.000
99.5%		0.000
97.5%		0.000
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	-3.000
25.0%	quartile	-4.000
10.0%		-5.000
2.5%		-6.975
0.5%		-7.000
0.0%	minimum	-7.000

Moments

Mean	-2.475
Std Dev	2.0999084
Std Err Mean	0.3320247
upper 95% Mean	-1.803417
lower 95% Mean	-3.146583
N	40

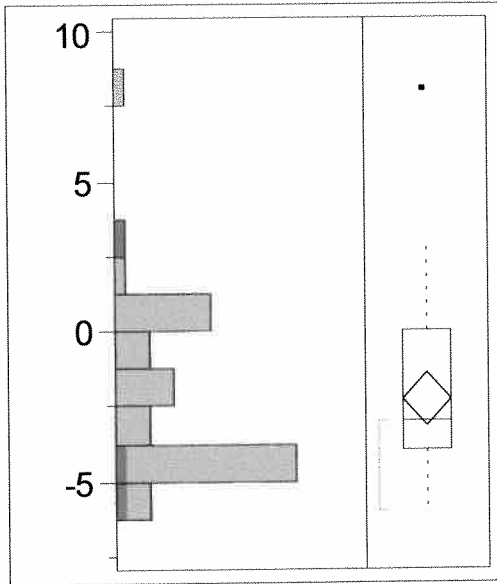
Test Mean=value

Hypothesized Value	0
Actual Estimate	-2.475
df	39
Std Dev	2.09991

	t Test	Signed-Rank
Test Statistic	-7.4543	-189
Prob > t	<.0001	0.000
Prob > t	1.0000	1.000
Prob < t	<.0001	0.000

Closed Comedones
Change from Baseline
Week 3

w3CC-b



Quantiles

100.0%	maximum	8.000
99.5%		8.000
97.5%		7.875
90.0%		0.000
75.0%	quartile	0.000
50.0%	median	-3.000
25.0%	quartile	-4.000
10.0%		-5.000
2.5%		-6.000
0.5%		-6.000
0.0%	minimum	-6.000

Moments

Mean	-2.3
Std Dev	2.8120619
Std Err Mean	0.444626
upper 95% Mean	-1.400659
lower 95% Mean	-3.199341
N	40

Test Mean=value

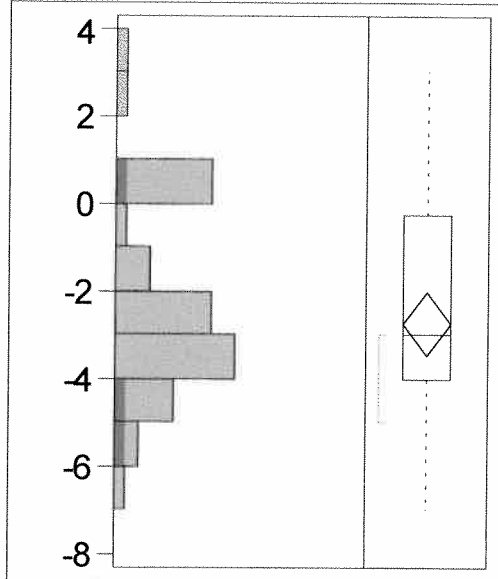
Hypothesized Value	0
Actual Estimate	-2.3
df	39
Std Dev	2.81206

	t Test	Signed-Rank
Test Statistic	-5.1729	-214
Prob > t	<.0001	0.000
Prob > t	1.0000	1.000
Prob < t	<.0001	0.000

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Closed Comedones
Change from Baseline
Week 4

CC 4-b



Quantiles

100.0%	maximum	3.000
99.5%		3.000
97.5%		2.975
90.0%		0.000
75.0%	quartile	-0.250
50.0%	median	-3.000
25.0%	quartile	-4.000
10.0%		-5.000
2.5%		-6.975
0.5%		-7.000
0.0%	minimum	-7.000

Moments

Mean	-2.75
Std Dev	2.2730303
Std Err Mean	0.3593976
upper 95% Mean	-2.02305
lower 95% Mean	-3.47695
N	40

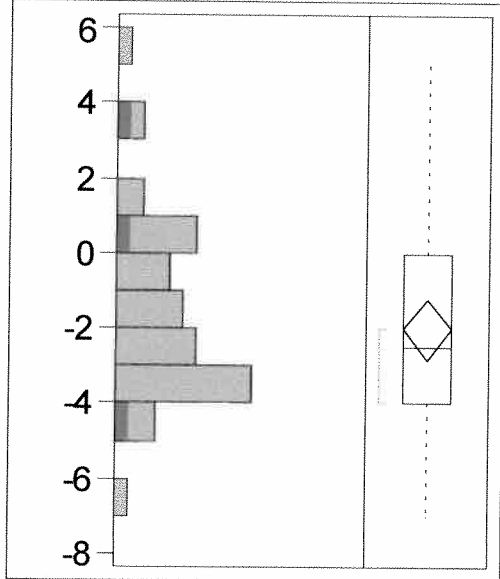
Test Mean=value

Hypothesized Value	0
Actual Estimate	-2.75
df	39
Std Dev	2.27303

	t Test	Signed-Rank
Test Statistic	-7.6517	-250.5
Prob > t	<.0001	0.000
Prob > t	1.0000	1.000
Prob < t	<.0001	0.000

Closed Comedones
Change from Baseline
Week 6

CC 6-b



Quantiles

100.0%	maximum	5.000
99.5%		5.000
97.5%		4.950
90.0%		1.000
75.0%	quartile	0.000
50.0%	median	-2.500
25.0%	quartile	-4.000
10.0%		-4.900
2.5%		-6.950
0.5%		-7.000
0.0%	minimum	-7.000

Moments

Mean	-2.025
Std Dev	2.4960225
Std Err Mean	0.3946558
upper 95% Mean	-1.226733
lower 95% Mean	-2.823267
N	40

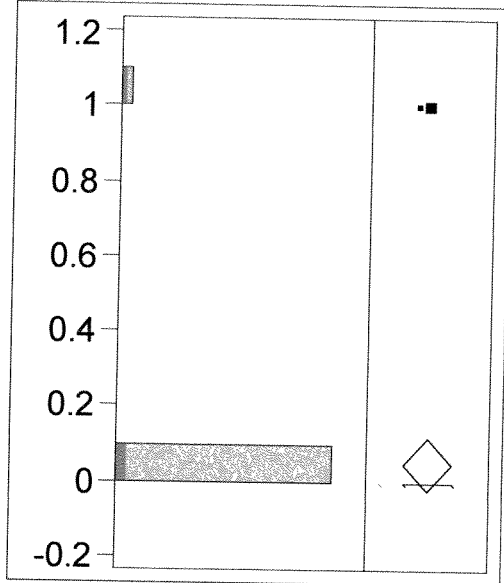
Test Mean=value

Hypothesized Value	0
Actual Estimate	-2.025
df	39
Std Dev	2.49602

	t Test	Signed-Rank
Test Statistic	-5.1311	-228
Prob > t	<.0001	0.000
Prob > t	1.0000	1.000
Prob < t	<.0001	0.000

Descriptive Statistics
Papules
Baseline

B PA



Quantiles

100.0%	maximum	1.0000
99.5%		1.0000
97.5%		1.0000
90.0%		0.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

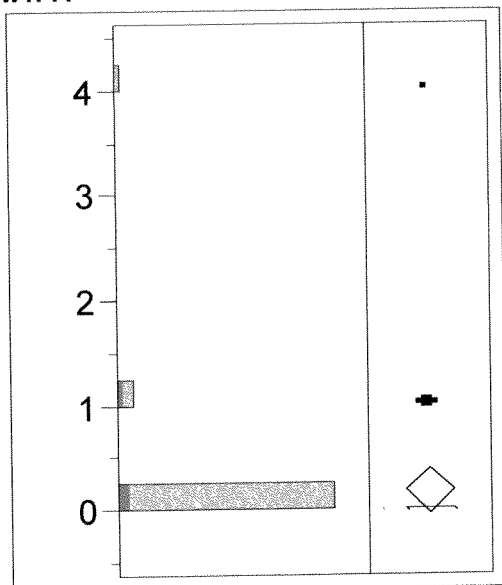
Mean	0.05
Std Dev	0.2207214
Std Err Mean	0.0348991
upper 95% Mean	0.1205901
lower 95% Mean	-0.02059
N	40

Descriptive Statistics

Papules

Week 1

w1PA



Quantiles

100.0%	maximum	4.0000
99.5%		4.0000
97.5%		3.9250
90.0%		0.9000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

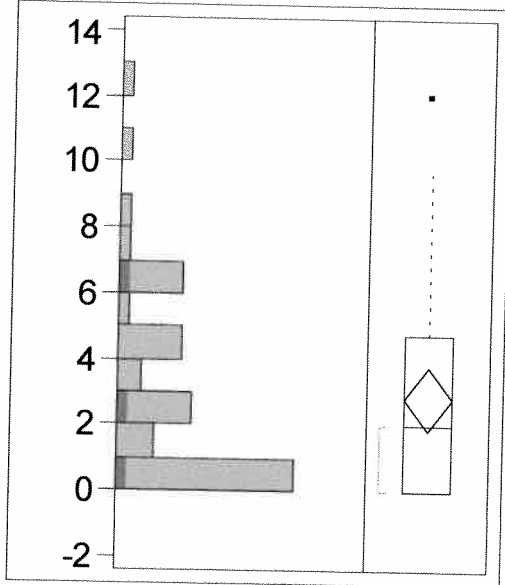
Moments

Mean	0.175
Std Dev	0.6751068
Std Err Mean	0.1067438
upper 95% Mean	0.3909096
lower 95% Mean	-0.04091
N	40

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Descriptive Statistics
Papules
Week 2

wk2 pa



Quantiles

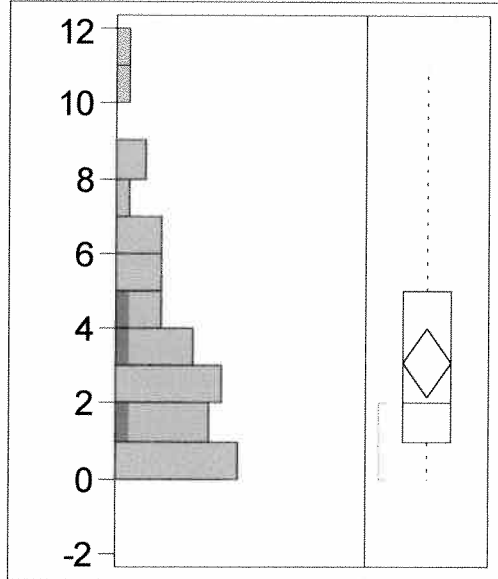
100.0%	maximum	12.000
99.5%		12.000
97.5%		11.950
90.0%		6.900
75.0%	quartile	4.750
50.0%	median	2.000
25.0%	quartile	0.000
10.0%		0.000
2.5%		0.000
0.5%		0.000
0.0%	minimum	0.000

Moments

Mean	2.825
Std Dev	3.0708514
Std Err Mean	0.4855442
upper 95% Mean	3.8071059
lower 95% Mean	1.8428941
N	40

Descriptive Statistics
Papules
Week 3

w3PA



Quantiles

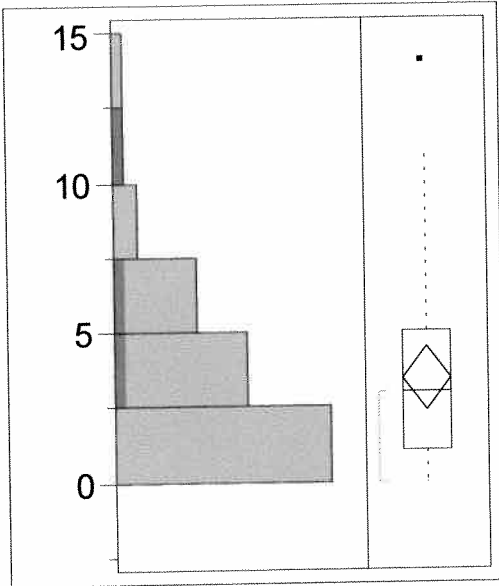
100.0%	maximum	11.000
99.5%		11.000
97.5%		10.975
90.0%		7.900
75.0%	quartile	5.000
50.0%	median	2.000
25.0%	quartile	1.000
10.0%		0.000
2.5%		0.000
0.5%		0.000
0.0%	minimum	0.000

Moments

Mean	3.1
Std Dev	2.880527
Std Err Mean	0.4554513
upper 95% Mean	4.0212372
lower 95% Mean	2.1787628
N	40

Descriptive Statistics
Papules
Week 4

wk4 PA



Quantiles

100.0%	maximum	14.000
99.5%		14.000
97.5%		13.925
90.0%		7.900
75.0%	quartile	5.000
50.0%	median	3.000
25.0%	quartile	1.000
10.0%		0.000
2.5%		0.000
0.5%		0.000
0.0%	minimum	0.000

Moments

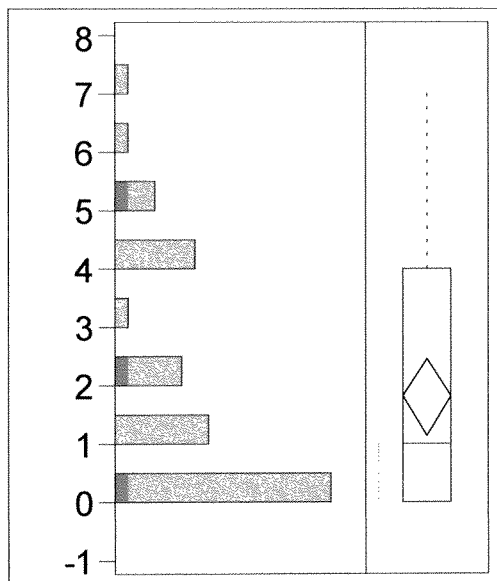
Mean	3.425
Std Dev	3.2255987
Std Err Mean	0.5100119
upper 95% Mean	4.4565965
lower 95% Mean	2.3934035
N	40

Descriptive Statistics

Papules

Week 6

wk6PA



Quantiles

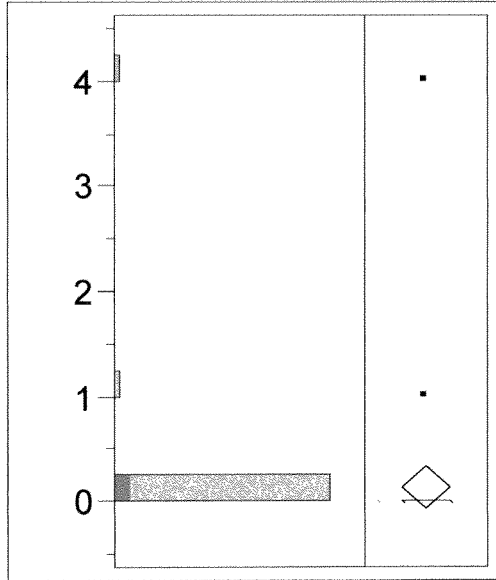
100.0%	maximum	7.0000
99.5%		7.0000
97.5%		6.9750
90.0%		5.0000
75.0%	quartile	4.0000
50.0%	median	1.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	1.8
Std Dev	2.0406133
Std Err Mean	0.3226493
upper 95% Mean	2.4526198
lower 95% Mean	1.1473802
N	40

Papules
Change from Baseline
Week 1

w1PA-b



Quantiles

100.0%	maximum	4.0000
99.5%		4.0000
97.5%		3.9250
90.0%		0.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.125
Std Dev	0.6479751
Std Err Mean	0.1024539
upper 95% Mean	0.3322325
lower 95% Mean	-0.082233
N	40

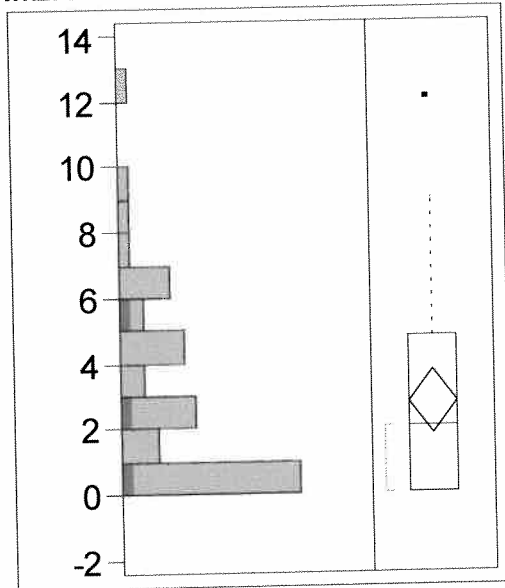
Test Mean=value

Hypothesized Value	0
Actual Estimate	0.125
df	39
Std Dev	0.64798

	t Test	Signed-Rank
Test Statistic	1.2201	1.500
Prob > t	0.2298	0.500
Prob > t	0.1149	0.250
Prob < t	0.8851	0.750

Papules
Change from Baseline
Week 2

wk2PA-b



Quantiles

100.0%	maximum	12.000
99.5%		12.000
97.5%		11.925
90.0%		6.900
75.0%	quartile	4.750
50.0%	median	2.000
25.0%	quartile	0.000
10.0%		0.000
2.5%		0.000
0.5%		0.000
0.0%	minimum	0.000

Moments

Mean	2.775
Std Dev	2.9913336
Std Err Mean	0.4729714
upper 95% Mean	3.7316749
lower 95% Mean	1.8183251
N	40

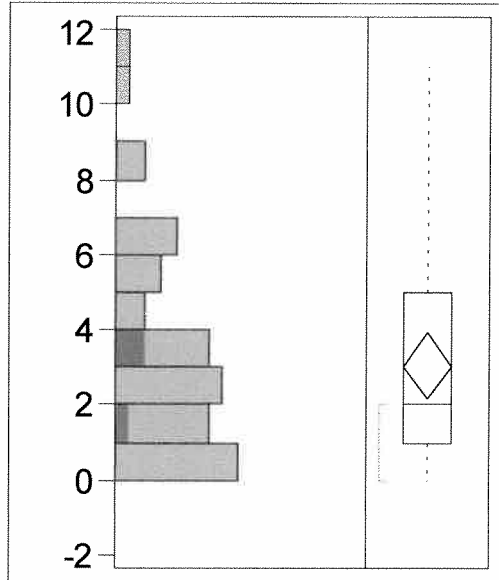
Test Mean=value

Hypothesized Value	0
Actual Estimate	2.775
df	39
Std Dev	2.99133

	t Test	Signed-Rank
Test Statistic	5.8672	175.500
Prob > t	<.0001	0.000
Prob > t	<.0001	0.000
Prob < t	1.0000	1.000

Papules
Change from Baseline
Week 3

w3PA-b



Quantiles

100.0%	maximum	11.000
99.5%		11.000
97.5%		10.975
90.0%		7.800
75.0%	quartile	5.000
50.0%	median	2.000
25.0%	quartile	1.000
10.0%		0.000
2.5%		0.000
0.5%		0.000
0.0%	minimum	0.000

Moments

Mean	3.05
Std Dev	2.8460499
Std Err Mean	0.45
upper 95% Mean	3.9602109
lower 95% Mean	2.1397891
N	40

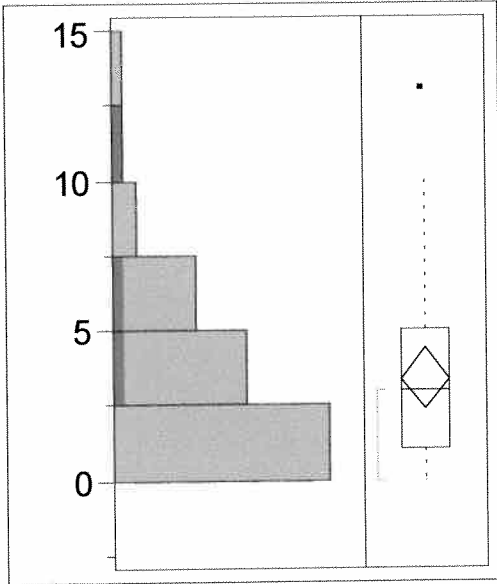
Test Mean=value

Hypothesized Value	0
Actual Estimate	3.05
df	39
Std Dev	2.84605

	t Test	Signed-Rank
Test Statistic	6.7778	264.000
Prob > t	<.0001	0.000
Prob > t	<.0001	0.000
Prob < t	1.0000	1.000

Papules
Change from Baseline
Week 4

PA 4-b



Quantiles

100.0%	maximum	13.000
99.5%		13.000
97.5%		12.925
90.0%		7.900
75.0%	quartile	5.000
50.0%	median	3.000
25.0%	quartile	1.000
10.0%		0.000
2.5%		0.000
0.5%		0.000
0.0%	minimum	0.000

Moments

Mean	3.375
Std Dev	3.0858444
Std Err Mean	0.4879148
upper 95% Mean	4.3619009
lower 95% Mean	2.3880991
N	40

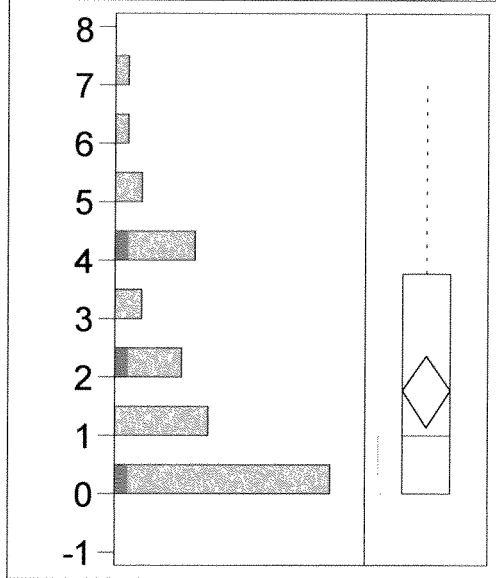
Test Mean=value

Hypothesized Value	0
Actual Estimate	3.375
df	39
Std Dev	3.08584

	t Test	Signed-Rank
Test Statistic	6.9172	280.500
Prob > t	<.0001	0.000
Prob > t	<.0001	0.000
Prob < t	1.0000	1.000

Papules
Change from Baseline
Week 6

PA 6-b



Quantiles

100.0%	maximum	7.0000
99.5%		7.0000
97.5%		6.9750
90.0%		4.9000
75.0%	quartile	3.7500
50.0%	median	1.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	1.75
Std Dev	1.9839096
Std Err Mean	0.3136837
upper 95% Mean	2.3844851
lower 95% Mean	1.1155149
N	40

Test Mean=value

Hypothesized Value	0
Actual Estimate	1.75
df	39
Std Dev	1.98391

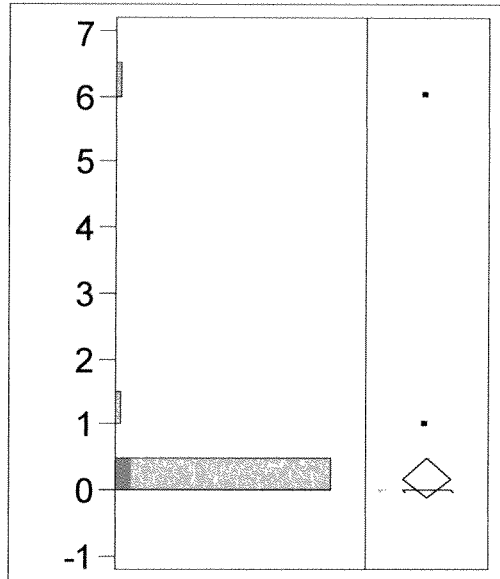
	t Test	Signed-Rank
Test Statistic	5.5789	150.000
Prob > t	<.0001	0.000
Prob > t	<.0001	0.000
Prob < t	1.0000	1.000

Descriptive Statistics

Pustules

Baseline

B PU



Quantiles

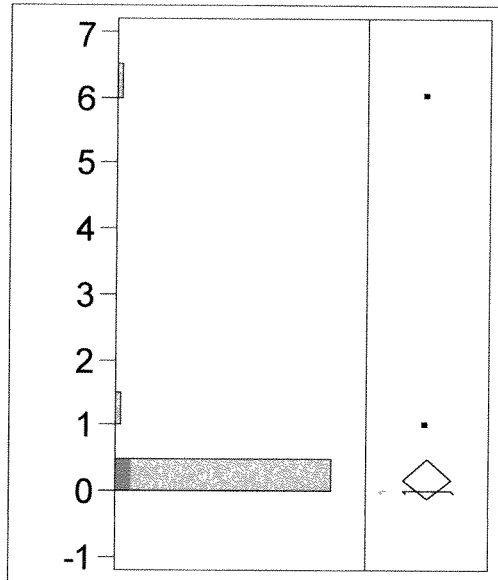
100.0%	maximum	6.0000
99.5%		6.0000
97.5%		5.8750
90.0%		0.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.175
Std Dev	0.9577618
Std Err Mean	0.1514354
upper 95% Mean	0.4813071
lower 95% Mean	-0.131307
N	40

Descriptive Statistics
Pustules
Week 1

w1PU



Quantiles

100.0%	maximum	6.0000
99.5%		6.0000
97.5%		5.8750
90.0%		0.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

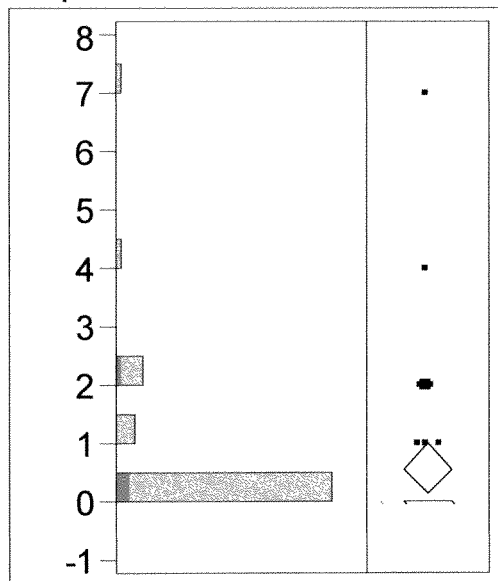
Mean	0.175
Std Dev	0.9577618
Std Err Mean	0.1514354
upper 95% Mean	0.4813071
lower 95% Mean	-0.131307
N	40

Descriptive Statistics

Pustules

Week 2

wk2 pu



Quantiles

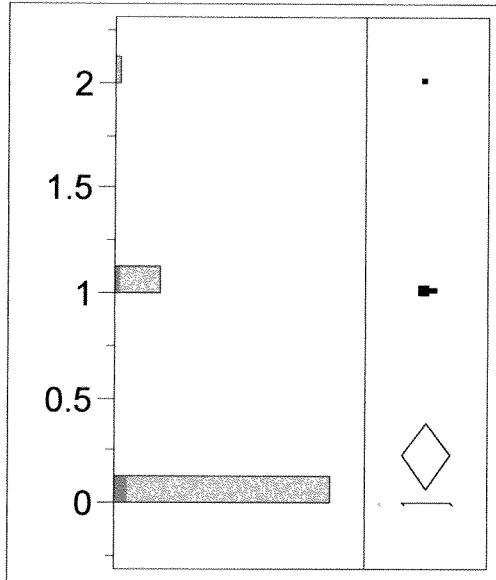
100.0%	maximum	7.0000
99.5%		7.0000
97.5%		6.9250
90.0%		2.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.55
Std Dev	1.3577885
Std Err Mean	0.2146852
upper 95% Mean	0.9842418
lower 95% Mean	0.1157582
N	40

Descriptive Statistics
Pustules
Week 3

w3PU



Quantiles

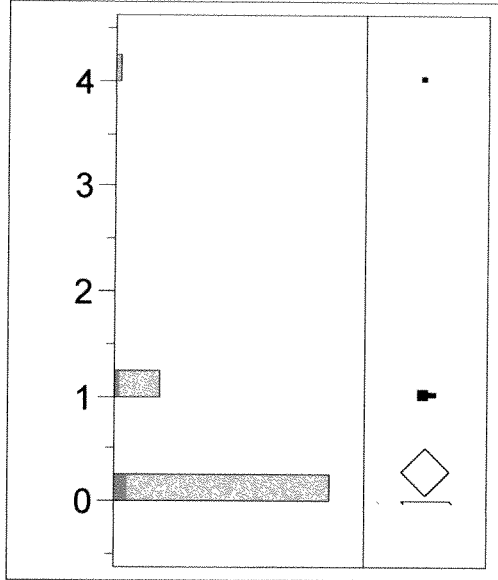
100.0%	maximum	2.0000
99.5%		2.0000
97.5%		1.9750
90.0%		1.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.225
Std Dev	0.4797168
Std Err Mean	0.0758499
upper 95% Mean	0.3784209
lower 95% Mean	0.0715791
N	40

Descriptive Statistics
Pustules
Week 4

wk4 pU



Quantiles

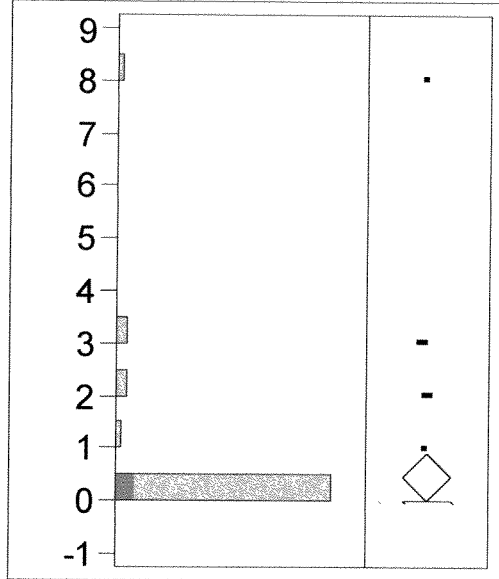
100.0%	maximum	4.0000
99.5%		4.0000
97.5%		3.9250
90.0%		1.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.275
Std Dev	0.7156672
Std Err Mean	0.1131569
upper 95% Mean	0.5038815
lower 95% Mean	0.0461185
N	40

Descriptive Statistics
Pustules
Week 6

WK6PU



Quantiles

100.0%	maximum	8.0000
99.5%		8.0000
97.5%		7.8750
90.0%		2.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

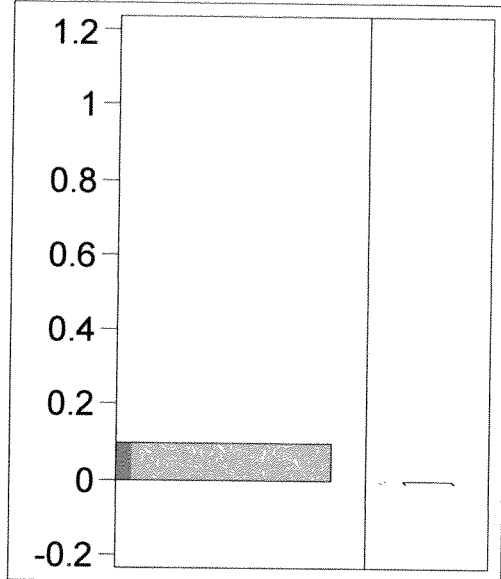
Moments

Mean	0.475
Std Dev	1.449801
Std Err Mean	0.2292337
upper 95% Mean	0.9386689
lower 95% Mean	0.0113311
N	40

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Pustules
Change from Baseline
Week 1

w1PU-b



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

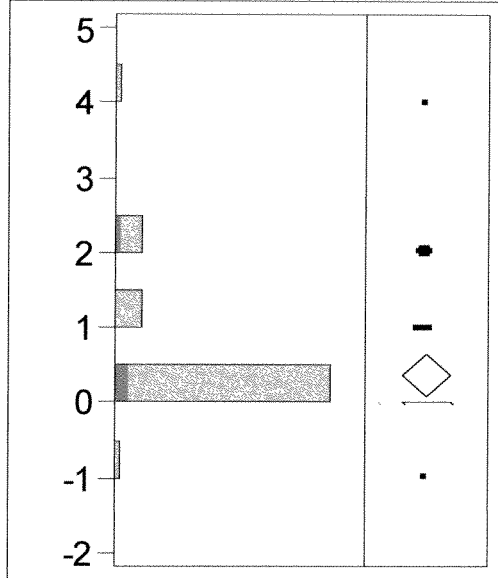
Test Mean=value

Hypothesized Value	0
Actual Estimate	0
df	39
Std Dev	0

	t Test	Signed-Rank
Test Statistic	.	0.000
Prob > t	.	1.000
Prob > t	.	0.500
Prob < t	.	0.500

Pustules
Change from Baseline
Week 2

wk2PU-B



Quantiles

100.0%	maximum	4.000
99.5%		4.000
97.5%		3.950
90.0%		2.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	0.000
10.0%		0.000
2.5%		-0.975
0.5%		-1.000
0.0%	minimum	-1.000

Moments

Mean	0.375
Std Dev	0.8969321
Std Err Mean	0.1418174
upper 95% Mean	0.6618528
lower 95% Mean	0.0881472
N	40

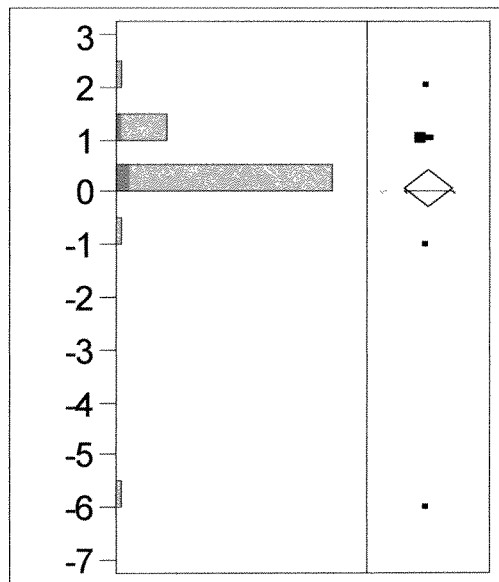
Test Mean=value

Hypothesized Value	0
Actual Estimate	0.375
df	39
Std Dev	0.89693

	t Test	Signed-Rank
Test Statistic	2.6442	24.500
Prob > t	0.0117	0.012
Prob > t	0.0059	0.006
Prob < t	0.9941	0.994

Pustules
Change from Baseline
Week 3

w3PU-b



Quantiles

100.0%	maximum	2.000
99.5%		2.000
97.5%		1.975
90.0%		1.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	0.000
10.0%		0.000
2.5%		-5.875
0.5%		-6.000
0.0%	minimum	-6.000

Moments

Mean	0.05
Std Dev	1.1082442
Std Err Mean	0.1752288
upper 95% Mean	0.4044337
lower 95% Mean	-0.304434
N	40

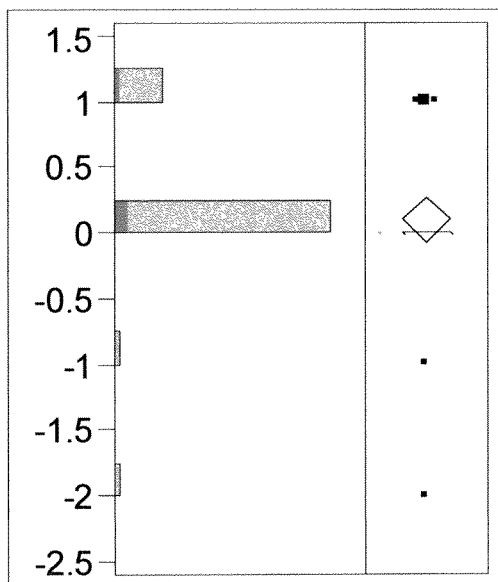
Test Mean=value

Hypothesized Value	0
Actual Estimate	0.05
df	39
Std Dev	1.10824

	t Test	Signed-Rank
Test Statistic	0.2853	13.000
Prob > t	0.7769	0.217
Prob > t	0.3884	0.108
Prob < t	0.6116	0.892

Pustules
Change from Baseline
Week 4

PU 4-b



Quantiles

100.0%	maximum	1.000
99.5%		1.000
97.5%		1.000
90.0%		1.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	0.000
10.0%		0.000
2.5%		-1.975
0.5%		-2.000
0.0%	minimum	-2.000

Moments

Mean	0.1
Std Dev	0.5453768
Std Err Mean	0.0862316
upper 95% Mean	0.27442
lower 95% Mean	-0.07442
N	40

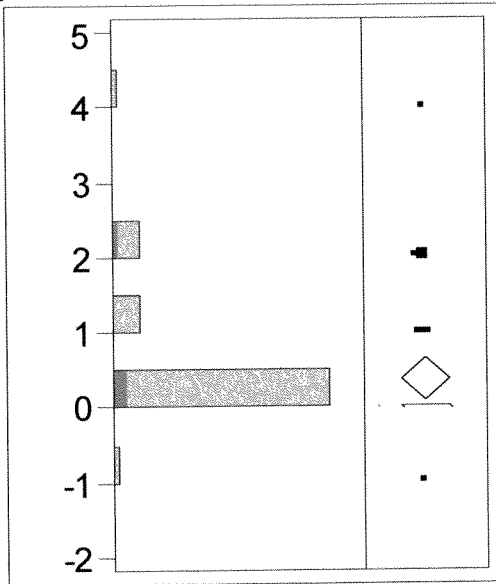
Test Mean=value

Hypothesized Value	0
Actual Estimate	0.1
df	39
Std Dev	0.54538

	t Test	Signed-Rank
Test Statistic	1.1597	9.000
Prob > t	0.2532	0.398
Prob > t	0.1266	0.199
Prob < t	0.8734	0.801

Pustules
Change from Baseline
Week 6

pu wk 6-B



Quantiles

100.0%	maximum	4.000
99.5%		4.000
97.5%		3.950
90.0%		2.000
75.0%	quartile	0.000
50.0%	median	0.000
25.0%	quartile	0.000
10.0%		0.000
2.5%		-0.975
0.5%		-1.000
0.0%	minimum	-1.000

Moments

Mean	0.375
Std Dev	0.8969321
Std Err Mean	0.1418174
upper 95% Mean	0.6618528
lower 95% Mean	0.0881472
N	40

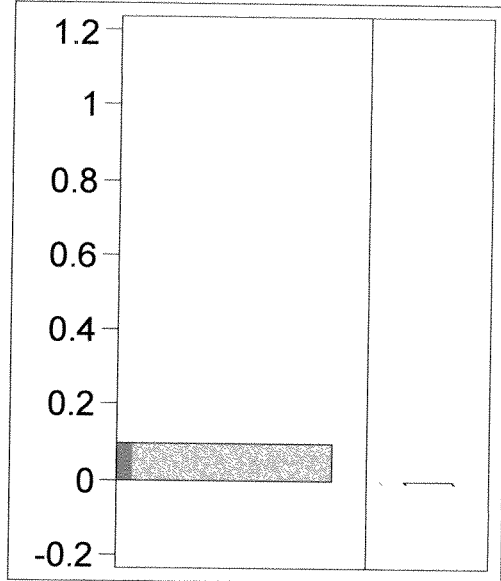
Test Mean=value

Hypothesized Value	0
Actual Estimate	0.375
df	39
Std Dev	0.89693

	t Test	Signed-Rank
Test Statistic	2.6442	24.500
Prob > t	0.0117	0.012
Prob > t	0.0059	0.006
Prob < t	0.9941	0.994

Descriptive Statistics
Nodules
Baseline

B NO



Quantiles

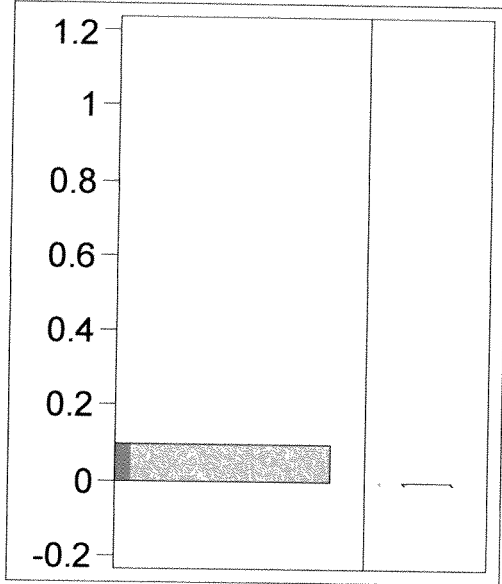
100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

Descriptive Statistics
Nodules
Week 1

w1NO



Quantiles

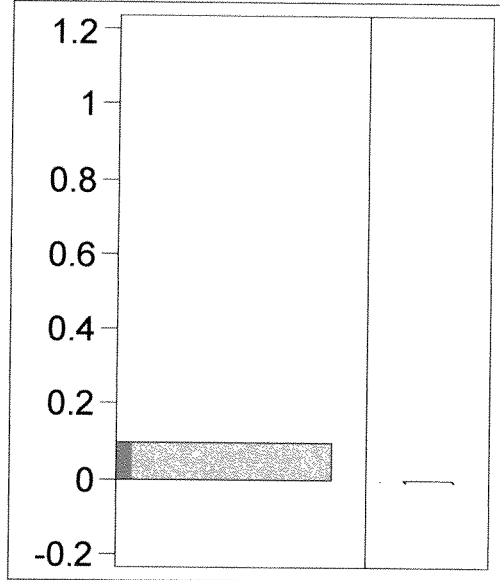
100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

Descriptive Statistics
Nodules
Week 2

wk2 NO



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

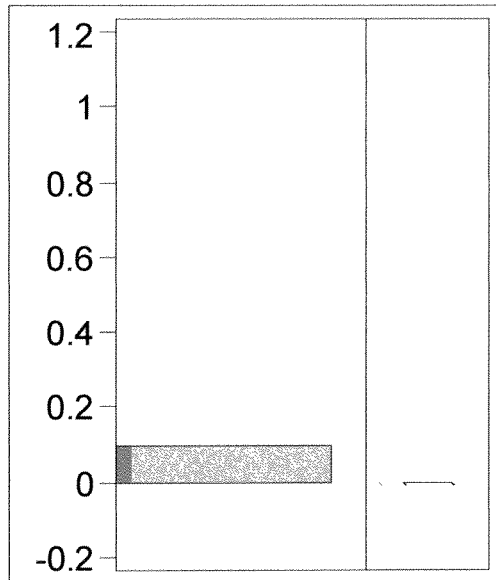
Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

Descriptive Statistics

Nodules

Week 3

w3NO



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

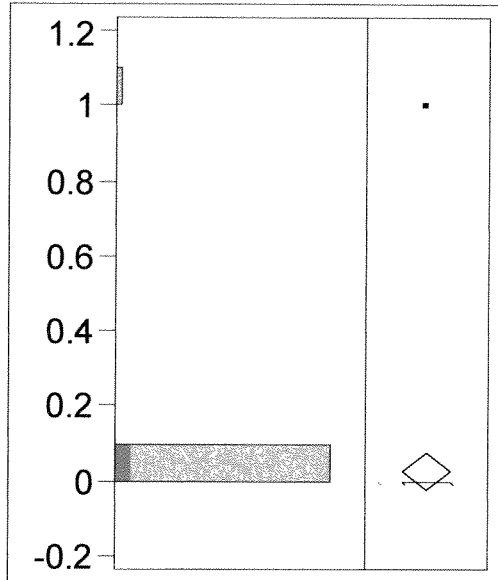
Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

Descriptive Statistics

Nodules

Week 4

wk4 NO



Quantiles

100.0%	maximum	1.0000
99.5%		1.0000
97.5%		0.9750
90.0%		0.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

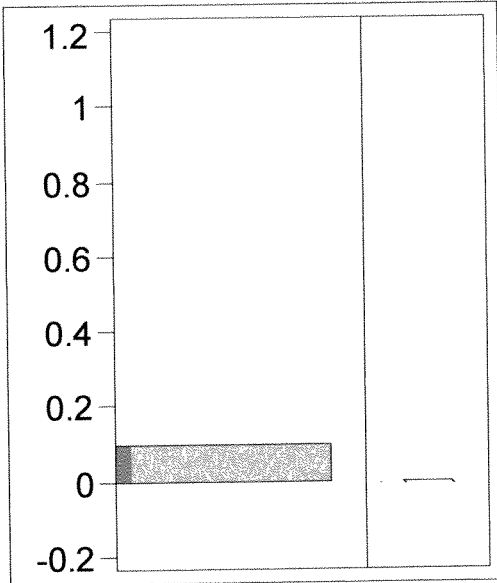
Moments

Mean	0.025
Std Dev	0.1581139
Std Err Mean	0.025
upper 95% Mean	0.0755673
lower 95% Mean	-0.025567
N	40

Descriptive Statistics

Nodules
Week 6

WK6 NO



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

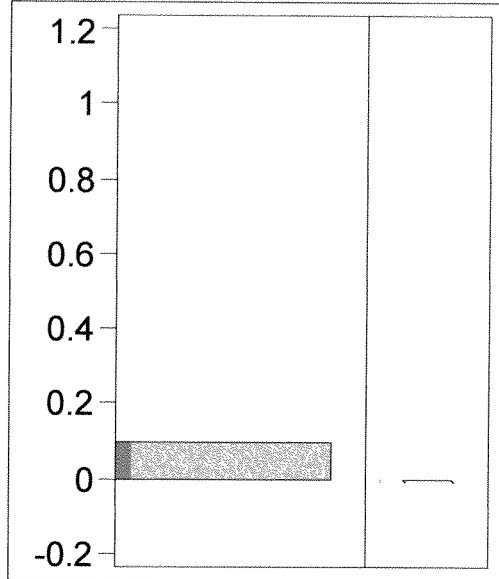
Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Nodules
Change from Baseline
Week 1

w1NO-b



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

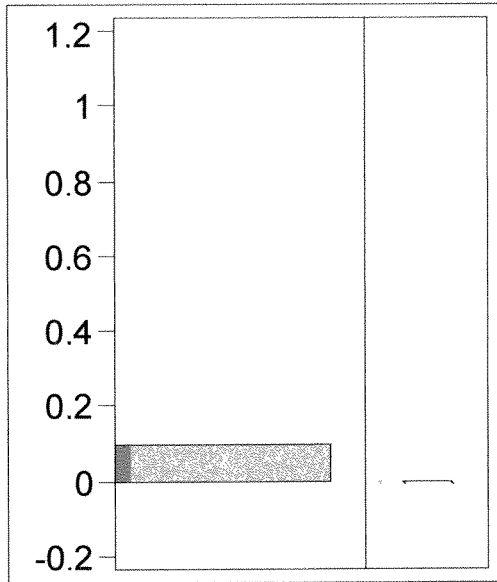
Test Mean=value

Hypothesized Value	0
Actual Estimate	0
df	39
Std Dev	0

	t Test	Signed-Rank
Test Statistic	.	0.000
Prob > t	.	1.000
Prob > t	.	0.500
Prob < t	.	0.500

Nodules
Change from Baseline
Week 2

wk2NO-b



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

Test Mean=value

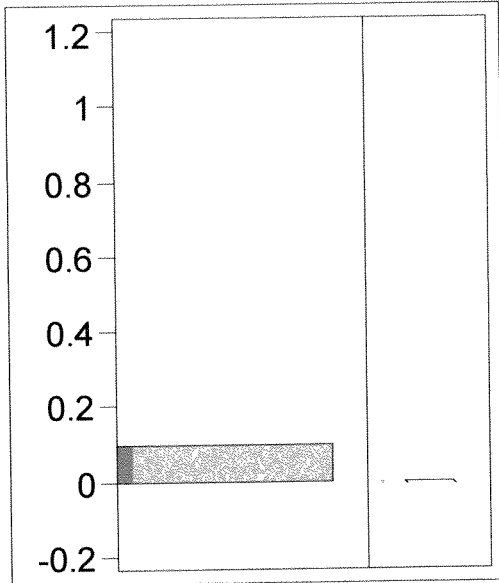
Hypothesized Value	0
Actual Estimate	0
df	39
Std Dev	0

	t Test	Signed-Rank
Test Statistic	.	0.000
Prob > t	.	1.000
Prob > t	.	0.500
Prob < t	.	0.500

ETC 09219
Lesion Counts
(JMP Statistical Software, SAS Inc., Cary NC)

Nodules
Change from Baseline
Week 3

w3NO-b



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

Test Mean=value

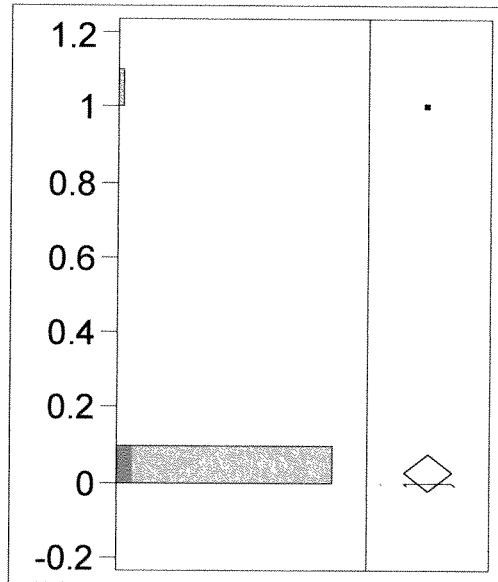
Hypothesized Value	0
Actual Estimate	0
df	39
Std Dev	0

	t Test	Signed-Rank
Test Statistic	.	0.000
Prob > t	.	1.000
Prob > t	.	0.500
Prob < t	.	0.500

ETC 09219
 Lesion Counts
 (JMP Statistical Software, SAS Inc., Cary NC)

Nodules
Change from Baseline
Week 4

NO 4-b



Quantiles

100.0%	maximum	1.0000
99.5%		1.0000
97.5%		0.9750
90.0%		0.0000
75.0%	quartile	0.0000
50.0%	median	0.0000
25.0%	quartile	0.0000
10.0%		0.0000
2.5%		0.0000
0.5%		0.0000
0.0%	minimum	0.0000

Moments

Mean	0.025
Std Dev	0.1581139
Std Err Mean	0.025
upper 95% Mean	0.0755673
lower 95% Mean	-0.025567
N	40

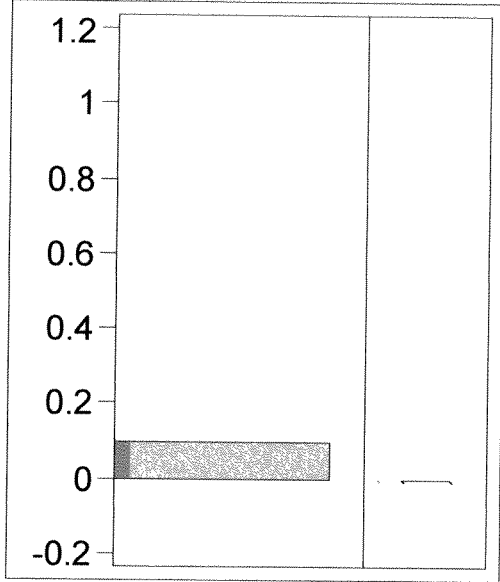
Test Mean=value

Hypothesized Value	0
Actual Estimate	0.025
df	39
Std Dev	0.15811

	t Test	Signed-Rank
Test Statistic	1.0000	0.500
Prob > t	0.3235	1.000
Prob > t	0.1617	0.500
Prob < t	0.8383	0.500

Nodules
Change from Baseline
Week 6

wk6NO-b



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

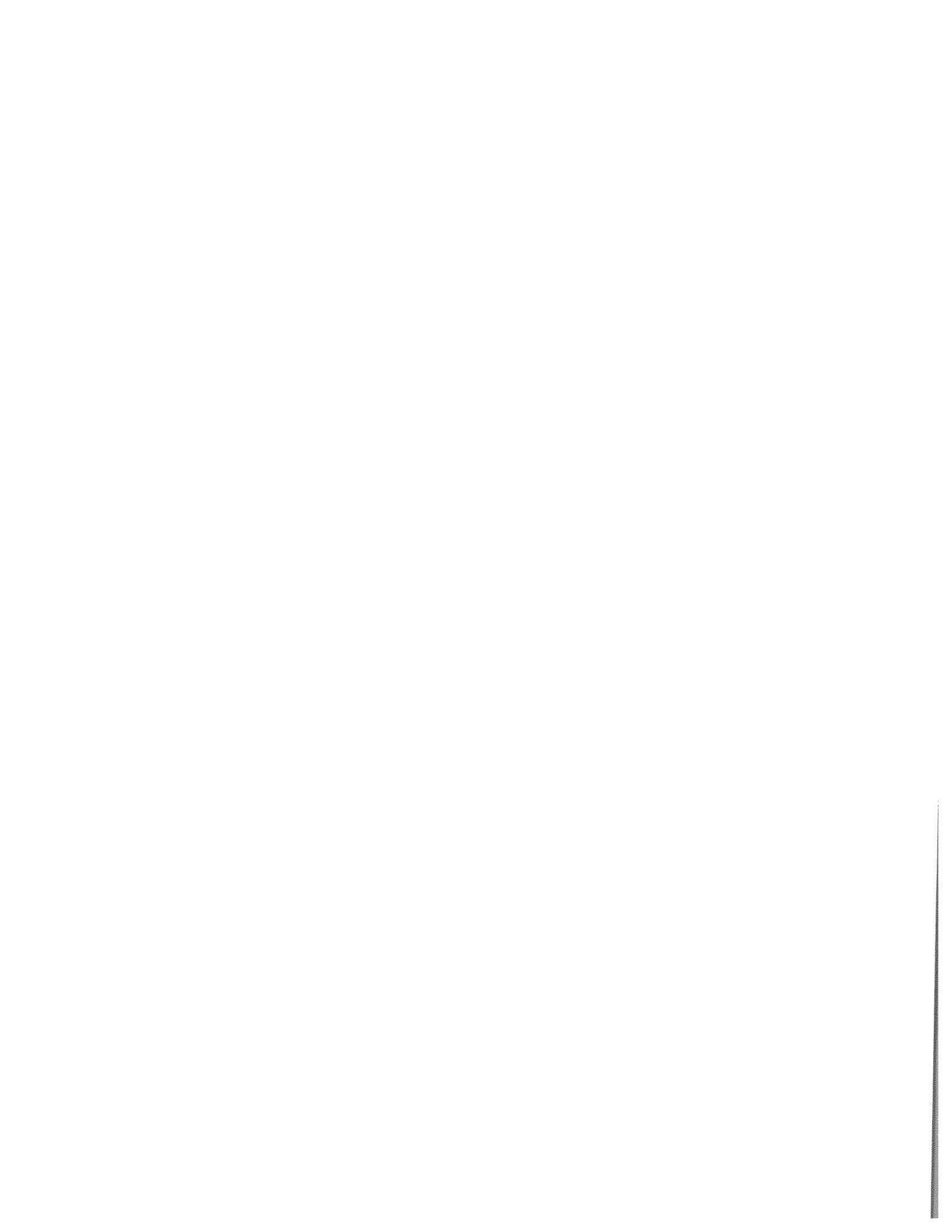
Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

Test Mean=value

Hypothesized Value	0
Actual Estimate	0
df	39
Std Dev	0

Test Statistic	t Test	Signed-Rank
Prob > t	.	0.000
Prob > t	.	1.000
Prob < t	.	0.500



APPENDIX 5

IRRITATION EVALUATION

Test Articles: Homeopathic Spray
 Glutathione Patches

Subject No.	Dermatologist Evaluation	Technician Evaluation	Technician Evaluation	Technician Evaluation	Technician Evaluation	Dermatologist Evaluation
	Baseline	1 Week	2 Weeks	3 Weeks	4 Weeks	6 Weeks
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	0	0	0	0	0	0
7	0	0	0	0	0	0
8	0	0	0	0	0	0
9	0	0	0	0	0	0
10	0	0	0	0	0	0
11	0	0	0	Discontinued		
12	0	Discontinued				
13	0	0	0	Discontinued		
14	0	0	0	0	0	0
15	0	0	0	0	0	0
16	0	0	0	0	0	0
17	0	0	0	0	0	0
18	0	0	0	0	0	0
19	0	0	0	0	0	0
20	0	0	0	0	0	0
21	0	0	0	0	0	0
22	0	0	0	0	0	0
23	0	0	0	0	0	0
24	0	0	0	0	0	0
25	0	0	0	0	0	0
26	0	0	0	0	0	0
27	0	0	0	0	0	0
28	0	0	0	0	0	0
29	0	0	0	Discontinued		
30	0	0	0	0	0	0
31	0	0	0	0	0	0
32	0	0	0	0	0	0
33	0	0	0	0	0	0
34	0	0	0	0	0	0
35	0	0	0	0	0	0
36	0	0	0	0	0	0
37	0	0	0	0	0	0
38	0	0	0	0	0	0
39	0	0	0	0	0	0
40	0	0	0	0	0	0
41	0	0	0	0	0	0
42	0	0	0	0	0	0
43	0	0	0	0	0	0
44	0	0	0	0	0	0
MEAN	0.0	0.0	0.0	0.0	0.0	0.0

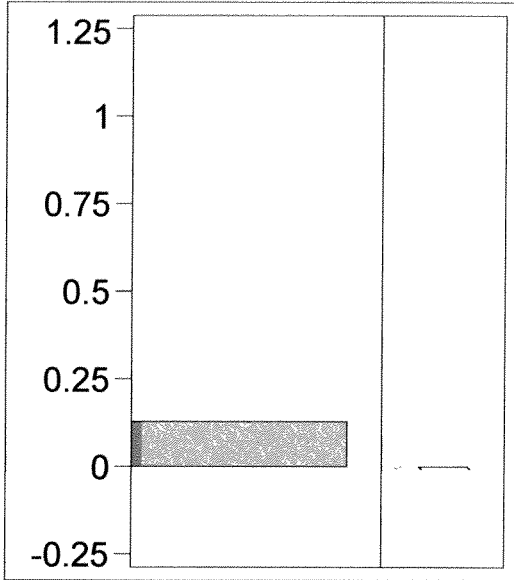
Irritation Grading Scale:

- 0 = No evidence of any effect
- + = Barely perceptible irritation present
- 1 = Mild irritation present
- 2 = Moderate irritation present
- 3 = Marked irritation present
- 4 = Severe irritation present

ETC 09219
Skin Irritation
Statistical Analysis (JMP/SAS, Cary NC)

Descriptive Statistics
Baseline

irr B



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

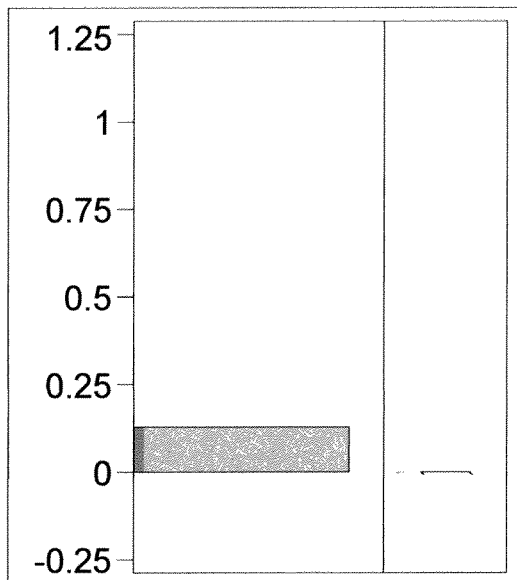
Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

ETC 09219
Skin Irritation
Statistical Analysis (JMP/SAS, Cary NC)

Descriptive Statistics
Week 1

irr w1



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

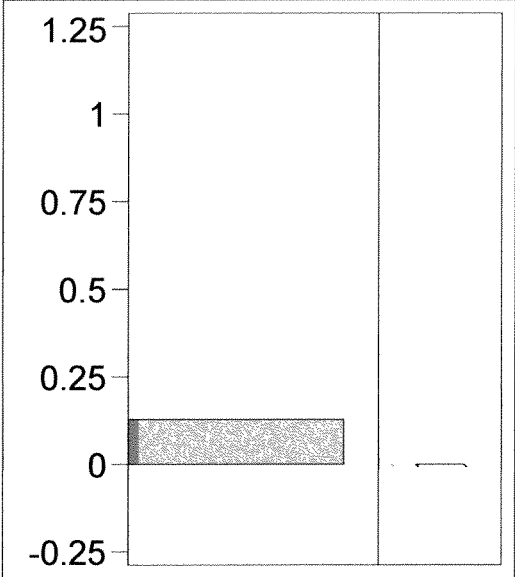
Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

ETC 09219
Skin Irritation
Statistical Analysis (JMP/SAS, Cary NC)

Descriptive Statistics
Week 2

irr w2



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

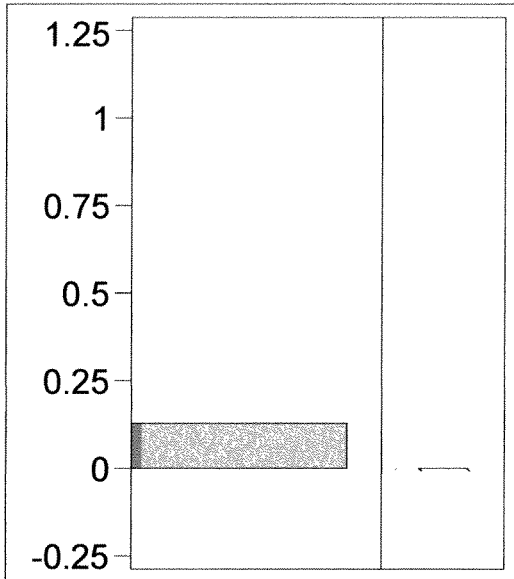
Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

ETC 09219
Skin Irritation
Statistical Analysis (JMP/SAS, Cary NC)

Descriptive Statistics
Week 3

irr w3



Quantiles

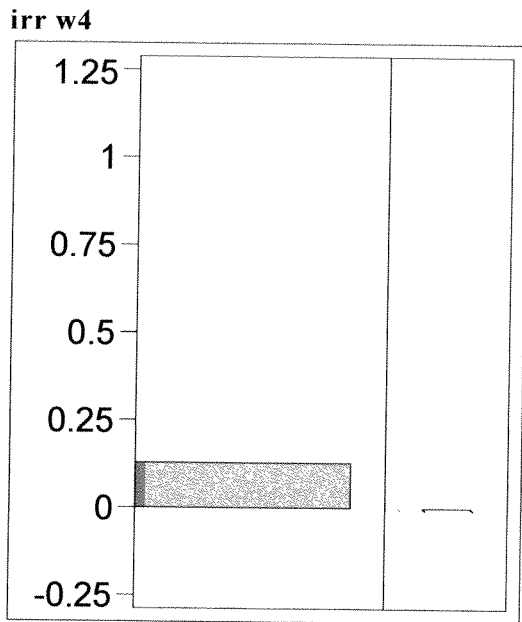
100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

ETC 09219
Skin Irritation
Statistical Analysis (JMP/SAS, Cary NC)

Descriptive Statistics
Week 4



Quantiles

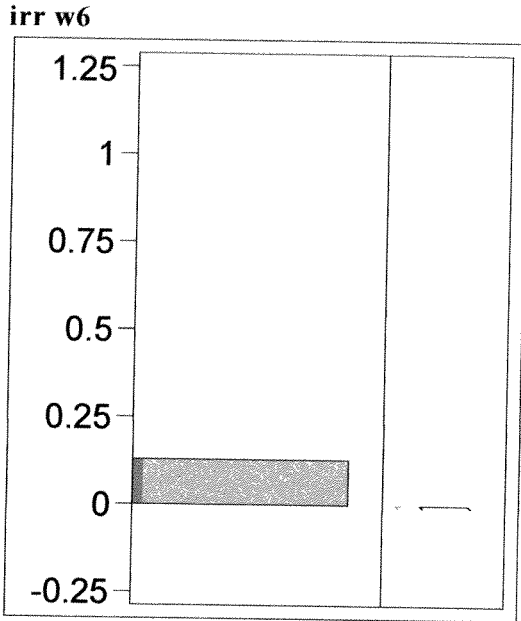
100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40

ETC 09219
Skin Irritation
Statistical Analysis (JMP/SAS, Cary NC)

Descriptive Statistics
Week 6



Quantiles

100.0%	maximum	0
99.5%		0
97.5%		0
90.0%		0
75.0%	quartile	0
50.0%	median	0
25.0%	quartile	0
10.0%		0
2.5%		0
0.5%		0
0.0%	minimum	0

Moments

Mean	0
Std Dev	0
Std Err Mean	0
upper 95% Mean	0
lower 95% Mean	0
N	40