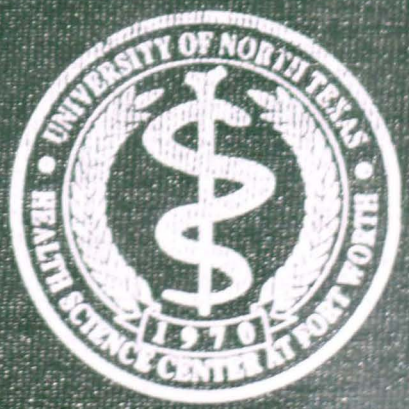
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Over 50% of the world's population has self-perceived sensitive skin. Many of these individuals believe that their skin sensitivity was caused by topical products which caused them to avoid certain skincare products. However, previous research has shown that geographical environments such as weather changes, temperature, pollution, diet, and lifestyle can cause or enhance skin sensitivity. The results from this study failed to confirm the results from earlier studies. Instead, data indicated that geographical environment effects on skin sensitivity were minimal. Moreover, analysis of transepidermal water loss for subjects with and without sensitive skin revealed that the skin barrier function for both skin types was not significantly different. Future studies are needed to investigate the sensitivity of the transepidermal water loss for evaluating skin barrier function. In addition, sample size for these studies should be increased to better represent the testing population. Moreover, if the Asian population is used in future clinical research studies, success will be governed by the effectiveness of the educational materials in minimizing the gap between Asian culture and clinical research in this population.

EVALUATION OF SENSITIVE SKIN IN THE ASIAN POPULATION

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the

Graduate School of Biomedical Sciences

University of North Texas

Health Science Center at Fort Worth

In Partial Fulfillment of the Requirements for the Degree of

MASTERS OF SCIENCE

in Clinical Research Management

By

Hanh Thuy Nguyen, B.S.

Fort Worth, Texas

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CHAPTER I

INTRODUCTION

Skin- Biological Structure and Function:

The skin is the largest organ of the integumentary system, made up of epithelial tissues to protect underlying muscles and organs. It also acts as a sensory organ to external changes: changes in environmental factors like pollution levels and seasons, changes in geographical residence, and changes in topical product application. The skin can be divided into three layers: epidermis, dermis, and hypodermis. The epidermis is responsible for serving as a barrier while the dermis serves as a source of nutrient. Together, these layers aid in preventing infection by maintaining a barrier, repairing injury, providing circulation, and regulating temperature [1].

The epidermis, averaging 50μm in thickness, is further divided into five strata with the stratum corneum, a semi-permeable laminated surface, being the outermost layer. The most observable function of the epidermis lies in the stratum corneum, which is responsible for acting as a physiological barrier to unrestrained passage of water and solutes across the skin [1, 2]. With a thickness of only 12-15μm, the stratum corneum not only acts as a physiological barrier, but also provides protection against invasion by microorganisms, toxic substances, and solar UV radiation from the sun [2].

The dermis, composed of the papillary and reticular layers, is as complex as the epidermis. The papillary layer, composed of fine connective tissue fibers, capillaries, and

some nerve endings, is adjacent to the basement membrane of the epidermis. In contrast, the reticular layer, composed of interlacing collagen fibers, some sweat glands, blood vessels and nerve endings, is the main fibrous bed of the dermis [3]. Above all, the dermis is responsible for providing nutrients to the epidermis, removing waste, and controlling temperature as well as many other functions. Beneath this layer lies the hypodermis, composed of a subcutaneous layer, which serves as a cushion for the dermis from underlying tissues [2]. Appearing as an extension of the dermis, the hypodermis carries the major blood vessels and nerves to the skin [3]. A depiction of the skin layers, epidermis, dermis, and hypodermis, can be found in Figure 1.

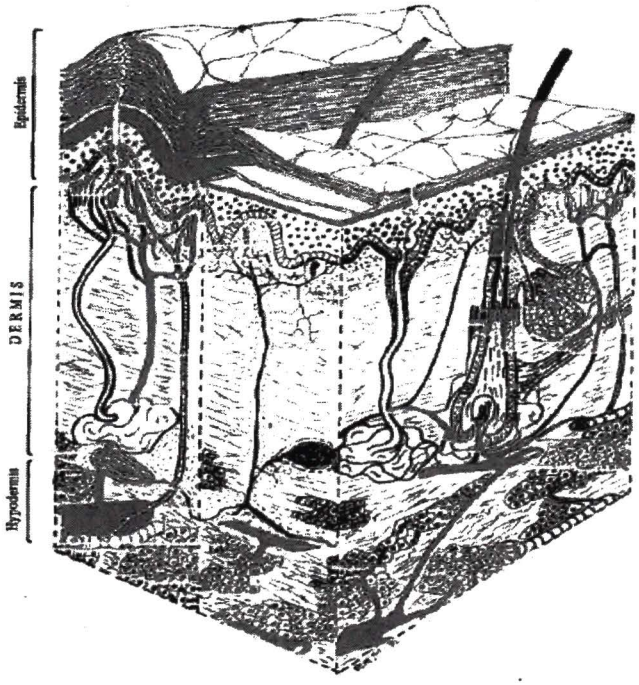

Figure 1: Diagrammatic representation of skin (not to scale)

Together these layers aid in maintaining internal homeostasis by thermoregulatory secretory activity, forming a self-repairing barrier, and providing a route to which

information about the external environment can be transmitted [3]. Understanding these interactions is essential for skincare and cosmetic companies to facilitate development of products that meet consumers' needs.

Skin Type Categories

Skin typing is universal in that people of different ethnic groups can share the same skin type [4]. The two skin type categories are skin hydration and skin sensitivity, which can be further broken down into: oily vs. dry and sensitive vs. resistant. Understanding these categories is crucial for individuals who are seeking appropriate skin care recommendations.

Category one is skin hydration: oily vs. dry. Individuals with oily skin often have shiny skin and are often more vulnerable to breakouts than individuals with dry skin. Breakouts are defined as having irregular tiny bumps on the skin that may be irritating and/or red. Dry skin is characterized by dull and/or rough texture. The degree of dryness and oiliness is regulated by the condition of the stratum corneum, which serves important functions such as helping the skin to retain moisture and to produce sebum [4, 5]. The moisture function is regulated by the proportion of different kinds of lipids located in the stratum corneum such as ceramides, fatty acids, and cholesterol. In the right amount, these lipids will help maintain the skin barrier, resulting in less moisture evaporation from the skin. Dryness is often the result of the stratum corneum impaired function. On the other hand, the oiliness function is regulated by the sebaceous glands, found in the hair follicles, which contain wax esters, triglycerides, and squalene. These fats also aid in retaining water, although too much can cause skin conditions such as acne [4, 5].

Category two is skin sensitivity: sensitive vs. resistant. Individuals with resistant skin have a strong skin barrier, stratum corneum, which shields the skin cells from allergens and irritating substances. In contrast, sensitive skin individuals have a weaker skin barrier, resulting in many kinds of skin reactions [5]. The sensitive skin group can be further divided in three clinical subgroups: severe sensitive skin (SSS), sensitive skin to the environment (SSE), and sensitive skin to topical factors [6]. Individuals are categorized into a subgroup based on the different factors that may cause their skin irritations. The SSS subgroup has a very high facial reactivity to a range of factors including: topical, environmental (including pollution), and also internal factors such as stress. The second subgroup, SSE, shows a high sensitivity to heat or to extreme changes in temperature. Finally, the third subgroup, the sensitive skin to topical factors, exhibits sensitivity to certain skincare or cosmetic products [6].

These skin types, oily vs. dry and sensitive vs. resistant, interact to determine the appearance, vulnerabilities, and needs of the skin. However, skin type is not static. Changes in climate, fluctuations in stress, or other endogenous events such as pregnancy or menopause can engender skin type changes [4]. In addition, there are also important skin type variations within each skin type group, resulting in multiple subgroups for each skin type group. For instance, while sensitive skin group can be broken into SSE and sensitive skin to topical products subgroups, but individuals that are in the SSE subgroup may not be able to use the same skincare products as those in the sensitive skin to topical factors subgroup. As a result, it is imperative that individuals understand their current skin type when choosing skincare products and treatment to achieve product tolerance.

Skin Barrier Function and Transepidermal Water Loss

The barrier function of the skin is attributed to the integrity of the stratum corneum. Thus far, this function is measured via indirect methods such as damaging the stratum corneum and then evaluating its function via transepidermal water loss (TEWL). Sodium lauryl sulphate (SLS) patch testing and the lactic acid sting test are commonly used methods to insult the skin barrier [7, 8, 9]. Used along with TEWL, these methods demonstrate the dynamic connection between TEWL and the skin barrier function.

TEWL refers to the total amount of water vapor loss through the stratum corneum under non-sweating conditions [10]. Since one of the functions of the skin is to maintain an effective barrier against loss of body fluids, TEWL readings are widely used to determine the barrier function of the skin in both physiological and pathological conditions. TEWL readings vary between anatomical sites, and could be ranked as follows: palms>soles>forehead=postauricular> nails=dorsum of hand>forearm= upper arm=thigh=chest=abdomen=back [11]. As a result, the anatomical site on which TEWL measurements are taken is important to consider when comparing any TEWL readings. According to Pinnagoda et. al., there is no apparent difference in TEWL readings between ethnicity, age, or gender [11, 12]. Based on earlier studies, TEWL readings are shown to be higher in individuals with sensitive skin; however, the actual numbers were not reported [12, 13]. TEWL is used to perform as an irritancy test as well as to evaluate the efficacy of therapeutic treatments on diseased skin [7, 10]. For example, TEWL measurements allow for parametric evaluations of the effects of barrier creams against irritants [12].

There are different methods for evaluating TEWL. These methods can be divided into two system types, closed and opened chamber. Each system type has its advantages and disadvantages. The opened chamber system, also called the ventilated chamber, is equipped with a thermister and humidity sensors to measure the water gradient above the skin surface. This water gradient is produced by water evaporation through the stratum corneum [14]. Although reliable and accurate, instruments that utilize this method are inconvenient because this method require the measurements to be taken in an environment with no air turbulence. In addition, instruments with the opened chamber system are not portable and highly expensive [14]. In contrast, the closed chamber system, also called the unventilated chamber, has many advantages over the opened chamber system. Equipped with the same sensors, instruments that utilized this system are more portable and less expensive. However, the drawback for this method is that it is unsuitable for continuous TEWL measurements [14]. Today, the most common instrument used to measure TEWL readings is the Vapometer, a closed chamber system. The vapometer is non-invasive and portable, has rapid assessments, and is flexible for various measurement locations [15].

Earlier studies have used TEWL measurements to evaluate the degree of damage to the skin barrier after exposure to irritants for clinical assessment of skin and therapeutic treatment purposes. For example, Pinnagoda et al. used changes in TEWL from baseline as a basis to predict the susceptibility of the skin to repeated exposures of an irritant [16]. TEWL was used to evaluate the effects of 0.5% SLS, a weak irritant. The subject's forearm was exposed to the irritant by application of a patch for 24 hours.

Another site on the subject's forearm was exposed to an application of a patch for twice a day for 4 days containing the same irritant solution. Individuals with higher baseline TEWL had higher TEWL after single and repeated exposure to the irritant compared to individuals with lower baseline TEWL. Multiple linear regression analysis indicated that a high baseline TEWL was a better indication of an individual's increased susceptibility to weak irritants than a high TEWL value following a single 24-hr patch test. Based on the results, Pinnagoda et al. concluded that TEWL could be used as an accurate preliminary "predictive" screening test for susceptibility to irritants [16].

In addition to the study by Pinnagoda et al., Smith et al. also conducted SLS patch testing with TEWL measurements and found similar results [17]. Twenty milliliters of seven descending concentrations of SLS from 20% to 0.1% were applied for 4 hours on the upper inner arm. In addition, distilled water was used as a control [17]. The lowest concentration of SLS to induce erythema was considered the threshold for SLS. Individuals with a lower irritant threshold had elevated TEWL levels compared to those with higher thresholds [17]. Smith et al. confirmed earlier studies that higher baseline TEWL was associated with higher TEWL following irritant exposure. Consequently, TEWL measurements could indicate skin susceptibility to irritants.

SLS is not the only irritant used with TEWL to test for skin barrier function and sensitivity. The Lactic Acid Sting Test, designed by Kligman and Frosch in 1977, is also a widely accepted marker of skin sensitivity for subjective irritation [18]. For instance, Susun An et al. used the Lactic Acid Sting Test and TEWL as a clinical tool to diagnose sensitive skin [19]. An's study was able to show a positive correlation between stinging

response and the TEWL readings during the lactic acid sting test [19]. As TEWL readings increased during the winter, stinging responses also increased.

A correlation between stinging response and TEWL readings was also seen in other studies such as Yanyu Wu et al. [8]. Yanyu Wu et al. showed a correlation between lactic acid sting response and skin barrier. 3% and 5% lactic acid was applied to each nasolabial fold randomly, one on each side. A clinical score of stinging was self-accessed by the subjects at 0, 2.5, 5 and 8 minutes using a 4-point scale. TEWL was then measured at 8 minutes and compared to baseline. Yanyu Wu et al. reported a correlation between higher baseline TEWL readings with earlier stinging response time. This result further supported TEWL as an accurate screening test for skin susceptibility to irritants.

Together, these studies confirm that TEWL is a predictable indirect method for determining skin barrier. From earlier studies, it could be concluded that a higher TEWL score than normal equated to a damaged stratum corneum. Consequently, a damaged stratum corneum allows irritants to penetrate the skin barrier faster which induces stinging response to be more rapid and stronger.

Perception of Skin Sensitivity

The phrase, "I have sensitive skin" is widely used by individuals who self-perceive their skin to be more intolerant to external factors such as temperature, climate, topical products, etc., than the general population [20]. Over the years, there has been an increase in the number of individuals who have self-perceived sensitive skin. For example, approximately 52% of the population in the San Francisco, California area alone perceive themselves to have sensitive skin. This perception has driven 78% of these

"self-perceived" individuals with sensitive skin to avoid certain kinds of cosmetic products [20]. In the United Kingdom in 2001, 51.4% and 38.2% of the surveyed women and men, respectively, self-perceived themselves to have sensitive skin [21]. A high incidence of self-perceived sensitive skin was also seen in Asia. For example, the incidence has been reported to be approximately 50% in Japan and 56% in Chengdu, China [6]. These results suggested that the perception of having sensitive skin is a common problem on a global scale.

Most commonly, self-perceived sensitive skin individuals believe that their skin sensitivity is caused by using incompatible skincare products. However, studies have shown that the cause of sensitive skin could vary, requiring different method of treatment[6]. For example, with the effects of geographical environments such as changes in the weather, temperature, pollution, diet, and lifestyle, individuals in the SSE subgroup could have similar symptoms as those of individuals in the sensitive skin to topical typical products subgroup. Nonetheless, the treatments for individuals in these two subgroups are different. The self-perceived sensitive skin perception has created opportunities and challenges for the skincare and cosmetic industry as manufacturers attempt to develop new products targeting this population. The challenge posed to the skincare and cosmetic industry is that many self-diagnosed individuals cannot distinguish between their sensitivity due to topical products or to geographical environments. Therefore, although self-assessment can be valuable, it is not always an accurate parameter for categorizing skin as sensitive or non-sensitive for cosmetics and skincare purposes.

For example, Jourdain et al. reported that Asians have a greater tendency to show skin reactivity to spicy food, sudden changes in temperature, and to wind [20]. As a result, Asians tend to suffer from itching more frequently, which has caused them to self-perceive to have sensitive skin. This perception has led them to believe that topical products are the cause of their irritation rather than their environment and lifestyle [20]. As a result, the wide variation in the perception of sensitive skin can create challenges when it comes to choosing compatible skincare products.

Skincare product sales globally reached over $65 billion in 2007; this is a 62% increase from 2002 sales [22]. This sales increase is due, in part, to growing awareness between consumers and manufacturers of skincare products that there are differences in skin types and different people can have varying skin types that require specific skincare products. It is essential for individuals with sensitive skin to evaluate the cause of their skin sensitivity. Manufacturers of skincare and cosmetics can better focus research on developing products suitable for each subgroup if the cause of sensitive skin and its perception is well-defined,

CHAPTER II

PART 1: RESEARCH PURPOSE AND BACKGROUND

Problems/ Specific Aims

Over the years, there has been an increase in the number of individuals who have self-perceived sensitive skin. In 1993, approximately 40% of the world population believed that they had sensitive skin, but presently the number has increased to 50% or more for some geographical areas [18]. For instance, 52% and 39% of the surveyed men and women in the UK, 52% in San Francisco, California, 50% in Japan, and 56% in Chengdu, China have self-perceived sensitive skin [6]. Thus, these results suggest that sensitive skin is a common problem globally.

Sensitive skin is clinically characterized by sensorial signs perceived by the subjects. Individuals with this skin type often define their skin to be more intolerant to external factors than the general population. Intolerant sensorial signs can range from erythema, stinging, burning, itching and tightness. Individuals with sensitive skin often perceive facial discomfort in specific situations such as sudden changes in temperature, climate, and/or changes in topical product application. Sensitive skin has been classified into three clinical subgroups: severe sensitive skin (SSS), sensitive skin to environment (SSE), and sensitive skin to topical factors [6]. It is crucial for individuals with sensitive skin to understand which subgroup they belong to in order for them to address the root of their skin problems.

More than 50% of individuals with sensitive skin believe that their skin sensitivity is caused by topical products, but recent studies have shown that geographical environments such as weather changes, temperature, pollution, diet, and lifestyle can also cause or increase skin sensitivity. For example, when women of Asian descent were asked if they perceived themselves as having sensitive skin, over half indicated that they do; however, studies have shown that their skin sensitivity was caused mainly by irritants found in the wind or in food products and not by topical products [20]. Nonetheless, self-reporting has driven 78% of these self-perceived sensitive skin individuals to avoid certain kinds of skincare products.

This study will focus on geographical environmental factors. It is important to note that population differences in skin physiology exist [6]. Therefore, to control for variance, only sensitive skin in the Asian population will be evaluated. The goal of this study is to investigate if there is a relationship between the incidence of sensitive skin in the Asian population and the relative time in which they reside in the United States. This study will test the hypothesis that there will be a higher incidence of clinically diagnosed sensitive skin in the Asian population of men and women who have resided in the United States for less than or equal to one year (Group 2) compared to those that have resided in the United States for longer than or equal to 1.5 years (Group 1). This higher incidence is predicted to be caused by the differences in previously exposed geographical environments. It is presumed that the longer the subject is exposed to their local environment, the more likely their skin barrier will be affected due to the effects of the environment on the skin.

Specific Aim #1:

To determine if there is a relationship between the relative time subjects reside in the United States to the number of subjects clinically diagnosed to have sensitive skin

Hypothesis:

It is presumed that environmental factors play a key role in causing skin sensitivity. The hypothesis is that the incidence of clinically diagnosed sensitive skin will be greater in subjects who have resided in the United States for less than or equal to one year compared to those that have resided in the United States for longer than or equal to 1.5 years.

Experimental Approach:

The Lactic Acid Sting Test is a standard test used in the cosmetic industry to clinically test for sensitive skin. It will be used in this study to determine subject's skin sensitivity. The Fisher's Exact Test will be used to statistically compare skin sensitivity between groups.

Specific Aim #2:

To determine if there is a relationship between transepidermal water loss (TEWL) measurements and the response to the Lactic Acid Sting Test

Hypothesis:

It is hypothesized that subjects that respond positively to the Lactic Acid Sting Test will have a higher baseline TEWL reading compared to subjects with a negative response.

Experimental Approach:

Since TEWL is proven to be an indirect measurement of the skin barrier, TEWL readings are expected to change as the skin barrier adapts to different geographical environments. TEWL readings will be taken in triplicate for each subject prior to the Lactic Acid Sting Test. Student's unpaired and paired T- test will be used to statistically compare inter- and intra- group TEWL readings, respectively.

Significance and Expectations

Based on earlier studies, skin types, such as sensitive and not sensitive (resistant), could change over time due to a wide variation of factors that could affect skin sensitivity. Consequently, individuals' perception about their skin type has to change accordingly as well. Unfortunately, many individuals, particularly in the Asian population with self- perceived sensitive skin, are not aware of changes in their skin type. Unawareness has caused 78% of Asians with self-perceived sensitive skin to mistakenly avoid certain topical products when their sensitivity is caused by weather changes, environmental temperature, pollution, diet, medication, pre-existing disease states, and lifestyle [20]. Similarly, other ethnicities have experienced the same problem. The percentages of individuals with self-perceived sensitive skin have increased globally over the years [18]. It is important for self-perceived sensitive skin individuals to understand the cause of their skin sensitivity to better select products more suitable for their skin type.

The purpose of this study is to examine the effects of geographical environmental

factor on skin sensitivity. The goal is to determine if a relationship exists between the relative time the subjects reside in the United States to the incidence of a clinical diagnosis of sensitive skin. In addition, this study will also compare TEWL readings between the Lactic Acid Sting Test responses. This relationship can be used to further confirm the association between geographical location and skin sensitivity. Furthermore, the results from this study can be used by investigators to improve and develop novel skincare products targeting this specific population.

CHAPTER II

PART 2: EXPERIMENTAL DESIGN/ METHODS OF RESEARCH

Experimental Design and Recruitment Methods

The study was divided into two main groups: Group 1 and Group 2. Group 1 was comprised of subjects that have resided in the United States for more than or equal to 1.5 years. Group 2 was comprised of subjects that have resided in the United States for less than or equal to one year. For both groups, the population from which the subjects were selected for this study was comprised of males and females of Asian descent between the ages of 18 to 65 years of age. There was a six month gap between the two groups to aid in data analysis. This gap prevented the clustering of subjects that could be enrolled in either group. Based on earlier studies, 1.5 years was ample time for detection of changes in the skin barrier as the skin adapted to the new environment [19]. Initially, 120 subjects were expected to be enrolled into the study, 60 subjects in each group. A total of 119 subjects were screened using the pre-screening questionnaire for qualification of enrollment into the study. At the conclusion of the study, 85 subjects were enrolled in Group 1, 10 subjects were enrolled in Group 2, and 24 subjects were not enrolled into the study. Subjects that were screened but not enrolled were due to recruitment problems such as study withdrawals, scheduling conflicts, and study criteria restrictions. All enrolled subjects met the following inclusion and exclusion criteria:

Inclusion Criteria:

1. Subject has to be of Asian descent.
2. Subject has self-perceived sensitive skin.
3. Subject is at least 18 years old but less than 65 years old.
4. Subject has read and signed the Informed Consent Form
5. Subject is dependable and able to follow directions

Exclusion Criteria:

1. Subject has an "active skin" condition that can interfere with the study result, i.e., active dermatitis, widespread acne, etc.
2. Subject has known allergy to specific formula components.
3. Subject is pregnant, lactating, or breastfeeding.
4. Subject is using topical or systemic steroids, antihistamines, or an investigational systemic drug.
5. Subject has already been tested with the Lactic Acid Sting Test.

Because the purpose of this study was to evaluate sensitive skin in the Asian population, only Asian subjects who self-perceived to have sensitive skin could participate. For this study, South Asians such as Indians, Pakistanis, etc, were also considered Asian descent. A screening questionnaire was used to select for eligible subjects for the study.

Various recruitment methods were attempted to recruit Asian subjects such as flyers, newspapers, and referrals. Initially, flyers were posted in the Asian communities such as supermarkets and small businesses within a 30 mile radius from Mary Kay, Inc.

and around the University of North Texas Health Science Center campus. Afterward, advertisements for the study were also printed in local Asian newspapers such as the Dallas Chinese Times, Chinese Livings, and Korea Daily. In addition, referrals from friends and families were used simultaneously with other mentioned methods to recruit subjects for this study. Overall, the majority of the recruitment was through the friends and families method. Subjects that completed the study would refer their friends and families for the study, creating multiple cascading effects.

Taking into account cultural and language barriers that could potentially impede the study, the informed consent document for the study was translated into the native languages of the subjects. Moreover, if subjects were not fluent in English, translators were available during the study to assist with the consenting process. In addition, scheduling appointments for the study were made flexible to accommodate those with family and work obligations.

Research Methods

After the prospective subjects were recruited, the student investigator conducted the consenting process and began the study. The consenting and study procedures were done at Mary Kay's Clinical and Consumer Evaluation facility. Verification for subject eligibility to participate in this study was conducted via a screening questionnaire. Subjects were assigned to the appropriate group based on the length of time they had resided in the United States. After determining the subject assignment to the group, the subjects were assigned a three digit subject identification number. The first digit represented the group number and the last two digits represented the number of subjects

enrolled in the study. The last two digits changed as new subjects were enrolled into the study. The following items were prepared prior to conducting each study.

1. Delfin Vapometer
2. room with relativity humidity $\leq 40 \pm 2\%$ and temperature $\leq 72 \pm 2°F$
3. clean tray with individual depressions
4. 2 blunt tip forceps
5. timer for each subject set at 5 minutes
6. two 100 μL dispensing micropipettes
7. Distilled Water***
8. 10% Lactic Acid Solution***

*** *Solutions were prepared fresh every Monday and used for the entire week.*

Preparation of Subjects

Subjects were asked if they were wearing any facial topical product such as make-up or moisturizer. If they were wearing any facial topical products, subjects were instructed to wash both sides of their nose with water and gently pat dry with a soft cloth. Then, in order to continue with the study, subjects were asked to sit in the waiting room for an additional 10 minutes. This allowed the washed area to acclimate to the room settings, such as temperature and humidity, so that the study environment could be controlled.

Transepidermal Water Loss (TEWL) Measurement Procedures

For this study, triplicate TEWL measurements were taken and recorded on one side of the nasolabial fold using a vapometer. Measurements were taken according to

Mary Kay Inc.'s Biophysical SOP #06 for Delfin Vapometer [23]. Subjects were asked to sit while the student investigator gently placed the end of the vapometer probe against one side of their nasolabial fold. The probe was held in place for approximately 20 seconds. The same procedure was repeated 2 more times at approximately the same site. All measurement sites (left and right) were randomized.

Lactic Acid Sting Test

One strip of 1x2 cm cloth was soaked in 100uL of 10% lactic acid, and the other strip in 100uL of de-ionized water. The subjects and the student investigator were blinded as to which treatment for the strips. Also, the nasolabial fold for the lactic acid solution was randomized for each subject. The student investigator used blunt-tip forceps to gently place the strips, one on each side of the nasolabial fold on each subject. Separate forceps were used for each solution. The strips remained on the nasolabial fold for five minutes. Subjects were instructed to sit quietly for five minutes and record all sensations felt at specified time intervals (0, 2.5, and 5.0 minutes) on the Lactic Acid Questionnaire. The first scoring (zero) was taken at about 30 seconds after application. There were two parts to the scoring. For the first part, subjects were asked to record the following sensations: stinging, itching, burning, or none. For the second part, subjects were asked to rate the degree of the sensation based from a score of 0 to 3, with intervals of 0.5. Although all strips were removed at the end of the 5-minute exposure, emphasis was given to the subjects that the strips could be removed before the end of the 5-minute exposure if severe discomfort was felt, in other words, a score of 3 was considered severe.

The remaining time point (e.g. five minutes) was scored with the same value recorded when the strips were removed.

Data Interpretation

Lactic Acid Sting Test

The individual scores for each time point in the exposure were recorded for both the lactic acid and water treatment. The score sheets were then scanned in Remark so that the data could be transferred to Microsoft Excel. Skin sensitivity of each subject was evaluated as followed: Step 1: If the difference of the score for the last time point (5 minutes) was ≥ 1 for the lactic acid, subject was diagnosed as having sensitive skin. If not, step 2 proceeded. Step 2: The average response over the three time points for each subject was calculated for the lactic acid and water. If the difference of the average scores was ≥ 0.5 for the lactic acid, subject was diagnosed as having sensitive skin. If subject's score failed to pass the score requirement to be diagnosed as having sensitive skin for Step 1 and 2, subject was considered as not having sensitive skin [24].

TEWL Measurement

Baseline TEWL measurements were taken before the Lactic Acid Sting Test. TEWL measurements were not taken after the Lactic Acid Sting Test. Triplicate baseline TEWL measurements were averaged for each subject, and the average was used for statistical analysis.

Statistical Analysis

The Fisher Exact Test was used to analyze for any associations, between skin sensitivity and length of time having resided in the United States, for the Lactic Acid Sting Test. Initially, the paired Student's T-Test was intended to be used to compare the TEWL measurements mean within Group 1 and 2; however, after discussion with two statisticians, we have decided to use the unpaired Student's T-Test to perform analysis for whether the TEWL means of the groups were significantly different.

In addition, the Factorial Analysis of Variance (FANOVA) was also recommended for statistical analysis. FANOVA was used to study the effects of skin type (sensitive and not sensitive) and Group (1 and 2) on TEWL measurements. The goal of this test was to determine whether the time the subjects resided in the United States affects TEWL measurements and whether the subject's skin type affects TEWL measurements. In other words, the question was whether there was an interaction between the time the subjects resided in the United States and skin type, in terms of these two variables effects on TEWL measurements.

Risk/ Benefit Assessment

Subjects participating in this study were not exposed to more than minimal risk. For the Lactic Acid Sting Test, possible skin irritation included, but not limited to, redness, dryness, itching, burning, and stinging. The degree of itching was similar to a mosquito bite and the burning and stinging sensation were similar to mild sunburn. During the study, subjects who showed signs of irritation were provided with hydrocortisone to put on the irritated nasolabial fold to help soothe the irritation. These

irritations were only temporary. There was no risk associated with TEWL measurements. Overall, there was no direct benefit for subjects that were participating in this study. However, the results from this study may further help our understanding of skin sensitivity in the Asian population.

CHAPTER II

PART 3: RESULTS

Sample Characteristics

Summary of sample characteristics can be found in Table 1. A total of 119 subjects were screened for qualification of enrollment into the study. Among those qualified, 85 subjects were enrolled for Group 1, 10 subjects for Group 2. Twenty-four subjects were not enrolled after the screening process for multiple reasons, such as study restrictions, scheduling conflicts, and family obligations leading to withdrawals. Female representation in this study was similar for both Group 1 and Group 2, 71% and 70% respectively. All subjects recruited were between the ages of 18 to 65 years of age. The majority of subjects that participated were Chinese, 48% for Group 1 and 70% for Group 2. However, in Group 1, there also was a dispersed representation of subjects from other countries as well: Taiwan, Korea, India, Indonesia, Japan, Vietnam, Canada, and the United States. The majority of the subjects were recruited based on referrals, 67% for Group 1 and 100% for Group 2 (Table 2).

Table 1: Sample of Population Characteristics

Sample Population Characteristics		Group 1		Group 2	
		N=85	%	N=10	%
Gender	Female	60	71%	7	70%
	Male	25	29%	3	30%
Country of Origin	Taiwan	16	19%	1	10%
	China	41	48%	7	70%
	Korea	5	6%	2	20%
	India	5	6%	---	---
	Indonesia	6	7%	---	---
	Japan	1	1%	---	---
	Vietnam	4	5%	---	---
	Canada	3	4%	---	---
	United States	4	5%	---	---

N: Number of subjects
%: Percentage of total group
Group 1: subjects that have resided in the United States $\geq$ 1.5 years
Group 2: subjects have resided in the United States $\leq$ 1 year

Table 2: Recruitment Method Results

Recruitment Methods	Locations	Group 1 Percentage of Enrollment	Group 2 Percentage of Enrollment
Flyers	Churches	4%	0%
	Grocery Stores	0%	0%
	Mary Kay Inc.	24%	0%
Newspapers	Chinese Livings	5%	0%
	Dallas Chinese Times	1%	0%
	Korea Daily	0%	0%
Referrals	Mary Kay Inc.	28%	80%
	Newspaper/ Churches	8%	0%
	Friends & Families	31%	20%

Lactic Acid Analysis

Subjects were diagnosed to have sensitive skin based on two calculation methods for the lactic acid scores. The first method involved determining if the difference between the last score for the lactic acid and distilled water was larger than or equal to 1.

For this method, if the score was larger than or equal to 1 for the lactic acid, then the subject was diagnosed to have sensitive skin. If the score was less than 1, then the second method was used to determine skin sensitivity. The second method was calculated for the difference between the average of the lactic acid and distilled water. If the difference was equal to or larger than 0.5 for the lactic acid, this would also indicate that the subjects would have sensitive skin. If the subjects did not have sensitive skin based on these two method calculations, then the subjects were considered not sensitive. The percentage of subjects who were diagnosed as having sensitive skin and non-sensitive skin for both Group 1 and Group 2 were very similar. The prevalence of clinically sensitive skin was the same for both groups, 80% (Table 3). The data were analyzed using the Fisher Exact Test and the results showed a significance of 1.00. Based on a significant *p-value* of 0.05, there was no significant difference between the time the subjects resided in the United States and the incidence of sensitive skin.

Table 3: Lactic Acid Sting Test Results

Skin Type	Group 1 N= 85	Group 2 N=10
Sensitive Skin	80%	80%
Non-Sensitive Skin	20%	20%

N: Number of subjects
Group 1: subjects that have resided in the United States ≥ 1.5 years
Group 2: subjects have resided in the United States ≤ 1 year

Transepidermal Water Loss (TEWL) Analysis

Baseline TEWL measurements were taken prior to the Lactic Acid Sting Test at 22.9°C ± 1.8°C and at 37.5% ± 3.3% relative humidity. The averaged baseline TEWL measurements for each subject were used for further statistical analysis. Baseline TEWL

measurements were compared on multiple levels such as: within groups (sensitive vs. non- sensitive), between groups (Group 1 vs. Group 2), and between diagnosed skin types (sensitive vs. non- sensitive).

Table 4: Overall Mean TEWL Statistics

* TEWL Statistics	N	Mean TEWL (Standard Deviation)
Group 1	85	25.2 (7.1)
Group 2	10	21.2 (4.5)
Sensitive (Group 1 +2)	76	25.1 (7.2)
Non- Sensitive (Group 1 +2)	19	23.4 (6.1)

*All TEWL values are in g/m^2h.
N: number of subjects
Group 1: subjects that have resided in the United States $\geq$ 1.5 years
Group 2: subjects have resided in the United States $\leq$ 1 year

Table 5: Subgroups Mean TEWL Statistics

* TEWL Statistics	Skin Type	N	Mean TEWL (Standard Deviation)
Group 1	Sensitive	68	25.5 (7.4)
	Non-Sensitive	17	24.0 (6.0)
Group 2	Sensitive	8	21.9 (4.4)
	Non-Sensitive	2	18.5 (5.5)

*All TEWL values are in g/m^2h.
N: number of subjects
Group 1: subjects that have resided in the United States $\geq$ 1.5 years
Group 2: subjects have resided in the United States $\leq$ 1 year

It was hypothesized that individuals that responded positively to the Lactic Acid Sting Test (diagnosed as sensitive skin) would have higher TEWL measurements than those who responded negatively to the Lactic Acid Sting Test (diagnosed as not sensitive). Overall across the study, TEWL measurements were greater for subjects with sensitive skin compared to subjects that did not have sensitive skin with the mean TEWL readings 25.1 and 23.4, respectively (Table 4). When comparing skin type within Group, this trend was also observed (Table 5). For Group 1, subjects with sensitive skin had mean

TEWL readings of 25.5 and subjects without sensitive skin had mean TEWL readings of 24.0. For Group 2, subjects with sensitive skin had mean TEWL readings of 21.9 and subjects without sensitive skin had mean TEWL readings of 18.5. However, when the Student's T-Test was used to analyzed the mean TEWL readings, these differences were not statistically significant at a *p-value = 0.05* (Table 6). Although higher TEWL readings were observed in subjects with sensitive skin, based on the Student's T-Test, there was not statistical evidence, within the setting observed, that the means of TEWL readings of subjects with sensitive skin was different than the means of TEWL readings of subjects without sensitive skin.

It was previously hypothesized that subjects in Group 1 would have lower TEWL readings than subjects in Group 2 due to the differences in previous environmental exposure; the longer the subjects resided in the United States, the more their skin barrier would change due to the effects of the environment on the skin. However, the opposite response was observed. Mean TEWL readings for Group 1 were higher overall when compared to Group 2, 25.2 and 21.2, respectively (Table 4). In addition, when TEWL means were compared between subgroups (e.g., Group 1 sensitive vs. Group 2 sensitive), similar results were observed. Group 1 sensitive group had higher mean TEWL readings compared to the Group 2 sensitive group, 25.5 and 21.9, respectively (Table 5). Similarly, Group 1 and Group 2 subgroup (non- sensitive) followed the same trend, 24.0 and 18.5, respectively (Table 5). Further analysis of the mean TEWL readings was performed using the Student's T-Test comparing between Group 1 and Group 2 subgroups mean TEWL readings. Within the setting observed, there was not a

significant difference at *p-value = 0.05*, two-tailed significance = 0.089, between Group 1 and Group 2 mean TEWL measurements (Table 6).

Table 6: Student's T-Test Mean TEWL Analysis

*TEWL Values Comparison	Student's T-Test Sig.(2-tailed)
Group 1 (Sensitive & Not Sensitive)	0.465
Group 2 (Sensitive & Not Sensitive)	0.362
Skin Type (Sensitive & Not Sensitive)	0.364
Group 1 and Group 2	0.089

* All TEWL values are in g/m^2h.
Group 1: subjects have resided in the United States $\geq$ 1.5 years
Group 2: subjects have resided in the United States $\geq$ 1 year

The mean TEWL readings were further analyzed with the Factorial Analysis of Variance (FANOVA), Table 7. The results consisted of three conclusions. Conclusion 1: At a *p-value= 0.05,* there was no significant evidence that the means of TEWL in Group 1 and Group 2, at a two-tailed significance level of 0.118, were different. Conclusion 2: At a *p-value= 0.05,* there was no significant evidence that the means of TEWL for subjects with sensitive skin and without sensitive skin, at a two-tailed significance level of 0.403, were different. These first two conclusions further confirmed the results obtained from the Student's T-Test. Conclusion 3: At a *p-value=0.05,* there was no significant evidence that the effects of skin type, sensitive and not sensitive, was the same for subjects in Group 1 as it was for subjects in Group 2, at a two-tailed significance level of 0.727.

Table 7: *FANOVA Mean TEWL Analysis

Independent Variables Effecting TEWL	FANOVA Sig.(2-tailed)
Group (1 & 2)	0.118
Skin Type (Sensitive & Not Sensitive)	0.403
Group * Skin Type	0.727

* All TEWL values are in g/m2h.
Group 1: subjects have resided in the United States ≥ 1.5 years
Group 2: subjects have resided in the United States ≤ 1 year

CHAPTER II

PART 4: DISCUSSION AND CONCLUSION

Discussion

The term sensitive skin is frequently used by individuals to indicate when there is a situation of facial skin sensitivity with topical products [18]. However, recent studies suggested that sensitive skin was not a single condition and that it compassed other mechanisms as well [6, 18, 21]. Factors which can affect skin sensitivity are geographical conditions such as weather and climate, lifestyles such as diet, and health conditions such as stress. The results from this study indicated that self-perceived sensitive skin individuals often complained of facial redness caused by changes in climatic temperature, after drinking alcoholic beverages, and exercise. Also, they often experienced facial itchiness during changes in climatic temperature. In addition, approximately, 68% of self-perceived sensitive skin individuals indicated that they easily react to cosmetic or skincare products causing 81% of them to avoid certain brands of topical products (Appendix A).

Over the years, there has been a global increase in populations with sensitive skin [6, 20, 21]. This problem has indicated a need for further research in the cause of heightened skin sensitivity. Although, there have been many studies conducted to attempt to explain the skin sensitivity phenomenon, little research has actually been conducted for the Asian population. In an attempt to analyze the association between skin sensitivity and

geographical factors in the Asian population, skin barrier of self-perceived sensitive skin subjects was evaluated as well.

It was originally hypothesized that there would be a higher percentage of Asians living in the United States for less than or equal to 1 year (Group 2) with clinically diagnosed sensitive skin compared to that of Asians that have lived in the United States for longer than or equal to 1.5 years (Group 1). In addition, it was presumed that individuals with clinically diagnosed sensitive skin would have higher TEWL readings than individuals without sensitive skin due to the weakening of the stratum corneum in individuals with sensitive skin. However, the results of this study did not support either hypothesis.

After the subject's score on the Lactic Acid Sting Test was calculated and analyzed for subject's skin sensitivity, the subject was designated as having sensitive skin or not having sensitive skin. The Lactic Acid Sting Test data indicated that the incidence of sensitive skin was not higher in Group 2. On the contrary, the percentage of subjects, with and without sensitive skin, was equal among both groups. As a result, an association was not observed for geographical factors and the incidence of sensitive skin.

Analyzing mean TEWL readings showed that there was not a significant difference between inter- and intra- groups' subjects with and without sensitive skin. Based on earlier studies, TEWL was considered an indirect measurement of the function of the skin barrier or stratum corneum [16-19]. Thus, a non-statistical difference could indicate that individuals with and without sensitive skin may have very similar skin barrier functions. Similar results were obtained in an earlier study performed by

Seidenari et al. comparing forearm TEWL readings in subjects with and without sensitive skin [18].

Further analysis of the mean TEWL readings showed that there was not a significant difference between Group 1 and Group 2. Prior to conducting this study, it was presumed that individuals in Group 1 would be less sensitive than individuals in Group 2 due to effects of geographical environments on the skin; however, the results from this study challenged this assumption. If TEWL is accepted as an indirect measurement of the function of the stratum corneum, then the results of this study would indicate that there is little difference between the skin barrier of subjects in Group 1 and individuals in Group 2. Since the only difference among both groups was the length of time they have resided in the United States, with both population statistics being very similar, it could be concluded that geographical environments played a minor role in affecting the function of the stratum corneum.

The results from this study showed that skin type and the length of time residing in the United States, individually or combined, have little interaction in affecting an individual's TEWL measurements; the results are equivocal. From the study by Distante et al., reported a high coefficient of variance for inter-individual TEWL, 35%-48% [12, 13]. This high variance could contribute to the insensitivity of TEWL to the effect of skin type changes and geographical environmental changes. As a result, an additional assay should be used along with TEWL for better understanding of skin barrier functions, such as the overall score of the Lactic Acid Sting Test or other biophysical parameters such as pH, capacitance, etc. Earlier studies conducted by Seidenari et al. have been able to observe

significant differences with these parameters in individuals with and without sensitive skin [18].

Limitations

The major limitation of this study was the reluctance of the Asian communities to participate in clinical research studies. Potential barriers that were the cause of this reluctance included both cultural and communication barriers. These barriers were examined and addressed prior to conducting this study to eliminate potential problems that could arise. Despite these efforts, it continued to play a major role in inhibiting the full functioning of the study

From a cultural standpoint, family obligations serve an important factor regarding Asian participation in a clinical research study. For instance, there is always a tension between responsibility to society and personal responsibility to family members [25]. This is particularly true in Asian cultures, as families served as the center focus of the individual's life [25]. Those with young children noted that looking after their families received higher priority than participating in clinical trials that could potentially be risky [25]. This brings up a second cultural concern. Many Asians fear participating in clinical trials because they believe that they are being used as a form of guinea pig [25, 26]. Most Asians want an absolute guarantee that there will be no long term side effects from the clinical study. To address these concerns, study scheduling was made with great flexibility. The study was conducted throughout the week, from 8:00 AM to 7:00 PM. Furthermore, emphasis was made to make clear that no new solutions were being tested,

but that standard solutions used in cosmetic industry to evaluate the subject's skin sensitivity.

Another barrier associated with this study included communication. In a previous study, language was the most common barrier for study participation by Asian- American women [26]. For instance, the inability to speak English was a major barrier to 50% of South Asian participation in clinical trials [25]. This lack of English fluency in understanding clinical trial methodology could lead to insecurities and doubts. This is particularly true with older Asian subjects. They believe that they are too old to learn English, causing the lack of English fluency in Asian communities to be more prominent [25]. To address this barrier, recruitment flyers and informed consent documents were translated into the subject's native languages such as Chinese, Korean, and Hindi to accommodate those that were not fluent in English. Moreover, if they could not speak or understand English, translators were available to assist with the consent process. Translators served as liaisons between the study's investigators and subjects so that all questions regarding the study could be answered.

It was anticipated that cultural and language barriers could affect some aspects of the study, ranging from the recruitment process to understanding the informed consent document to complying with study procedures. However, by addressing these barriers from the beginning, potential problems that could arise during the study were thought to be minimized.

In spite of addressing these problems, there was still resistance in the Asian communities with regard to participating in this clinical research study. During the

recruitment process, several subjects withdrew from the study due to family influences. One noted that she could not participate in the study because her husband said that he did not want her involved with solicitors. Several subjects withdrew due to family obligations. One said that she had to take care of her family and participating in the study would take too much time, even when it was clarified that the study would take less than 30 minutes. In addition, there existed a significant level of distrust among Asians with clinical research studies in general. One subject said that he saw the study advertisement in the Chinese newspaper. However, he did not contact the student investigator for more information about the study until two months later. He claimed that he wanted others to try it first to see if it was safe; then he would try it. In summary, these cultural barriers have played a major role in limiting the recruitment process.

The results from this study indicated that referrals constituted the majority of subject recruitment. For example, for Group 1, approximately 67% of the recruitments were from referrals, while only 33% were from primary sources such as newspapers and flyers. This brings up another limitation while conducting this study, time. Time was the controlling factor in Asian recruitment for clinical research study. Since referral, or word of mouth, was the method of choice based on subject response to the study, the recruitment time needed to be longer in order to achieve the desired enrollment number. This was especially important for the success of Group 2 enrollment since 100% of the recruited subjects were from referrals. However, this was not possible due to the time constraint with the approval process with IRB and sponsor, resulting in the number of recruited subjects for Group 2 to be low. It should be noted that given a longer

recruitment time, the study enrollment number would be higher since many potential subjects had contacted the student investigator after the termination of the study asking to participate.

Even though there were many limitations controlling the success of this study, overall, the study could be thought of as a success. A better understanding of the problems associated with recruiting the Asian population for clinical research study was achieved. Referral was found to be the best method to inform and recruit for Asian participation in clinical research. Future studies should consider ways to better inform the Asian population about clinical research, its purpose and potential risks. Emphasis should be given on subject safety since many Asians believed that they are being used as "guinea pigs" for clinical research study. This myth has to be addressed for future success of Asian population recruitment. Accordingly, this study has served as a pilot study for understanding Asian participation in clinical research.

Conclusions

Previous studies have indicated that the skin barrier function could be affected by geographical environmental factors such as changes in weather and climate, pollution, diet, and lifestyles [6, 20]. The conclusions from the previous studies have raised awareness among researchers that the cause of sensitive skin is more complex. As a result, self-perceived sensitive skin individuals are advised to find the root of their skin sensitivity as this sensitivity can change over time. Sensitivity caused by topical products might be lasting; however, sensitivity to geographical factors can fluctuate over time.

The results from this study showed that 20% of individuals with self-perceived

sensitive skin did not have sensitive skin. In addition, although there was a difference in mean TEWL readings between individuals with and without sensitive skin, this difference was not significant. Furthermore, there was not a significant difference for the mean TEWL readings based on geographical environments.

However, although geographical environments showed to play a minor role in affecting the skin sensitivity, this result is not conclusive as other factors could interfere with the study result. For instance, internal factors are known to have an effect on the function of the skin [6]. As a result, hormonal differences between women before and after menopausal and between gender hormone differences could affect the results of this study. However, due to the small sample size of this research, the Groups could not be divided into subgroups to study the effects of these factors on the function of the skin. Future studies should evaluate the effects of these internal factors as it could potentially play a more important role in affecting skin sensitivity. It will further aid in cosmetics and skincare research so that products could be tailored to age and gender needs.

In addition, further research needs to be conducted to address the sensitivity of TEWL for evaluating skin barrier function. More than one biophysical parameter should be measured along with TEWL to assess for changes in skin barrier function. It should also be noted that the sample size for this study was small. For future studies, a larger sample size should be targeted to better represent the Asian population in their native country and those that have been in the United States for long periods of time.

In addition, special clinical research awareness tools such as pamphlets, educational posters, or other forms of educational methods should be created to help

familiarize the Asian population with clinical research to minimize the cultural gap. Addressing this cultural gap will enhance the Asian population understanding of clinical research, leading them to be better represented in research in general.

CHAPTER III

INTERNSHIP ACTIVITIES AND EXPERIENCES

Internship Site: Clinical and Consumer Evaluation at Mary Kay Inc. in Addison, TX

The clinical research internship and the practicum activities were done in the Clinical and Consumer Evaluation (CCE) Department at Mary Kay Inc. The CCE department is further divided into groups: Clinical Safety, Clinical Efficacy, Biophysical Clinical Instrumentation, and Consumer. Each group is responsible for different aspects of product testing on humans.

Clinical Safety provides preliminary and final safety testing for Mary Kay's products. Forty-eight hour patch studies and facial discomfort test are some of the tests that evaluate for product safety. Since subject safety is set as the highest priority, these studies precede all other studies. Most often, these tests are overseen by a dermatologist or ophthalmologist. Although this group is of high importance, others are also as critical for a successful product. For instance, Clinical Efficacy is responsible for the efficacy of all products and regimens. By also utilizing dermatologist as evaluator for certain skin criteria, Clinical Safety can support variety of claims such as: reduce fine lines and wrinkles, improvement up to 33% in skin clarity, etc.

Biophysical Clinical Instrumentation evaluates skin biophysical parameters such as hydration, barrier, roughness, and sebum content. Measurements of these parameters are made possible by various instruments such as the Novameter, Vapometer, Primos 3D,

and sebumeter. Data obtained from these instruments are often used for claims substantiation, formula selection, or research guidance.

Lastly, the Consumer group is responsible for testing the final product for aesthetics. They provide consumer perception on Mary Kay's products compared to competitive brands which can provide guidance to global brand development. Some of the studies conducted in this group are prototype screening, sales force evaluation, packaging use study, and competitive assessment. In short, these studies give the company an idea about the consumer perception of the products, from the way it feels to how the packaging looks. Ultimately, even when the product passes safety and efficacy claims, if there is significant negative consumer feedback, little support is given to launch the product.

While interning at Mary Kay Inc., I was fortunate to have two on-site mentors, Ms. Hanh Pham, M.A. and Mrs. Wendi Armbrister, Ph.D., who helped me in every way to complete my internship. They have provided guidance, advice, and instructions throughout my internship. The goal of this chapter is to give an overall summary of my internship experiences and obstacles encountered at Mary Kay Inc. by way of a narrative commentary.

My Internship Experiences- What I've Learned

From the beginning, I was brief about the history of Mary Kay Inc. and its contribution to women's lives. In brief, Mary Kay Ash struggled throughout her lifetime to enrich women's lives through recognition, motivation, support, and opportunities. The company holds on to her philosophy till today; "If you think you can," goes the

Mary Kay philosophy, "you can. And if you think you can't, you're right." This philosophy has influenced women on a global scale. More than 400 National Sales Directors worldwide have average annual incomes into six figures, and more than 200 in the United States have earned over $1 million in commission. As an intern, I found the figures hard to believe, but the Emerald seminar at the Dallas Convention Center changed my view.

I was privileged to have the opportunity to attend the Mary Kay Inc.'s 45th year-Celebrating the Dream Emerald seminar. It was a fantastic experience. I heard first hand stories from sales director about how Mary Kay Inc. changed their lives. One said that she was able to pay for her son's tuition at Harvard with just one paycheck, something that she had never dreamt of before. Others said that Mary Kay's way of life have changed how they approached their family problems and life. A Mary Kay Ash famous quote:

> "Every failure, obstacle or hardship is an opportunity in disguise. Success in many cases is failure turned inside out. The greatest pollution problem we face today is negativity. Eliminate the negative attitude and believe you can do anything. Replace if I can, I hope, and maybe with I can, I will, and I must."

It is this attitude that has attributed to the company's success in the cosmetic industry thus far. The seminar was a great learning experience culturally and spiritually, but at the same time, other experiences at Mary Kay Inc. are just as important.

Attending the off-site quarterly meeting at Alphonsus's house was another

memorable experience. "The box" was the topic of discussion. "In the box" can be considered as a mindset that causes an individual to be trapped in his or her own judgment, in other words, self-betrayal. There were multiple acted scenarios during the meeting, yet the most memorable scenario was the I Love Lucy scenario.

In this scenario, Ethel came over to ask Lucy to make her Lucy's famous red velvet cake so that she could bring to Beverly's that night. Lucy promised but after Ethel left, she began to ponder why Ethel didn't just purchase one at the store. After much pondering she convinced herself that Ethel was trying to steal the next Charity Banquet Coordinator position, a position that she was running for, by using Lucy's velvet cake. Lucy didn't bother to ask Ethel; rather, she schemed up a plot to destroy the cake. At the end, Lucy learned that Ethel was making the cake to get Lucy the position and not for herself, but her scheme destroyed her chance of getting it.

Lucy's perception of Ethel changed over the course of the scenario. She first thought of Ethel as a friend. But later, when she thought Ethel was trying to steal her position, Lucy thought Ethel was a "double crossing devil". From beginning to end, Ethel was still Lucy's friend, but her skewed perception or self-deception had justified her actions to destroy the cake. I learned much from this scenario. To approach any meeting or any one, I learned to not be "in the box". When you are "in the box", self deception can cause one to change one's normal course of action, and this is called "Self Betrayal". Once you are in there, it is hard to see the actual problem. This was just one of the many things that I have learned while interning at Mary Kay Inc.

Other positive experiences lied in my everyday activities. I was fortunate to be

trained with Talisma Campaign and Remarks Office OMR by Candy. These two software applications are mostly utilized at CCE for creating questionnaires and exportation of data. For example, one of the many functions of Talisma Campaign is to personalize a survey and track responses to that survey. Potential subjects would be able to fill out the survey online by clicking the link sent via email. CCE would then be able to see the responses in the survey, such as customer satisfaction with the tested products. In the beginning, this was the method of choice for subjects in my study to fill out the screening questionnaire, but as subjects were recruited, this method was not utilized due to lack of convenience for subjects. On the other hand, the software application of choice for my study was Remark Office OMR.

Remark Office OMR is a form-processing-software for tests and surveys. The software could read bubbles and barcodes so that you could analyze your own test or survey. The scanned form data could be analyze by Remark Office OMR and exported. Knowledge of Remark Office OMR enhanced productivity and eliminated manual analysis of each answer bubbled. My screening questionnaire and lactic acid questionnaire was created with Remark Office OMR in mind. By knowing how to utilize this software, I was able to analyze my data more efficiently.

My Internship Experiences- My Struggles

In spite of many great experiences at Mary Kay Inc., I still had several hurdles to overcome. Some of the obstacles worth mentioning are recruitment obstacles, IRB obstacles, and time.

I found out mid-way through my project that all UNTHSC student projects have

to go through the UNTHSC IRB to get approval before projects could be initiated. This was a tremendous problem because that left me with a little over 2 months to gather all required documents for IRB submission, to conduct my study, and to write my internship report. Gathering all the required documents took time, as my original documents were tailored to my internship criteria and not to UNTHSC criteria. I spent over one month, and four revisions though IRB to obtain IRB approval to conduct the study. This was a significant loss of time.

However, the major obstacle I faced was recruiting enough subjects for the study. I knew from the beginning of the study that recruiting Asian for research study was not an easy task. As an Asian myself, I tried to recruit subjects based on my family lifestyles. Hanh Pham and I spent several weeks posting flyers around Asian supermarkets, Chinese and Korean churches, Asian restaurants, and UNTHSC campus. Only, 4% of the subjects were recruited based on this method. We also posted advertisements in the Korean and Chinese newspaper. However, only 6% of the subjects recruited were from the newspaper postings. In addition, I went to each floor of Mary Kay Inc. to recruit Asian employees for my study. I also asked Asian employees to refer Asian friends and families for the study. This method was 24% successful. Study enrollments were very slow at first, but slowly referrals caused a domino effect. This method was responsible for 67% of the study's subject enrollments. In spite of the domino effect, I still had trouble recruiting enough subjects. I believe that time was the greatest obstacle of all, contributing to this recruitment obstacle.

My internship began in June and ended mid November. I spent the month of June

researching and understanding skin biology while at the same time writing my proposal for my project. The beginning of July was dedicated to software application training, validation of vapometer, designing recruitment flyers, writing study protocol, creating screening questionnaire and lactic acid questionnaire documents. At the end of the month, Hanh Pham and I began posting flyers and recruiting. We started recruiting Mary Kay Inc. employees to participate in the study, hoping that they would create more referrals. Response from newspapers and flyers and referrals didn't pick up until the beginning of September. Simultaneously, IRB document problems had to be resolved with UNTHSC, and this did not resolve until mid October. By then, I had to stop recruiting in order to begin my data analysis and to draft my internship practicum report. In conclusion, time was the greatest obstacle that I had encounter during my internship.

Summing It Up

Although my internship had its ups and downs, overall, the experiences gained from my internship are irreplaceable. From this, I have gained a broader understanding of clinical research in the cosmetic industry. Moreover, I now have a deeper understanding of IRB documents and its submission process. My internship experiences have given me insights on what it takes to be a better investigator and clinical coordinator. In conclusion, these experiences will aid me in any clinical research profession, whichever I decide to pursue.

INTERN'S JOURNAL

Intern's Journal

June 2, 2008- *First Day*

- Introduction to Mary Kay Inc. via tour and Culture kit.
- Discussion about potential projects with Hanh, Wendi, Brian, and Regina
- Administrative paper work/ ID badge

June 3, 2008

- Attended Lecture at Mary Kay Inc. Manufacturing Facility (MFG)
    - *Cannabinomimetric Plant Natural Products*
      -Dr. Jurg Gertsch-
- Committee Meeting to discuss about proposal topics – *Sensitive Skin Project*
- Literature review on sensitive skin in Asian populations
- Toured of Clinical Consumer Evaluation (CCE) lab and briefing of available instruments

June 4, 2008

- Literature review on sensitive skin in Asian populations
- Read on skin biology
- Visited CCE lab for briefing of sebumeter

June 5, 2008

- Worked on Proposal
- Literature Review

June 6, 2008- *Friday*

- Attended Journal Club Meeting
    - *The Effect of Acute Social Stress on Epidermal Langerhans' Cell Frequency and Expression of Cutaneous Neuropeptides*
- Worked on Proposal
- Literature Review

June 9, 2008- *Monday*

- Conference call with Dr. Trout (Statistician)
    - Decided that there needs to be at least a 6 months gap between studied groups for stronger statistical analysis.
    - Decided that t-test and Chi –square/ Fisher Test are good test to use to analysis the data for the *Sensitive Skin Project*
- Worked on Proposal

June 10, 2008

- Worked on Proposal
- Monthly Innovation Meeting at MFG

June 11, 2008

- Worked on Proposal and submitted to Hanh for feedback

June 12, 2008

- Discussed Proposal with Hanh
- Worked on Protocol

June 13, 2008 *Friday*

- Revised Proposal and resubmitted to Hanh and Wendi
- Worked on Protocol

June 16, 2008 *Monday*

- Worked on Protocol

June 17, 2008

- Worked on Protocol
- Designed randomization list for panelists

June 18, 2008

- Discussed revised Proposal with Hanh and Wendi
- Submitted Protocol to Hanh for feedback
- Worked on recruitment flyers

June 19, 2008

- Attended Seminar
    - *Understanding dermal matrix turnover in human in- vivo: lessons learned from UV insults and acne*
      -Dr. Sewon Kang-
- Worked on Proposal
- Discussed revised Proposal with Hanh and Wendi

June 20, 2008 *Friday*

- Revised Proposal

June 23, 2008 *Monday*

- Revised Proposal and reviewed proposal with Hanh

June 24, 2008

- Worked on Screening Questionnaire

- Worked on recruitment Flyer Design

June 25, 2008
- Trained with Online Survey using Talisma
- Discussed revised Proposal with Hanh and Wendi

June 26, 2008
- Revised Proposal and submitted to Dr. Gwirtz for feedback
- Worked on recruitment flyer design
- Designed screening questionnaire using Talisma

June 26, 2008
- Revised Proposal from Dr. Gwirtz and submitted to Dr. Dimitrijevich for feedback
- Worked on recruitment flyer design

June 27, 2008- *Friday*
- Worked on recruitment flyer design
- Worked on Protocol

June 30, 2008- *Monday*
- Met with Brigida for advice on designing recruitment flyer
- Worked on recruitment flyer
- Worked on Screening Questionnaire

July 1, 2008
- Worked on Flyer
- Worked on Screening Questionnaire
- Practiced operating the Vapometer

July 2, 2008
- Met with Hanh to review Screening Questionnaire and flyer designs
- Revised Screening Questionnaire and flyer

July 3, 2008
- Designed more recruitment flyers
- Practiced operating the vapometer

July 7, 2008 *Monday*
- Finalized Screening Questionnaire and submitted to Hanh and Wendi for feedback
- Submitted Informed Consent Form to Hanh for feedback

- Submitted Lactic Acid Sting Test Questionnaire to Hanh for feedback
- Reviewed skin biology

July 8, 2008
- Finalized recruitment flyers and submitted to Hanh
- Validated Vapometer with different aperture sizes

July 9, 2008
- Attended Seminar
    - *Demands of Dermal Delivery- Formulating for Efficacy*
      -Dr. Mark Chandler-
- Revised proposal from Dr. Dimitrijevich
- Revised Lactic Acid Sting Test Questionnaire

July 10, 2008
- Validated Vapometer with different aperture sizes and settings
- Attended Off-Site Quarterly Meeting

July 11, 2008 *Friday*
- Revised Informed Consent Form
- Revised Lactic Acid Sting Test Questionnaire

July 14, 2008 *Monday*
- Searched for potential flyer posting sites
- Read on Basic Skin Biology
- Revised Proposal from Brain

July 15, 2008
- Read on Basic Skin Biology
- Continued to validate Vapometer
- Revised Proposal
- Added barcode to Lactic Acid Sting Test Questionnaires to use with Remark

July 16, 2008
- Revised Proposal and resubmitted to all Committee Members for Final Approval
- Trained with Remark Software

July 17, 2008
- Revised Informed Consent Form
- Revised Protocol
- Revised Recruitment Flyers with Chinese translation by John

July 18, 2008 *Friday*

- Vapometer validated. No significant differences between aperture size
- Revised Recruitment Flyers with Chinese translation by John
- Went to UNTHSC to submit proposal to the Graduate Office

July 21, 2008 *Monday*

- Created Screening Questionnaire with Talisma
- Revised Flyers with Hindi translation

July 22, 2008

- Revised Informed Consent
- Finished Screening Questionnaire with Talisma
- Revised Flyers with Korean translation

July 23, 2008

- Revised Protocol
- Printed and cut recruitment flyers

July 24, 2008

- Searched and mapped out Asian grocery stores around Mary Kay Inc.

July 25, 2008 *Friday*

- Searched and mapped out Asian grocery stores around Mary Kay Inc.

July 28, 2008 *Monday*

- Attended Emerald Seminar at Dallas Convention Center
- Reviewed Literature on sensitive skin in Asian populations to be used in thesis

July 29, 2008

- Reviewed Literature on sensitive skin in Asian populations to be used in thesis
- Followed up with Candy with regards to internal recruitment
- Searched and mapped out Asian grocery stores around Mary Kay Inc.

July 30, 2008

- Contacted Elsevier Publishing Company for permission to use skin images from book in thesis
- Revised Protocol

July 31, 2008

- Revised Protocol
- Mapped out Asian grocery stores with driving directions

August 1, 2008 *Friday*

- Prepared recruitment flyers for posting
- Posted recruitment flyers at nearby Asian Grocery Stores

August 4, 2008 *Monday*

- Recruited company's employee for study.
- Searched for nearby Churches

August 5, 2008

- Recruited company's employee for study.
- Searched for nearby Churches

August 6, 2008

- Recruited company's employee for study.
- Searched for nearby Churches

August 7, 2008

- Posted flyers at Churches
- Contacted Asian newspaper for advertisement options
- Translated Informed Consent in Korean using online software
- Scheduled panelists for 08/13/08 research study

August 8, 2008 *Friday*

- Attended Journal Club Meeting
    - *Hormetic modulation of differentiation of normal human epidermal keratinocytes undergoing replicative senescence in vitro*
- Contacted Asian newspaper for advertisement options
- Revised Protocol

August 11, 2008 *Monday*

- Gathered required documents for 08/13/08 research study

August 12, 2008

- Prepared Lactic Acid for 08/13/08 research study
- Attended Monthly Innovation Meeting at MFG
- Revised Protocol and submitted to Hanh for final review

August 13, 2008

- Conducted Sensitive Skin research study
- Recruited panelists for research study

August 14, 2008

- Attended RCTS meeting
- Recruited panelists for study
- Completed IRB submission form

August 18, 2008 *Monday*

- Gathered required documents for 08/19/08 research study
- Prepared Lactic Acid for 08/19/08 research study
- Drafted Protocol Synopsis for IRB submission

August 19, 2008

- Conducted Sensitive Skin research study
- Revised IRB submission forms
- Drafted Protocol Synopsis for IRB submission

August 20, 2008

- Contacted newspaper to submit flyers
- Drafted Protocol Synopsis for IRB submission
- Helped Candy with qualification study

August 21, 2008

- Attended Society of Cosmetic Chemists Educational Seminar

August 22, 2008 *Friday*

- Attended conference call with Dr. Gwirtz and Hanh regarding IRB submission
- Revised Consent Form following UNTHSC guidelines

August 25, 2008 *Monday*

- Recruited panelists for study
- Submitted Revised Consent Form to Hanh for review

August 26, 2008

- Recruited panelists for study
- Revised Protocol Synopsis for IRB Submission

August 27, 2008

- Recruited panelists for study
- Revised Protocol Synopsis according to Jill's comment
- Revised Consent Form according to Jill's comment

August 28, 2008

- Recruited panelists for study

- Revised Protocol Synopsis according to Jill's comment
- Revised Consent Form according to Jill's comment

August 29, 2008 *Friday*

- Recruited panelists for study
- Revised Protocol Synopsis according to Jill's comment
- Revised Consent Form according to Jill's comment
- Reviewed IRB Submission paperwork with Hanh
- Gathered required documents for 09/02/08 research study

September 2, 2008

- Prepared Lactic Acid for 09/02/08 research study
- Conducted Sensitive Skin research study
- Reviewed IRB Submission

September 3, 2008

- Prepared Lactic Acid for 09/04/08 research study
- Gathered required documents for 09/04/08 research study
- Recruited panelists for study

September 4, 2008

- Conducted Sensitive Skin research study
- Recruited panelists for study
- Contacted Dallas Chinese Times Newspaper to put ad in newspaper

September 5, 2008 *Friday*

- Recruited panelists for study
- Reviewed IRB Submission

September 8, 2008 *Monday*

- Contacted Hanuri Church for potential panelists
- Recruited panelists for study
- Prepared Lactic Acid for week of 09/09/08 research study
- Gathered required documents for 09/09/08 research study
- Met with Candy for potential referrals from current Asian panelist database

September 9, 2008

- Attended Monthly Innovation Meeting at MFG
- Conducted Sensitive Skin research study
- Gathered required documents for 09/10/08 research study

September 10, 2008

- Conducted Sensitive Skin research study
- Gathered required documents for 09/11/08 research study
- Submitted IRB Application/ paperwork to UNTHSC IRB office

September 11, 2008

- Conducted Sensitive Skin research study
- Gathered required documents for 09/12/08 research study
- Recruited panelists for study

September 12, 2008 *Friday*

- Conducted Sensitive Skin research study
- Prepared Product Listing for Hanh
- Entered TEWL Readings into Excel
- Gathered required documents for 09/15/08 research study

September 15, 2008 *Monday*

- Recruited panelists for study
- Prepared Lactic Acid for 09/15/08 research study
- Conducted Sensitive Skin research study

September 16, 2008

- Recruited panelists for study
- Began Internship Practicum Report draft
- Checked TEWL Readings input in Excel

September 17, 2008

- Reviewed Literature on sensitive skin in Asian populations to be used in Practicum Report
- Recruited panelists for study
- Designed Spreadsheet to input Lactic Acid Scores
- Gathered required documents for 9/18/08 research study

September 18, 2008

- Helped Candy with the front desk duties
- Conducted Sensitive Skin research study
- Gathered required documents for 9/19/08 research study
- Updated TEWL Readings in Excel

September 19, 2008- *Friday*

- Conducted Sensitive Skin research study
- Updated TEWL Readings in Excel

- Scanned study documents into RGT-shared drive

September 22, 2008- *Monday*

- Prepared Lactic Acid for week of 09/22/08 research study
- Gathered required documents for 09/23/08 research study
- Reviewed Literature on sensitive skin in Asian populations to be used in Practicum Report
- Helped Candy with packaging of products for shipping

September 23, 2008

- Conducted Sensitive Skin research study
- Gathered required documents for 09/24/08 research study
- Revised Protocol Synopsis and Consent Form according to Sharon's comment.
- Update TEWL readings in Excel
- Reviewed Literature on sensitive skin in Asian populations to be used in Practicum Report

September 24, 2008

- Conducted Sensitive Skin research study
- Gathered required documents for 09/25/08 research study
- Update Product Listing for Hanh
- Began outlining Practicum Report
- Helped Tierney with labeling for 09/25/08 Facial Discomfort Study
- Met with Hanh and Wendi for defense date consensus

September 25, 2008

- Conducted Sensitive Skin research study
- Gathered required documents for 09/26/08 research study
- Began writing the Introduction of Practicum Report
- Updated TEWL Readings in Excel
- Helped Candy with the front desk duties

September 26, 2008- *Friday*

- Conducted Sensitive Skin research study
- Gathered required documents for 09/29/08 research study
- Continued writing the Introduction of Practicum Report
- Updated TEWL Readings in Excel
- Helped Candy with the front desk duties

September 29, 2008- *Monday*

- Prepared Lactic Acid for week of 09/29/08 research study
- Conducted Sensitive Skin research study

- Gathered required documents for 09/30/08 research study
- Continued writing the Introduction of Practicum Report
- Finalized Draft 2 of IRB submission documents
- Submitted IRB Draft 2 to Hanh for feedbacks

September 30, 2008
- Conducted Sensitive Skin research study
- Gathered required documents for 10/01/08 research study
- Continued writing the Introduction of Practicum Report
- Created Screening Questionnaire in Remark for future data analysis

October 1, 2008
- Conducted Sensitive Skin research study
- Continued writing the Introduction of Practicum Report

October 6, 2008- *Monday*
- Prepared Lactic Acid for week of 10/06/08 research study
- Started writing the Specific Aims of Practicum Report

October 7, 2008
- Continued writing the Specific Aims of Practicum Report
- Attended IRB Review at UNTHSC
- Gathered required documents for 10/08/08 research study

October 8, 2008
- Conducted Sensitive Skin research study
- Gathered required documents for 10/09/08 research study
- Continued writing the Specific Aims of Practicum Report
- Helped Candy with scanning files

October 9, 2008
- IRB Approved *Evaluation of Sensitive Skin in Asian Population Research Study*
- Conducted Sensitive Skin research study
- Gathered required documents for 10/10/08 research study
- Continued writing the Specific Aims of Practicum Report
- Started writing the Methodology of Practicum Report

October 10, 2008- *Friday*
- Conducted Sensitive Skin research study
- Gathered required documents for 10/11/08 research study
- Continued writing the Methodology of Practicum Report
- Gathered required documents for 10/13/08 research study

October 13, 2008- *Monday*

- Prepared Lactic Acid for week of 10/13/08 research study
- Conducted Sensitive Skin research study
- Continued writing the Methodology of Practicum Report
- UNTHSC Recruitment

October 14, 2008

- Monthly Innovation Meeting at MFG
- Continued writing the Methodology of Practicum Report
- UNTHSC Recruitment

October 15, 2008

- Continued writing the Methodology of Practicum Report
- UNTHSC Recruitment
- Helped Sharon with labeling of products for shipping

October 16, 2008

- Began Writing Internship Experience section of Practicum Report
- UNTHSC Recruitment
- Helped Sharon with labeling of products for shipping

October 20, 2008- *Monday*

- Continued writing Internship Experience section of Practicum Report
- UNTHSC Recruitment
- Helped Sharon with labeling of products for shipping

October 21, 2008

- Continued writing Internship Experience section of Practicum Report
- UNTHSC Recruitment
- Revised Introduction Section of Practicum Report according to Dr. Gwirtz comments
- Helped Sharon with labeling of products for shipping

October 22, 2008

- Scanned Data into Remark
- Verified Data Scanned

October 23, 2008

- Calculated Lactic Acid Scores
- Start Data Analysis Fisher Exact Test

October 24, 2008- *Friday*

- Continued Data Analysis
- Conference call with Dr. Biswas (UNTHSC Biostatistics Professor)
    - Confirmed that can use T-test for comparing within group data; therefore have agreed on not using Paired – T-test
    - Confirmed that can use Mann-Whitney Test along with T-test for more information.
- Helped Sharon with labeling of products for shipping

October 27, 2008- *Monday*

- Continued Data Analysis
- Helped Sharon with labeling of products for shipping

October 28, 2008

- Continued Data Analysis
- Began writing Results Section
- Helped Sharon with labeling of products for shipping

October 29, 2008

- Continued Data Analysis
- Continued writing Results Section
- Began writing Discussion Section
- Helped Sharon with labeling of products for shipping

October 30, 2008

- Continued writing Results Section
- Began writing Discussion Section
- Meeting with Hanh and Wendi regarding data analysis

October 31, 2008- *Friday*

- Continued writing Results Section
- Continued writing Discussion Section
- Conference call with Dr. Trout (Statistician)
    - Decided that un-paired T-Test was inapproiate for comparing intra- group TEWL
    - Decided that Factorial ANOVA should be used along with T-Test for more in-depth conclusions.

November 3, 2008- *Monday*

- Submitted 2nd part (Results, Discussions, Experiences) of Report to Gwirtz for feedbacks
- Submitted 1st part (Introduction, Specific Aims, Methods) of Report to Hanh and Wendi for feedbacks

- Entered 2008- Clinical Study Survey of subjects for this study into database

November 4, 2008
- Entered 2008- Clinical Study Survey of subjects for this study into database
- Revised 2nd part of Report according to Dr. Gwirtz's feedbacks

November 5, 2008
- Helped Candy with updating recruitment schedule for 2951-2953 study
- Revised 2nd part of Report according to Dr. Gwirtz's feedbacks
- Submitted 2nd part (Results, Discussions, Experiences) of Report to Hanh and Wendi for feedbacks

November 6, 2008
- Began working on PowerPoint
- Helped Candy with updating recruitment schedule for 2951-2953 study
- Revised 2nd part of Report according to Dr. Gwirtz's feedbacks
- Submitted 2nd part (Results, Discussions, Experiences) of Report to Hanh and Wendi for feedbacks

November 7, 2008- *Friday*
- Continued working on PowerPoint

November 10, 2008- *Monday*
- Continued working on PowerPoint
- Continued to revised Practicum Report

November 11, 2008
- Continued working on PowerPoint
- Continued to revised Practicum Report
- Monthly Innovation Meeting at MFG

November 13, 2008
- Continued working on PowerPoint
- Continued to revised Practicum Report
- Received Hanh's feedbacks for Practicum Report Part 1

November 14, 2008- *Friday*
- Practice for presentation
- Presented presentation to Hanh and Wendi

November 17, 2008- *Monday*
- Continued to revise PowerPoint

- Continued to revised Practicum Report

November 18, 2008

- Continued to revised Practicum Report
- Meet with Dr. Gwirtz for feedbacks on PowerPoint

November 19, 2008- *Last Day*

- Continued working on PowerPoint
- Continued to revised Practicum Report
- Returned study materials and documents to Hanh

APPENDICES

APPENDIX A

Screening Questionnaire Response Statistics

Questions (1-6)		Response (%)	
		YES	NO
1	Are you currently under the care of a Dermatologist?	1	99
2	Have you been diagnosed with psoriasis, eczema, rosacea by a physician?	6	94
3a	Does your face tend to turn red when you take hot showers?	61	39
3b	Does your face tend to turn red when you are exposed to hot/cold weather?	75	25
3c	Does your face tend to turn red when you exercise?	79	21
3d	Does your face tend to turn red when you eat spicy food?	47	53
3e	Does your face tend to turn red when you drink alcoholic beverages?	63	37
4a	Does your face tend to itch when you take hot showers?	32	68
4b	Does your face tend to itch when you are exposed to hot/cold weather?	55	45
4c	Does your face tend to itch when you exercise?	37	63
4d	Does your face tend to itch when you eat spicy food?	30.5	69.5
4e	Does your face tend to itch when you drink alcoholic beverages?	28	72
5a	Do you experience burning sensation on your face when you take hot showers?	27	73
5b	Do you experience burning sensation on your face when you are exposed to cold/hot weather?	48	52
5c	Do you experience burning sensation on your face when you exercise?	28	72
5d	Do you experience burning sensation on your face when you eat spicy food?	28	72
5e	Do you experience burning sensation on your face when you drink alcoholic beverages?	30.5	69.5
6a	Does your skin easily react to cosmetic/ skincare products?	67	33
6b	Do you tend to avoid using the products after the reaction?	81	19

APPENDIX B

Screening Questionnaire Form

CONTACT INFORMATION (please print):

Last Name:_____First Name:_____MI: _____

Physical Address: _____

City_____State_____Zipcode_____

Daytime Phone Number(s) :(____)_____
Evening Phone Number(s) :(____)_____
Email Address:_____

Contact Preference(s): O Daytime Phone O Evening Phone O Email

DEMOGRAPHICS

What is your gender?

O Male

O Female

Are you between the ages of 18-65?

O YES

O NO

What is your ethnicity?
O Asian/ Pacific Islander
O African America
O Caucasian
O Hispanic
O Native American

How long have you lived in the US?____ Where did you lived before_____?

How did you hear about our study?_____.

When is the most convenient day/ time for you to come to participate in our study?_____

<u>Please Bubble in YES/ NO for the following questions.</u>

1. **Are you currently under the care of a DERMATOLOGIST/ Skin doctor?**

   O YES O NO

2. **Have you been diagnosed with PSORIASIS, ECZEMA, or ROSACEA by a physician?**

   O YES O NO

3. **Does your face tend to turn RED when you…? Respond to all of the followings:**

   Take Hot Showers

   O YES O NO

   Expose to cold/ hot weather

   O YES O NO

   Exercise

   O YES O NO

   Eat spicy foods

   O YES O NO

   Drink alcoholic beverages

   O YES O NO

4. **Does your face tend to ITCH when you…? Respond to all of the followings:**

   Take Hot Showers

   O YES O NO

   Expose to cold/ hot weather

O YES O NO

Exercise

O YES O NO

Eat spicy foods

O YES O NO

Drink alcoholic beverages

O YES O NO

5. Do you experience BURNING sensation on your face when you...? Please respond to all of the followings:

Take Hot Showers

O YES O NO

Expose to cold/ hot weather

O YES O NO

Exercise

O YES O NO

Eat spicy foods

O YES O NO

Drink alcoholic beverages

O YES O NO

6a. Does your skin easily react to cosmetic/ skincare product(s)?

O YES O NO

6b. Do you tend to avoid those product(s) after the reaction?

O YES O NO

7. Overall, do you considered yourself to have sensitive skin?

O YES O NO

8. **How long have you had SENSITIVE SKIN?**

   O **Years_____# of Years**

   O **Months _____# of Months**

9. **Are you currently pregnant/ planning to be pregnant/ nursing?**

   O **YES** O **NO**

THANK YOU FOR COMPLETING OUR QUESTIONNAIRE!!!

For Office Use Only:
Panelist ID:_____

APPENDIX C

LACTIC ACID STING TEST'S QUESTIONNAIRE WITH TEWL MEAURESMENTS

Name:_____ **Date:**_____ **Panelist ID:**_____

TEWL READINGS: 1)_____ **2)** _____ **3)** _____

TEWL readings taken on _____ **side. ROOM TEMP:** _____ **HUMIDITY:** _____

INSTRUCTIONS:
Please record any sensory irritation (for example stinging burning) you notice on either side of your nose/cheek (**please ignore cooling**).

MARKING INSTRUCTIONS

Use pencil only.

Make solid marks that fill the response completely.

Erase cleanly any marks you wish to change.

Do not fold or un-staple this questionnaire.

Correct: ● **Incorrect:**

INSTRUCTIONS: Please record any sensory irritation (for example stinging burning) you notice on either side of your nose/cheek (**please ignore cooling**).

IMMEDIATELY AFTER APPLICATION

TIMER READS 4:30

LEFT	RIGHT
1. PRODUCT CODE _____	**2. PRODUCT CODE** _____
1a. Describe the nature of the reaction: Cheek/Nose: None O, Itching O, Stinging O, Burning O	**2a. Describe the nature of the reaction:** Cheek/Nose: None O, Itching O, Stinging O, Burning O

1b. Rate degree of reaction:

None	Barely Perceptible	Slightly Perceptible	More than slightly perceptible	Moderately Perceptible	More than moderately perceptible	Severely Perceptible
0	0.5	1.0	1.5	2.0	2.5	3.0
O	O	O	O	O	O	O

2b. Rate degree of reaction:

None	Barely Perceptible	Slightly Perceptible	More than slightly perceptible	Moderately Perceptible	More than moderately perceptible	Severely Perceptible
0	0.5	1.0	1.5	2.0	2.5	3.0
O	O	O	O	O	O	O

TIMER READS 2:30

LEFT	RIGHT
1c. Describe the nature of the reaction: Cheek/Nose: None O, Itching O, Stinging O, Burning O	**2c. Describe the nature of the reaction:** Cheek/Nose: None O, Itching O, Stinging O, Burning O

1d. Rate degree of reaction:

None	Barely Perceptible	Slightly Perceptible	More than slightly perceptible	Moderately Perceptible	More than moderately perceptible	Severely Perceptible
0	0.5	1.0	1.5	2.0	2.5	3.0
O	O	O	O	O	O	O

2d. Rate degree of reaction:

None	Barely Perceptible	Slightly Perceptible	More than slightly perceptible	Moderately Perceptible	More than moderately perceptible	Severely Perceptible
0	0.5	1.0	1.5	2.0	2.5	3.0
O	O	O	O	O	O	O

END OF 5 MINUTES

TIMER BEEPS

LEFT	RIGHT
1e. Describe the nature of the reaction: Cheek/Nose: None O, Itching O, Stinging O, Burning O	**2e. Describe the nature of the reaction:** Cheek/Nose: None O, Itching O, Stinging O, Burning O

1f. Rate degree of reaction:

None	Barely Perceptible	Slightly Perceptible	More than slightly perceptible	Moderately Perceptible	More than moderately perceptible	Severely Perceptible
0	0.5	1.0	1.5	2.0	2.5	3.0
O	O	O	O	O	O	O

2f. Rate degree of reaction:

None	Barely Perceptible	Slightly Perceptible	More than slightly perceptible	Moderately Perceptible	More than moderately perceptible	Severely Perceptible
0	0.5	1.0	1.5	2.0	2.5	3.0
O	O	O	O	O	O	O

APPENDIX D

Transepidermal Water Loss Readings (g/m^2h)

ID #	Side	1st Reading	2nd Reading	3rd Reading	Relativity Humidity (%)	Temperature (°C)
101	R	33.7	23.6	29.2	36	25
102	L	24.4	24.1	16.6	35	24
103	L	25.6	20.6	17.1	33	25
104	R	20.4	11.4	11.0	31	25
105	R	40.6	27.1	26.7	38	24
106	R	27.5	25.2	23.4	30	26
107	L	33.3	16.8	20.0	30	26
108	L	32.0	20.6	21.4	35	22
109	R	30.8	19.3	24.7	31	26
110	L	25.6	22.0	20.7	32	25
111	R	37.6	26.5	30.8	30	26
112	L	35.2	34.5	26.3	35	23
113	L	23.9	19.8	20.2	39	22
114	R	27.5	19.9	16.7	32	22
115	R	38.9	28.6	31.3	35	22
116	R	24.2	14.7	15.1	35	22
117	L	25.0	20.5	16.0	34	23
118	L	39.4	36.0	32.3	35	22
119	L	23.7	17.6	14.1	38	22
120	R	19.9	34.9	22.3	41	23
121	R	31.2	14.7	19.4	33	25
122	L	29.7	19.7	23.2	40	22
123	L	19.6	25.0	24.8	43	21
124	L	21.0	16.8	24.2	35	22
125	R	33.4	20.3	22.7	39	24
126	L	21.2	24.1	17.5	37	23
127	L	13.2	29.1	13.1	40	23
128	L	21.6	22.7	21.2	46	20
129	L	30.4	20.3	19.4	36	23

ID #	Side	1st Reading	2nd Reading	3rd Reading	Relativity Humidity (%)	Temperature (°C)
130	R	13.4	12.1	15.0	40	21
131	R	14.1	9.2	14.6	46	21
132	R	26.4	23.7	19.5	38	22
133	R	29.4	16.2	20.0	40	20
134	L	42.0	41.4	33.9	35	22
135	R	25.3	27.4	22.3	40	23
136	R	15.3	23.8	26.5	33	23
137	L	50.0	49.4	50.7	36	25
138	L	32.3	20.7	21.0	40	22
139	L	39.2	34.2	33.3	40	24
140	R	33.4	30.9	21.3	38	24
141	R	18.6	20.2	13.9	37	24
142	R	23.7	27.3	25.1	39	25
143	L	25.2	20.0	24.4	36	25
144	R	22.4	22.0	11.1	40	21
145	R	20.4	20.5	20.4	40	22
146	R	27.3	21.3	19.9	37	23
147	R	37.3	28.4	32.0	40	24
148	R	32.7	22.8	22.1	40	21
149	L	49.5	35.4	23.8	39	22
150	R	31.5	26.2	30.0	40	22
151	L	26.4	30.3	25	37	28
152	L	23.0	17.3	17.7	40	25
153	R	18.9	27.9	28.5	38	23
154	L	24.4	24.2	24.4	38	24
155	L	23.8	15.1	17.4	42	22
156	L	21.3	16.0	17.3	40	21
157	L	18.3	20.0	15.1	40	20
158	R	15.9	17.5	17.3	40	22
159	R	11.5	13.5	17.0	42	20
160	R	21.2	17.7	13.6	42	20
161	R	25.8	20.1	25.4	36	23
162	R	17.8	21.6	16.0	39	23
163	L	21.9	22.6	21.4	38	25
164	R	19.9	14.0	20.0	38	25
165	L	33.6	25.3	25.4	39	25
166	R	17.7	25.1	23.3	40	26

ID #	Side	1st Reading	2nd Reading	3rd Reading	Relativity Humidity (%)	Temperature (°C)
167	L	23.8	24.0	15.0	35	23
168	L	25.0	33.6	28.1	37	22
169	R	33.0	26.1	24.8	36	23
170	R	28.7	21.8	16.9	35	23
171	L	50.9	54.9	54.3	35	22
172	L	37.6	27.6	21.3	33	22
173	L	23.0	21.4	21.2	37	21
174	L	22.9	36.9	28.8	35	23
175	L	31.0	39.1	29.1	39	23
176	L	34.4	30.7	37.8	40	23
177	L	21.8	31.9	27.2	39	21
178	L	25.7	30.8	28.3	37	23
179	R	35.1	30.5	29.2	36	22
180	R	35.7	38.4	32.3	39	22
181	R	25.8	22.7	22.6	40	21
182	L	22.9	31.4	27.4	39	21
183	R	29.3	27.6	28.6	39	21
184	L	25.4	21.1	24.4	39	21
185	L	38.9	32.1	41.9	39	21
201	R	28.7	12.5	17.9	31	25
202	L	26.0	23.9	24.9	33	24
203	L	18.9	24.9	34.3	40	26
204	R	22.4	12.2	17.8	33	27
205	R	14.7	16.9	12.3	40	20
206	R	27.9	16.4	20.0	40	22
207	L	29.6	24.3	18.7	40	21
208	L	34.3	24	22.1	42	23
209	R	21.9	20.9	24.2	40	23
210	L	10.5	16.5	16.7	40	21

APPENDIX E

Lactic Acid Sting Test Scores

	Product		SCORE AT 30 SECONDS		SCORE AT 2.5 MINUTES		SCORE AT 5 MINUTES	
ID #	LT	RT	LT	RT	LT	RT	LT	RT
101	641	368	1.5	1.5	0	1.5	0	2.5
102	641	368	0	0	1.5	1.5	2.5	2.5
103	368	641	2	0.5	3	1.5	3	2.5
104	368	641	1.5	0	2	0	2.5	0
105	368	641	2	0	2	0	2.5	0
106	641	368	0	0	0	0	0	0.5
107	368	641	2	0	1.5	0	1	0
108	641	368	0	0	0.5	1	0.5	1.5
109	641	368	0	0	0	1	0	2
110	368	641	0	0	1.5	0	2.5	0
111	368	641	2	0	2.5	1	3	1.5
112	641	368	0	0	0.5	1.5	2	2.5
113	368	641	0	0	1.5	0	2	0
114	641	368	0	1	0	1.5	0	2
115	641	368	0	2	0	2	0	2.5
116	641	368	0	0	0.5	0.5	0.5	0.5
117	368	641	1	1	1.5	1.5	2.5	1
118	368	641	1	0	2.5	0	3	0
119	641	368	0	0	2	2	2	2.5
120	368	641	0.5	0	1.5	0	2	0
121	368	641	0	0	1	0	0	0
122	641	368	0	2	0	2	0	2
123	368	641	2.5	0	3	0	3	0
124	368	641	0	1.5	2	1.5	2.5	0.5
125	368	641	0	0	1	0.5	2	0.5
126	641	368	0	1	0	1.5	0	2
127	641	368	0	0	0	0.5	0	1
128	641	368	0	1	0	1.5	0	2.5
129	368	641	0	0	1	0	0.5	0
130	368	641	0	0	1	1	1.5	1.5

	Product		SCORE AT 30 SECONDS		SCORE AT 2.5 MINUTES		SCORE AT 5 MINUTES	
ID #	LT	RT	LT	RT	ID #	LT	RT	LT
131	368	641	0	0	1.5	0	2	0
132	368	641	0	0	0	0	1	0
133	641	368	0	0	0	1	0	1.5
134	368	641	2	0	2.5	0	2.5	0.5
135	368	641	0	0	1	1	2.5	2
136	641	368	0.5	1	0.5	1.5	0.5	3
137	368	641	0.5	0	1.5	0	2.5	0
138	368	641	0	0	0.5	0	0.5	0
139	368	641	0	0	0	0	0	0
140	641	368	0	0	0.5	0	0.5	0
141	641	368	0.5	2	0	3	0	3
142	368	641	0	0	1	0	1	0
143	368	641	0.5	0	1	0	2	0
144	641	368	0.5	0.5	0	1	0.5	1.5
145	368	641	1	1	0.5	0.5	0.5	0
146	641	368	0	0	0	1.5	0	2
147	641	368	0.5	1	0.5	1	1	1
148	368	641	1.5	0	1.5	0	2	0
149	368	641	0	0	1	0	2	0
150	641	368	0	0.5	0	1.5	0	1.5
151	368	641	0	0	0	0	2.5	0
152	368	641	0	0	0	0	0	0
153	641	368	0	0.5	0	0.5	0	1
154	641	368	0	1	1.5	2	2	2.5
155	641	368	0	0	0	1	0	2
156	641	368	0	0	0.5	0.5	1	1
157	368	641	0	0	3	0	3	0
158	368	641	1.5	0	1.5	0	1.5	0
159	641	368	0	0	0	1	0	1
160	368	641	1	0	1.5	0	2	0
161	641	368	0	1	0.5	1.5	0.5	1.5
162	641	368	0	0.5	0	0.5	0	0.5
163	368	641	0	0	0.5	0	2	0
164	641	368	0	0	0.5	1	0	3
165	368	641	1	0	1.5	0	1.5	0
166	641	368	0	1	0	1.5	0	2
167	368	641	0	0	0	0	2	0
168	641	368	0	0	2.5	2.5	2	3
169	368	641	2.5	0	1.5	0	1.5	0
170	641	368	0	1	0	2.5	0	3
171	641	368	0	2	0	3	0	3
172	641	368	0	0	1	0	1.5	1

	Product		SCORE AT 30 SECONDS		SCORE AT 2.5 MINUTES		SCORE AT 5 MINUTES	
ID #	LT	RT	LT	RT	ID #	LT	RT	LT
173	641	368	0	0	0	1	0	2
174	368	641	1	0	1.5	0	1.5	0
175	368	641	0	2	0.5	2	1	2
176	368	641	0	0	0	0	1	0
177	368	641	0	0	1.5	0	2	0
178	641	368	0	0	0	0.5	0	1
179	641	368	0	1	0	0.5	0	0.5
180	641	368	0	2	0	2.5	0	2.5
181	368	641	0	0	0	0	1.5	0
182	368	641	1	0	1.5	0	1.5	0
183	368	641	0.5	0	0.5	0	1	0
184	641	368	0	0.5	0	0	0	0
185	641	368	0.5	1.5	0.5	1.5	0.5	1.5
201	641	368	0	1	0	2	0	3
202	641	368	0	1	0	3	0	3
203	641	368	0	2.5	0.5	2	0	3
204	368	641	1	0	1.5	0	3	1
205	368	641	0	0	2.5	0	3	0
206	641	368	1	0	0	0	0	1.5
207	368	641	0	0	1.5	0	2	0
208	641	368	0	0	0	2	0	2
209	641	368	0	0	0	0	1	1.5
210	368	641	0	0	0	0	0.5	0

CHAPTER IV

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