ISBS World Congress Tampa, USA, 2011
BOOK of ABSTRACTS

(**O-01**)
Historic perspective of Clinical Research

Neelam Muizzuddin, PhD

Three major events had the biggest impact on shaping federal regulations that are in force today, namely the Doctors' Trial, The Nuremberg Code and regulations after it was established that Thalidomide caused birth deformities. The Declaration of Helsinki, was developed by the World Medical Association (WMA) as a set of ethical principles for the medical community regarding human experimentation. On April 18, 1979 The *Belmont Report* was created entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and is an important historical document in the field of medical ethics which focuses on protecting the autonomy of all research subjects allowing for informed consent. In addition, the important factors in an informed consent will be discussed.

(**O-02**)
Techniques for evaluating instrumental performance

Gary Grove, PhD

It is generally appreciated that there are various instruments such colorimeters, evaporimeters, conductance meters, etc. that measure different aspects of skin structure and function noninvasively which are now readily available from several commercial sources. Indeed, many of these instruments have become so user friendly, that little or no training is required before the operator can begin to take measurements. Seldom is any concern given to whether or not the instrument was properly calibrated, the measurements correctly performed or even the instrument was suitable for the application for which it is being utilized. In this presentation, we will introduce some basic concepts from metrology, the science of measurement. Chief among these is the use of traceable physical standards to determine the accuracy, precision and reliability of the measurement. Methods for evaluating the performance of the measurement device and operator competence will be presented and illustrated with case studies of some of the more popular devices.

(**O-03**)
Research studies in the real world

Randy Wickett, PhD

Conducting skin research studies in the "real world", i.e., settings such as factories, hospitals, clinics and intensive care units presents unique challenges but may be necessary to achieve study goals. In clinical research laboratories it is possible to control many variables that may affect biophysical measurements on skin. Environment can be controlled and subjects can be equilibrated to that environment. This may not be possible in a work place. However, real world studies may be more appropriate given that both the skin exposure and interventions designed to modify the results of exposure will occur in the workplace with its "uncontrolled" environment.

We have been conducting skin research in hospital settings for several years on both patients and staff. This talk will focus on our studies on staff in the Neonatal Intensive Care Unit at Cincinnati Children's Hospital Medical Center to illustrate the strategies, general requirements and issues that can occur. The first step is to ensure cooperation and "buy in" from both the staff and the supervisory personnel and to manage the perceptions of "time away from patient care". Second, the study schedule must be adjusted to fit the work schedule of the subjects. This requires creativity in the research design to reflect realistic product usage and may require making measurements at either the beginning or end of shifts because the subjects may not be able to take time off to equilibrate during the work period. This will mean long hours for those making the measurements, e.g. 6 am and again at 6 pm for several hours. Equilibration times will have to be adjusted and environmental control will not be a good as in a testing lab. It is also necessary to find a space to safely do the measurements, securely store equipment and provide adequate control of aspects such as "time from last product application" and to control the environment as much as possible. Some changes in measurement technology may be required providing a role for groups such as the ISBS. For example, we find that closed chamber TEWL measurements may be more reliable than open chamber due to inability to control air flow. Photography will require excellence in standardization for lighting and subject positioning to color correct the images and insure the ability to compare them over the treatment period. Electrical measurements (Corneometer® or NOVA DPM®) are more forgiving than TEWL even under less than ideal conditions since they rely on probe contact for moisture determination. Study personnel must also be sensitive to high level of stress that subjects may be under due to their work. Flexibility, persistence, patience and the ability to negotiate when subjects are unexpectedly called to duty are highly desirable traits in study personnel.

(**O-04**)
From bench to skin-side: The "soft" requirements to turn a concept into a successful clinical study

Joachim Fluhr, MD

New molecules both for topical drugs and cosmetics are developed by high-throughput screening assays and in in vitro methods. Subsequently these new products need clinical validation in healthy volunteers or defined patient populations. The controlled studies for efficacy testing both in topical drugs and cosmetic studies have to follow specific regulatory and ethical requirements. Furthermore published guidelines should be integrated in the protocol design in cosmetic testing especially for non-invasive biophysical instrumentation. Choosing meaningful endpoints in study design based on the original mechanisms discovered in the in vitro studies will be discussed in this presentation. Another important point, factors that influence the accuracy of in vivo measurements and the critical evaluation of the results on the background of these influencing factors is of great importance. Examples in developing meaningful test designs based on new concepts will be presented and discussed.

(**O-05**)
Skin Statistics Basic and Applied

James P. Bowman

This talk will provide an understanding to the team approach to designing studies, discuss ways to get involved with your data (i.e. don't leave it all to the statistician), explain the meaning of a significance test and continue to re-iterate the message to "Involve your local statistician".

The outline for the talk is as follows:
- Study Design
- Data Description
- The essential nature of a Significance Test
- Non-Significant p-values
- Statistical Tools available
- Types of statistics used in skin testing
- What can go wrong when you choose the wrong test? (and don't use a statistician)
- Clinical vs Statistical Significance

(**O-06**)
Elements of a Perfect* Clinical Claims Support Study Design

Judy Woodford, PhD

At first glance, it seems easy to set the basic elements of a perfect* clinical claims study: subject qualification, panel size, product application, measurements, calculations. But how do you know what factors are impacting these elements? Why would this study which is just fine for formulation guidance, not work so well for claims support? Why might this study be sufficient in the US or Canada, but not in the UK? How do you choose the proper subjects? How do you figure out the best measurement tool? How do you determine the best timing for applying the product and taking measures? What are suitable controls? This session will explore how your internal and external clients influence good claims study design.
*Study design accepted by the relevant external facility in support of Marketing's most highly desired claims wording.

(**O-07**)
Photoaging: New Concepts for Old Skin

Barbara A. Gilchrest, MD
Department of Dermatology, Boston University School of Medicine, Boston, MA

Photoaging is the superposition of chronic UV damage on the intrinsic aging process in skin. In addition to ultraviolet radiation, carcinogens present in cigarette smoke and air pollution may aggravate or accelerate these unwanted age-associated changes. Indeed, most changes in habitually exposed skin are due to environmental factors rather than to chronologic aging, but the underlying molecular mechanisms for both processes appear to overlap substantially. Both result from the interrelated phenomena of signaling imbalances that affect gene transcription, oxidative stress, cumulative DNA damage, and telomere shortening. In particular, recent insight into the role of telomeres in cellular senescence (aging) and DNA damage responses have suggested that telomere-based protective responses are centrally involved in both intrinsic aging and photoaging, acting to protect the genome while reducing the risk of UV-induced skin cancer.

Although photoaging has traditionally been viewed as a "cosmetic problem," in contrast to the premalignant and malignant lesions that constitute a major socioeconomic burden for society, it is now clear that there is a continuum between truly normal skin and skin cancer. At the molecular, histologic and clinical levels photoaged skin occupies much of the spectrum and, accordingly, treatments developed for eradication of cancers and precancers also ameliorate

"cosmetic" photoaging changes. Like prophylactic use of high SPF sunscreens, intermittent field therapies, when clinically indicated, appear to not only reduce skin cancer risk but also improve skin appearance. This information should be used to motivate patient compliance with sometimes trying cancer-prevention regimens and to educate third parties regarding the medical benefit from treatment of photoaged skin.

(**O-08**)
***In vivo* method development for detecting micronized sunscreen particles on adult and infant skin**

Georgios N. Stamatas [a], M. Catherine Mack [b], Fanny Le Goff [a], Elise Boireau [a], Wei Song-Clauzier [a]
[a] Science & Technology, Johnson & Johnson Santé Beauté France, Issy-les-Moulineaux
[b] Science & Technology, Johnson & Johnson Consumer Companies Inc, Skillman, NJ, USA

Sunscreens containing light scattering filters, ZnO and TiO_2 particles, are used as alternatives to those containing light absorbing filters, particularly for use on baby and children skin. Although there is considerable evidence by *in vitro* or *ex vivo* experiments that ZnO and TiO_2 nanoparticles do not penetrate adult skin, there are no *in vivo* data and no data on infant skin. To this end we developed two methods based on reflectance confocal laser scanning microscopy (CLSM) and confocal Raman microspectroscopy (CRM). CLSM was modified to minimize the native reflectance signal of the skin in order to increase the contrast of the reflected signal due light scattering by the sunscreen filter particle. In CRM we followed the characteristic signals of TiO_2 and ZnO in the fingerprint region. Both methods were used to construct intensity profiles of the particle-related signal through the skin. The methods were first tested in adults and both demonstrated that the sunscreen particles were not detected at significant concentrations beyond 6-7 microns in the SC. The methods were then applied on infants and confirmed these observations. CLSM is not as specific as CRM, but it provides the structural information of where the particles end up: top of the SC and in the microrelief lines. The detection limit of each method was established by analysis of serial dilutions of the sunscreen product in an appropriate lipid-base solvent. Both methods have a detection limit of about 1 part per thousand. In conclusion, these methods provide *in vivo* confirmation of previously published *ex vivo* experiments on adult skin and demonstrate for the first time on infant skin that there is no statistically significant penetration of micronized particles beyond the stratum corneum.

(**O-09**)
Regional Variation in Skin Function: Man and Animal

Howard I. Maibach, MD
Department of Dermatology, University of California, San Francisco, CA 9413-0989

Pharmacologists and toxicologists often model skin as a single function organ. This presentation capsules a half-century of observations, utilizing quantitative metrics (such as electrical properties, percutaneous penetration, molecular markers, etc.) suggesting the contrary: i.e., that in embryologic evolutionary development, we have evolved into a highly complex regional anatomy functional mosaic -- whose details are just now coming into focus.

(**O-10**)

Nik Kollias, PhD

(**O-11**)
Influence of skin pigmentation in polarization spectroscopy imaging for assessment of erythema and blanching

GERT E. NILSSON
Department of Biomedical Engineering, Linköping University, 58185 Linköping, Sweden

Background: The local concentration of red blood cells (RBCs) in the skin microcirculation can be mapped by analyzing the components of the red and green plane in a photo captured by a digital camera equipped with cross-polarizing filters to eliminate the adverse effects of direct surface reflections. Since RBCs mainly absorb light in the green wavelength region, areas in the green plane of the photo corresponding to a high RBC concentration display attenuated values, while corresponding areas in the red plane are virtually unaffected. By the use of an algorithm that calculates the relative difference between each element in the red and green plane, an RBC concentration map can be constructed in which the values of the individual elements scale linearly with the local RBC concentration in the skin.
Purpose: Since the light eventually reaching the photo-detector array passes through the epidermal layer twice, the spectral content and thereby the RBC map is, however, influenced by the amount of melanin in this layer. This presentation discusses the extent of this influence and suggests measures to compensate for the influence of epidermal layer pigmentation on the RBC concentration maps.
Methods: A two layer Kubelka-Munk mathematical model was used to assess the influence of melanin in the epidermal layer on the RBC concentration maps.
Results: The melanin content in the epidermal layer primarily adds an offset - the value of which relates to the amount of melanin in the epidermis - to the elements of the RBC concentration map, while the sensitivity to RBC concentration remains virtually unaffected. In short term studies of the vascular effect of topically applied vaso-active agents, the melanin content of the epidermal layer can generally be assumed to remain constant. By subtracting each element of the first RBC map in a sequence of maps from the corresponding elements of the remaining RBC maps, changes in local RBC concentration can therefore be quantified independently of the epidermal melanin content at least for low and moderately pigmented skin. The results from the theoretical considerations were verified by mapping the development of erythema following topical application of methyl nicotinate to skin sites including areas of both high and low pigmentation.
Conclusion: Changes in local RBC concentration can be quantified independently of the epidermal melanin content for low and moderately pigmented skin.
Key words: Erythema, polarization spectroscopy

(**O-12**)
Ageing signs evaluation in 3D on the face

Jean-Jacques SERVANT, EOTECH SA; Etienne Camel, IEC Group, and Jean-Christophe Pittet, Orion Concept

Purpose: Ageing characterization on the face has been widely developed using 2D imaging by means of visual score, and more over by the quantification of ageing signs density and severity (Atlas of facial aging signs among caucasian women by Roland Bazin and Eric Doublet). By experience we know the specific areas where skin aging shows the most visible signs. Specialized in 3D non contact measurement using fringe projection technique, we think there is

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a space for 3D characterization of those signs which would help visual score providing more sensitivity to evaluate them, to objectively quantify them and even more classify those signs.

Methods: 250 volunteers, Caucasian type, all skin photo type, from 25 to 70 years old has been measured and classified every 5 years. Having acquired in 3D the full face of all of them, we like to describe this method which uses automatic extraction of the zones of interest on the face, compensate local shape of individual morphology and provides the amplitude of the wrinkles or folds in these different regions. We also have developed some global approach to quantify globally the severity and density of those wrinkles and folds

Results: We will provide results, and correlation compared with the 2D reference method using visual score. We also will present the tendency versus the age of each region (zones) and globally

Conclusions: An finally we will conclude with the perspectives and potential of such a 3D analysis technique and method of ageing signs of the face which can widely being used to support claim

Keywords: Fringe projection technique, Imaging, Skin aging, wrinkles and folds, morphology,3D analysis

(**O-13**)
The examination of nitric oxide-accelerated wound healing by laser Doppler perfusion imaging of percutaneous sulfur mustard lesions

Joseph D. Boecker, Robert S. Stevenson, Roy F. Railer, Robin R. Deckert, Robert D. Brodnick
US Army Medical Research Institute of Chemical Defense, 3100 Ricketts Point Road, Aberdeen Proving Ground, MD 21010-5400

Background: Exposure to liquid sulfur mustard (HD) produces skin lesions which can incite long-lasting physiologic complications and cosmetic disfigurements. Efforts are ongoing in the search for more comprehensive means to ameliorate the effects of exposure to HD.

Purpose: A variety of noninvasive biophysical measurements are employed in our evaluation of wound healing. Recently laser Doppler perfusion imaging (LDPI) was added to that battery to examine changes in both wound size and microvascular blood perfusion within and around the wound site. Nitric oxide (NO) provides vital assistance in wound healing by modulating inflammation, promoting angiogenesis, regulating tissue remodeling and serving as an antibacterial. In addition to excessive inflammation, the oxidative stress of HD exposure significantly diminishes NO levels. We therefore hypothesized that the application of exogenous NO to cutaneous HD injuries would result in decreased inflammation and accelerated wound healing.

Methods: For this study, NO delivering nanoparticles suspended in a topical gel were evaluated as a post-exposure topical treatment for HD on weanling Yorkshire swine at 0.1% (w/w, nanoparticles/gel) (n=6) and 1.0% (n=6). LDPI was performed pre-exposure, three days post-exposure, and seven days post-exposure.

Results: Wounds treated with 1.0% (w/w) NO delivering nanoparticles in a topical gel presented the smallest mean wounded area at three days post-exposure. A reduction in perfusion of the wound area was observed between three and seven days post-exposure in 67% of sites treated with the 0.1% NO-gel and 100% of sites treated with the 1.0% NO-gel. Treatment with NO also produced a leveling of perfusion between the wounded tissue and surrounding area at seven days post-exposure, which was not observed in the positive controls.

Conclusions: These results indicate the 1.0% NO produced an early benefit to the HD wound both in mediating the initial inflammatory response and accelerating progression of the wound through the inflammation phase and into the repair phase of healing. The corroboration of these results with previously validated biophysical measurements, clinical observations, and histology

provide evidence that LDPI can prove an effective analytical tool in evaluating the initial stages of wound healing.

Key words: laser Doppler perfusion imaging, nitric oxide, sulfur mustard, wound healing

(**O-14**)
Modern Wrinkle Analysis: Shadow Analysis with the CK Visioline

Tim Houser, Gary L. Grove PhD, Randy Wickett PhD
CyberDERM, inc., University of Cincinnati

Background: Since the earliest development of instrumentation to measure the human skin there has been an interest in the analysis of wrinkles in the skin and how they are altered by the application of anti-aging products. Techniques such as stylus profilometry have yielded to novel methods such as optical profilometry and the budding field of 3D imaging for skin analysis. With progress being focused on more difficult techniques to quantify changes in skin wrinkling a need has developed for an instrument which provides easy and quick skin replica analysis which is reproducible and customizable to particular needs.
Purpose: The intent of this research is to validate the CK Visioline for this purpose and provide an assessment of shadow analysis as an alternative to other methods of wrinkle analysis.
Methods: Validation was performed via analysis of a custom set of physical standards as well as of replicas taken from individuals representative of each point on a 0-8 expert grader scale of skin wrinkling. Analysis of these replicas was used to assess the impact of calibration and changes in software settings (such as threshold and classification) on the results as well as to compare the measured results to the grading scale.
Results: The results of this research show a strong correlation between expert grader ratings of skin wrinkling and the "Area Ratio" value reported by the device. This research also revealed some minor flaws with other reported values (such as form factor) which indicate that extra care should be taken when trying to use these data.
Conclusions: It is apparent from this research that shadow analysis is valuable for quick and easy analysis of skin surface replicas. The best data from analysis is the "Area Ratio" value with the "Form Factor" value requiring extra attention to ensure accuracy. The Visioline is also designed to tailor your data to specific needs, such as analyzing only wrinkles of certain sizes or segmenting the data between size ranges. Other features allow you to adjust replicas during analysis to maximize the quality of the data when dealing with imperfect replicas. Shadow analysis is shown to be a good means of assessing the relative efficacy of one product or formulation over another or assessing changes over time and may be useful at quantifying those changes. This should be helpful early in product development to make quick and easy in-house assessments.
Key Words: Imaging, shadow analysis, wrinkling, instrument validation

(**O-15**)

A Framework for Learning Common Skin Imaging Analysis Tasks

Paul Wighton[1,2,3]**,** Tim K. Lee[1,2,3], Harvey Lui[2,3], David I. McLean[2], M. Stella Atkins[1,2]
[1]School of Computing Science, Simon Fraser University; [2]Photomedicine Institute, Department of Dermatology and Skin Science, University of British Columbia and Vancouver Coastal Health Research Institute; [3]Cancer Control Research Program and Cancer Imaging Department, BC Cancer Research Centre, Vancouver, BC, Canada

Background: Many tasks in skin imaging analysis can be generalized into a single formulation: "for each pixel in the image, assign a label from a set of mutually exclusive labels". In the realm of cosmetics, this generalization encompasses many complexion analysis tasks such as locating/grading structures such as wrinkles and acne, or measuring the degree of porphyrin concentration. In the realm of computer aided diagnosis, this generalization encompasses such tasks as detecting occluding artifacts like hair or oil bubbles, segmenting lesions and identifying dermoscopic structures.
Purpose: To explore probabilistic models capable of performing this generalized task, and to explore ways to automatically infer model parameters given a set of image/label example pairs so that the system can quickly "learn" new tasks.
Methods: The first model is based on maximum a-posteriori (MAP) estimation, which uses linear discriminant analysis to automatically determine model parameters. We call this the MAP model. The second model is based on conditional random fields (CRFs), and uses maximum likelihood estimation and regularized gradient descent to determine model parameters. We call this the CRF model.
Results: We have taught the MAP model how to detect occluding hair, with performance comparable to more specialized algorithms. We then taught the framework how to segment skin lesions. The performance was compared to 5 other previously published specific methods. Our framework performed comparably to four and outperformed the fifth. Additionally, the probabilistic nature of our approach allows it to operate over the entire range of sensitivities, as well as create visualizations of confidence intervals for feedback to the user. We then apply the CRF model to the same tasks and achieve slightly better accuracies; however the training time (time needed to infer model parameters) increases from minutes to hours.
Conclusions: Probabilistic models, with automatic and empiric ways to determine model parameters is a promising way to automatically learn and perform a variety of tasks in skin imaging analysis.
Key Words: Computer Vision, Image Labeling, MAP estimation, CRF parameter inference

(**O-16)**
Joachim Fluhr, MD

(**O-17**)
Clinical scoring and instrumental analysis to evaluate the skin types and efficacy of dermocosmetics

Daiane G. Mercurio, Patricia M. B. G. Maia Campos
Universidade de Sao Paulo - Faculdade de Ciencias Farmaceuticas de Ribeirao Preto, Ribeirao Preto, SP, Brazil

Considering the biology of the skin and the intended use of the active ingredients, is essential to choose an appropriate cosmetic formulation for both the stability and skin penetration of these as to obtain the expected pharmacodynamic effect, which means that skin type influences

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decisively in the choice of raw materials and the type of cosmetic vehicle to be formulated. This way, the biophysical and skin image techniques, combined with clinical evaluation by a dermatologist is very useful for the characterization of skin type, and therefore to choose the appropriate cosmetic formulation to be applied on the skin. Thus, the aim of this work was to characterize clinically the skin types by dermatological evaluation and through biophysical and skin image techniques, allowing the choice of the appropriate type of cosmetic product for each skin type and evaluate the immediate effects of the cosmetic treatment. For this purpose, 26 female volunteers, between 20 and 58 years old participated of the study. Clinical scoring was performed by a dermatologist, who classified the skin as normal to dry skin (Group 1) and combination and oily skin (Group 2). The objective measurements, using non-invasive techniques, were made in terms of skin hydration (Corneometer® CM 825), transepidermal water loss - TEWL (Tewameter® TM 210), pH (pHmeter® PH 900), oiliness (Sebufix® F16), and skin microrelief (Visioscan® VC98). In addition, in order to analyze the immediate effects of cosmetic products under study, it was performed an application of a gel cream containing vitamin A, E, C and panthenol and *Ginkgo biloba* at the volunteers classified as Group 1 and a gel cream containing *Spiraea ulmaria* extract, panthenol and α-bisabolol at the volunteers classified as Group 2. Before and after 2 hours of application of these formulations, were done measurements of the parameters above mentioned. The results of this study demonstrate that skin classified as normal to dry presented different clinical characteristics when compared with the skin classified as combination and oily skin, which presented higher sebum secretion, higher TEWL and slightly lower values of hydration. The immediate effects of the cosmetic treatment of Group 1 was the improvement skin hydration and decrease of TEWL and in Group 2 the cosmetic treatment was able to improve skin microrelief and hydration. Thus, the biophysical and skin image techniques are effective tools to help characterize the type of skin, assist in clinical dermatology and useful to choose the appropriate cosmetic product, which is essential to provide the desirable cosmetic benefits as well as improve skin conditions.

(**O-18**)
Stratum corneum changes after damage with sodium lauryl sulfate

Lisa Kroll[1], Douglas Hoffman[1], Andrew Basehoar[1], Barry Reece[2], Corey Cunningham[1], and David Koenig[1]. [1]Kimberly-Clark Corporation, Neenah, WI 54956 and [2]Reliance Clinical Testing Services Irving, TX 75062 USA

BACKGROUND: Raman spectroscopy is a noninvasive method that allows for the *in vivo* investigation of biochemical compounds in skin at varying depths. The stratum corneum can be damaged by both chemical and mechanical means, requiring upwards of 17 days to recover. Relatively little is known regarding the biochemical steps required to restore the SC barrier after damage.
PURPOSE: To follow the recovery of SC after damage with sodium lauryl sulfate.
METHODS: In the study described here, sodium lauryl sulfate (SLS) was applied to the volar aspects of the forearms of 12 female subjects' skin to induce barrier damage. A deinozied water challenged site was used as the vehicle control. NMF, lipid, and water profile measurements were taken on each test site using a Raman spectrometer (Model 3510 Skin Analyzer, River Diagnostics, Rotterdam, Netherlands). Water profiles were quantitative, while NMF and lipid profiles were semi-quantitative. Transepidermal Water Loss (TEWL) and Chromameter measures were also collected.
RESULTS AND CONCLUSIONS: Immediately following SLS-induced barrier damage, Raman spectroscopy revealed significant decreases in all amino acid components of NMF except proline, ornithine, and urea. A significant increase in ceramide 3 was observed, the increase

being most pronounced near the surface. Most components had returned to indistinguishable levels to the control by Day 12. The study provides insight into the biochemical processes used by the stratum corneum to resolve damage. This data will help define further research for improving skin healing and limiting damage.

(O-19)
Multivariate validation of injury consistency in an established swine model for cutaneous sulfur mustard exposures

John I. Azeke, Robert S. Stevenson, Roy F. Railer, Robin R. Deckert, Jennifer L. Devorak, Horace L. Lumpkin, Bryce F. Doxzon, Joseph D. Boecker, Larry W. Mitcheltree, Tracey A. Hamilton, John S. Graham, Ernest H. Braue Jr.
United States Army Medical Research Institute of Chemical Defense (USAMRICD).

Background: The use of a reliable animal injury model is a necessary component in the study of cutaneous sulfur mustard (HD) injuries. However, the successful execution of any *in vivo* wound healing study is often dependent on extraneous systematic factors (i.e. confounding variables) that, if not properly accounted for, might have serious effects on study outcomes. These unintended factors may include differences due to animal vendor, research technician, anatomical site, animal-to-animal variations, and environmental conditions. Generally, sourcing animals from the same vendor, following strict standards of operation (SOP), including internal negative (NC) and positive (PC) controls, and randomizing the anatomical locations of experimental and control injuries should aid in minimizing these effects. However, logistics often dictate that these studies be conducted in manageable batches, thereby introducing additional systematic effects (e.g., effects due to experiment batch, run order, or time of study). Together, these systematic effects become especially important when attempting to draw conclusions from studies that may have taken place over a period of months to years.
Purpose: To evaluate our hypothesis that our established swine model produces reliable superficial dermal HD injuries, we conducted an injury validation study to confirm the equivalency of cutaneous HD injuries investigated in our lab between 2004 and 2009.
Methods: Between 2004 and 2009, we conducted 18 wound healing studies involving 188 weanling Yorkshire swine acquired from 4 animal vendors. Each animal received a NC (non-exposed) and PC (HD-exposed) site in one of four predetermined ventral locations. Each site was evaluated using bioengineering, visual scoring, and histological methods up to 16 days post-exposure. Multivariate analysis of the NC and PC sites was performed to validate that the effects of cutaneous HD exposure were independent of animal number, animal vendor, experiment number, site location, time of year, and year of study.

Results: When all data were normalized to each animal's internal NC, we confirmed that all cutaneous HD injuries were statistically equivalent and independent of the systematic factors ($p < 0.05$) during the five-year period.
Conclusions: Our established injury model in the weanling Yorkshire swine reliably produces equivalent superficial dermal HD lesions irrespective of systematic factors inherent to wound healing research.
Keywords: Validation, Multivariate analysis, Bioengineering, Claims support, Population variation

The experimental protocol was approved by the Animal Care and Use Committee at the United States Army Medical Research Institute of Chemical Defense and all procedures were conducted in accordance with the principles stated in the Guide for the Care and Use of Laboratory Animals (National Institutes of Health, 1996), and the Animal Welfare Act of 1966 (P.L. 89-544), as amended.

(**O-20**)
Effect of an anti-inflammatory blend on reducing skin irritation caused by UVB or a chemical irritant

Neelam Muizzuddin, PhD, Donald Collins, Chia Chen, Daniel Maes, PhD
Clinique Laboratories, Melville, NY

Background: Hydrocortisone, is typically used for reduction of topical inflammation. It is of considerable interest to develop a topical agent, containing no hydrocortisone that can both reduce the onset of chemically or environmentally induced skin irritation and ameliorate this irritation once it occurs.

Purpose: A blend of ingredients with anti-inflammatory activities has been developed that outperforms topical 1% HC with regard to UVB induced or Balsam of Peru (BOP) induced skin irritation. This blend contains an inhibitor of histamine release, inhibitors of the PLA2, 5-LO, COX-2, collagenase, elastase and PDE IV enzymes, neutrophil chemotaxis and adhesion blockers, a histamine receptor blocker and an inhibitor of NF☐B activation.

Method: A cosmetically acceptable oil/water emulsion containing the anti inflammatory ingredients was prepared and applied to human subjects either 20 minutes before exposure to the irritant (UVB or BOP) or after irritant exposure once erythema was achieved. It was also tested for the reduction of lactic acid induced stinging after one treatment and multiple treatments.

Results: When applied before the irritant, this blend was able to reduce BOP induced erythema by 82% and UVB induced erythema by > 90%. When applied after the irritant, the blend was able to reduce existing UVB irritation by 22% and existing BOP induced erythema by 28%. This blend was also found to be more effective than 1% hydrocortisone at reducing existing UVB induced erythema. As well as "sting" induced by 10% lactic acid.

Conclusion: A blend of ingredients has been developed that is more effective than topically applied 1% hydrocortisone at reducing the cutaneous irritation/inflammation.

Key words: erythema, sting, hydrocortisone, UV

(**O-21**)
Quantitative measurement of dark circles around eyes by image analysis of VISIA-CR photographs

Di Qu, PhD
Research and Development, Amway Corporation

Background: The appearance of under eye dark circles is a common concern of many people. Various products have been developed that are aimed to mitigate the concern. Meaningful evaluation of treatment efficacy becomes an important topic. Conventionally, under eye dark circles are assessed by clinical visual grading with which subjectivity is a major concern for accuracy. In this study, a quantitative measurement of under eye dark circles using image analysis of VISIA-CR photographs is presented.

Purpose: This study was aimed to establish an accurate and consistent method that can quantitatively measure the severity of under eye dark circles.

Methods: Image analysis of VISIA-CR photographs was employed in this study. Appropriate settings of photographic conditions were selected with a set of standard color plates included in

each picture. Post capture image color correction was carried out using a set of in-house developed algorithms to ensure the colors in the picture were accurate against the standards. The region of interest of eye area skin was carefully selected and the procedure was automated to ensure exact match of eye area features between pictures taken at different times. The reflective intensity of the skin was then measured in a fashion which scans across the selected region of interest to produce an intensity profile using a set of in-house developed plugins in ImageJ.

Results: The eye area reflective intensity profile accurately captures the severity of under eye dark circles. A step change of 1.28% was visibly shown by the profile when a small area of the picture was artificially adjusted to a slightly higher brightness which was originally not visible in the picture to the naked eye. The features of eye were aligned accurately between photos before and after a 12 week clinical study. A 30 photo validation study using manikin showed excellent reproducibility of under eye skin intensity with a maximum percent error less than 0.78% (average %error=0.12%). The method was then used in a 5-member pilot clinical study and the lightening effect in under eye area skin was quantitatively detected.

Conclusions: The image analysis method can quantify the severity of under eye dark circles using skin reflective intensity from VISIA-CR photographs. The unique eye alignment procedure makes it possible to accurately compare before and after results in almost identical region of interests. It is a useful method capable of providing claims support with quantifiable clinical efficacy.

Key words: under eye dark circles, image analysis, VISIA-CR, reflective intensity

(**O-22**)
An Evaluation of Exaggerated Use Methods for Testing Mechanical Irritation Potential on Skin

Lisa M.P. Stabe, C. Eliza Geier, Jason C. Cohen, Chantel S. Mundschau
Kimberly-Clark Corporation, Neenah, Wisconsin USA

Background/purpose: There are many methods that test consumer products (i.e. bath and facial tissue, adult incontinent products, diapers and wipes) for potential consumer discomfort attributed to regular use. Usage tests may provide the most accurate assessment of end use results, but these tests are very costly and time intensive, which makes them unsuitable for screening multiple design options during the product development phase. For this, exaggerated use methods have proven to be successful alternatives. However, continuous improvements in materials have uncovered limitations to current exaggerated use methods' abilities to detect and measure differences in increasingly skin friendly materials. This in turn has limited a developer's ability to differentiate products for adverse effects on the skin. In efforts to find a cost and time effective test method for screening modern materials, in this case diapers for softness, exaggerated use methods which evaluate materials for mechanical irritation to the skin were compared and a new, more sensitive method developed.

Key Words: skin irritation – mechanical irritation – exaggerated use – consumer products

(**O-23**)
Stem Cell Research

Robert Lavker, PhD

(**O-24**)
Advances in Measuring the Water Content of Dry Skin by In-Vivo Confocal Raman Spectroscopy

Arne Böhling, Stephan Bielfeldt, Klaus-Peter Wilhelm
proDERM Institute for Applied Dermatological Research GmbH, Kiebitzweg 2, 22869
Schenefeld/Hamburg, Germany

The evaluation of dry skin is an important parameter in cosmetic and clinical trails. The standard method in addition to the objective visual evaluation by a trained rater is measuring the capacitance of the skin which shows a good correlation compared to the visual evaluation. It was shown that in some cases these measurements do not represent the moisture of the skin properly due to the fact that capacitance is not only influenced by water but also by components of test products and especially by the skin roughness. In fact the physical water content is not measured directly. This problem was solved by the development of in-vivo confocal Raman spectroscopy. This technique allows the evaluation of the water profile in the stratum corneum (SC) and to calculate several parameters like water content in the SC, the SC thickness and the water gradient within the SC.

However the standard process of measuring the water profile is difficult for dry and especially for very dry and flaky skin. In normal skin condition a direct optical contact between the window and the skin surface is given without changes of the reflectance index. This direct optical contact is essential for the light transmission and proper measurements. In case of flaky skin the number of air filled holes between window and skin increases so that light transmission is not assured. The standard process to measure the water profile instructs the operator to exclude areas without direct optical contact. According to this the stratum disjunctum can not be evaluated by this process, but even this intermediate layer is essential for the correlation between clinical scores and technical parameters. Consequently parameters measured by Raman spectroscopy do not correlate necessarily with capacitance measurements and clinical scores.

We developed a method with a special non polar, minimal penetrating index matching fluid to provide a direct optical contact between the window and the skin surface thereby avoiding air filled holes. This preparation method leads to proper representation of the physical water content of the outer parts of the SC including the stratum disjunctum. Furthermore this method is suitable to assess dry and very dry skin by confocal Raman spectroscopy.

(**O-25**)
Assessment of ageing effects using non contact device: the Tonoderm,®

G. Boyer* — J. Molimard*** — H. Zahouani **— M. Pericoi *
* Laboratoire PERITESCO, Paris, France; **Laboratory of Tribology and Systems Dynamics UMR5513 CNRS/ECL/ENISE/EMSE, France; *** Centre SMS, Ecole des Mines de Saint-Etienne, France

Background: of the various dermatological evaluation methods involving touch, palpation is one of the most used to evaluate the skin properties. Indentation technique is the closest instrumental test to perform this type of clinical movement. However, the contact between the probe and the skin forces one to take into account the adhesive behaviour of the skin, which is physically very complex. Moreover, most areas of the body are not flat in shape, which highly complicates the measure due to the positioning of the probe. Thus, it could be very interesting to use a non contact device to assess the mechanical properties of the skin.
Purpose: the aim of this work is the development of a new non contact device to assess the mechanical properties of the skin. Validation has been performed and the ability of the device to discriminate two different tissues has been assessed.

Methods: the device stretches the skin using an air flow through a 2 mm diameter pipe. The flow is controlled by a thermal mass flow. The total force applied varies from 0.4 to 20 g. The maximal depth, varying from 200 μm to 2 mm, is measured using a high accuracy laser sensor. The whole device is controlled by a specific program, allowing constant force or constant depth tests, in order to observe the creep, the relaxation and the natural motion of the skin. Validation was performed on inert materials. In order to evaluate ageing effects, an *in vivo* study was performed on two groups of healthy young and mature women, respectively 23.2±1.6 (group 1, 14 subjects) and 60.4±2.4 (group 2, 14 subjects). Then, in order to evaluate the ability of the device to assess product effects, an *in vivo* study of a cosmetic cream applied on the cheek of 21 subjects at T0 and T4 weeks was performed.

Results: a comparison with classical indentation tests on inert materials confirms the validity of the Young's modulus measured with this new device. *In vivo* results show a statistically significant difference for the measured parameters between the two groups with ageing. The Young's modulus found varies from 7 for the mature group to 15 kPa for the young group. The study of the effect of the cosmetic cream performed on the cheek shows the capability of the device to quantify product effects with a significant increase of the Young's modulus between T0 and T4 weeks.

Conclusion: the developed device is able to discriminate ageing and product effects. The non contact principle permits to access to most of body areas like the cheek without the interference of the adhesive behaviour of the skin. The use of this non contact technique could be extended to sensitive skin and to wounded skin for example burn or reconstructive tissues.

Key words: skin mechanical properties, non contact, ageing.

(**O-26**)
Infrared Thermography to Measure Heat Transfer to Skin from a Heated Device

James Mayne, Jesse Leverett, Esther Patrick, Joanna Klapacz, Matthew DePauw, Robin Fleser
Amway Corporation

Method: Thermograms were captured at several locations on the face including the forehead, crow's feet, outer canthus of the eye and in the nasolabial fold.

Results: Infrared thermography provided objective data for establishing a proper probe temperature to meet safety requirements. Data also suggested that increases in skin temperature were transient and varied with probe temperature. There was little variation between facial skin sites for a given probe temperature. Induced skin temperatures were dependent on the duration of skin contact with the heated probe and whether or not a topical product was applied. Both clinical redness and subjective heat sensation were dependent on temperature and skin site.

Conclusion: The results demonstrated a method using thermograms from an infrared camera can provide fast and accurate data to characterize heat transfer to skin from a heated device.

Key Words: thermography, infrared, skin temperature, heat transfer.

(**O-27**)
A clinical comparative evaluation of two techniques to measure facial lines/wrinkles

R. Chhibber[1], S.Sharma[1], S.Schwartz[2], **R.Frumento[2]**
[1]BrighTex Bio-Photonics, LLC, San Jose, CA United States; [2]International Research Services, Inc., Port Chester, NY United States

Background: The measurement of facial fine lines and wrinkles is used in clinical research product claims settings. Silicone replication (replicas) under standard conditions provides information on the number, length and width of facial fine lines and wrinkles. These quantitative values provide invaluable information regarding the severity of fine line and wrinkles as well as a quantitative measurement of a products utility over time to reduce facial skin abnormalities. Recently, image analysis systems have been developed for the collection of facial fine lines and wrinkles information. It is imperative that newly developed instruments used for facial fine lines and wrinkle measurements are valid and reliable. Information regarding both validity and reliability, however, is not available for replicas or any image analysis systems. In addition, because few instruments are compared under standard conditions, it is difficult to determine how much of the total variation is due to physiologic rather than instrument variation.

Purpose: The silicone replica technique (CuDerm, TX) to measure facial fine lines and wrinkles has been a well-established reference technique used over the past 15 years. However, although often viewed as the industry "gold standard" the validity and reliability of this technique has never been closely examined; furthermore, image analysis may offer benefits over replicas that have not been examined. Thus, there is a need to validate new systems that either closely mimic or improve upon the validity and reliability of the silicone replica technique, which is the objective of this study.

Methods: A five day, monadic evaluation completing with no less than fifteen subjects. The study will be twelve days in duration, including a seven-day washout period, with subjects using one test product according to package insert directions. Bilateral crow's feet fine lines and wrinkles will be evaluated for validity and reliability of two techniques; silicone replicas and Clarity Pro R&D image analysis at baseline and again after five days of treatment. Visits will occur at days minus seven (washout), day zero (baseline) and Day 5 (final visit).

Results & Conclusions: This study is in progress and data is to be available in mid-February.

(**O-28**)
Appearance of the cheeks with age and relationship to physical properties of the skin

Akihiro Tada, Aya Sakata, Hiroshi Ohshima
POLA Chemical Industries, Inc.

Background: Many studies have focused on changes in facial appearance that occur with aging, such as crows feet and sagging, but few studies have examined changes in the cheek that occur with age.

Purpose: The objective of this study was to clarify changes in the cheek that occur with age and assess the relevance of these changes to physical properties of the skin.

Methods: Experiment I. Subjects comprised 140 healthy Japanese women (mean age, 49.0 years; range, 19-82 years). Using a photograph of the cheek, aging appearance was graded on a 5-point scale. Experiment II. Subjects comprised of 40 healthy Japanese women (mean age, 38.1 years; range, 20-56 years). We evaluated the aging appearance with a photograph of the cheek. Measurements were taken at the cheek using a Venustron tactile sensor to assess skin softness, a Cutometer for skin elasticity, a SPEX SkinSkan spectrofluorimeter to evaluate the amount of advanced glycation end products (AGEs) in the dermis (AGEs index), and a portable full-band reflectance spectrophotometer for L*, a* and b*. A surface micro-texture of the silicone replica from the cheek was measured in three-dimensional parameters using TalyMap. Using tape-stripped stratum corneum (SC), levels of AGEs in the SC were assessed by immunohistochemical staining. Experiment III. Subjects comprised 87 healthy Japanese women (mean age, 49.2 years; range, 20-79 years). Aging appearance of the cheek was evaluated with photographs. Measurements were taken at the cheek using a Reviscometer to assess skin mechanical directionality and a Cutometer for skin elasticity. Evaluation of skin sagging was

performed by making marks on the face of the subject and taking photographs of the face while the subject was in a supine and a sitting position.

Results: A significant correlation between aging appearance of the cheek and the subject's age was found. No significant correlations were seen between aging appearance of the cheek and skin softness, AGEs in the SC, mean surface roughness (Ra), surface isotropy, a*, b*, maximum resonance running time (RRT), minimum RRT, and mean RRT. In contrast, aging appearance of the cheek closely correlated in a linear fashion with skin elasticity, AGEs index, average distance between skin surface furrows (RSm), L*, skin sagging, and anisotropy (RRTmax/RRTmin).

Conclusions: We found a method to evaluate the aging appearance of the cheek using photographs. We suggest that aging appearance of the cheek may involve a decrease in skin elasticity, an increase of the amount of AGEs in the skin, loss of brightness, sagging, disorder in surface texture, and changes in skin's mechanical directionality.

Key words: aging appearance, cheek

(**O-29**)
The Critical Role of Instrumentation in Intellectual Property

Jeffrey K. Mills, Ph.D., Esq.
Fanelli Strain & Haag PLLC, 1455 Pennsylvania, Ave. NW, Suite 400, Washington, DC 20004
Ph: 202.621.1840; Fx: 202.621.1844; Em: jmills@fshlegal.com

Skin-property measurement and imaging techniques play a significant part in the development of dermatologic products. Whether to evaluate potential active agents or to support a product claim for regulatory approval, instrumentation is utilized throughout the skin-care product life-cycle.

In patent law, a recent decision by the U.S. Supreme Court dramatically changed the way the "obviousness" of a patent application is evaluated. As a result, there is an increased need to demonstrate that your product possesses unexpected or surprising properties in comparison to what was previously available in the field. In addition, in the rapidly developing area of nanotechnology, using standardized techniques to characterize and measure these "nanoscale" products are crucial before filing a patent application to protect them.

This talk will discuss the critical role that instrumentation plays in the support of patent applications and some of the considerations that should be taken so as to make the most of the data that can be generated from characterizing the skin.

POSTERS

(P-01)
A new level of clinical photography: development of the USR-CliP (Unit for Standardized and Reproducible Clinical Photography)

Arne Böhling, Stephan Bielfeldt, Peter Buttgereit, Klaus-P. Wilhelm
proDERM Institute for Applied Dermatological Research GmbH, Kiebitzweg 2, 22869 Schenefeld/Hamburg, Germany

Clinical photography is a widely used and well accepted parameter in clinical trails. The images are used for documentation, for scoring by experts and lay people and also for color or image analysis. Skin, however provides some challenges for photography because of low contrast,

partial translucency etc. Reproducibility of positioning, illumination and the capture process is a mandatory prerequisite for high quality clinical photography. However off the shelf camera systems and even dedicated professional systems often fail to meet these conditions. Especially failure of control of automated functions like color or luminance enhancers may cause problems in clinical studies. Tools for the exact positioning of volunteers and equipment is often lacking and changes in light intensity and color over the course of a study can impair the value of photographic time series.

Based on a 31M Pixel professional camera system we developed an optimized photographic unit which fulfills all requirements associated with clinical images. It is equipped with a mid-size CCD Chip and a color temperature controlled flash unit enabling color reproducibility even over long time periods. Biases of color due to wall reflections are limited to a minimum degree as the system is located in a dedicated room with dark walls. The system features online overlay images and further specific positioning functions for the volunteers and also for the camera and system illumination to guarantee accurate reproducibility of all settings.

Thanks to these features, the USR-CliP represents a system for clinical photography with optimal repositioning of the volunteers, a minimization of optical distortion and a consequent optimization of color reproducibility.

The poster provides an overview of the different application fields of the USR-CliP with presentation of accordingly high resolution macroimages (visual effects documentation of decorative cosmetics in healthy volunteers, camouflage of a rosacea patient, macrophotography of a volunteer suffering from herpes and images for tooth color determination). It further shows results of a color measurement of (i) the skin of 65 volunteers during a time period of 3 month and (ii) a color standard within 115 images. The results illustrate that the stability in the luminance (L* values) as well as for a* and b* color values is high in volunteers images and for the color standard.

(P-02)
In vivo tension test using full field optical measurement: ageing effects.

G. Boyer, J. Molimard,*** H. Zahouani,** M. Pericoi,* S. Avril ****
* Laboratoire PERITESCO, Paris, France; **Laboratory of Tribology and Systems Dynamics UMR5513 CNRS/ECL/ENISE/EMSE, France; *** Centre SMS, Ecole des Mines de Saint-Etienne, France, ****Center for Health Engineering, CNRS UMR 5146 & INSERM IFR143, France

Background: the assessment and the knowledge of the mechanical properties of the skin are very useful for clinical or cosmetology research. Among the skin's different characteristics, the anisotropy is an important parameter, for example, for surgery incision. Due to the fact that it is a directional test, tension is very useful in understanding this anisotropic behaviour.
Purpose: the aim of this work was to develop a device combining mechanical and optical measurement to perform an *in vivo* tension test in order to improve the understanding of the biomechanical properties of the skin, in particular the anisotropic aspect.
Methods: an *in vivo* extensometer composed of one static and one movable pad has been developed. Each pad is fixed on a tangential and a normal force sensor and is linked to the skin using double sided adhesive tape. A micro metric motorised translation stage, controlled by computer, allows for a movement with a velocity ranging from 0.1 to 1.5 mm/s with an accuracy of less than 1 μm. A camera placed over the stressed area records frames during the test. A complete Digital Image Correlation procedure was developed to calculate the displacement fields. Validation of the device and the method has been performed. An *in vivo* study was performed in order to evaluate the ageing effects. The measurements were performed on the volar forearm of two groups of healthy young and old women, respectively 23.2±1.6 (group 1, 14

subjects) and 60.4±2.4 (group 2, 14 subjects). Extension tests were performed with distortions of 5, 10, 15 and 20 % and according to 4 directions, with angles of 0, 45, 90 and 135° with respect to the axis of the forearm.

Results: experimental results were combined with a numerical finite element model under an inverse analysis to determine the complete mechanical properties of the skin. An orthotropic elastic material was considered. Validation of the model using the combination of the 4 directions tests shows that the five constitutive parameters of the orthotropic law can be calculated. Values of the Young's modulus E_1 and E_2 are higher for the young group compared to the mature group. Differences on the modulus G_{12} and the Poisson ratio v_{12} are also found.

Conclusion: The developed method allows the assessment of all the constitutive parameters of the skin considering an orthotropic elastic material. Perspective of this work is to improve the geometrical parameters of the model used in order to have more realistic boundary conditions.

Key words: anisotropy, mechanical properties, tension test.

(P-03)
Assessment of skin softness using an acoustic method.

G. Boyer and M. Pericoi
Laboratoire PERITESCO, Paris, France

Background: the assessment of the softness of a material is a very complex problem. In the cosmetic domain, the clinician usually touches the skin and tries to assess the softness of the tissue according to its own subjective sensations. Standardisation and reproductive evaluations between different experimenters are also very difficult to obtain. It could be very interesting to measure the sensation perceived by the experimenter in order to have quantitative and reproducible data in order to compare different studies.

Purpose: the aim of this work is to present a new technique based on the acoustic measurement of the sound induced by the touch movement and to evaluate the correlation of the measurement with the experimenter's evaluation by touch.

Method: the sound is produced by the contact between the finger of an experimenter and the tested material. The measurement is performed using a specially developed device called Acouskin®. It is composed of a rigid part which amplifies the sound, and a measurement part which records the acoustic signal. Treatment of this acoustic signal is then performed. The average sound level and the distribution of the sound in the frequency domain are calculated. Tests on inert materials of varying roughness have been performed. An *in vivo* study of a cosmetic cream applied on the cheek of 21 subjects was performed in order to evaluate the capability of this new method to assess product effects.

Results: all the tests performed on inert materials show the correlation between the perception of softness evaluated by the experimenter and the average sound level. An *in vivo* study of the effect of a cosmetic cream shows a significant decrease of the average sound level after applying a cosmetic product.

Conclusion: the developed method is able to objectively evaluate the softness of the skin and to compare this softness to another materials. Perspective of this work is the study of the frequency distribution of the sound according to the material properties.

Keywords: softness, acoustic measurement.

(P-04)
***In vitro* antioxidant activity and clinical efficacy of cosmetic formulation containing chamomile extract**

Patricia M. B. G. Maia Campos, Ananda T. Nobrega, Daiane G. Mercurio, Mirela D. Gianeti

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Universidade de Sao Paulo - Faculdade de Ciencias Farmaceuticas de Ribeirao Preto, Ribeirao Preto, SP, Brazil.

Botanical extracts have attracted great interest in the cosmetic area due to its rich composition and medicinal properties. Among these extracts it can be mentioned the *Matricaria chamomilla* L. extract, which has been commonly used in cosmetics. This extract has had its use recognized and it has being well studied once it presents therapeutic properties due to its rich composition. However, there are only a few studies about its topical application. This way, the aim of this study was to evaluate the antioxidant activity of *Matricaria chamomilla* L. extract and to evaluate the clinical efficacy of a cosmetic formulation containing this extract. In order to evaluate the *in vitro* antioxidant activity of *M. chamomilla* L. a chemiluminescence assay was performed. For the clinical evaluation, one formulation based on ammonium acryloyldimethyltaurate/ vinylpyrrolidone copolymer (A/VPC) was developed and supplemented or not (vehicle) with 5% *of M. chamomilla* L. extract. In order to evaluate the immediate effects, it was analyzed the skin hydration (Corneometer® CM 825), transepidermal water loss (Tewameter® TM 210), the viscoelastic properties (Cutometer® CM 525), skin microrelief (Visioscan® VC98) and skin sensitivity (Neurometer® CPT/C) on the region of the volunteer's face skin, before and after 2 hours of the following formulations application: vehicle (F1) and vehicle + M. chamomilla L. extract (F2). For the long-term study, the volunteers applied the formulations twice a day in the forearms and face skin; after 15 and 30 day-period of application, the parameters above mentioned were measured and the skin dermis echogenicity and thickness were also evaluated by 20mHz ultrasound (Dermascan C®). The results showed that *M. chamomilla* L. extract has antioxidant activity and the formulations studied demonstrated immediate moisturizing effects, but only the formulation containing *M. chamomilla* L. extract provides such effects in long-term study. Regarding the perception threshold, results suggest that the chamomile extract can act on skin sensitivity, with respect to the tactile perception by the increase of fibers Aβ perception and the decrease of the sensibility of fibers C, responsible for slow and prolonged pain. In addition, changes in dermal were not observed in a 30-day period, which can suggest that the formulation studied showed efficacy in epidermis only and a long term study can be suggested to obtain effects in dermis. Finally, chamomile extract can be suggested for the application in cosmetic products, once it has antioxidant effects, promotes a pronounced hydration effect and keeps skin physiological balance.

(P-05)
Seasonal Effect on Reproducibility of the Relative Hydration Potential of Wash-off Products

E Pomaski, D Hassenbein, LB Aust and **LK Lockhart**
Henkel Consumer Goods Inc., Scottsdale AZ

Background: The single application test for determination of skin benefits by moisturizers has been reported as early as 1992 and was adapted for personal cleansing products by Oddo et al (1997) and Patrick and Tallman (1998). These tests reflect the short term benefits consumers experience after bathing. Lukacovic et al reported the sensitivity of washing studies for evaluating relative mildness of personal cleansing products to be sensitive to weather conditions during the study period. When the dew point was greater than 4 °C they found it difficult to detect differences in the relative mildness of bar soaps leading to the recommendation that these studies be conducted at lower dew points. This general principle has often been applied to all manner of washing studies. However, in the studies reported here, the results were considerably less sensitive to weather effects. Because of the brevity of the study period, the

dew points in the conditioning period prior to the study are more relevant to skin condition than those during the study.

Purpose: These studies were conducted to evaluate the impact of weather on the reproducibility of moisturization effects on acute washing studies.

Methods: Studies were conducted from fall 2010 through spring 2011 with a set of liquid hand soaps and body washes. Approximately 20 female subjects, 18-55 years of age, with mild to moderate dryness on the lower legs were enrolled on the study. Test sites were washed by technicians according to a standardized protocol Oddo et al (1997). Relative skin hydration was measured by conductance (Skicon 200E) and capacitance (Corneometer CM 825) at baseline and 0.5, 1, 2 and 3 hours post-treatment. Evaluations by expert graders were also conducted for visual dryness.   Moisturization was defined as significantly higher relative skin hydration than the vehicle, water.

Results: These studies showed the same product performance profile and comparable statistical differentiation under different climatic conditions. These results suggest that acute washing tests are not as sensitive to dew point as repeated washing tests and can effectively be conducted at dew points above 4 °C.

Key Words: Skin hydration, body wash, dew point

(P-06)
Comparative effects of an anti-inflammatory blend on reducing skin irritation caused by UVB or a chemical irritant to 1% hydrocortisone.

Donald Collins, Neelam Muizzuddin PhD, Chia Chen, Daniel Maes PhD
Clinique Laboratories, Melville, NY

It is of considerable interest to develop a topical agent, containing no hydrocortisone (HC), that can both reduce the onset of chemically or environmentally induced skin irritation and ameliorate this irritation once it occurs. A blend of ingredients with anti-inflammatory activities has been developed that outperforms topical 1% HC with regard to UVB induced or Balsam of Peru (BOP) induced skin irritation. This blend contains an inhibitor of histamine release, inhibitors of the PLA2, 5-LO, COX-2, collagenase, elastase and PDE IV enzymes, neutrophil chemotaxis and adhesion blockers, a histamine receptor blocker and an inhibitor of NF□B activation. A cosmetically acceptable oil/water emulsion containing the anti-inflammatory ingredients was prepared and applied to human subjects either 20 minutes before exposure to the irritant (UVB or BOP) or after irritant exposure once erythema was achieved. When applied before the irritant, this blend was able to reduce BOP induced erythema by 82% and UVB induced erythema by > 90%. When applied after the irritant, the blend was able to reduce existing UVB irritation by 22% and existing BOP induced erythema by 28%.

(P-07)
SebumScale: a quick microbalance method for direct quantification of oily skin

Jouni Nuutinen*, Tapani Lahtinen and **Aki Immonen***
*Delfin Technologies Ltd., University of Kuopio, Department of Physics, Kuopio, Finland

Background: Current sebum excretion methods are indirect and apply mostly a photometric method. After a touch of glass or plastic sensor with the skin the optical transmission changes due to attached sebum.

Purpose: To provide a method for a quick measurement of the mass of excreted sebum in quantitative units.

Methods: A fully portable and battery operated device SebumScale (patent pending, Delfin Technologies Ltd., Kuopio, Finland) was developed. The device applies a microbalance technique. When the quartz crystal of the microbalance touches the skin, the attached sebum will change the quartz oscillation frequency being proportional to the amount of sebum on the surface of the crystal. The amount of collected sebum was measured in a sensitive laboratory scale. Sebum excretion in forehead of test persons was followed for two hours after degreasing.
Results: An excellent correlation was found between SebumScale device readings calculated from the sebum-induced changes in quartz crystal oscillations and a gravimetric method ($p < 0.001$). Individual sebum excretion at 2 h being in a typical range of healthy human skin varied from 15 to 50 μg/cm^2.
Conclusions: The microbalance technique can be applied in a quick and accurate estimation of sebum excretion rates in quantitative units.
Key words: oily skin, sebum excretion rate

(P-08)
Applications of the new Colorimeter CL 400 for skin colour measurement

[1]**Paola Perugini,** [1]Mariella Bleve, [2]Antonella Mondelli, [2]Gianfranco Secchi, [1]Franca Pavanetto
[1]Department of Drug Sciences, University of Pavia, Via Taramelli 12, 27100 Pavia, Italy;   [2]GF Secchi, Via Urago 13/b, 22038 Tavernerio (CO), Italy

Background: The needs of measuring changes in the skin colour are of great importance in cosmetic and pharmaceutical efficacy tests. The physical properties of the skin make skin colour measurement very complex. Established devices like Chromameter are now commercially available to express the skin colour as an xyz-value (tristimulus) and calculated into L*a*b related values. A new CL 400 colorimeter probe (CK electronic GmbH, Germany) permits to obtain very reproducible results ideal tool for comparison measures; it is economic, extremely easy to handle and short measuring time (1s).
Purpose: The aim of this work was to compare skin colour values obtained from CL400 probe with respect to Mexameter MX18 in order to understand the applications and the limits of the two CK probes.
Methods: 20 healthy tanned volunteers were enrolled in according to Helsinki declaration (Ethical Principles for Medical Research Involving Human Subjects).
The evaluation of skin colour, erythema index and skin brightness were performed before and after 7 wash cycles using a body wash product onto damp skin with a sponge, followed by aqueous rinsing and drying without rubbing. One skin zone was treated only with water, as control. The instrumental assessment of skin parameters was performed with Cutometer MPA580 equipped with Skin Colorimeter CL400 and Mexameter MX18 probes.
Results: Results highlight the correlation between the CIE colour space and the human skin for the CL400 colorimeter; the L-value (brightness) is inversely proportional to the pigmentation. The higher L*, the less pigmented. The a*-value is proportional to the redness (erythema/microcirculation).
However the melanin content is better measured by a Mexameter probe; in fact the results show a correlation between the increase in brightness and the reduction of melanin content, measured by CL400 and MX18 probes, respectively.
Conclusions: In conclusion, this work highlights that the simultaneous use of the two
 probes allows an optimization of the measurement of parameters related to skin colour. In fact, the CL400 colorimeter probe is a useful device to express the erythema index and the skin brightness, such as already marketed established devices, but the melanin content is more accurately measured with the Mexameter probe.

Key words: skin colour measurement, colorimeter, efficacy test, erythema, melanin content

(P-09)
A Comparison of Hair Removal Methods Prior to Sulfur Mustard Exposure

Roy F. Railer, **Robert S. Stevenson**, Robin R. Deckert, Joseph D. Boecker, Jennifer L. Devorak, Kimberly A. Whitten, Horace L. Lumpkin, Bryce F. Doxzon, John S. Graham, John I. Azeke, and Ernest H. Braue, Jr.
U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD 21010-5400

Background: Our group conducts comprehensive research to determine the efficacy of candidate treatment regimens that promote improved healing of cutaneous sulfur mustard (HD) injury. Under current protocol, a depilatory agent (Magic® Shaving Powder, SoftSheen-Carson, LLC, New York, NY) is used to remove hair prior to HD exposure, ensuring complete contact of the dosing template with the skin surface. Scientific literature has indicated that depilatory agents enhance delivery of transdermal drugs.
Purpose: The goal of this study was to determine if application of this agent prior to chemical exposure would exacerbate the degree and depth of sulfur mustard injury when compared to hair removal using only traditional clipping methods.
Methods: Four experimental sites were assigned on the abdomen to each of five weanling Yorkshire swine. Twenty four hours prior to exposure, hair was removed from each site using a depilatory agent or electric clippers. At 48 hours post-exposure, non-invasive bioengineering tools and clinical assessments were used to monitor mechanical, cosmetic, dimensional, and physiological properties of all experimental sites. Following euthanasia, tissues were collected for routine histopathological evaluation.
Results: Statistical analyses ($p<0.05$) indicated that no significant difference in depth or degree of HD injury was attained using either a depilatory agent or electric clippers to remove hair.
Conclusion: These consistent results will allow for further screening of transdermal drugs, and eliminate current dependence on depilatory agents and their potential influence on the pharmacokinetics of promising candidate therapeutics.
Keywords: skin, hair, wound healing, sulfur mustard, depilation, percutaneous, therapeutics

(P-10)
A TRIAL TO DEMONSTRATE THE POTENTIAL OF AN INGREDIENT TO REDUCE PROPIONIBACTERIUM ACNES

R. Chhibber[1], S.Sharma[1], S.Schwartz[2], R.Frumento[2]
[1]BrighTex Bio-Photonics, LLC, San Jose, CA United States; [2]International Research Services, Inc., Port Chester, NY United States

Background: This study was intended to evaluate the effectiveness of a test ingredient in a panel of fifty subjects randomized in a 1:1 ratio to test and control products. Data from this study will be analyzed to determine whether the test product was effective in the reduction of P. acnes and evidence of its effects on facial skin, and whether it was more effective than another product in the reduction of P. acnes and its effects on facial skin.

Purpose: The objective of this study was to evaluate the anti-acne potential of one test ingredient during normal usage conditions using clinical and bio-instrumental assessments, BTBP Clarity Pro R&D technology.

Methods: This was a four (4) week study, with a one-week washout period prior to baseline, wherein subjects were to discontinue use of all topical facial products, anti-aging and anti-acne medications (topical or systemic), and anti-inflammatory medications. Visits occurred at baseline and week four. Visual and instrumental evaluations were performed by qualified IRSI staff.

Results & Conclusions: The test ingredient demonstrated statistically significant outperformance in the reduction of Propionibacterium acnes (p acnes) on facial skin following four weeks of treatment compared to control product. A statistically significant reduction was shown in the total counts of acne lesions, spots/scars (pigment) and pores after four weeks of treatment. The test ingredient demonstrated superior reduction in post inflammatory hyperpigmentation after four weeks of treatment compared to control product.

(P-11)
Antimicrobial activity and Clinical Safety of Biocide (Benzalkonium Chloride) Encapsulated in a Starch-Oil Microemulsion

John J. Wille, PhD
Bioderm Technologies, Inc., Chesterfield, NJ

The wear performance of a benzalkonium chloride containing hand sanitizer lotion produced by an aqueous starch microencapsulation method was studied clinically. The hand sanitizer was formulated with moisturizers and protectant oils to yield a greaseless and cosmetically-acceptable lotion. The results validate its safety and broad-acting antimicrobial and anti-viral efficacy along with a significant four-hour antibacterial persistence on skin. The skin friendly soft feel imparted by the starch-based lotion reduces roughened skin often experienced by end users of alcohol and foam-based hand sanitizers. Safety tests confirmed its lack of oral toxicity and absence of skin irritation or sensitization. Prototypes that incorporate Chlorhexidine in to a starch-oil microemulsion were also studied.