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Dermoscopy: An Evidence-Based Approach for the Early Detection of Melanoma

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DERMOSCOPY: AN EVIDENCE-BASED APPROACH FOR
THE EARLY DETECTION OF MELANOMA

by

Angela Armstrong

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Abstract

The purpose of this project was to evaluate the effectiveness of a practice-based dermoscopy training program for dermatology healthcare providers in order to improve their technique of performing clinical skin exams for the early detection of melanomas.

The overall incidence of melanoma continues to rise. More than 75% of all skin cancer deaths are from melanoma. Advanced melanoma spreads to lymph nodes and internal organs and can result in death. One American dies from melanoma almost every hour (American Cancer Society [ACS], 2009). Early diagnosis and excision are essential to reduce morbidity and to improve patient survival.

This one-group before-and-after study design utilized a convenience sample of three dermatology healthcare providers (DHPs). The primary investigator conducted a retrospective review of the pathology logs for each provider. The time frame for the review was a three-month period in 2010, which represented the same time frame that the study was conducted in 2011. The DHPs participated in a four-hour training workshop that included pattern analysis recognition using dermoscopy. Following the workshop, each DHP was given a DermLite 3Gen DL100 to use in practice when performing clinical skin examinations. All DHPs completed a data collection sheet to document their pattern of decision making with and without a DermLite. The outcome of interest was the use of dermoscopy by DHPs to demonstrate an increased detection of melanoma when compared to naked-eye examination. The outcome was evaluated 12 weeks post-workshop training.

There were 120 evaluations made with the DermLite as compared to the naked eye. The overall agreement was 0.52, AC1 coefficient (95% CI) was 0.36 (0.30, 0.42),

p < .001, and kappa coefficient (95% CI) was 0.27 (0.20, 0.43), p < .001. Overall, the risk of lesion under exam being suspicion for skin cancer was higher on 27.5% (33 out of 120) of the evaluations and lower on 20.8% (25 out of 120) evaluations. The risk of lesion was evaluated the same on 51.7% (62 out of 120) of the evaluations. This is an indication of "Poor" agreement between the two methods. The diagnosis and disposition made using DermLite compared to naked-eye results for both coefficients provided an "Intermediate to Good" agreement between the two methods in assigning diagnosis and disposition. This indicates that there is no difference between DermLite and naked-eye evaluations.

More studies are needed in order to provide better evidence on the value of dermoscopy in clinical practice at the Dermatology and Laser Center. Future projects should be more explicit regarding the methods used and lesion selection in order to better understand the benefits of dermoscopy.

Chapter One: Introduction

Chapter One introduces the challenges/problems with performing a clinical skin examination with the use of dermoscopy, provides an abbreviated literature review, and briefly describes the project. Chapter One also includes the research questions and definition of terms.

Challenges

Melanoma, the most serious form of skin cancer, is characterized by the uncontrolled growth of pigment-producing cells. A melanoma might appear on the skin suddenly without warning, but it can also develop on an existing mole. The overall incidence of melanoma continues to rise. More than 75% of all skin cancer deaths are from melanoma. Advanced melanoma spreads to lymph nodes and internal organs and can result in death. One American dies from melanoma almost every hour (ACS, 2009). People of all ages are affected by melanoma, causing more years of lost life than any other cancer, excluding leukemia (High, 2008).

Diagnostic criteria for the diagnosis of melanoma have changed since the 1960s and 1970s, when melanomas were diagnosed based on itching, bleeding, and ulceration of the tumor. Once the symptoms were observed, however, the prognosis was very poor. The ABCD rule was introduced in the 1980s. This rule is based on simple clinical morphological features of melanoma: asymmetry, border irregularity, color variation, and a diameter greater than five millimeters. The worldwide use of the ABCD rule has

allowed for early detection of some melanomas. To improve on this rule, the letter E was added in 2004 as the fifth criterion and explains evolution of the lesion over time (Guibert, Mollat, Ligen, & Dreno, 2000).

There are two problems associated with the ABCD rule. First, the rule only has 65 - 80% sensitivity because the rule does not allow for melanomas less than five millimeters. Melanomas can be less than five millimeters and have a regular shape and color, which would consequently be falsely classified as benign. Second, benign melanocytic nevi can mimic melanomas, causing unnecessary excisions to be performed on a daily basis (Argenziano & Soyer, 2001).

Contributing factors that place patients at high risk for developing melanoma include sun exposure, personal history of atypical moles, personal or family history of melanoma, more than 75 - 100 moles on the body, repeated sun burns, fair skin with red or blonde hair, and chronic tanning bed use. A significant increased risk of melanoma is linked to the intermittent exposure to UV radiation (Cattaruzza, 2000). The American Cancer Society (2007) concluded that the most preventive tools available are full body examinations by a health care provider, sun protection, and sun avoidance.

Melanoma presents a substantial clinical challenge to healthcare providers. The early detection of this skin cancer provides the patients with the best chance for a cure. The frequency of melanoma has increased over the last twenty years. Therapies for metastatic melanoma are inadequate, making the best treatment early diagnosis with immediate surgical excision of the tumor. There is a critical need to have current diagnostic practices evaluated in order to have the best technique used when performing a clinical skin exam (Argenziano & Soyer, 2001).

Dermoscopy is an in vivo diagnostic technique that is noninvasive and used to magnify the skin. Dermoscopy allows the colors in the structures of the epidermis, dermo-epidermal junction, and papillary dermis to show detail far beyond the ability of the unaided eye. The portable polarized imaging system has made it convenient for the healthcare provider to examine a suspicious lesion for possible malignancy. Dermoscopy, used for many years in Europe, is currently becoming the standard of care for clinical skin examination (Arrazola, Mullani, & Abramovits, 2005).

Pattern analysis is the procedure used by most dermatology healthcare providers when conducting a skin examination. The first step requires the examiner to determine if the lesion is melanocytic or nonmelanocytic. The identification of the pigmented network, aggregated dots and globules, branched streaks, and homogenous blue pigmentations are all highly characteristic of pigmented lesions. Once the examiner has identified the lesion as pigmented the next step is to determine if the lesion is clinically benign or malignant. Benign lesions have global features that are uniform. Malignant lesions have atypical global features. There are three criterions that are important in distinguishing melanoma from benign lesions: asymmetry, atypical network, and blue white structures (Johr, Soyer, Argenziano, Hofmann-Wellenhof, & Scalvenzi, 2004).

Abbreviated Literature Review

The diagnostic accuracy of dermoscopy in detecting melanoma was assessed by performing a meta-analysis of eight studies that met the selection criteria from the 672 studies obtained in the MEDLINE database. A meta-analysis is a statistical procedure that integrates the results of several studies. Once data are combined, a quantified and reproducible synthesis of data can provide an objective appraisal of the evidence. A well

conducted meta-analysis should also diminish the bias of each study (D'Agostino & Weintraub, 1995).

The eight retained studies came from dermatology departments and were published between 1993 - 2000. All studies used histological findings as a standard criterion. Fifty percent of the studies had histological findings verified by an external review or from a consensus of at least two observers. Clinical and dermoscopic examinations were conducted in all studies (Bafounta, Beauchet, Aegerter, & Saiag, 2001).

The results determined that healthcare providers trained in dermatology and working in a specialized clinic with dermoscopy experience yield increased detection of melanomas compared to the naked eye. The conclusion of the study was favorable for the use of dermoscopy. One of the studies in the meta-analysis recommended that healthcare providers working in dermatology should take the necessary steps to master this useful tool (Bafounta et al., 2001).

The Problem

The overall incidence of melanoma continues to rise. More than 75% of all skin cancer deaths are from melanoma. Advanced melanoma spreads to lymph nodes and internal organs and can result in death. One American dies from melanoma almost every hour (ACS, 2009). Early diagnosis and excision are essential to reduce morbidity and improve patient survival.

There is no current recommendation from the American Academy of Dermatology regarding the use of dermoscopy to aid detection of melanoma during a clinical skin examination. Despite the lack of recommendations, some experts

acknowledge full body skin cancer screening as a simple, practical way to reduce skin cancer incidence and mortality. Dermoscopy has also been shown to be a useful diagnostic tool.

Therefore, the purpose of this project was to evaluate the effectiveness of a practice-based dermoscopy training program for dermatology healthcare providers in order to improve their technique of performing clinical skin exams for the early detection of melanomas.

Project Description

This project was designed to improve clinical skin examination techniques in healthcare providers working in dermatology at a dermatology and laser practice in northeast Florida. The practice strategic plan includes keeping up with the latest advancements in dermatology in order to provide patients with the most up-to-date services available. A prospective study to examine whether provider education with a four-hour training course delivered by an expert in dermoscopy, regarding the science behind the regular use of dermoscopy, while also using pattern analyses, will increase the number of melanomas diagnosed over a three-month time period in the practice.

A board certified dermatologist with expertise in dermoscopy was asked to deliver the four-hour training workshop. One nurse practitioner currently using dermoscopy, one dermatologist not currently using dermoscopy, and one physician assistant not currently using dermoscopy attended the lecture. The practice pathology logs were assessed at a three-month period before the training and a three-month period after the training. The number of pathology reports that were positive for melanoma

were evaluated by each healthcare provider. Each healthcare provider was provided with a Derm-lite DL100 dual polarized LED made by 3Gen LLC to use during the study.

Research Questions

The following research questions guided the literature review:

1. What is the difference in the detection of melanoma in dermatology when dermoscopy is used versus the naked eye?

2. Does dermoscopy decrease the number of biopsies of benign skin lesions?

Definition of Terms

Dermoscopy: A vivo noninvasive diagnostic technique that magnifies the skin in such a way that color and structures in the epidermis, dermo-epidermal junction, and papillary dermis become visible (Johr et al., 2004, p. 1).

Melanoma: A malignancy of melanocytes that occur in the skin, eye, ears, gastrointestinal tract, leptomeninges, and oral and genital mucous membranes (Habif, 2004, p. 786).

Sensitivity: The proportion of individuals with the disease who are correctly diagnosed by the test (Petrie & Sabin, 2009, p. 171).

Specificity: The proportion of the individuals without the disease who are correctly identified by a diagnostic test (Petrie & Sabin, 2009, p. 172).

Asymmetry: Asymmetry of color and structure in one or two perpendicular axes (Johr et al., 2004, p. 2)

Atypical network: Pigment network with irregular holes and thick lines (Johr et al., 2004, p. 2).

Blue-white structures: Any type of blue and/or white color (Johr et al., 2004, p. 2).

In summary, Chapter One introduced the challenges/problems with melanoma diagnosis, the potential benefits of using dermoscopy when performing clinical skin examinations, an abbreviated literature review, and a brief description of the proposed project. Research questions used to search the literature and definitions were also provided.

Chapter 2: Review of the Literature

A critical appraisal of the literature will be presented in this chapter in order to determine if completing a full skin examination with the aid of dermoscopy would improve the early detection of melanoma compared to the unaided eye examination. A literature search was conducted using Medline, CINAHL, and ScienceDirect for high level evidence using the following key terms: *dermoscopy*, *melanoma*, *diagnosis*, and *skin examination*. Articles dating back to 1997 that had two of the key terms were reviewed. Two other websites were used to locate research articles on dermoscopy: *Journal of the American Academy of Dermatology* (www.eblue.org) and *Archives of Dermatology* (www.archdermtol.com).

Melanoma

Melanoma is a fatal disease requiring early diagnoses and treatment. Recognition of early melanoma is a daily challenge for dermatology healthcare providers. Morbidity and mortality related to melanoma of the skin has increased significantly in recent years. There is a strong inverse correlation between survival rates and tumor thickness, with no effective therapy for advanced melanoma. Early diagnosis and excision of the tumor is essential to reduce the morbidity and mortality rates related to melanoma (Bafounta et al., 2001).

Early diagnosis of melanoma is of critical importance for patient prognosis. Patients with a cutaneous melanoma thinner than 1 mm have a 95% 5-year survival rate,

while patients with an ulcerated melanoma greater than 4 mm thick have a 45% 5-year survival rate (Balch et al., 2001). Diagnosing melanoma clinically will allow early detection and surgical excision of thin melanomas. Excision is the only efficient treatment available (Tsao, Atkins, & Sober, 2004). Melanomas should be considered when a patient reports a new pigmented lesion or a change in an existing mole. In order to decrease mortality rates early, detection of melanoma is key (Marks, 1996).

Dermoscopy

Dermoscopy is a noninvasive in vivo technique used to examine the structures that lie beneath the skin surface; it has increased the understanding of the clinical morphology of skin lesions. Dermoscopy allows subsurface structures in the epidermis, dermoepidermal junction, and papillary dermis to be seen, structures that are otherwise invisible to the naked eye (Grin, Friedman, & Grant-Kels, 2002).

Dermoscopy is a diagnostic test with high levels of sensitivity and specificity. Diagnostic tests are helpful if the results will alter the clinical management of the disease, allowing for better patients outcomes. In the case of a pigmented skin lesion, dermoscopy helps the provider to decide if excision of the lesion is necessary (Mayer, 1997).

History of Dermoscopy

Skin surface microscopy started hundreds of years ago. In 1663, Johan Kolhaus first looked at nail fold vessels with a microscope. Unna published a paper in 1893 entitled "Diaskopie", which described the use of oil immersion with a microscope for skin surface microscopy. The term *dermatoscopy* was introduced in the 1920s with the introduction of a new diagnostic tool resembling a binocular microscope with a built-in

light source for the examination of the skin. The term *dermoscopy* was introduced in 1950 when a dermatologist used the instrument for the evaluation of pigmented skin lesions. In 1971, Rona MacKie identified the advantage of surface microscopy for the improvement of preoperative diagnosis of pigmented skin lesions and for the differential diagnosis of benign versus malignant skin lesions (Grin et al., 2002). The technique utilized in the 21st century was studied and refined by Austrian, German, and Italian investigators. In 1989, the first Consensus Conference on Skin Surface Microscopy was held in Hamburg, Germany, and in 2001 the Consensus Net Meeting on Dermoscopy was convened in Rome, Italy. The goal of both meetings was to standardize the definitions of structures seen in benign and malignant pigmented skin lesions (Soyer, et al., 2001).

Literature Review

In appraising the literature, multiple levels of evidence were reviewed. Articles on dermoscopy ranging from case studies to systematic reviews were all appraised. This paper reviews the highest levels of evidence: randomized studies, meta-analysis, and systematic reviews.

Randomized Control Trial

A randomized control trial (RCT) by Carli et al. (2004) enrolled 913 patients with pigmented skin lesions. The study was conducted at a pigmented lesion clinic to assess the difference in lesion management between combined examination (naked eye and dermoscopy) and conventional naked-eye examination in the evaluation of melanoma. The patients were randomized to either combined examination with mandatory excision of equivocal lesions or to conventional naked-eye examination for melanoma with mandatory excision of equivocal lesions. The study showed that the examination of a

pigmented skin lesion using dermoscopy allows for the visualization of morphologic

features not visible to the naked eye. This allowed trained observers to reach a more

reliable diagnosis of most skin lesions, including melanoma, compared to conventional

naked-eye examination. The study was done to investigate the impact of the addition of

dermoscopy to conventional naked-eye examination in routine melanoma screening. The

findings in the study were confirmed by means of a multivariate analysis. The study

demonstrated that the addition of dermoscopy to the routine screening of melanoma is

associated with clinically relevant lesion management, reducing the number of cases of

excisional biopsies. The authors hypothesize that the reduction of surgical excisions

aimed at diagnostic verification was obtained through better classification of equivocal

lesions compared to conventional screening, lowering the number of false-positive

diagnoses. The debate continues over the issue of false-negative diagnoses by

dermoscopy. Based on formal studies on melanoma classification, dermoscopy does not

have 100% sensitivity; this makes excluding false-negative results unlikely. This could

be due to the high number of benign lesions that are excised in an effort to avoid leaving

a melanoma unexcised.

One study in the literature addressed the issue of false-negative results after

dermoscopy. This was done through a local cancer registry that showed 3.7% of

melanomas left unexcised after screening. Two out of 55 cases of melanomas examined

were not excised. This resulted in a sensitivity of 96.3% (Stanganelli, Serafini, & Bucch,

2000).

An RCT was performed to determine if the use of dermoscopy with standard

clinical examination improves the accuracy of primary care physicians to triage lesions

suggestive of skin cancer. A total of 73 physicians were given a one-day training course in dermoscopy evaluation and skin cancer detection. Following the training, the providers were randomly assigned to the dermoscopy group or the naked-eye examination group. The providers evaluated 2,522 patients with skin lesions. The lesions were scored as "benign" or "suggestive of skin cancer". All patients were then evaluated and scored by two expert dermatologists who used dermoscopy. The dermatologists were blinded regarding patients' randomization schedules. The lesions that the dermatologist examined as being suggestive of skin cancer were excised and diagnosed histopathologically. Histopathologic examination of equivocal lesions demonstrated 23 malignant lesions missed by naked-eye examination and 6 by dermoscopy. The investigators concluded that dermoscopy improves the primary care physicians' ability to triage lesions suggestive of skin cancer (Argenziano et al., 2006).

In an RCT by Westerhoff, McCarthy, and Menzies (2000), 74 practicing primary care physicians (PCPs) completed a pre-test of 50 melanomas and 50 atypical non-melanoma pigmented skin lesions (PSLs) containing matched clinical and surface dermoscopy photographs. PCPs were randomized between dermoscopy education intervention or control group followed by an identical post-test.

Before training, there were no significant differences in the pre-test results between the clinical and the surface dermoscopic diagnosis on melanoma or non-melanoma PSL. No significant differences were seen in the pre-test results between the education intervention group and the non-education intervention group. After training, the clinical diagnosis of melanoma was compared by looking at the clinical images only. There was a significant improvement in the education intervention group between the

pre-test (54.6%) and post-test (62.7%) results (P = .007). In contrast there was no difference between the clinical melanoma diagnosis between the pre-test and post-test in the non-intervention group (P =.21). This is an important indication that the education intervention also created a heightened awareness of the clinical signs of melanoma. This is consistent with the content of the intervention that contains both clinical and dermoscopic images of PSL (Menzies, Crotty, Ingvar, & McCarthy, 1996).

Following the education intervention, dermoscopy further improved the PCPs diagnosis of melanoma. The clinical correct diagnosis was 62.7% compared with 75.9% when dermoscopy was utilized (p = .000007). The difference between dermoscopy and clinical score in pretest versus post-test (p = .0004); this supports that the education intervention was responsible for the improved diagnostic accuracy.

Meta-Analysis

A meta-analysis by Kittler, Pehamberger, Wolff, and Binder (2002) reviewed relevant studies from a MEDLINE search from January 1987 to December 2000. The search produced 157 articles, of which 116 were excluded because they did not report sufficient data for the sensitivity and specificity to be estimated. Studies that involved computerized image analysis were also excluded. The final sample included 27 studies, of which 20 were identified by the MEDLINE search, three by manual searches of the reference list of retrieved articles, and four by communication with experts.

The eligible studies were classified with no masking. Two readers were responsible for the review using defined characteristics important for the assessment of diagnostic tests. From each report the authors' names, year of publication, description of pigmented skin lesions, experience of examiners, independence of clinical and

histological assessment, type of diagnostic algorithm, mode of presentation, and results were extracted.

Most of the lesions were verified by excision. Only one study looked at benign lesions that were not excised. In 14 studies (52%), the diagnostic accuracy for melanoma with and without dermoscopy was directly compared. In three studies (11%), two or more diagnostic algorithms for dermoscopy were compared. Pattern analysis was used in 16 studies (59%), the ABCD rule in seven (26%), and modified pattern analysis in conjunction with a scoring system in seven (26%). Five studies (19%) compared the performance of experts and non-experts, and two (7%) assessed the influence of training on the performance of non-experts. Dermatologists were included in 26 of the 27 studies that were reviewed.

The use of dermoscopy yielded a higher diagnostic accuracy for melanoma compared to the unaided eye when used by an experienced examiner. The studies found that the diagnostic performance of dermoscopy was significantly increased when a group of examiners made the diagnosis in consensus. A consensus diagnosis may not be practical in most clinical settings. The examiners' experience with dermoscopy determines the diagnostic accuracy of the tool. Dermoscopy applied by non-experts is equal to the unaided eye examination. This is a significant finding that underlines the importance of the need for training in order to utilize dermoscopy as a diagnostic tool (Binder et al., 1997).

Diagnostic accuracy for melanoma was found to be higher with dermoscopy (odds ratio 4.0, 95% CI: 3.0 - 5.0) than without dermatocopy (odds ration 2.7, 95% CI: 1.9 - 3.4). There is an overlap in the confidence intervals, which may cause dermoscopy

and non-dermoscopy melanoma diagnosis to be equal in regards to the odds ratio value. There was no significant difference in diagnostic accuracy arising from the use of different dermoscopy diagnostic algorithms. The experience of the examiners is the significant factor. The odds ratio was 3.8 (95% CI: 3.3 - 4.3) for experts versus 2.0 (95% CI: 1.4 - 2.6) for non-experts. The results of this meta-analysis documents that dermoscopy improves the diagnostic accuracy for melanoma compared to inspection by the unaided eye. Dermoscopy requires a basic training course and continual practice following training in order to learn the skill. Dermoscopy is not recommended for untrained users. A diagnosis involving two or more experts is recommended to yield the highest possible diagnostic accuracy (Kittler et al., 2002).

The meta-analysis by Bafounta et al. (2001) identified 564 articles from MEDLINE, 223 from EMBASE, 117 from PASCAL-BIOMED, and 2 doctoral theses from BIUM database. Duplicates were eliminated, making the final count 672. The authors selected studies that had a spectrum of lesions well described, histological findings as standard criterion, and calculated or calculable sensitivity and specificity. Only eight of the 672 retrieved studies met the inclusion criteria.

The eight retained studies came from dermatology departments and were published between 1993 and 2000. The settings were dermatology clinics or PSL clinics. Two of the studies were performed based on images obtained from a computerized database. Six of the studies recorded dermoscopy results in vivo. Four studies had histological findings verified by an external review or obtained by agreement between at least two observers (Stanganelli et al., 2000).

The studies had 2193 total lesions, of which 328 (15%) were melanomas. The sample size among the studies varied from 15 to 824 lesions. Melanoma lesions represented 3% to 49% of the excised lesions. Most of the melanomas were thin (< 0.76 mm) from what was obtained in the four studies that provided melanoma thickness information. The number of lesions represented as non-melanoma totaled 1865 (85%) and their histologic findings were detailed in all but one study (Stanganelli et al., 2000); theses lesions were mainly melanocytic lesions (67% - 100% of all non-melanoma PSLs). There was no demographic information given on any of the patients included in the studies.

The authors used the summary receiver operating characteristic curves of clinical and dermoscopic evaluations of melanoma, which indicated that dermoscopy had a significantly higher discriminatory power, with an estimated odds ratio of 76 (95% CI: 25 - 223) versus 16 (95% CI: 9 - 31) for naked-eye examination (p = .008). Similar values were seen with the weight least squares, the robust resistant line, and other exploratory data analysis methods (Moses, Shapiro, & Littenberg, 1993).

The authors concluded that more studies need to be conducted within dermatology clinics. An increased number of melanoma and benign PSLs need to be evaluated. More studies to evaluate the false-negative results need to be conducted.

Vestergaard, Macaskill, Holt, and Menzies (2008) conducted a meta-analysis on prospective studies of consecutive patients in a clinical setting to evaluate the evidence for improved diagnostic accuracy when using dermoscopy in addition to naked-eye examination for accurate clinical diagnosis of melanoma. Nine studies met the criteria and were included in the review. According to the authors, the diagnostic odds ratio was

estimated to be 15.6 times higher for dermoscopy than for naked-eye examination. (95%

CI: 2.9-83.7, p = .016). The wide CI reflects heterogeneity in the relative accuracy

between studies. The summary estimate of sensitivity was higher for dermoscopy (0.90,

95% CI: 0.80 - 0.95) than for naked-eye examination alone (0.71, 95% CI: 0.59-0.82),

with an estimated difference of 0.18 (95% CI: 0.09-0.27, P = .0002). There was no

statistical evidence of a difference in specificity: dermoscopy 0 - 90, 95% CI: 0.57 - 0.98;

naked-eye examination 0.81, 95% CI: 0.48 - 0.95; difference 0.09, 95% CI: 0.06-0.23,

P = .18.

This meta-analysis provides evidence that clinical examination with the use of

dermoscopy is more accurate than the naked eye alone for discriminating melanoma from

non-melanoma in suspicious skin lesions for clinicians with at least minimal training in

dermoscopy. The results of this study were consistent with previous meta-analysis,

including studies that utilized mainly experts in clinical and experimental settings. Like

other diagnostic techniques, some training in dermoscopy is needed to be able to achieve

improvement in diagnostic accuracy. Studies have shown that when dermoscopy is used

in an experimental setting by dermatologists with no formal training in the technique, the

diagnostic performance will be decreased (Binder et al., 1997).

Systematic Review

Mayer (1997) conducted a systematic review of six articles that each compared

diagnostic accuracy of dermoscopy to clinical diagnosis in order to assess their usefulness

in clinical practice. Five of the six studies compared dermoscopy with clinical diagnosis.

Positive likelihood ratios for dermoscopy diagnosis of melanoma ranged from 2.9 to

10.3. Two studies found that dermoscopy had higher sensitivity than non-dermatoscopy.

One study found no difference in diagnostic accuracy. Dermoscopy had a higher sensitivity when performed by expert examiners. This sensitivity was decreased when the dermoscopy was performed by healthcare providers not trained in the use of dermoscopy (Binder et al., 1995).

Nachbar et al. (1994) compared two forms of dermoscopy with and without explicit structured diagnostic criteria, but combined with clinical diagnosis. They found that dermoscopy with structured ABCD criteria had higher sensitivity and specificity than dermoscopy performed without the use of the ABCD criteria. Clinical diagnosis varied widely in sensitivity and specificity between the studies. This could have been due to the lesions varied in their ease of diagnosis. Observers may have varied in their ability to make the diagnosis. The studies provided results that favored handheld monocular demoscopy with 10 times magnification. Handheld dermoscopy devices are most relevant to clinical practice. Cristofolini, Zumiani, Bauer, Cristofolini, Bpi, and Micciolo (1994) found that dermoscopy with pattern analysis criteria had slightly higher sensitivity (88%) and specificity (79%) than clinical diagnosis performed with the use of the ABCDE criteria.

The systematic review by Rajpara, Botello, Townend, and Ormerod (2009) retrieved 765 articles from with 30 studies eligible for inclusion. The review shows strong diagnostic performance by dermoscopy and artificial intelligence as evidence by diagnostic odds and likelihood ratios. The review on dermoscopy showed it improves diagnostic accuracy of melanoma diagnosis for experienced examiners. There was no significant difference between different algorithms. The diagnostic performance of

dermoscopy improved when the diagnosis was made by a group of examiners in consensus and diminished as the prevalence of melanoma increased.

Multiple comparisons were done of the different dermoscopy algorithms. There was no significant difference in the overall diagnostic performance of the different dermoscopy algorithms. Dermoscopy showed significantly higher specificity than artificial intelligence ($p < .001$) but lower sensitivity ($p = .076$). The review on diagnostic accuracy of artificial intelligence showed that melanoma diagnosis by computer is as accurate as an expert dermatologist under experimental conditions.

The computer diagnosis performance was better for studies that used dermoscopic images than for studies that used clinical images. The studies in this present review were performed on databases of previously collected lesions rather than in the clinical setting. The external validity of these studies needs to be interpreted with caution (Rajpara et al., 2009)

Conclusion

Evidence from systematic reviews showed that dermoscopy yields greater diagnostic accuracy than naked-eye examination. There were no effects found from the use of different dermoscopy diagnostic algorithms. Diagnostic accuracy of dermoscopy is dependent upon the degree of experience the examiner has with using dermoscopy. The systematic review by Mayer (1997) estimated the likelihood ratios for a positive diagnosis of melanoma by dermoscopy as having a range of 2.0 - 10.3. The systematic review by Bafounta et al. (2001) found the sensitivity of dermoscopy to have a range of 75 - 96% and specificity of 79 - 98%. The odds ratio for diagnosis of melanoma by

dermoscopy was 76 (95% CI: 25 - 223) versus 16 (95% CI: 9 - 31) for naked-eye examination (p = .008).

A meta-analysis by Kittler et al. (2002) found diagnostic accuracy for melanoma to be higher with dermoscopy (odds ratio 4.0, 95% CI: 3.0 - 5.1) than without dermoscopy (odds ratio 2.7, 95% CI: 1.9 - 3.4). The 95% confidence intervals overlap, which could imply that the odds ratio values may be equal for dermoscopy and non-dermoscopy melanoma diagnoses. There was no significant difference in diagnostic accuracy arising from the use of different dermoscopy diagnostic algorithms. Diagnostic accuracy of dermoscopy significantly depends on the degree of experience of the examiners, with odds ratio 3.8 (95% CI: 3.3 - 4.3) for experts versus 2.0 (95% CI: 1.4 - 2.6) for non-experts (p = .001).

The RCT by Westerhoff, McCarthy, and Menzies (2000) found that following a brief training intervention there was a significant improvement in both clinical diagnosis of melanoma and in diagnosis of melanoma using dermoscopy. The improvement was significantly larger for the use of dermoscopy compared to clinical diagnosis alone.

In the last few years, three meta-analyses and two randomized studies have concluded that dermoscopy has an increased sensitivity for detecting melanoma when compared to the naked-eye examination (Carli et al., 2004). The last piece of evidence provided by Vestergaard et al. (2008) was a meta-analysis done on dermoscopy studies performed in clinical settings. The relative diagnostic odds ratio for melanoma was 15.6 (p = .0016) for dermoscopy compared to naked-eye examination alone. The average sensitivities for melanoma of the naked eye and dermoscopy examinations were 74% and

90% respectively. The results suggest that there was better melanoma detection without increasing the number of unnecessary excisions of benign lesions.

Based on findings in this literature review, dermoscopy should be used only by trained examiners. Providers not trained in dermoscopy will not experience good results from the use of dermoscopy. The evidence supports the training of DHPs on the practice of using dermoscopy for the early detection of melanoma.

Chapter 3: Methodology

In this chapter, the design and methodology are explained. The design is an interventional one-group before-and-after study. The purpose of this evidenced-based project is to evaluate the effectiveness of an office-based dermoscopy training program for DHPs to improve their technique of performing clinical skin examinations for the early detection of melanomas.

Sample

The sample consisted of one board certified dermatologist, one dermatology certified nurse practitioner, and one certified physician assistant. All participants worked in dermatology for two years or greater, and have worked at the dermatology practice for at least 6 months seeing general dermatology patients. The dermatologists, nurse practitioners, and physician assistants that worked at the dermatology practice and agreed to participate in the study are included in the study. The exclusion criteria included medical doctors, physician assistants, and nurse practitioner students completing clinical hours in dermatology at the dermatology practice as well as new dermatologists, physician assistants, or nurse practitioners joining the practice after December 2010.

After approval was obtained from the University of North Florida Institutional Review Board (IRB), a date and time for the four-hour dermoscopy training course was determined. The training course was held at the dermatology practice, and presented by a dermoscopist expert (see Appendix A for the "Abbreviated Curriculum Vita of the

Expert"). Each participant was given a DermLite 3Gen DL100 at the completion of the course to use in their practice when conducting clinical skin examinations. Informed consent was obtained prior to completing any study related activities. Participation in the study was voluntary, and participants could chose to take part in the study or stop at any time.

Methods

The interventional, one-group before-and-after study design consisted of the following:

1. The primary investigator conducted a retrospective review of the pathology logs for each provider. The time frame for the review was a three-month period in 2010 from the same time frame that the study was conducted in 2011.

2. A designated code number was assigned to each DHP by the primary investigator. All pathology information was assigned a code. All Health Insurance Portability and Accountability Act information was honored. Data on individual patients was used in aggregate form only.

3. All DHP participants attended a four-hour training workshop that included pattern analysis recognition using dermoscopy. (See Appendix B for the "Dermoscopy Course Curriculum".)

4. Following the workshop, each DHP was given a DermLite 3Gen DL100 to use in practice when performing clinical skin examinations. Each DHP completed a data collection sheet (see Appendix C for the "Data Collection Sheet") to document their pattern of decision-making with and without a

DermLite.

5. Pathology logs of the three-month period of time following the workshop were assessed for the type of lesions biopsied by participating DHPs. The pathology logs from the nurse practitioner who was using dermoscopy prior to the workshop was included in the assessment.

The outcome of interest was the use of dermoscopy by DHPs to demonstrate an increased detection of melanoma when compared to naked-eye examination. This outcome was evaluated 12 weeks post-workshop training.

Time Frame

The time frame for this study was 14 weeks. The study began once approval was obtained from the University of North Florida IRB. The workshop date and time was announced to the DHPs; written informed consent was obtained from all participating DHPs (see Appendix D for the "Informed Consent"); and, the four- hour training course was held on a Saturday for the participating DHPs who agreed to participate in the study.

Project Evaluation Plan

The data collection sheets were evaluated by the investigator to determine if dermoscopy raised or lowered the index of suspicion in equivocal lesions examined by DHPs. The three-month block of histopathological data obtained pre-intervention was compared to the three-month block of histopathological data obtained post-intervention. The objectives for the project included

- post-intervention histopathological data would show an increase in the number of melanomas detected using dermoscopy;

- dermoscopy would raise the level of suspicion in equivocal lesions examined by DHPs; and

- the use of dermoscopy would become the standard of care for DHPs employed at the Dermatology and Laser Center.

Feasibility

The project was designed to improve the quality of care for patients receiving a clinical skin examination (CSE). It is of the utmost importance that the best evidence-based tools available in the field of dermatology are used during a patient CSE. When melanoma is diagnosed early, patients have the best chance of survival. Patients diagnosed early with melanoma are usually able to avoid extensive and costly procedures with general surgery, sentinel lymph node biopsy, oncology visits, radiation, and repeat computed tomography.

At the time of the study, the use of dermoscopy for CSE's was not the standard of care in dermatology in the United States or in the practice where the data was collected.

Income and Expenses

The DHPs did not pay for any study related expenses. They were not compensated for their time or any expenses related to completing the dermoscopy training workshop. The dermoscopy workshop was held on a Saturday to avoid interference with patient care during the week. Detailed expense report (see Appendix E for "Reported Expenses").

Institutional Review Board

IRB approval was granted by the University of North Florida (see Appendix F for "IRB Approval Documents"). A letter of permission to complete the study at the

Dermatology and Laser Center was obtained from the owner of the center (see Appendix G for the "Permission Letter" form).

Benefits and Risks

The benefit-risk ratio was assessed for this study and it indicated minimal risk and potential benefits, which included

- a free four-hour dermoscopy training course given by a dermoscopy expert;

- a free DermLite 3Gen DL100 used during the study, given to all DHPs who consented to participate;

- an improvement in the ability to differentiate skin lesions and to initiate the appropriate treatment;

- a decrease in the number of unnecessary procedures performed; and

- an increase in the quality of care given to patients with potential life-threatening skin lesions.

Confidentiality

All study source documents were kept confidential. Data collected during the study was scanned and uploaded to a secure electronic server at the University of North Florida. The secure server is password protected and available only to the investigator. After all study information was scanned, the source documents were shredded.

Data Analysis

Descriptive statistics were utilized to summarize the collected data. A computer-assisted statistical analysis was done using SAS®9.2 software. Categorical variables were described using percentages and counts, while interval variables were described using median and interquartile range (IQR). To evaluate the extent of agreement between

naked-eye examination as it compared to DermLite examination, Fleiss's Kappa

coefficient and Gwet's AC1 coefficient were calculated.

Chapter 4: Data Analysis

This chapter describes the project and results. The project objectives as outlined in Chapter Three are evaluated. All DHPs working at the Dermatology and Laser Center were potential participants. Out of four total possible participants, three entered the study.

Statistical Analysis

Statistical analysis was conducted using SAS®9.2 software. Descriptive statistics were used for demographical information. Categorical variables were described using percentages and counts, while interval variables were described using median and interquartile range (IQR).

To evaluate the extent of agreement between the use of DermLite and the naked eye, Fleiss's kappa coefficient and Gwet's AC1 coefficient were calculated. The AC1 is not affected by the rater's classification and trait prevalence of the subjects, contrary to the kappa statistics, and still adjusts for chance agreement. Coefficients were interpreted using Fleiss' benchmarking scale (1981). Coefficient values ranging between 0 - 40% represent "Poor" extent of agreement, values in the 40% - 75% range represent an "Intermediate to Good" extent of agreement, while all kappa values in the 75% - 100% range indicate an "Excellent" extent of agreement. Proportion of change in evaluations when using DermLite compared to the naked eye were calculated for each provider, along with an exact 95% confidence interval.

Implementation

This project began with the three DHPs attending a four-hour educational work shop on dermoscopy held Saturday June 11, 2011, at eight o'clock in the morning at the Dermatology and Laser Center in Orange Park, Floirda. The workshop was given by Dr. Chavez-Frasier. A power point presentation was used to aid in the review of basic dermoscopy. During the interactive parts of the workshop, the DHPs were required to review 11 cases and to determine the risk that they associated with the lesion using the scale of "low", "intermediated", or "high". They had to diagnose the lesion type and state their disposition. The DHPs had to use the pattern analysis algorithm that was reviewed during the workshop to determine melanocytic lesions from non-melanocytic lesions and decide if they would perform a biopsy or not. Following the workshop, the project material was reviewed to include the project timeline. All DHPs were given a DermLite 3Gen DL100 for their use while they participated in the project. Each DHP completed forty data collection sheets in order to evaluate their use of the DermLite while completing a full-body skin examination as it compared to a naked-eye examination.

Project Objectives

The first objective was that post-intervention histopathological data would show an increase in the number of melanomas detected using dermoscopy. There was an increase in the number of melanomas detected by the dermatologist; the nurse practitioner had a small increase, while the physician assistant had a decrease noted by post-intervention histopathological data. A key barrier to this objective was the changes made to the schedules this summer in order to accommodate the cosmetic caseload of the practice. The physician assistant had a decrease in the number of medical patients that

she would usually see over a three-month time period. The dermatologist experienced an increase in the number of general dermatology patients and the nurse practitioner experienced a decrease in the number of general dermatology patients seen in a day when 2010 totals were compared to 2011 totals. The total number of biopsies performed was a key facilitator as they related to the number of melanomas detected.

The second objective was that dermoscopy would raise the level of suspicion in equivocal lesions examined by DHPs. The facilitator that helped achieve this objective was the dermoscopy workshop, and the dermoscopic criteria that were employed during the clinical exam using a DermLite. A healthcare provider does not want to misdiagnose melanoma on a patient. The workshop demonstrated how important it is to use a DermLite to be able to see with cross-polarization pigmented networks and variety of color to help determine whether or not to biopsy suspicious lesions. This diagnosis is very important, as when melanoma is involved it can mean the difference between life and death. Fear of change was a key barrier expressed by the dermatologist participating in the project.

In the third objective, dermoscopy would become a standard of care for DHPs employed at the Dermatology and Laser Center. This objective was not achieved, as evidenced by the dermatologist and physician assistant discontinuing use of the DermLite once the project data collection was completed. This may or may not change once they are able to review project results. A key barrier to this objective not being met was that one of the dermatologists declined to participate in the project due to his prior commitment to working Saturdays at another dermatology office. Without this

dermatologist's use of the DermLite at the practice, the standard of care will not be dermoscopy use.

Unintended Consequences

The investigator's plan of obtaining project data following the dermoscopy training workshop was detained at different time points. Scheduling issues with the physician assistant made collecting data difficult. The physician assistant had several cosmetic training workshops to attend, which decreased the amount of time she was available to see general dermatology patients. Scheduled vacation time also conflicted with data collection.

A decrease in the number of patients seen in the summer of 2011 was significant when compared to the number of patients seen summer of 2010. This is reflected in the number of patients presenting for skin examinations. Specialty co-pay amounts may have played a role in the decreased number of patients scheduling appointments. New issues related to healthcare reform and the increased unemployment rate may have also caused a decrease in the usual patient flow for the practice.

Demographics

There were 120 cases examined between the three DHPs. Each DHP examined 40 cases independent of each other over a three-month period of time in 2011. The demographic information related to the cases is listed in Table 1.

Table 1

Demographics

Variable	Percentage (Count)*
Gender	
Male	49% (59)
Female	51% (61)
Age (Median, IQR)	60 years, 47 – 70 years
Race	
Caucasian	99% (119)
African-American	1% (1)
Phototype (skin type)	
Phototype I-II	58% (69)
Phototype III-IV	42% (51)
Familiarity (family History)	
Yes	20% (24)
No	80% (96)
Previous melanoma	
Yes	12% (14)
No	88% (106)
Cancer history	
Yes	42% (50)
No	58% (70)
Number of Nevi	
Less than 30	91% (109)
More than 30	9% (11)

*Otherwise specified for Age

Evaluation of the Level of Risk

Overall, there were 120 evaluations made with DermLite compared to the naked

eye. The evaluations of risk made using DermLite and naked eye are presented in Table

2. The overall agreement was 0.52, the AC1 coefficient (95% CI) was 0.36 (0.30, 0.42),

$p < .001$, and the kappa coefficient (95% CI) was 0.27 (0.20, 0.43), $p < .001$. The

estimate of the AC1 coefficient was typically larger than the kappa coefficient because of

the sensitivity of kappa to the unequal trait prevalence in the population, but both

indicated "Poor" agreement between the two methods.

Table 2

Evaluations of the Level of Risk

Method	Low	Intermediate	High
Naked eye	41% (49)	45% (54)	14% (17)
DermLite	44% (53)	34% (41)	22% (26)
Raw Agreement		.52	
Kappa Coefficient		0.27 (95% CI: 0.20, 0.43)	
AC1 Coefficient		0.36 (95% CI: 0.30, 0.42)	

Overall, the risk of a lesion under exam being suspect for skin cancer was higher on 27.5% (33 out of 120) of the evaluations and lower on 20.8% (25 out of 120) of the evaluations. The risk of a lesion was evaluated the same on 51.7% (62 out of 120) of the evaluations (Table 3).

The proportion of changes in evaluation of risk made by Provider 1 using DermLite compare to naked eye was 0.23 (95% CI: 0.11, 0.38). Provider 2 had changed the evaluation of risk in proportion of 0.88 (95% CI: 0.73, 0.96) when using DermLite. Provider 3 had changed the evaluation of risk in proportion of 0.35 (95% CI: 0.21, 0.52) when using DermLite (Table 3).

Table 3

Evaluations Using the Naked Eye Compared to DermLite

	Provider 1	Provider 2	Provider 3	Overall
Agreement	77.5% (31)	12.5% (5)	65.0% (26)	51.7% (62)
Change	22.5% (9)	87.5% (35)	35.0% (14)	48.3% (58)
Increased suspicion	17.5% (7)	35.0% (14)	30.0% (12)	27.5% (33)
Decreased suspicion	5.0% (2)	52.5% (21)	5.0% (2)	20.8% (25)

Diagnosis

The diagnosis made using DermLite compared to the naked eye are presented in Table 4. The overall agreement was 0.72, AC1 coefficient (95% CI) was 0.75 (0.71, 0.79), p < 0.001, and the kappa coefficient (95% CI) was 0.73 (0.68, 0.78), p < .001. Both coefficients provided an "Intermediate to Good" agreement between the two methods in assigning a diagnosis. The diagnosis made included dysplastic nevus, seborrheic keratosis (SK), basal cell carcinoma (BCC), squamous cell carcinoma (SCC), melanoma and other lesions noted but were not include on the data collection sheet.

Table 4

Diagnosis Using the Naked Eye and DermLite

Method	Dysplastic Nevus	SK	BCC	SCC	Melanoma	Other
Naked eye	28% (34)	15% (18)	17% (20)	2% (2)	7% (8)	32% (38)
DermLite	31% (37)	15% (18)	13% (16)	3% (3)	6% (7)	39% (32)
Raw Agreement			.79			
Kappa Coefficient		0.73 (95% CI: 0.68, 0.78)				
AC1 Coefficient		0.75 (95% CI: 0.71, 0.79)				

Overall, the diagnosis was considered more serious on 10.8% (13 out of 120) of the evaluations and less serious on 10% (12out of 120) of the evaluations. The same diagnosis was pronounced on 79.2% (95 out of 120) of the evaluations (Table 5).

The proportion of changes in diagnosis by Provider 1 using DermLite compared to the naked eye was 0.08 (95% CI: 0.02, 0.20). Provider 2 had changed the diagnosis in proportion of 0.38 (95% CI: 0.23, 0.54) when using DermLite. Provider 3 had changed the diagnosis in proportion of 0.18 (95% CI: 0.07, 0.33) when using DermLite (Table 5).

Table 5

Diagnosis Using the Naked Eye Compared to DermLite

	Provider 1	Provider 2	Provider 3	Overall
Agreement	92.5% (37)	62.5% (25)	82.5% (33)	79.2% (95)
Change	7.5% (3)	37.5% (15)	17.5% (7)	20.8% (25)
Increased suspicion	2.5% (1)	27.5% (11)	2.5% (1)	10.8% (13)
Decreased suspicion	5.0% (2)	10.0% (4)	15.0% (6)	10.0% (12)

Disposition

The disposition made using DermLite compared to the naked eye are presented in Table 6. The overall agreement was 0.66, the AC1 coefficient (95% CI) was 0.51 (0.43, 0.56), $p < .001$, and the kappa coefficient (95% CI) was 0.47 (0.40, 0.53), $p < .001$. Both coefficients provided an "Intermediate to Good" agreement between the two methods in assigning a disposition.

Table 6

Disposition Using the Naked Eye and DermLite

Method	No intervention	Follow-up	Pathology
Naked eye	23% (27)	38% (45)	40% (48)
DermLite	22% (26)	27% (32)	52% (37)
Raw Agreement	.66		
Kappa Coefficient	0.47 (95% CI: 0.40, 0.53)		
AC1 Coefficient	0.51 (95% CI: 0.43, 0.56)		

Overall, the disposition was considered more serious on 20.8% (25 out of 120) of the evaluations and less serious on 13.3% (16 out of 120) of the evaluations. The same

disposition was given on 65.8% (79 out of 120) of the evaluations (Table 7). The

proportion of changes in disposition by Provider 1 using DermLite compared to the

naked eye was 0.15 (95% CI: 0.06, 0.30). Provider 2 had changed the disposition in

proportion of 0.58 (95% CI: 0.41, 0.73) when using DermLite. Provider 3 had changed

the disposition in proportion of 0.30 (95% CI: 0.17, 0.47) when using DermLite (Table

7).

Table 7

Disposition Using the Naked Eye Compared to DermLite

	Provider 1	Provider 2	Provider 3	Overall
Agreement	85.0% (34)	42.5% (17)	70.0% (28)	65.8% (79)
Change	15.0% (6)	57.5% (23)	30.0% (12)	34.2% (41)
Increased suspicion	12.5% (5)	25.0% (10)	25.0% (10)	20.8% (25)
Decreased suspicion	2.5% (1)	32.5% (13)	5.0% (2)	13.3% (16)

Histopathological Data

Aggregated data from 2010 and 2011 was collected from the same time period

that represented the three-month period of time in which the study was completed. This

data is descriptive only between the two time periods (Table 8).

Table 8

Histopathological Data

	June 2010- August 2010			June 2011- August 2011		
	Provider 1	Provider 2	Provider 3	Provider 1	Provider 2	Provider 3
Total # of melanoma	5	1	5	8	0	6
Number of pts seen	1,400	500	2,160	1,300	420	1,620
Biopsies done	118	98	208	185	73	254

Chapter 5: Discussion

This chapter provides a discussion of the implementation of dermoscopy, looking at dermoscopy use in clinical practice at the Dermatology and Laser Center by DHPs when they perform clinical skin examinations for the early detection of melanoma. This discussion will include the limitations, implications, and recommendations for future practice.

Discussion

Skin cancer is more common than any other cancer, melanoma accounting for five percent of skin cancer cases. For melanoma to represent such a small percent, the majority of skin cancer deaths are from melanoma. New melanoma cases are estimated to be 70, 230. The incidence rate for melanoma has been rising for 30 years (ACS, 2011). Melanoma presents a substantial clinical challenge to healthcare providers. The early detection of this skin cancer provides patients with the best chance for a cure.

Dermoscopy is an important part of the clinical skin examination. Studies suggest clinicians learn to use a DermLite in order to integrate dermoscopy into clinical practice to improve patients' outcomes. Being able to differentiate melanocytic from non-melanocytic skin lesions is the foundation upon which dermoscopic diagnosis is built (Bowling et. al., 2007).

The purpose of this project was to evaluate the effectiveness of a practice-based dermoscopy training program for dermatology healthcare providers in order to improve their technique of performing clinical skin exams for the early detection of melanomas.

This project was conducted in a private practice dermatology office in Florida. Patients in the state of Florida have open access to dermatological care. Most patients do not utilize this open access appropriately for preventative services. Patients frequently seek care when they have a problem or concern or have had a friend or loved one diagnosed with malignant melanoma.

Results of this project demonstrated a "Poor" agreement between the two methods when the level of risk was evaluated. Diagnosis and disposition using the two methods provided an "Intermediate to Good" agreement. Theses results only look at agreement between examinations when the naked eye was compared to the DermLite for the individual providers in the study. The providers did not examine the same cases and without histopathological confirmation of the identified lesions documented by the 120 cases reviewed, there was no way to confirm sensitivity and specificity for the Dermlite versus the naked eye.

Histopathological data identified melanoma for the time period reviewed in 2010, which was then compared to the time period of the study for 2011. There was a difference in the number of melanomas seen in the 2010 aggregated data compared to the 2011 aggregated data. The cases identified during the project were not confirmed using histopathological data as standard criteria.

Limitations

The main limitation of this project was not being able to compare histopathological data that was obtained from the 120 cases. Without histopathological confirmation, there was no way to confirm if dermoscopy increased the detection of melanoma. Second, aggregated data demonstrated an increased incidence of melanomas

after the dermoscopy training compared to the number of melanomas identified prior to training of DHPs in the area of dermoscopy. Aggregated data is a limitation for this study since there is no way to confirm information obtained during this project. Lastly, the skin examinations should have been limited to patients with pigmented skin lesions or a previous history of dysplastic nevi, which would help better understand the benefits of dermoscopy.

Implications for Future Practice

The project design for this evidence-based project was different than the studies identified in the literature. The project design was chosen because it was a good fit for the practice where the investigator works. Many studies demonstrated the positive benefit of using dermoscopy for the early detection of melanoma. All studies in the literature pointed out that training was required in order for dermoscopy to be able to achieve improvement in diagnostic accuracy.

This project did not produce the results that the investigator expected to obtain. In order to determine if dermoscopy would increase the detection of melanoma when compared to naked eye examination by DHPs, comparisons of a single lesion on a patient by all providers should be made in order to determine the sensitivity and specificity of dermoscopy use.

The investigator recommends revision of the protocol to include the use of histopathological data as standard criteria in confirming diagnosis made with dermoscopy. DHPs would each evaluate a single lesion on the same patients and complete their own data collection sheet. This method of data collection would allow for comparison among all providers on each lesion, with confirmation by histopathological

evaluation. This method would allow the determination of dermoscopy versus naked-eye examinations with confirmation. Patient type for the project would be limited to those patients with pigmented skin lesion or a history of dysplastic nevi.

Recommendations

The practice strategic plan includes keeping up with the latest advancements in dermatology in order to provide patients with the most up-to-date services available. The use of dermoscopy fits into the strategic plan of the practice. All providers at the Dermatology and Laser Center need to be involved in future projects. Consecutive patients seen in the practice who present a concern for a pigmented skin lesion or have a history of dysplastic nevi would be examined.

This project could easily be reproduced in family practice. Family practice providers see patients with a concern of skin lesions daily. Having the ability to triage all patients with concerns of a pigmented skin lesion is an important assessment skill for family practice providers. Melanoma is a serious form of skin cancer when not detected early and can result in death.

Conclusion

The investigator's knowledge of an evidence-based practice change project was very limited at the start of this project. While the investigator realized the importance of evidence-based practice as it relates to how patients are cared for in clinical practice, this does not compare to completing a project based on the evidence. The networking that the investigator had to partake in was time consuming and a lot of hard work. Taking care of all the details on the front end ensured that the project would start and finish based on the timeline established.

The providers at the Dermatology and Laser Center who participated in the project change were excited and eager to use dermoscopy in practice. This was evident by the questions that were asked during the dermoscopy workshop. Their cooperation with completing data collection sheets during the project was also evident. The investigator has hopes that the providers will use reference books on dermoscopy that are available at the practice to continue to increase their knowledge of dermoscopy. Continued self-directed learning is imperative, since dermoscopy is a different language full of particular terms varying in meaning depending on any given lesion that is evaluated.

During the project it was evident that patients had a sense of reassurance when the providers' use the DermLite to reevaluate what was seen by the naked eye. Some of the patients commented on the light and wanted to know how it worked. The providers were more than happy to explain the features of the DermLite.

More studies are needed to provide better evidence on the value of dermoscopy in clinical practice at the Dermatology and Laser Center. Future projects should be more explicit in regards to methods used and lesion selection in order to better understand the benefits of dermoscopy. Completion of a project that would allow further assessment of intraobserver and interobserver variability combined with assessment of the impact of training could prove positive results. Potential clinical benefits and limitations of dermoscopy at the Dermatology and Laser Center need to be more clearly understood.

Appendix A: Abbreviated Curriculum Vita of the Expert

Arianne E Chavez-Frazier, M.D.

Curriculum Vitae

PERSONAL DATA

Email:	txdermdoc@yahoo.com
Current Position:	Procedural Dermatology/Mohs Surgeon Park Avenue Dermatology Orange Park, FL

CERTIFICATIONS

Clinical Staff: Orange Park Medical Center

Board Certified: American Board of Dermatology

Fellowships: AGME Procedural Dermatology/Mohs
           Fellowship
Mohs Micrographic Surgery and Reconstruction.
Dayton Skin Surgery Center/Wright State University
Psoriasis and Phototherapy Clinical Research Fellowship
University of California San Francisco
Department of Dermatology

Medical License: Florida – active and current

WORK

1/11 – present   **Park Avenue Dermatology P.A.**
                   906 Park Avenue, Orange Park, FL 32073
                   Employee: Procedural Dermatologist/Mohs Surgeon

10/09- 1/11   **Dayton Skin Surgery Center**
                   3025 Governor's Place Blvd. Kettering, OH 45409
                   Employee: Procedural Dermatologist/Mohs Surgeon

8/07-7/08   **Advanced Dermatology**
                   430 Mason Rd. Katy, TX 77450
                   Employee: Moonlighting Dermatologist Saturday clinic

Appendix B: Dermoscopy Course Curriculum

Basic Dermoscopy Course

Objectives:

- Dermatology healthcare providers will understand the benefits of dermoscopy.

- Dermatology healthcare providers will learn to diagnose and manage skin lesions using dermoscopy.

Course Content:

- Interactive pre-test

- Why Dermoscopy?

- Two Step Algorithm to include Pattern Analysis

- Global Features and Local Criteria

- Melanocytic and Non-Melanocytic Lesions

- Classification of Nevi

- Melanoma Criteria

- Cases

- Interactive post-test

- Questions

Text Book: Dermoscopy: An Illustrated Self-Assessment Guide

Appendix C: Data Collection Sheet

Provider Number_____ Visit Type_____ Date_____

Provider not using a Derm-lite

Risk (Check one)
☐ Low
☐ Intermediate
☐ High

Diagnosis: (check one or write in if diagnosis is not listed)

☐ Dysplastic Nevus
☐ Seborrheic Keratosis
☐ Basal Cell Carcinoma
☐ Squamous Cell Carcinoma
☐ Melanoma
☐ Other_____

Disposition: (circle one)
☐ No Intervention
☐ Follow- Up
☐ Histopathologic diagnosis

_____
Provider using a Derm-lite

Risk (Check one)
☐ Low
☐ Intermediate
☐ High

Diagnosis: (Check one or write in if diagnosis is not listed)

☐ Dysplastic Nevus
☐ Seborrheic Keratosis
☐ Basal Cell Carcinoma
☐ Squamous Cell Carcinoma
☐ Melanoma
☐ Other_____

Disposition: (circle one)
☐ No Intervention
☐ Follow- UP
☐ Histopathologic diagnosis

Additional
Comments_____
Age_____

Race: ☐ Caucasian ☐Black/African American ☐Asian ☐Hispanic ☐Other

Gender: ☐M ☐F

Phototype: ☐I-II ☐ III-IV

Total Number of Nevi: ☐ ≤ 30 ☐ >30

Number of clinically atypical nevi: ☐None ☐1-5 ☐6-10 ☐ >10

Familiarity: ☐None ☐Yes

Previous Melanoma: ☐No ☐Yes

Chief complaint: ☐Full Skin Check ☐Concern with a mole

History of Skin Cancer: ☐Yes ☐No

Appendix D: Informed Consent

INFORMED CONSENT

1. SOURCE OF RESEARCH: This project is being conducted under the direction of the Department of Nursing, Brooks College of Health, at the University of North Florida.

2. TITLE OF RESEARCH: Dermoscopy: An Evidenced-Based Approach for the Early Detection of Melanoma.

3. IRB NUMBER: _____

4. PRIMARY INVESTIGATOR: Angela Y Armstrong, MSN, FNP-BC, DCNP.

5. PARTICIPATION: Participation is VOLUNTARY. Refusal to participate will involve no penalty or loss of benefits to which you would otherwise be entitled. If you refuse to participate or withdraw your consent there will be no consequences. No explanation will be requested for withdrawal from the study. You are not waiving any legal claims because of your participation in this study. If you have any questions regarding your rights as a research subject, you may contact Dr. Katherine Kasten, Chair UNF Institutional Review Board at 904 620 2498 for questions regarding the rights of research subjects.

6. PARTICIPANT CONFIDENTIALITY: [Your information will remain confidential and only the researcher(s) will be able to tie your data to your identity by using a secure list containing a participant code that is linked to your responses. The researcher(s) will use a study number instead of your name when at all possible.] By signing this Informed Consent form you give permission for the use and disclosure of your information for purposes of this study at any time in the future.

7. RISK: [There are no foreseeable risks to you as a participant.] There is no cost for you to participant except for your time. Participants may contact the primary investigator Angela Y Armstrong by email at ayarn1@comcast.net. Email will be checked several times during each day and will remain active for six (6) months after the study is completed. Participants may also contact Ms. Armstrong by phone (904) 728 4733 from 8:00 am to 5:00 pm Monday thru Friday for questions regarding the study or procedures related to the study. [For questions regarding the rights of research subjects you may contact Dr. Katherine Kasten, Chair of UNF's Institutional Review Board at 904 620 2498.]

8. PURPOSE: The purpose of this project is to evaluate the effectiveness of a practice based dermoscopy training program for dermatology healthcare providers in order to improve their technique of performing clinical skin exams for the early detection of melanomas. The study is expected to continue for three (3) months after the recruitment period which is expected to be two (2) weeks in duration.

9. PROCEDURES: If you decide to participate in this project, you will be asked to do the following: Attend a dermoscopy training course given by an expert in dermoscopy. The training course will be held on a Saturday and last approximately four hours. You will be given a derm lite following the training and asked to use the derm lite when you perform clinical skin exams in your daily practice. The PI will record your findings on a data collection sheet that will list your results with the derm lite and without the derm lite.

10. BENEFITS TO PARTICIPANTS: The following are possible benefits to you:
   • A free four hour dermoscopy training course given by a dermoscopy expert.
   • [A derm lite 3Gen DL100 for the temporary use during this study]
   • An anticipated improvement in the ability to differentiate skin lesions and to initiate the appropriate treatment.
   • An anticipated decrease in the number of unnecessary biopsies performed.

11. ALTERNATIVE TREATMENTS: If you chose not to participate in this study you can continue to provide care as you always have in your daily practice.

12. PAYMENT TO PARTICIPANTS: There will be no direct monetary reimbursement for participation in this study. All items given to the participants during the study will remain with them at the end of the study.

13. PARTICIPATION OF MINORS: No one under the age of 18 at the time of consent will be eligible to participate.

14. PARTICIPANT CERTIFICATION:

I have read and I understand the information provided above. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction. I have been given a copy of this form.

By signing this form, I willingly agree to participant in the research it describes.

_____   _____   _____
Name of Participant   Signature of Participant   Date

I have explained the research to the subject, and answered all of his or her questions. I believe that he or she understands the information described in this document and freely consents to participate.

Angela Armstrong____   _____   _____
Name of Investigator   Signature of Investigator   Date

Appendix E: Reported Expenses

Cost of Project

Copies…………………………………………………………… 15.00

Batteries for DermLites…………………………………………… 25.00

Cost for Expert…………………………………………………… 300.00

Cost of Statistician…………………………………………….....500.00

Appendix F: IRB Approval Documents

UNF
UNIVERSITY of
NORTH FLORIDA.

Office of Research and Sponsored Programs
1 UNF Drive
Jacksonville, FL 32224-2665
904-620-2455   FAX 904-620-2457
Equal Opportunity/Equal Access/Affirmative Action Institution

MEMORANDUM

DATE: May 19, 2011

TO: Ms. Angela Armstrong
              Department of Nursing

FROM: Dr. Katherine Kasten, Chairperson
              On behalf of the UNF Institutional Review Board

RE: Review by the UNF Institutional Review Board IRB#11-035:
              Dermoscopy: An Evidenced-Based Approach for the Early Detection of Melanoma

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This is to advise you that your project, "Dermoscopy: An Evidenced-Based Approach for the Early Detection of Melanoma" was reviewed on behalf of the UNF Institutional Review Board and was declared Exempt, Category 2." Therefore, this project requires no further IRB oversight unless substantive changes are made.

This approval applies to your project in the form and content as submitted to the IRB for review. Any variations or modifications to the approved protocol and/or informed consent forms as they relate to dealing with human subjects must be cleared with the IRB prior to implementing such changes. Any unanticipated problems involving risk and any occurrence of serious harm to subjects and others shall be reported promptly to the IRB within 3 business days.

As you may know, **CITI Course Completion Reports are valid for 3 years**. Your completion report is valid through 11/07/2013. If your completion report expires within the next 60 days or has expired, please take CITI's refresher course and contact us to let us know you have completed that training. If you have not yet completed your CITI training or if you need to complete the refresher course, please do so by following this link: http://www.citiprogram.org/. Based on your research interests we ask that you complete either the "Group 1 Biomedical Research Investigators and Key Personnel" CITI training or the "Group 2 Social Behavioral Researcher Investigators and Key Personnel" CITI training.

Should you have any questions regarding your project or any other IRB issues, please contact Kayla Champaigne at 904-620-2312, or K.Champaigne@unf.edu.

UNF IRB Number: 11-035
Approval Date: 05-19-2011
Expiration Date: exempt - none
Processed on behalf of UNF's IRB _

Appendix G: Permission Letter

DLC | Dermatology & LASER CENTER

N Fred Eaglstein, DO PA* • Mark A Cohen, MD** • William H Garvin, MD (ret)
Diplomates, American Board of Dermatology • Fellows, American Academy of Dermatology
Fellow, Florida Society of Dermatologic Surgery* • Fellow, American College of Mohs Micrographic Surgery & Cutaneous Oncology**
Bruce H Paley, DO* • Angela Y Armstrong, ARNP, Natalie Husband, MSPAS, PA-C
Fellow, American Osteopathic College of Dermatology*

March 21, 2011

University of North Florida
1 UNF Drive
Jacksonville, FL 32216

Dear Institutional Review Board:

I give Angela Armstrong, permission to conduct her study entitled Dermoscopy: An
Evidenced-Based Approach for the Early Detection of Melanoma at the Dermatology and
Laser Center. Angela is a doctoral student at the University of North Florida (UNF).
Pending UNF IRB approval the Study is estimated to start May 2011.

If you should have any questions I can be reached from 9:00 am to 5:00 pm Monday thur
Friday at 904 276-4500 or email nfe1244@aol.com.

Sincerely,

Signature Deleted

N. Fred Eagistein, D.O.

UNF IRB Number: <u>11-035</u>
Approval Date: <u>05-19-2011</u>
Expiration Date: <u>exempt - none</u>
Processed on behalf of UNF's IRB

2055 Professional Center Drive • Orange Park, Florida 32073
904-276-4500 • fax 904-276-4160 • www.dermatologyandlasercenter.net
Diseases, Surgery & Laser of the Skin, Hair & Nails

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Vita

Angela Armstrong was born in Pensacola, Florida and raised in the San Fernando Valley of California. She moved with her husband to Jacksonville, Florida, in 1988. In 1992 she graduated with an *Associated Degree in Nursing* from Florida Community College at Jacksonville, in Jacksonville, Florida. Her *Bachelor of Science in Nursing* (1996) and *Post Baccalaureate* in 2003 are from the University of North Florida in Jacksonville. She completed a *Masters of Science in Nursing* in 2000 from University of Phoenix. She is currently enrolled in Doctor of Nursing Practice program at University of North Florida, Jacksonville, Florida.

Ms. Armstrong is currently employed as an Advanced Registered Nurse Practitioner with the Dermatology and Laser Center, where she has worked since 2004. Her previous work experience includes 5 years as a Clinical Research Director, 5 years staff nursing in emergency room, critical care units, and home healthcare, and 2 years practicing as a registered general nurse in London, England.

She maintains certification as a Dermatology Certified Nurse Practitioner and Family Nurse Practitioner. She is a member of the Jacksonville Society of Dermatology Associates serving as President from 2008-2009 the American Academy of Nurse Practitioners, the Nurse Practitioner Society of the Dermatology Nursing Association, and Lambda Rho Chapter at Large Sigma Theta Tau International Honor Society.