Evaluation of Exposure to Optical Radiation in Medical Diagnostics and Treatment

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Evaluation of Exposure to Optical Radiation
Used in Diagnostic and Treatment in Medicine and Dentistry

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Dedication

This work is dedicated to my wife, Dianne and to our children, Aeron, Mishalea, Christine and Scott.
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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dedication</td>
<td>ii</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>iii</td>
</tr>
<tr>
<td>Table of Contents</td>
<td>iv</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Literature Review</td>
<td>4</td>
</tr>
<tr>
<td>Material</td>
<td>30</td>
</tr>
<tr>
<td>Methods</td>
<td>32</td>
</tr>
<tr>
<td>Results</td>
<td>36</td>
</tr>
<tr>
<td>Discussion</td>
<td>38</td>
</tr>
<tr>
<td>Conclusions</td>
<td>57</td>
</tr>
<tr>
<td>References</td>
<td>58</td>
</tr>
<tr>
<td>Appendices</td>
<td>69</td>
</tr>
<tr>
<td>Abstract</td>
<td></td>
</tr>
</tbody>
</table>
INTRODUCTION

Overview

Very few studies have been completed so far to evaluate the health effects and exposure levels of optical radiation in clinical settings. Both the exposure of medical personnel and clients are potential concerns resulting from optical radiation use in medicine. Optical radiation is a term used to collectively describe the ultraviolet (UV) radiation, visible light and infrared radiation portion of the electromagnetic wave spectrum. However, here the main health issue is exposure to UV radiation and blue visible light at high intensity.

In this report, the term optical radiation is used only to include UV radiation and blue light. Repeated exposure to optical radiation produces cumulative effects. Optical radiation exposure can result in both immediate and long-term damage to the human skin and eyes, though many effects of optical radiation on human tissue are still to be understood.

The most common concerns of exposure to optical radiation are photomutations, photoaging, various types of skin cancer, and immune suppression. A specific potential adverse effect of optical radiation exposure includes triggering herpes simplex (Smith, 2003). Optical radiation damages tissue primarily by two mechanisms: photochemically (changes in chemical bonds caused by the photon energy of the radiation) and thermal damage (which causes chemical bond changes due to heat produced by the radiation exposure). Generally, photochemical interactions are more damaging than thermal effects. Specifically, the damage from photochemical interactions is significant at higher frequencies that are able to transmit higher energy into tissue and the damage caused by this action is time-dependent.
Sources of Optical Radiation

The major optical radiation sources of interest include tungsten halogen lamps, high-pressure gas discharge lamps, arc lamps (including xenon or mercury xenon), high-pressure lamps, some low-pressure lamps and special phosphor fluorescent lamps (the UV fluorescent lamps).

Problem Statement

The effect of exposure to optical radiation in medical settings is a relatively unexplored area. Until recently, the assumption has been that optical radiation is harmless. It is only fairly recently that the researchers have begun to document the harm caused by the optical radiation. The discovery that sun light, particularly the UV radiation portion, can contribute to cancer and other health conditions has motivated researchers to explore the effects of optical radiation in other areas and settings. One of these areas is the use of optical radiation in medical practice.

The actual exposure to the optical radiation and the appropriate exposure assessment criteria need to be explored and this study has been designed to address this issue. The typical research questions include the followings: What level of exposure is common? What potential harm, if any, does the typical use of optical radiation have on the health of medical technicians and others who are exposed?

Objectives

The main objective of this study is to characterize the potential exposure to optical radiation used for diagnosis and treatment in various clinical conditions in medicine and dentistry. The issues explored in this study include primarily exposure level, employee training on the proper use of optical radiation, and effective control methods.
The major problem studied is the safety and effectiveness of the current medical use of optical radiation. The literature has been reviewed to determine potential areas of concern. The medical applications of optical radiation has been surveyed to assess current use and to determine if the levels of exposure is safe. The focus has been on both diagnosis and treatment. The study has specifically looked at the use of radiation in dental material curing, in helping to diagnose eye problems, and in treating skin disorders such as eczema.

It is anticipated that the levels of UV radiation exposure during the use of:

1. optical radiation in dental material curing will be within the limits of the criteria recommended by ACGIH TLVs,
2. optical radiation used for eye examination will be within the limits of the criteria recommended by ACGIH TLVs,
3. UV radiation for the treatment of eczema and other skin conditions, such as acne will be within the limits of the criteria recommended by ACGIH TLVs.
LITERATURE REVIEW

General Information on the Common Radiation Sources Used in Medicine

Among the common radiation sources used in medicine are those utilized in various ophthalmic instruments such as in slit lamps, endoscopes, light treatment lamps used for seasonal effective disorder (SAD), light treatment systems used in dermatological phototherapy, and for the treatment of hyperbilirubinaemia neonatal jaundice (Sliney, 1997, p. 982).

Most existing exposure limit recommendations are not based on firm scientific research, rather they are based on the past practice and research in the area of optical radiation in other areas. This work is a pilot study that attempts to measure optical radiation exposure levels of patients and the technicians or other medical practitioners, their training, and safety practices related to the use of optical radiation in a clinical setting.

Optical radiation is used in a wide variety of different medical procedures. For example, some specific uses of UV radiation in medical settings include:

1. For curing fillings and other dental repair in dental practice.
2. For treatment of certain skin disorders, such as eczema in dermatology.
3. In medical diagnosis, such as in spectrophotometers.
4. In medical and genetic research, such as for transluminators.
5. UV lamps used in dermatology for purposes including psoralen phototherapy designed to produce beneficial erythemal reactions.
6. Germicidal lamps used in hospital settings, biological microbiology labs, and other areas where germ control is the goal. Typically, low-pressure quartz germicidal lamps are used, especially where infections from new, multi-drug-resistant bacterial strains must be controlled.
7. Phototherapy lamps used to treat neonatal jaundice.
8. Ophthalmic light sources used to evaluate the retina or other parts of the eye.
9. Phototherapy for seasonal effective disorder (SAD) often uses some sort of high intensity fluorescent lamp box.
10. The advent of worry over bioterrorism has motivated exploring the use of UV germicidal irradiation as one appropriate countermeasure (Brickner et al., 2003).
11. The use of air cleansing/disinfecting technologies, not only in hospitals but also in schools, offices, auditoriums and private houses. Use of this method has also increased as a potential protection against bioterrorism. These methods can be effective in reducing the problem in certain situations but, unfortunately, they also open up the possibility of extensive, unnecessary exposure to UV radiation by employees and others.

The concern about optical radiation exposure for all the above procedures applies to not only patients and health care workers, but also to bystanders (Sliney, 1997).

The Electromagnetic Spectrum

The ultraviolet radiation frequency range is located just above the violet end of the visible electromagnetic spectrum. The Sun produces all regions of UV (UVA, UVB, and UVC) radiation but the higher frequencies of UVC are largely filtered out by the Earth’s atmosphere. The UVA and UVB ranges cause a suntan and, if exposure is significantly long, can produce sunburn in humans. Ultraviolet radiation is invisible to human retinal detection, but can be detected when it strikes a material that has a chemical property called fluorescence. Fluorescent substances react to UV radiation by producing light in the visible electromagnetic range.

By using various mixtures of fluorescent substances, different colors of light can be produced by this technique. Detergent manufacturers often add a fluorescent substance to washing powders in order to make white clothes appear brighter by producing extra white light when UV radiation from the Sun strike them. Both visible
light and infrared radiation from the Sun can pass through glass, but most UV radiation is absorbed by standard window glass.

**Health Concerns**

The most obvious immediate health problem due to excessive optical radiation exposure may include erythema and the initiation of the inflammatory response (Longuet-Perret and Paic, 1997). Erythema is likely caused by vascular permeability changes, specifically those involving either vascular permeability factors, or vascular endothelial growth factors, both potent inducers of microvascular permeability (Longuet-Perret and Paic, 1997).

Conversely, exposure to UV radiation also induces certain desirable changes in the skin, including increased pigmentation and thickening of the epidermis, both responses that were initiated by the body to protect the skin against damage by UV radiation.

Studies of the reasons given by clients for using commercial tanning beds, which people utilize for many reasons (including in order to increase their level of protection against the sun), have generally found that sunbed-induced tanning is not significantly protective, although some evidence indicates that tanning may positively influence immunological reactions (Ruegemer et al., 2002).

Also, differences and similarities between commercial tanning beds and UV radiation exposure from sunlight need to be more carefully evaluated. Although several studies reported increased skin thickening resulted from UV exposure, at least one study (Ruegemer, et al., 2002) did not confirm this effect.

**UV Radiation Exposure and Cancer**

The major risk of UV radiation exposure is skin cancer, especially basal cell carcinoma and melanoma (Mahroos et al., 2002). The major risk factors for both of these
types of skin cancers are exposure to sunlight and genetic family history. A major factor involved in photocarcinogenesis is improper cellular repair of UV radiation-caused DNA damage, and the most common incorrect repair is the thiamine dimers that form as a result of UV radiation damage (Mahroos et al., 2002).

**Oxidative Stress**

UV radiation is a major factor in basal cell carcinoma induction in Caucasians. It has long been assumed that highly exposed areas of the human body are also the most frequent sites of basal cell carcinoma.

In a study done to evaluate this, Heckmann et al. evaluated 3,065 patients with basal cell carcinoma in the facial area and found that the most frequent sites of cancer were the nose (n = 1373), the orbital area (n = 386), and the ears (n = 2269). The study concluded that site-specific UV radiation exposure alone is not an accurate predictor of the likelihood of basal cell carcinoma in a specific area. For example, an evaluation of UV radiation exposure on the face found that the areas of the nose with the most exposure, such as the nose apex, were not significantly more likely to develop basal cell carcinoma than areas where less exposure occurred, such as the nose base area.

The study concluded, at least for basal cell carcinoma, that those areas of the face exposed to more UV radiation are not necessarily more likely to develop cancer. Furthermore, cancer does not necessarily develop in a high optical radiation exposure area, specifically in the areas of highest exposure (Heckmann et al., 2002). Considering the importance of the interplay between genetic factors, chance, and exposure level in carcinogenesis, this finding is not unexpected.

UV radiation also induces oxidative stress (commonly called free radical damage) in the skin and suppresses the normal cell-mediated immunological response (Mittal et al., 2003). One reason for oxidative stress is due to the effects of UV radiation-induced infiltration of leukocytes. Mittal, et al. (2002) used hydrogen peroxide as a marker of
oxidative stress. They specifically evaluated the infiltrating CD11b+ cell level, as measured by flow cytometric analysis, in a clinical situation where the major source of oxidative stress was UV irradiated skin.

The researchers found that the oxidative stress level peaks from between 48 and 72 hours after UV radiation exposure. The researchers concluded that these cells, in turn, produce hydrogen peroxide, which contributed to both photoaging and the promotion of skin tumors. The authors suggest that the methods that reduce skin infiltration of CD11b+ cells may also reduce oxidative stress levels and, consequently, ameliorate both photoaging and photocarcinogenesis.

The adverse effects of UV radiation to the immune system need to be evaluated more carefully. Because UV radiation results in generating reactive oxygen species, which in turn produces oxidative stress, reduction of the generation of reactive oxygen species by photochemoprevention is a potential protection strategy. The most common photochemoprevention is through the use of chemical agents (such as botanical antioxidants and sunscreens) that can ameliorate or prevent the adverse effects of UVB radiation on skin.

The specific mechanism underlying the role of UV in causing skin cancer is still unclear (Wei et al., 2003). The finding that patients suffering from xeroderma pigmentosum (a defect in nucleotide excision repair) have a very high incidence of melanoma indicates that DNA repair defects is a major causative factor that can influence the development of melanoma. To evaluate the influence of DNA repair capacity, Wei et al. (2003) compared 312 melanoma patients to 324 control subjects, matched for age, sex, and ethnicity. The host-cell reactivation assay was used to measure DNA repair capacity.

The study found that the melanoma skin cancer patients in the study had a 19 percent lower ($p < 0.001$) mean of DNA repair capacity compared to cancer free control subjects. Furthermore, patients with tumors on an area of normally sun-exposed skin, such as the face, had a statistically significantly ($p = 0.04$) lower DNA repair capacity, as
measured by the above test, than patients with tumors on unexposed skin. Other individual factors have also increased the risk for sunlight induced DNA damage, indicating the risk varies according to individual factors, such as genetic inheritance. Ideally, individual risk can be considered when determining the exposure risk of patients and health care workers.

A major concern is that UV radiation damages DNA, producing genomic alterations that can vary from point mutations to chromosomal dislocations (de Gruijl, 2002). Mahroos et al. (2002) tested the effectiveness of sunscreens in reducing the likelihood of UV radiation-induced DNA damage and, consequently, lowering the risk of skin cancer. The study found no significant difference in thiamine dimer formation between non-irradiated and irradiated skin in subjects that applied a broad-spectrum Sun Protection Factor (SPF) type of sunscreen before each irradiation exposure.

Conversely, if sunscreen application was omitted even once prior to radiation, a statistically significant increase in thiamine dimer formation was found. The researchers concluded that broad-spectrum sunscreen is effective in preventing this major form of UV radiation-induced DNA damage. In this case, mutations that resulted from UV radiation exposure clearly caused specific kinds of damage in specific areas of the human body. Likewise, studies are necessary to determine the effect of UV radiation exposure on other parts of the body, such as the cornea, the retina, and, in the case of medical procedures, the lips, tongue, buckle (cheek) or other areas.

DNA Repair

Several studies indicate that individual sensitivity to UV radiation is highly variable (i.e., some persons are extremely sensitive, such as those with xeroderma pigmentosum), while others are relatively insensitive. All evaluators of UV exposure must be cognizant of this observation. Ideally, the exposure level is significantly below the safe level for those persons with the highest sensitivity. In the case of the rare
xeroderma pigmentosum condition, this is not practical because these patients, ideally, should not receive any exposure whatsoever to UV radiation.

Another variation that must be considered in skin cancer etiology is the damage to one or more of the cell’s DNA repair systems. One example is the melanolcortin 1 receptor (MC1r) chain, a highly polymorphic gene in which certain allelic variants associated with, not only phenotypic variety such as red hair, but also with melanoma and non-melanoma skin cancer (Scott et al., 2002). In addition, melanocytes with a non-functional Mc1r gene are significantly more sensitive to the cytotoxic effect of UV radiation compared with melanocytes expressing a functional Mc1r gene (Scott et al., 2002).

Another study researched lymphoblastoid cell lines from melanoma-affected patients compared to unaffected individuals that were tested for sensitivity to UV radiation. Specifically, the cell’s ability to repair transfected UV-damaged plasmid templates was evaluated. The researchers concluded that the results indicate the presence of melanoma susceptibility genes, other than CDKN2A and CDK4, do not impair the cell’s net capacity to repair UV radiation-induced repair damage (Shannon et al., 1999, p.133).

**Damage Caused by UV Radiation**

The effects of UV radiation vary due to many individual factors. A major individual factor is the presence of undamaged p53 tumor suppressor genes. Research with p53 knock out mice and mice constitutively lacking one or both copies of a functional p53 gene has demonstrated the critical importance of p53 in protecting against UV radiation-induced cancers (Jing et al., 1999). Often called the guardian of the genome, p53 accumulates in cells in response to DNA damage. The accumulation of p53 translocates a signal to the nucleus, which in turn activates the transcription of several
genes that produce a number of major effects, including cell cycle arrest and, in some cases, activating an apoptosis pathway.

Jing, et al. (1999) found that p53 -/- mice exhibit significantly reduced apoptosis compared to p53 +/- mice that show an intermediate response (compared to wild-type mice, which produced a normal apoptosis rate). The study also found differences between chemically and UV-induced carcinogenesis and, further, that the UV irradiation can induce a variety of carcinomas and sarcomas. This study also found a high incidence of ocular tumors in the p53 -/- mice, most of which were melanomas (Jiang et al., p. 42-51). The researchers also noted that the application of sunscreen to the skin of mice prior to UV irradiation greatly decreased the number of p53 mutations in all of the groups that they studied. The UV radiation used in this study was broad spectrum (250 to 400 nm) range with a peak emission at 313 nm.

Afaq and Mukhtar (2002) concluded that UVA and UVB radiation cause mutations by significantly different mechanisms. UVB radiation (280-315 nm) is more energetic and also more carcinogenic than UVA radiation (315-400 nm). UVB radiation specifically causes cancer by adversely effecting proto-oncogenes and tumor suppressor genes, especially p53. In contrast, the damage caused by UVA radiation is believed to be a result of damage caused by reactive oxygen species. For example, exposure to UVA1 (340-400 nm) often induces squamous cell carcinoma without causing point mutations in p53 genes. Although exposure to UVB radiation is implicated as the main cause of skin cancer, the effects of UVA radiation need to be studied in more detail and evidence now exists that UVA radiation could also be a health concern (Afaq and Mukhtar, 2002).

Another concern is that the photocarcinogenesis risk is now increasing in America, as evidenced by the rise of the level of basal cell, melanoma, and other skin cancers. One possible reason for this is the increase in UV radiation exposure from non-sunlight sources, which has added to the total exposure level. Another possibility, which
may partially account for the problem, is that the total mutation load of the population has increased due to other factors, such as environmental pollution.

Inherited susceptibility must also be considered. For example, familial melanoma is found to exhibit germ line mutations in CDKN2A (p16INK4a), or its target protein, a cell cycle regulatory protein (Shannon et al., 1999). The UV radiation sensitivity varies among cell types and also may, in some situations, have an adverse effect on the immune system and other bodily systems. Although the main focus has been on cancer, other adverse effects of UV radiation also have been noted by researchers including destruction of collagen, causing the breakdown of the skin’s elasticity and, concurrently, its aesthetic appearance (Hertl et al., 1991).

The Concept of Hormesis

It has long been widely assumed that low levels of radiation (such as those related to UV) are harmful. The evidence for this conclusion is not based on direct proof, but inference from studies that have evaluated the effects of higher levels of radiation. Calabrese, et al. (1999, 2000) has compiled what many consider a convincing case that small doses of both radiation and toxic compounds, such as arsenic, can produce a positive health effect. He first came across this idea while researching the herbicide known as phosfon on plants.

Calabrese’s first experiment with the herbicide backfired; instead of shriveling as he expected, the exposed crop grew green and luxuriant. Further investigation found that he had diluted the poison too much and, as a result, the plants thrived. By every measure (height, weight, and, root length) the phosfon-exposed plants grew about 40 percent better than not-exposed-to-phosfon plants. As expected, Calabrese (1999, 2000) found the use of higher doses of phosfon were lethal to the plant.

Baldwin and Calabrese (1998) reviewed the literature on cancer, and found clear evidence that those chemicals causing cancer in a single large exposure can be beneficial
in low doses. He then studied mutagens, such as aflatoxins, and concluded that they can be beneficial in low doses. Another study has found that humans exposed to low-level radiation all lived longer in controlled experiments compared to the non-exposed subjects (Calabrese, 1995).

The idea of hormesis can be traced back to Paracelsus, who stated that all compounds are toxic, and it is the dose level that makes a chemical poisonous. The assumption was that, chemicals labeled poisons might simply have a lower threshold of toxicity. Furthermore, poisons such as radiation if taken in the right quantity at subtoxic levels, can prime the immune system and produce protection against higher doses. In the early 1900s, researchers found that low doses of x-rays actually stimulated plant growth (Calabrese, 1995).

Studies of hormesis found that low doses (below a level as defined by the researchers) are about 2.5 times more likely to produce a measurable protection level in the subjects than zero level doses (Celabrese, and Baldwin, 2002a). The researchers now have close to 4,500 cases showing evidence for hormesis (Celabrese, and Baldwin 2002a,b). The research on hormesis has became so widely accepted (often unequivocally so) that some people have begun touting radioactivity (or other toxins) as a means of treating a wide variety of human ailments.

Much work in the hormesis area has been conducted on exposing people to water with naturally high radon content (Parsons, 2000), such as those found in Bad Gastein, Austria, and in Montana. Unfortunately, only a few studies have been performed to evaluate the hormesis effects of UV radiation. Interestingly, mercury is perhaps the most studied element that shows a hormetic result.

Another factor is the variation of individual sensitivity. A certain dose level that stimulates hormesis in one person may be toxic to someone else (Calabrese, 1999). Sometimes the doses used for hormesis protection were too high, producing sickness, illness, and, occasionally, even death (Calabrese and Baldwin, 2000a,b). Further studies
also have shown that a substance having a hormetic effect for one species of animals may result in a detrimental effect for another species, indicating a difficulty in applying the results of animal research to humans (Calabrese and Balwin, 2000a,b).

The principle of hormesis is small amounts of harmful agents produce a healthy response to an adverse condition that results in greater protection against large doses in the future. This is similar to phenomenon such as "a rise in temperature causes sweating," or "invading microbes cause the immune system to develop." Hormesis occurs when the body overcompensates, producing a healthier equilibrium as a result, in essence confirming Nietzsche's dictum “What doesn't kill you makes you stronger.”

Other researchers in the field hypothesize that hormesis stimulates heat shock proteins and/or stimulates the immune system and DNA damage control mechanisms (Pollycove, 1998). Heat shock proteins are produced in cells in response to hyperthermia and other similar stresses. These proteins help other proteins to effectively refold properly (the heat shock is what causes them to be denatured).

Clinical trials at Harvard found that low doses of radiation boosts four-year metastatic cancer survival rates from 40 percent to 70 percent and from 52 percent to 74 percent (Calabrese, et al., 1999). The work of Myron Pollycove (1998) found that low-levels of radiation also benefits the body by stimulating the immune system to search for, and destroy, cancerous cells, and also by stimulating DNA repair. Evidently, low-level radiation may also cause damage, but the stimulation it provides, its advocates argue, more than compensates for the damage.

**Use of Optical Radiation for Curing Polymers**

Radiation-cured resin composites, requiring high intensity curing radiation, are now almost universally used in modern, clinical dentistry (Unterbrink and Muessner, 1995, p. 183). Reasons for their common use include wear resistance, and appearance (a filling quality can be achieved that approaches the natural tooth color). Use of optical
radiation for curing polymers is a method, first introduced in 1973, that uses various frequencies of optical radiation in order to polymerize a variety of materials (Tanoue and Atsuta, 1999).

Polymers that utilize radiation for curing include those designed for crown and fixed partial denture veneer, inlay, onlay, and similar dental repair work (Tanoue and Atsuta, 1999, p. 595). Curing materials are used for restoration and veneering both to repair damage from wear or accident caused damage, or to improve the teeth’s physical appearance, i.e., for cosmetic functions.

Radiation sensitive restorative materials that polymerize by visible light include various resin composites, resin modified glass ionomers, polyacidmodified resin composites, and pit and fissure sealants (Leonard et al., 2002). Visible light curing units are also required for most other bonding systems. A concern in the literature has been adequate polymerization (inadequate polymerization causes premature failure or other problems). Adequate polymerization requires sufficient intensity (or power density), proper wavelength and proper exposure duration. All three of these parameters must be adequate to achieve complete polymerization.

Radiation is used to control exactly when polymerization occurs, and to avoid premature hardening. Typically, these polymers becomes active by using a diketone photoinitiator that responds to radiation by creating free radicals that, in turn, initiate the polymerization process. A common diketone photoinitiator now used is camphorquinone (Leonard et al., 2002).

A variety of curing radiation is available, including quartz-tungsten-halogen and, recently, light-emitting diodes. Curing radiation ranges enormously in intensity, from 400 mW/cm² to 1900 mW/cm² (Christensen et al., 1999). Delivery modes include constant radiation (a continuous delivery of radiation at the same intensity and frequency), and stepped radiation (a discrete variation of the intensity and /or frequency
of radiation). Curing times can range from one to 40 seconds and light spot sizes ranged from 6.7 mm to 10.9 mm.

Halogen dental curing radiation, first introduced in the late 1970s, were the mainstay until radiation emitting diodes were introduced as an alternate energy source. Use of light-emitting diode units is an attempt to lower the cost, as well as lower potential safety problems caused by use of radiation curing composites. A problem, especially with halogen lamps, is that much radiation generated is in wavelengths outside of the effective curing spectrum. To reduce this problem, internal filters restrict the radiation to the wavelength range that have been found experimentally to be the most effective which is in the blue light range between 450 and 490 nm (Leonard et al., 2002).

Another problem is, as the halogen bulb degrades, the reflector can blister, crack, or deteriorate with age, use, and misuse. A number of studies have concluded that the majority of radiation-curing instruments in use by dentists are not properly maintained and deliver less than the minimum power density required to adequately polymerize the restorative material. To compensate, usually longer times is now recommended to insure that sufficient curing is achieved.

The radiation emitting diode is an alternative that, depending on the semiconductor used, produces radiation within a narrow spectral range. Light Emitting Diode (LED) units are also less likely to produce radiation in the undesirable ranges then other types. Commonly used are gallium nitride diodes, which produce visible light with wavelengths between 450 and 490 nm (Leonard et al., 2002). The LEDs also require less power to operate, and reduce the level of radiation in the heating (infrared wavelength) area. Since less power is required, LED units can be used with rechargeable batteries, allowing the manufacture of cordless, portable, and fairly lightweight units. With normal use, LEDs can last thousands of hours before they need replacement, whereas a halogen bulb produced optical radiation units may only last around a hundred hours.
A study that compared the curing efficiency of commercially available LED-based instruments with quartz tungsten halogen found that the LEDs required between 83 and 131 sec to adequately cure a microfilled resin composite, compared to only 21-42 sec for the quartz tungsten halogen curing instruments (Leonard et al., 2002). The advantages of LED instruments, though, more than compensate for the much longer time required for curing. The intensity and frequency of the radiation source must be sufficient to cure the material to the depth necessary for proper solidification and bonding of the polymer (Tanoue and Atsuta, 1999). To insure proper curing, many dentists apply and cure the polymer in thin layers until the fill area is completed.

The photo cured polymer method is used in dental practice because it is considered highly safe, produces a material that is extremely hard, has excellent strength and wear-resistance qualities and, importantly, does not transmit heat or cold to the cavity area, which produces pain (a common problem with the use of metal alloys for filling cavities). Specifically, resin-veneered restorations have been shown to be superior to other polymerization materials and methods. The effectiveness of the process depends upon the wavelength, frequency, and intensity, of the radiation used. Disadvantages of light cured polymers include metal alloys often last longer, often for the lifetime of the patient.

The use of photoactivated composite materials for both cast restorations and fixed partial dentures have recently increased enormously (Tanoue and Atsuta, 1999, p. 358). Major reasons for this increase include recent improvements in both photo curing units and the composite materials, greater availability of funds to pay for restoration work from dental insurance plans, the now common perception that damaged teeth should be repaired as needed, and less willingness in our society to live with less than perfect teeth.

It is usually assumed that higher intensity lights produce greater hardness and curing effectiveness. In contrast to the common perception, Unterbrink and Muessner (1995) found that, when using the clinically relevant layer thickness, higher intensity
produces less satisfactory results due to increased shrinkage stress. Another study (Nicholls, 1997) evaluated the amount of shrinkage of hybrid composite resins between visible light and laser light, finding no significant difference.

To evaluate the light emitted by curing lights, commercial radiometers are available. One study of radiometers found that light output level consistency depends upon the age of the unit, the state of repair, the calibration details, the frequency used, etc. These variables were found to be so great in this study that it was impossible to evaluate the accuracy of the radiometers in measuring light intensity delivered by the light curing unit (Rossouw, 2001).

Studies on the results of pulsed (a method that rhythmically varies the radiation intensity or increases the intensity with time) versus continuous optical radiation curing systems found the bond strengths obtained with the standard radiation were significantly better than those obtained with a pulsed or stepped curing radiation technique (p<0.01). Furthermore, with the continuous radiation technique the 24-hour bond strength was significantly greater at the 0.01 level than the 10-minute bond strength. A critical factor in achieving good results is the specific resin formulation used, i.e., micro filled resins have the least shrinkage and the lowest modulus. Shrinkage is a major concern because it is the most common problem encountered in achieving satisfactory dental work with resin-based polymers.

The problem of optimizing the level of conversion (polymerization) also increases shrinkage. The goal is to achieve the greatest conversion with the least shrinkage. One study (Tarle et al., 1998) found that the application of strong bluish visible light (the color of the frequency that they studied) produces precancerous conditions in the gingival, as well as the surrounding area, including the tongue. In addition, it produced abnormal levels of certain enzyme in the liver. In vitro studies of HeLa cells all these abnormalities were successfully reversed by an oral intake of a mixture of several
pharmacological agents augmented by a non-invasive drug applied topically to the skin uptake enhancement method.

High intensity radiation is used because it increases the curing depth considerably, regardless of the resin matrix composition (Tanoue and Atsuta, 1999). Adequate polymerization is a major issue because inadequate polymerization can adversely affect a number of polymer properties, including strength, stiffness, color, and color stability. A current intention is to reduce potentially damaging UV exposure while improving curing abilities. For example, one study found that certain materials cured with metal halide radiation source units were superior to all of those cured with xenon radiation sources, regardless of the type of material used (Tanoue and Atsuta, 1999). The next step would be to compare UV levels given off by each lamp type.

Effective curing requires proper maintenance of the curing radiation devise, proper controlling the duration of exposure, and the type of restorative material used (Caughman et al., 1995). Other factors found to be important in effective curing include the shade of a composite used, the wavelength and bandwidth of the radiation used the distance of the instrument from the composite, and the intensity and duration of the curing radiation used (Fan et al., 2002, p. 429). This study found that radiation with an intensity of 300 mW/cm² appeared to be most effective in curing most resin-based composite materials. This assumes that the appropriate curing time is used, which varies according to the material being cured.

The specific optical radiation emitted needs to be evaluated not only for each light source, but also for the brand and type of lamp (halogen, for example, versus fluorescent) used. A growing number of curing units are being introduced into the market, requiring some standard to make comparisons between equipment to better judge, not only the effectiveness of the equipment, but also the potential for excessive UV exposure.

One evaluation of 105 curing radiation instruments used in dental clinics in Japan (Miyazaki et al., 1998) found the intensity of visible light produced by the units that they
tested ranged from 28 W/cm² to a whopping 1,368 W/cm². Many dentists were unaware of the output of their curing instrument, and the researchers concluded that the output according to their measurements was inadequate to properly polymerize the polymers used (Miyazaki et al., 1998).

Poulos and Styner (1997) found the radiation intensity given off by the unit significantly decreased in time. Concurrently, radiation intensity increased by replacing either the lamp, the filter, or the fiber optics or some combination of all three. These researchers also found that 1-2 year old radiation instruments had mean outputs of 423 mW/cm²; and 3 year old instruments had a mean output of 376 mW/cm².

Another study found that autoclaving also diminished the ability of the curing instrument tip to transmit radiation and that the effect can be minimized if the tip is polished at frequent intervals between autoclaving cycles (Rueggeberg et al., 1996).

Attempts to improve blue light based procedures for polymerization of resin-based composites were evaluated by Dunn and Bush (2002). These researchers found that light-emitting diodes designed to cure resin-based composite polymers are, at this stage of development, inferior to halogen-based radiation curing units. Since the light-emitting diode units were only introduced in the year 2001, little long-term experience exists with this technology. The current research also indicates that diode light sources may not adequately polymerize resin-based composites, which can lead to failures (Dunn and Bush, 2002).

**Optical Radiation and Ophthalmic Instruments**

Other means of exposure to radiation include the ophthalmic instruments used to examine the eye and eye structures (Wolffe, 1999). The medical diagnostic uses of optical radiation include to aid in diagnosing retinal damage. Many physicians use quartz halogen lamps, which deliver a relatively high level of UV radiation.
Unfortunately, if the literature discusses illumination concerns at all, it usually specifies only the illumination levels (such as at the patient’s eyes) and the type of lamp box and light source used. A potential problem is, the illumination levels at the patient’s cornea surface and at the retina surface at the back of the eye (usually the concern) are normally different. The transparent parts of the eye, including the cornea, the aqueous humor, and the vitreous humor, all block certain optical radiation frequencies.

A major concern is both the cornea and the retina can be damaged by excessive UV radiation exposure (Sliney, 1997, p. 895). This has resulted in the formation of an international standards, the International Medical Light Standards Association, formed to: (1) evaluate radiation hazards, (2) provide information to the users of these instruments about the hazards, and (3) research ways in which potential risks can be controlled. For ophthalmic instruments used by a physician to visually examine the eye, radiation outside the visible spectrum, i.e., in the UV spectrum is not useful. It is not only hazardous, but also unnecessary.

Because of an inability to filter out only UV radiation, but not violet and blue light, the manufacture cannot filter out all of the UV radiation from the visible light-producing portion. Filtering out too much of the blue light will result in a distortion of the color, which makes it more difficult to evaluate the fundus part of the eye (Wolffe, 1999, p. 363). To solve this problem, the concept of a “safe exposure time” has been developed to allow minimal, or no, UV radiation damage and yet allow the physician to perform the necessary evaluation. This approach is, so far, not yet feasible.

The other factors that are more difficult to control that need to be explored are the pupil size, the health of the eye (diseased eyes are at a higher risk of being damaged by UV radiation exposure), and other unknown factors, such as variations in the ability of the patient’s body to repair photochemical retinal damage. Current standards are often based on the assumption that the a normal repair mechanism is fully functional, which may not be the case, especially for an unhealthy or diseased patient. As a result, the
persons in need of various eye evaluations typically receive more exposure. These concerns require more research in order to improve the ability of clinicians to make appropriate judgments on the side of safety, and yet still be able to render optimal care.

The body has a built-in aversion to bright light, such as is illustrated by looking at the sun, which normally protects the observer. Another complication is anesthetization impedes the normal way the eye protects itself against excessive radiation. In a non-anesthetized person, excessive radiation will cause eye watering, blinking or the person will move into a position so as to avoid the excessive radiation. When a patient is under anesthesia, the normal aversion to hot sensations of exposed skin and, consequently, the normal response, also may not be available. Anesthetization for an eye exam interferes with blinking (or turning away from the offending light source), that is a normal protective response in non-anesthetized patients.

The retina is one of the more vulnerable body structures, partially because it does not have the same protective mechanism as does the skin. Skin has natural protective mechanisms that are commonly enhanced by the use of sunscreen, clothing, shade, and other means of protection (Sliney, 1997). In addition, in a diagnostic and treatment situation, the risk and benefit ratio must be evaluated. Many patients are willing to take more risks in exchange for higher benefits. This is especially true if the condition being treated is painful, interferes significantly with their lifestyle, or could potentially be incapacitating, such as blindness.

**Optical Radiation used for Medical Treatment**

The most common use of UV radiation is to treat various skin disorders such as atopic eczema (a common immune-mediated skin disorder that causes inflammation, blistering, oozing and often intense itching), psoriasis (a common immune-mediated skin disorder that causes thickened blotches with silvery scales and, often, intense itching), folliculitis (a group of skin conditions that involve inflamed hair follicles), and pruritus (a
sensation caused by a wide variety of factors that results a desire to itch, which can be intense). Optical therapy is also used to treat certain kinds of depression, such as seasonal affective disorder (SAD), and various mood disorders (Rosenthal, 1989, 1993; Pierpaoli et al., 1995).

**Use of UV Radiation to Treat Eczema**

Eczema is now the most common inflammatory disease of childhood in the Western world. The symptoms (and results) of eczema include intractable itching, skin damage, soreness, and, as a result of these problems, sleep loss, and social stigma. The exact cause of atopic eczema is unknown, but it always involves an abnormal immune response. Krutmann (2000) noted that T-lymphocytes play an important role in many atopic dermatitis conditions in addition to eczema. The development of eczema also involves several genetic factors and a combination of allergic and non-allergic influences (Hoare et al., 2000).

In one study, 272 eczema cases that met the criteria specified by the researchers were evaluated (Hoare et al., 2000). The main treatments used were light therapy, oral cyclosporine, and topical corticosteroids. In addition to these main treatments, other studies have explored the use of oral antihistamines, dietary recommendations, and other medicines and techniques. Krönauer et al., (2003) concluded UV radiation is widely used to treat atopic eczema and many dermatologists use a combination of treatments (p. 531).

For example, one study by Morrison et al. (1978) explored the use of 8-methoxypsoralen therapy combined with exposure to high intensity UV radiation. The 8-methoxypsoralen photochemotherapy protocol is used to treat not only eczema, but also a number of other skin conditions, such as psoriasis, folliculitis, and pruritus (Akaraphanth and Lim, 1999). In a study of 15 patients with atopic eczema, this treatment was superior to both conventional UV radiation therapy alone and to a control group.
Eczema is often defined as a result of an inflammatory infiltrate. UV radiation inhibits rapid proliferation of cells (psoriasis) and inhibits excessive proteolytic enzymes that produce scleroderma (Polderman et al., 1989). The UV radiation fraction of the solar spectrum is more effective for treatment than other UV frequencies for a number of reasons, including this frequency range is almost completely absorbed by the skin and, thus, is the most biologically active optical radiation frequency (Shriber, 1975). UVB radiation and various psoralens combined with UVA radiation (pUVA) are now among the most important therapeutic methods used to treat eczema (Polderman et al., 1989).

The therapeutic mechanism radiation stimulates is believed to involve the influence of UV radiation, especially UVA-1, on histamine release from human basophils and mast cells (Krönauer et al., 2003). To evaluate this hypothesis, researchers in an in vitro study irradiated both damaged human basophils and mast cells with increasing doses of UVB, UVA, and UVA-1 radiation regions. Next, stimulants were added to induce histamine release. The researchers concluded that UVA and UVA-1 radiation significantly inhibited histamine release from both the basophils and mast cells studied (Krönauer et al., 2003, p. 531). Furthermore, they found that UVB radiation also had an inhibitory effect on mast cells.

The researchers concluded that UV radiation has been used “with great success” for a variety of skin diseases, especially atopic eczema and urticaria pigmentosa (Krönauer et al., 2003, p. 531). This study confirms the finding of other researchers that concluded UV radiation acts by inhibiting the stimulation of histamine release from human basophils and mast cells. The mechanism involved in UV radiation treatment is also thought to involve UV radiation caused alterations in the cell membrane. Specifically, changes in intracellular calcium ion content are believed to be involved. The net effect is an inhibition of histamine release, which, in turn, reduces the itch.

Suppression of the itch is critical in treatment because the major adverse result of eczema, aside from the undesirable physical appearance, is the itch. Scratching the itch
only aggravates the condition, causing a worsening of both the skin’s appearance and the itch itself. This response sets up a negative circular response that is very difficult to break. Scratching produces inflammation, which typically aggravates the condition, resulting in more itching, which in turn results in more scratching (Bobroff, 1962, p. 80). Pain immobilizes, preventing (or at least reducing) further injury. Scratching, on the contrary, often causes further injury by converting relatively intolerable itching to relatively tolerable pain (Bobroff, 1962, p. 209). Consequently, relief from itching is a major solution to the problem of many kinds of dermatitis, especially eczema.

Another study found that the photo-oxidation products that resulted from various treatments, including UV radiation, caused oxidative damage, which, in the case of eczema, produced therapeutic benefits (Potapenko et al., 1999). The oxidative damage affected the histamine response which, in turn, reduced the itching, the major problem in eczema.

Eczema also can be accompanied by specific allergic reactions. For example, one study researched nickel allergies in eczema patients compared to patients who were allergic to nickel but did not have eczema. The study concluded that variations in nickel reactivity are an important compounding factor involved in eczema and other skin disorders, such as allergic contact dermatitis (Hindsen et al., 1999).

A study that explored the thesis that cutaneous diseases are a common result of human immunodeficiency virus infection and, therefore, UV radiation might have adverse effects on these patients. The researchers found that UV radiation, when used according to the standard phototherapy protocol with 8-methoxypsoralen, when used for photochemotherapy, do not have any adverse effect on HIV-infected patients.

Much of the work on phototherapy for eczema has focused on the specific band of radiation that is most effective. For example, Krutmann (2000) concluded that, although UVA-1 radiation and 311 nm UVB radiation are commonly used phototherapeutic
frequencies, the best modality seems to depend upon the specific type of atopic dermatitis, its severity, and its location.

Although it is widely recognized that UV radiation can be very beneficial in treating atopic skin diseases such as eczema, it is also widely recognized that the UV radiation risk should be minimized to reduce the likelihood of photocarcinogenesis and photoaging (Oikarianen et al., 1991). One compromise is to use longer wavelengths such as UVA-1 radiation, which produce less risk of skin cancer development and penetrate more deeply into the skin. Another approach to reducing the cancer risk when utilizing UV radiation phototherapy is to use UV radiation in conjunction with anti-carcinogenic chemotherapies, such as retinoids, which enhance skin repair caused by UV radiation damage (Oikarianen et al., 1991, p. 497).

Many patients utilize heliotherapy (UV radiation from the sun) to treat eczema or psoriasis, which is ineffective for the parts of the body that it is not socially acceptable to expose in public. One solution is a tan-through bathing suit, which claims to have a sun protection factor of 10 sunblock protection factor (a measure of the ability of a material to reduce UV radiation; a level 10 protection factor would allow a person to stay out in the sun 10 times longer than a person without the sun block and produce the same level of damage).

A study by Alora et al. (1997) found these type of suits had a protection factor of between 4.5 and 5.6, which would allow enough UVB radiation penetration under ambient conditions to benefit dermatitis patients with skin conditions that are responsive to UVB radiation. The affected cells absorb UV radiation, and the energy transfer can cause both beneficial and adverse effects. The most well known beneficial influence is the formation of vitamin D in the skin (Luca and Ponsonby, 2002).

Because UV radiation can induce the onset of, or exacerbate, the symptoms of certain autoimmune diseases, but can also prevent or reduce the symptoms of others, the goal is to manipulate UV radiation to exaggerate its beneficial effects and to minimize its
negative effects. The effects of UV radiation involve the interaction between the radiation and individual biological factors differences, especially those relating to immune system. UV radiation likely alters the delicate regulatory immune system network, causing the body to overreact (or under react) to certain chemical substances. UVB radiation effects are evidently more associated with autoimmune alterations than other UV radiation regions.

Individual differences in the effectiveness of UV radiation therapy include differences in the gene that codes for glutathione S-transferase, which neutralizes the effect of certain reactive oxygen species (Luca and Ponsonby, 2002). Those patients who cannot produce this enzyme, or produce it in smaller amounts than normal, may be at increased risk of DNA damage. In addition, damaged DNA can be interpreted by the body’s immune system as a foreign substance, triggering an immunological response and producing diseases such as lupus (Ponsonby et al., 2002). The result is a chronic inflammatory disease that affects the skin, joints, blood, and kidneys.

How UV radiation exposure affects the cellular immune response is not yet clear. No doubt, it affects lymphocytes, macrophasias, and langerhan cells in the skin. The langerhan cells and dermal macrophasias present antigens to lymphocytes. UV radiation affects langerhan cells, which, in turn, suppresses the local cellular immune response. As a result, the cellular immune response is suppressed locally.

People who are exposed to high levels of UV radiation have a low prevalence of multiple sclerosis, evidently as a result of the immunological suppression that result from UV radiation exposure (Dumas et al., 2000). Multiple sclerosis results from chronic inflammation of the central nervous system, producing demyelination. The UV radiation may promote immunological tolerance toward specific antigens, such as (in the case of multiple sclerosis) myelin autoantigens (Dumas et al., 2000).
Hazard Evaluations

Effective hazard evaluations need to consider all of the following factors:

*Lamp envelope and filtration system.* These qualities can reflect certain spectrum greater than others. Filtration selectively removes certain wavelengths. An example is, if glass is used for the lamp, most UV radiation should effectively be filtered out, but if quartz is used, this filtration will not occur.

*Source size and distance.* The inverse square law describes the level of reduction of energy intensity as distance is increased, and thus the effect of the radiation (which is a inversely related to the distance of the source from the patient). The farther away the source, the less energy intensity. In addition, the smaller the source size, controlling for distance, in general the less potential for damage.

*Source uniformity.* UV radiation from the source may be in higher levels only in certain areas of the output beams such as the center, distorting the evaluation of the actual exposure.

*Source stability.* A change in the supply voltage can produce major changes in optical output, as can an increase in operating temperature. Higher operating temperatures usually produce greater UV radiation emission than lower operating temperatures.

*Aging characteristics.* Most UV radiation sources will change in time and, typically, the level of UV radiation output becomes less as the lamp ages and the lamp’s life expectancy and output decrease.

*Radiant efficiency.* Radiant efficiency is the ability of a radiation producer, such as a halogen lamp, to convert energy (usually electrical energy) into radiation energy such as
UV radiation. The radiant efficiency varies enormously with the radiation frequency produced.

Radiation range produced. Measurement of broad-band spectral response is necessary in order to determine if the source produces radiation in the frequency range that may cause damage, especially damage to sensitive parts of the body such as the eye structure.

Accidental Exposure

Accidental exposure is a concern that can be dealt with primarily by monitoring optical radiation use and determining common sources. The key to dealing with accidental exposure is to anticipate potential sources of exposure and prevent their likelihood by implantation of appropriate procedures and safeguards such as plastic guards.
MATERIAL

Operators

Questionnaires (Appendix 1)

Informed consent form (Appendix 2)

Permission form to conduct the research (Appendix 3)

Research site included:

1. Two dental clinics
2. Two eye examination clinics
3. One dermatology clinic

Optical radiation sources included in the study:

1. Curing light devices
2. Optical microscopes and retinasopes
3. UV booth used in dermatology

Monitoring instruments used:

1. Model IL 1400A radiometer/photometer manufactured by International Light, Inc. (1-978-465-5923). The meter was first zeroed by activating the zero control with the sensor cap on. The power signal mode was used to measure the power intensity given off by the source in watts per square meter (or microwatts per square centimeter). The integrate mode was used to measure the total exposure in Jules per cubic meter (or micro Jules per cubic centimeter). Factory calibrated on 09/02/04.

2. UV Actinic Hazard Detector Model SEL240/T2ACTS. Factory calibrated on 09/02/04. This detector measures effective irradiance as per ACGIH. Factory calibrated on 09/02/04.

4. The visible lightmeter used was a Davis Instrument Extech meter (serial number L098633) calibrated by Extech on March 6, 2002.
METHODS

General Information

By using a convenience (rather than random) sampling approach, a set of clinics was selected as the study locations. At each location, the clinic director was interviewed to determine if the optical radiation equipment was used in their clinical practice. Next, the operator of the optical radiation equipment was asked to sign the informed consent form to participate in the study.

Each operator was briefed on the scope of the study and on how the optical radiation would be quantified. The study also involved the completion of a short questionnaire by the principle operator of the optical radiation source in the practice. In all 5 clinics selected, the permission was granted to conduct the study.

The goal of this research was to characterize the optical radiation produced by the radiation sources. The specific details included: clinical use of the sources and the intensity of radiation at varied distances, angle, time, and other factors such as the application of certain filters. The measuring instrument substituted for the patient.

Last, a questionnaire was given to each operator to provide information on his or her professional background, training, and practice in the application of the optical radiation source.

Data Collection

The data was collected by a site visit to each of the clinics agreed to participate in the study. A radiometer was used to measure the optical radiation intensity given off by each radiation source used. The type of radiation measured included UV radiation, blue light and visible light. The measurements attempted to, as far as possible, measure the patient exposure and the expected exposure by the operator. To do this, a treatment or examination was simulated and the sensor was placed where the exposure of concern
would affect the patient or the operator. The optical radiation intensity was measured at several angles if the medical instrument will allow for a range.

At each site visit, an operator using the equipment was asked to complete a questionnaire (see appendix for a copy) and to allow measurements to be completed of the optical radiation given off by the instruments that they used in their practice.

The parameters used to evaluate the radiation sources were based on an interview with the medical practitioner, and included the type of sources used (brand, serial number, calibration, age if known), the settings used (including optical radiation intensity, the filter used, the distance from where the patient would normally sit, the duration of exposure, the persons usually present during the application of optical radiation, and other relevant factors as determined by the interview). Also the room traits were evaluated (the size, temperature, humidity, light level, location of the optical radiation such as location relative to window).

The data were then evaluated, the implications of the findings of the study to current and future medical practice were discussed and recommendations for further research were discussed.

**How the Sites Were Selected**

The sites were selected by obtaining a list of local dentists, ophthalmologists, and dermatologists in Williams County from various sources, including professional society lists. The clinics were then called and read the introduction to the study recruitment. Those centers that qualified were then asked for permission to make a site visit. At the site visit the purpose of the study was explained to the clinic director. The director was then asked to complete a form agreeing to cooperate in the study.
How the Questionnaires Were Filled Out

The questionnaires were first field tested by showing them to the operators of optical radiation sources in the field for feedback and recommendations for modifications and revisions. These were then used to revise the questionnaire. The questionnaire was then given to the responsible person at the clinic. On each site visit, the researched endeavored to obtain the following information:

1. The type of optical radiation sources used
   a. brand
   b. serial number
   c. last calibration date
   d. age of the medical devise

2. The settings used
   a. optical radiation intensity
   b. the filter used, if any
   c. the distance from patient the light source is normally used
   d. the typical time of exposure
   e. the persons usually in room during the use of optical radiation
   f. other relevant factors as determined by the interview

3. The room traits
   a. the size
   b. temperature
   c. humidity
   d. light level
   e. location of the optical radiation source (such as near a window)
   f. other factors noted

How the Optical Radiation was Measured

Optical radiation was measured by placing the radiation sensor at the position that most accurately represented the optical radiation received by the patient. This was done by determining the parameters used with the patient (the optical radiation intensity commonly used, the distance away from the patient that the radiation source is normally located and other relevant factors, such as the radiation filter and lamp type used). Then
the distance was changed by about 20 percent in each direction (closer and farther from the source) and again the intensity of optical radiation was measured. The measurements were repeated by changing the angle. The reflectance and background radiation was also measured.
RESULTS

The results of optical radiation measurements in dental, eye, and dermatology clinics are presented in Tables I-VI.

Table I. Optical Radiation in Dental Use*

<table>
<thead>
<tr>
<th>Dental Curing Light</th>
<th>UV (µw/cm² eff*)</th>
<th>Blue light (µw/cm² Sr)</th>
<th>Visible Light (lux)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm away</td>
<td>27.7 - 35.4</td>
<td>55.3 - 57.3</td>
<td>134,100</td>
</tr>
<tr>
<td>45 degree angle 3 to 4 mm away</td>
<td>5.9 - 6.1</td>
<td>21.4 - 24.6</td>
<td>15,750</td>
</tr>
<tr>
<td>Maximum value</td>
<td>42.1</td>
<td>70.2</td>
<td>135,000</td>
</tr>
<tr>
<td>Background</td>
<td>0.02 - 0.03</td>
<td>0.77 - 1.9</td>
<td>69 - 347</td>
</tr>
</tbody>
</table>

Litex 680 Dental Curing Light

<table>
<thead>
<tr>
<th>UV (µw/cm² eff*)</th>
<th>Blue light (µw/cm² Sr)</th>
<th>Visible Light (lux)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm away</td>
<td>27.2 - 28.5</td>
<td>53.1 - 55.2</td>
</tr>
<tr>
<td>45 degree angle 3 to 4 mm away</td>
<td>4.1 - 4.3</td>
<td>24.6 - 25.8</td>
</tr>
<tr>
<td>Maximum value</td>
<td>28.7</td>
<td>56.2</td>
</tr>
<tr>
<td>Background</td>
<td>0.02 - 0.03</td>
<td>6.7 - 71.3</td>
</tr>
</tbody>
</table>

Litex 680a Dental Curing Light

<table>
<thead>
<tr>
<th>UV (µw/cm² eff*)</th>
<th>Blue light (µw/cm² Sr)</th>
<th>Visible Light (lux)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm away</td>
<td>18.7 - 20.3</td>
<td>46.2 - 49.3</td>
</tr>
<tr>
<td>45 degree angle 3 to 4 mm away</td>
<td>10.1 - 11.5</td>
<td>5.9 - 6.7</td>
</tr>
<tr>
<td>Maximum value</td>
<td>24.3</td>
<td>49.2</td>
</tr>
<tr>
<td>Background</td>
<td>0.02 - 0.03</td>
<td>6.7 - 71.3</td>
</tr>
</tbody>
</table>

Table II. Optical Radiation in Ophthalmology at Site 1*

<table>
<thead>
<tr>
<th>Slit Lamp Measurements</th>
<th>UV (µw/cm² eff*)</th>
<th>Blue light (µw/cm² Sr)</th>
<th>Visible Light (lux)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narrow beam</td>
<td>0.02 - 0.03</td>
<td>72.5 - 73.7</td>
<td>21,329 - 2,400</td>
</tr>
<tr>
<td>Wide beam</td>
<td>0.08 - 0.09</td>
<td>131.1 - 135.9</td>
<td>37-340 - 39,800</td>
</tr>
<tr>
<td>Background</td>
<td>0.04 - 0.10</td>
<td>0.04 - 1.5</td>
<td>191 - 217</td>
</tr>
<tr>
<td>Retinoscope Measurements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixed beam</td>
<td>0.03 - 0.04</td>
<td>0.43 - 0.46</td>
<td>34 - 37</td>
</tr>
<tr>
<td>Background</td>
<td>0.02 - 0.03</td>
<td>0.04 - 1.5</td>
<td>217 - 243</td>
</tr>
</tbody>
</table>
Table III. Optical Radiation in Ophthalmology at Site 2**

<table>
<thead>
<tr>
<th>Slit Lamp Measurements</th>
<th>UV (µw/cm² eff*)</th>
<th>Blue light (µw/cm² Sr)</th>
<th>Visible Light (lux)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narrow beam</td>
<td>0.05 - 0.07</td>
<td>0.59 - 0.64</td>
<td>2,730 - 2,900</td>
</tr>
<tr>
<td>Wide beam</td>
<td>0.07 - 0.09</td>
<td>0.77 - 0.82</td>
<td>41,700 - 42,800</td>
</tr>
<tr>
<td>Background</td>
<td>0.04 - 0.05</td>
<td>0.67 - 1.4</td>
<td>201 - 229</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Welch-Allen Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narrow beam</td>
</tr>
<tr>
<td>Wide beam</td>
</tr>
<tr>
<td>Background</td>
</tr>
</tbody>
</table>

Table VI. Optical Radiation in Dermatology Use**

<table>
<thead>
<tr>
<th>UV Light Booth</th>
<th>UV (µw/cm² eff*)</th>
<th>Blue light (µw/cm² Sr)</th>
<th>Visible Light (lux)</th>
</tr>
</thead>
<tbody>
<tr>
<td>After one minute</td>
<td>17.27 - 19.46</td>
<td>214 - 410</td>
<td>11,000 - 11,600</td>
</tr>
<tr>
<td>After five minutes</td>
<td>23.9 - 25.8</td>
<td>220 - 485</td>
<td>11,800 - 12,600</td>
</tr>
<tr>
<td>Background</td>
<td>0.03 - 0.04</td>
<td>0.79 - 1.8</td>
<td>211 - 249</td>
</tr>
</tbody>
</table>

* Effective irradiance as per ACGIH (2003).
**Note: If only one value was given this represents the maximum reading.
DISCUSSION

Dental Curing Light

The date of visit was 11:49 a.m. to 12:44 p.m. on Thursday, March 25, 2004. Usually the dentist, but also a dental assistant, used the curing light. The only training the assistant was provided was by the doctor and the manufacturer. The time required to cure the dental filling depended on the compound used, the type of filling, and the location of the filling or repair work. The compound used contains the setting required for curing on the label on the container, which ranges from 10-60 sec, usually close to 30-40 sec. The hair dryer shaped unit had a small optical fiber extension unit about 3” long extending from the end and, at the tip, was located at .5 cm diameter lens that emits the blue curing light.

The only protection normally used was a small hand plastic shield constructed out of brown plastic about 15 cm square, and some of the units contain a built in plastic shield on top of the unit to shield the doctor or technician from the light. In this office were five curing light units, used by several persons including the dentists and the dental assistants. Each light is used from twice a week to several times a day.

The staff member interviewed concluded that silver amalgam was superior in holding power and durability compared to light cured compounds. As a result, at this clinic the polymer compound was used only in specific situations, mostly for repair work involving the more visible areas of the teeth. On the unit was printed the following warning: “Warnings: use stable protective eye ware for operator, assistant, and patient. Do not direct light toward gingiva or oral mucosa as may cause tissue discomfort.”

Measurements

Temperature 72 degrees F and Humidity 67 percent. The room was 12’ x 14’ and had one window. UV radiation measurement was 27.7-35.4 µw/cm² effective irradiance
approximately 1 mm away from the light source of the unit. The exposure time was from 30 to 60 sec, significantly below the TLV standard of 5.0 µw/cm² effective irradiance for 10 min. At a 45 degree angle from 3 to 4 mm away, 5.9-6.1 µw/cm² effective irradiance was measured. The maximum value produced by the unit was 42.1 µw/cm² effective irradiance. The room UV measure was from 0.02 to 0.03 µw/cm² effective irradiance.

For the blue light measurements at a 90 degree angle, 1 mm from the light, the measure was 55.3 - 57.3 µw/cm² Sr. At a 45 degree angle, the level was 21.4 - 24.6 µw/cm² Sr. and at 1 mm away the measure was 65.4 µw/cm² Sr. The maximum blue light value measured was 70.2 µw/cm² Sr. The background blue light radiation was 0.77 - 1.9 µw/cm² Sr.

The light measurement range was 69-105 lux in the room and the maximum was 347 lux when the sensor was aimed up toward the ceiling light. Visible Light produced by the dental curing light at a 90 degree angle about 1 mm away was 134,100 lux and, at a 45 degree angle, about 1 mm away the value was 15,750 lux.

**Dentist Office 2**

The unit used at this clinic was a Dentamerica Litex 680 and a Litex 680A. No warnings were printed anywhere on the unit. The bulb was designed like a car headlight that fit into a large reflector. About 20 to 25 patients a week used the composite, mostly for dental work done in the anterior of the oral cavity. The most common reason was for appearance (the color can be made to match the natural teeth) and for the posterior teeth (mostly molars) mercury amalgam is preferred unless the patient requests the composite type. Patient preference was a major factor in the type of filling material used, and appearance and longevity were the two major concerns considered in the decision. This clinic put the composite on in layers and each layer was cured separately. The curing time for each layer was about 30-40 sec.
The curing light had only an on and off switch and a timer that could provide from about 10-60 sec of light. The first mark on the lower setting was 10 sec, but the unit would go on when set below this value, but if the time was set below 10 sec it was difficult to accurately determine the time of the exposure. The only protection used was a small orange tinted shield placed on the unit itself. A major factor affecting light was the cleanliness of the light source tip (some of the lights had dental filling composite on them). When cleaned, the light level was significantly higher.

The temperature was 70 degrees F and the humidity was 58 percent. The room used to take the measurements was not a room where the curing lights were used because, when I was at the clinic all the patient rooms were being used or will be used. The patient rooms were about 10 ft by 12 ft and each had one window. The room UV measure was from 0.01 to 0.03 µw/cm² eff, depending on where the sensor was pointed.

Measurements

Litex 680:

The UV radiation measurement was 27.2 - 28.5 µw/cm² effective irradiance approximately 2 mm away from the light source of the unit, significantly below the TLV standard of 100.0 µw/cm² effective irradiance for 30 sec and 50 for 1 min. At a 45 degree angle from 3 to 4 mm away, 4.1 - 4.3 µw/cm² effective irradiance. was measured. The maximum value produced from any measurement by the unit was 28.7 µw/cm² effective irradiance.

The blue light measurements at a 90 degree angle, 1 mm from light equaled 53.1-55.2 µw/cm² Sr. and at 2 cm away from the radiation source measured 43.6 µw/cm² Sr. At a 45 degree angle, 3 to 4 mm away, the level was 24.6 - 25.8 µw/cm² Sr. and at 1 cm away was 35.2 µw/cm² Sr. The maximum value measured was 56.2 µw/cm² Sr. The background blue light radiation was 71.3 µw/cm² Sr. when pointed at a fluorescent light that was only about 26 inches away, and 6.7 µw/cm² Sr. when pointed away from this
source. The range room light measurement was 262 lux in the room, and the maximum value measured was 546 lux when pointed up toward the ceiling light. The maximum visible light produced by the dental curing light at a 90 degree angle, 2 mm away was 154,600 lux and, at a 45 degree angle 2 mm away, was 94,300 lux.

**The Litex 680A Unit**

The UV radiation measurement was 18.7-20.3 µw/cm² effective irradiance approximately 1 mm away from the light source of the unit, significantly below the TLV standard of 100.0 µw/cm² effective irradiance for 30 sec and 50 for 1 min. At a 45 degree angle from 2 to 3 mm away, 10.1-11.5 µw/cm² effective irradiance was measured. The maximum value produced by any measurement by the unit was 24.3 µw/cm² effective irradiance.

At a 90 degree angle, 2 mm from the blue light measurements equaled 46.2-49.3 µw/cm² Sr. At a 45 degree angle, 3 to 4 mm away, the level was 5.9 - 6.7 µw/cm² Sr. and at 1 cm away the measure was 4.7 µw/cm² Sr. The maximum value measured was 49.2 µw/cm² Sr. The visible light produced by the dental curing light at a 90 degree angle, 1 mm away, was 94,200 lux, and at a 45 degree angle 1 mm away was 68,200 lux. The maximum value was 95,100. This instrument was less bright than the unit at the previous clinic.

**Eye Clinic Measurements**

Mentor Slit Lamp (biomicroscope) Model 253.

The unit, about 15 yr old, used a 7 yr old Halogen bulb (12 volts, 50 watts, 4.2 Amps). The normal life expectancy for this bulb at this clinic was about 14 yr. The unit projects a thin, intense beam of light into the patient's eye. This unit is not calibrated.
because the only criterion for proper use is the production of a sufficient amount of visible light to complete the exam. The unit does not need to produce a consistent amount of light because the usable illumination output level can be adjusted with a rheostat to achieve the level necessary for the exam, and the bulb does not noticeably dim with use.

The unit also could be adjusted from a narrow beam mode to a wide beam mode. The beam is set as narrow as possible to keep the pupil from constricting, and at the same time as wide as possible to view the gross morphology of the retina and the rest of the eye for the exams. The slit lamp also allows the medical practitioner, to use of a binocular microscope, to magnify the structure of the eye to evaluate potential abnormalities such as those related to the eyelid, conjunctiva, cornea, iris and lens. Specific abnormalities include infections, foreign bodies, or cataracts. The light is aimed at the center of the eye and is placed about 50 mm away from the cornea.

To measure optical radiation, the sensor was placed inside the medical device to simulate retina optical radiation exposure — and the sensor had to be held very steady until the meter reading was stable. Several measurements were made at different angles and distances from the optical radiation source. Little change in UV measurements was observed when the optical radiation source was moved about 20 percent closer or farther away from the radiometer sensor. This was partly due to the fact that this unit puts out a very narrow diameter optical radiation beam and a very small level of UV radiation.

For the blue light measurements, when the angle of the radiometer sensor was tilted from the 90 degree angle to a 45 degree angle, the irradiance of blue light dropped off considerably. It also was difficult to accurately measure the optical radiation at
different angles because the narrow biomicroscope frame was confining and did not permit accurate positioning at intended measurement angles. The radiometer sensor was confined to the small space inside a frame that has been designed to steady the patient’s head.

In some cases little variation was noted, such as the values for UV radiation in most cases. In other cases the range was enormous, such as the values for background visible light. The values for visible light varied by a factor of up to three, depending on where the sensor was pointed. If it was pointed up at the source of the light, the reading would obviously be the highest, and if pointed at a dark corner, the lowest. The light was, however, measured at the height of the eye of an average person.

**UV Radiation Measurements**

The UV irradiance for narrow beam was 0.02 - 0.03 µw/cm² effective irradiance and for the wide beam was 0.08 - 0.09 µw/cm² effective irradiance. Both were significantly below the TLV standard of 5.0 µw/cm² effective for 10 min (the length of the exam). Normal room UV irradiance ranged from 0.04 - 0.10 µw/cm². This was greater than the UV radiation given off by the devise. At normal visual field and looking forward, the UV measurement in the room was close to 0.06 µw/cm². The reading was the highest when the sensor pointed directly at the light, and lowest when pointed into a windowless corner.

**Blue Light Measurements**

Use of narrow adjustment and blue light sensor at about 50 mm away measured 72.5 - 73.7 µw/cm² Sr. Use of wide beam blue light sensor at about 50 mm away measured 131.1 - 135.9 µw/cm² Sr.
The normal patient exposure would be somewhere between the low and high end of these two values, depending on the patient and the type of exam required. The high light end is used to evaluate specific conditions or patients (such as patients with cataracts). The time of exposure for each patient is normally about 10 -12 min.

Use of the blue filter (used for color correction) produced no measurable change in the readings. The room light is normally dimmed for the exam, thus this source adds little additional light. Normal room light using the blue light sensor was measured and ranged from 0.04 - 1.5 µw/cm² Sr.

Most of this radiation source is now manufactured according to accepted industry standards. The International Standards (ISO 10989:1998) state that “The amount of energy exiting the slit-lamp microscope in the wavelength ranging from 700 nm - 100 nm shall not exceed either the amount of energy exiting the slit-lamp in the range between 380 nm and 700 nm or 100 mW/cm², whichever value is the smaller.”

Retinoscope Measurements

The second instrument measured was a Baush and Lomb Copeland Retinoscope (also called a skiascope). The unit was 60 yr old and used a battery powered 5 Volt, tungsten filament bulb. The normal life expectancy for this bulb was about 10 yr. The unit cannot be calibrated, and does not need to put out a consistent amount of light and the bulb does not noticeably dim with use. The only criterion for proper use is the production of a sufficient amount of light to properly complete the examination involving refraction of light by the eye to determine the refractive error.

This unit is held by hand by the medical practitioner about an arms length away from the patient to examine the eye by shining the light into the pupil. An example of its use is to check the need for glasses and also to evaluate proper lens prescription by obtaining an objective measure of the refractive error. It is especially useful for the problem of checking the eyes of children for glasses who are too young to understand the
slit lamp procedures required, or with patients for whom communication is not possible—such as infants, deaf persons, stroke victims, and non-English speakers. This technique is also helpful to reduce the problem of children wanting glasses to imitate their friends that have new glasses (and they think they look good in them). This technique works by evaluation of light reflected from the retina and then is refracted by the lens and cornea. The operator evaluates this effect and then checks for the reflective refraction pattern. If a patient is near sighted, a double pattern is present if the phoroptor is used, and the double pattern is reduced if the correct prescription lens is used. The doctor will see the reflection of light in the pupil move either with the motion of the retinoscope or against it. The doctor then will hold a lens in front of the eye.

Movement with the retinoscope indicates that the lens needs to be changed in a plus direction (a more convex lens) and movement against the retinoscope indicates that the lens needs to be changed in a minus direction (a more concave lens). A refractive, or focusing error is determined when the reflection of light in the pupil has been neutralized, and appears to fill the pupil entirely. If the neutralization point is the same in both the horizontal and vertical movements, then the patient is either long or short sighted. If there is a difference between the two directions, this indicates astigmatism.

To complete the retinoscope optical radiation measurements, The researcher sat in the examining chair and the operator (physician) did a simulated eye exam on him. The operator then moved the light into the center of the radiometer sensor, and the researcher took a set of readings. This medical unit had only one light setting. The measurement (all checked twice to insure accuracy, and averaged) for UV radiation was 0.03 - 0.04 µw/cm² effective (significantly below the TLV standard of 5.0 µw/cm² effective for 10 min) and for Blue light was 0.43 - 0.46 µw/cm² Sr. and the background UV irradiation was 0.02 - 0.03 µw/cm² effective. The visible light in the examination room, which was dimmed for the exam, did not add measurable UV radiation.
All of the optical radiation and light readings reveal that a relatively small amount of light is normally required to complete the medical procedure, and an extremely small level of the UV radiation was given off by the medical device. The area of optical radiation beam was considerably less than the sensor surface area, thus it gave a value that likely underestimated the main bright beam illumination and optical radiation produced by the pen light used for the exam. Ideally, the sensor surface area could be designed so as it is about the same size as or larger than the light source beam. There were no warning signs about radiation exposure on any of the medical devices. The medical practitioner used no protection with any of the devices investigated, however, they used protective equipment when they made physical contact with the patients.

Study at the second eye clinic.
Date of visit March 25, 2004 3:30 p.m. 4:50 p.m. Room 4 in clinic.

SL 980 CSO Ophthalmic

At this clinic, slit lamp indirect ophthalmoscopy is used to evaluate the both the anterior segment (or individual structures) and the posterior segment of eye (the retina) and all areas that are posterior to the lens. The binocular viewer allows the practitioner to see depth, thus he/she can better evaluate the retina traits of concern and for possible pathology. It uses a 6 volt 120 watt lamp that lasts up to several years.

The built in filters on the medical device are designed to filter out infrared radiation. Normally, the light level of this unit is set as dim as possible because the light typically bothers the patient and constricts the pupil, which then interferes with the exam. This unit is a fairly new device (about 15 yr old) that produces a very high level of light to evaluate specific patients, such as those that have cataracts. In this case the practitioner may have to turn up the illumination level well beyond that normally used, especially if the cataracts are severe.
Slit Lamp Measurements

When the UV radiation rheostat set at low, the irradiance measured at 0.05 - 0.07 µw/cm² effective and when it set at high the irradiance was 0.07 - 0.09 µw/cm² effective. The irradiance in both cases was significantly below the TLV of 5.0 µw/cm² effective for 10 min. The background UV irradiance was 0.04 - 0.05 µw/cm². When the light source set on low, the irradiance of blue light, ranged from 0.59 - 0.64 µw/cm² Sr and when the light set was on high the irradiance was 0.77 - 0.82 µw/cm² Sr and the background was 0.07-1.4 µw/cm² Sr. The measure of visible light was 2,730 -2,900 lux when the unit was set on low and 41,700 - 42,800 lux when it set on high.

Welch Allen Small Light

Welch Allen small light can be adjusted to change the light output enormously to complete an exam, such as to see into the sinuses for infections or other problems - the sinus area is darker than its normal color where inflammation is present. The time used for the exam with this device varied from 2 to 10 min. When this device set on low mode, the UV radiation measurement was 0.01-0.02 µw/cm² effective and when set on high mode the irradiance value was 0.39 - 0.42 µw/cm² effective. In both modes, the irradiance values were significantly below the TLV of 5.0 µw/cm² effective for 10 min. When set on low mode, the blue light, irradiance was 1.6 - 1.7 µw/cm² Sr and when the device set on high mode the irradiance ranged from 3.8 - 3.9 mw/cm² Sr. The visible light when on low was 375 lux and when set on high was 15,750 lux.

3. Copeland Optec 360 Retinoscope

This device is used to perform an objective exam. When used with a small child a subjective exam cannot be used. Therefore, the retinoscope can be used to determine the correct vision correction eyeglass lenses. The lens is placed in front of the eye by the
examiner and, if it is the proper refraction, the image should stay in one place when the
light is moved. Typically the examiner must change lenses and evaluate the response
several times to determine the correct eyeglass lens.

This unit uses bulbs that range from 2.5 to 3.5 volts. The UV irradiance ranged
from 0.01 - 0.04 µw/cm² effective significantly below the TLV of 5.0 µw/cm² effective
for 10 min. Very little change resulted when the rheostat adjustment changed from low to
the high setting. When the device set on low mode, the Blue Light ranged from 0.38 -
0.39 µw/cm² Sr and when the device set on high mode, the measure was 131.2 142.7
µw/cm² Sr. Visible light was 29 lux on low mode and 460 lux on high mode.

**Exeter Direct (Keeler Direct) Ophthalmoscope**

This device produces a real image (upside down) and projects the image with a
convex lens in order to further evaluate the eye structure. This instrument has one setting
only for measurements. The UV radiation was 0.04- 0.05 µw/cm² effective,
(significantly below the TLV standard of 5.0 µw/cm² effective for 10 min), for the blue
light it was 1.1-1.2 µw/cm² Sr, and the light measurement was 45-49 lux.

**Measurement of Optical Radiation in Dermatology**

Date of measurements: March 25, 2004 8:00-9:15 a.m. temperature 71.4 degrees
F and humidity 48 percent (both changed when the machine lights went on, and
continued to change as the procedure progressed due to the great amount of radiant
energy given off by the instrument.)

A light booth unit made by Daavlin (Daavlin Co., 220 Paige St., Bryan, OH
43543) (serial number P2323 AF5BH 2424; 240 volts, 30 amps, 60Hz) uses UV radiation
used for phototherapy dermatology treatment. It uses both UVA broadband (290 – 320
nm.) and UVB narrow band (311-312 nm.) bulbs to achieve the optimum treatment level
and at the same time reduce the risk of skin cancer to as low as possible. A total of 48
bulbs are used in this unit. Each bulb is 6 ft tall, and arranged in sets mounted vertically and extending from floor to ceiling. The UV radiation level increases for up to about 2 min after the unit is turned on, and then stabilizes. To compensate for the intensity changes. The Daavlin unit has a built in UV meter that adjusts the exposure time to insure that the treatment level conforms to the patients specifications. The subject can either stand up or sit on a stool located inside of the unit, and then closes the double doors. The person is then surrounded by lights. The unit produces a great deal of heat and is cooled by a fan on top.

The operator sets the exposure time by the use of an electronic control panel located on the outside of the machine on the side panel. Or the treatment protocol can be entered into the machine computer and the patient given a PIN number. For each further treatment, the operator need only enter the PIN number. The computer also displays the patient’s last treatment dose and a suggested dose for the current treatment. The unit used a digital readout to indicate the settings used for a treatment and can also print out a hard copy of each patient’s dose history. The dose is determined by a test using Psoralen drug that makes the patient more photosensitive so as to determine the erythermal dose level.

The exposure control sets both the time and the number of bulbs to be turned on for each treatment. For most treatments, the patient walks into the machine, closes the double doors, and a programmed voice tells him or her that “the lights will turn on in 10 seconds. Be sure to have your goggles on.” This gives the nurse time to leave and the patient time to prepare for the treatment.

As soon as the time is set and the unit is turned on, the operator leaves the light booth room (a small windowless closet about 8’ x 5’ in size) and closes the room door behind her. This procedure insures that the machine light does not turn on until after the operator leaves. The operator does not use protection unless he or she stays in the room with the patient. In rare cases, older patients that are unsteady require the operator to be
in the room with them. In this case, the operator uses special UV protective glasses, a
gown, and a face shield for protection.

After every few minutes, the computer voice tells the patient how many minutes
of treatment remain. When the time is finished, the power goes off and the patient is told
by the computer generated voice that the treatment is completed. If the patient leaves the
booth before this time, the lights go off and can be turned on again when the patient
reenters by pressing a large 4 in by 4in button inside of the booth. The unit then
continues treatment with no loss of exposure or data.

Many patients use a head shield to reduce face and neck exposure. If feasible, the
part of the body that needs treatment only is exposed. An example is, if the treatment
need is limited to the arms, the patient puts his arms only inside of the unit. Treatment is
more commonly done in the winter when sun exposure opportunities are much less than
early fall, late spring, and summer. In the summer, many patients spend more time in the
sun; consequently, less need exists for treatment then. The number of patients at this
clinic ranges from an average of 10 to 12 per day, more in the winter, and less in the
summer.

No warnings were on the equipment except on the bulbs. The nurse explained to
patients that he or she must use goggles (brown tinted plastic units designed to reduce
both brightness and UV) when in the unit due to the UVB radiation produced by this unit,
and also because it is extremely bright inside the unit when the lights are on. The
exposure is set as per the doctor’s order according to standard guidelines as published in
the medical literature, modified by patient feedback, and treatment progress. The time
for each treatment ranges from 2 to as long as 20 min, and the number of treatments can
range from 2 to 60 or more. No specific training was provided to operators except that
given by the doctor and the company. The company also makes a home unit and will
provide training for its use. The manufacture recommends the unit for eczema, psoriasis,
vitiligo, atopic dermatitis, and among other skin conditions.
Maintenance

All maintenance, including calibrating the machine, changing the bulbs and related, is completed by a contract with the Daavlin company, which is located nearby in Bryan, Ohio. The company provides training when the unit is delivered and additional training is provided later if necessary, such as for new employees. An 800 number also is provided for operation questions that can be dealt with over the phone.

The optical radiation level highly depends specifically on where the sensor is pointed. If the sensor is directed to the vertical middle of a bulb that is on, UV is highest and, if aimed at the space between two lit bulbs, it is the lowest. Also, not all bulbs were on (this depends on the setting used). The UV level also increased towards the middle (center) of the unit, and the patient exposure (and thus dress) depends on the part of the body needing treatment. The exposure would seem to be uneven, although movement by the patient would, no doubt, reduce this concern enormously.

The UV radiation given off the unit after one minute was 17.27-19.46 μw/cm² effective and after 5 min was 23.9-25.8 μw/cm² effective. This value was significantly above the TLV standard of 5.0 μw/cm² effective for 10 min but is permissible because the exposure is used for therapeutic treatment. The UV radiation exposure in the 5’x 6’ room was 0.03 μw/cm² effective. Blue light optical radiation measurements after 1 min was 214-410 μw/cm² Sr and after 5 min was 220 - 485 μw/cm² Sr.

The Radiation Protection Findings

A questionnaire was used to determine the protection used at all five sites studied. It was found that none of the workers in the three areas researched used protection for optical radiation except the technicians that used the curing lights. Even here the protection was limited to small shields or a small fan shaped portable shield. The light was clearly bothersome even painful (this investigator got a headache both times that he
did measurements on the dental curing light). The reason was that they did not use protection was the staff did not feel that there was any harm due to exposure and protection was both unnecessary and could interfere with proper use of the equipment. For the light booth, it required only about two minutes to complete the measurements, and this was long enough to give the investigator a mild sunburn on the face that pealed the skin.

The effect of UV radiation on human skin has been studied extensively but its effect on gum and other tissue in the oral cavity has been little studied, partly because the normal exposure is far less than that provided to the skin. Skin has a protective pigment and a layer of dead cells that provide some protection, whereas the internal oral cavity does not have this protection and, therefore, would be expected to be more sensitive to, not only UV, but also other types of radiation.

The Concern of Training

None of the workers had any formal training in the use of the equipment tested in this study. Both eye doctors and the dermatologist were all trained on the equipment in medical school, and had continuing education credits, but they did not have training specifically in the safe use of optical radiation. The technicians and nurses were trained by the staff doctors only. None had any other formal or informal training aside from personal experience with the equipment.

Exposure Standards

Some researchers claim that the many studies that have researched the adverse effects of prolonged radiation exposure are often flawed, as indicated by the fact that levels of retinal exposure vary by more than 1,000-fold, even if the study employs the same light source (Sarck et al., 2002; Wegener, 1994-1995).
A concern is high doses of UV radiation exposure in a normal outdoor environment may not produce as great a problem compared to its use in the medical and therapeutic environment because defensive eye protection is naturally elicited by damaging exposures outdoors in order to prevent or reduce acute injuries. Long-term, low-dose exposure by users of medical optical radiation spread over an entire workday, though, can produce much more damage because the normal defense mechanisms are not triggered, or are less likely to be triggered.

To deal with these problems, certain individual organizations, such as the Health Council of the Netherlands, have drafted UV radiation exposure standards. These standards are often based on inadequate data and questionable assumptions. The current American Conference of Government and Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) standard (ACGIH, 2004) for visible light (400 - 760 nm) have been largely unchanged for about a decade and are based, in a large part, on ocular injury data from both animal studies and human retinal studies due to injuries resulting from conditions such as viewing welding arcs or the sun.

The TLVs also assume, without firm evidence, that, in general, outdoor environmental exposure to visible light is normally not hazardous to the healthy person. Among the many exceptions include visible light levels existing in large snowfields, deserts, and direct (or reflected sunlight such as reflections off of water.

Evaluation of radiation exposure requires the study of radiometric qualities (radiance used to describe brightness) and irradiance (used to describe the radiation level on the surface, as opposed to the brightness of the source). The second factor is photometric qualities, such as brightness measured in candela per square centimeter. The key concern is not the number of photons per square centimeter (photon flux) but the energy level transmitted to the tissue surface. The energy depends upon the radiation frequency: the higher the frequency, the more photobiologically active the radiation. Penetration level is another factor that must be considered. For example, UVA radiation
although less photobiologically active, is more penetrating than UVB radiation. UVC radiation is more photobiologically active for several reasons, including because the wavelength resonates more effectively (and thus is better absorbed) by certain amino acids, adversely affecting their structure and, consequently, their function. Another concern is certain wavelengths, even those within the UVB spectrum, are far more carcinogenic than the rest of the UVB spectrum. The narrow band lamps used for dermatology treatments is an example where this information is used to reduce the exposure to the harmful parts of the UV spectrum and yet achieve significant therapeutic benefits.

**Discussion of Future Research Concerns**

All of the measurements should be standardized by the use of a specially designed bracket to position the meter sensor in the exact place on the medical device for each measurement actually used with a typical patient. Ideally, the eye exam equipment using optical radiation can be adjusted to do an actual exam, and then the monitoring instrument sensor can be substituted for the patient. This then can be replicated. This approach would also help control for the level of radiation, if necessary.

The problem is, the level of radiation used for some exams such as for patients that have severe cataracts, is around 2 to 3 times greater than the level needed for a normal eye exam. By doing an examination on an actual typical patient, this factor can be better controlled. Without data on typical light levels used and rheostat adjustments for typical patients, the results obtained using the eye exam devices are, at best, estimates. Also, records should be kept as to the length of exposure and the specific technique used (such as in dental work composite is applied in layers or as a unit) for each patient.

Another concern is the energy produced by specific frequencies needs to be evaluated. This study looked at only a range of frequencies labels UV radiation, blue
light, and visible light. Comparisons with ACGIH standards for each frequency are required to achieve more definitive conclusions.
SUMMARY

The effects of optical radiation exposure in medical settings are a relatively unexplored area. Until recently, the widespread assumption in the medical community has been that all forms of optical radiation that are lower frequencies than x-ray are harmless. This study explored this topic by measuring several common devices used in medical practice that produce optical radiation.

A total of five medical clinics that used optical radiation for medical diagnostic and treatment purposes were selected for this study. The main instrument used to measure optical radiation produced by the devise evaluated was a Model IL 1400A radiometer/photometer, with either a UV Actinic Hazard Detector Model SEL240/T2ACTS or a Blue Light Hazard Detector Model SEL033/TBLU/SCS395/R. A Davis Instrument Extech meter was used to measure visible light. In addition, a questionnaire was used to determine the protective equipment used, the training of the users, and the methodology employed to use the medical devise in the clinic.

The study found that the patient and worker exposure to UV radiation was within the limits of the criteria recommended by ACGIH TLVs. It was also found that none of the workers had any formal training in the safe use of the radiation sources tested in this study. All of the physicians and dentists claimed that they were trained in the use of the equipment in medical school and by continuing education credits, but they did not have training specifically in the safe use of optical radiation. The only training the technicians and nurses had was that provided by the staff physicians.
CONCLUSIONS

1. Exposure to UV radiation during the use of dental curing radiation was lower than the recommended limits.

2. Exposure to UV radiation from the devices evaluated that were used for eye examination purposes does not produce a significant level of radiation energy in the UV radiation or Blue light frequencies.

3. Exposure to UV radiation during the treatment of eczema and other skin conditions, such as acne, does not result in a level of radiation above recommended limits.
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## Medical Collage of Ohio, Department of Public Health
### Optical Radiation Survey Form

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Researcher Name: Gerald Bergman</th>
<th>Survey #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Location of Dental Office

<table>
<thead>
<tr>
<th>Building</th>
<th>Dept.</th>
<th>Floor</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Room #</th>
<th>Lab</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Instrument used

**Type of Instrument:**

**Manufacturer**

(Name, address, phone):

### Application(s) of instrument (circle & explain):

- Diagnostic
- Material curing
- Other application:

### Power Output as Provided by the Manufacturer

- **Power (µW/cm² or mW/cm²):**
- **Wavelength range capability (nm):**
- **Wavelength in operation (nm):**
- **Other:**

---

69
Exposure
Number & job titles of individuals exposed to the curing light:
Dentist                      Staff
Dental assistant             Other

Operator interviewed:        Dentist  Faculty  Dental Assistant
Average daily exposure time: Minutes ____  Hours ________
Total duration of exposure:  Months ____  Years ________

Do you think exposure to radiation from the dental curing light is harmful to the operator?

Have you had any safety training on the dental curing light?   Yes  No
If yes, what type (circle all)?  Instruction manual  Safety class  Internet
Supervisor                  College Class  From Manufacture
Other (describe).

Do you use any shielding for personal protection?
Face shield

At what distance from your eyes the unit while you are working with the patient?
< 5 inches     5 – 10 in    11- 25 in

Which of the following protective equipment do you normally use when using the curing light?

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Summer</th>
<th>Winter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Long sleeves</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Lab coat</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Apron</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Other Remarks:
### Medical College of Ohio, Department of Public Health
### Questionnaire – Optical Radiation Survey

<table>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Gerald Bergman</td>
<td></td>
</tr>
</tbody>
</table>

**Location:**
- **Institution:**
- **Building:**
- **Dept.:**
- **Floor:**
- **Section:**
- **Lab/Room #:**

**Curing Light**
- **Manufacturer (Name, address, phone):**
- **Make:**
- **Model:**
- **Who cleans and maintains the Curing Light?**
- **How often are the lamps changed?**
- **Date of last lamp change:**

**Number using Light:**
- **Doctor:**
- **staff:**
- **Students:**
- **Other:**

### Exposure Control Methods

<table>
<thead>
<tr>
<th>blocking cover:</th>
<th>exists___</th>
<th>none___</th>
<th>Do not know___</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interlock:</td>
<td>Yes____</td>
<td>no____</td>
<td>Do not know___</td>
</tr>
<tr>
<td>Used:</td>
<td>always___</td>
<td>by some___</td>
<td>rarely___</td>
</tr>
<tr>
<td>Type:</td>
<td>hinged___</td>
<td>removable___</td>
<td>hand-held___</td>
</tr>
<tr>
<td>Condition:</td>
<td>good/clean___</td>
<td>good/dirty___</td>
<td>broken___</td>
</tr>
</tbody>
</table>

| Face Shield:    | exists___ | not-exists___ |
| Used:           | always___ | by some___ | rarely___ |
| Type:           | headset___ | hand-held___ |
| Condition:      | good/clean___ | good/dirty___ | broken___ |

| Eye Protection | exists___ | not-exists___ |
| Used:          | always___ | by some___ | rarely___ |
| Type:          | glasses___ | goggles___ | prescription___ |
| Condition:     | good/clean___ | good/dirty___ | bad/dirty___ |

| Hand/Finger Protection | exists___ | none___ |
| Used:                  | always___ | by some___ | rarely___ |
| Type:                  | surgical gloves___ | others (list)___ |
| Condition:             | good/clean___ | good/dirty___ | bad/dirty___ |

| Sunscreen: | used___ | not used___ | if used, type___ |

- **Is there any warning sign regarding exposure prevention?**
  - **Yes:**
  - **No:**

- **Are the only authorized persons allowed to use the light?**
  - **Yes:**
  - **No:**

- **Has ever the levels of light been measured?**
  - **Yes:**
  - **No:**
  - **If yes, explain:**

- **Have you ever been a formal training on safety with this instrument?**
  - **Yes:**
  - **No:**

### Comments:
Please add whatever information that you feel would be helpful to our research project.

### Remarks:
MEDICAL COLLEGE OF OHIO

RESEARCH CONSENT FORM FOR ADULT SUBJECT
INFORMED CONSENT

RESEARCH PROJECT TITLE: Assessment of Exposure to Optical Radiation used in Medical Diagnostic and Treatment

Principal Investigator: Farhang Akbar, Ph.D.
Co-Investigator: Gerald Bergman
Phone number: (419) 267-5511

What you should know about this research study:

- We give you this consent form so that you may read about the purpose, risks, and benefits of this research study. All information in this form will be communicated to you verbally by the research staff as well.
- Routine clinical care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.
- We cannot promise that this research will benefit you. Just like routine care, this research can have side effects that can be serious or minor.
- You have the right to refuse to take part in this research, or agree to take part now and change your mind later.
- If you decide to take part in this research or not, or if you decide to take part now but change your mind later, your decision will not affect your routine care.
- Please review this form carefully. Ask any questions before you make a decision about whether or not you want to take part in this research. If you decide to take part in this research, you may ask any additional questions that you may have at any time.
- Your participation in this research is voluntary.

PURPOSE

You are being asked to take part in a research study of optical radiation. The purpose of the study is to research the use of optical radiation in medicine. You were selected as someone who may want to take part in this study because you use or are exposed to optical radiation.
PROCEDURES AND DURATION
If you decide to take part in this study, you will be asked to show how optical radiation is used in clinical treatment and diagnosis.

RISKS AND DISCOMFORTS
There are no known risks involved in this study. All data will be kept confidential.

RISKS TO UNBORN CHILDREN
This research represents no known risk to unborn children:

BENEFITS AND/OR COMPENSATION
We cannot and do not guarantee or promise that you will receive any benefits from this study other than adding in the accumulation of medical knowledge.

CONFIDENTIALITY
By agreeing to take part in this research study, you give to the Medical College of Ohio, the Principal Investigator and all personnel associated with this research study your permission to use or disclose information that can not be identified with you that.

The information that we will use or disclose includes information about optical radiation. We may use this information ourselves, or we may disclose or provide access to the information to other researchers as part of the research study. Under some circumstances, the Institutional Review Board and Research and Grants Administration of the Medical College of Ohio may review your information for compliance audits.

The Medical College of Ohio is required by law to protect the privacy of this information, and to use or disclose the information we obtain in connection with this research study only as authorized by you in this form. There is a possibility that the information we disclose may be re-disclosed by the persons we give it to, and no longer protected. However, we will encourage any person who receives your information from us to continue to protect and not re-disclose the information. Your permission for us to use or disclose information as described in this section is voluntary. Except as noted in the above paragraph, your permission for us to use and disclose information about optical radiation has no expiration date.

A more complete statement of Medical College of Ohio's Privacy Practices are set forth in its Joint Notice of Privacy Practice. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the person identified in the Notice.

COST TO YOU FOR TAKING PART IN THIS STUDY
The only cost is the time investment required.

IN THE EVENT OF A RESEARCH-RELATED INJURY
In the event of injury resulting from your taking part in this study, treatment can be obtained at a health care facility of your choice. You should understand that the costs of such treatment will be your responsibility. Financial compensation is not available through Medical College Hospital. By signing this form you are not giving up any of your legal rights.
VOLUNTARY PARTICIPATION

Taking part in this study is voluntary. If you decide not to take part in this study, your decision will not affect your future relations with the Medical College of Ohio, its personnel, and associated hospitals and the named cooperating institution. If you do decide to take part in this research, you are free to withdraw your consent and to discontinue your participation at any time without a penalty.

OFFER TO ANSWER QUESTIONS

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

AUTHORIZATION

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED ABOVE, HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND HAVE DECIDED TO PARTICIPATE.

BY SIGNING THIS DOCUMENT YOU AUTHORIZE US TO USE OR DISCLOSE YOUR PERSONAL HEALTH INFORMATION AS DESCRIBED IN THIS FORM.

The date you sign this document to enroll in this study, that is, today’s date, MUST fall between the dates indicated on the approval stamp affixed to the bottom of each page. These dates indicate that this form is valid when you enroll in the study but do not reflect how long you may participate in the study. Each page of this Informed Consent Form is stamped to indicate the form’s validity as approved by the MCO Institutional Review Board (IRB).

Name of Subject (please print) __________________________ Signature of Subject or Legally Authorized Representative __________________________ Date __________________________

Relationship to the Subject __________________________

Name of Person Obtaining Informed Consent (please print) __________________________ Signature of Person Obtaining Informed Consent (as required by ICH guidelines) __________________________

Signature of Witness to Consent Process (when required by ICH guidelines) __________________________

YOU WILL BE GIVEN A SIGNED COPY OF THIS FORM TO KEEP.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related injuries, please feel free to contact R. Douglas Wilkerson, Ph.D.; Associate Vice President for Research; Medical College of Ohio at (419) 383-4251.
ABSTRACT

The effects of optical radiation exposure from devices used for medical diagnostic and treatment is a relatively unexplored area. A total of five medical clinics that used optical radiation for medical diagnostic and treatment purposes were studied. The main instrument used to measure optical radiation was a Model IL 1400A radiometer/photometer using either a UV Actinic Hazard Detector Model SEL240/T2ACTS or a Blue Light Hazard Detector Model SEL033/TBLU/SCS395/R. A Davis Instrument Extech meter was used to measure visible light. The study suggested that exposure to UV radiation for the sites measured was within the limits of the criteria recommended by ACGIH TLV. It was also found that none of the workers had any formal training in the safe use of the radiation sources tested in this study.