Photodynamic Therapy for Sun Damage and Skin Cancers

This Information Package has been designed by Dr. Searles to answer your questions on this service.



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Applying Science to the Art of Skin Care

What is photodynamic therapy?

Photodynamic therapy (PDT) is a medical treatment that uses a photosensitizing drug (a drug that becomes activated by light exposure) and a light source to activate the applied drug. The result is an activated oxygen molecule that can destroy nearby cells. Precancerous cells and certain types of cancer cells can be treated this way. The procedure is easily performed in a physician's office or outpatient setting.

PDT essentially has three steps. First, a light-sensitizing liquid, or cream, (photosensitizer) is applied. Second, there is an incubation period of several hours. Finally, the target tissue is then exposed to a specific wavelength of light that then activates the photosensitizing medication.

Steps:

- 1. application of photosensitizer drug
- 2. incubation period
- 3. light activation

Although first used in the early 1900s, PDT in the modern sense is a fairly new, evolving science. Current PDT involves a variety of incubation times for the lightsensitizing drug and a variety of light sources depending on the target tissue. The basic premise of PDT is selective tissue destruction. Although the photosensitizer may be absorbed all over by many cells, atypical or cancerous cells take up more of the drug and retain the drug for a longer duration than normal tissues. At present, the primary limitation of available PDT techniques is the depth of penetration of the light and ability to target cells within at most 1/3 of an inch (approximately 1 cm) of the light source. Therefore, tumors or atypical growths must be close to the surface of the skin or treatment surface for PDT to work.

PDT is currently used in a number of medical fields including oncology (cancer), dermatology (skin), and cosmetic surgery.

In dermatology, PDT with the photosensitizer Levulan Kerastick® (20% delta-aminolevulinic acid HCI) or Metvix (methyl aminolevulinate) is used for the treatment of pre-skin cancers called actinic keratoses (AK). The initial approval was specifically for normal (nonhyperkeratotic) actinic keratosis of the face and scalp with a specified 3-hour drug incubation time, and 9 minutes of activation by a red light source. PDT is also used for acne, rosacea, skin cancer, sun damage, cosmetic skin improvement, oily skin, enlarged sebaceous glands, wrinkles, rejuvenation (anti-aging), warts, hidradenitis suppurativa, psoriasis, and many other skin conditions. It is not used to remove moles or birthmarks.

What photosensitizer drugs are available?

FDA-approved photosensitizers include Levulan (<u>5-aminolevulinic</u> acid or ALA), and Metvix (methyl aminolevulinate [MAOP]). More drugs may become available in the near future. Levulan and Metvix are applied topically for skin therapy.

What light sources are available, and how are they applied?

PDT light sources include laser, intense pulsed light, light-emitting diodes (LEDs), blue light, red light, and many other visible lights (including natural sunlight). Photosensitizer drugs may become activated by one or several types of light. The optimal light depends on the ideal wavelength for the particular drug used and target tissue.

The light source needs to be directly applied to the target tissue for a specific amount of time. For surface skin treatments, the light is easily directly applied to the area of the skin where the photosensitizer drug has been applied (such as face, scalp, arms, etc.).

How does PDT work?

PDT works by direct injury to the target cells and tissues. This involves an activated oxygen molecule that can injure or destroy nearby cells. By preferentially attacking the active or abnormal cells, PDT combines a very high success rate with good preservation of normal skin without significant risks for scarring. Once the areas have healed following PDT, the areas are reexamined to see if additional treatments or biopsies are needed.

PDT is a targeted treatment aimed at more rapidly dividing cells and atypical skin growths. With regular or traditional cryosurgery (freezing with liquid nitrogen) or burning, only the visible pre-skin cancers can be treated, potentially leaving behind cancers that are hidden. PDT allows for treatment of an entire area of sun damage, thereby reducing the chance that undetected pre-skin cancer cells will be left untreated.

Does PDT make me permanently more sensitive to light?

No, PDT causes a temporary sensitivity to light, including natural sunlight and some indoor lights. The light sensitivity resolves with time, depending on both the photosensitizer drug and dosage used.

Light avoidance is generally required after PDT. The duration depends on the drug and dosage used. Proper protection, including long sleeves and sunglasses, may be required. Topically applied aminolevulinic acid or methyl aminolevulinate may cause skin sensitivity only on the treatment areas for approximately 24-72 hours. These do not usually cause sensitivity on other body parts other than where the drug was directly applied. Your physician will need to discuss with you the required sun- and light-avoidance period required after your particular treatment.

How is PDT used to treat the skin?

PDT using Levulan or Metvix and a proprietary blue or red light is currently FDA approved for the treatment of skin precancers called actinic keratosis (rough scaly spots generally on sunexposed skin). PDT is also known as "ALA/PDT treatment" or "Super Blue or Red Light." It has been referred to as a "super photo facial" when the photosensitizer is used with a machine called intense pulsed light or IPL. These treatments may help remove sun-damaged precancerous skin. Sun damage, fine lines, and blotchy pigmentation may also be improved because of the positive effect of PDT. PDT also has been shown to help decrease the appearance of pores and reduce oil glands, effectively treating some stubborn acne, ro-

sacea, and improving the appearance of some small superficial acne scars.

Although PDT's use in skin was first investigated in 1990s for actinic keratosis, it was not as popular or widely used because of the required long incubation times (usually 18-24 hours) and limited indications. Since approximately 2001, PDT has become more widespread in use primarily because of advances including shorter incubation times (30-180 minutes) and more applications, including acne and cosmetic skin rejuvenation.

What is a typical skin PDT session like?

You may be given a written procedure-consent form to read and sign before your first treatment. The medical staff may take some pretreatment photography prior to applying the photosensitizer medication.

In the treatment room, you may be sitting or comfortably lying back on a table. Often a thorough cleansing of the face is done using alcohol and or acetone to degrease the skin. The less oil on the skin, the more readily the skin will absorb the applied topical medication. In some patients, microdermabrasion may additionally be performed prior to the application of the medication to further prepare the skin to optimally absorb the photosensitizer.

The photosensitizer liquid or cream is applied topically to the whole area being treated (such as the entire face, scalp, back of the hands, back part of the forearms, legs, feet, scalp, chest, or back).

The medication is allowed to air dry for a few minutes, and then you will wait anywhere from 30-180 minutes for the incubation time. Some areas such as chest, back, and particularly forearms and legs require longer incubation times of two to four hours for bet-



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ter results. No two people or skin on different areas of the body are exactly alike. PDT requires physician adjustments for specific individualized incubation times and treatment durations.

After the proper incubation time, you are brought back into the light-source room where the medication is activated with a specific wavelength light source. There may be sensations of warmth, tingling, heat, or burning in some patients. A fan can be used to help cool off during the treatment. The treatment area is then washed off and sunscreen applied. Instructions are given on how to care for the skin at home.

How much improvement can I expect?

No two individuals are the same, and results may vary. Some conditions can improve dramatically in some patients and not respond in others.

Overall, patients with severely sundamaged skin with actinic keratosis, texture, and tone changes including mottled pigmentation, dull or sallow skin, and skin laxity may see good to excellent improvement with PDT. There can be improvement of large pores, nonpitted acne scars, and active acne.

Depending on the area being treated and the recommended incubation time, different numbers of treatment sessions spaced four to six weeks apart may be required to achieve the desired improvement and reduction in lesions. On average, a series of two treatments are performed. It is not always possible to predict ahead of time how many treatments your specific condition may take or how you will respond to PDT.

Photodynamic therapy requires staying out of the sun for 24-48 hours depending on the area treated.

Where can I have photodynamic therapy, and who performs the procedure?

Photodynamic therapy for skin therapy is usually comfortably performed in an outpatient setting like a doctor's office and without any sedation or anesthesia.

Most skin PDT is performed only by specially trained dermatologists and their medical staff. Other physicians, including oncologists, family physicians, internal medicine doctors, plastic surgeons, or ear, nose and throat (ENT) surgeons



Before PDT with Metvix



After PDT with Metvix

and their medical staff who are trained, may also perform photodynamic therapy. While it is generally advisable to undergo this or any medical treatment in an established board-certified physician's office, there are medical spa-type environments that may also offer these skin services with or without physician supervision.

What are the advantages with photodynamic therapy for treating skin precancers?

The greatest advantage of PDT is the ability to selectively treat an entire area of skin damage and precancers (blanket or field treatment). PDT generally decreases the likelihood of lighter or darker skin spots (postinflammatory hyper- or hypopigmentation) caused by routine freezing with liquid nitrogen. Additionally, PDT frequently may facilitate smoother skin and an overall improved appearance, tone, color, and enhanced skin texture.

In several studies, PDT has been preferred by many patients for ease of use and recovery as compared to alternative treatments including freezing and chemotherapy creams like fluorouracil (Efudex). The PDT side effects may be milder with less downtime than with fluorouracil.

For patients with many skin lesions, PDT may be generally more effective than repeated spot treatment with topical liquid nitrogen. Some patients are unable to tolerate the prolonged treatment required with fluorouracil or imiquimod (Aldara) because of the irritation, redness, and possible downtime with these topical creams. PDT has become a very well tolerated, essentially painless, noninvasive (no needles or surgery required) procedure to help reduce sun damage and enhance the overall cosmetic outcome (particularly in sensitive areas of the face and chest).

Am I a good candidate for photodynamic therapy?

The best candidates for PDT may be those with lighter or fair skin with sun damage.

You may not be a good candidate for photodynamic therapy if you have darker skin that tends to turn brown or discolor with certain light or laser treatments. You may also not be a good candidate for PDT if you are very sensitive to light, burn extremely easily, would be unable to stay out of sunlight for the required 24-48 hours, or are taking medications which may make you very sensitive to sunlight or light-based therapies.

Your decision on the best treatment choice may depend on different factors such as the location and type of skin lesions, your past treatments, your overall health, and level of comfort. Your physician can help you sort through the different treatments.

Your photodynamic therapy physician needs to know of any other medical conditions that may affect your procedure or overall wound healing. You would want to make sure to tell your physician beforehand if you have any extreme sensitivity to light-based treatments, take medications which make you very sensitive to light, have had a problem or bad effect from prior PDT, have systemic lupus erythematosus, or suffer from a condition called porphyria.

Your PDT physician needs to know if you have had a history of Staph or other skin infections in the recent past. You will also want to advise your physician if you have a history of frequent cold sores (Herpes virus infections on your face). In that case, you may be prescribed an antiviral tablet (cold-sore prevention pill) to take before and after your procedure. You may be asked to wash with a special antibiotic soap or wash like Hibiclens (chlorhexidine) the night or morning before your procedure to help reduce the number of bacteria on your skin.

Patients may need to also advise their physician of any drug allergies such as to topical anesthetics or other photosensitizers. Additionally, the surgeon may need to know of any bleeding or bruising tendencies, hepatitis, HIV/AIDS, or pregnancy.

Your physician will want to know of any factors that may affect your surgery or wound healing.

What growths is PDT not good for?

PDT is not as effective for thick skin precancers called hypertrophic actinic keratosis (HAK). This may be due to the inability of the photosensitizer drug to penetrate the thick skin. These growths may need to be frozen or surgically removed or thinned using a curette prior to PDT.

PDT may also not be very useful for more advanced skin cancers like morpheaform or sclerosing basal cell carcinoma, moderately to poorly differentiated squamous cell carcinomas, recurrent tumors (tumors that were previously removed and have regrown at the same site, or lesions in previously radiated (X-ray or radiation treatments) sites, and malignant melanoma.

What are possible complications of photodynamic therapy?

Overall, most patients tolerate the minor procedure very well without any complications. However, PDT is associated with some possible minor risks and complications. Since an exaggerated lightsensitive reaction is expected by definition of PDT, most patients understand and expect some type of a sunburn or red reaction after skin PDT. Not everyone gets a sunburn reaction, however. Some patients may have no visible reaction or redness.

Possible risks and complications of photodynamic therapy include (but are not limited to) burning, skin discoloration, skin redness, prominent tiny blood vessels (telangeictasia), pain, infection, cold-sore activation, blisters, scabs, unsightly scars, keloids (raised, thick scars), cosmetic disfigurement, skin discoloration, eye injury or swelling, allergic reactions, prolonged sun sensitivity, reaction to topical anesthesia, precancer or cancer recurrence, need for further treatment including biopsy, radiation or plastic surgery, and rarely death.

Minor, serious, or life-threatening reactions can occur with the use of anesthetics or with medications given before, after, or during a procedure.

Is there scarring from photodynamic therapy?

No, PDT usually does not leave scars in typical cases. Overall when you undergo PDT, there will be some type of a red skin reaction and irritation for three to 10 days after the treatment. Some people are more sensitive to PDT and the light treatment than others. Similarly, some people heal better or faster than others. Some residual redness may be more noticeable depending on the location and skin type. Some people may have temporary skin discoloration that may last weeks to months. Patients with darker skin types may have more skin discoloration after treatment.

What are alternatives for photodynamic therapy?

It is important to understand that as with any medical treatment, there are alternative treatments and options to PDT. You may want to discuss alternative treatment options with your doctor at your consultation appointment.

There are many options for treatment of actinic keratosis (AK), including but not limited to freezing (cryotherapy or cryosurgery), burning, chemical peels, lasers, chemotherapy creams (like fluorouracil and immune modulator creams like imiquimod), local radiation, plastic surgery, curettage and desiccation (scrape and burn), surgical removal, no treatment, and other choices depending on the skin condition. In acne, there are many alternatives to PDT, including oral Accutane (isotretinoin), oral antibiotics, topical washes, acne facials, and many acne creams.

What about insurance coverage and costs?

Photodynamic therapy is currently considered a medical service for the treatment of some conditions, particularly for skin precancers called AKs. However, it may be considered cosmetic, off' label, or not medically indicated for conditions for which it is regularly used.

Currently, some insurance plans cover the procedure under their provided benefits. However, with the many changes in insurance plans, it is always advisable to contact your insurance carrier prior to scheduling any treatment and confirm your eligibility and benefits.

Photodynamic therapy, like any procedure, will result in additional procedure charges above the routine office-visit fees. These fees may range from two to several hundred dollars depending on the area, number of treatments, and the type of insurance you purchase. The greater number of treatments and greater the amount of photosensitizer medication required, the higher the cost.

Insurance benefits vary, and reimbursement depends on what benefits you have contracted for with your insurance company. Currently, Alberta Health Care generally typically covers the treatment coses of the photodynamic therapy itself for precancers. However, some drug coverage insurance plans do not cover the cost of the medication.

You may want to get to know and understand your insurance benefits before having surgery. In many cases, you may also ask your insurance coordinator for an approximate estimate of your charges before scheduling the procedure.

What about other treatments options?

You may decide to have alternative treatments instead of PDT. Alternatively, you may also choose a hybrid option where you have photodynamic therapy and additional other treatments. In some cases, the most effective treatment for certain conditions may utilize a combination treatment using two or more modalities to treat the condition.

How do I prepare for my procedure?

Your personal physician and their medical personnel will likely let you know the preoperative instructions specific for your condition.

For many typical PDT procedures in a physician's office, most patients are advised come in with a clean, washed area without any lotions or makeup. You may generally eat your regular diet on the day of their procedure and take all of your regular daily medications. Your skin should be fully clean and free of all makeup, moisturizers, and sunscreens. Bring a wide-brimmed hat (6 inches), sunglasses, and scarf when appropriate to the appointment. Patients are advised to wear comfortable casual clothes and bring a wide-brimmed hat for facial or scalp treatments. You should bring gloves or a long-sleeve shirt if having hands or forearms treated.

In nearly all cases, patients are usually able to drive after most procedures and do not necessarily need a driver unless they feel uncomfortable or have taken any sedative medications.

Since you will be in the office for generally at least one hour, you may want to bring some personal snacks, drinks, and reading or knitting material. Personal music headsets or iPods may also provide relaxation and help pass time during your PDT application, incubation time, and treatment.

Most patients continue all prescribed medications including aspirin and any blood thinners unless specifically advised otherwise only by the doctor.

While there is no absolute contraindication, smoking is discouraged for at least a few days before and one to two weeks after your procedure. As with any procedure, smoking can slow down wound healing and cause an increased risk of wound infections.

Heavy alcohol use is not advised at least a few days before PDT. Heavy alcohol use can cause more bleeding and thin your blood. An occasional glass of wine or small cocktail may not cause severe bleeding.

How is recovery?

Recovery is usually fairly easy and uneventful. Many patients have mild dryness and a faint to mild sunburn of the treated area. A small percent of patients may have moderate or marked discomfort and a harder recovery because of more skin dryness, redness, or burning.

Some of these patients have had inadvertent sun exposure even as short as a minute or two during their immediate posttreatment time, causing a more severe reaction. A handful of patients have reported some minor sun-exposing activities like briefly stepping out to fill their yard bird feeder or walking out for a moment to grab the mail from the mailbox.

You will want to plan to stay indoors and avoid any sunlight for 24-48 hours as directed by your physician. Overall, you may be able to resume all normal indoor activities the first day.

Most patients are able to return to work or school the 24-48 hours after photodynamic therapy. Avoiding direct sunlight for the first one to two days in crucial to avoiding getting an exuberant (red) response. Your physician will need to let you know what activity precautions are required based on the area and size of your procedure.

Is there pain after PDT?

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Typically, there is not much pain with PDT. No two individuals are exactly the same, and individual reactions and tolerance to discomfort levels vary. Most patients report mild skin irritation including minimal to mild dryness and tight feeling of their skin after PDT. This discomfort is usually improved with frequent application of bland topical emollients or plain Vaseline.

A small number of patients may actually complain that they felt nothing and didn't have any pain or peeling. Less commonly, a small percentage of patients for various reasons may have significant pain, a very exaggerated sunburn response, moderate overall discomfort, and pain from the tightness and warmth of the skin.

If there is pain, many patients find that they prefer to take something for pain at the first hint of discomfort instead of waiting until the pain builds up to an unbearable level. If you have mild or moderate pain, your doctor may advise you to take acetaminophen (Tylenol) or another pain reliever. Rarely, prescription pain medications may be required for severe pain.

Your physician will let you know what pain medications are recommended for your specific condition.

How do I take care of my treatment area after photodynamic therapy?

It is generally required to check with your doctor for their specific wound care instructions before your procedure. Often, you will be asked to go home and stay indoors for the rest of the day. Your physician will usually give you more detailed instructions depending on the area and size of the procedure.

Many physicians suggest you shower and wash the area immediately and as often as you would like. Wound care may require gently washing the area with soap and water or hydrogen peroxide two to three times a day and applying an over-the-counter antibiotic ointment or a nonirritating moisturizer like Purpose, Cetaphil, or Aquaphor to the area. Avoidance of harsh or abrasive cleansers is advised. Picking or scrubbing the skin could cause in severe irritation or scarring.

Most patients are advised to try to avoid applying makeup or powder directly on a fresh or open wound unless the surface is fully healed. A nonirritating sunscreen such as zinc or titanium may be applied immediately after the procedure before leaving the physician's office. Sunscreens are ideally also applied twice a day after PDT. It is important to follow your own physician's instructions for wound care.

Mild to moderate redness and or swelling is not uncommon the first day or two after PDT and can be lessened by application of an ice baa, ice cubes or chips in a small Ziploc bag, or frozen peas in their bag. Applying cool packs or ice every five to 15 minutes every hour for the first eight to 24 hours after your procedure may be very soothina. Swellina may be more common for procedures around the eyes or lips. Sleeping propped up on a few pillows or in a reclining chair may help decrease swelling after treatment of the head and face area.

Your physician should be notified of any infections, cold-sore outbreaks, extreme swelling, or other unexpected reactions. Rarely, a visit to the physician's office may be necessary for severe swelling or infection. Oral antibiotics, cortisone creams or tablets, or other medications may be required for adverse reactions.

Your physician will need to know if pain is increasing after one to two days after your procedure or if you are having fever or other concerning symptoms. In such cases, you may need to be seen at the physician's office.

What is the chance that my precancers will recur?

While PDT is a very effective treatment, there is a reasonable chance that you may continue to need periodic treatments for precancers depending on your individual skin and severity of prior sun damage. Often there are layers of underlying sun damage from prior years that rise to the surface over time.

A skin precancer or cancer may recur or a new cancer may arise in the same or adjacent area even after photodynamic therapy or other treatments. Some skin precancers are more aggressive than others and need additional treatment and closer follow-up.

Sun-damaged skin frequently needs additional follow-up and possible further treatment, at least annual rechecks and possible touchup PDT treatments are advised. Several studies have shown that photodynamic therapy tends to have a cure rate comparable to the traditional treatment with fluorouracil.

It is important to note that PDT may not be necessarily curative in advanced skin cancer (rare cases). This may require one or more procedures such as biopsy, surgery, radiation or other procedures to fully treat the lesion.

Follow-up appointments with your dermatologist or physician are very important, especially in the first few years after photodynamic therapy. Many patients are seen every four to six months after their diagnosis of precancers of the skin.

Self-skin examinations monthly are good practice for patients with a history of skin cancer. Any changing or new growth should be promptly checked by your physician. More regular follow-up appointments may be needed for those with more aggressive tumors or tumors in high-risk areas. Your physician will recommend the proper follow-up for your specific condition. INFORMATION FOR PATIENTS ON LASERS AND LIGHT TECHNOLOGY

VERSION I.I

Getting to Know your Options through the Consultation Process

Aesthetic dermatology, laser services and healthy skincare are the most effective ways to enhance your natural beauty and to prevent further skin damage. Dr. Searles and his team of trained nursing staff offers consultations for all cosmetic and laser procedures and skincare offered at our office.

A consultation includes a complete evaluation of your skin history, depicting your skin care concerns and goals, and a treatment and skincare reaimen based on those areas evaluated. The treatment and skincare options will be described in-depth to you so that you understand all of the necessary information for beginning the recommended regimen. This information includes, but is not limited to, description of the treatment, pre- and post- treatment protocols, risks and side effects, costs, and before and after examples.

If an area of concern is not treatable with the technology and therapies available at Keystone Dermatology, we will refer you to a qualified professional in that field.

The consultation is designed to provide you with all of the information necessary for you to feel most comfortable in receiving the benefits of these treatments and skincare programs.

About Dr. Searles...

Dr. Searles is dually certified by the Royal College of Physicians of Canada in both Internal Medicine and Dermatology. He has been honoured to be elected as a Fellow of the prestigious American College of Physicians. He is a member of numerous National and International medical organizations devoted to the discovery and application of new ideas and techniques for treating medical and esthetic skin conditions.

Dr. Searles is a Clinical Professor in Medicine at the University of Alberta, and is the Director of Resident Training for Dermatology.

Dr. Gordon Searles' primary mission is to deliver the best care possible through the use of the latest advances in medical research and new technologies.



A Fellow of the CDA



This Information Package is prepared for you by:



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