

MIXTO SX LASER STUDY INFORMATION SHEET
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Is it true that I can improve my sun-damaged skin with a laser that requires very little "downtime"?

Currently, there are many lasers used to treat sun damage/photoaging of the skin. One older laser system, the carbon dioxide laser, has been very effective for treating sun damaged skin but has fallen out of favor. This is because it routinely caused extensive rawness of the skin that typically required over 2 weeks of "hiding out" or "downtime" to recover. In addition to the time it took to heal, it frequently caused skin discoloration and occasionally scarring. Many lasers available today require very little downtime and yield some improvement of the skin but are not nearly as effective as the carbon dioxide laser. Dr. Cedars and Dr. Wall are doing a study designed to assess the effectiveness of a new, modified carbon dioxide laser system.

How is the MiXto laser different?

The MiXto SX machine (Lasering, USA <http://www.laseringusa.com>) is a "fractional" carbon dioxide laser, meaning that, rather than "zapping" 100% of a treated region of skin, it zaps scattered tiny zones of skin comprising a total of perhaps 25% of the treated region. Tiny treatment zones mean no skin rawness. The trade-off appears to be that more than one treatment is needed to get good results. The laser has been used to safely treat over 160 patients in Italy. It has been FDA-approved for treatment of fine lines. Patients who have been treated with this laser report less pain, less downtime, and better results than are reported with other lasers. Dr. Michael Cedars and Dr. Tomi Wall have successfully treated patients in their office with this laser. They wish to quantify their results with a formal IRB-approved study.

Am I a good candidate?

As is true for all lasers, some people may be better candidates than others. If you have sun-damaged skin of the face (freckling/brown spots, wrinkles, coarse texture), you may be a good candidate. You must be able to complete all the required visits (6 in total) and be willing to have photographs taken for medical publications. Please read and answer the questions below. If you answer yes to any of them, you are not a candidate for this study.

Yes	No	Question
		Do you have a history of keloids or abnormal scarring?
		Have you used an oral medication called isotretinoin (Accutane or others) in the past 12 months?
		Are you pregnant or breastfeeding or planning on becoming pregnant during the treatments?
		Do you have a history of immunosuppression (HIV/AIDS/transplant)?
		Are you under the age of 18?
		Are you out in direct sunlight for longer than 1-2 hours daily? It is important before and after each laser treatment to stay out of direct sunlight. If you are wearing a hat and using good protective sunscreen (#30 or higher), you may still be a candidate.
		Do you have the type of skin that rarely or never burns when outdoors in the sun? People with darker pigment in the skin are at higher risk of long-lasting discoloration and scarring with certain laser treatments.
		*Have you had a facelift, browlift, or midface lift in the past 12 months?
		*Have you had a full face laser treatment with another type of laser in the past 6 months? If the treatment was only for a very focal area, you may still be a candidate.

*If you answered yes to either of the last 2 questions, you are not a candidate for the study. However, you might still be able to have the laser treatments. You should discuss this with Dr. Cedars or Dr. Wall directly.

How much does the treatment cost?

The charge for this type of laser treatment ranges from \$5,000 - \$8,000 for 2 treatments in offices across the United States. Our charge for patients in the study will be \$1,500 total for 2 treatments. You will be provided with a cooling pack and sunscreen to use after the treatments. At the end of the study, you will be reimbursed for parking for the 6 visits.

What does the treatment feel like?

Most people will feel some stinging and burning during the procedure and for several hours afterwards. The stinging and burning will usually subside by 1-2 days. You may take ibuprofen/acetaminophen or similar medications to minimize this discomfort.

What do I look like after the treatment?

Your skin will look red and swollen from 1-3 days after each treatment. In rare cases, the swelling and redness may last for 1 week. In approximately 3-4 days, you will probably have some flaking and bronzing of your skin. The flakes usually resolve within a week.

Can I cover the redness with makeup?

We ask that you not apply anything to your face, except the ointment that we will recommend, for the first 2-3 days. You may wear make-up after that time.

How many treatments will it take?

For the purposes of the study, we shall be treating you twice, spaced approximately one month apart. We shall ask that you come in first for a consultation, then return at 1 day after the first treatment, 1 week after the first treatment, and 3 months after the second treatment for follow-up and photographs. This means a total of 6 visits to our office. If you cannot make it to all visits, you are not a candidate for this study. If you do not want photographs taken and published in scientific articles, you are not a candidate for this study.

What are the side effects of this treatment?

Common side effects from treatment with the MiXto SX laser include the following: redness lasting for a few hours to a few days, swelling lasting for a few hours to a few days, tenderness during the treatment and immediately after, flaking of skin. Less commonly, you may have significant swelling lasting over one week, hyperpigmentation (darker discoloration), or hypopigmentation (lighter discoloration). Rare side effects include blistering or scarring.

Who will be performing the treatments?

Dr. Michael Cedars, a board-certified plastic surgeon, or Dr. Tomi Wall, a board-certified cosmetic dermatologist, will be performing all of your treatments. Both have had extensive training with lasers and cosmetic procedures. Both are on the medical staff of Alta Bates Medical Center. If you would like more information about these doctors, we will be happy to provide you with their CVs.

How do I sign up for the study?

In order to participate in this study, you must have carefully read 1) this information sheet, 2) the study consent form, and 3) the pre/post treatment sheet. If you have not received all of these forms, you may download them at www.drcedars.com or pick up a packet at our Webster St. office in Oakland. After reading the forms, if you feel you are a good candidate for the study, please call our office at (510) 763-2662. Ask to make an appointment with either Dr. Michael Cedars or Dr. Tomi Wall. Please inform the person making your appointment that you are interested in participating in the MiXto study. The doctor will assess your eligibility.