Study of the Efficacy of 532nm Laser and 1064 nm Laser in the Treatment of Cutaneous Lupus Erythematous Versus Topical Corticosteroids Alone

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1) Protocol Title

A Comparative Study of the Efficacy of 532nm Laser and 1064 nm laser as Adjuncts to Topical Corticosteroids in the Treatment of Cutaneous Lupus Erythematosus Versus Topical Corticosteroids Alone

2) Principal Investigator

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3) Objectives

This study aims to compare the efficacy of 532nm Potassium Titanyl Phosphate (KTP) laser and 1064 nm Neodymium-doped Yttrium Aluminum Garnet (Nd:YAG) laser as adjuncts to topical corticosteroids in the treatment of cutaneous lupus erythematosus versus topical corticosteroids alone.

Our hypothesis is that adding laser treatment to standard of care will result in quicker resolution of lesions of cutaneous lupus. Furthermore we hypothesize that the 532nm laser will be more effective than the 1064nm laser.

The results of the study will either be submitted for publication in a journal or presented at a conference. Data from this study also could be used for further studies to clarify the ideal laser settings for use in cutaneous lupus.

4) Background

Systemic Lupus Erythematous (SLE) is an autoimmune disorder characterized by the production of autoantibodies that can affect almost every organ in the human body. Most commonly there is a skin and musculoskeletal involvement, but there also can be hematologic, renal, and central nervous system manifestations as well.[1]

It is estimated that 80% of people with SLE have skin involvement referred to as Cutaneous Lupus Erythematous (CLE). CLE can develop independently of SLE and is more prevalent than SLE alone. Women ages 20 to 50 years old are most commonly affected by CLE although males and other ages can be affected as well. [2]

CLE is typically categorized as acute (ACLE), subacute CLE (SCLE), and chronic (CCLE). ACLE develops in nearly one half of patients with SLE, but most or all people with ACLE have SLE. Also known as "malar rash" or "butterfly rash", ACLE is characterized by erythema distributed over the cheeks and nasal bridge of the face.[1] SCLE is less common but may appear as round, scaly lesions with central clearing. Discoid Lupus Erythematosus (DLE), a form of CCLE, is one of the most common forms of cutaneous lupus and can appear as erythematous and hyper- and hypopigmented lesions with telangiectasias. Frequently these lesions lead to scarring and can be permanently disfiguring.

First line management of CLE involves photo protection along with topical corticosteroids and possibly systemic agents. Other treatments include intralesional steroids and/or topical calcineurin inhibitors.[1] Both topical and systemic medications carry a wide range of adverse and toxic effects.[3–5]

Though not well-known, laser therapy has been shown to be effective in the treatment of cutaneous lupus.[6–8] Many providers may be wary of using lasers on these patients given the ability of ultraviolet light to exacerbate or flare SLE.[9,10] It is believed that by targeting the superficial vasculature the lasers are able to attenuate the inflammatory response seen in the skin.[11]

The 585 nm, 595 nm and 1064 nm wavelength lasers have all been shown to be effective in the treatments of cutaneous lupus.[6–8,12] Given their ability to target vasculature, these lasers are currently used to treat vascular lesions and inflammatory conditions such as port wine stains, telangiectasias, hemangiomas, rosacea, and scars.[13,14]

Lasers utilizing the 532nm wavelength also have been shown to treat the same vascular and inflammatory conditions as the above mentioned wavelengths. This is due to the fact that the 532nm laser targets the same chromophore of oxyhemoglobin.[15,16]

Therefore, given that the 532nm has very similar properties and same mechanism of action as other vascular lasers shown to be effective at treating cutaneous lupus it would be reasonable to consider that the 532nm laser could be utilized to treat cutaneous lupus as well.[17]

However, since the 532 nm should be used with caution in darker skin people and SLE is 2 to 4 times higher in African-American women than Caucasian women, utilizing only the 532nm would limit the applicability of the proposed study.[14,18]

Therefore, we are proposing investigating the use a 1064nm laser as well in treating cutaneous lupus as this wavelength is safe on people of all skin types.[9] The 1064nm laser has previously been shown to be effective in cutaneous lupus though further studies are needed to confirm the preliminary findings and better characterize the effectiveness.[11]

When compared to available topical and systemic therapies, laser therapy generally has been shown to have minimal side effects. The most common adverse effect is bruising

but that usually clears within 10 days. Other adverse effects include temporary dyspigmentation and very rarely scarring, vesiculation, and crusting that usually fade within a few weeks.[14]

The 532nm laser and 1064nm wavelength lasers are currently being used in an off-label manner by Dr. David Weinstein of UCF Health to treat patients with cutaneous lupus with excellent clinical results. As there is limited data on the use of the 532nm and 1064nm lasers for cutaneous lupus, we hope to quantify the magnitude of the results in a prospective manner.

As lasers with these wavelengths are present in many dermatology practices, we hope that data from this study will educate and encourage more providers to use lasers, such as the one in this study, to benefit their patients with cutaneous lupus.

5) Setting of the Human Research
   - The human research will be conducted at UCF Health Clinic at 9975 Tavistock Lakes Blvd., Orlando, FL 32827.
   - UCF College of Medicine's resources will be used during data analysis
   - We have obtained permission and approval from UCF Health medical director Dr. Maria Cannarozzi

6) Resources available to conduct the Human Research
   - Participants will be recruited through the UCF Health Clinic, Lupus Foundation of Florida, and the Central Florida Society of Dermatology. This represents a large pool of potential participants from which to recruit.
   - The study's small sample size (N=25) makes it likely that the required number of participants will be recruited in less than 12 months.
   - Research will be conducted during Dr. Weinstein's clinical time. Dr. Weinstein, a UCF Health board-certified physician, will perform the screening of eligible participants. Dr. Weinstein has significant prior experience conducting research, knowledge of the regulations and customs at UCF Health, and works regularly with patients performing laser treatments. Off-label laser treatments currently performed are fractionated CO2 laser for morphea, 1064nm and 532nm laser for sarcoidosis and acne, and 532nm laser for cutaneous lupus among others. Experience has been presented at invited talks/grand rounds. All treatments will be administered by Dr. Weinstein.
   - All individuals assisting in the research study will be provided a copy of the approved IRB study protocol and given the opportunity to meet with the principal investigator before recruitment begins. The principal investigator, Dr. Weinstein, will be responsible for informing all research staff of their research-related duties during a personal meeting or via phone or email. The contact information of the principal investigator and co-principal investigators will be distributed to all research staff and the participants.

- The study will be will be conducted at the UCF Health Clinic, see section 5 (Setting of the Human Research). Extramural funding will be sought from various organizations or industry.
- The chances of a research related injury are extremely rare. However treatment for research related minor injuries will be made available at no cost by Dr. Weinstein if possible. For injuries that cannot be treated by Dr. Weinstein the participant will be referred elsewhere. Costs associated with this treatment may be billed to the participant's insurance company. Costs not covered by participant's insurance company will be the participant's responsibility.
- The study has been approved by the UCF Health Privacy Officer.

7) Study Design

a) Recruitment Methods

- For this study, we will recruit 25 adult male and female volunteers age 18 years and older. This number was calculated with the Univeristy of California San Francisco (UCSF) Clinical and Translational Science Institute Sample Size Calculator with a power of 0.8, effect size of 0.25, and alpha of 0.05.
- Participants with a diagnosis of cutaneous lupus will be recruited from the UCF Health Clinic during a patient's visit (medical records will <u>not</u> be searched for patients with a diagnosis of cutaneous lupus) and through advertising on the UCF Health website and within the UCF Health clinic. Potential participants also will be identified through email by the Lupus Foundation of Florida to its membership and the Central Florida Society for Dermatology. (See attached "Advertisement").
- Dr. Weinstein and Dr. Sami will rely on prior labs, pathology reports, and physical examination to determine if the participant has cutaneous lupus.
- If interested in participating, participants will contact the primary or co-investigator, who will provide instructions on how to enroll in the study.
- The investigator will describe the details of the study and answer any questions the participant may have about the study. Participants will be given an informed consent about the study and the primary investigator's contact information. Those participants who express interest in the study will be required to sign the HIPAA Authorization form (attached), Informed Consent form (attached) to ensure that there is no coercion in the study. Each of these will be signed both by the participant and by Dr. Weinstein.

b) Participant Compensation

- The study participants will not be receiving any compensation for their participation in the study.

c) Inclusion and Exclusion Criteria

- For this study, we will recruit approximately 25 male and female volunteers ages 18 and older. All volunteers will be asked to give informed consent and sign a

HIPAA authorization before participation in the experiment. Participants will be screened in person before the research takes place. Participants will be screened and evaluated in the clinic to verify diagnosis through history, physical findings, health records, and previous labs. Participants who fit the diagnosis of cutaneous lupus will be asked whether they wish to participate in the study during the patient visit.

- Inclusion Criteria:
    - Male or female adult 18 years of age or older
    - Ability to rate level of pain
    - Ability to rate visual satisfaction
    - At least 2 active lesions of CLE

- Exclusion Criteria:
    - New or change in systemic medication for cutaneous lupus in past 6 months
    - Allergy to triamcinolone or betamethasone dipropionate cream
    - Pregnancy
    - Currently a prisoner
    - Unable to read and speak English since consent will only be available in English

d) Study Endpoints

- Primary endpoints: Participation in the study will end after the third visit.
- Primary safety endpoints: none
- Secondary safety endpoints:
    - Adverse reaction to the laser treatment such as blister, ulceration, and scarring.
    - Adverse reaction to the topical steroid such as atrophy, telangiectasias or striae.
    - Intolerance to pain of laser procedure.

e) Study Timelines

- Each participant will be in the study for a maximum of 8 weeks. Participants will receive 2 laser treatments. The laser treatments will be spaced 4 weeks apart between visit 1 and visit 2. Finally, 4 weeks after visit 2, the participants will be followed up during visit 3.

- The duration expected for all study participants to be recruited is estimated to be 28 weeks.

- The study will end when the last participant has completed the 2 laser treatments and follow up. The goal is to conclude the data collection by October 31, 2018 and complete primary analysis by December 31, 2018.

f) Procedures involved in the Human Research.

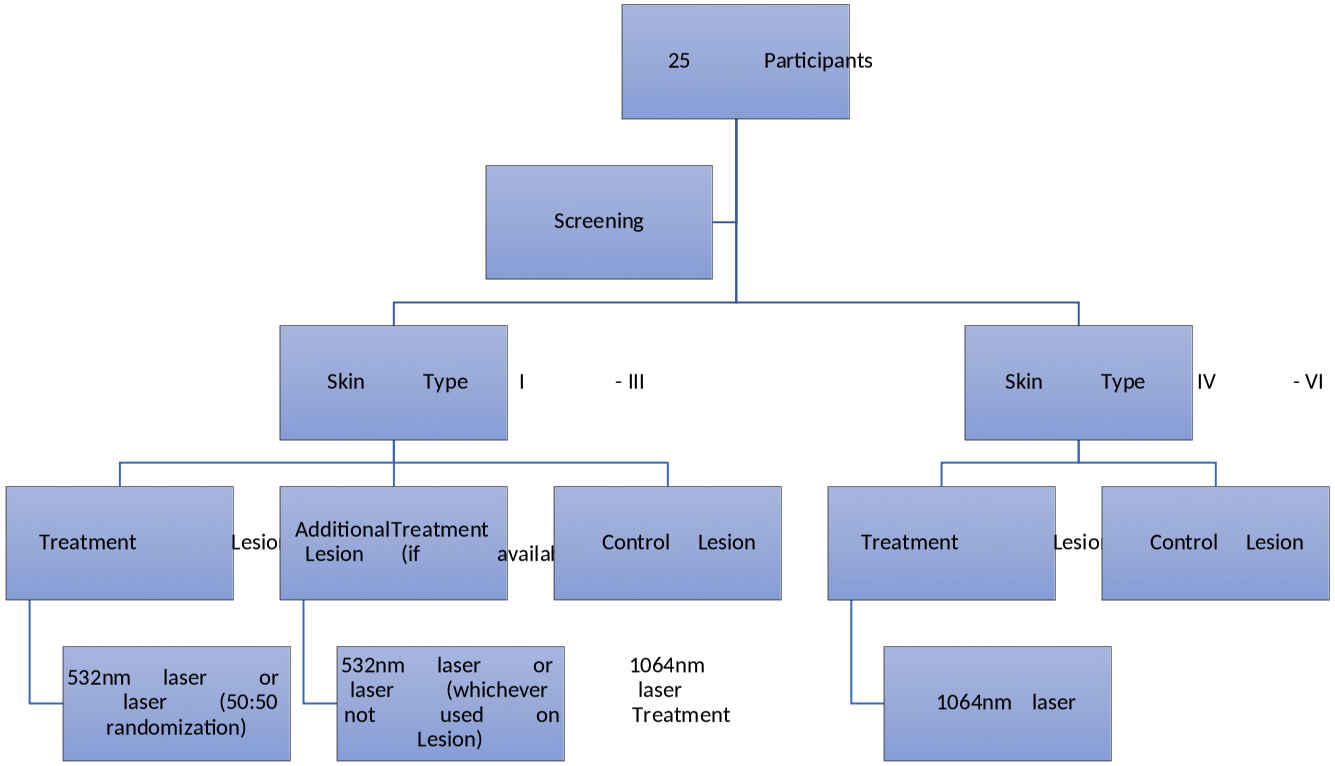
- This study will be a randomized prospective study. All study lesions will receive topical treatment. One lesion will only receive topical treatment to serve as a control, and up to 2 others will also receive laser treatment in addition to the topical treatment.

- Standard of care treatment will be a topical corticosteroid as follows:
    - Discoid lupus lesions: Betamethasone dipropionate augmented 0.05% cream twice a day as needed
    - Non-discoid cutaneous lupus lesions: Triamcinolone acetonide 0.1% cream twice a day as needed

- Laser treatment will be randomized based upon the participant Fitzpatrick Skin Type as follows:
    - Fitzpatrick Skin Types I – III:
        - § Treatment lesion will be treated with 532nm laser or 1064nm laser
        - § 50:50 randomization for laser used (determined by coin flip)
        - § If the participants have an additional lesion then this will be treated with the laser not used for the treatment lesion
    - Fitzpatrick Skin Types IV - VI
        - § Treatment lesion will only be treated with the 1064nm laser. This is because the 532 nm wavelength is absorbed easily by melanin and thus can cause skin pigmentation abnormalities when used with darker skin participants.

- Laser treatment system details and parameters:
    - The Excel V laser system manufactured by Cutera (Brisbane, CA) will be used to administer all laser treatments. This laser has the capability of emitting both 532nm and 1064nm wavelengths.
    - Treatments with the 532nm wavelength will utilize parameters in the following ranges:
        - § Spot size: 1-12mm
        - § Fluence: 5-12 J/cm^2
        - § Pulse Duration: 3-15ms
        - § Temperature: 5-10°C
    - Treatments with the 51064nm wavelength will utilize parameters in the following ranges:
        - § Spot size: 1-12mm
        - § Fluence: 10-60 J/cm^2
        - § Pulse Duration: 10-60ms
        - § Temperature: 5-10°C

- Note: If the lesions are ill-defined such as those of ACLE and SCLE then a lesion will be defined as a 2cm^2 within the involved area.


25 Participants
Screening
Skin Type I - III
Skin Type IV - VI
Treatment Lesio
Additional Treatment Lesion (if availa
Control Lesion
Treatment Lesio
Control Lesion
532nm laser or laser (50:50 randomization)
532nm laser or laser (whichever not used on Lesion)
1064nm laser Treatment
1064nm laser

- Timeline:

  Pre-Week 0: Screening Visit
  - Screening: participant will be screened for inclusion and exclusion criteria, including urine pregnancy test if necessary.

  Week 0: Visit 1
  - Baseline lesion assessment, lesion selection, randomization and treatment 1 will occur.

  Week 4: Visit 2
  - Follow up lesion assessment
  - Treatment 2

  Week 8: Visit 3
  - Final lesion assessment

- Lesion assessment:

  Limited CLASI:

  The classification of cutaneous lupus will be recorded for each participant.
  A ‘‘limited’’ CLASI scoring system will be used, subdivided into an ‘‘active’’ and ‘‘damage’’ components.
  The limited active CLASI for a lesion will include the following:
  - Erythema (ranging from 0 = absent to 3 = dark red/purple)
  - Scale/Hypertrophy (ranging from 0 = absent to 2 = verrucous/ hypertrophic)
  - The addition of these scores result in a total limited active CLASI score of the studied lesion, ranging from 0 to 5.

  The limited damage CLASI for a lesion will include the following:
  - Dyspigmentation (0 = absent or 1 = present)
  - Scarring/Atrophy/Panniculitis (ranging from 0 = absent to 2 = severely atrophic scarring or panniculitis).
  - The addition of these scores result in a maximum damage score of 3.

  The total limited CLASI reflects the sum of both active and damage CLASI, resulting in a score ranging from 0 to 8.

  Photographs will be taken of all study lesions during every assessment.

  All participants will evaluated by Dr. Weinstein at baseline and at subsequent visits. All participants will be evaluated via photograph by Dr. Sami at baseline and subsequent visits. Dr. Sami will be blinded to the treatment type so as to be an independent observer. He will utilize the “Independent Observer Survey” to document his assessments.

  Visual Satisfaction of Appearance:

  In addition participants will rate the cosmetic results on a visual analog scale (VAS). A score of 0 will represent a cosmetically fully unsatisfactory result and 10 will represent cosmetically excellent result.

- Adverse Effects:

Pain: After each treatment pain will be recorded on VAS. A score of 0 will represent absence of pain and 10 will represent maximal pain.

Other adverse effects that will be monitored for:

- Hyperpigmentation
- Hypopigmentation
- Crusting
- Vesiculation
- Scarring

- Risk Management:
  Participants will be directly observed for any adverse effects during treatment. The chances of a research related injury are extremely rare. However treatment for research related minor injuries will be made available at no cost by Dr. Weinstein if possible. For injuries that cannot be treated by Dr. Weinstein the participant will be referred elsewhere. Costs associated with this treatment may be billed to the participant's insurance company. Costs not covered by participant's insurance company will be the participant's responsibility.

Participants will not be misled in anyway about procedures/activities being performed

Research will be conducted during Dr. Weinstein's clinical time.

The duration of research should take approximately 12 months. The research study will begin recruitment directly after IRB approval in hopes of being finished by December of 2018.

No audio or video recordings will be used in this study. However photographs will be taken of the lesions for assessment purposes. Though the photos will not contain any identifiers, participants are potentially identifiable from the photos and thus they will be stored in the HIPAA-compliant electronic health record (EHR) of UCF Health.

A study survey document (see attached "Survey" and "Independent Observer Survey") will be used to record the following:

- Age
- Gender
- Pregnancy Status
- Fitzpatrick Skin Type
- Past Medical History
- Medications
- Allergies
- Lesion locations
- Lesion type
- Lesion treatment
- Limited CLASI
- Patient cosmetic assessment

- Whether patient would recommend treatment
- Pain and adverse effect assessment

Note: the above information will be collected from the medical records and during the study visits.

Medical records in the HIPAA-compliant EHR at UCF Health will be used to obtain the following data:

- Age
- Gender
- Past Medical History
- Medications
- Medication Allergies
- Social History
- Photographs
- Laboratory Results

Student/school records are not to be used.

g) Data and specimen management

There will be no specimen collection, and thus there will be no management of physical specimens.

If a participant withdraws from the study, the reason for the withdrawal will be noted but data collected up to that point will be used.

All data will be collected on the survey documents (see attached documents "Survey" and "Independent Observer Survey"). These survey documents will be stored in regulatory binder in a locked drawer in locked room at UCF Health. This will only be accessible only to the principal investigator and co-principal investigators. These survey documents will then be used to transfer the data to the REDCap database, afterwards they will be disposed of in HIPAA-compliant shred bin.

Photographs of study lesions will be stored directly in the EHR.

The data will be analyzed for significant differences with aid of a statistician. A significance level of 0.05 will be used for statistical hypothesis testing. The results of the data analysis will be graphed for each parameter.

h) Provisions to monitor the data for the safety of participants

The principal investigator and statistician will periodically review cumulative CLASI scores and adverse effect data every 10 patients.

If the change in the active CLASI score for the treatment lesion is 3 points higher than the change in the active CLASI score for control lesions with $p < 0.05$ then the study will be suspended immediately.

If participants have ulceration or scarring attributable to the laser treatment as an adverse effect with $p < 0.05$ then the study will be suspended immediately.

i) Withdrawal of participants

Participants will be withdrawn from the research without their consent if they become intolerant to the laser treatments and/or the investigators determine that they are too nervous, anxious to continue.

Participants may terminate their participation in the research study at any time by informing a member of the research team. If the participant declines any further laser treatments he or she may still participate in the study with follow up assessments being completed.

If participants miss study Visit 2, the researchers will attempt to reach the participant to reschedule. If the participant is unable to reschedule within 2 weeks of the missed appointment then the participant will forego the 2nd treatment and attempted to be scheduled for Visit 3.

If participants miss study Visit 3, the researchers will attempt to reach the participant to reschedule. If the participant is unable to reschedule within 6 weeks of the missed appointment then the participant will be withdrawn from the study. Further data collection will not be continued.

8) Risks to participants

Laser treatment association risks[15,16,19]:

Risks: >50%

- Pain/Discomfort – Additionally sharp burning/stinging pain can occasionally be felt.

Risks: <10%

- Redness/Swelling/Bruising – Short term redness (erythema) or swelling (edema) of the treated area is common and may occur. There also may be some bruising.
- Skin Color Changes – During the healing process, there is a possibility that the treated area may become either lighter (hypopigmentation) or darker (hyperpigmentation) in color compared to the surrounding skin. This is usually temporary, but, on a rare occasion, it may be permanent.
- Itching/Burning/Dry skin – Treatment may results in itching, burning, and/or dry skin during the recovery period.
- Red Rash/Bumps – Red rash/bumps may appear after treatment. This resolves with time.
- Acne flare-up or cold sore – this may occur after treatment.

Risks: <1%

- Wounds – Treatment can result in burning, blistering, scabbing, or bleeding of the treated areas.
- Infection – Infection is a possibility whenever the skin surface is disrupted, although proper self-wound care should prevent this.
- Scarring – Scarring is a rare occurrence, but it is a possibility when/if the skin surface is disrupted. To minimize the chances of scarring, it is important that participants follow all post-treatment instructions provided by the research staff. (see attached pre- and post-treatment instructions)

Other risks:

- Sun Exposure / Tanning Beds/ Artificial Tanning - May increase risk of side effects and adverse events and must be avoided.
- Eye Exposure – Protective eyewear (shields or goggles) will be provided to the participant during the treatment. Failure to wear protective eyewear during the entire treatment may cause severe and permanent eye damage.
- Lack of improvement (procedure may not work) or exacerbation of cutaneous lupus.

There is unknown risk to the an embryo or fetus should the participant be pregnant as none of the clinical trials with the laser were performed on pregnant women.
There are no risks to an embryo or fetus should the participant become pregnant.
There is no risk to non-participants.

Topical corticosteroid associated risks[20]:

- Atrophy
- Telangiectasias
- Striae
- Perioral dermatitis
- Hypertrichosis
- Folliculitis
- Note: All risks are approximately <5%[21]

9) Potential direct benefits to participants

While there are no guarantees that participants will receive any benefits from their participation in this study, potential benefits include quicker improvement of cutaneous lupus lesions less scarring than standard of care, and topical treatment at no cost for cutaneous lupus for duration of study participation.

10) Provisions to protect the privacy interests of participants

Participants will be seen and treated in the same manner as patients in the UCF Health clinic. In the clinic, efforts are made to protect patients' privacy whenever possible as per HIPAA guidelines.

11) Provisions to maintain the confidentiality of data

Data will be stored in the secure HIPAA-compliant database called REDCap. Unique identifiers will be created using sequential numbers (i.e. 1, 2, 4 etc.).

No data collection instrument in REDCap will contain identifying information

A screening and enrollment log (see attached document "Screening and Enrollment Log") will be stored in a regulatory binder in a locked drawer in a locked room at UCF Health. Only Dr. David Weinstein will have access to this locked drawer.

A subject ID assignment list (see attached document "Subject ID Assignment List") that links the subject name and contact information with their unique identifier will be stored in a separate folder in locked drawer in a locked room at UCF Health. Only Dr. David Weinstein will have access to this locked drawer.

Identifying information such as the "Subject ID Assignment List" will only be accessed by the PI and co-PIs for initial entry. It is possible the identifiable information may be referenced if questionable data are detected during data analysis (e.g.: number out of range, missing data).

The "Screening and Enrollment Log" and the "Subject ID assignment List" will both be disposed of in a HIPAA-compliant shred bin at the completion of the study.

Informed consents and HIPAA authorizations will be stored in locked drawer in a locked room at UCF Health and kept for a minimum of six years after the conclusion of the study (per UCF data retention policies.)

Only de-identified data will be used and exported for analysis.

De-identified data will be stored for a minimum of five years after the conclusion of the study (per UCF data retention policies).

12) Medical care and compensation for injury

The chances of a research related injury are extremely rare. However treatment for research related minor injuries will be made available at no cost by Dr. Weinstein if possible. For injuries that cannot be treated by Dr. Weinstein the participant will be referred elsewhere. Costs associated with this treatment may be billed to the participant's insurance company. Costs not covered by participant's insurance company will be the participant's responsibility.

13) Cost to participants

The only costs to the participant are his or her time (approximately 1.5 hours) and transportation costs (gas, tolls, etc.). There are no other expected costs that

subjects will incur as a result of participating in the study. For cost of research related injury please see section 12).

14) Consent process

Participants will be given the option of picking up the consent prior to enrolling to discuss with their primary care physician, significant other, etc., to help minimize the possibility of coercion or undue influence.

On the day of enrollment, participants will meet with the PI in one of the clinic rooms and be given an informed consent form. HIPAA authorization form and the PI's contact information. The PI will describe the details of the study and answer any questions the participant may have about the study. Afterwards, the PI will thoroughly explain every section of the informed consent to the participant and give the participant as much time to review the informed consent as needed. Participants will be given the opportunity to voice questions or concerns to the PI or co-principal investigators following their review of the informed consent. Those participants who wish to participate in the study will then be asked to sign the informed consent. The informed consent document will be signed both by the participant and the PI.

After signing the Informed Consent, Visit 1 will take place and potential participants will be screened in person at UCF Health to determine if they meet the inclusion/exclusion criteria for study.

The "SOP: Informed Consent Process for Research (HRP-090)" will be followed.

The written informed consent and other documents will be made available in English only.

The Human Research does not involve a waiver or alteration of the consent process.

The Human Research does not involve persons who have not attained the legal age for consent to treatment.

The Human Research does not involve adults who may be unable to consent.

15) Process to document consent in writing

All participants will be required to complete and sign the informed written consent document (see attached) and the HIPAA authorization form (see attached) to ensure that there is no coercion in the study. The informed consent and HIPAA authorization forms will be signed both by the participant and by the principal investigator.

The informed consent and HIPAA authorization forms will be scanned and uploaded the REDCap database. Afterwards they will be disposed of in a HIPAA compliant shred bin.

The consent process will be documented in writing

16) Vulnerable populations

We are not recruiting members of a vulnerable populations. The participants are aware of their CLE diagnosis and will be informed on the risks and benefits of both laser treatment and traditional first line topical treatment.

This study will not use participants that are unable to consent.

This study will not use participants who have not attained the legal age for consent

This study will not use participants who are pregnant

This study will not use participants who are prisoners

17) Drugs or Devices

The following laser will be used in this study:

Laser model:	Excel V
Manufacturer:	Cutera, Inc.
	3240 Bayshore Blvd.
	Brisbane, California 94005

The laser used in this study is not experimental and is an FDA-approved device which will be used in an FDA-approved manner for an off-label indication.

The laser is kept in one of the procedure rooms in clinic which has access restricted by key and/or keycard. The key necessary to turn on and use the laser is stored in a lock drawer within clinic.

18) Multi-site Human Research

Not applicable. Research will only be conducted at UCF-affiliated institutions in Orlando, FL.

19) Sharing of results with participants

There are no plans to share results with participants unless requested by the participants.

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