LIGHTMED
Enlightening Vision

Treatment Guidelines for
Transscleral Cyclophotocoagulation

The following guidelines relate to treatment of Transscleral Cyclophotocoagulation (TSCPC) and SP-Mode® Transscleral Cyclophotocoagulation (SP-TSCPC) with LIGHTMED's LIGHTLas 810 or LIGHTLas TruScan Pro 810 laser systems.

It is important to note that all information contained herein has been compiled based on results of various clinical studies and investigations, and intended to serve as general guidance only. While Transscleral Cyclophotocoagulation provides a highly effective treatment, LIGHTMED strongly recommends that all physicians novel to this technique seek adequate training, and understand the latest suggested methods of treatment prior to commencing treatment.

What is TSCPC?

Transscleral Cyclophotocoagulation (TSCPC) is clinically known as an effective and non-invasive laser treatment of the ciliary processes and ciliary body reducing the production of aqueous humor. This procedure leads to decrease of the Intra Ocular Pressure (IOP) in cases of Advanced Uncontrollable or Refractory Glaucoma with effects similar to several types of glaucoma medications and other laser surgeries. Clinical research indicates that TSCPC may be successfully used as a primary treatment for glaucoma in challenging situations when other interventions are not possible.

How does TSCPC work with the Infrared Diode Laser?

TSCPC utilizes a specialized laser probe called the Cyclophotocoagulation probe, in conjunction with the 810nm wavelength from the LIGHTMED Lasers: LIGHTLas 810 and LIGHTLas TruScan Pro 810.

This non-invasive surgery utilizes the 810nm laser energy delivered through the Cyclophotocoagulation probe. The probe is placed on the sclera, where the laser is delivered to the ciliary body with continuous wavelength. The laser is highly absorbed by the ciliary body pigment epithelium, which treats the ciliary processes by coagulating the cells in the ciliary body. This results in decreasing the production of the aqueous humor, causing a drop in the IOP (Intraocular Pressure). The goal is to bring aqueous humor inflow into a better balance with its outflow resulting in a lower IOP.

This office-based procedure has been clinically proven to be successful in treating many cases of refractory glaucoma, and is also safe, effective and repeatable.

Indications for using TSCPC for Treatment of Glaucoma

Ongoing clinical research and publications demonstrate for TSCPC to be a safe and effective treatment indicated for Severe Uncontrolled and Refractory Glaucoma. As a result, almost all patients with elevated IOP may also be treated.

clinicalmd@lightmed.com | www.lightmed.com

Treatment Guidelines for Transscleral Cyclophotocoagulation

TSCPC is indicated to be effective for the following types of cases:

- Aphakic Glaucoma
- Neovascular Glaucoma
- Uveitic Glaucoma
- Refractory Pediatric Glaucoma
- Glaucoma after intravitreal silicone oil

And for patients who:

- Have failed prior filtration surgery and are expected to fail further filtration surgery
- Have a secondary glaucoma in which failure is a likely outcome of filtration surgery (e.g neovascular, inflammatory, post-penetrating keratoplasty, post scleral buckling)
- Have lost ambulatory level vision and is being treated with Cyclophotocoagulation for comforting or preventing further visual loss
- Have failed or are not a suitable surgical candidate for filtering surgery
- Have not effectively responded to previous medicine treatments
- Have not effectively responded to previous laser therapies such as Nd:YAG

TSCPC is not suitable for the following conditions:

- Albino patients
- Patients with eyes having a total occlusion of outflow as they would require almost a total stoppage of aqueous inflow for postoperative IOP to reduce to acceptable levels

How to perform Laser Treatment for TSCPC

Setting Up the Cyclophotocoagulation probe:
The Cyclophotocoagulation probe (LIGHTMED SKU# 620231) is compatible with LIGHTLas 810 and LIGHTLas TruScan Pro 810.

1. Release the probe from the packing, and remove the protective cap
2. Connect the probe to the LIGHTMED device by fastening the probe into the laser fiber optic port (Port 2 on the LIGHTLas TruScan Pro)
3. If using the probe in SP-Mode®, unscrew the footplate carefully from probe exposing only the metal threaded rod and ball fiber. Please refer to the section on **“Recommended Treatment Protocols for SP-TSCPC”**
4. Connect the LIGHTMED Laser Delivery Key that says “ENDO” by plugging it into the laser key port marked as “Delivery Key”
5. The probe is now ready for use

Note: If handled improperly such as bending, loose or poor connecting, or improperly securing, the glass optical fiber within the probe product may be damaged leading to harming the patient or the physician.

Pre-Treatment Steps:

1. TSCPC requires local anesthesia (retrobulbar or peribulbar injection, or subconjunctival anesthesia, with for example 2% mepivacaine, or equivalent agent) or general anesthesia in an OR setting.
2. Moisten the eye surface and keep the tip of the probe moist while putting it in contact with the eye. Apply a film of methylcellulose solution to the fiber-optic tip, or ask the patient to close their eyelids, pre-treatment, to assure that a natural tear film exists.
3. You may also use a lid speculum to hold the lids open, in which you must apply artificial tears to the eye with the speculum in place.
4. Either method will require a reapplication after every four laser applications to keep the eye moist.

Treatment Guidelines for Transscleral Cyclophotocoagulation

Laser Safety: Please make sure that there is an appropriate laser safety filter or laser safety goggles worn during the procedure. All personnel within the room should also wear safety goggles. No one should look directly into the laser light source or the tip of the probe.

Recommended Treatment Protocol for TSCPC

Treatment:
(For SP-TSCPC, please refer to the section "How to perform Laser Treatment for SP-TSCPC)
TSCPC protocols and techniques will vary depending on the physician's patients, personal experiences and clinical outcomes. The infrared 810nm wavelength interacts with the patient's pigmentation levels. Therefore, the laser treatment power should be titrated accordingly to individual patients and will increase absorption by the level of pigmentation.

Dark Brown Iris:	Power at 1250mW for Duration of 4 sec (4000ms)
All Other Iris:	Power at 1500mW for Duration of 3.5 sec (3500ms)

These are recommended settings for most eyes. For those who are unsure or just getting started, we recommend starting with a low power and go up to the recommended parameters in this section to get a "pop" sound. "Pop" may be heard during the laser application, but it does not have to be heard continuously.

It's important to ensure that there is no visibly blackened fiber after each laser, and that it is free of adherent tissue. It should retain its spherical shape (with no cracks). The aiming beam should emerge from the optic fiber tip with a diverging beam profile and produce a round spot on a perpendicular target with uniform brightness.

1. Set the laser with the desired treatment power and laser duration. Activate the Treatment Mode by pressing the "STANDBY" button and it should change to "TREAT" on the button. Engage the treatment beam into the eye by pressing on the foot pedal.
2. **Placement (see figure 1):**
   a. Hold the probe parallel to the visual axis of the eye and perpendicular to the iris plane.
   b. The shorter edge of the footplate tip of the probe should be held firmly against the area located between the middle and the anterior border of the limbus. Laser delivery is Transscleral.
   c. If operating on a phakic eye **"see Caution section".**
3. **Treatment Applications:**
   a. Use one-half of the footplate width to determine the correct spacing between treatment sites. Position the probe without dragging or rotating the probe tip on the conjunctiva, and select the next point about half the width of the probe apart **(see figure 2)**.
   b. **Left Eye:** Start treatment counter-clockwise from 1 o'clock to 9 o'clock and then clockwise from 4 o'clock to 9 o'clock **(see figure 3)**.
   c. **Right Eye:** Start treatment clockwise from 10 o'clock position to 3 o'clock position, and then counter clockwise from 7 o'clock to 3 o'clock **(see figure 4)**.
   d. You should apply 18-21 applications total, avoiding application in the temporal quadrant.
   e. Temporal quadrant is usually omitted during the first procedure, allowing for natural ciliary production of aqueous humor **(see figure 5)**.
4. Apply the laser by pressing the foot pedal and minimizing the distinctive audible pop sounds indicating tissue disruption within the eye. If pops occur frequently, please adjust the power.

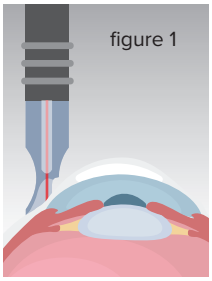


figure 1

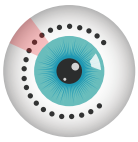


figure 2

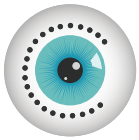


figure 3

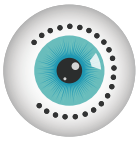


figure 4

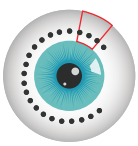


figure 5

Treatment Guidelines for Transscleral Cyclophotocoagulation

Note: the probes must be kept clean throughout the treatment, as charred debris on the tip may heat and burn into or through the sclera.

Disposal of the Probe: Follow standard facility procedures for handling of biohazardous material after each use of the delivery device.

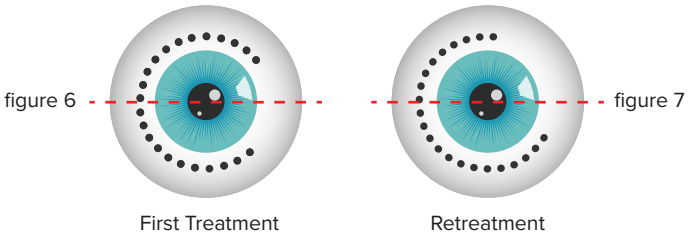
WARNING:
Excess treatment power may result in ocular surface burns or ciliary body hemorrhage. The maximum possible laser power for this device is the lesser of the maximum power of the laser system and 2500 mW. Contamination of the tip or reuse of the probe may result in these types of burns. Excessive energy settings on the laser may result in burn at the ocular equator. Heavy pigmentation at the perilimbal conjunctiva may also result in burns, therefore these areas should be avoided.

Post Treatment:

After the procedure, physicians usually prescribe a topical cycloplegics and corticosteroids in anticipation of secondary postoperative inflammation and discomfort. The treated eye is then patched over-night. Patient is usually examined on the first postoperative day to remove the eye patch and verify possible fluctuations in IOP and procedure related side effects.

Patient Retreatment:

If necessary, patients may revisit the clinic for another treatment. Begin treatment 45 degrees from the initial treatment. The second 270 degree treatment will cover a half of the untreated quadrant, plus two and a half quadrants from the previously treated area **(see figures 6 & 7)**.



Recommended Treatment Protocol for SP-TSCPC

Remove the probe from the packaging, and unscrew the footplate carefully from probe exposing only the metal threaded rod and ball fiber.

1. **Marking the Eye (see figure 8):**
   a. Mark the eye with an ophthalmic marker, or an ophthalmic measuring tool.
   b. Mark the eye approximately 3mm from the limbus on both the superior quadrant and inferior quadrant of the eye.
   c. Place and hold the probe approximately perpendicular to the surface of the eye **(see figure 9)**.

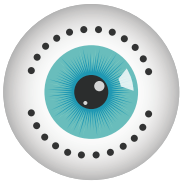
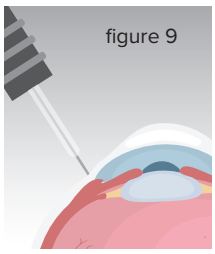


figure 8



2. **Setting up the Laser**
   a. Set power to 2000mW. Turn on **SP-Mode®**, and set the duty cycle to **31.3% (this equates to 0.5ms on 1.1ms off)**
   b. Set the duration to 60-90 seconds, depending on the physician's preference and patient's IOP. When ready to treat, press the "STANDBY" Button and the button will say "TREAT."

3. **Application (see figure 10):**
   a. Superior Quadrant: treat by applying firm pressure and move the probe tip in a continuous arc motion from the 9:30 to 2:30 clock positions. Ensure to avoid 3'o clock and 9 o'clock position.
   b. Apply laser continuously, "PAINT" for 4-7 complete passes between the clock positions for a total of 60-90 seconds in SP-Mode®.

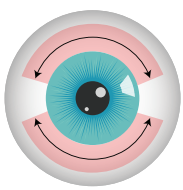


figure 10

c. Inferior Quadrant: treat by applying firm pressure and move the probe tip in a continuous arc motion from 3:30 to 8:30 clock positions.
d. Apply laser continuously, "PAINT" for 4-7 complete passes between the clock positions for a total of 60-90 seconds in SP-Mode®. For the superior and inferior quadrants, the total maximum duration should not exceed 180 seconds to avoid excessive energy and heat applied.

CYCLOPHOTOCOAGULATION PROBE CLEANLINESS:

Keep the probe tip clean to lower the risk of burns to the ocular surface. If the tip becomes dirty during the procedure, clean it gently with an alcohol swab.

Solvents of flammable solutions used for cleaning should be allowed to evaporate before laser equipment is used. If discoloration on the tip cannot be removed by gentle cleaning, discard the Cyclophotocoagulation Probe. Scleral burns are not typical when using this probe. If a burn occurs, discard the probe (it is probably contaminated), and replace it with a new probe. This product is a single use product.

CAUTION:

- The Cyclophotocoagulation probe is a disposable one-time use only to avoid risk of any infections.
- This device is to be used only by qualified ophthalmologists after considering patient conditions.
- After procedure, monitoring the IOP may help prevent secondary post-operative complications.
- For phakic eyes, the probe must be placed at more than 1mm behind the limbus as to avoid the risk of damage to the lens with the laser beam.
- In order for correct treatment, the probe must be directly parallel to the visual axis for each laser treatment.
- Keep the probe and eye surface moist throughout the treatment.

Side Effects of TSCPC:

Although ongoing studies have demonstrated the relative safety and efficacy of TSCPC for various forms of glaucoma, a number of postoperative complications still exist and has to be considered prior to treatment. Some of these side effects include:

- Postoperative pain, inflammation and hyphema
- IOP spikes occur in a small percentage of patients and can typically be controlled with medical therapy
- A decrease of two Snellen lines or more have been reported in some studies appearing mainly in eyes with preexisting poor vision. The decrease is known to improve or stabilize with the healing and has to be measured against expected vision deterioration that would occur in the absence of intervention.
- Some cases reported a loss of vision.

Reimbursement

CPT Code – 66710

Under Destruction Procedures on the Iris, Ciliary Body of the Eye.

LIGHTMED USA
1130 Calle Cordillera
San Clemente, CA 92673
USA

LIGHTMED TAIWAN
No. 1-1, Lane 1, Sec. 3, Pao An St.
Shulin District, New Taipei City 238
TAIWAN

LIGHTMED JAPAN
3F Orchis-Takebi, 2-Chome 22-1
Hatagaya, Shibuya, Tokyo 151-0072
JAPAN

clinicalmd@lightmed.com | www.lightmed.com