

Treatment Guidelines for Retinopathy of Prematurity

The following guidelines relate to treatment of Retinopathy of Prematurity or ROP with the LIGHTMED LIGHTLas 810 laser system.

It is important to note that all information contained herein has been compiled based on results of various generic clinical studies and investigations, and intended to serve as general guidance only. While using a diode laser photocoagulator provides a highly effective outcome, and is considered the established, gold standard treatment for ROP, 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.

Q: What factors should I look for to qualify my patient?

Many infants with ROP can be effectively treated with an 810nm laser photocoagulator, although it's absolutely necessary to undertake a comprehensive pre-treatment assessment of the individual patient to determine their associated risk factors and need for treatment. ROP is considered a multifactorial disease that requires a number of important considerations such as:

- Oxygen supplementation
- Lung and heart disease
- Nutrition
- Low birth weight
- Extrauterine growth retardation
- Sepsis
- Glucose imbalance
- Blood transfusion
- Hydrocephalus
- Intraventricular hemorrhage

The Revised Joint Policy Statement issued in 2018 by the American Academy of Pediatrics, the American Association of Pediatric Ophthalmology and Strabismus, and the American Academy of Ophthalmology provides guidelines on screening and follow-up of premature neonates*. In the United States, premature neonates are examined for ROP if they have a birth weight of less than or equal to 1,500g or a gestational age of 30 weeks or less (as defined by the attending neonatologist). Selected infants with a birth weight between 1,500g and 2,000g or a gestational age at birth of greater than 30 weeks with an unstable clinical course should also have an eye exam.

However, in emerging economies such as certain countries in Asia, Eastern Europe and Latin America, these guidelines should be in accordance with local factors and medical agreements between neonatologists and ophthalmologists. They may consider screening neonates when birth weight is up to 2,000g or gestational age is up to 36 weeks or more with associated risk factors. In developing countries, it has been proven that ROP development risk could be different from one NICU to another, even when they are located in the same city.

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Key points include:

1. While laser therapy remains the standard treatment for advanced ROP, surgeons should use their own judgement to select the right treatment spots. Certain cases may require laser burns to be placed around the edge of the retina up to the ora serrata for 360 degrees, leaving no untreated “skip” areas; while in other cases, it may be possible to leave some untreated areas and achieve advantageous vascularization.
2. The most important step in treating ROP is a good screening program in the early neonatal period when the premature infant is at NICU. Screening of preterm infants for ROP should be performed by an experienced ophthalmologist using a binocular indirect ophthalmoscope. Close communication between neonatologists and ophthalmologists (and the referring and receiving hospitals) is essential to ensure appropriate retinal screening and treatment.
3. Examination timing should be based on local guidelines, considering the severity of comorbidities, and starts in most cases at 31 weeks post-menstrual or 4 weeks of chronologic age, whichever comes first.
4. Screening should be done according to local guidelines and prior experience, in order to detect ROP as early as possible.
5. Earlier (20 days after birth) screening has been recommended for babies under 30 weeks, and/or those with birth weight less than 1,500g in some European countries. This statement should be considered according to local experience and guidelines.
6. Delaying the timing of the first screening increases the likelihood of encountering advanced retinal disease, and consequently reduces the success rates.
7. The patient may need more than one laser photocoagulation treatment. Make sure to inform the family before performing the first treatment.
8. The ophthalmologist may consider anti-vegf treatment in certain aggressive or posterior cases.

Q: What are the side effects of the laser photocoagulation procedure?

When patients are screened and laser photocoagulation treatment is performed in a timely manner, avoiding retinal detachment, long term eye complications and side effects are rare, and include:

- Modest visual field loss
- Exudative detachment
- Excessive conjunctival and/or eyelid inflammation
- Cataracts
- Myopia
- Anterior segment ischemia
- Hypotony
- Irregular or permanently dilated pupil or adhesion between iris and lens or iris and cornea
- Retinal hemorrhage
- Retinal holes
- Crunch phenomenon

Treatment Overview

Pre-Treatment

1. Discuss the risk/benefits and alternatives to ROP laser treatment and document informed consent. It is important to discuss appropriate expectations with the patient’s family when obtaining consent.

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2. Once the decision to treat is taken, the following should take place:
 - A. Treatment should be initiated as soon as feasible, preferably within 72 hours of the decision to treat.
 - B. Treatment must occur in a temperature-controlled, clean environment so that risk of hypothermia, infection, and apnea are minimal.
 - A. Pupils are dilated using 1% tropicamide and 2.5% phenylephrine instilled twice, 10 minutes apart, at least 30 minutes before the treatment.
 - B. If tropicamide is not available, 0.5% cyclopentolate may be used instead. The lids must be wiped with cotton to remove spilled droplets.
 - C. If local anesthesia is used, the child should not be fed within the prior two hours. If general anesthesia is used, the child should not eat for 6 hours prior to treatment.
 - D. If the pupil does not dilate sufficiently for laser treatment, then consideration should be given for anti-veg treatment or a short course of steroids and cycloplegics prior to attempting to treat with a laser.

Laser Settings

Generally, laser photocoagulation for Type 1 ROP takes 20 minutes to 1 hour, depending on the surgeon's experience, and between 300 to 1,200 spots per eye are administered during that time. It's important to adjust laser power and duration settings for each patient based on the area being treated and the patient's pigmentation. Lightly pigmented eyes require higher laser power to cause a burn.

1. The power varies between 100 to 450mW depending on the level of pigmentation in the patient's retinal epithelium. The goal is to produce burns that are dull grey in color, avoiding white burns.
2. The pulse duration is typically between 200 to 300ms.
3. The pulse interval may be as fast as one burn each at 200 to 300ms with the repeat mode set. Faster intervals may result in inadequate burns.
4. Burn spot diameter may be adjusted as necessary to achieve adequate treatment; however, setting it with the largest size of 500 microns may help to shorten surgical time.

Treatment Tips

- Depending on surgeon's preference, he/she may either treat one eye first, then the other eye and take a short break in between, or he/she may shift from lasering one eye to the other eye every 5 to 10 minutes. For example: If lasering the temporal retina in the right eye, shift the treatment to the left eye's nasal retina after 10 minutes of treatment without moving surgeon's position. This will give some "rest" to the cornea (less edema) and conjunctiva swelling during a long procedure.
- It's useful to put some antibiotic/steroid eye drops such as Tobradex during the laser procedure.
- The surgeon may switch to a larger spot size when targeting larger areas at the retinal periphery to minimize the number of spots lasered, and decrease surgical time.

Post-Treatment

1. Immediately after laser treatment, antibiotic and steroid eye drops or ointment may be applied. While the patient's eyelids may be a little puffy for the first 24 hours, pain medications are rarely needed. Follow-up examinations are performed every few days until regression of Plus disease and/or neovascular proliferation occurs, then every week and then every 2 to 4 weeks until complete ROP regression occurs.
2. In a small number of cases if the patient has more severe disease, re-evaluation and completion of laser ablation must be done every 3 to 4 days until complete regression is seen.

* American Academy of Pediatrics, American Academy of Pediatric Ophthalmology and Strabismus, American Academy of Ophthalmology; Screening Examination of Premature Infants for Retinopathy of Prematurity; Pediatrics 2018; 142(6): 1-9

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