CYCLOCRYOTHERAPY
ERIC S. MANN M.D., Ph.D.

A. INTRODUCTION:

Cyclocryotherapy is the use of “cold therapy” ablating (destroy) the ciliary processes (structures which produce fluid in the eye) in order to control intractable glaucoma (high pressure in the eyes which cannot be adequately controlled by medications or by other means). Multiple “cryo lesions” are placed right behind the limbus (the border between the clear part and the white part of the eye). Sometimes the lesions are placed around the entire eye. However, the treatment may be limited to only one or two quadrants of the eye. Repeated sessions may be necessary. Pain control at the time of the procedure is accomplished through retrobulbar anesthesia (placement of anesthetics behind the globe), or less commonly, subconjunctival injection (placement of anesthetics under the tissue in front of the eye).

METHOD:

B. BENEFITS:

Cyclocryotherapy attempts to prevent or decrease the production of fluid in the eye in order to control the high pressure in the eye. However, its effects are not precise. Adequate intraocular pressure control is the goal of treatment. In spite of treatment the intraocular pressure may still be too high in some cases. In other cases, the intraocular pressure may become too low.
C. RISKS AND COMPLICATIONS:

1. Common:

   a. Redness and swelling of the eyelid and the front tissues of the eye. This usually lasts for a few days to a few weeks.
   b. Temporary pain and discomfort which can be controlled by medications.
   c. Glare and sensitivity to light.
   d. Inflammatory reaction in the eye.
   e. Poor vision may be associated with this procedure. However, most eyes which require this type of treatment is already at an advanced stage of deterioration with poor vision even before treatment.
   f. Some patients experience nausea and vomiting.
   g. Some patients may experience headache and aching around the eye.
   h. The doctors may discuss other potential complications and risks not listed here.

D. ALTERNATIVES:

Laser treatment to the ciliary processes may be possible in some cases to achieve the same results.

E. POST-TREATMENT COURSE:

Minimal restriction is required unless otherwise specified. Anti-pressure medications and steroid eye drops are usually prescribed. Their usage would be important. Retrobulbar anesthesia is usually used; thus the eye is patched for 6-12 hours after treatment.
PERIBULBAR & RETROBULBAR ANESTHESIA

Absence of pain (anesthesia) and immobilization of the eye (akinesia) are often necessary to allow effective laser and cryotherapy treatment or intraocular surgery. Both anesthesia and akinesia can be obtained to a variable degree by injection of anesthetic (Lidocaine and/or Marcaine) around and behind the eyeball prior to treatment or surgery.

The following are common effects of the anesthetic injection but are usually temporary:

1. Blurring of vision
2. Numbness and swelling around the eye
3. Ptosis (drooping of the eyelid)
4. Diplopia (double vision)

The following are uncommon complications of the anesthetic injection:

1. Retrobulbar or periorbital hemorrhage (bleeding behind or around the eyeball)
2. Globe perforation (puncture of the eyeball by the needle used for anesthetic injection)
3. Optic nerve injury or vascular damage (central retinal artery or vein occlusion)
4. Allergic reaction to the anesthetic
5. Seizure
6. Cardiorespiratory arrest (death)
7. Bilateral akinesia

These uncommon complications may result in permanent loss of vision, need for further surgery or treatment, or loss of the globe. Other less common complications may be discussed as well.

Post treatment care may include applying ointment to the eye and wearing a patch for 24 hours.
PROCEDURE NOTE

Patient: ___________________________ MR#: _________ Date: ________________

Surgeon: Dr. Eric S. Mann

Procedure: Cryotherapy (Panretinal and / or Cyclocryotherapy)____
Indications: _____________________________

Va: OD___________________OS_________________________

Informed consent: All the risks, benefits, alternatives and intent of cryotherapy treatment with anesthesia were presented to the patient in an extensive discussion and in written form(s)_________. The patient understood cryo treatment is performed not to improve vision but to prevent progression of neovascularization, retinal ischemia and further visual loss. The patient stated they had a good understanding of their clinical situation including the specific ocular and anesthetic risks (loss of vision, need for further surgery, and rarely loss of globe) and consented to cryo treatment.

Treatment: ( ) Under topical anesthesia.
( ) Under retrobulbar anesthesia: With the patient supine and fixating straight ahead, 3cc of 2% lidocaine was injected into the retrobulbar space using a #25 guage 1.5 inch needle and a 10cc syringe. Adequate anesthesia and akinesia was obtained. Following treatment the eye was patched for 24 hours.

A speculum was placed in the operated eye. Cryotherapy was applied to retinal periphery which was extended to the ora and/or ciliary body. A total of _____ cryo spots were performed. There were _____ complications. The patient tolerated the procedure well and left in good condition.

Post-operative care & management: Tylenol #3, Pred Forte qid & Hyoscine bid was prescribed for four days. The patient was instructed to return in follow-up ___________ or immediately upon any decreased vision, pain, side effects of meds, or symptoms of RD or RB (which was reviewed). Specific post-operative instructions included HOB elevated and restricted activities with no physical exertion.
POSTOPERATIVE INSTRUCTIONS FOLLOWING EYE SURGERY

ACTIVITY:
Avoid driving, bending, heavy lifting, vigorous coughing and/or sneezing, straining with bowel movements, vomiting, and any other activity that increases intra-ocular pressure. No exercise or physical exertion for 4-6 weeks.

WOUND CARE:
1. Avoid squeezing eyelids shut or touching eye.
2. During the day, keep operated eye covered with eyeglasses or shield.
3. At night, always wear shield to prevent rubbing eye and causing injury.
4. Wear dark glasses if photosensitivity occurs.
5. Crusting on the eyelids may be removed with a clean washcloth run under warm tap water.
6. DO NOT PRESS ON THE EYE.
7. Call your surgeon if you develop any signs and symptoms of infection: eye pain, decreased vision, itchy/watery eyes or increased redness/swelling/discharge.
8. Wash your hands before giving eye drops.

SAFETY PRECAUTIONS:
1. To avoid falls and/or accidents, remove throw rugs, clutter, cords and furniture in walking paths.
2. Turn head fully to affected side to view objects.
3. Use up and down head movements to judge stairs and oncoming objects. MOVE SLOWLY.

POSITIONING:

NONE    SIDE DOWN    FACE DOWN    SIT UP     DAYS
1. Do not lay prone or flat on back if special positioning is necessary.
2. Maintain special positioning as much as possible, taking a 5 minute break every 120 minutes.
3. Do not ascend altitudes greater than 2000 feet; do not fly in an airplane; no non-ocular surgery unless both the surgeon and anesthesiologist know you have gas in your eye.

MEDICATIONS:
1. Avoid over-the-counter medications unless discussed with your doctor.
2. Shake eye drops before applying; shake Pred Forte 1% Eye Drops 30 times before using.
3. Avoid contaminating tip of eye drop applicator by touching eye with tip.
4. Wait three-five minutes between application of different eye drops.
5. Take Tylenol for pain.
6. Avoid aspirin, aspirin containing products such as Anacin and anticoagulants such as Heparin and Coumadin unless approved by your doctor.

FOLLOW UP CARE:
Follow up care is a critical part of a successful surgery. Your surgeon needs to assess your eye healing and see that you are recovering safely.

YOUR SCHEDULED FOLLOW UP APPOINTMENT IS: ________________________

REPORTABLE SIGNS: Call Dr. Mann immediately if any sudden eye pain not relieved by Tylenol, increased redness/swelling/discharge, or loss of vision or any systemic complaint.

EMERGENCY PHONE NUMBER TOLL FREE: 866-856-7882
OFFICE NUMBER MISSOURI: 314-835-9400
OFFICE NUMBER ILLINOIS: 618-632-8100
RECEIPT OF POST-OP INSTRUCTIONS

I ........................................have been given postoperative instruction information. I have had the opportunity to read, understand and ask questions regarding my planned surgical procedure(s). Dr. Mann has explained this procedure to me in depth. I have been informed in regard to the potential benefits, complications, risk and alternatives of the procedure. Sufficient time was allowed for me to ask questions and these questions were answered to my satisfaction.

_________________________________________  _____________
Patient signature           Date

_________________________________________  _____________
Witness signature                 Date
INFORMED CONSENT

I, _____________________________ have been given the brochure(s) on cyclocryotherapy, panretinal cryotherapy and retrobulbar anesthesia. I have had the opportunity to read, understand and ask questions regarding this procedure(s).

Dr. Mann has explained this procedure to me in depth. I have been informed in regard to the potential benefits, complications, risks and alternatives of the procedure. Sufficient time was allowed for me to ask questions and these questions were answered to my satisfaction.

________________________________                     ___________
Patient signature           date

________________________________                     ___________
Witness signature                   time
CONSENT SPECIAL/INFORMED TO SURGERY OR OTHER PROCEDURE

Name: ___________________________________________                Date: _______________

Medical record number ______________________________

1. I hereby authorize Dr. Mann and / or such assistants, associates, or other health care providers that may be selected by him, to perform the following procedure(s)
   CYCLOCRYOTHERAPY / PANRETINAL CRYOTHERAPY ___________ EYE.

2. Dr. Mann has discussed with me the procedure(s) listed above and the items of information that are briefly summarized below:
   a. The nature and purpose of the proposed procedure(s): arrest the progression of neovascularization / retinal ischemia by causing new blood vessels to regress.
   b. The risks and possible consequences of the proposed procedure(s), including the risk that treatment may not accomplish the desired objective(s) and including, but not limited to: glare and light sensitivity, ocular irritation, decreased peripheral vision with narrowed visual field, decreased accommodation, decreased dark adaptation, choroidal neovascularization, retinal breaks or detachment.
   c. All reasonable alternative treatment, including risks, probable effectiveness of each and consequences if this proposed treatment is not received : alternative treatment: panretinal photocoagulation.

3. I am aware that, in addition to the risk specifically described in Item 2 above, there are other risks, such as severe loss of blood, infection, cardiopulmonary arrest, respiratory difficulties, injury to proximate/adjacent blood vessels, nerves, organs or structures, unanticipated allergic reaction to substances, pressure/position related injuries and other risks related to the performance of any surgical procedure.

4. I acknowledge that no guarantees have been made to me as to the results of the procedure(s) and am also aware that complications and risks may occur despite precautions.

5. I consent to the performance of unforeseen operation(s) and procedure(s) in addition to or different from those now contemplated and describe herein that the named doctor and his associates or assistants may deem necessary or advisable during the course of the presently authorized procedure(s).

6. I consent to the administration of such anesthetics as may be considered appropriate by the physician responsible for anesthesia administration or such assistants or associates as may be selected by him. I understand that this procedure is to be performed using retrobulbar/general anesthesia. I understand that all types of anesthesia involve some risk. I further understand that if a regional, spinal or epidural anesthesia is planned, it may be necessary to also administer a general anesthetic during this procedure, and I consent to the administration of a general anesthetic. I understand the risk of a general, spinal, epidural or regional anesthesia include, but are not limited to, mouth and/or throat pain or injury, cardiopulmonary arrest, cardiac
arrhythmias, heart attack, respiratory difficulties, stroke, brain damage, headache, backache and other sensory, nerve, focal and systemic injuries.

7. I also consent to the administration of blood or blood components, drugs, medicines and other substances considered advisable by the physician(s) responsible for this procedure and the use of x-rays or other diagnostic testing, procedures and devices, which the above-named physician or his associates, consultants or assistants may consider useful.

8. I hereby authorize The Retina Group LTD PC or staff to preserve for scientific or teaching purposes or to otherwise dispose of any tissues, parts, organs, or implants removed during this procedure.

9. For teaching or educational purposes, I consent to the admittance of students, staff or other observers to the operating and procedure rooms, and to the taking of any videos or photographs deemed appropriate or necessary by the physician in the course of the procedure(s). I also consent to the taking of photographs or videos for the purpose of documenting the condition or procedure in the medical record. I understand that if data, photographs, videos or other information are used for teaching/educational purposes or for scientific publication, that my (the patient’s) identity will remain confidential unless otherwise authorized by the undersigned.

10. I certify that I have read or have had the above information read to me and that I understand the above consent to operation or diagnostic procedure, that the explanations referred to were made to my satisfaction and I hereby give my informed and voluntary consent to the proposed procedure(s) or operation(s).

Signature of patient:

_________________________________________________

If the patient is unable to give informed consent because of physical or mental incapacity or is a minor (under 18 and unemancipated), complete the following:
Patient is unable to give consent because _____________________________________________
________________________________________

Witness to signature

I certify that I have explained to the above individual the nature, purpose, risk and potential benefits of the above procedure and have answered any questions that have been raised.

________________________________________

Signature of Physician