



Clinical Process Instruction Manual

Keratolimbal Allograft (KLAL) Whole Globe Process Instruction

Policy:

The Tissue Recovery Coordinator (TRC) is responsible for eye recovery surgical procedures. This document describes the procedures for Keratolimbal allograft (KLAL) tissue recovery.

If the donor has been maintained on a ventilator, the TRC ensures the ventilator has been disconnected at least 20 minutes prior to enucleation to allow blood clotting and to prevent facial disfigurement.

Process:

Set-Up

1. TRC refers to *Ocular Recovery Preparation, CPI-9-518*.
2. TRC refers to *Physical Examination for Tissue, CPI-9-510* and *Blood Collection, CPI-9-511*.
3. TRC refers to *Gowning and Surgical Scrub, CPI-9-519*.
4. Prior to starting the KLAL recovery, TRC obtains wet ice for packaging.
5. TRC performs the KLAL recovery using the following steps:
 - 5.1. Begins enucleation with the left or right eye using sterile 2 x 2 gauze or sterile cotton tipped applicators, to gently open the upper lid by pulling towards the top of the head, inserts the closed lid speculum under the upper and lower lids near the nose. Slowly opens the speculum while moving the speculum towards the middle of the eye. Uses care to not touch the cornea with the speculum.
 - 5.2. Grasps the conjunctiva with the forceps, near the lateral edge of the cornea as long as possible, to a minimum of 4mm from limbus. While ensuring that the conjunctiva is not pulled from the limbal line, TRC cuts the conjunctiva with tenotomy scissors pointed away from the cornea and continues this 360° around the cornea.
 - 5.3. Care must be used to ensure that the limbus is not disturbed while performing the conjunctival incision. 4mm of undisturbed conjunctiva surrounding the limbus is an absolute minimum. TRC will ensure that adequate undisturbed conjunctiva is included to ensure positive tissue outcomes.



Clinical Process Instruction Manual

Keratolimb Allograft (KLAL) Whole Globe Process Instruction

- 5.4. Inserts the closed tenotomy scissors under the conjunctiva and performs a blunt dissection around the globe.
- 5.5. Inserts the muscle hook into the medial quadrant and hooks the medial rectus muscle. A hemostat may be applied to clamp the medial rectus muscle. Removes the muscle hook and cuts the medial rectus muscle on the distal side (outside) of the hemostat (if used).

KLAL Process Instruction

- 5.6. Begins cutting the remaining ocular muscles one at a time (superior, lateral and inferior rectus) by sliding the muscle hook posteriorly and hooking the muscle. Then pulls the muscle anteriorly while gently rotating the globe inferiority. Cuts the muscle distal to the muscle hook with the tenotomy scissors.
- 5.7. Optionally, locates and cuts the superior and inferior oblique muscles. Rotates the globe laterally using the hemostat. Ensures care is taken not to rub the cornea against the speculum. Opens the large scissors about half an inch, and slides it into the superior medial quadrant. Then severs the superior oblique muscle. This is repeated in the inferior medial quadrant for the inferior oblique muscle.
- 5.8. Inserts the closed blades of the large enucleation scissors behind the back of the eye with the globe still rotated laterally. Opens the blades slightly and positions the optic nerve between the blades. Pushes the scissors towards the back of the orbit and cuts the optic nerve, leaving $\frac{1}{4}$ - $\frac{1}{2}$ inch stump.
- 5.9. Uses the hemostat or forceps to grasp the medial rectus muscle and gently lift the globe from the socket. Carefully cuts any residual fat or remaining connective tissue from under the globe if necessary. The whole eye is carefully transferred to the sterile container, using the hand-under-whole-eye technique, in case the tissue is dropped.
- 5.10. While maintaining sterility, cautiously opens the eye jar lid (covered with sterile gauze) by lifting gauze using fingers of one hand. Using forceps or hemostat in the opposite hand, gently places the globe, with cornea facing up, into the eye jar with the optic nerve resting on the cotton. Ensures that the sterility of the inside of the eye jar is not compromised. Also,



Clinical Process Instruction Manual

Keratolimb Allograft (KLAL) Whole Globe Process Instruction

ensures that the dental roll is wrapped around the eye to keep the eye from rotating. Takes precautions to protect the cornea and intact conjunctiva from rubbing against the sides or top of the jar. Places the eye in the appropriately labelled eye jar (i.e., Right eye or Left eye. Write MRN and TGLN number on both labels.

5.9.1. Repeats steps (5.1 to 5.9) above for the other eye. The second eye should already be draped.

5.9.2. After recovering the last ocular tissue, note the time.

5.11. Removes outer surgical gloves.

5.10.1 If not done so already, pours a small amount or approximately 5 mL of sterile irrigating solution over the eye to moisten the cotton or gauze in the bottom of the jar. Ensures that the saline is not squirted directly onto the cornea to minimize damage to epithelium. Ensures that the eye does not float in the fluid.

5.10.2. Tighten the lids on both jars, careful not to touch the inside of the jar.

5.10.3. Attach the label on the circumference of the jars. Package tissue in transport cooler. Note the time of packaging.

6. TRC performs the following steps post ocular recovery:

6.1. Removes the drapes.

6.2. If necessary, controls excessive bleeding.

6.3. Places a folded and wetted piece of gauze or a cotton ball in the socket, inserts an eye cap and closes the eyelid to ensure normal appearance is restored. Gently wipes off any excess povidone-iodine or bodily fluids by patting with moist gauze.

6.4. Applies 4 x 4 gauze over the closed eye lids and securely wrap the head with conforming wrap gauze.

6.5. Leaves the donor's head elevated if possible.

6.6. Removes surgical gloves and puts on exam gloves.

6.7. Rewraps the donor in the body bag (with any donor belongings) or shroud and returns to the storage location from which it was removed.



Clinical Process Instruction Manual

Keratolimb Allograft (KLAL) Whole Globe Process Instruction

- 6.8. Cleans the work area and discards all used disposables in the appropriate bags and all sharps in a sharp's container.
7. TRC performs the following steps for the documentation, labelling and shipping of the ocular tissue:
 - 7.1. Ensures that the jars are labelled as left and right. Places the label on the circumference of the jar. The TGLN number and MRN number should be written on the label.
 - 7.2. Places the blood samples (wrapped in a sponge and placed in a biohazard bag) and both jars in a plastic container.
 - 7.3. Places the plastic container into a ziplock bag and seals the ziplock.
 - 7.4. Lines the transport cooler with a large clear garbage bag.
 - 7.5. Places the sealed ziplock bag containing the plastic container (7.2 above) in the center of the transport cooler. Three (3) medium sized ziplock bags, ½ full with ice (approximately 1.5lbs of ice each bag) used to fill around the container. One bag can be placed under the container, while the other two can be placed around the container.
 - 7.6. Tie or seal large clear plastic bag
 - 7.7. Completes the enucleation information on the *Eye Recovery Form* or equivalent (iTransplant). See Exhibit 1. If the *Eye Recovery Form* is being used this must be included in the shipment of the ocular tissue to the Eye Bank of Canada and a copy uploaded to iTransplant.
 - 7.8. Completes an Eye Recovery Note and leaves this note in the patient's chart or equivalent - if the recovery occurs at a hospital (i.e., fax to health records), and attaches a copy to the donor chart for all cases.
 - 7.9. Completes the Recovered Ocular Tissue Label (CSF-9-234) and the Recovered Ocular Tissue Package Insert (CSF-9-233) for shipping the recovered tissues and attaches a copy to the donor chart.
 - 7.10. Recovered Ocular Tissue Package Insert (CSF-9-233) to be placed on top of closed cooler, and zipped into cooler liner. Recovered Ocular Tissue Label (CSF-9-234) to be placed in transparent sleeve on outside of cooler liner, ensuring that all information is visible
8. TRC performs the following steps upon completion of the ocular recovery:
 - 8.1. Notifies the Provincial Resource Centre (PRC) that the enucleation is complete so that multi-tissue recovery can take place or body can be released to next step in the process. Also



Clinical Process Instruction Manual

Keratolimb Allograft (KLAL) Whole Globe Process Instruction

- 8.2. informs the PRC of the transportation arrangements (if applicable) or if the eyes are being left at the hospital and what transportation arrangements are pending.
- 8.3. If requested, notifies hospital staff when recovery is complete.
- 8.4. Drops the eyes off at the Eye Bank of Canada (GTA TRCs) or an alternate site if necessary (i.e., ER triage, etc.), and arrange transport with Courier service.

Records:

Record Name	Form No. applicable)	(if Record Holder	Record Location	Record Retention Time (as a minimum)
Eye Recovery Form	CSF-9-80	PRC	PRC	16 years
Recovered Ocular Tissue Package Insert	CSF-9-233	PRC	PRC	16 years
Recovered Ocular Tissue Label	CSF-9-234	PRC	PRC	16 years

References:


- *Eye Bank of Canada Standard Operating Procedures E1.050 Donor Preparatory Procedures for Enucleation and E1.100 Enucleation-Whole Globe*



Clinical Process Instruction Manual

Keratolimbal Allograft (KLAL) Whole Globe Process Instruction

Exhibit 1: Eye Recovery Form (Page 1)



Trillium Gift of Life Network
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9
Telephone: (24/7) 1 877 363 8456 Facsimile: 1 888 557 8100
Website: www.gilhof.life.on.ca

CSF-9-80

Eye Recovery Form

Part A Chart Review

(1) Donor Information

TGLN # _____ Donor Name _____
Last Name, First Name

MRN # _____

(2) Hospital Information

Hospital Name	Hospital Address

(3) Consent Information

Consent: Eyes Corneas Heart Skin Bone and Connective Tissue
 Research Medical Education Transplant

(4) Coroner Information

Coroner's Case Yes No If "yes" coroner consent given: Yes No Coroner: _____

Tissue required by Coroner None Vitreous Blood CV Residual Other _____

Restrictions/comments _____

(5) Cause of Death

Asystole (cross clamp/LTKA) ____/____/____ @ ____:____ EST hours Attending and/or Pronouncing Physician _____

dd mm yyyy HH:MM

Immediate Cause (a) _____
of death, giving due to (or as a consequence of)

Antecedent cause(s), (b) _____
if any, next due to (or as a consequence of)

(6) Ocular Technician Recovery Timelines

Date-Time Notified:	@	EST hours
____/____/____		____:____
Date-Time of Departure to Recovery Site:	@	EST hours
____/____/____		____:____
Date-Time of Arrival at Recovery Site:	@	EST hours
____/____/____		____:____
Date-Time of Departure from Recovery Site:	@	EST hours
____/____/____		____:____

Comments: (List any problems, unusual circumstances, instructions received or positive experiences) N/A

January 25, 2023

TGLN #: _____

Page 1 of 10