



Clinical Process Instruction Manual

KeratolimbAl Allograft (KLAL) In Situ Process Instruction

Policy:

KLAL – In situ corneal excision is the removal of corneas directly from a donor, with the specific purpose of maintaining Limbal conjunctival tissue, performed in a hospital, funeral home, coroner's office, or other location suitable for tissue recovery. This process provides a standardized method for the aseptic excision of the corneoscleral disc while maintaining limbal integrity and minimizing conjunctival loss. The Tissue Recovery Coordinator (TRC) is responsible for performing the KLAL In Situ corneal excision process.

Process:

The TRC is responsible for performing the process steps below.

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.

Recovery

4. Using a sterile cotton tipped applicator, gently open the upper lid and insert the speculum under the upper and lower lids near the nose. Slowly open the speculum moving towards the middle of the eye without touching the cornea.
5. For tissue to be used for KeratolimbAl allograft (KLAL), The TRC will use the tenotomy scissors and sterile forceps to perform a peritomy between 2 - 4mm from the limbus, leaving a "skirt" of conjunctival tissue undisturbed from the limbus outward from 2mm - 4mm. The limbal conjunctiva must be left intact and undisturbed.
6. After peritomy of the conjunctiva has been completed, use a blade to make a partial incision 2 – 4 mm from the limbus 360° around the globe. Care should be taken to leave the conjunctival "skirt" at the limbus undisturbed. This scoring should be done without penetrating the underlying uveal tissue.
7. Use a scalpel blade to make an incision through the sclera into the suprachoroidal space 2 mm – 4mm from the limbus and parallel to the limbus. Extra care must be taken to cut all the way



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through the sclera without perforating the choroid. Perforation of the choroid leads to vitreous leakage, which may cause the collapse of the globe, including the anterior chamber which could result in endothelial damage.

8. Insert one blade of the Castroviejo scissors in the suprachoroidal space. Keep the incision parallel to the limbus to produce an even scleral rim following the trephine mark. Complete the scleral incision of 360° around the corneoscleral disc. Avoid perforating the choroid, breaking into the anterior chamber, or causing any deformation of the corneoscleral disc's normal curvature. Trauma to the corneoscleral disc during excision due to bending, loss of the anterior chamber, or collapse of the globe through vitreous loss could severely compromise the conjunctival skirt at the limbus and subsequently reduce its suitability for surgical use.
9. Inspect the incision to ensure it is complete and that the anterior chamber is intact. If the incision has been made properly, the corneoscleral disc should be attached to the uvea only at the scleral spur.
10. Complete the corneoscleral disc removal using one pair of small forceps to grasp the scleral rim and hold it stationary. Use the second pair of small forceps to pull the ciliary body/choroid downward and away from corneoscleral disc. Aqueous fluid should escape from the anterior chamber at this point, assuring that the anterior chamber was indeed intact.
11. Gently separate remaining adhesions away from the corneoscleral disc, working side to side avoid pulling on the cornea and creating folds. The corneoscleral disc should never be allowed to drop back onto the anterior chamber while making this separation. Ensure the corneoscleral disc is never pulled in a way to cause cross-corneal tension. Do not allow instruments to touch the conjunctival skirt during this step. Care must be taken to prevent the corneoscleral disc from contacting the eyelids or other facial skin while removing it from the eye to avoid contamination of the ocular tissues.
12. Holding the corneoscleral disc by the scleral rim with the forceps, transfer it to the labeled chamber of storage solution. While transferring, place your free hand underneath the hand holding the forceps and corneoscleral disc in the unlikely event it is dropped. Using sterile gauze, lift the pre-loosened lid off of the viewing chamber, and immediately place the corneoscleral disc into the storage solution. Replace the lid immediately afterward. Removing the chamber lid at the time the corneoscleral disc is placed in the storage solution minimizes the solutions exposure to airborne contaminants.
13. Repeat the corneoscleral disc excision on the second eye (steps 4 - 15).
14. After the second corneoscleral disc is placed in the storage solution, change gloves and tighten both chamber lids. Also ensure that both chambers are appropriately labeled.



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15. Examine the posterior chambers for a crystalline lens. Absence of a crystalline lens indicates previous ocular surgery and may contraindicate the use of the corneoscleral disc for penetrating keratoplasty.
16. Complete corneal excision:
 - 16.1. Insert eye caps and close the eyelids. Remove drapes and clean the donor's face to remove all remaining povidone-iodine and/or bodily fluids. Use saline or alcohol wipes to loosen residual povidone-iodine on donor's face, followed by gauze pads moistened with water or saline.
 - 16.2. Apply 4 x 4 gauze over the closed eye lids and securely wrap the head with conforming gauze.
 - 16.3. Obtain blood specimen or make arrangements for blood to be obtained from the hospital laboratory if not previously obtained.
 - 16.4. Wrap the donor's body and return to the storage location from which it was removed.
 - 16.5. Clean the work area. Place all sharps in the sharp's container and all other used disposables in a biohazard bag.
 - 16.6. Wash hands using anti-microbial soap. If no hand washing facilities are available, use an anti-microbial gel to cleanse hands.
 - 16.7. Using clean gloves and pack the corneal viewing chambers and blood samples into the transportation container. Ensure that wet ice is in the transportation container.
 - 16.8. Leave an eye recovery note with the patient's chart and upload a copy into TGLN's electronic chart.
17. Transport or arrange transportation of the corneoscleral discs to the Eye Bank with an approved coolant as soon as possible following excision.

Records:

None