Jordan Eye Bank

Medical Standards / December 2017

Introduction:

- Appreciating the fact that poor vision is a very disabling problem, which many people suffer from, and recognizing the importance of better vision for better life, Jordan Eye Bank (JEB) was established in 1979 as a national, non profit institute, based at Jordan University Hospital, and funded by:
  - Ministry of Health (MOH)
  - The University of Jordan.
  - Royal Medical Services.
  - Jordan University for Science and Technology (J.U.S.T).

- **Goals and Objectives**
  - Organize and provide basic structure for corneal transplantation in Jordan.
  - Spread the awareness of the importance and need for local corneal donation.
  - Provide corneas for patients who need them via local donation or importation from international eye banks suppliers.
  - To control the quality and coast of corneal grafts to be used for our patients and upon the recommendation of the M.O.H, the Cabinet made a decision allowing only Jordan Eye Bank to ***import*** corneas, along with controlling the quality of ***local*** donations.
  - JEB started implementing its new role since 1st, August 2003 by importing corneas for all the health sectors in the Kingdom.

- **Sources of Corneas:**
  - Corneas of dead people being donated by next-of-kin.
  - Imported corneas from international eye banks suppliers.

- **Cost of corneas:**
  - Locally donated corneas are free of charge (excluding serological tests and cost of storage media).
  - Imported corneas cost 1200 JDs (are payable cost of tests and shipment, it is not covered by insurance).

- **Donation:**

Donation is a self-simulated act through which a person can register his / her corneas to be used after death for patients who need it.

- **The Judgment of the religion on the Donation of the cornea:**

There under is a reply to a request for a Jordanian legal Islamic opinion on grouting directed by the Jordan eye bank.

"Praise is to God, the cherisher and sustainer of the worlds".

The principles of Islamic Sharia permit the removal of corneas of the deceased for the purpose of grafting these into the eyes of the blind or those with very poor vision under the following conditions:

a. The death of the donor is verified.

b. That the deceased person has, prior to his death, donated his cornea or that his relatives have agreed to do so.

*** See appendix number 1.**

- **Donation Forms:**
  - It implies the consent of the person that his cornea may be taken after his death and be used for a patient who needs it.
  - Donation is completely optional before death and by the consent of 1st of kin or anyone responsible after death.

*** See appendix number 2.**

Donor Screening:

- All donors must be identified by name. A donor shall undergo a physical examination as close as possible to the donation with special attention to physical signs of HIV disease, infectious hepatitis and injecting drug use.
- The eye banks should have a consistent policy for conducting and documenting this examination.
- Review of available records on each donor should be performed by an individual who is qualified by profession, education, or training to do so and who is familiar with the intended use of the tissue.
- Medical and social histories are important aspects of donor evaluation.
  Adequate donor evaluation includes:

a. Donor history evaluation: this must include the donor's name and donor information obtained from at least one of the following:
    1- Pathologist or physician assessment of death report.
    2- Police investigation report (if needed).
    3- Medical examination investigative report.
    4- Family interview.
    5- Medical report or hospital chart.
    6- Treating physician interview.

b. Physical assessment of the donor.

*** See appendix number 3.**

c. Serologic testing for HIV, Infectious Hepatitis (B & C).

*** See appendix number 4.**

d. Tissue evaluation.

- Medical director oversight to review any donor information where questions arise in the above areas.

Check list for CI for Graft Harvesting

Tissue form donors with the following are potentially health threatening for the recipient or pose a risk to the success of the surgery and should not be offered for surgical purposes:

1- Age of the donor less than 2 years or more than 75 years.
2- Death of unknown cause.
3- Death with neurological disease of unestablished diagnosis.
4- Creutzfeldt – Jakob disease.
5- Dementia, unless due to cerebrovascular disease, brain tumor, or head trauma.
6- Sub acute sclerosing panencephalitis.
7- Progressive multifocal leukoencepholopathy.
8- Congenital Rubella.
9- Reyes syndrome.
10- Active septicemia (bacteremia, fungemia, viremia)
11- Active bacterial or fungal endocarditis.
12- Active viral hepatitis.
13- Rabies.
14- Leukemias
15- Active disseminated lymphomas.
16- Intrinsic eye disease, such as:
    - Retinoblastoma.
    - Malignant tumors of the anterior segment.
    - Active ocular or intraocular inflammation e.g., keratitis, conjunctivitis, scleritis, iritis, vitritis, choroiditis, retinitis.
    - Congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use e.g., a central donor corneal scar for an intended Penetrating Keratoplasty, Keratoconus, and Keratoglobus.
    - Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button.
17- Prior intraocular or anterior segment surgery, such as:

- Refractive corneal procedures e.g., redial keratotomy, lamellar inserts …etc.
- Corneal laser photoablation surgery is allowed to be used in cases of tectonic grafting and posterior lamellar procedures.
- Laser surgical procedures such as Argon laser trabeculoplasty, retinal and pan retinal photocoagulation do not necessarily preclude use for Penetrating Keratoplasty (PKP) but should be cleared by the medical director.

Laboratory and Other Medical Exclusionary criteria:

1- Persons who cannot be tested for HIV infection because of refusal inadequate blood samples, or any other reason.
2- Persons with repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of the supplemental assays.
3- Persons whose history, physical examination, medical records or autopsy reports reveal evidence of :
   - HIV infection or high- risk behavior.
   - Kaposi sarcoma.
   - Hepatitis B or C infection.
   - Injecting drug abuse

Interval Between Death and Excision of The Corneal Tissue:

- Acceptable time interval from death to corneal excision may vary according to the circumstances of death and interim means of storage of the body.
- It is generally recommended that corneal excision and preservation should be as soon as possible after death.

- It is preferably done within 12 hours of death, the sooner the better. Recovery up to 24 hours after death is acceptable if the body has been refrigerated or an ice bag placed over the eyes.
- The decision to donate must be made in a timely manner.
- Post mortem viability of eye tissue is very limited, and to insure that the tissue is safe and viable, we prefer to have decision made in the first 6 hours following death.

Excision of Corneal Tissue:

- Excision of corneal tissue from the donor eye should be performed by a qualified person and within acceptable time interval from death.
- The donation should be verified and responsible person informed and agreed.
- Procedure:
  - Eye speculum is applied.
  - The eye is irrigated with 5 % povidone-iodine solution in the sac and with 10% povidone-iodine for swapping around
  - 360° periotomy cut along with the posterior limbus is then performed using a corneal scissors.
  - Corneal-scleral tissue can be excised using a large (18 mm) simple manual trephine then completed with universal corneal scissors Alternatively, Posterior limbal wound is created with a knife and anterior chamber is penetrated.
  - The corneal-scleral tissue is then removed using a fine-toothed forceps and immediately placed in preservative solution.
  - The donor eye is closed by suturing the eyelids.

*** See appendix number 5.**

Tissue Evaluation:

The ultimate responsibility for determining the suitability of the tissue for transplantation rests with transplanting surgeon.

1- Gross examination:

The corneal-scleral segment should be initially examined grossly for clarity, epithelial defects, foreign objects, contamination and scleral color e.g., jaundice.

2- Slit – Lamp examination:

The cornea should be examined for epithelial and stromal pathology and in particular endothelial disease.

If in situ corneal excision is performed; examination of the donor eye anterior segment with a penlight or a portable slit lamp is required.

- After corneal excision, the corneal scleral rim should be evaluated by slit-lamp biomicroscopy, even if the eye donor has been examined with the slit lamp prior to excision of the corneal-scleral rim, to insure that damage to the corneal endothelium or surgical detachment of Descement's membrane did not occur.
- Document that a slit lamp examination has been performed with particular attention to the epithelium, stroma and endothelium, such as but not limited to, scars, edema, significant arcus senile, epithelial defects, guttea, polymegathism, pleomorphism, infiltrates or foreign bodies.

3- Endothelial Cell Density via specular microscope.

*** See appendix number 6.**

Records:

The eye bank will maintain records identifying all donors and recipients of corneal tissue. These records will be maintained for a minimum of 10 years.

Storage:

Each tissue recovered and preserved will be assigned an expiration date. Tissues retained post the expiration date will be discarded, and will not be used for surgery.

Storage Media	Tissue Use	Expiration Date*
Cornea In Optisol GS	**PKP, Anterior Lamellar, Tectonic**	**14 days from placement in Optisol GS**
Cornea In Glycerin	**Tectonic**	**One year from placement in 95% Ethanol**
Sclera In 95% Ethanol	**Glaucoma Shunt Patch**	**One year from placement in 95% Ethanol**
Cornea In Eusol - C	**PKP, Anterior, Lamellar, Tectonic**	**C / with Kevin**
*** Or As Assigned by source eye bank**		

Tracking of grafted tissues

All grafted tissue are tracked by special form completed and sent to the bank by the surgeon who did the surgery. These will be maintained in the bank for a minimum of 10 years.

*** See appendix number 7.**

Appendix No (1)

The General Iftaa Department of the Ministry of Awqaf and Religious Affairs has issued a fatwa on 22 June 1988 (number 1/88) permitting partial or complete donation of human organs, including corneas, after death conditional to the donors' tacit and voluntary approval in their lifetime.

Hashemite Kingdom of Jordan
Ministry of Awqaf and Islami Affairs
Department of General Legal Opinion
Amman

"As for after death, the principles of Islamic Shari'a permit benefiting from organs of dead bodies"

1. Verifying the donor's death: The Jordanian Council for Legal Opinion specified it in its decision number 1/88 issued on 8/11/1408, equivalent to 22/6/1988 number 2/9/1025.
2. Donor's explicit approval during his lifetime to donate the organ mentioned, or to donate one of them voluntarily and at his own will, or the approval of his kin according to inheritance hierarchy if his identity is known and his family and relatives are known.
3. A high likelihood of success of the transplant operation based on the opinion of specialized physicians.
4. Total inability of treatment in the absence of organ transplant. Scholars based the permission to permit donation of organs after death to the fact that those in need of one of these organs are in dire need for it. Necessities permits prohibitions, and the necessity is estimated at its magnitude. The true Islamic law (Shari'a) is with doing good and with legitimate benefit for mankind, Alleviation damage and bringing about benefit are among the objectives of Islamic law. The Prophet said. "God wants ease and benefit for you, and not hardship and poverty." Treatment is permissible, and organ transplant is one

type of treatment, that goes under the general message of Osama Ben Shareek,رضي الله عنه who said: “I was at the Prophets home (صلى الله عليه وسلم) and Bedouin Arabs came and said “Prophet of God should we get treatment?” He said, “Yes followers of God do get treatment, because God the Almighty did not create a disease except with its treatment to go with it, except for one disease.” They asked. “And what is that” “Getting old,” He answered.

The benefit of the living takes precedence over that of the dead. God said: “The living and the dead are not equal.”

Scholars talked about cutting the womb of a pregnant woman open after her death to extract the fetus if it has an opportunity to live. “And they have permitted opening the belly of the dead for the necessity of preserving life”.

Donating one of these organs, or all of them, after death in order to give life to people threatened by death, or relieve them from pains and difficulties that made their lives intolerable, and relieve people around them specifically and the state in general, from burdens. In donating, they shall have great retribution and generous remuneration from the God of the word, in return for maintaining life and alleviating harm for other. God has said: “Anyone who kills a life without reason or wreaked havoc in the land. It is similar to killing all people.” It has assistance to others, and charity that will be rewarded, as the Prophet said: “Anyone who relieves a believer’s difficulty, God will relieve him from a difficulty on judgment day. And anyone who relieves a person in difficulty, God will relieve him in life and the other life. God is there to assist his children as long as they assist their brethren.” If remuneration is achieved in benefititing anyone with a soul, as the Prophet said: There is reward in relieving difficulty, “it is deserving to man and God the Almighty is knowledgeable.

General Acting Mufti

Amman Mufti Said Abdul Hafith Hayyari