

Corneal Transplants - an overview with an emphasis on legal aspects and current scenario in Mauritius

Dr. Lakshmi Priya Karthi MBBS DOMS and Dr. A K Agnihotri MBBS MD

SSR Medical College, Belle Rive, Mauritius

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ABSTRACT: A healthy cornea is an essential component of clear vision. Any condition that distorts the clarity of the cornea to a greater extent has to be treated by keratoplasty. This article discusses by large about the various aspects of corneal transplants like modes of storage and their legal aspects with an emphasis on the scenario in Mauritius

KEY WORDS: Corneal transplantation, Legal aspects, Keratoplasty

INTRODUCTION:

Transplantation of human organs from one individual to other is an important and life saving measure. Corneal transplants have so far been the most successful of all the transplants because of vascularity of cornea, and for the fact that partial thickness grafts do not involve the corneal endothelium, and so rate of rejection is less.

This review has been aimed to highlight the significant milestones in the history of corneal transplantation, to discuss its scenario in the Republic of Mauritius along with legal aspects, and to pay tribute to the many inspired and dedicated individuals involved in the corneal transplant surgery so that more than a million people have enjoyed restoration of useful sight.

HISTORY:

Descriptions of organ transplantation are available in ancient Indian and Chinese medical texts. The technical basis for modern organ transplantation was laid by the French surgeon Alexis Carrel in a series of animal experiments conducted from 1902 onwards. Skin transplantation was used more than 2,000 years ago but became part of western medicine only in the last century. This article is concerned with corneal transplantation. As early as 1905, doctors had discovered that corneal blindness could be cured by removing the damaged cornea and replacing it with another clear human cornea. These transplants were rarely performed, however, because donor tissue was not readily available. Then it was an ophthalmologist

R. Townley Paton who started performing corneal transplantations at the John Hopkins hospital, Baltimore from donor tissues obtained from prisoners in death row¹. One hundred years ago, on 7 December 1905, Dr. Eduard Zirm performed the world's first successful corneal transplant. This significant milestone was achieved only after many decades of unsuccessful trial and error².

In the later half of the 20th century, many ophthalmologists evolved significant refinements in technique and instrumentation with the development of corticosteroids, antibiotics, surgical microscopes, improved trephines, viscoelastics and suture materials, that enable this delicate procedure to be routinely performed with the prospect of success. But there are still limitations to corneal transplantation, and corneal allograft rejection still poses the greatest challenge to the ophthalmologist in modern time.

SCENARIO IN MAURITIUS:

Till the passage of the recent bill, there was no comprehensive law regulating the removal of human organs. The recipients either procure their donor tissues from outside Mauritius or they are being sent abroad for their transplantations. The Human Tissue (Removal, Preservation and Transplant) Act 2006 was passed in parliament in May 2006. The objective of this Bill is to provide the legal frame work for carrying out the removal, preservation and transplant of human tissue, other than blood, under appropriate medical supervision.

Corresponding Author: Dr. Lakshmi Priya Karthi, Email: drmadhu77@rediffmail.com

This act prohibits the removal of any tissue for the purpose of transplantation from the body of a person where that body is lawfully required to be examined for the purpose of determining the cause or circumstances of the person's death. In accordance with this act, any tissue may be removed from the body of a person after conclusion of an examination or when an authorized medical practitioner, after consultation with police medical officer (forensic pathologist) designated to carry out the examination, certifies that he has reason to believe that tissue will not be required for the purpose of such an examination³.

The first corneal transplant in Mauritius was done in early 1980's and more than 90 have been done till now. The donor tissues are procured mainly from places like Srilanka and South Africa. There is no separate storage of grafts here. As and when, grafts are recovered transplantation is performed within 48-72 hours. Most of the transplants done here are partial thickness grafts hence the incidence of rejection is also lesser. Out of the performed 90 cases of corneal transplantations, about 80% have been successful and 20% have been rejected.

METHODS OF CORNEAL TRANSPLANTATION:

Basically there are two types of Keratoplasties- *Lamellar keratoplasty (partial thickness corneal grafting)* and *Penetrating keratoplasty (full thickness corneal grafting)*. The indications of Keratoplasty are:

1. Optical- Improving visual acuity by replacing the opaque host tissue by clear healthy donor tissue. The most common indication in this category is Pseudophakic Bullous Keratopathy, followed by keratoconus, corneal degeneration and dystrophy, as well as scarring due to keratitis and trauma.
2. Tectonic- To preserve corneal anatomy and integrity such as patients with stromal thinning and descemetocoeles.
3. Therapeutic- Removal of inflamed corneal tissue refractive to treatment by antibiotics or anti-virals.
4. Cosmetic- The indication in this group is the patients with corneal scars giving a whitish opaque hue to the cornea.

DSAEK (Descemet Stripping Automated Endothelial Keratoplasty) is the latest technique in corneal transplantation which offers clear post-operative vision and short recovery time to patients in need of new corneas. During this

procedure, the unhealthy, diseased, posterior portion of a patient's cornea is removed and replaced with healthy donor tissue obtained from the eye bank. Unlike conventional corneal transplant surgery (penetrating keratoplasty or PK), the DSAEK procedure utilizes a much smaller surgical incision and requires no corneal sutures⁴. Descemet's stripping and automated endothelial keratoplasty uses a mechanical microkeratome to harvest the donor corneal lenticule and mechanical stripping of the diseased host endothelium and Descemet's membrane⁵. According to **Gorovoy MS**⁶, DSAEK surgery allows rapid, excellent BSCVA visual recovery. The rate of visual recovery is more rapid than usually found with penetrating keratoplasty.

CORNEA DONATION AND LEGAL ASPECTS:

An active program of corneal transplantation depends upon a constant supply of high quality donor tissue. In many countries the number of corneal donations is far too low to graft all patients listed within reasonable time. French law and regulation regarding tissue collection are based on consent presumption but it requires verifications to be made with the relatives to ensure that potential donors were not opposed to such tissue procurement before their death⁷.

Criteria for cornea donation:

1. Obtaining consent from relatives is an essential criterion for cornea donation. When face-to face interview is not possible, telephone contact is an efficient method to obtain cornea donation consent⁸. The study conducted in a tertiary care hospital in India by **Tandon R. et. El**⁹ showed willingness for eye donation in 41.5% cases, whereas 58.5% families refused eye donation. Socio-economic factors such as education, marital status, residential area and situational factors such as the cause of death play an important role on the willingness for eye donation¹⁰. A high positive response can be obtained when a trained and motivated group manages the postmortem cornea donation request¹¹.
2. As soon as the death occurs the donor's family is supposed to inform the neighboring eye bank. Any fan or air conditioner should be switched off to prevent the moisture from the eye drying off and the eyes should be closed and a moist water soaked eye pad should be kept on top of the eyelids ideally. The eye donation

should be done within 24 hours of the time of death. The efficient notification and 'on-call' retrieval system led to very rapid corneal retrieval, resulting in an average death to storage medium time of less than two hours¹².

3. After brain stem death, diagnostic tests should always be carried out for confirmation and the patients should be routinely assessed for suitability for corneal donation¹³. But still if the patient has willingly pledged his eye whatsoever may be the reason of death or the condition of the donor corneal button, ethics point out that enucleation should be done from the patient even though investment of the graft is not done.
4. We prefer corneal donations in the age group of 2 to 70 years. Clinical evidence suggests that there is no influence of donor tissue age on graft survival, but usage of donor tissue less than 2 years of age is restricted mainly because of resultant myopia¹⁴. The critical endothelial cell density below which the cornea goes for decompensation is speculative although many clinicians estimate it to be between 300 – 500 cells per mm¹⁵, that is the reason why corneal buttons from people over the age of 70 years and from those who have certain changes such as "cornea guttata" are not preferred.
5. There should not be any contraindications for corneal donations such as death of unknown cause, death for unknown lesions involving the CNS, Subacute sclerosing pan encephalitis, congenital Rubella, Reye's syndrome, Active viral encephalitis or of unknown origin, Active Septicemia (bacterial, fungal or viral), Active viral hepatitis, Rabies, Active leukemia, Active bacterial or fungal endocarditis, Active disseminated lymphomas, Active HIV infections, Hepatitis B surface antigen positive donors, Hepatitis C sero positive donors, Intrinsic eye diseases, Previous intra ocular surgeries and anterior segment surgeries, etc.
6. The medico-legal cases particularly victims of accidents are the major potential donors. After declaration of brain stem death, cornea can be retrieved in medico-legal cases after observing the procedure prescribed under the law without interfering the functioning of the investigating agencies, autopsy surgeons and the courts of law¹⁶.

STORAGE OF THE DONOR BUTTON:

The aim of any current cornea storage technique is to maintain the viability of the tissue. Techniques developed over the past 30 years have enabled reliable corneal storage for approximately 1 month. Techniques which are done to extend this time period such as cryopreservation are still not reliable enough for them to be routinely employed¹⁷. The 3 main techniques of storage are a) moist chamber storage b) hypothermic corneal storage and c) organ culture.

1. **Moist chamber storage:** Filatov achieved this by placing an enucleated eye in a sealed chamber together with gauze usually moistened by saline or antibiotic solution and stored at 4° C. care should be taken not immerse the cornea as stromal edema may set in. Although it is a very successful medium of storage its main disadvantage is that the time limitation is around 24 hrs as the corneal endothelium is subjected to toxic build up of metabolic waste from the stagnant aqueous humor.
2. **Hypothermic corneal storage:** McCarey and Kaufman modified an existing tissue culture media Tc 199 by adding Dextran as an osmotic agent to compensate for the inactivity of the cornea's normal water removing metabolism at 4°C and this extended the reliable storage time for 2 – 3 days. Thereby the MK media became the storage of choice in many eye banks following successful transplantations¹⁸. Over the years many changes have been made to the MK media such as adding of the more stable HEPES buffer, replacing the penicillin antibiotic with gentamicin, adding 2.5% chondroitin sulphate – resultant K-sol which has made the solution more stable and extended storage time to 7 -10 days^{19, 20}. An improved solution to this in the name of dexol has also been introduced which has added dextran to this mixture. Optisol the latest available storage media has even better efficacy than others because it maintains better endothelial cell morphology. When stored between 2 and 6° C Optisol GS – added with gentamicin and Streptomycin has a storage time of 7 to 10 days²¹.
3. **Organ culture:** Developed by Doughman and Sperling this media uses storage temperatures between 31 and 37° C. This technique provides preservation up to 35 days.

CONCLUSION:

To conclude, active counseling by a motivated team to the families with no prior knowledge of corneal donation and low socioeconomic status, using efficient method for obtaining consent, early corneal retrieval preferably less than two hours, and retrieving cornea even in medico-legal cases without interfering with the functioning of the investigating agencies, autopsy surgeons and the courts of law, will increase the effectiveness of corneal transplantation.

With regards to the current scenario in Mauritius there is a considerable backlog of patients waiting for corneal transplantation. But as the law has been recently passed for allowing "Eye banking" the backlog could very well be treated with in the near future. In the foreseeable, corneal transplantation may be carried out in the laboratories rather than the theatre, that further milestones will be achieved.

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