

Chapter 3

THE LEGISLATIVE ASPECT

The legislation has helped a great deal in several countries for overcoming the problem of the huge gap between the demand and the actual procurement of corneas. Thus, in the U.S.A. where the first eye bank was opened as far back as in 1945, the real momentum for the growth of eye banking and Keratoplasty has taken place after the suitable legislative measures were introduced in the mid-seventies. For example, as against the total of 20,000 corneal transplants performed in the U.S. between 1961 and 1971, the number of transplants touched a figure of 36,900 in 1988 alone. As against the 6,000 eye donations received in 1967, the figure jumped to 83,758 in 1987. There is practically no patient wait-list as of today. The provisions relating to the "Presumed Consent" and "Required Request" incorporated in the legislation (see Appendix 'C' - Maryland Anatomical Gift Act, U.S.A., 1975¹) have played a great role in this regard in the U.S.A. It may be mentioned that like the U.S.A., similar laws are also in existence in other countries.

Provision of Presumed Consent¹

Maryland State was the first to enact a legislation in this regard in 1975 and many other States have followed suit in enacting similar legislation. The beneficial impact of the passing of this Act in Maryland was that the State became the largest supplier of corneas in the United States. The Act enables the Chief Medical Examiner, the Dy. Chief or an Asst. Medical Examiner, as the case may be, in any case where a patient is in need of corneal tissue for a transplant, to remove corneas from a dead body where the autopsy is required in accordance with the law (unless there is a pre-recorded objection or an intimation of objection from the next of kin of the deceased). As the removal of cornea does not affect the post-mortem findings in almost all the cases of death unlike the removal of other organs such as heart, liver or kidney (which would affect the post-mortem findings), the Chief Medical Examiner is empowered to remove the cornea without any other legal formality required to be completed. (See appendix C for full details of the Act). It may be also mentioned that the corneas received from these medical/legal cases constitute the most concentrated source of excellent quality tissue from relatively young donors predominantly deceased from trauma and it makes the chief pathologist the pivotal figure in determining whether the eye

¹ Article - "The Promise of International Eye Banking" by Frederick N. Griffith, Ex-Chief Executive Officer, International Federation of Eye & Tissue Banks, U.S.A. (Mr. Griffith on behalf of the IFETB had played an active role in upgrading the standards of eye banking in India).

collection will succeed or not. As compared to this, the quality of corneas procured from the dead body of a person dying due to old age is generally poor as the endothelium cell count, which is vital for a successful transplant especially in the case of a penetrating graft, deteriorates as the age advances. This is more so in a developing country like ours because of the generally poor standard of health of the average citizen.

In States where the presumed consent laws have not been yet enacted and where the permission to remove cornea must be obtained from the family of the deceased, new acquisition techniques have been developed. Hospital or organ procurement agency personnel, specifically trained in the appropriate techniques, are the most successful in approaching a bereaved family.

Provision of Required Request

Besides the inclusion of "Presumed Consent", the "Required Request" provisions of the law enacted in many States have also contributed to the increase in the volume of donor material. Under these provisions, it is mandatory for the individual hospital authorities to solicit eye donation from the next-of-kin in all cases of death. The effectiveness of this legislation has been varied depending on the specific terms of the law from State to State. Overall, however, this approach has had positive beneficial results.

Amending the Legislation - Indian Scenario

The first legislation in regard to eye donation was enacted by the then Bombay State under the name "The Bombay Corneal Grafting Act, 1957". Similar Acts were also passed by several other States.

The Eye Bank Association of India (EBAI), which is a registered body representative of all eye banks in the country, had felt that the then existing Acts passed by various states as well as by the Parliament had resulted in many difficulties and lacunae. To remove these difficulties, the EBAI prepared a Model Corneal Grafting Act (see Appendix A), which was sent in 1991 to the Ministry of Health and Family Welfare, Government of India, with a request that it should be passed by the Parliament and State Legislatures, with a view to help increase the procurement of corneas for combating corneal blindness. However, instead of enacting a comprehensive legislation on the pattern of the Model Act as proposed by the EBAI, the Central Government deemed it fit to pass the "Transplantation of Human Organs Act, 1994 (See Appendix 'B' for relevant extracts). The Act aims to regulate removal, storage and transplantation of all human organs including eyes for therapeutic purposes and for the prevention of commercial dealings in human organs and other related matter. The Act is applicable, in the first instance, to the States of Maharashtra, Goa and Himachal Pradesh and all Union Territories. The Act is also applicable to any other State which adopts it in accordance with the procedure prescribed therein.

The Act instead of making separate provisions for corneal grafting as was the case with "The Eye (Authority For Use For Therapeutic Purposes) Act, 1982," which was applicable to the Union Territory of Delhi and which has been repealed by the aforesaid Act, has clubbed the removal of eyes for therapeutic purposes along with the removal of all other human organs from the body of the deceased person.

Earlier, when the Bill titled "Transplantation of Human Organs Bill, 1992" was introduced in the Rajya Sabha in August 1992, the EBAI had pressed for certain amendments so as to facilitate an appreciable increase in the supply of corneas. It was then emphasized to the Government by the EBAI that what applies to other human organs cannot cover the donation of eyes inasmuch as eyes have to be donated within a time-limit of 4-6 hours after death during which period the corneas continue to be viable and they could then be preserved and utilised for corneal grafting. Further, eyes can be enucleated at any place, even at homes of the deceased and not necessarily in a hospital. Because of these basic differences, the EBAI had urged the Government that a separate Act governing the removal of eyes of deceased persons for therapeutic purposes should be enacted as was the case before. However, the Bill was passed by the Lok Sabha dealing with all human organs including eyes in the same form as it was earlier passed by the Rajya Sabha.

Effect of Human Organ Act on Eye Donation

The provisions of the Act, which adversely affect the eye donation and which require amendment, are dealt with below.

Permitting Trained Technicians to Enucleate Corneas

The Act empowers only a registered medical practitioner to remove a human organ including eyes for the purpose of transplantation. The provision of allowing a 'Technician' trained in enucleation procedure in the Ophthalmic Department of a hospital or teaching institution or certified by the Eye Bank Association of India for removal of corneas for the purpose of transplantation has not been included in the Act. (See provisions of Clause 3 (4) of Model Corneal Grafting Act - Appendix 'A'). This provision is necessary because the removal of corneas from a dead body can be easily effected by a trained technician, while the same is not possible in case of other organs such as kidney, liver or heart. This will save precious time of a Registered Medical Practitioner as it is very cumbersome for the practicing medical practitioner to spend a minimum of two to three hours for attending to a call for enucleation of corneas from a dead body, in cases where the cornea is to be enucleated at the residence of the deceased. Sometimes, such calls may be received at odd hours when it is impossible for a medical practitioner to leave his practice and rush to the spot where the dead body is lying for the purpose of enucleation.

Removal of Corneas from Unclaimed Dead Bodies

In case of unclaimed dead bodies lying in a hospital or prison, Section 5 (1) of the Act provides for removal of human organs including eyes from the dead body only after 48 hours from the time of death. In fact, Section 5 (2) of the Act further provides that the authority for the removal of human organs including eyes cannot be given even after the lapse of 48 hours after the occurrence of death if the person competent to give such authority has reasons to believe that any near relative of the deceased person is likely to claim the body even after the lapse of 48 hours in question. This is a damaging provision as the cornea removed after 4 to 6 hours of death, has no viability for the purpose of transplant. It is, therefore, necessary that the period during which the eyes can be removed should more or less conform to the provisions existing in the Delhi Eyes Act, 1982 with suitable alterations in order to improve the supply of corneas appreciably.

Further, the term "Unclaimed Bodies" occurring in Section (5) of the Act need to be defined as follows as suggested by the EBAI. "Unclaimed Body means (a) the body of deceased person who was admitted in the hospital without any address or who has not been visited in the hospital by any attendants from the time of his admission and remains unattended till death and has no relatives to claim his body within such time as may be prescribed; (b) Dead body of a person or a child recovered by the police as unclaimed; (c) A prisoner, who does not get any letters or has not been visited by any relation in the jail and dies or is hanged and his body is not claimed by any relation."

Removal of Corneas from Bodies sent for Post-mortem Examination for Medico-Legal or Pathological Purposes

In case of bodies sent for post-mortem examination for medico-legal or pathological purposes, the Human Organs Act, while giving the authority for removal of human organs including eyes from the body of the deceased person provides that the person competent under the Act to give authority for the removal of any human organ from such dead body (who, it is presumed, should be the Coroner/Doctor carrying out post-mortem examination) has to **satisfy himself** that the **deceased person has not expressed**, before his death, any objection to any of his organs being used for therapeutic purposes after his death or where he had granted an authority for the use of any of his organs for therapeutic purposes after his death, he had not revoked such authority before his death. These wordings make it somewhat difficult for the Coroner / Doctor performing post-mortem to remove corneas without asking the relatives of the deceased to ascertain if the deceased had expressed any objection to removal of corneas. It may be noted that in the Presumed Consent Law as prevailing in the USA, this formality is not required and the Law is more positively framed. See Page 51. The provisions in our Act ought to have been worded on the similar lines as in the USA.

Registration of Eye Banks, Eye Donation Centres & Hospitals or Places where corneal transplants are performed

Section 14 of the Act also provides for compulsory registration of hospitals engaged in removal, storage or transplantation of any human organ for therapeutic purposes. This would mean that eye donation centres / eye banks / hospitals or other places where corneal transplants are performed will require the registration by the State Government. Under the rules framed by the State Government in Maharashtra, a common form is prescribed for registration of all the places (see page 26. After the necessary application is made for registration, a visit is made by the official from the Health dept. for verification of the information provided in the form. The rules also require renewal of registration every five years. In the author's opinion, separate forms for registration of eye donation centres / eye banks and places where the actual transplants take place would have been more appropriate.

Restrictions on Removal and Transplantation of Eyes during Life-time

Section 9 of the Act provides for removal of human organs for the purpose of transplantation before death of a person under certain restricted circumstances specified therein. Ethically, eyes are not removed during the life time of a person and cannot be donated. It will be, therefore, necessary that the human eyes should be excluded from the purview of the donation of human organs before death of a person as provided for under Section 9.

Need for Inclusion of "Required Request" provisions

While initially the EBAI had not asked for inclusion of 'Required Request' provisions in the Act, after having interaction with the IFETB, has followed up with the Government of India to include the same. It would be certainly helpful if such a request is made by the hospital or other concerned authorities and in quite a few cases the family of the deceased, if motivated properly would respond positively to such a request.

Conclusion

The legislation in the U.S.A. and other developed countries, which provides especially for the inclusion of the positively worded 'Presumed Consent Law' and the 'Required Request Law' has led to a completely altered scenario vis-à-vis procurement of viable quality of corneas. The author having been convinced that this will go a long way in our country too, had followed up vigorously for the same amendment in our Act during his tenure as President Elect and as President of EBAI (1995-2001). This included the follow-up and meetings with Ex-Attorney General Shri Ashok Desai and Ex-Law

Ministers Shri Ramakant Khalap and Shri Ram Jethmalani besides the follow-up with concerned officers in the Health Dept., Govt. of India.

As per the latest feedback received, the provisions as regards the amendment for Presumed Consent and the inclusion of Required Request have been accepted by the Govt. of India and the Law Ministry has already cleared the same. It is now expected that the Parliament will clear the same. However, the other amendments viz. permitting the trained technicians for enucleation and the retrieval of corneas from unclaimed dead bodies have not been accepted.

APPLICATION FOR REGISTRATION OF EYE BANK/EYE BALLS COLLECTION CENTER/EYE BALL COLLECTION & PROCESSING, STORAGE & UTILIZATION CENTER

(A) HOSPITAL :

1. Name :
2. Location :
3. Government/Private/ Voluntary :
4. Teaching/Non-Teaching :
5. Approached By :
6. Demand Generation For Eye Donation :

(B) REMOVAL OF EYE BALLS AND STORAGE :

1. Availability of adequate trained & Qualified personnel for removal of eye balls (give details) :
2. Names, Qualification & address of the doctors who will be doing enucleation :
3. Whether register of recipient wait list available :
4. Telephone arrangements available :
5. Availability of ambulance or vehicle or funds to pay taxi for collecting eye balls from outside :
6. Sets of instruments for removal of eye balls :
7. Refrigerator for preservation of eye balls :
8. Special bottles with stands for preservation of eye balls during transit :

(C) PRESERVATIONS OF CORNEAS :

Arrangements for preservation of Corneas, Sclera and vitreous in glycerine & molecular sieve or other preservative :

(D) PATHOLOGY & RECORDS :

1. Arrangements for maintaining the records. It should have one clerk-cum typist available to maintain the records :
2. List lamp with Camera :
3. Pachymeter with A Scan :
4. Photographic arrangements :
5. Arrangements for registration of cases of donors & follow up of cases :

(E) EQUIPMENT

1. Instruments for keratoplasty and Corneal Surgery work and other ophthalmic instruments :
2. Full-fledged operation theatre with Anaesthesia :

(F) LABORATORY FACILITIES

(If the information is exhaustive, please annex it) :

1. No. of permanent staff with their designations :
2. No. of temporary staff with their designations :
3. Names of the investigations carried out in the department :
4. Names and no. of equipment available :YES/NO

If no where do you avail it? Please mention name, address of institute & distance from the said unit.

(G) KERATOPLASTY TEAM

(If the information is exhaustive, please annex it)

1. No. of Beds :
2. No. of permanent staff member with their designations :

3. No. of temporary staff with their designations :
4. No. of Eye Balls collected, if any, if yes, mention the collection during last 2 years :YES/NO
5. No. of Eye Balls processed, if any, if yes, mention the processing during last 2 years :YES/NO
6. No. of keratoplasty operations done, if any. If yes, mention no. of keratoplasties done during last 2 years :
7. No. of trained persons available for keratoplasty transplantation, their name, qualification :

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank draft / Cheque of Rs.1000/- is being enclosed.

Head of the Institute

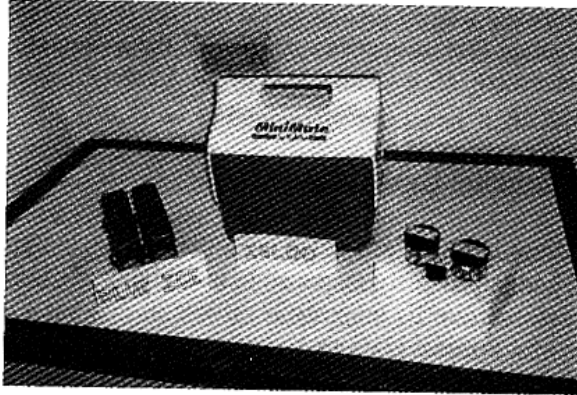


Illustration 3
Igloo containing blue ice and two bottles for holding eye balls.
The smaller bottle contains blood sample

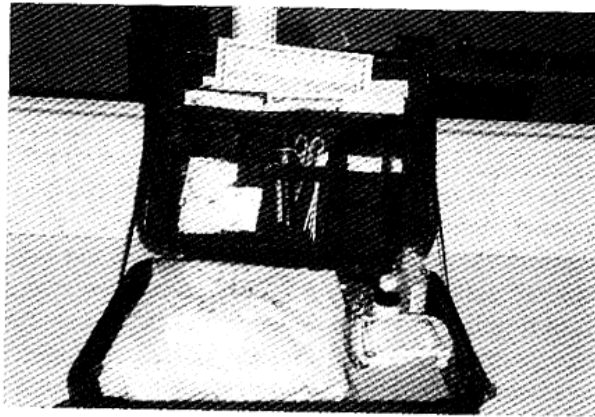


Illustration 4
A briefcase carried by technician or doctor containing enucleation set
and other items while attending call for enucleation.

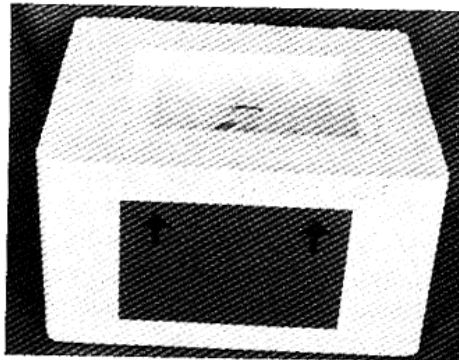


Illustration 5
Thermocole box (top cover removed) for transplant of eye balls /
corneas. The bottles containing eye balls / corneas are kept in the
hollow space in the middle and packed in ice all around