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**Corneal Donor Study (CDS)
Questions and Answers**

1. What is the cornea?

The cornea is the clear tissue covering the front of the eye. It is the “front window” through which light enters the eye.

2. Why is the cornea important for vision?

It is the main focusing element of the eye. Vision will be dramatically reduced if the cornea becomes cloudy from disease, injury or infection.

3. What is a corneal transplant?

This is a surgical procedure which replaces a disc-shaped segment of an impaired cornea with a similarly shaped piece of a healthy donor cornea.

4. How many transplants take place in the U.S.?

Each year in the United States, more than 33,000 people need cornea replacements to regain their sight. The cornea is one of the most frequently transplanted parts of the human body. Source: Eye Bank Association of America. 2006 Eye Banking Statistical Report. Washington, DC: EBAA; 2006.

5. How successful are cornea transplants?

In the United States, over 90% of all cornea transplant operations successfully restore the corneal recipient's vision. Source: EBAA website (<http://restoresight.org/general/faqs.htm#6>)

6. Is there a waiting list for corneas?

Although the supply of donor corneas has been adequate for the last decade in the United States, at times there may be waiting lists for corneas at individual eye banks. Internationally, there is a great shortage of donor corneas. Recent changes in the Food and Drug Administration's regulations regarding corneal transplantation are even more stringent with regard to testing and safety. These changes will impact the supply and decrease the pool of eligible donors.

7. What impact will refractive surgery have on cornea donation?

Patients who have had refractive surgery are not candidates for cornea donation. Therefore the increasing number of refractive surgeries will impact the donor pool.

8. Is the international demand for corneas high? Can corneas from the U.S. be used internationally?

International demand for corneas is high and corneas not used in the U.S. can be used internationally.

- There are currently five million people in India who are waiting for cornea transplants. A great number of those who are blind in India are young adults or children.
- People who live in developing countries are five to ten times more likely to go blind than those who live in highly-industrialized nations. Ninety percent of the world's blind live in developing countries.
- Every minute a child somewhere in the world goes blind.
- Treatments available to prevent and cure blindness are among the least expensive, most successful, and most cost-effective of all health interventions.
- Eighty percent of blindness in the world is avoidable.

Source: SightLife Eye Bank website (http://sightlife.org/sight_faq.cfm)

9. Who can be a cornea donor?

Anyone can. Cataracts, poor eyesight (wearing glasses or contact lenses), or age do not prevent you from being a donor.

10. What is an eye bank?

An eye bank is the link between people who donate their eyes and people who help restore sight. An eye bank is a non-profit organization which obtains, medically evaluates and distributes eyes donated by individuals for use in corneal transplantation, research, and education.

11. How are donor corneas tested?

The donated eyes and the donor's medical history are evaluated by the eye bank in accordance with the Eye Bank Association of America's (EBAA) strict Medical Standards and Food and Drug Administration (FDA) Regulations. EBAA provides standards for eye banks to use in training personnel to evaluate donor eyes.

12. How are donor corneas stored?

Corneas are stored at refrigerator temperatures in a protective fluid (tissue culture medium) with added antibiotics.

13. How long can corneas be stored?

A cornea is usually transplanted within three to seven days of donation, but corneas may be stored for up to two weeks in some situations.

14. What is the Cornea Donor Study (CDS) and what were the goals of the CDS?

The Cornea Donor Study (CDS) is a prospective cohort study with the following objectives:

- To determine whether the graft-failure rate over a 5-year follow-up period following corneal transplantation is the same when using corneal tissue from donors older than 65 years of age compared with tissue from younger donors.
- To assess the relationship between donor/recipient ABO blood type compatibility and graft failure due to rejection.
- To assess corneal endothelial cell density, the number of the critical cells on the back of the cornea which help keep the cornea clear, as an indicator of the health of the cornea and as an alternate outcome measure (in an optional secondary study).

15. When did the CDS begin?

The study enrolled its first patient in January 2000 and completed patient enrollment in August 2002. The last patient completed their five-year follow up exam in December 2007.

16. How many people participated in the CDS?

The study enrolled 1101 individuals who needed a cornea transplant.

17. Who paid for this study?

The CDS was supported by the National Eye Institute, National Institutes of Health, Department of Health and Human Services. Additional support was provided by the Eye Bank Association of America, Bausch & Lomb, Inc., Tissue Banks International, Vision Share, Inc., San Diego Eye Bank, The Cornea Society, Katena Products, Inc., ViroMed Laboratories, Inc., Midwest Eye-Banks (Michigan Eye-Bank, Illinois Eye-Bank), Konan Medical Corp., Eye Bank for Sight Restoration, SightLife, Sight Society of Northeastern New York (Lions Eye Bank of Albany), and Lions Eye Bank of Oregon.

18. How was the study conducted?

The study coordinating center directed donor corneas from eye banks to corneal surgeons with eligible patients. The donor corneas were assigned to recipients in a way that randomized donor age. Surgeons and patients were not given information on donor age, so that bias in determining outcomes would be avoided.

19. Where was the study conducted?

The CDS was coordinated by the Jaeb Center for Health Research in Tampa. One hundred and five corneal surgeons and 43 individual eye banks throughout the United States participated.

20. What did the CDS find out about donor age effect?

- Cornea transplants using tissue from older donors have similar rates of survival to those using tissue from younger donors.
- The five-year transplant survival rate was 86 percent for both the 12 to 65 and the 66 to 75 donor age groups.

- The distribution of the causes of corneal graft failure did not differ between donor age groups.

21. What did the CDS find out about donor cells?

- Results from our Specular Microscopy Ancillary Study, the portion of the study that evaluated cells in the cornea before and after transplantation and over time, indicate that among the successful cases, there is a slight association between donor age and endothelial cell loss, with the cell loss after 5 years being slightly lower in corneas from younger donors.
- Whether this slight association between cell loss and donor age is of clinical importance is not known.
- Irrespective of donor age, endothelial cell loss is substantial over the first five years after transplant even when the graft has been successful.

22. What do the study results mean for the cornea donor supply?

The Eye Bank Association of America (EBAA) does not set an upper limit on donor age. However, many eye banks in the United States set a limit of 65 years of age because some surgeons were reluctant to use corneas from older donors due to uncertainty about whether transplants using corneas from older donors did as well as those from younger donors.

The CDS findings are likely to expand the available donor pool for many eye banks and to persuade surgeons to use corneas from older donors.

23. Would the recommended change in medical practice have an impact on visual outcome?

Corneal transplantation, itself, improves visual outcome. However, the recommended inclusion of older corneas in the donor pool has no effect on visual outcome. It will have a favorable effect on availability of corneas for transplantation.

24. What will be the economic impact of the recommended change in medical practice?

- From a cost perspective, there will be a savings for each transplant that can be performed on a scheduled rather than emergency basis.
- For a patient, it is far preferable to have a reduced waiting time, to have corneal transplantation surgery scheduled, and to be able to plan for time off from work and other life situations rather than living with the uncertainty of when tissue will be available.
- Acquisition of corneas from older donors will increase the cost to eye banks because corneas from older donors are less likely to be suitable for transplantation for reasons other than age. However, if the increased retrieval of older tissue increases the number of transplants that are performed, the costs to the eye bank will be offset by the reimbursements they receive from use of the corneas.

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25. What is the quality of life impact of the recommended change in medical practice?

Expansion of the donor pool will have a positive effect on quality of life for individuals who need a corneal transplant by increasing the efficiency of providing donors and potentially the number of recipients.

26. What is the most important thing the public should know about the Cornea Donor Study result?

- The cornea donor age pool should be expanded to 75 years.
- Surgeons and patients now have evidence that older donor corneas are suitable for transplantation.

27. What will happen next in this study?

Patients already followed through 5 years who give permission to continue in the CDS will be followed for at least 5 more years to allow us to get more information on possible long-term effects of donor age and other variables of corneal transplantation.

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