

***In situ* cornea harvesting through the Red Cross Organization: a new approach to relieving severe cornea donor shortage in Chinese eye banks**

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Abstract

• **Corneal diseases are currently the second main cause of blindness in China. Although most of the corneal blindness could be treated by corneal transplantation, only about 10 000 operations were carried out each year owing to the severe shortage of corneal donors and limited eye bank programs. A feasible cornea donation program was established through the organization of the Red Cross, and *in situ* corneal removal techniques were developed to avoid conflicts with Chinese traditions of keeping the deceased intact. The number of donated corneas, which had a safe and secure quality, increased significantly year by year.**

• **KEYWORDS:** cornea; donor; transplantation; eye bank

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INTRODUCTION

Corneal diseases are currently the second leading cause of blindness in China, with approximately 500 000 of 3 million patients who have corneal diseases losing eye sights binocularly^[1-3]. Although 90% of the corneal blindness can be successfully treated by corneal transplantation, only about 10 000 corneal transplantation surgeries can be carried out every year in China owing to the severe shortage of corneal donors and uneven development of eye bank programs in China^[4]. As a result, most of the corneally blinded patients

have to spend the rest of their lives in darkness, waiting for a piece of freshly donated cornea.

With regard to the scarcity of cornea donors in China, there are profound social and cultural roots. First, influenced by thousands of years of traditional view that body must remain intact even after death, most people are not in favor of organ donation (cornea donation included), with less than 0.1% of the deceased donated each year^[5]. Second, China has not yet promulgated any law regarding organ donation; thus to solve donation problem through legislation is not possible at the moment^[6].

From 2007 onwards, we have been exploring ways to establish feasible cornea donation programs with the help and Organization of the Red Cross. Meanwhile, we have innovatively modified the method of corneal removal to obtain quality donor corneas without damaging the eye globe^[7]. Consequently, the number of cornea donation in Shandong Province has increased steadily year by year.

METHODS

The study was approved by the Ethics Committee of Shandong Eye Hospital and conformed to the tenets of the Helsinki Declaration.

Preparation Before Corneal Donation and the Donating Process The consent forms of donation offered by the Red Cross were signed by donors when they were alive, or by relatives of those deceased who had wills to donate. After the deaths were announced, the doctors of the eye bank would acquire the corneas from the donors. The timing and medical standards for donor cornea harvesting were established based on the Eye Bank Association of America guidelines^[8].

Modified *in Situ* Cornea Harvesting Procedure The corpses were required to be kept in hospitals or relatively sanitary conditions before cornea removal. The cornea removal procedure was as follows: 1) sterilize the eye before removing the cornea. After puncturing the anterior chamber near the corneal limbus, fill the anterior chamber with Healon to protect the endothelium, remove the cornea with 1 mm sclera, and then directly place it in the preservation medium (Figure 1). A contact lens was used to cover the operation area; 2) the donor cornea was detected by slit lamp microscopy for the transparency, folds in the Descemet membrane, integrity

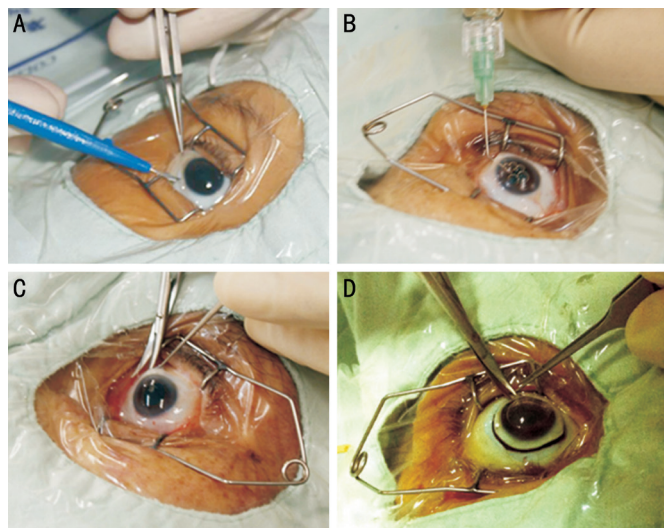


Figure 1 Process of obtaining corneas *in situ*. Puncture the anterior chamber using a 15° straight knife from 1-2 mm outside of the edge of cornea (A), and then inject Healon to the anterior chamber to protect the endothelium (B); cut off the cornea with 1 to 2 mm sclera (C). The sclera is cut with scissors for 360 degrees at 2 mm posterior to the limbus (D).

of the corneal epithelium. Time of harvesting and storage was recorded. Endoscopy was used to examine the density of corneal endothelium. If the density was more than 1800 cells/mm², the donor could be applied to penetrating keratoplasty. Otherwise, the donor was used for emergency penetrating keratoplasty or lamellar keratoplasty; 3) donors were detected for hepatitis B, hepatitis C, syphilis and HIV through the vein blood or heart blood to prevent the spread of such diseases^[9]. Part of the donor conjunctiva or sclera was collected for bacterial, fungal and other biological tests.

RESULTS AND DISCUSSION

According to the survey, over 80% of the donors' families were in favor of *in situ* cornea donation, which was in contrast to less than 20% of acceptance for enucleation. According to the statistical data from the Shandong Red Cross Eye Bank, 2532 donor corneas were obtained from June 2007 to December 2016, in which 775 cases (30.6%) were obtained through the traditional method (enucleation), while 1757 cases (69.4%) were through the new *in situ* method. The latter constituted only 17% in 2007, but steadily increased in the following years (Figure 2). This clearly showed a growing acceptance of the new method among people.

Of all the 1757 corneas harvested with our modified *in situ* procedure, no contamination ever took place, despite three cases of bacteria detection (two cases of staphylococcus epidermidis and one case of micrococcus roseus) through swab culture. There was no corneal graft infection after surgery. The cornea quality was observed by slit lamp microscopy in the early years, and about 4/5 donor corneas could be used for penetrating keratoplasty. Corneas with an endothelium

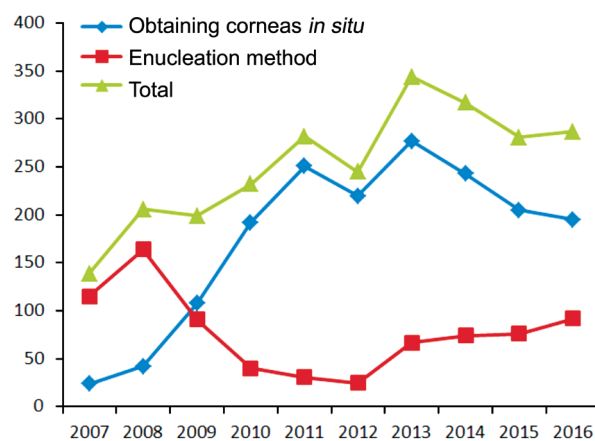


Figure 2 The number of donor corneas from 2007 to 2016 in the Shandong Red Cross Eye Bank.

density of more than 1800 cells/mm² remained transparent after penetrating keratoplasty. Positive hepatitis B surface antigen was found in 18 blood samples. These donor corneas were sent to the laboratory for research, but not for clinical transplantation. No syphilis or AIDS-positive specimen was detected. A study entitled “Survey of Infectious Keratitis Patients” was carried out in 28 provinces and municipalities in 2013. As many as 150 thousand to 200 thousand corneally blind patients emerged as a consequence of trauma, in which bacterial and fungal keratitis contributed to about 51% to 69%^[10-11]. According to a previous study, the status of most eye banks is depressing^[12], with extremely limited source of donor corneas, and almost no stock^[13-15]. Lots of eye banks are trying to live on importing donor corneas from the US, Sri Lanka, and other countries, but this hardly solves the problem. The fact that over 95% of corneally blinded patients have to wait for donor corneas in dark for the rest of their lives is China's tragedy. In 2011, Jiefu Huang, Ex-Deputy Minister of Health Ministry of China, promised that the abnormal practice of obtaining organs mainly from the executed prisoners must be stopped within 3 to 5y. Indeed, the government has made tremendous efforts in strengthening the management and promoting organ donation. Cornea donor shortage remains an urgent medical problem in China, and there is a long way to go to resolve it.

Currently in China, collaboration with the Red Cross in donation programs has at least 3 advantages. First, it has a mature system with a large number of branches all over China, making it possible to publicize the idea and merit of cornea donation even in the smallest districts like counties and villages. Second, consent form filling-in and related processes can be done locally with the help of the Red Cross, which encourages and avails more potential donors. Third, it also plays a great role in bridging donors to eye banks, which prevents the possibility of cornea trading since direct contact of donors with doctors is avoided. Our innovative

method of corneal removal represents an important alternative to the traditional procedure in keeping the eye intact while sustaining cornea quality. It hardly changes the appearance of the deceased, which in China, is far more acceptable by the relatives of the donors. By contrast, the traditional method of obtaining cornea, *i.e.* to extract the whole eyeball, can be a torment to the kin of the deceased. It is inspiring that the number of cornea donations is on the rise every year in Shandong Province due to the support of the Red Cross and the new tradition-respected method. We believe that our success will significantly improve the lives of millions.

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