

# The lived experiences of patients undergoing acellular porcine corneal stroma transplantation

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## Abstract

• To explore the lived experiences of patients undergoing acellular porcine corneal stroma (APCS) transplantation, a descriptive, qualitative design was performed. A purposive sample of 13 patients who underwent APCS transplantation to treat progressive infectious keratitis were enrolled in the semi-structured, open-ended interviews. The taped and transcribed interviews were analyzed using a thematic analysis approach. Alterations in the transparency of APCS grafts were accompanied by a gradual improved visual acuity (before surgery:  $1.38 \pm 0.91$  logMAR; 3mo postoperatively:  $0.40 \pm 0.24$  logMAR, respectively). Accordingly, in terms of lived experiences, the patients generally reported “negative” experiences before the operation and during the early postoperative period, but this was greatly improved 3mo after surgery. Four main themes were derived: anxiety and fear, stigma, lifestyle change, and gratitude and insights. Conclusively, health care professionals should provide holistic care for patients, proactively promoting patients’ physical and mental health.

• **KEYWORDS:** corneal transplantation; xenotransplantation; quality of life

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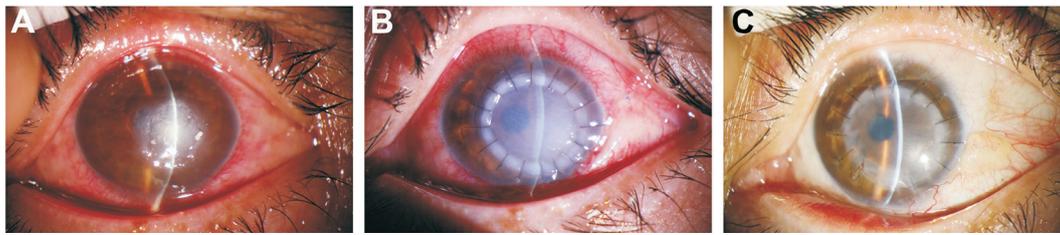
## INTRODUCTION

Therapeutic keratoplasty is an effective strategy for managing progressive infectious keratitis when infections do not respond to systemic and topic antimicrobial therapies<sup>[1]</sup>. However, many patients miss the optimal time-window for surgical treatment due to the limitations of the donor cornea source<sup>[2]</sup>. There have been many efforts to fabricate corneal replacements. Of them, acellular porcine corneal stroma (APCS) has been shown to be a promising alternative for human donor corneas, as it exhibits similar structure and refractive properties to that of human tissue and is not limited by availability. APCS is made from porcine cornea after decellularization<sup>[3]</sup>. Its efficacy and safety has been validated in both pre-clinical animal studies and human clinical applications<sup>[4-5]</sup>. Nevertheless, very little is known about the lived experiences of patients in the context of APCS transplantation. Organ transplant patients have been reported to face varying degrees of social function problems, such as difficulty interacting with the social environment (*e.g.* families and friends) and incapability of carrying out social tasks (*e.g.* return to work)<sup>[6]</sup>. Despite that the cornea is the most successful organ to transplant, these patients might still inevitably be at risk of a variety of psychological problems. Therefore, in this study, we conducted qualitative research to investigate the lived experiences of Chinese patients undergoing APCS transplantation. The aim of the study was to better understand changes in recipients’ psychological issues and social adaptations before and after the operation, thus offering health care professionals practical suggestions for APCS recipients.

## METHODS

This study was approved by the Ethics Committee of the study hospital, performed according to the principles of the Declaration of Helsinki and registered at <http://www.clinicaltrials.gov> (No.NCT03105466). Each participant signed an informed consent form before the study.

**Study Design and Participants** Purposive sampling was used to select a group of patients who underwent APCS-based deep anterior lamellar keratoplasty (DALK) to treat progressive infectious keratitis at a university-affiliated ophthalmic center during 2016. The sample size was determined based on the concept of data saturation. The eligible participants were aged 18y or older with infectious keratitis and able to understand and express themselves in Mandarin or Cantonese. The



**Figure 1** Representative slit lamp biomicroscope photographs of APCS transplants A: Preoperatively; B: 1wk after surgery; C: 3mo after surgery.

exclusion criteria included: 1) patients with nonkeratitis vision deterioration (except cataract and ametropia); 2) patients with a history of other ophthalmic surgeries; 3) patients with serious heart, lung, or brain disease; and 4) patients who underwent repeated transplantation with human corneas because of recurrent infection.

**Data Collection and Analysis** The data were reported following the guidelines of Consolidated Criteria for Reporting Qualitative Research (COREQ)<sup>[7]</sup>. Semi-structured, face-to-face, in-depth interviews were conducted at 3mo after operation by an experienced qualitative researcher. The interviews were recorded with a Sony ICD-TX650 stereo audio digital recorder. Within 24h after the interview, the recording was imported to Nvivo11.0 (QSR International Pty Ltd., Australia) and transcribed verbatim. Thematic analysis was used to treat the data following the 7-step Colaizzi method<sup>[8]</sup>.

**RESULTS AND DISCUSSION**

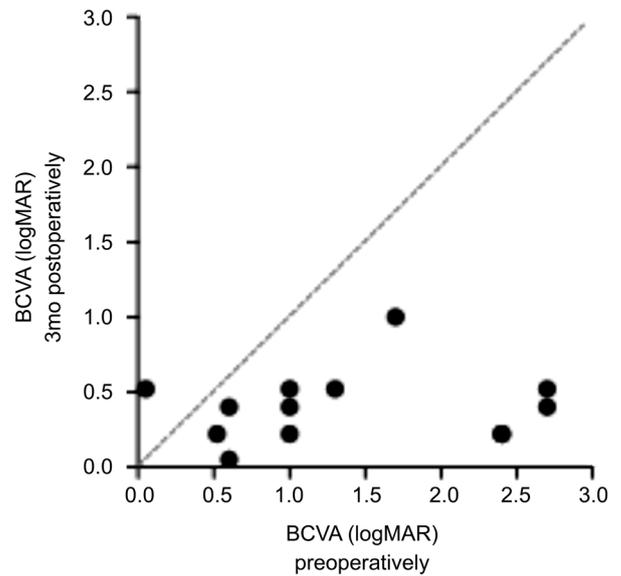
**Patient Demographics** Thirteen patients were enrolled in the study (Table 1). The participants had an average age of 48.31y, and 69% of them were male. All the participants were married. The 54% of the participants graduated from elementary school, 23% graduated from junior high school, and 23% graduated from senior high school. Moreover, 69% were farmers or physical laborers, and 46% had a monthly income of ≤3000 CNY (per person, equal to 434.43 US\$).

**Clinical Assessment** Ten patients were diagnosed with fungal keratitis, two with herpes simplex keratitis (HSK), and one with *Acanthamoeba* keratitis. The APCS transplants were opaque at the time of transplantation and became increasingly transparent over time (Figure 1). Visual acuity in the affected eyes before keratoplasty and at 1wk, 1 and 3mo after surgery was 1.38±0.91, 1.83±0.56, 0.83±0.47, and 0.40±0.24 logMAR, respectively. Twelve out of 13 patients showed improvement in visual outcomes 3mo postoperatively (Figure 2). The visual acuity of the unaffected eye was 0.17±0.47 logMAR (Table 2).

**Lived Experiences**

**Theme 1: Anxiety and Fear**

**Preoperative fear of pain and loss of vision** Before the operation, six patients complained of unbearable eye pain, sensitivity to light, tearing, and eyelid spasms. Moreover, these participants expressed concerns about loss of vision and even enucleation of the eye.



**Figure 2** Visual outcomes improvement after APCS transplantation Counting fingers, hand motion and light perception were given logMAR values of 0.004, 0.002 and 0.001, respectively.

**Table 1** Characteristics of the participants n (%)

Parameters	Data
Age, y	48.31±7.09
Gender	
Male	9 (69)
Female	4 (31)
Level of education	
Illiterate	0 (0)
Primary school	7 (54)
Junior high	3 (23)
Senior high	3 (23)
College	0 (0)
Marital status	
Married	13 (100)
Occupation	
Farmer	5 (38)
Physical labor	4 (31)
Cadre	1 (8)
Other	3 (23)
Monthly income (CNY)	
<3000	6 (46)
3000-5000	1 (8)
5000-8000	2 (15)
>8000	4 (31)

SD: Standard deviation.

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**Table 2 Preoperative clinical assessment of participants** n (%)

Parameters	Data
Indications for surgery	
Fungal keratitis	10 (76.9)
<i>Acanthamoeba</i> keratitis	1 (7.7)
HSK	2 (15.4)
Ulcer size (mm, mean±SD)	4.54±1.27 (3-7)
≥3 and ≤5	10 (76.9)
>5	3 (23.1)
Graft size (mm, mean±SD)	7.46±0.2 (7.25-7.75)
Hypopyon	1 (7.7)
Preoperative BCVA (logMAR, mean±SD)	
Affected eye	1.38±0.91
Better eye	0.17±0.47

HSK: Herpes simplex keratitis; SD: Standard deviation; BCVA: Best corrected visual acuity.

*I could not stand the eye pain, especially at night. Painkillers did not work (#10, female, 47 years old).*

*I was worried about having to remove my eye. I saw this happen to other patients at my local hospital because of keratitis (#1, male, 46 years old).*

**Postoperative concerns about outcomes** The recipients were anxious early after the operation and were concerned about surgical outcomes, including recurrent infection and graft rejections.

*It had been a while since the operation. I still could not see things clearly. I was very worried and could not get this out of my mind (#2, male, 58 years old).*

**Worries about medical expenses** In this study, nine participants had borrowed money from their friends or relatives to pay for medical expenses. Moreover, after discharge, the family members of all participants resigned from work or took a leave of absence in order to take care of the participants.

*My wife stayed at home to take care of me. I had no job and no income (#5, male, 43 years old).*

### Theme 2: Stigma

**Hiding the truth** Most participants generally chose not to tell their relatives other than their spouses and children that they had a porcine cornea. Furthermore, the participants were even concerned that their spouses and children would not be supportive if informed.

*I told my friends that it is a human cornea. Otherwise, they may say “she has a porcine eye” or the like behind my back (#12, female, 45 years old).*

**Shunning media interviews** APCS received a great deal of attention from domestic and international media. Our study showed that seven participants shunned media interviews. Two of these participants, who originally accept media interviews, mentioned that they were reluctant to participate in the interview, even though they did not decline the interview

beforehand. Six participants said that they would agree to media interviews and hoped that APCS could help other patients as well.

*I shunned media interviews. This was not a glorious condition. I do not want others to know about my condition (#7, male, 51 years old).*

**Changed appearance of the eye** Unlike human corneas, APCS was not yet fully transparent in the early postoperative period. Therefore, early after discharge, the participants usually stayed indoors and reduced social activities. They did not want others to notice the changes in their eyes. In public, the participants would try to cover up by closing their eyes or wearing sunglasses. Three months after the operation when the APCS graft became transparent, most participants gradually resumed normal social activities and no longer tried to cover up when interacting with others.

*In the early postoperative stage, my eye looked white and ugly.*

*I wore sunglasses so hopefully others would not notice. Now I think my eye is getting better, and I no longer wear sunglasses (#5, male, 43 years old).*

### Theme 3: Lifestyle Change

**Sexual life** In our study, all participants were noted to have varying degrees of problems in their sexual life since the time of disease onset, including less sexual activity and shorter sexual intercourse, because of eye discomfort or concern about the surgical outcomes affected by sexual behaviors. Moreover, the participants were found to be interested in learning whether sexual activity may affect their eye rehabilitation. However, before the interview, they were too shy to ask the health care professionals about sexual activity.

*Since I got sick, I did not have sex life, as I was concerned that it may affect my eye. Now I am no longer concerned, but I still rarely have sex (#11, male, 33 years old).*

**Daily activities limitations** All participants were working before disease onset. However, since onset, their family members limited the participants' activities, even if it was within the participants' capability. Three months after the operation, only nine participants returned to work.

*After discharge, I stayed at my daughter's home. She forbade me from going out. I was not allowed to engage in any farm work (#6, female, 50 years old).*

### Theme 4: Insights for Organ Donation

Two participants reported that they intended to donate their cornea and any other usable organs upon death in order to help others.

*With this experience, I would like to donate my cornea (if still usable), as well as any other usable organs (such as the kidneys), upon death (#5, male, 43 years old).*

To health care professionals, APCS transplantation raises a number of new challenges for psychological rehabilitation in patients. Xue *et al*<sup>[9]</sup> previously showed that APCS recipients

had predominantly “negative” experiences through three days after the operation. However, it should be noted that Xue *et al*<sup>[9]</sup> enrolled both patients who underwent therapeutic keratoplasty and those who underwent optical keratoplasty. Patients undergoing optical keratoplasty may have higher expectations for vision restoration than those undergoing therapeutic keratoplasty. In addition, another cause accounting for predominantly negative experiences in Xue *et al*'s<sup>[9]</sup> study may be related to the different healing pattern of APCS transplants. The APCS graft is still opaque early after the operation, but in the later recovery stage, the graft became more transparent and vision acuity was improved accordingly<sup>[4]</sup>. Therefore, our findings indeed show varying degrees of negative experiences in patients early after the operation. However, the negative experience was ameliorated thereafter. Therefore, before surgery, there is a need for health care professionals to provide detailed information about the postsurgical recovery process. After APCS transplantation, especially during the early postoperative period, paying attention to both psychological and physiological rehabilitation is necessary to help recipients cope with their physical and mental issues.

APCS transplantation is xenotransplantation by nature. At present, xenografts used in clinical practice include heart valves and islet cells<sup>[10-11]</sup>. Studies have shown that patients with xenotransplantation may present various psychosocial issues, including concerns about zoonoses and the risk of animal-derived infection<sup>[12]</sup>. The acceptance of animal transplants by potential recipients and the general public, though recently improved recently, is still relatively low<sup>[13]</sup>. The acceptance is even lower in areas under conservative cultural dominance, such as China. In our study, all participants expressed concerns about the origin of APCS. They felt shameful and stressed with a porcine cornea. Most participants shunned media interviews, believing that this was not a glorious condition. Therefore, our findings serve as a useful reminder to the media and health care professionals to protect patients' privacy, which sometimes may still be ignored in China.

Sex is an important factor in determining quality of life and has attracted a great deal of attention in recent years. Many patients, especially those undergoing surgical treatment, face the issue of an impact on sexual activity. Several studies reached a similar conclusion to that of our study. Health care professionals generally do not proactively educate patients about sexual activity, and many do not have an in-depth knowledge of sexual health. Additionally, patients and their spouses are too shy to inquire about a postoperative sex life, even when they need guidance<sup>[14]</sup>. This situation is especially pronounced in China owing to the influence of traditional Chinese culture. At present, Chinese health care professionals were found to generally lack the necessary knowledge to provide guidance on sexual health and turn a blind eye to

the patient's sexual health<sup>[15]</sup>. However, no studies have been conducted to investigate when patients could resume sexual activity, the frequency of sex, or sexual positions after keratoplasty.

This study also has some limitations. First, the interview was conducted three months after the operation when the sutures were removed and vision acuity was largely restored. The long-term lived experiences of APCS recipients needs to be investigated. Second, only a small number of patients were enrolled in this study. Conclusively, this study demonstrated physical and psychological issues in APCS recipients during the course of treatment. It provides a valuable reference for medical practice in a number of ways. First, health professionals should provide detailed information about APCS before the operation to improve the acceptance of APCS. However, during their decision-making process, the patients' right to self-determination should be fully respected. Second, health care professionals should provide ongoing care before and after the operation and proactively help patients effectively cope with their physical and mental issues. Finally, at any time, the privacy of APCS recipients should be protected across the treatment.

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**Conflicts of Interest:** Tian BS, None; Li SQ, None; Zhang EE, None; Xiao HM, None; Su LJ, None; Zhang JE, None; Yuan J, None.

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