Clinical Observation of Therapeutic Keratoplasties for Infectious Keratitis: A Retrospective Cohort Study

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Research article

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Abstract

**Background:** To investigate the therapeutic outcomes of two types of keratoplasties in patients with infectious keratitis.

**Methods:** This retrospective cohort study enrolled 52 consecutive patients (52 eyes) with medically uncontrolled infectious keratitis who underwent deep lamellar keratoplasty (DLKP) (n=16 eyes) or penetrating keratoplasty (PKP) (n=36 eyes; 24 nonperforated ulcers; 12 perforated ulcers) with a follow-up of 12 to 36 months (mean follow-up duration: DLKP, 24.6 months; PKP: 25.7 months) between June 2014 and 2019 at the Department of Ophthalmology, The Third Hospital of Hebei Medical University. The clinical characteristics, preoperative, and postoperative best-corrected visual acuity (BCVA) outcomes, therapeutic success rate, graft rejection, management, and complications were assessed.

**Results:** The postoperative BCVA increased by 93.8% (15/16 eyes) and 77.2% (27/36 eyes) at the one-year follow-up in the DLKP and PKP groups, respectively: the differences were not statistically significant (p=0.149). The therapeutic success rates did not differ (statistically significantly) between the DLKP (81.2%) and PKP (80.6%) groups (p=0.953). The incidence of secondary glaucoma was 6.25% and 33.33% in the DLKP and PKP groups, respectively, and the difference between them was statistically significant (p=0.037). The graft survival rates at the one-year follow-up differed significantly between the DLKP (12.5%) and PKP (42.9%) groups (p=0.033).

**Conclusion:** Infectious keratitis is common in male farmers in northern China. Therapeutic keratoplasty is the most commonly performed vision-saving procedure for patients with severe serious infectious keratitis, which can improve the quality of life significantly. Bandage contact lenses were commonly used to protect the cornea and ameliorate pain. DLKP and PKP elicited good clinical outcomes with respect to visual recovery and therapeutic success. The frequencies of graft rejection and complications were lower with DLKP compared to PKP. Surgery should be considered at the early stage in patients with refractory infectious keratitis to improve the therapeutic success.

**Background**

The clinical presentation of infectious keratitis may vary depending on its underlying etiology. It is one of the major causes of ocular blindness resulting from bacterial, viral, fungal and acanthamoebal infections. Surgical intervention is a suitable treatment modality if conventional pharmacotherapy fails to resolve the condition. Corneal transplantation is the most commonly performed, well-established technique, and the best method to prevent corneal blindness, with well over 100,000 procedures performed annually worldwide. Therapeutic keratoplasty aims to resolve medically uncontrolled infectious keratitis by restoring the structural integrity of the ocular surface, which is essential owing to the risk of scleral involvement or corneal perforation. Surgical keratoplasty techniques include penetrating keratoplasty (PKP), deep anterior lamellar keratoplasty (DLKP), and anterior lamellar keratoplasty (ALK). ALK and DLKP are extraocular procedures and differ with respect to the surgical
depth of the cornea layer included in the procedure. ALK entails removal of the affected corneal stroma only. DLKP, which entails removal of the entire affected corneal stroma, while maintaining the integrity of the host Descemet’s membrane (DM) and endothelium, is currently considered as the first line of surgical treatment. In this study, we investigated and compared the therapeutic success rate, graft survival, visual acuity outcomes, and complications between DLKP and PKP for the treatment of medically uncontrolled infectious keratitis.

Methods

Participants

This retrospective cohort study reviewed the clinical charts of all consecutive patients with infectious keratitis, who underwent therapeutic keratoplasty at the Department of Ophthalmology, The Third Hospital of Hebei Medical University, Shijiazhuang, Hebei, China between June 2014 and June 2019. Fifty-two consecutive patients (52 eyes; 36 men and 22 women) with infectious keratitis refractory to conventional pharmacotherapy who underwent DALK (n = 16 eyes) or PKP (n = 36 eyes; 26 nonperforated ulcers; 12 perforated ulcers) were included in this study (Table 1). Forty-five patients (77.6%) hailed from the countryside in northern China. All patients underwent corneal scraping for the acquisition of microbiological cultures and smears immediately on admission. All surgical procedures were conducted by one or two surgeons. This study was reviewed and ethic approved by the institutional review board of Hebei Medical University and adhered to the tenets of the Declaration of Helsinki. Informed written consent to participate was obtained from each patient for the use of their clinical images and data after explaining the possible consequences of the study for publication.

Surgical techniques and indications

The donor corneal tissues were obtained from Hebei OPO Eye Bank, The Third Hospital of Hebei Medical University, Shijiazhuang, Hebei, China within 8 h postmortem and stored at 4°C in Optisol-GS Corneal Storage Medium (Bausch & Lomb, Rochester, NY, USA). Corneal transplantation was performed within one week of punching the donor corneas for DLKP or PKP. The dehydrated corneal graft was preserved until the DLKP procedure. The endothelium and DM were removed from the rest of the cornea and the graft was punched out before DLKP. All surgical procedures were performed under retrobulbar or general anesthesia by one and/or two of the authors who are cornea specialists. Patients with nonperforated lesions underwent DLKP depending on the perceived clinical severity determined by the lesion size and depth. However, patients with perforated lesions, those with unperforated lesions with limbal and scleral extensions, and those with deep lesions extending to the DM underwent PKP (Table 1). Each patient was fitted with a bandage soft contact lens after surgery.

Postoperative management

After the keratoplasty procedure, tobramycin and dexamethasone eye ointment (Alcon, Novartis, USA) QN, and tobramycin and dexamethasone eye drops (Alcon, Novartis, USA) were administered 2 h/day and
tapered off to a dose of 4 h/day and discontinued at the end of the 3rd week for patients with bacterial keratitis. Multiple high-dose applications of topical steroids were generally not performed for patients with fungal, viral, and acanthamoeba infections. From the second week, all patients were administered topical tacrolimus 0.1% (Senju Pharmaceutical Co, Japan), or cyclosporine 1% (North China Pharmaceutical Co, China) for 18 months postoperatively.²

**Statistical Analysis**

Data were presented as the mean ± standard deviation (SD). The therapeutic success of the two keratoplasty treatment groups was compared using the two-way ANOVA. Kaplan–Meier survival curves were used to analyze graft survival 1 year after surgery. P < 0.05 was considered to be statistically significant. Statistical analyses were performed using the SPSS software on a personal computer (SPSS, ver. 6.1; SPSS Science, Chicago, IL).

**Results**

**Preoperative data**

Each of the 52 patients (52 eyes) underwent routine preoperative examination and management on admission to the hospital. The sex, mean age, mean follow-up period, and etiology of infectious keratitis are summarized in Table 1. The participants’ ages and best-corrected visual acuity (BCVA) did not differ significantly between the two groups (p = 0.45) (Table 1).

**Postoperative visual outcomes**

Patients underwent visual examination at each visit. The mean follow-up duration and final complete visual examination following surgery was 24.6±5.8 and 25.7±6.9 months for the DLKP and PKP groups, respectively. The postoperative BCVA increased by 93.8% (15/16) and 77.2% (27/36) for the DLKP and PKP groups at the one-year follow-up (Table 2). The mean increment in the Snellen lines of visual acuity was 6.5 and 3.9 in the DLKP and PKP groups, respectively. The vision improvement in the DLKP was statistically significant as compared with PKP group (p = 0.042). Patients with graft rejection or failure were excluded from the statistical analysis. Figures 1 to 3 depict 4 patients with infectious keratitis (patients A and D had bacterial keratitis and patients B and C had fungal keratitis). Figure 2 illustrates the pre- and postoperative optical coherence tomography (OCT) images of patients A and B.

**Therapeutic success rate**

The therapeutic success rates of DLKP and PKP were 81.2% (3/16) and 80.6% (7/36), respectively, at the one-year follow-up. The difference between the success rates of DLKP and PKP was not statistically significant (p = 0.953). Following medical management, the condition was controlled in 9 eyes without further surgical intervention; one eye with fungal keratitis underwent repeat PKP, which failed to control it and the eye was enucleated.
Graft survival rate

The one-year graft survival rate in this study was 87.5% (2/16) and 57.1% (15/36) in the DLKP and PKP groups, respectively. The Kaplan–Meier survival curves generated at the one-year follow-up demonstrated a better graft survival rate of 87.5% after DALK than that with for PKP (57.1%) (Figure 4). The graft survival differed (statistically) significantly between the DLKP and PKP groups (p = 0.033). All patients with immune rejection were managed by the administration of immunosuppressants, except one patient with fungal keratitis, who had multiple rejections, which led to graft opacity.

Complications

The occurrence of postoperative complications following therapeutic keratoplasty largely depends on the underlying conditions in each patient and the surgical procedure used. Secondary glaucoma was the most notable postoperative complication. It commonly occurred within the 3-month postoperative at the rate of 6.25% (1/16) and 33.33% (12/36) in the DLKP and PKP groups, respectively and differed statistically significantly between the DLKP and PKP groups (p=0.037). Conventional therapy was used to treat the complications of elevated IOP and secondary glaucoma in 9 eyes and four eyes required trabeculectomy.

Discussion

Therapeutic lamellar keratoplasty, an alternative technique to PKP, has become a popular technique for the management of corneal diseases with an intact corneal endothelium. It has several advantages over the PKP technique. Moreover, the DLKP procedure has some advantages and disadvantages in patients with medically uncontrolled infectious keratitis. DLKP is an extraocular surgical procedure, which reduces the risk of infection into the anterior chamber and endophthalmitis, but is unable to completely remove the infectious organisms, which may lead to recurrence of infection compared to PKP, where the entire cornea is replaced.

Xie et al have reported higher recurrence rates following DLKP for fungal keratitis. One study showed that recurrence of infection occurred in 15.3% of patients in the DLKP group, and 12% of patients in the PKP group, but the infection did not recur after the modified Anwar big-bubble DLKP technique, which entails removal of the entire corneal stroma. The data from the current study showed that the rate of recurrence was 18.8% (3/16) in the DLKP group and 19.4% in the PKP group. Therapeutic DLKP with complete removal of the infected stroma down to the DM can be more effective compared to PKP for managing corneal infections and improving BCVA and visual acuity. The higher recurrence was attributed to the presence of keratitis with corneal perforations. We did not observe any case of endophthalmitis in the DLKP group. Only one eye developed endophthalmitis in the PKP group.

The main advantage of DLKP is that it maintains the integrity of the patient’s endothelium, thus eliminating the risk of endothelial immunological allograft rejection and endothelial failure. We found that the frequency of graft rejection was 12.5% in the DALK group, while 42.9% of patients developed
graft rejection in the PKP group. Studies have shown that the rate of graft rejection following PKP depends on the patient’s condition and related risk factors\textsuperscript{1,2}. Corneal neovascularization (CNV) is one of the factors responsible for graft rejection, CNV is characterized by the outgrowth of blood vessels from the limbus, which causes loss of corneal transparency and even graft failure\textsuperscript{2,12,13}.

Manual techniques for lamellar keratoplasty are usually associated with worse visual outcomes than those with PKP due to the inability to consistently perform complete lamellar dissection down to the DM layer.\textsuperscript{1} Studies have reported that incomplete removal of the posterior stroma and residual infectious keratitis in the deep stroma following DALK resulted in higher rates of recurrence compared to that following PKP for fungal or acanthamoeba keratitis\textsuperscript{1,11}.

This study did not find significant differences in the BCVA improvements between the DLPK and PKP groups. The average increment in the number of Snellen lines was 6.8 in the DLKP group and 4.2 in the PKP group, and the difference between the two was statistically significant (p = 0.03). Another study showed a trend toward better visual acuity outcomes following DLKP compared to PKP, although the difference was not statistically significant\textsuperscript{1}. Several studies have reported variable visual acuity changes after DLKP and PKP\textsuperscript{9,11,14,15}.

Graft survival is closely related to the size of the graft, quality of the donor graft, severity of the preoperative and postoperative infections, surgical technique used, and postoperative complications such as CNV\textsuperscript{13,16,17}. In our study, the graft survival rates at the one-year follow-up were significantly higher in the DLKP group than those in the PKP group (p = 0.033). Anshu et al.\textsuperscript{1} reported similar outcomes with 90% graft survival rates after DALK and 78.4% after PKP, although the difference lacked statistical significance owing to the small sample size. They also showed that nonperforated ulcers exhibited better graft survival rates than those of perforated ulcers. Corneal perforation is considered to be amongst the important high-risk factors for graft survival\textsuperscript{18}. Previous studies have demonstrated that DLKP is a safe surgical procedure for the treatment of corneal perforation resulting from keratoconus and hereditary dystrophies to severe corneal infection and corneal perforation\textsuperscript{8,19}. Graft failures mainly consisted of the recurrence of primary infection, CNV, postoperative DM detachment, endothelial failure, and endophthalmitis.

DLKP has several advantages over PKP, including the reduced incidence of secondary cataract and glaucoma. One study showed that the elevation of intraocular pressure (IOP) following DLKP is a transient condition, which is related to a low incidence of secondary glaucoma.\textsuperscript{20} The use of topical steroids is one of the risk factors for IOP. Higher IOP and secondary glaucoma are common sequelae of the PKP procedure\textsuperscript{14}. Postoperative complications after therapeutic keratoplasty require early recognition and adequate management.

Bandage contact lenses are widely used for the postoperative management of persistent corneal epithelial defects. A previous study noted that fitting epidermal growth factor-treated bandage contact lens onto the damaged eye may aid in the regrowth of the corneal epithelium in patients with delayed
wound healing\textsuperscript{21}. However, another recent prospective study demonstrated that 29.8\% of these contact lenses were contaminated\textsuperscript{22}. Frequent replacement of these lenses could decrease incidence of contamination and hypoxia-related complications.

This study had some limitations. This investigation was a clinical retrospective cohort study, in which statistical comparisons were not performed for the risk factors, size of infiltration and severity of corneal infections of each surgical group. The number of patients with advanced infectious keratitis, with respect to the donor graft size and cases of perforation, in the PKP group was obviously higher than that in the DLKP group.

**Conclusion**

Therapeutic keratoplasty is considered to be the last resort for severe corneal infections that are refractory to conventional management. Several surgical techniques are currently available for such cases. PKP is the standard procedure, which entails replacement of the entire layer of the cornea, and is associated with a high risk of graft failure, similar to therapeutic lamellar keratoplasty. Alternative management strategies are needed to prevent graft rejection or failure postoperatively. We found that DLKP provided safe and better effective outcomes with respect to visual recovery, therapeutic success, and lower graft rejection compared to PKP, by virtue of keeping the host DM and endothelium intact. The therapeutic success rate increased with early surgical intervention in patients with refractory infectious keratitis.

**Abbreviations**

- BCVA: best-corrected visual acuity
- DLKP: deep anterior lamellar keratoplasty
- IK: infectious keratitis
- OCT: optical coherence tomography
- PKP: penetrating keratoplasty

**Declarations**

**Ethics approval and consent to participate**

This study was reviewed and approved by the institutional review board of Hebei Medical University and adhered to the tenets of the Declaration of Helsinki. Informed written consent to participate was obtained from each patient.

**Consent for publication**
Written informed consent was obtained from each patient who was used their photos and OCT images for publication of this article. A copy of the written consent is available for review on request.

**Availability of data and materials**

The data used and analyzed during the current study are available from the corresponding author on reasonable request.

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**Competing Interests**

The authors declare that they have no competing interests.

**Authors’ contributions**

YM, YZ and XRZ contributed to the design of the study; YM, YZ, XRZ, LYH and HL conducted the study; YM, JY and ECH acquired the data; YM and XRZ prepared the manuscript; YM and XRZ drafted the manuscript; and XRZ revised the manuscript. All authors have read and approved the final manuscript.

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Tables

Table 1. Patients’ clinical data and etiology of infectious keratitis in the DLKP and PKP groups

|                        | DLKP  | PKP  |
|------------------------|-------|------|
| Sex (male/female)      | 11/5  | 25/11|
| Mean age (years) (M ± SD) | 56.3±5.6 | 58.5±6.9 |
| Follow-up (months) (M ± SD) | 24.6±5.5 | 26.8±6.9 |
| Total number of eyes   | 16    | 36   |

Etiology of infectious keratitis

|                | DLKP | PKP  |
|----------------|------|------|
| Bacteria       | 9    | 12   |
| Fungus         | 7    | 23   |
| Acanthamoeba   | 0    | 1    |

DLKP: deep lamellar keratoplasty, PKP: penetrating keratoplasty

Table 2. Patients best corrected visual acuity pre- and post-surgical procedures

|                        | DALK | PKP  |
|------------------------|------|------|
| No. of eyes            | 16   | 36   |
| Preoperative BCVA range| HM* to 0.4 | HM to 0.1 |
| Postoperative BCVA changes | 0.2-0.8 | 0.1-0.7 |
| No. of eyes increased  | 15   | 27   |
| P value                |      | 0.149|

*HM: hand motion, DLKP: deep lamellar keratoplasty, PKP: penetrating keratoplasty, BCVA: best-corrected visual acuity
Figures

Figure 1

Pre- and postoperative outcomes of two patients with infectious keratitis following DLKP and PKP
Patient 1 was a 64-year-old man who had bacterial keratitis in his right eye for 12 days (A1) and was treated by DLKP. The photograph was acquired 1 day postoperatively with a clear graft (A2). The patient’s graft appeared clear 30 days after the surgical procedure, the sutures were in place, and the pupil was round (A3). The sutures were removed 10 months postoperatively, and the corneal graft was clear (A4).
Patient 2 was a 30-year-old man who had fungal keratitis in his right eye for 2 months (B1) and was treated using PKP with a clear graft on the second day of follow-up (B2). The patient had a clear graft, the sutures were in place and the pupil was round 30 days after the surgical procedure (B3). The sutures were tightly in place, and the corneal graft was clear on the 3-month follow-up examination (B4).

Figures

DLKP: deep lamellar keratoplasty, PKP: penetrating keratoplasty

Figure 2

Pre- and postoperative OCT examination of patients A and B A5 and B5 depict the respective OCT images of the anterior segment of the two patients preoperatively. A6 and B6 demonstrate the respective results 10 months and 1 month postoperatively. OCT: optical coherence tomography
Figure 3

Pre- and postoperative outcomes following DLKP and PKP in two patients with infectious keratitis. DLKP: deep lamellar keratoplasty, PKP: penetrating keratoplasty. Patient 3 was a 60-year-old man with fungal keratitis in his left eye for 20 days (C1), which was unresponsive to conventional management: he tested positive for fungal infection on admission. He underwent DLKP and had corneal graft edema and his pupil was moderately dilated 1 day postoperatively (C2). At the one-month follow-up, he had a clear graft, the sutures were in place, the depth of the anterior chamber was normal, and the intraocular pressure was 16 mmHg (C3). Patient 4 was a 52-year-old man who had bacterial keratitis in his left eye for 2 weeks with hypopyon, which was not responsive to medical therapy (D1). He was treated by PKP with a clear graft on the second day of follow-up (D2). The patient had a clear graft, the sutures were in place and the pupil was round and moderately dilated 30 days after the surgical procedure (D3). DLKP: deep lamellar keratoplasty, PKP: penetrating keratoplasty.

Figure 4

![Graph showing non-rejection rate over time with two lines, one for DLKP and one for PKP, with a p-value of 0.033.](image)}
Kaplan-Meier survival curves showing graft survival rates of the DLKP and PKP groups (P= 0.033) DLKP: deep lamellar keratoplasty, PKP: penetrating keratoplasty