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Visual Outcomes and Prognostic Factors of Successful Penetrating Keratoplasty in 0- to 7-Year-Old Children With Congenital Corneal Opacities

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Purpose: To determine the visual acuity and prognostic factors after successful penetrating keratoplasty (PK) in 0 to 7-year-old children with congenital corneal opacities.

Methods: Sixty eyes (50 patients) with clear grafts after PK for congenital corneal opacity were enrolled and followed for 6 to 82 months. Visual acuity was measured using Teller acuity cards or Snellen charts, and cycloplegic refraction and flash visual-evoked potentials were measured. Mean age at primary keratoplasty was 2.5 ± 1.7 years. The mean follow-up duration was 18.9 ± 19.3 months.

Results: Ambulatory vision (≥20/960) was achieved in 43 of 60 eyes (71.7%) at last follow-up, and 14 eyes (23.3%) had visual acuities >20/260. Compared with unilateral opacity eyes (58.8%), a significantly higher proportion of bilateral opacity eyes (88.5%) achieved ambulatory vision (P = 0.012). Of all the surgical indications, unilateral sclerocornea was associated with the worst visual outcome—only 12.5% obtained ambulatory vision. Additional intraocular surgery was also associated with a reduced ambulatory visual acuity outcome. There were no significant differences in visual acuity among the different follow-up subgroups (<12 months, 12–36 months, and >36 months after operation; P = 0.928). Patients with bilateral opacity had a higher proportion of abnormal amplitude flash visual-evoked potentials than did patients with unilateral opacity (P = 0.033). Ten of the 14 eyes that achieved 20/260 vision had corneal astigmatism ≤3 diopters.

Conclusions: Most of the clear grafts after PK in children with congenital corneal opacities achieved ambulatory vision. The visual outcome was better in binocular opacity cases than in monocular ones.

Key Words: congenital corneal opacity, visual outcome, penetrating keratoplasty

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Pediatric penetrating keratoplasty (PK) is considered the first choice for management of congenital corneal opacity.[1] However, PK in pediatric patients has been reported to have a poor surgical outcome compared with PK in adults, and congenital corneal opacities show a lower survival rate than do acquired corneal pathologies after pediatric PK.[2] However, with advancements in surgical techniques and the use of antirejection medicines, more corneal transplantation procedures have been performed with better reported outcomes in pediatric patients.[3–7] The overall probability of a patient with Peters anomaly maintaining a clear first graft is 56% at 6 months, 49% at 12 months, 44% at 3 years, and 35% at 10 years.[5] Previous research showed that 32.6% to 78.6% of grafts performed for congenital corneal opacities remain clear for more than 1 year.[2,3,5,8–13] A clear graft is essential to obtain visual acuity; however, not all children with transparent grafts obtain optimal visual acuity.[14,15] It is important to know which of the patients with clear grafts after PK will achieve good visual outcomes because it would help in setting clear expectations for surgeons and families of patients.

Most of the previous studies have reported graft survival times, graft survival rates, and significant prognostic factors for PK in patients with congenital corneal opacities.[2,3,5,8–13] However, few studies have reported on the visual outcome after PK in infants and young children because of the difficulty of visual assessment in these patients.[3,9,12] Moreover, there has been no comprehensive analysis of the relative prognostic factors for the visual outcome in pediatric cases with successful PK (those whose grafts remain clear).

We evaluated the visual outcomes of 0- to 7-year-old patients with clear grafts after PK and identified prognostic factors for the visual outcome including age at the time of the primary graft, surgical indication, unilateral versus bilateral

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grafts, other ocular surgery, follow-up timing, refraction, and flash visual evoked potential amplitude.

MATERIALS AND METHODS

This retrospective study followed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of Beijing Capital Medical University. The medical records of 112 children aged ≤7 years who underwent primary PK at Beijing Tongren Eye center between January 2010 and December 2016 were reviewed. Cases of acquired traumatic, acquired nontraumatic, and lamellar keratoplasty were excluded. Some corneal tissue was from Eversight (Ann Arbor, MI), and some was from Beijing Tongren Eye Bank (donated).

Of the 112 patients, 57 were eliminated because of graft failure or their being lost to follow-up. Graft failure was defined as irreversible loss of central graft clarity due to any cause. Five children who were not cooperative with Teller acuity card (TAC) evaluations were also excluded because of concerns about accuracy of the outcome assessment.

The remaining 60 eyes of 50 patients (29 male and 21 female) provided the data for this study. Mean age at the time of primary surgery was 2.5 ± 1.7 years (range, 0.1–7 years). The mean follow-up duration was 18.9 ± 19.3 months (range, 6–82 months). Clinical diagnoses were confirmed by preoperative examinations, the intraoperative findings, and histopathology results. Data were gathered by a retrospective review of medical records, operative reports, pathology reports, and by personal communication.

Surgeries were performed under general anesthesia by 1 of 2 experienced corneal surgeons who used similar techniques. The surgical techniques included an oversized graft from 0.75 to 1.0 mm. For all grafts, 12 or sixteen 10-0 nylon interrupted sutures were used. Additional procedures such as synechiolysis and cataract extraction were performed as required. Suture removal was completed in most cases within 3 months. A typical medication regimen involved prednisolone acetate ophthalmic suspension 1%, (Pred Forte Allergan, Westport, Ireland) every 4 hours and tobramycin and dexamethasone eye ointment (TobraDex, Alcon, Puurs, Belgium) every night for the first few weeks. Treatment was then changed to fluorometholone 0.1% eye drops (Santen, Ishikawa, Japan) and was continued until 24 months after operation. Antiinfection treatment included tobramycin 0.3% eye drops, (Tobrex, Alcon, Puurs, Belgium) or Cravit (levofloxacin 0.5% eye drops, Santen, Ishikawa, Japan) and was continued until all sutures were removed. Topical calcineurin inhibitors, such as tacrolimus 0.1% eye drops (Talymus, Senju, Hyogo-ken, Japan) or cyclosporine A 1% eye drops (North China Pharmaceutical Company Ltd, Shijiazhuang, China), were applied every 4 hours between day 3 and 3 months after operation and then were gradually decreased over the next 24 months. In general, postoperative examinations were performed at 1 day, 1 week, and 1 month after surgery and then every 3 months for 2 years.

Slit-lamp examinations were performed to evaluate the cornea preoperatively and graft clarity postoperatively. Fundus and vitreous examinations were performed by A- and B-scan ultrasonography. The best-corrected visual acuity was measured using the Snellen vision chart in patients older than 4 years and the TAC in patients younger than 4 years. Ambulatory vision was defined as visual acuity ≥20/960.[3,16] Cycloplegic refraction and flash visual-evoked potentials (FVEPs) were measured for all subjects by special optometrists at the last visit, and the hypnotic drug chloral hydrate was used if necessary. The normal FVEP amplitude is >10 μv. A slight decrease in amplitude (<20%) was defined as 8.1 to 10 μv, a moderate decrease (20%–55%) as 4.5 to 8 μv, and a severe decrease (>55%) as <4.5 μv.[17] The follow-up results at the last visit were included.

RESULTS

The 60 clear grafts of the 50 patients had undergone primary PK at age ranging from 1 month to 7 years (median age, 2.3 years). Among the 60 eyes, 11 eyes that failed within 1 year after primary PK received a second PK and maintained clear grafts for more than 6 months. Ten patients underwent bilateral grafting.

Of the 60 included clear eyes/grafts, 14 (23.3%) eyes had postoperative visual acuity ≥20/260, 29 (48.4%) eyes had visual acuity form 20/960 to 20/260, and 17 (28.3%) eyes had postoperative visual acuity < 20/960. In total, 43 (71.7%) eyes obtained ambulatory vision (≥20/960).

Thirty-four unilateral opacity patients had undergone unilateral PK. Of these 34 patients with unilateral opacity, 20 (58.8%) achieved ambulatory vision or better. Ten patients

TABLE 1. Visual Acuity of Unilateral or Bilateral PK

Patients	Surgery Eye	Visual Acuity	No. Eyes	Above Ambulatory
Unilateral PK (n = 34)	Uni (n = 34)	<20/960	14	14/34 (41.2%)
		20/960–20/260	14	14/34 (41.2%)
		≥20/260	6	6/34 (17.6%)
Bilateral PK (n = 26)	Uni (n = 6)	<20/960	1	1/26 (3.8%)
		20/960–20/260	2	2/26 (7.7%)
		≥20/260	3	3/26 (11.5%)
	Bi (n = 20)	<20/960	2	2/26 (7.7%)
		20/960–20/260	13	13/26 (50%)
		≥20/260	5	5/26 (19.3%)

Bi, bilateral; Uni, unilateral.

TABLE 2. Postoperative Visual Outcome in Different Age Groups

			Vision Acuity			
	Surgery Age	No. Eyes	<20/960	20/960–20/260	≥20/260	Above Ambulatory
Total, n = 60	≤12 mo	12	3	5	4	9 (75%)
	12 mo–4 yrs	39	11	20	8	28 (71.8%)
	>4 yrs and ≤7 yrs	9	3	4	2	6 (66.7%)
Unilateral PK, n = 34	≤12 mo	8	3	3	2	5 (62.5%)
	12 mo–4 yrs	22	9	10	3	13 (59.1%)
	>4 yrs and ≤7 yrs	4	2	1	1	2 (50%)
Bilateral PK, n = 26	≤12 mo	4	0	2	2	4 (100%)
	12 mo–4 yrs	17	2	10	5	15 (88.2%)
	>4 yrs and ≤7 yrs	5	1	3	1	4 (80%)

with bilateral opacity had undergone bilateral PK, and another 6 patients had bilateral opacities but received unilateral PK because of a poor ocular condition or economic reasons. Of a total of 26 eyes with bilateral opacity, 23 (88.5%) achieved ambulatory vision or better. The visual acuity of bilateral opacity eyes was significantly greater than that of the unilateral opacity eyes ($\chi^2 = 6.374$, $P = 0.012$; Table 1).

According to age at the time of primary keratoplasty, patients were divided into 3 age groups (≤12 months, 12 months to 4 years, and 4 years to 7 years), in which 75%, 71.8%, and 66.7% eyes achieved ambulatory vision, respectively. Age at primary keratoplasty ($P = 0.915$), including unilateral PK and bilateral PK ($P = 0.917$ and $P = 0.646$, respectively), was not associated with the visual outcome (Table 2).

In the 34 patients with unilateral opacity, only 1 of 8 (12.5%) sclerocornea eyes reached ambulatory vision, whereas 12 of 18 (66.7%) eyes with Peters anomaly reached ambulatory vision or better. In the 26 bilateral opacity eyes, 11 of 13 (84.6%) sclerocornea eyes and 5 of 6 (83.4%) eyes with Peters anomaly achieved ambulatory vision or better. There were 2 eyes with huge dermoid tumors covering the pupil, 4 corneal opacities that crossed the pupillary region without iridocorneal adhesions (suspected to have been caused by intrauterine infections), and 3 eyes with congenital hereditary endothelial dystrophy—ambulatory vision was obtained in all cases (Table 3).

Of all 60 included eyes, 43 underwent grafting once and 9 underwent grafting twice without other procedures performed, the remaining 8 eyes (6 eyes underwent PK once and 2 eyes underwent PK twice) underwent combined PK; of these, 33 (79.1%) eyes, 5 (55.6%) eyes, and 4 (50%) eyes, respectively, achieved ambulatory vision. Among the 8 eyes that underwent combined PK, 5 eyes underwent PK once or twice combined with extracapsular cataract extraction. One eye underwent cataract extraction and was implanted with an intraocular lens at 8 months after primary PK. Two eyes underwent trabeculotomy before undergoing PK (Table 4).

Patients were split into 3 groups according to their follow-up timing from primary PK: <12 months, 12 to 36 months, and >36 months, and 71.4%, 68.8%, and 77.8%, respectively, reached 20/960 visual acuity. There were no significant differences in visual acuity among the 3 groups ($\chi^2 = 0.275$, $P = 0.928$) (see Supplemental Table 1, Supplemental Digital Content 1, http://links.lww.com/ICO/A695).

All patients were examined using cycloplegic retinoscopy. The degree of corneal astigmatism also had an impact on the visual outcome. Of the 60 eyes, 14 eyes achieved 20/260,

TABLE 3. Indications for Penetrating Keratoplasty in the Pediatric Study Patients

		Visual Acuity			
Preoperation Diagnosis	No. Eyes, n = 60	<20/960	20/960–20/260	≥20/260	Above Ambulatory
Unilateral (n = 34)					
Sclerocornea	8	7	1	0	1/8 (12.5%)
Peters anomaly	18	6	8	4	12/18 (66.7%)
Congenital glaucoma	2	1	0	1	1/2 (50.0%)
Other*	6	0	5	1	6/6 (100%)
Bilateral (n = 26)					
Sclerocornea	13	2	8	3	11/13 (84.6%)
Peters anomaly	6	1	2	3	5/6 (83.4%)
Congenital glaucoma	4	0	4	0	4/4 (100%)
Corneal dystrophy†	3	0	1	2	3/3 (100%)

*"Other" diagnoses included large dermoid tumor covering the pupil (2 cases) and corneal opacity across the pupillary region without iridocorneal adhesion (4 cases; believed to be secondary to intrauterine infection).

†Congenital hereditary endothelial dystrophy (CHED) was present in all.

TABLE 4. Ocular Surgeries Performed in the Pediatric Study Patients

Surgery Performed	No. Eyes, n = 60	Visual Acuity			Above Ambulatory
		<20/960	20/960–20/260	≥20/260	
PK* once	43	9	21	13	34/43 (79.1%)
PK twice	9	4	5	0	5/9 (55.6%)
Combined PK†					
PK once + ECCE	3	1	2	0	4/8 (50%)
PK once + ECCE + IOL	1	1	0	0	
PK twice + ECCE	2	1	1	0	
PK + trabeculotomy	2	1	0	1	

*Penetrating keratoplasty only.
†ECCE, extracapsular cataract extraction; IOL, intraocular lens.

10 of them had low astigmatism (≤3 D), 3 eyes had 3 to 6 D astigmatism, only 1 eye had astigmatism >6 D. However, in all the 13 eyes with high astigmatism of more than 9 D, 8 eyes (61.5%) did not achieve ambulatory vision (<20/960) and only 1 eye achieved 20/260 (Table 5).

Fifty patients underwent FVEP examination together with cycloplegic refraction. Of the 34 patients with unilateral opacity, only 8 eyes showed subnormal amplitudes (<10 μv), and the visual acuities were all <20/960. Of the 26 eyes with bilateral opacity, 13 showed abnormal amplitudes and 12 eyes (8 patients) showed a moderate to severe decrease (<7 μv); however, visual acuity was <20/960 in only 1 eye. There was a significant difference between bilateral and unilateral eyes ($\chi^2 = 4.538$, $P = 0.033$) (see Supplemental Table 2, Supplemental Digital Content 2, http://links.lww.com/ICO/A696).

DISCUSSION

Although corneal transplant surgery in children is difficult and daunting, a child with dense central congenital corneal opacity cannot develop the vision without corneal transplantation. The survival rate for pediatric PK has improved significantly with advances in surgical techniques and more effective preoperative and postoperative management. Overall graft survival has previously been reported to vary greatly, ranging from 32.6% to 78.6%. In our study of children aged 0 to 7 years, the transparent graft rate of congenital corneal opacities was about 55.6% during the 6- to 82-month follow-up period.

A clear corneal graft, which enables visual development and prevents deprivation amblyopia, is a prerequisite for good visual acuity. Our goals were to assess the visual function of these children with clear grafts and to identify the factors that promote vision. Choosing 0 to 7 years of age was aimed for subsequent amblyopia treatment because this age range was believed to be the best time for such treatment.

TABLE 5. Astigmatism and Visual Acuity

Astigmatism	No. Eyes, n = 60	Visual Acuity			Above 20/260
		<20/960	20/960–20/260	≥20/260	
≤3 D	27	6	11	10	10/27 (37.0%)
3–6 D	8	2	3	3	3/8 (37.5%)
6–9 D	12	1	11	0	0/12 (0%)
>9 D	13	8	4	1	1/13 (7.7%)
Total	60	17	29	14	14/60 (23.3%)

For children aged 0 to 3 years, the gold standard for visual examination is the preferential looking procedure.[18] The TAC assessment is commonly used in clinical and laboratory settings to assess visual acuity in infants and young children.[19] Five children in our study could not complete the TAC examination because of fear or inability to cooperate and were excluded. Postoperative visual acuity was >20/960 and consistent with ambulatory vision in 43 eyes (71.7%). Although some studies[2,4] have shown a trend for worse survival and visual outcomes in patients with congenital opacities compared with those with acquired opacities, our finding that more than two-thirds of eyes with clear grafts achieved ambulatory vision is encouraging. Moreover, in cases with bilateral grafts, an even greater proportion of eyes (88.5%) achieved ambulatory vision or better; this is significantly more than the proportion seen in unilateral opacity cases (58.8%). Therefore, when a child presents late with bilateral dense corneal opacities, surgical treatment should not be discounted on the grounds of irreversible amblyopia; the theory that deprivation amblyopia is irreversible has been proven incorrect in the case of children.[20] Furthermore, visual improvement would promote global development even if the grafts failed 1 or 2 years after PK.[21,22]

We analyzed the age at surgery, but there were no statistically significant differences between age at primary keratoplasty and visual outcomes. We believe the negative results were related to the differences in the sample size among age groups. Chinese doctors currently prefer to perform PK in children of congenital corneal opacities at age 1 to 3 years because of technical challenges, high rejection rate, and children's inability to cooperate. There were only 12 eyes ≤12 months of age and 9 eyes more than 4 years old, but 39 eyes were 12 months to 4 years in our case series. However, our results have shown a trend that the younger the age at surgery, the better the visual acuity.

Many studies have reported that graft survival mainly depends on the type of congenital corneal anomaly.[23–25] Our

results showed that the visual outcome of clear graft cases was also associated with the surgical indication. Many now believe that "sclerocornea" is not a distinct diagnosis but a sign of severity of another condition, often Peters anomaly or Axenfeld–Rieger syndrome.[26] However, we still use the traditional classification in this study, for our cases were collected from 2010 to 2016. Of all the clear grafts, unilateral sclerocornea cases showed the worst visual outcome. Only 1 of 8 (12.5%) of these eyes obtained ambulatory vision, whereas 12 of 18 (66.7%) eyes with unilateral Peters anomaly reached ambulatory vision. We propose that sclerocornea might be associated with denser opacification and the complication of anterior segment dysplasia. After transplantation, unilateral patients might also encounter serious suppression by the healthy eye and worse deprivation amblyopia. Fortunately, patients with a bilateral sclerocornea may achieve better visual acuity. Huge dermoid tumors, opacities without iridocorneal adhesions, and congenital hereditary endothelial dystrophy cases all obtained ambulatory vision. We believed that the good outcomes were achieved because the pathology in these cases was primarily corneal, with no anterior chamber or iris involvement.

Of primary graft cases, 79.1% of clear grafts achieved ambulatory vision, whereas 55.6% of regrafted eyes did so. Only 50% of clear grafts that underwent additional surgeries (including extracapsular cataract extraction, intraocular lens implantation, and trabeculotomy) reached a visual acuity of 20/960. Retransplantation and lensectomy may be prognostic for poor final visual acuity. However, the eyes with congenital corneal opacities were usually associated with lens–corneal adhesion or lens dysplasia. Lensectomy was unavoidable in some cases. The absence of a lens had a negative effect on children's vision. Even with refractive correction, the prognosis was not optimistic. Moreover, parents often refused to get contact lenses for their children because of worry about their influence on grafts, and some children are reluctant to wear glasses with high hyperopia and astigmatism. This eventually leads to a poor visual outcome. Thus, for children, lens removal is one of the prognostic factors for poor postoperative visual acuity.

Patients were assigned to 3 groups for different follow-up timing, and there were no statistically significant differences in visual acuity among them. Visual acuity was stable after 12 months if the patient did not receive amblyopia training. However, because 35 of the included 60 eyes were followed up for ≤12 months, these results predict only the outcome trend; a longer follow-up period is required for validation.

Interrupted sutures are more suitable for children because it is easy to adjust for astigmatism and to remove one suture if it becomes loose. In this study, 37.0% of clear grafts achieved 20/260 visual acuity after cycloplegic refraction and refractive correction with corneal astigmatism of no more than 3 D. Therefore, reducing astigmatism is an important strategy to explore for better visual outcomes.

All patients underwent FVEP measurement. A higher proportion of patients with bilateral opacity were found to have abnormal amplitudes, but the proportion with ambulatory vision was not low. Thus, even when FVEP testing showed an optic nerve conduction block, it was possible for bilateral patients to obtain ambulatory visual acuity after PK. In unilateral patients, however, moderately or severely decreased amplitude may indicate a poor visual outcome. So FVEP does not correlate well with visual acuity in these eyes, especially in the case of binocular opacity. Using only FVEP to estimate postoperative visual acuity is not reliable.

In conclusion, most children with clear grafts after PK can achieve ambulatory visual acuity, especially patients with bilateral opacity. Of all the surgical indications, unilateral sclerocorneal eyes show the worst visual outcome. Reducing astigmatism and reinforcing amblyopia treatment are possible measures for obtaining better visual outcomes after PK. We believe that future studies should evaluate visual outcomes in children with more patients from different age groups. Furthermore, deep lamellar keratoplasty or posterior lamellar keratoplasty might be a promising option in properly selected cases of congenital corneal opacity,[27] and further studies are needed to compare the visual outcomes of different types of keratoplasty.

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