Corneal transplant for keratoconus: Results in early and late disease

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ABSTRACT

Purpose: To evaluate the results and complication rates associated with corneal transplantation for keratoconus and assess the prospects of using penetrating keratoplasty at a much earlier stage.

Setting: Buzard Eye Institute, Las Vegas, Nevada, USA.

Methods: In this prospective clinical study, 104 eyes of 76 patients had corneal transplantation for keratoconus identified by corneal topography, keratometry, pachymetry, and/or retinoscopy. Sutures were removed at a mean of 15 months; mean follow-up was 42 months. All surgeries were performed by one surgeon using a torque–antitorque suture method. Eyes were grouped according to severity of the disease: early (n = 24); moderate (n = 47); high (n = 33). Preoperative keratometry was 40.00 to 49.00, 50.00 to 59.00, and 60.00 to 90.00 diopters (D), respectively. The criteria for corneal transplant were a best spectacle-corrected visual acuity of 20/40 or worse and keratoconus clearly identified by one of the above methods. Secondary procedures included repair of wound dehiscence (33 eyes, 31%), relaxing incisions (33 eyes, 31%), wedge resections (5 eyes, 5%), and automated lamellar keratoplasty (4 eyes, 4%).

Results: Mean postoperative uncorrected visual acuity at last follow-up was 0.43 ± 0.3 (20/50), with 46 eyes (44%) achieving 20/40 or better. Mean best corrected visual acuity (BCVA) at last follow-up was 0.83 ± 0.2 (20/25). Sixty eyes (58%) achieved 20/40 or better BCVA at 1 month and 92 eyes (88%), at 3 months. At last follow-up, mean average keratometric astigmatism was 3.10 ± 1.70 D, mean keratometry was 43.30 ± 2.20 D, and mean spherical equivalent was −1.70 ± 3.00 D. Complications included 21 graft rejections (20%); 19 were successfully treated with topical and oral steroids. No expulsive hemorrhage or endophthalmitis occurred.

Conclusion: The risk–benefit ratio for corneal transplantation has been significantly altered by improved surgical and postoperative techniques. The improved results, low complication rate, and postoperative enhancement management indicate that corneal transplantation is a viable option early in the clinical course of keratoconus.
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Anterior keratoconus, first described in 1854 by Nottingham,[1] accounts for approximately one third of total corneal transplants[2] and more if only younger patients are considered. Defined as a noninflammatory bilateral axial thinning of the cornea with protrusion, the etiology and heredity of keratoconus remain ill-defined.[3] Its reported incidence varies widely, from 1 in 286 to 1 in 40,000, depending on the method used to make the diagnosis.[4–7]

In its late stages, the disease is easily diagnosed by slitlamp evaluation, Munson sign, and central corneal scarring. In earlier cases, the diagnosis can be more difficult; careful examination for vertical stria[5,8] and the iron deposits of Fleischer ring[9] can lead to a diagnosis of keratoconus. Additional useful tests include scissoring of

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the reflex on retinoscopy, serial pachymetry mapping showing inferior or central thinning, and signs of irregular astigmatism on keratometry (e.g., jumping, angulation, or minification of mires).

The most significant development in detecting the early stages of keratoconus is videokeratography.[10,11] Asymmetry with an inferior or central steepening is characteristic of keratoconus and can be appreciated by subjective analysis at a fairly early stage. Differences in corneal curvature from the superior to the inferior cornea greater than 2.00 to 2.50 diopters (D) may be significant for keratoconus. Although these techniques allow for early detection of keratoconus, the diagnosis should always be supported by clinical evidence.[12,13]

The management of keratoconus has depended on its severity.[14,15] Spectacle or even no correction is suitable for mild cases. Contact lenses have been the mainstay of optical correction for more severe disease.[16] Traditionally, penetrating keratoplasty (PKP) has been reserved for patients who cannot be successfully fitted with contact lenses or who have visually debilitating corneal scarring.[17,18] This was predicated on the relative risk–benefit analysis of contact lenses vis-a-vis corneal transplantation.

In the past several years, there have been substantial improvements in transplantation techniques,[19(pp 349–404),20] quality of donor material,[21,22] and instrumentation to perform and measure the refractive consequences of corneal transplantation.[13,23] Perhaps most important, several secondary or enhancement procedures have been developed to improve iatrogenically induced astigmatism and myopia.[24–27] Individually, each provides an incremental improvement in the procedure. However, we believe that taken as a whole, these improvements should reposition the role of keratoplasty in the treatment of keratoconus.

We present the results of a consecutive, long-term, prospective study of transplantation in early, moderate, and late keratoconus that demonstrate stable refraction and a complication rate consistent with that of other refractive procedures. These results support our thesis that corneal transplantation should be considered in lieu of contact lens fitting when spectacle-corrected visual acuity (BSCVA) drops to 20/40 or worse.

Materials and Methods

This prospective study comprised 104 eyes of 76 consecutive patients who had corneal transplantation by the same surgeon (K.A.B.). The indications for surgical intervention were clinical evidence of keratoconus identified with the slitlamp, keratometry, photokeratometry, and/or videokeratography accompanied by a BSCVA of 20/40 or worse. Mean patient age was 32 years ± 11 (SD); 54% were men. Mean follow-up was 3.5 ± 1.8 years (range 14 to 96 months), with 95 (91%) having a 1 year follow-up; 69 (66%), 2 years; 40 (38%), 3 years; 33 (32%), 4 years.

Mean preoperative keratometry was 57.30 ± 10.40 D (range 44.00 to 90.00 D). Eyes were grouped according to preoperative keratometry: Group 1 (n = 24), 44.00 to 49.00 D; Group 2 (n = 47), 50.00 to 59.00 D; Group 3 (n = 33), 60.00 to 90.00 D. Table 1 shows the patients' preoperative characteristics.

Mean uncorrected visual acuity (UCVA) was 20/200 (0.10 ± 0.13). Mean best corrected visual acuity (BCVA) was 20/50 (0.41 ± 0.25).

All corneal tissue was obtained from the Eye Bank Association of America (EBAA) certified eye banks with the following general criteria: death to preservation time, fewer than 10 hours; preservation to surgery time, five days or fewer in Optosol media. All transplant corneal tissue had endothelial cell counts of 2000 cells/mm^2 or greater, light to no folds, less than 25% epithelial sloughing, and light to no exposure. At the local eye bank, corneas were obtained under sterile conditions with prophylactic ciprofloxacin (Ciloxin®) antibiotic

Table 1. Preoperative patient characteristics and refractive data (mean ± SD).

	Number of Eyes	Age (Years)	Spherical Equivalent (D)	Refractive Cylinder (D)	Keratometric Astigmatism (D)	Average Keratometry (D)
Group 1	24	34 ± 13	−4.02 ± 2.60	4.23 ± 2.30	6.56 ± 3.80	47.20 ± 2.00
Group 2	47	31 ± 10	−4.98 ± 4.70	4.30 ± 2.50	7.76 ± 3.50	53.50 ± 2.40
Group 3	33	33 ± 10	−5.52 ± 6.30	5.37 ± 2.80	13.00 ± 6.10	70.00 ± 8.30
Total	104	32 ± 11	−4.85 ± 4.60	4.51 ± 2.50	9.14 ± 5.20	57.30 ± 10.00

drops and the cul-de-sac was washed with diluted povidone–iodine (Betadine®). Rim cultures were obtained in all cases with a 4% positive rim culture rate.

All transplants were performed using general anesthesia. A Honan balloon was placed over each operated eye for a minimum of 10 minutes to soften the eye and retrobulbar contents. In addition, the patients received pilocarpine every 5 minutes beginning 15 minutes before surgery (three doses).

Donor corneas were prepared using a Troutman punch set with a trephine disparity of 8.00 mm for the recipient and 8.25 mm for the donor. The donor cornea was placed on a Teflon® disc, covered, and brought to the patient's side. A Pierse ring was sutured to the eye using a running 6-0 silk TG140-8 (Ethicon) suture.

The patient's cornea was incised with an 8.00 mm corneal trephine centered on the pupil. After the anterior chamber was entered, the incision was completed using corneal scissors. The edges of the incision were trimmed to present a vertical edge for transplantation. Viscoelastic was placed in the anterior chamber beneath the corneal rim. The donor cornea was brought to the eye and rotated under subjective keratometry to find the best fit.[25] It was secured using six, interrupted, 10-0 nylon sutures.

After the anterior chamber was re-formed, the cornea was secured using an 18-bite, clockwise, running, 10-0 nylon suture armed with a CS-C-6 (Ethicon) needle followed by an 18-bite, counterclockwise, running suture. The suture bites were placed full thickness using a Troutman needle facilitated by the "fishhook" needle design. The interrupted sutures and Pierse ring were removed and under subjective keratometric control, the sutures were adjusted to present a round surgical keratometer reflex at the end of surgery. Viscoelastic was placed on the corneal surface, and a collagen lens was placed on the eye. Ciloxin drops and tobramycin and dexamethasone (TobraDex®) ointment were placed in the cul-de-sac. Subconjunctival injections of betamethasone (Celestone®), gentamicin, and cefazolin sodium (Ancef®) were given. The eye was patched and shielded.[19(pp 349–404)]

On average, patients were seen 1 day, 1 week, and 1, 3, 6, and 9 months postoperatively; sutures were removed at 1 year. At each visit, photokeratometry, computed corneal topography, and BCVA were used to assess corneal wound healing. If evidence of poor corneal wound healing was identified with a microdehiscence, the patient was taken back to surgery for repair of the wound-healing abnormality.[28] Thirty-three eyes (31%) had wound dehiscence repair. Short-term recovery was usually rapid, with most patients able to function without significant correction.

Upon suture removal, secondary procedures were performed in 49 eyes (47%) to minimize regular and irregular astigmatism and spherical equivalent (Table 2). Of these, 31 eyes needed one enhancement, 14 needed two, 9 needed three, and 5 needed four.

The technique for Troutman relaxing incisions is described elsewhere. Briefly, the patient is asked to look at a fixation light and the cornea is marked with a 3.0 mm optical zone. A six-cut radial keratotomy marker is used to mark the cornea; one set of marks is placed along the flat axis. Under subjective keratometric observation, incisions are made in the donor–host interface with a guarded diamond knife set at 0.5 mm, 60 degrees in length. If astigmatism is not corrected, the incisions are enlarged to 90 degrees and the keratometric corneal reflex re-examined. If the astigmatism has not been fully corrected, interrupted compression sutures are placed in the flat meridian to induce a 2.00 to 3.00 D overcorrection at the conclusion of surgery. The technique for Troutman wedge resection has been described.[19(pp 405–450)]

Outcome data are presented as means ± standard deviations.

Results

Refractive

The mean average keratometry 3 months postoperatively was 43.40 ± 2.60 D. This mean fluctuated by ±0.20 D over the postoperative period (Figures 1 and 2).

Table 2. Postoperative enhancement procedures.

Procedure	Eyes		Comments
	Number	(%)	
ALK	4	(4)	—
Relaxing incisions	33	(31)	6 eyes needed 2
Add sutures	20	(19)	3 eyes needed 2
Wedge resection	5	(5)	—
Wound dehiscence	33	(31)	4 eyes needed 2
Total enhancements	108	—	Mean = 1 per eye

The mean keratometric astigmatism was 4.07 ± 2.50 D at 1 year postoperatively and 3.10 ± 1.80 D at last follow-up (Figure 3). Mean postoperative spherical equivalent was −1.85 ± 2.80 D and −1.75 ± 3.10 D at 3 months and 1 year, respectively (Figures 4 and 5). Mean cylinder was 2.73 ± 1.70 D and 2.61 ± 1.50 D, respectively.

Sutures were removed at a mean of 14.8 ± 5.8 months. Table 3 shows the refractive data from follow-up visits immediately before and after suture removal.

Visual Acuity

Postoperatively, UCVA was 20/60 (0.33 ± 0.2) and 20/60 (0.36 ± 0.3) at 3 months and 1 year, respectively. At last follow-up, mean UCVA was 20/50 (0.43 ± 0.3), with 46 eyes (44%) having 20/40 or better (Figure 6).

At last follow-up, 86% of eyes had gained lines of BCVA. Two eyes (2%) had lost two lines. No eye lost more than 2 lines.

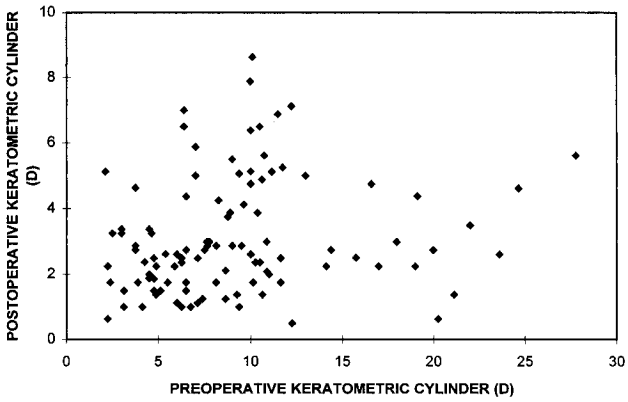

Figure 3. (Buzard) Preoperative versus postoperative keratometric cylinder at last follow-up.

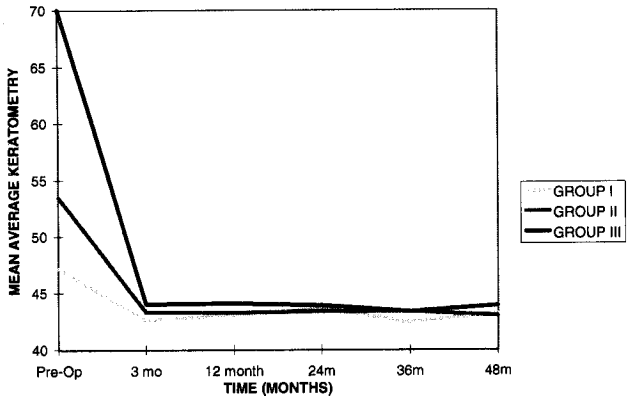

Figure 1. (Buzard) Average keratometry over time.

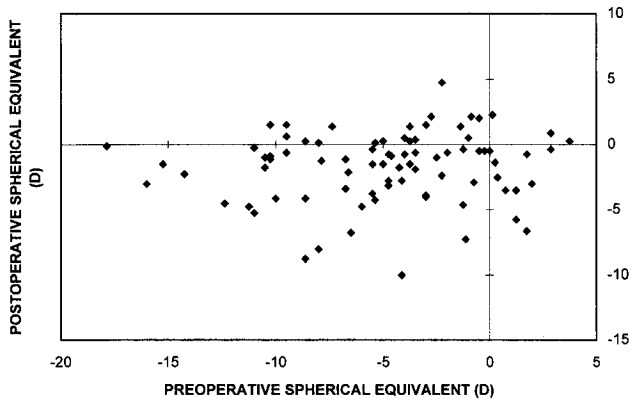

Figure 4. (Buzard) Preoperative versus postoperative spherical equivalent at last follow-up.

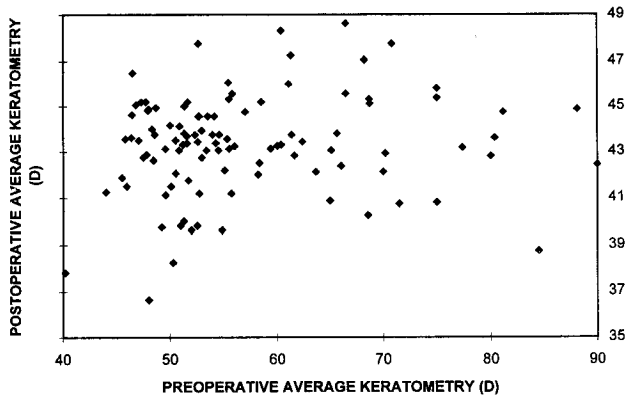

Figure 2. (Buzard) Preoperative versus postoperative mean keratometry at last follow-up.

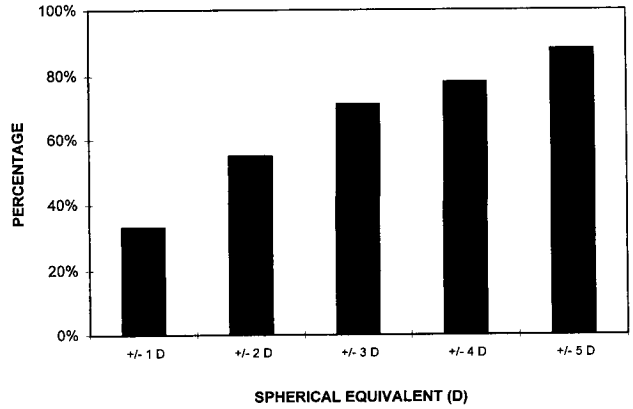

Figure 5. (Buzard) Percentage of cases within 1.00, 2.00, 3.00, 4.00, and 5.00 D of emmetropia at last follow-up.

ately before and after graft suture removal.

Measurement (D)	Preoperative	Postoperative
Keratometry	43.80 ± 2.20	43.50 ± 2.10
Cylinder	2.85 ± 1.90	2.88 ± 1.80
Spherical equivalent	−1.37 ± 3.20	−1.80 ± 3.10

Sixty eyes (58%) had a BSCVA of 20/40 or better 1 month postoperatively; 92 eyes (88%) had a BSCVA of 20/40 or better by 3 months (Figure 7).

Enhancements

Four eyes had an automated lamellar keratoplasty (ALK) enhancement at a mean of 18 months (range 13 to 28 months) after the corneal transplant. Before the enhancement, mean spherical equivalent was −6.97 ± 0.90 D and mean UCVA, 0.05 ± 0.04 (20/400). At last follow-up after the ALK, mean spherical equivalent was −2.59 ± 1.00 D and mean UCVA, 0.31 ± 0.30 (20/60). Subsequently, these eyes were further enhanced with laser in situ keratomileusis; mean UCVA improved to 20/25.

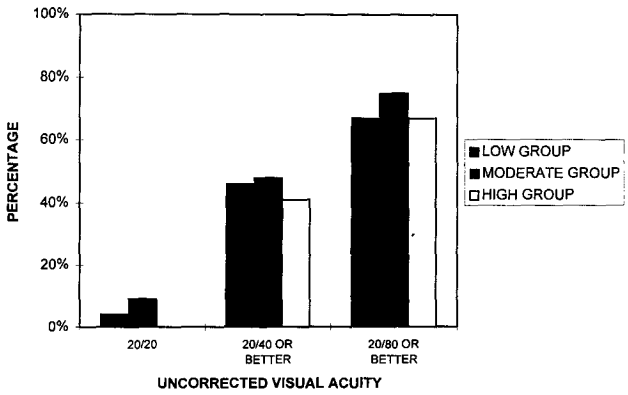

Figure 6. (Buzard) Percentage of cases with 20/20, 20/40 or better, and 20/80 or better UCVA at last follow-up by keratometric group.

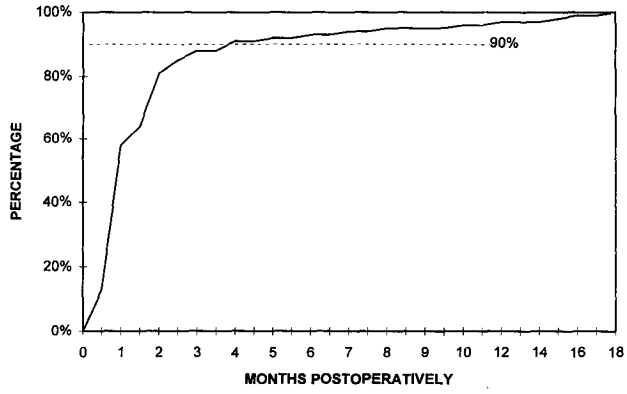

Figure 7. (Buzard) Cumulative time from PKP until the patients achieved at least 20/40 BSCVA.

Thirty-three eyes had astigmatic relaxing incisions a mean of 16 months (range 4 to 58 months) after corneal transplant. Six had their incisions deepened, extended, or both at a later date. Before the enhancement, mean keratometric cylinder was 5.70 ± 2.80 D and mean refractive cylinder, 3.81 ± 2.00 D. At last follow-up, the mean keratometric cylinder was 3.04 ± 1.60 D and the mean refractive cylinder, 2.59 ± 1.50 D. Mean uncorrected visual acuity before the incisions was 0.32 ± 0.20 (20/60), improving to a mean of 0.45 ± 0.20 (20/40) at last follow-up.

Five eyes had a corneal wedge resection a mean of 19 months (range 1 to 58 months) after the corneal transplant. Before the enhancement, mean keratometric cylinder was 7.90 ± 3.20 D and mean refractive cylinder, 4.95 ± 2.10 D. At last follow-up, mean keratometric cylinder was 3.77 ± 1.60 D and mean refractive cylinder, 3.45 ± 1.60 D. Mean UCVA before the incisions was 0.10 ± 0.03 (20/200), improving to 0.20 ± 0.20 (20/100) at last follow-up.

Complications

No cases of endophthalmitis occurred in this study, nor in 947 consecutive corneal transplants performed by the surgeon in this study (Table 4).

There were no cases of expulsive hemorrhage in this study. In the overall group of 947 cases performed by the surgeon, 4 expulsive hemorrhages occurred; 1 eye was lost (Table 5).

In the current study of 104 eyes, no grafts experienced primary failure (within the first postoperative week). Twenty-one eyes (20%) had secondary graft rejection that was successfully treated with therapy in 19 of the cases. Two eyes (2%) required a regraft (Table 6).

Discussion

Penetrating keratoplasty has a long history that in many ways predates and has anticipated the dramatic changes in corneal surgery seen in the past few decades. Significant changes in spherical equivalent and astigma-

Table 4. Endophthalmitis rates in different studies.

Study*	Year	Total Eyes in Study	Incidence		Positive Rim Cultures	
			Eyes	(%)	Number	(%)
Buzard†	—	947	0	(0.0)	52	(5.5)
Kloess[28]	1993	1010	4	(0.4)	128	(13.7)
Antonios[29]	1991	2210	9	(0.4)	406	(29.0)
Kattan[30]	1991	1783	2	(0.1)	80	(7.2)
Gus[31]	1983	445	11	(2.5)	45	(10.1)
Leveille[32]	1983	1876	4	(0.2)	236	(12.6)

*Only first author listed
†Includes 104 eyes from current study

Table 5. Expulsive suprachoroidal hemorrhage rate in different studies.

Study*	Year	Total Eyes in Study	Incidence		Local Block Anesthesia		Mean Age (Years)
			Eyes	(%)	Eyes	(%)	
Buzard†	—	947	4	(0.40)	0	(0)	68.0
Price[33]	1993	2011	9	(0.40)	2	(22)	69.0
Speaker[34]	1991	1436	8	(0.56)	8	(100)	71.7
Purcell[35]	1982	—	14‡		10	(71)	63.3

*Only first author listed
†Includes 104 eyes from current study
‡Four surgeons, 5 years

tism, particularly in PKP for keratoconus, have provided the insight required to refine today's corneal refractive operations.

Despite this, PKP remains an enigma. Seemingly small details such as suture depth and pattern, sizing and orientation of the graft, and postoperative follow-up seem to have significant effects on the final outcome. It has taken many years to identify and describe treatments for these disorders.

However, the results presented here, which correspond to those of other published reports, show that PKP today, with the aid of better tissue, instruments, and follow-up as well as secondary enhancement operations, is close to being a refractive surgery procedure. Attention to detail at eye banks and in the operating room has greatly reduced complications, and corneal topography provides the means for resolving many postoperative problems (e.g., poor UCVA or BCVA) in most patients.

These advancements provide three reasons for considering PKP as a primary treatment for keratoconus patients.

1. The torque–antitorque suture method gives rapid visual rehabilitation and long-term stability when sutures are removed 1 year postoperatively. Our long-term data with sutures out (average keratometry approximately 43.00 D) confirm the stability of the surgical technique (Figure 1). The lack of significant change in astigmatism or myopia after suture removal shows the firm healing induced by the suture pattern. In addition, rapid return of BSCVA minimally disables the vision during the "sutures in" period after PKP. Finally, a mean of 20/50 final UCVA gives results close to those of a refractive procedure.

2. One deterrent to early corneal transplantation has been the fear of complications including endophthalmitis, expulsive hemorrhage, and irreversible graft rejection. Each complication has been significantly affected by the availability of better eye-bank tissue, surgical techniques, and anti-inflammatory medications including cytotoxic agents.

Lower infection rates are achieved by strict standards imposed on EBBA-certified eye banks, and we believe our low rim culture rate reflects these standards.

Study*	Year	Eyes in Study							Follow-up (Years)
			Eyes	(%)	Eyes	(%)	Eyes	(%)	
Buzard									
Keratoconus†	—	104	0	(0.0)	21	(20.0)	2	(2.0)	3
Overall	—	947	3	(0.3)		—		—	—
Exclusive keratoconus studies									
Price[36]	1991	2011	2	(1.6)		—	0	(0.0)	2
Lass[17]	1990	140	1	(0.7)	7	(5.0)	1	(0.7)	2
Epstein[37]	1987	325		—	68	(20.9)	33	(10.2)	4
Paglen[38]	1982	326		—	30	(9.2)	24	(7.4)	11
Buxton[39]	1981	134	5	(3.7)	28	(20.9)	3	(2.2)	4
General PKP studies									
Girard[40]	1993	91		—	9	(10)	1	(1.0)	7
Williams[41]	1993	2248	15	(0.7)		—		—	—
Chipman[42]	1993	1224	48	(3.9)		—		—	—
Price[36]	1991	1046	7	(0.7)		—	38	(3.6)	2
Buxton[43]	1988	1351	17	(1.2)		—		—	—

*Only first author listed
†Current study

Table 7. Refractive visual results in different studies.

Study*	Year	Total Eyes in Study	Follow-up (Years)	Mean (±SD) Spherical Equivalent (D)	Mean (±SD) Astigmatism (D)	Mean UCVA	Mean BCVA	Correction
Buzard†	—	104	3	−1.70 ± 3.00	3.10 ± 1.80	20 /50	20/25	3% HCL/97% G or NC
Crews[44]	1994	28	2	−2.20 ± 3.40	3.30 ± 2.20	—	20/80	—
Goble[45]	1994	49	2	−0.50 ± 3.00	3.80 ± 2.60	≤20/40§	≤20/40‖	>50% G/HCL
Tuft[46]	1992	60	—	−4.80	—	—	—	—
Price[47]	1991	84	—	—	—	—	≤20/40¶	6–22% HCL
Fronterre[48]	1991	30	3–6	−1.50	3.20	20 /63	20/20#	—
Lass[17]	1990	140	2	—	<5.00‡	—	20/25	56% HCL; 34% G; 10% NC
Sayegh[49]	1988	104	0.5–9	−3.30 ± 3.50	2.60 ± 1.90	—	20/30	—
Girard[50]	1988	55	3	−4.90	4.00	—	—	—
Smiddy[16]	1987	88	4.5	—	4.50	—	≤20/40**	60% HCL; 40% G
Troutman[20]	1987	86	2	—	4.30	—	≤20/40††	—

HCL = hard contact lens; G = glasses; NC = no correction
*Only first author listed
†Current study
‡47% of eyes <5.00 D
§43% of eyes ≤20/40
‖98% of eyes ≤20/40
¶91% of eyes ≤20/40
#Without contact lens
**90% of eyes ≤20/40
††97% of eyes ≤20/40

In particular, we believe washing the cul-de-sac with diluted Betadine, accompanied by good sterile technique and antibiotic drops, has resulted in the low incidence of endophthalmitis in this study and in our overall surgical practice. The low rates of expulsive hemorrhage in this study primarily reflect the young age of the patients (mean 32 years). We believe, however, that the use of general anesthesia has contributed to the low rate of

expulsive suprachoroidal hemorrhage because it allows a more stable blood pressure/heart rate and provides complete nerve block without risking orbital hemorrhage.

Finally, corneal graft rejection is multifactorial. Better quality tissue results in less inflammation and faster healing and, coupled with more effective cytotoxic medications such as low dose methotrexate and cyclophosphamide, can keep irreversible graft rejection to a minimum. In general, the rate of complications with corneal transplantation has reached historic lows, encouraging the application of PKP at a much earlier stage of keratoconus.

3. Secondary or enhancement operations for astigmatism (both regular and irregular) and spherical error encourage transplantation at an earlier stage of keratoconus. Never before have we had such an array of effective operations to treat postoperative ammetropias. The advent of lamellar refractive surgery, particularly with the excimer laser, led to improved refractive results in these patients. The low levels of spherical equivalent (-1.75 ± 3.10 D) and astigmatism (2.61 ± 1.50 D), coupled with the high percentage (44%) of patients with uncorrected visual acuity of 20/40 or better, point to a high level of satisfaction with the procedure.

In conclusion, the results of this study indicate that the high level of refractive improvement from keratoplasty combined with a growing ability to correct postoperative refractive problems and the low complication rate have made corneal transplantation the primary choice for permanently eliminating visual problems in eyes with early and moderate keratoconus. Now, rather than presenting corneal transplantation as the last alternative to the keratoconus patient and simply accepting the poor vision provided by high-power spectacle correction and rigid hard contact lenses, we offer corneal transplantation as a primary treatment option to the patient with a loss of BSCVA to 20/40 or worse.

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