Long-term Results of Deep Anterior Lamellar versus Penetrating Keratoplasty

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Objective: To compare deep anterior lamellar keratoplasty (DALK) with penetrating keratoplasty (PK) in eyes with corneal diseases not involving the corneal endothelium (keratoconus, scars after infectious keratitis, stromal dystrophies, and trauma).

Design: Retrospective, comparative case series.

Participants: One hundred forty-two consecutive DALK (DALK group; big-bubble technique or manual lamellar dissection using a slitlamp) and 142 matched PK (PK group).

Methods: Three models were used to describe the postoperative outcomes of the endothelial cell density. A joint regression model was used to predict long-term graft survival. Visual acuity, ultrasound pachymetry, specular microscopy, and optical coherence tomography (OCT) findings were recorded.

Main Outcome Measures: Postoperative endothelial cell loss and long-term predicted graft survival.

Results: The average 5-year postoperative endothelial cell loss was −22.3% in the DALK group and −50.1% in the PK group ($P<0.0001$). The early- and late-phase annual rates of endothelial cell loss were −8.3% and −3.9% per year, respectively, in the DALK group and −15.2% and −7.8% per year in the PK group ($P<0.001$; biphasic linear model). The median predicted graft survival was 49.0 years in the DALK group and 17.3 years in the PK group ($P<0.0001$). The average visual acuity was lower in the manual dissection subgroup compared with the PK group (average difference, 1.0 to 1.8 line) and with the big-bubble subgroup (average difference, 2.2 to 2.5 lines). The average central corneal thickness at 12 months was 536 μm in the PK group, 523 μm in the big-bubble subgroup, and 562 μm in the manual dissection subgroup ($P<0.001$). The average thickness of the residual recipient stroma measured by OCT was 87 ± 26 μm in the manual dissection subgroup. No correlation was found between this figure and logarithm of the minimal angle of resolution at any postoperative time point ($P>0.05$).

Conclusions: Long-term, model-predicted graft survival and endothelial densities are higher after DALK than after PK. The big-bubble technique gives better results than manual dissection and PK. Compared with PK, manual dissection provides higher survival of both the corneal endothelium and graft, but lower visual acuity.

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There is currently a trend among corneal surgeons toward replacing penetrating keratoplasty (PK) with various types of lamellar techniques that aim to remove only damaged tissue. Deep anterior lamellar keratoplasty (DALK) is currently considered to be the first-choice operative procedure in patients with corneal diseases not involving the endothelial layer, including keratoconus, stromal scars, and lattice dystrophy.[1–3] Patients suffering from these corneal diseases may require transplantation during the first 3 decades of life. A long graft survival is then expected in these young patients.

Removal of the damaged corneal stroma may be achieved by manual dissection with a surgical blade and scissors, microkeratome-assisted lamellar cut, or femtosecond laser-assisted cut. Descemet's membrane detachment from the corneal stroma can be achieved using air injection (the "big-bubble" technique), hydrodelamination through a sclerocorneal flap, or sodium hyaluronate injection.[4–13] Whereas a successful big-bubble procedure allows removal of all the recipient stroma, a layer of the recipient posterior stroma usually remains with the other techniques. The objective of the present retrospective study was to compare the long-term results of deep lamellar anterior keratoplasty with those of PK in eyes with the same preoperative corneal conditions. The influence of remaining recipient posterior stroma on the long-term results of DALK was also assessed.

Patients and Methods

Study Design

This retrospective, comparative case series was designed from a consecutive series of keratoplasties performed in a single center. Inclusion criteria were keratoplasty procedures performed by 1 surgeon (V.M.B.) between January 1995 and April 2010 for optical indications in eyes with corneal diseases not involving the corneal endothelium (i.e., keratoconus, scars after infectious keratitis, stromal dystrophies, and trauma). For patients who received 2 grafts in the same or contralateral eye during the study period, only the first graft was included. The study group (DALK group) included all DALK procedures that met the inclusion criteria (n =

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142). These operative procedures were performed between September 2002 and April 2010. The control group (PK group) was selected from PK procedures performed between January 1995 and August 2002. Two hundred seventy-four PKs that met the inclusion criteria were performed during this period. Among these 274 PKs, 142 cases matched for preoperative diagnosis and recipient rejection status were selected for the control group (PK group). Patients who underwent DALK between January 1995 and February 2010 were excluded from the control group so that a patient could contribute only for 1 graft to the study. PKs were selected according to the date of transplantation, with the most recent grafts being selected and the latest grafts being excluded. They were included until the same number of high-risk recipients and the same numbers of eyes with the various preoperative diagnoses were obtained in both groups. Donor corneas were stored at 31°C in an organ culture medium before surgery.[14] All donor corneas were processed with the same technique by a single eye bank during the study period. The composition of the culture medium used for corneal storage was not modified during that time. Data were recorded prospectively and then analyzed retrospectively.

In accordance with French law, institutional review board and ethics committee approval were not required for this study because no modifications to French standards of treatment or follow-up were made. Described research adhered to the tenets of the Declaration of Helsinki.

Operative Procedures

All transplantations were performed at a single institution. Deep anterior lamellar keratoplasty was performed under general anesthesia.[15] A first nonpenetrating trephination was performed using the Hanna device in the recipient cornea (trephination depth, 80% of corneal central thickness [CCT]), and the anterior and middle stroma were removed using crescent blade. Air was injected into the posterior stroma. When air injection induced detachment of the Descemet's membrane (65 out of 142 cases; 46%), sodium hyaluronate was injected between the posterior stroma and the Descemet's membrane and the remaining posterior stroma was completely removed using scissors (big-bubble subgroup). When no detachment of the Descemet's membrane could be obtained after repeated air injection (77 out of 142 cases; 54%), deep posterior stromal dissection was performed using a crescent blade (manual dissection subgroup). Dissection depth was controlled using a slit-lamp operating microscope. Donor tissue used for DALK was trephined from the posterior corneal surface using the Hanna device, and the Descemet's membrane was removed. A DALK was scheduled in 157 eyes during the study period. Significant perforation occurred during stromal dissection in 15 of these 157 eyes (9.6%), and DALK was converted to PK with no notable difficulties and normal subsequent outcomes (data not shown). In all, 142 DALKs were performed. The PKs were performed using the Hanna device as previously described.[16] Graft suturing was performed according to standardized methods in all patients (DALK and PK), with mixed suturing (8 interrupted sutures and a 16-bit running suture) used in most patients. Sutures were removed after at least 18 months. All the patients were treated with topical dexamethasone (1 mg/ml) and neomycin (3400 IU/ml). This treatment was tapered for several months without standardization of postoperative corticosteroid management. The initial corticosteroid regimen was 1 drop hourly in patients with vascularized corneas and 1 drop every 6 hours in the other patients. Corticosteroid use was never stopped in the former patients, and it was discontinued when all the sutures were removed in the latter.

Recipients and Transplantation Outcome

High-risk recipients were defined as having a vascularized cornea (>2 quadrants of corneal vascularization). No eyes had limbal deficiency. Patients were hospitalized up to the time of graft re-epithelialization. They were then examined prospectively at 1 and 2 weeks; 1, 3, 6, 9, 12, 18, 24, 30, and 36 months; and 3, 4, 5, 6, 7, 8, 10, and 15 years after surgery.

Manifest refraction (with spectacle correction), CCT (ultrasound pachymetry), intraocular pressure (mean of 2 measurements obtained along the steepest and flattest corneal meridians using the Goldmann applanation tonometer (Haag Streit, Koeniz, Switzerland)), and graft transparency were recorded at each examination. The criteria for graft failure were irreversible graft stromal edema and corneal opacification. At 1, 3, 5, 7, and 10 years after keratoplasty, the graft was evaluated using wide-field specular microscopy (Topcon, Clichy, France) as part of routine care. In addition, eyes with DALK performed with the manual dissection technique were evaluated with optical coherence tomography (OCT; Visante OCT, Carl Zeiss Meditec France SAS, Le Pecq, France) 1 year after keratoplasty.

Statistical Analysis

To describe postoperative endothelial cell loss, 3 models were fitted to grafts with at least 2 endothelial cell density (ECD) measurements in time ($n = 238$). The linear model assumes a constant endothelial cell loss with time: $ECD = ECD_0 - (t \times CL)$, where ECD_0 is the preoperative ECD, t is the postoperative time point in years, and CL is the annual rate of endothelial cell loss. In the biphasic linear model, the endothelial density was described as a mixed piecewise linear model in time with a change in slope 1 year after surgery: $ECD = ECD_0 - (t \times E)$, for $t < 1$ year; $ECD = A - (t \times L)$, for $t > 1$ year, where E is the slope of the early phase endothelial cell loss and L is the slope of the late phase endothelial cell loss. For the biexponential model, the following equation was used: $ECD = a \times \exp(-bt) + c \times \exp(-dt)$.[17] Half-times for the 2 components of the endothelial cell loss were calculated as follows: $0.693/b$ for the early phase and $0.693/d$ for the late phase. The least-squares estimates were used to calculate the coefficients of the various equations for each patient. Then, a joint regression model was fitted on survival and ECD as described previously.[18] Model-predicted graft survival was obtained for each patient and was used in a Kaplan–Meier plot to predict long-term graft survival. The log-rank test was used to compare the groups of patients.

For statistical analysis of visual acuity, astigmatism, corneal thickness, intraocular pressure, and ECD, only eyes with clear grafts were included. Visual acuity was converted to logarithm of the minum angle of resolution (LogMAR) units before statistical analysis. For quantitative variables, the unpaired t test was used to compare the DALK group with the PK group and analysis of variance was used to compare the 3 subgroups. Correlation was assessed using the Pearson regression test. Qualitative variables were analyzed using the chi-square test. Statistical analysis was performed using a software program (Statistica version 6.1; StatSoft France, Maisons-Alfort, France).

Results

Table 1 shows the baseline comparison of the DALK group with the PK group. We examined 142 (100%), 134 (94.4%), 108 (76.1%), and 80 (56.3%) eyes at 0, 12, 24, and 36 months in the DALK group, respectively. In the PK group, these figures were 142 (100%), 134 (94.4%), 123 (86.6%), and 112 (78.9%), respectively.

Table 1. Comparison of DALK with PK

Variable	DALK Group (n = 142)	PK Group (n = 142)	*P*-Value
Preoperative diagnosis			
Keratoconus	100 (70.4%)	100 (70.4%)	
Stromal dystrophies	3 (2.1%)	3 (2.1%)	
Scars after infectious keratitis	37 (26.1%)	37 (26.1%)	
Trauma	2 (1.4%)	2 (1.4%)	1.00
Recipient rejection status			
Low risk	121 (85.2%)	121 (85.2%)	
High risk	21 (14.8%)	21 (14.8%)	1.00
Preoperative intraocular pressure			
≤20 mmHg and no history of glaucoma	136 (95.8%)	136 (95.8%)	
>20 mmHg and/or history of glaucoma	6 (4.2%)	6 (4.2%)	1.00
Donor trephination size (mm)	8.15±0.24	8.19±0.19	0.12
Recipient trephination size (mm)	7.89±0.24	7.93±0.19	0.12
Recipient age (y)	39.0±16.1	39.0±17.4	0.99
Donor age (y)	70.0±13.2	70.2±13.9	0.90
Follow-up (mos)	42.9±22.9	80.5±50.3	<0.001

DALK = deep anterior lamellar keratoplasty; PK = penetrating keratoplasty.
Shown are numbers (percentages) and mean ± standard deviation.

In the DALK group, graft failures were the result of persistent postoperative double anterior chamber (n = 1), late infectious keratitis (n = 1), and trauma (n = 1). In the PK group, they were the result of rejection associated with epithelial defects (n = 3), ocular hypertension associated with recurrence of stromal dystrophy (n = 1), infectious keratitis (n = 1), infectious keratitis associated with ocular hypertension (n = 2), and trauma (n = 1). Table 2 shows the postoperative complications observed in each group.

Table 3 shows the observed and model-predicted postoperative endothelial cell loss. The ECD was significantly higher in the DALK group than in the PK group at all postoperative time points ($P<0.001$; Fig 1). The average 5-year postoperative endothelial cell loss was −22.3% in the DALK group and −50.1% in the PK group ($P<0.0001$). The early- and late-phase annual rates of endothelial cell loss in the DALK group were half those obtained in the PK group ($P<0.0001$).

The median model-predicted graft survival was 49.0 years in the DALK group and 17.3 years in the PK group ($P<0.0001$; Fig 2). No differences in predicted graft survival were found between the big-bubble and the manual dissection subgroups ($P = 0.16$).

Table 2. Postoperative Complication Observed after Deep Anterior Lamellar Keratoplasty (DALK) and Penetrating Keratoplasty (PK)

	DALK Group (n = 142), n (%)	PK Group (n = 142), n (%)
Eyes with ≥1 postoperative complication	27 (19)	83 (59)
Rejection episodes	17 (12)	31 (22)
Epithelial	0	2 (1)
Subepithelial	1 (1)	1 (1)
Stromal	16 (11)	1 (1)
Endothelial	0 (0)	21 (15)
Associated endothelial and stromal	0 (0)	6 (4)
Ocular hypertension	8 (6)	38 (26)
Double anterior chamber	7 (5)	0
Infectious keratitis	2 (1)	8 (6)
Trauma	3 (2)	3 (2)
Miscellaneous	4 (3)	10 (7)

Comparison of DALKs with PKs for the best-spectacle corrected LogMAR visual acuity showed no significant differences at all postoperative time points (Fig 3).

Analysis of variance showed that the preoperative diagnosis significantly influenced visual acuity at all postoperative time points ($P\leq0.001$). The surgical technique (i.e., PK, big bubble, or manual dissection) had a significant influence on visual acuity at 6, 12, 18, 24, 30, and 36 months ($P\leq0.02$). The average visual acuity was lower in the manual dissection subgroup than in the PK group (average differences ranged from 1.0 to 1.8 lines) and lower in the manual dissection subgroup than in the big-bubble subgroup (average differences ranged from 2.2 to 2.5 lines). Among 200 eyes with keratoconus, the visual acuities at 18, 24, 30, and 36 months were significantly better in the big-bubble subgroup than in the manual dissection subgroup ($P<0.05$) and better in the PK group than in the manual dissection subgroup ($P<0.05$), whereas no differences were found between the big-bubble subgroup and the PK group ($P>0.05$). A best spectacle-corrected LogMAR visual acuity of ≤0.10 (20/25 or better). At 12, 24, and 36 months was achieved, respectively, in 35%, 50%, and 60% of cases in the big-bubble subgroup (n = 54); in 27%, 41%, and 52% of cases in the PK group (n = 100); and 9%, 9%, and 17% of cases in the manual dissection subgroup (n = 46). A best spectacle-corrected LogMAR visual acuity of ≤0.30 (20/40 or better) at 12, 24, and 36 months was achieved, respectively, in 87%, 95%, and 97% of cases in the big-bubble subgroup; in 72%, 88%, and 85% of cases in the PK group; and 45%, 59%, and 74% of cases in the manual dissection subgroup.

The average central corneal thickness at 12 months was 536±54 μm (mean ± standard deviation) in the PK group, 523±40 μm in the big-bubble subgroup, and 562±50 μm in the manual dissection subgroup ($P<0.001$). The average thickness of the residual recipient stroma measured by OCT was 87±26 μm in the manual dissection subgroup (range, 48–150 μm). In this subgroup, no correlation was found between the thickness of the residual recipient stroma measured by OCT (central point and 1-, 2-, and 3-mm central zones) and the LogMAR visual acuity at 1, 3, 6, 9, 12, 18, 24, 30, and 36 months after surgery ($P>0.05$). No

Table 3. Observed and Model-predicted Postoperative Endothelial Cell Loss

Group	Postoperative Endothelial Cell Loss; % Cell Loss (Observed Data); % Cell Loss Per Year (Linear Models); Half-time in Years (Biexponential Model)			
	Early Phase		*Late Phase*	
	Mean ± Standard Deviation	*P*	*Mean ± Standard Deviation*	*P*
Observed data at 1 year				
PK	−20.2±16.6			
DALK	−10.0±7.1	<0.0001		
DALK: Big-bubble subgroup	−9.8±7.1			
DALK: Manual subgroup	−10.1±7.1	0.82		
Observed data at 3 years				
PK			−37.2±21.0	
DALK			−16.7±9.8	<0.0001
DALK: Big-bubble subgroup			−17.7±10.1	
DALK: Manual subgroup			−15.8±9.6	0.43
Observed data at 5 years				
PK			−50.1±19.0	
DALK			−22.3±12.7	<0.0001
DALK: Big-bubble subgroup			−27.3±13.3	
DALK: Manual subgroup			−18.1±10.8	0.01
Linear model				
PK	−10.5±8.4		−10.5±8.4	
DALK	−5.9±4.6	<0.0001	−5.9±4.6	<0.0001
DALK: Big-bubble subgroup	−6.3±4.1		−6.3±4.1	
DALK: Manual subgroup	−5.6±4.9	0.13	−5.6±4.9	0.13
Biphasic linear model				
PK	−15.2±12.8		−7.8±5.5	
DALK	−8.3±6.0	<0.0001	−3.9±3.8	<0.0001
DALK: Big-bubble subgroup	−8.2±6.2		−4.2±3.3	
DALK: Manual subgroup	−8.4±5.6	0.81	−3.6±4.3	0.06
Biexponential model				
PK	0.04±0.01		10.0±15.7	
DALK	0.23±1.21	0.12	28.6±32.6	<0.0001
DALK: Big-bubble subgroup	0.28±1,47		29.3±34.9	
DALK: Manual subgroup	0.18±0.96	0.94	27.7±30.1	0.66

DALK = deep anterior lamellar keratoplasty; PK = penetrating keratoplasty.

correlation was found between the coefficient of variation of the thickness of the residual recipient stroma measured by OCT (1-, 2-, and 3-mm central zones) and the LogMAR visual acuity at 1, 3, 6, 9, 12, 18, 24, 30, and 36 months after surgery ($P>0.05$). For 57 patients who had ultrasound pachymetry and OCT performed at the same postoperative time point, no differences in the average central corneal thickness was observed between OCT and ultrasound measurements ($P = 0.07$).

No differences in intraocular pressure between the DALK and the PK groups and between subgroups were found at any postoperative time point ($P>0.05$). Finally, no differences in refractive cylinder were found between the DALK and the PK groups and between subgroups at any postoperative time point ($P>0.05$).

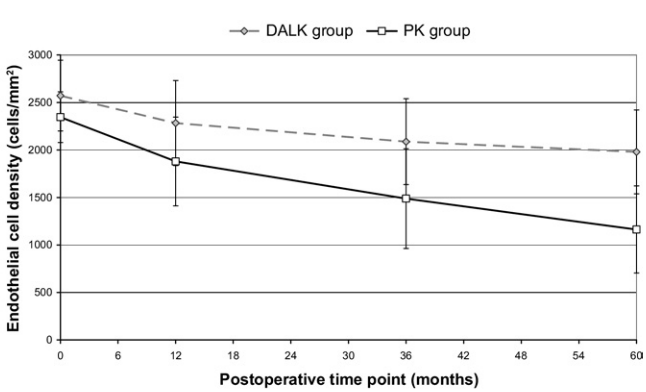

Figure 1. Outcome of the corneal endothelial cell density after deep anterior lamellar keratoplasty (DALK) versus penetrating keratoplasty (PK).

Discussion

In this retrospective study of patients with keratoconus, corneal scars after infectious keratitis, stromal dystrophies, and trauma, long-term model-predicted graft survival was dramatically greater in the DALK group than in the PK group. The median model-predicted graft survival was 49 years in the DALK group and 17.3 years in the PK group. This implies that a young patient undergoing DALK should not require regrafting in the long term. Conversely, regrafting is likely to be required in the long term for a young patient undergoing PK. However, these median predicted graft survival times are statistical theorems and clinical assessment cannot be provided because DALK has not been used for such a period yet. The dramatic improvement in

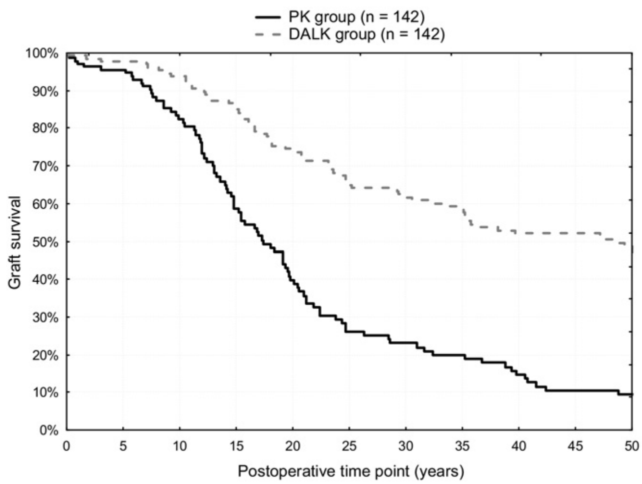

Figure 2. Predicted long-term graft survival after deep anterior lamellar keratoplasty (DALK) versus penetrating keratoplasty (PK; log-rank = 5.95; $P<0.0001$).

long-term model-predicted graft survival after DALK is explained by better survival of the corneal endothelium as reported by several other studies and decrease in the incidence of rejection.[18–23] In fact, the observed 5-year postoperative endothelial cell loss was −22.3% in the DALK group and −50.1% in the PK group. Furthermore, the model-calculated long-term endothelial cell loss was dramatically lower in the DALK group than in the PK group. The half-time for the late component of the endothelial cell loss was 10.0 years in the PK group and 28.6 years in the DALK group. This means that, in the long term, the ECD decreases by 50% every 10 years after PK and every 29 years after DALK.

Overall, no differences in visual acuity were found between the DALK and the PK groups at any postoperative time point. However, among keratoconic eyes, manual dissection gave significantly lower visual recovery than the big-bubble technique and PK. The former operative technique gave also the lowest 5-year endothelial cell loss. Visual acuity did not correlate with the thickness of the remaining recipient posterior stroma or with the regularity of the thickness of this stromal layer assessed by its coefficient of variation. It seems likely that lower visual recovery is related to opacity of the interface or opacity of the remaining recipient posterior stroma. We previously reported that, after anterior lamellar keratoplasty, complete removal of the recipient stroma provides the greatest keratocyte densities.[15] Conversely, the thickness of residual recipient corneal stroma has been shown to significantly influence visual recovery in a series of 32 eyes with a recipient corneal bed thickness of ≤20 μm being associated with visual acuities similar to those obtained after PK.[24] We did not find this relationship. However, the level of opacity of the recipient corneal bed is not assessed currently. Furthermore, the thickness of the recipient corneal bed (including Descemet's membrane and endothelium) after manual dissection is difficult to assess precisely. Postoperative Visante OCT measurements resulted in a mean thickness of 87 μm, with a minimum of 48 and a maximum of 150 μm. Ultrasound pachymetry showed that the difference between the mean CCT in the big-bubble subgroup and the mean CCT in the manual dissection subgroup was 39 μm. If the thickness of the Descemet's membrane and endothelium is considered to be in the range of 15 to 20 μm, it can be hypothesized that OCT would overestimate the thickness of the recipient posterior stroma by 30 μm. With the currently available techniques, it seems difficult to dissect deeper during DALK because the slit lamp does not allow differentiation of a 50-μm-thick stromal layer from a 100-μm-thick stromal layer during surgery. Intraoperative use of high-definition OCT could provide surgeons with a more

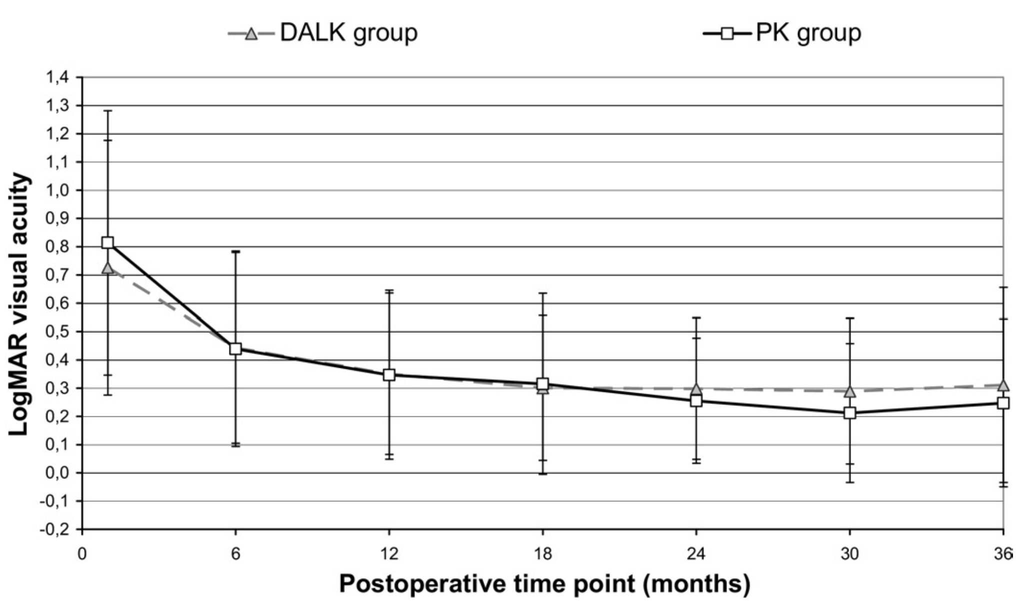

Figure 3. Outcome of visual acuity after deep anterior lamellar keratoplasty (DALK) and penetrating keratoplasty (PK). Values are presented as means ± standard deviation. LogMAR = logarithm of the minimal angle of resolution.

precise assessment of the depth of dissection. It could also permit assessment of tissue transparency. Then, the decision to further dissect the posterior stroma could be made according to the thickness and reflectivity of the recipient corneal bed.

A recent study has shown the results of the big-bubble technique in 234 eyes with keratoconus.[25] A best spectacle-corrected LogMAR visual acuity of ≤0.30 (20/40 or better) was achieved in 79.9% of cases and ≤0 (20/20 or better) in 16.2%. These figures are in good agreement with our results (i.e., 87% of eyes achieving ≤0.30 at 12 months, 95% at 24 months, and 97% at 36 months; 35% achieving ≤0.10 at 12 months, 50% at 24 months, and 60% at 36 months). Han et al[26] have reported the 12-month results of keratoplasty for keratoconus in a series of 125 eyes. They compared the 3 techniques used in the present study (i.e., PK, big bubble, and manual dissection). Their results were close to those observed at 12 months in our study, with a mean LogMAR visual acuity of 0.15 in the big-bubble group, 0.27 in the PK group, and 0.41 in the manual dissection group. In the present study, these figures were 0.19, 0.27, and 0.40, respectively. An analysis of the UK registry including 2152 first grafts for keratoconus (PK, 81%; DALK, 19%) showed that 33% of patients who underwent PK achieved a best-corrected LogMAR visual acuity of ≥0 (20/20) at 2 years compared with only 22% of those who underwent DALK.[27] However, no analysis of subgroups was provided and the percentage of DALKs performed with the big-bubble technique was not reported. These results may be in agreement with our results and those reported previously if the number of eyes operated with manual dissection largely exceed the number of big-bubble procedures.[15,26] Conversely, when a big-bubble procedure can be performed, visual recovery seems to be better than after PK.

In the present study, the percentage of eyes with a visual acuity of ≤0.30 (20/40 or better) increased from 12 to 36 months postoperatively in all subgroups. The increase was greatest in the manual dissection subgroup and there was a trend toward fewer differences between subgroups with increased postoperative time.

In the present series, the percentage of Descemet's membrane perforation requiring conversion of DALK to PK was 9.6%. Previous studies reported a rate of conversion to PK from 2.5% to 9.1%.[25,28–30]

Limitations of this study include its retrospective design and an absence of randomization. From the results of the present and other studies, it seems clear that the big-bubble technique should be considered as the best technique for grafting eyes with corneal stromal diseases.[2,3,15,25,26] However, when detachment of the Descemet's membrane cannot be obtained, the surgeon has to make a decision. If the objective is to get the best visual recovery, PK should be performed. If the main goal is to get the highest probability of long-term survival of the graft, DALK should be preferred.

In conclusion, long-term model-predicted graft survival and endothelial densities are greater after DALK than after PK. The big-bubble technique gives better results than manual dissection and PK. Compared with PK, manual dissection provides greater survival of both the corneal endothelium and graft, but lower visual acuity.

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