Original Article

Demographic and clinical profile, surgical outcome, and quality of life in patients who underwent bilateral lamellar corneal grafts

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Purpose: Lamellar corneal grafts have revolutionized the management of corneal blindness by replacing only the disease specific corneal layers. To the best of our knowledge, there is no study in literature describing the outcomes of bilateral lamellar keratoplasty in the Indian population. The aim of this work was to study the demographic profile, surgical outcomes, and quality of life in patients who underwent bilateral lamellar keratoplasty and to assess the correlation between these three. **Methods:** An observational cross-sectional study was conducted on 47 patients who underwent bilateral deep anterior lamellar keratoplasty (DALK) (n = 31) or descemet stripping automated endothelial keratoplasty (DSAEK) (n = 16) with a minimum follow-up of 6 months after the second surgery. Demographic parameters were collected by interview, surgical outcomes by clinical examination, and quality of life by a questionnaire. **Results:** A total of 47 patients were evaluated, women 42.56%, (n = 20) and men 57.44% (n = 27) with 38.3% being in 18–30 years age group and 23.4% above 60 years; 17.02% patients had a good socioeconomic status (score >60) and 61.70% had poorer socioeconomic status (score <50). Quality of life score (VR-QoL) was ≥50 in 82.9% patients and ≥70 in 14.89%. No significant association existed between VR-QoL scores and demographic factors. However, statistically significant association existed between VR-QoL and age of patient (P < 0.05), postoperative vision (P ≤ 0.05), and contrast sensitivity (P ≤ 0.01). **Conclusion:** Bilateral lamellar corneal grafts provide satisfactory visual outcomes compatible with day-to-day functioning. VR-QoL has a direct correlation to the age, visual acuity, contrast sensitivity, and inverse correlation with lenticule thickness in DSAEK and residual bed thickness in DALK.

Key words: Bilateral, deep anterior lamellar keratoplasty, descemet stripping automated endothelial keratoplasty, quality of life

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Lamellar corneal grafts offer several advantages over penetrating keratoplasty (PK). These include reduced risk of graft rejection, early visual rehabilitation, lesser incidence of intraoperative, and postoperative complications associated with PK and wider criteria for donor tissue selection.[1,2] In patients with bilateral corneal pathology, such as scars, corneal stromal dystrophies, keratoconus, and fuch's endothelial corneal dystrophy (FECD) bilateral corneal surgery may be indicated. In these cases, objective measurements like postoperative visual acuity alone as an indicator of success may not suffice and the subjective assessment of quality of life (QoL) provides a more holistic measure of the impact of bilateral surgery on the patient's lifestyle and their rehabilitation.

World Health Organization (WHO) defines QoL as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. Functional vision is defined as the vision that can be used to perform tasks involving sight.[3] This can be assessed by means of various questionnaires that have been developed.[4] These consist of a set of questions to assess the daily functioning of the patient. Most questions involve a rating from the patient on a scale varying from 1 to 5. An overall score is reached by summing or averaging the individual scores. One of these questionnaires is a 33-item Indian Vision Functioning Questionnaire (IND-VFQ-33) which has been validated for the Indian population and has been implemented to determine the vision related quality of life (VR-QoL).[5,6] Few studies have assessed the correlation between visual impairment and QoL following PK and deep anterior lamellar keratoplasty (DALK).[7-9] However, there is no study that evaluates the QoL following bilateral lamellar keratoplasty.

Methods

This study was an observational cross-sectional study conducted at a tertiary eye care center. The study was approved by the institutional review board and ethics approval was obtained. The study adhered to the tenets of Declaration of Helsinki. Written informed consent was obtained from all

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patients. We recruited all patients who came for follow-up between February 2017 and December 2018 after bilateral lamellar keratoplasty (DALK/DSAEK) and had completed a minimum follow-up period of 6 months after the second surgery. Patients who had not completed the postoperative period were less than 15 years of age or did not give consent to be part of the study were excluded.

The following demographic parameters were collected by direct interview: age, gender, address, occupation, and net income. The following parameters were collected from the patients' documents or hospital records: history, diagnosis, preoperative best-corrected visual acuity (BCVA; converted to the logarithm of the minimum angle of resolution [logMAR]), type of surgery, date of surgery, postoperative BCVA, astigmatism (diopters), contrast sensitivity (Pelli Robson chart), specular count (SP 3000P, Topcon Medical Systems, Inc.), donor lenticule thickness in DSAEK, residual stromal bed thickness (RSBT) in DALK, intraocular pressure (IOP)(NT-530P Non-contact tonometer, Nidek Technologies), and any postoperative complication. All investigations were repeated by the investigator at the time of collection of data to corroborate the findings.

An objective evaluation of the socioeconomic status of the patients enrolled in the study was done using the Standard of Living Index (SLI) which was calculated as per the norms given by the National Family Health Survey-2 (NFHS-2). The SLI scores for each patient were calculated based on questionnaire provided therein.[10] Index scores range from 0–14 for a low SLI to 15–24 for a medium SLI and 25–67 for a high SLI.

VR-QoL was assessed objectively by the VFQ-IND-33, which is a 33-point, interviewer administered questionnaire with three major subscales: general functioning (Q1–21), psychosocial domain (Q22–26), and visual symptoms (Q27–33). It was developed and field tested in three eye institutions in India.[11] Each item has four to five active response options targeting difficulty or frequency ranging from "no problems at all" to "cannot do this because of your vision" (five response categories) or from "no problems at all" to "a lot" (four response categories). The maximum score for all the statements under each scale for a respondent is 105 for general, 20 for psychological and 28 for vision related statements. The scale scores were determined by summing up the weights for the responses chosen for the statements in each scale. The raw scores for each statement were converted into indices. After obtaining the indices, the degree of satisfaction was determined on the basis of a scale as per Table 1.

Nonparametric data were expressed as median (range), parametric qualitative data as percentage and quantitative data as a mean ± standard deviation. Pearson Chi-square, likelihood ratio, and linear by linear association were used for finding a correlation between variables.

Table 1: Degree of Satisfaction

Index	Degree of Satisfaction
≥60	High degree of QLI
50-60	Average QLI
≤50	Low QLI

Results

Demographic parameters

A total of 47 subjects were evaluated who underwent bilateral lamellar keratoplasty of which 31 underwent DALK and 16 underwent DSAEK with a minimum follow-up of 6 months following second surgery (range 6–13 months). Of the 47 subjects enrolled into the study, 42.56% (n = 20, 11 DALK, 9 DSAEK) were women and 57.44% (n = 27, 20 DALK, 7 DSAEK) were men**.** Nearly 38.3% (n = 18) of study population belonged to the age group 18–30 years, 38.3% (n = 18) between 31 and 60 years and 23.4% (n = 11) to the group above 60 years; 34.04% (n = 16) of the study group were graduates, and 19.14% (n = 9) had no formal education. Nearly 17.02% (n = 8) of the population fell into the category of good socioeconomic status with a score of >60, 21.3% (n = 10) between 51 and 60 and the large majority, 61.70% (n = 29) of the study group belonged to a poorer socioeconomic background with a score of <50. The patients included 21 unemployed people, 13 farmers, 7 manual laborers, 3 students and 3 teachers. Most of our subjects hailed from the northern belt of India with 88% belonging to Delhi and adjoining states of Rajasthan, Haryana, and Uttar Pradesh and the remaining 12% from Bihar, Jharkhand, Madhya Pradesh, Chhattisgarh and Jammu and Kashmir.

Subgroup analysis DALK

Indications

Subgroup analysis for patients with DALK was performed. The most common indication for bilateral DALK was keratoconus (45.2%, n = 14) followed by corneal dystrophies (macular 22.6%, n = 7; granular dystrophy n = 2, gelatinous drop like dystrophy n = 1) and healed keratitis (22.6%, n = 7).

Visual outcomes

All eyes had a BCVA ≤6/60 prior to surgery. The range of follow-up period for patients with DALK was between 10-13 months after the second surgery. Sequential suture removal had been initiated in all patients. Of the 31 patients who underwent DALK, 58.06% (n = 18) gained an uncorrected visual acuity of >6/12 bilaterally postoperatively with an astigmatism in the range of 1-3 D. They were prescribed refractive correction; however, they were not spectacle dependent. The remaining 13 patients had an astigmatism ranging between 3-11 D with an overall mean of 3.58 ± 1.97D. Five patients (16.13%) could be fitted with contact lenses and 8 (25.8%) were rehabilitated with corrective glasses.

No complications were seen in 65% eyes undergoing DALK (n = 40); four eyes developed secondary glaucoma, four cataract, four coexisting cataract and glaucoma, two pseudopterygium, two recurrence of macular dystrophy, two graft rejection, two graft failure, and two graft infection.

The clinical outcomes are elaborated in Table 2. Average specular count was 2011.94 ± 579.62 cells/mm^2. The mean residual bed thickness was 90.60 ± 36.18 microns (30-179). Mean contrast sensitivity was 0.94 ± 0.49 log CS (0-1.65). The composite VR-QoL Score was 59.60 ± 12.66 (20.39-77.46). The individual scores as per separate domains were also calculated and were 14.68 ± 2.548 (9–19) for psychosocial, 19.13 ± 2.604 (11–23) for visual symptoms and 68.48 ± 13.29 (34–89) for general, respectively.

Statistically significant inverse correlation between residual bed thickness and contrast sensitivity could be observed in our

study group (Pearson correlation –0.67). Better postoperative vision had a statistically significant positive association with VR-QoL scores ($P = 0.02$). There was no association between the astigmatism and perception of QoL in patients who underwent bilateral DALK ($P = 0.27$).

Subgroup analysis DSAEK

Indications

Subgroup analysis for patients with DSAEK was also performed. The most common indication for which bilateral DSAEK was done in our study group was FECD (68.8%, $n = 11$), followed by congenital hereditary endothelial dystrophy (CHED) (31.3%, $n = 5$).

Visual outcomes

All eyes had a BCVA <6/24 prior to surgery, 31.25% ($n = 10$) had a BCVA <6/60. The range of follow-up period after second DSAEK was between 6-13 months. Postoperatively, of the 16 patients who underwent DSAEK, 68.75% ($n = 11$) had a vision better than 6/12 bilaterally. Their manifest refractive spherical equivalent was ± 0.6D. These patients were prescribed refractive correction, but were not spectacle dependent. Five patients did not improve with refractive correction due to coexisting ocular pathologies including secondary glaucoma and graft failure.

The mean contrast sensitivity was 0.42 ± 0.57 log CS (0–1.50). Mean postoperative specular count was 1090.59 ± 331 cells/mm^2. Significant negative association between the graft thickness and contrast sensitivity was obtained indicating better contrast sensitivity with thinner lenticules ($P = 0.003$). The composite VR-QoL Score was 55.59 ± 11.68 (36.19-75.08). The individual scores as per separate domains were also calculated and were 51.04 ± 16.76 (25–78.57) for psychosocial, 48.21 ± 19.97 (14.29–76.19) for visual symptoms and 67.5 ± 9.39 (46.67–80) for general, respectively. The clinical outcomes are elaborated in Table 3.

Overall outcomes

Overall analysis for both the subgroups together was as follows: postoperatively, the BCVA was ≥6/18 in the better eye in 80.8% ($n = 38$) patients and ≥6/60 in the better eye in 85.8% ($n = 40$) patients. In 14.9% patients ($n = 7$), the BCVA remained less than 6/60 in the better eye postoperatively. Mean contrast sensitivity was 1.051 and 1.059 log CS for right eye (RE) and left eye (LE), respectively. The specular count was 1867 and 1851 cells/mm^2 for RE and LE. The mean astigmatism was 3.10 and 3.35 diopters for RE and LE.

Mean IOP was 15.59 ± 3.52 mm of Hg. Nearly 14.8% ($n = 7$) of patients developed glaucoma and 6.38% ($n = 3$) required filtration surgery. Glaucoma was the most frequent postoperative complication, others being graft failure, cataract, graft detachment, graft infection, graft rejection, recurrence of disease and pseudopterygium. Nearly 63.8% ($n = 30$) patients did not have any of these complications.

Quality of life

The mean VR-QoL score obtained was 59.06 ± 12.66 (20-80). Of the 47 respondents, 82.9% ($n = 39$) of patients had a VR-QoL score ≥50; 14.89% ($n = 7$) had a score of ≥70. There was no significant association between the patient's VR-QoL and his or her gender, income, educational status or occupation. The association between age of the patient and his or her perception of VR-QoL showed a positive association ($P = 0.027$). Scores calculated in higher age group patients were more satisfactory compared to the younger age group. The association between the postoperative visual acuity and VR-QoL scores was significant statistically ($P = 0.01$). Patients who gained a better vision following surgery reported better QoL [Table 4].

Statistically significant association ($P = 0.003$) existed between VR-QoL scores and contrast sensitivity indicating that better contrast sensitivity facilitated easier functioning and execution of day-to-day activities [Table 5].

Discussion

Corneal diseases rank as the fifth leading cause of vision impairment globally with an increased prevalence in the developing countries.[12] It is estimated that 0.45% of the Indian population (around 6 million) has corneal blindness with at

Table 2: Surgical Outcome in Patients who underwent Bilateral DALK

Parameters	Minimum	Maximum	Mean	Std. Deviation
Intra Ocular Pressure (mm Hg)	10.00	24.00	15.69	3.34
Corneal Thickness (Microns)	502.00	785.00*	597.15	46.17
Contrast sensitivity	0.00	1.65	0.94	0.49
Specular Count (Cells/mm^2)	943.0	3080.00	2011.94	579.62
Graft Thickness (Microns)	362.00	674.00	509.74	53.78
Astigmatism (Diopters)	1.00	11.00	3.58	1.97
Residual Bed Thickness	30.00	179.00	90.60	36.18

*Graft failure due to stromal rejection in one patient

Table 3: Clinical outcomes in bilateral DSAEK

Parameters	Minimum	Maximum	Mean	Std. Deviation
Intra Ocular Pressure (mm Hg)	8.00	22.00	15.88	4.19
Contrast sensitivity	0.00	1.50	0.42	0.57
Corneal Thickness (microns)	417.00	1320.00	668.84	180.12
Graft Thickness (microns)	21.00	300.00	118.16	48.82

Table 4: Distribution of VR-QoL Scores with relation to Postoperative Visual Acuity in the better seeing eye

DALK	Composite Index (VR-QoL)			Total
Vision of better eye	<50	50-60	>60	
6/18-6/6	4	4	18	26
6/60-6/24	0	2	1	3
<6/60	1	1	0	2
Total	5	7	19	31
DSAEK	**Composite Index (VR-QoL)**			**Total**
Vision of better eye	<50	50-60	>60	
6/18-6/6	8	4	0	12
6/60-6/24	1	0	0	1
<6/60	3	0	0	3
Total	12	4	0	16
				47

Table 5: Distribution of patients according to Contrast Sensitivity and VR-QoL scores

VR-QoL Score	Contrast Sensitivity Recorded (log CS)		Total
	<1.0	>1.0	
<50	12	1	13
50-60	4	7	11
>60	7	16	23
Total	23	24	47

least a million being bilateral.[13] Bilateral corneal pathologies account for approximately 21.7% of the corneal blindness in India according to another study.[14] When classified based on prognosis for keratoplasty, two-thirds of the unilateral cases carry an unfavorable prognosis, whereas almost two-thirds of the bilateral cases carry a favorable prognosis for keratoplasty.[14] The common causes for bilateral corneal blindness in India are infectious keratitis, corneal dystrophies, pseudophakic or aphakic corneal decompensation and ectasias. Lamellar keratoplasties offer several advantages over the conventional PK in these cases. These include reduced endothelial rejection, reduced need for long term immune suppressive therapy, earlier removal of sutures, faster visual recovery and reduced complications associated with open sky surgery.[15,16]

Our study endeavored to explore the significance of lamellar keratoplasties in bilaterally visually impaired patients. We sought to assess the impact of these surgeries in the Indian population and how the surgical interventions had impacted on the patients' QoL.

Our study revealed no significant difference in the gender distribution pattern. A multitude of studies offered variable reports, nevertheless with a higher male predominance among the patients who underwent surgical interventions.[17,18] Thomas *et al*. found that 50% of the patients who underwent PK were above the age group of 40 years. In our study population, 38.3% of study population belonged to the age group 18–30 years, 38.3% between 31 and 60 years and 23.4% to the group above 60 years signifying increased lamellar keratoplasties in the younger age group.[19] The mean age at which patients underwent DALK for keratoconus was 32.6 years according to a study by Watson *et al*.[20] In our study, of the patients who underwent bilateral DALK 48.38% belonged to the age group between 18 to 30 years.

In our study, we used the SLI Score described by the NFHS-2 to calculate indices regarding the socioeconomic status of the patients. We found that 61.7% of the study population belonged to the lower socioeconomic strata. The greater prevalence of disease in poor socioeconomic groups can be assumed to be due to paucity of proper eye care in rural areas and inability to assess them timely.

Of the 47 subjects who underwent lamellar keratoplasty, keratoconus ranked as the most common indication (30%), followed by FECD (23%) and corneal dystrophies (21%). In another study, FECD (40%) and bullous keratopathy (33%) were the most common indications for DSAEK and keratoconus (57%) and corneal scarring (35%) were the most common indications for DALK.[21] However, our study being only based on bilateral surgeries, bullous keratopathy was not seen as a cause.

In our study, postoperatively 72.34% ($n = 68$) of eyes had a BCVA ≥6/18. Only 20.21% ($n = 19$) of the eyes had a visual acuity less than 6/60 postoperatively. In the DALK category none of the patients had a vision ≥6/60 prior to surgery, but 58.06% of patients gained a vision of 6/12 or more postoperatively. A similar study by Noble BA *et al*.[22] divulged that in patients, who underwent DALK, BCVA of 6/12 or better was present in 84.9% of the eyes postoperatively and 24.7% of the eyes had a postoperative BCVA of 6/6 or better. Anwar *et al*. in his study evaluating big bubble technique achieved a best spectacle-corrected visual acuity of 20/40 or better in 89%, and 20/20 or better in 10%.[23] It may be inferred that in the Indian scenario, the paucity of adequate donor tissue and economic dependence has contributed to the hesitancy seen in performing surgery in a fairly seeing eye. In patients who underwent DSAEK, 68.75% ($n = 22$) had a BCVA >6/12. These were patients with FECD. In patients with CHED, the BCVA remained <6/60 postoperatively.

In our study, the mean VR-QoL score obtained was 59.06 ± 12.66. Of the 47 respondents, 82.9% of patients had a VR-QoL score ≥50, 14.89% had a score of ≥70 which reflected favorable outcomes with regard to QoL. Although former studies described age, education and occupation to be related factors, we observed that the gender, occupation, education or income did not significantly affect the perceived VR-QoL ($P \leq 0.05$). However we derived a positive association between the age of the patient and VR-QoL with the higher age group patients expressing better improvement. This could be explained by the fact that these patients were probably not occupationally or socially active and had lower expectations regarding postsurgical improvements. In our study we found that there was a statistically significant ($P \leq 0.05$) correlation between the VR-QoL and postoperative visual acuity and contrast sensitivity in the better eye. There was also a significant negative association between occurrence of complications ($P \leq 0.001$), the need for additional surgical interventions ($P \leq 0.05$) and VR-QoL. A greater incidence of complications necessitated more numerous and frequent follow-up visits which had economic as well as emotional and mental repercussions on the patient's QoL.

In our study, we found that there was a statistically significant ($P \leq 0.05$) correlation between the VR-QoL and postoperative visual acuity in the better eye. Among the domains considered under the VFQ IND-33, maximum correlation of statistical significance was with the General Function domain. We also assessed the contrast sensitivity postsurgery and its bearing on the VR-QoL and found that again, there was positive significant association ($P \leq 0.01$) between VR-QoL scores and contrast sensitivity. Other studies have reported a similar correlation between the visual acuity and QoL.[24,25]

Incidence of elevated IOP was 13% (n = 4) in patients with DALK. In study by Huang O *et al*., an episode of elevated IOP occurred in 36.1% patients following DALK. Causes included pupillary block from air, swollen grafts, and corticosteroid response.[26] The average specular count was 2011.94 ± 579.62 cells/mm^2. In cases of superficial corneal opacities or significant corneal edema, examination of endothelial cell counts was not available preoperatively. However, studies with specular microscopy 6 months after DALK have shown that 60% of the eyes had endothelial cell counts of more than 2000/sq mm. The loss of cell density maybe due to surgical manipulation or inadvertent perforation.[27,28] The mean residual bed thickness in our study was about 90.60 ± 36.18 microns (30-179). In a study by Ardjomand *et al*. the level of visual acuity in DALK eyes was related to the RSBT.[9] Eyes with a RSBT of <20 micron had visual acuity similar to eyes with PK, whereas those with a RSBT of >80 micron had a significantly reduced visual acuity. In our study, there was a statistically significant inverse correlation between RSBT and contrast sensitivity ($P \leq 0.05$). Higher the residual stromal layers left, greater was the chance of developing postoperative interface haze leading to depreciation of vision and contrast.

The average postoperative IOP in patients with DSAEK in our study was 15.88 ± 4.19 mm Hg. Other studies have shown IOPs of patients post DSAEK to be in a similar range.[29] Three patients progressed to have glaucoma and required trabeculectomy in both eyes for control of the same. Statistical analysis in our DSAEK subgroup revealed a significant inverse association between the thickness of the lenticule used and the final contrast outcomes with thinner grafts performing better. This is in harmony with observations of Busin who advocated the use of ultra-thin DSAEK in view of superior quality of vision comparable to DMEK and other studies.[30,31]

We sought to derive an association between patient dependent factors that were likely to influence patient satisfaction and found that statistically significant correlation exists between the age, SLI, postoperative visual acuity and contrast in the better eye with the VR-QoL. There was a significant inverse association between the incidence of complications and VR-QoL. No significant association could be derived with other demographic factors.

One of the limitations of this study was the observational cross-sectional nature of the study. Patients were recruited from the follow-up OPD after a minimum period of 6 months had passed after the second surgery. Hence, data regarding the level of visual impairment and QoL prior to performing the first surgery was not available. Further prospective studies conducted on a similar population, prior to enrolling patients for the first eye surgery could provide more information about the correlation of VR-QoL in the pre and postoperative period. Another limitation of the study was a shorter follow-up period of 6–13 months. In patients with DALK especially, a longer follow-up period, where all sutures have been removed and a final acceptable refraction obtained, would give a more accurate assessment of the QoL in this subgroup. However, the study does fill in important gaps in the literature as no similar studies reporting the quality-of-life indices in patients with bilateral lamellar keratoplasty have been reported in the Indian population.

Conclusion

We could conclude that bilateral lamellar corneal grafts provide satisfactory visual outcomes compatible with day-to-day functioning. However, they may have complications, most commonly encountered among them being glaucoma in patients with DALK and primary graft failure in patients with DSAEK. Vision related QoL has a direct correlation to the visual acuity and contrast sensitivity which in turn directly correlates to the lenticule thickness in DSAEK and to the RSBT in DALK.

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Conflicts of interest

There are no conflicts of interest.

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