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ORIGINAL ARTICLE

Visual outcomes and quality of life post-keratoplasty at a secondary center in North India

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Abstract

Aim: The aim of the study was to assess visual outcomes and quality of life (QoL) of patients undergoing keratoplasty at a secondary center in North India.

Materials and Methods: Analysis was done of records of 80 patients who underwent keratoplasty at a secondary center. Visual outcomes and QoL analysis at the last follow-up (minimum 2 years) post-keratoplasty were compared to pre-operative data. Two validated questionnaires were administered to patients: EQ-5D for generic and IND-VFQ-33 for disease-specific QoL status. Correlation between visual outcomes and QoL scores was analyzed. For analysis patients were stratified according to the one-eyed status and type of surgery; optical (optical penetrating keratoplasty [OPK]); or therapeutic penetrating keratoplasty (TPK).

Results: The mean age of participants was 51.5 years (range, 24–85 years) and 68.75% of patients were males. Sixty-six participants underwent OPK while 14 underwent TPK. Thirty-one participants (38.75%) were one-eyed before surgery. Follow-up rate at 2 years was 81.25%. There was a statistically significant improvement ($P < 0.001$) in vision across all subgroups except TPK group. There was a significant improvement in QoL in all parameters assessed by EQ 5D (mobility, self-care, daily activities, pain relief, and anxiety/depression) and IND-VFQ-33 (general functioning, psychosocial impact, and visual function). Correlation of visual outcome with EQ 5D and IND-VFQ-33 (visual function) was statistically significant ($P < 0.05$) in all groups. QoL improved significantly in all patients and was recorded highest among one-eyed patients.

Conclusion: Keratoplasty performed at a secondary health-care center in North India, closer to rural population, showed good follow up rates, and improved visual outcomes and QoL.

Introduction

Corneal diseases are among the major causes of vision loss and blindness in the world today, next only to cataract and glaucoma according to the WHO.[1] In India, approximately 68 lakh people suffer from corneal blindness in at least one eye; of these, 10 lakh people are blind in both their eyes.[2] The National Blindness and Visual Impairment Survey 2019 reported that corneal blindness was the leading cause of blindness among patients aged <50 years in India, accounting for 37.5% of the cases and was the second leading cause of blindness among patients above the age of 50 years.[3] Besides, there is an addition of 25,000–30,000 corneal blindness cases every year in the country.[4] There is also a tendency of sequential involvement of other eye in majority of cases with unilateral corneal blindness.[5]

As reported by Gopinathan *et al.*,[6] patients with agriculture-based activities in rural areas were at 1.33-times greater risk of developing microbial keratitis. It is evident that rural population is more at risk of corneal blindness (0.79% prevalence) as compared to urban areas (0.66% prevalence), whereas accessibility remains a problem for them as most

tertiary hospitals are in urban areas.[4,7,8] Rural health services with an increased burden of corneal blindness are in dire need of well-trained specialists and super-specialists.[9] Poor access to specialists in rural areas and financial constraints remains a barrier.[9,10] According to Das *et al.*[11] patients undergoing therapeutic keratoplasty (TPK) from rural districts (47.12%) are higher than urban districts (47.12%) and metropolitan regions (2.99%). This deficit has been further aggravated by the COVID-19 pandemic. A significant drop in both corneal tissue retrieval and utilization has been experienced during COVID-19 lockdown.[12]

According to the pyramidal model of eye care as described by Rao *et al.*,[13] secondary care centers (SCs) serve a population of 500,000. Approximately 80–90% of eye care problems could be dealt at the level of SC or vision center. The secondary center and vision center attract more patients, due to easier access for patients. The present literature, however, suggests that tertiary center remains main center for performing keratoplasty surgery all over the world.[14-17]

Various studies have reported objective clinical outcomes, such as refractive error, graft clarity, and visual acuity, of different types of corneal transplant surgeries.[18] However, patients are more interested in their visual function and its impact on their daily life.[19] The disconnect between a surgeon's definition of success and patient's perception of success underscores importance of patient-perspective QoL.

In this study, we have assessed generic and condition specific QoL post-keratoplasty using two validated questionnaires EQ-5D[20] and IND-VFQ-33[21-23] in patients undergoing keratoplasty surgery at a secondary center in North India.

The hypothesis of this study was that by doing surgeries at a center closer to patients (especially from rural areas) in need of keratoplasty would result in better uptake of surgery, good follow-up rates, and a substantial impact on QoL of operated patients.

Materials and Methods

This retroprospective study was conducted at a secondary health-care center under the aegis of Dr. Shroff's Charitable Eye Hospital in Alwar district, Rajasthan. From 2013 to 2015, patients with corneal conditions needing keratoplasty at this secondary center were examined and referred to their tertiary center in New Delhi. After receiving Transplantation of Human Organs Act (THOA)[24] certification in November 2015, keratoplasty was performed locally at this secondary care center itself. Cornea patients surgically managed at secondary center were included in the study. Eighty patients who underwent all types of keratoplasty were enrolled. Retrospective data from the medical records were analyzed from December 2015 to February 2016 and remaining duration of the study was prospective.

All patients underwent a comprehensive ophthalmic examination including slit lamp assessment, tonometry using a calibrated Goldman Applanation Tonometer, fundus examination, and ultrasound B-scan in patients with opaque media. All corneal transplants were performed by two ophthalmologists who were initially trained at tertiary centers and then performed surgeries at secondary center after training completion with a minimum experience of 5-year post-training. All surgeries were done under monitored anesthesia care and ophthalmologists at the secondary center were trained to manage post-operative keratoplasty follow-ups and complications.

Data regarding demographic information, baseline visual acuity, indications for keratoplasty, type of keratoplasty, repeat surgery if required, visual comorbidities, post-operative complications if any, graft clarity, and secondary glaucoma were collected from each patient using a predefined proforma. Follow-up data were collected for all parameters at day 1, day 7 ± 3 days, 1 month ± 7 days, 3 month ± 2 weeks, 6 months ± 1 month, 12 months ± 1 month, and 24 months ± 1 month. For analysis, patients with a minimum follow-up of 2 years (2–4 years) were included in the study.

Interviews were conducted by primary investigators in local language. This study was approved by Institutional Review Board and followed the tenets of Declaration of Helsinki. Informed signed or thumb-print consent was obtained from all participants. Questionnaire for QoL was administered preoperatively and postoperatively on the last follow-up by the same observer. Patients filled both questionnaires (EQ-5D and IND VFQ 33) together to have a snapshot of the patients' perceptions for both questionnaires. Patients who were illiterate were asked the questions in their vernacular language and the answers were recorded by the observer without influencing the outcome. For the ease of analysis, these patients were divided into five subgroups depending on the surgery, they underwent (OPK or TPK) and whether they were one eyed.

- Group 1: Optical penetrating keratoplasty (OPK) and one-eyed
- Group 2: OPK and non-one-eyed
- Group 3: TPK
- Group 4: All OPK
- Group 5: Non-one-eyed (OPK and TPK)

Visual outcomes were measured using a Snellen chart and converted to a standard logarithm of minimum angle of resolution (logMAR) scoring system. Vision from 20/200 to 20/500 was scored as logMAR 1.3, while vision of hand movement was scored as 2.2. Perception of light was scored as 2.5 and no perception of light was scored as 2.8. For analysis, we have considered all patients with vision < 20/500 (logMAR 1.4) due to irreversible causes in the non-operated eye as one-eyed patients.

Measuring generic QoL

The instrument used for measuring generic QoL was Euroqol's EQ5D-5L questionnaire.[20] EQ-5D consists of a descriptive system and visual analog scale (VAS). The descriptive system comprises five dimensions: Mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-VAS records

patient's self-rated health on a vertical VAS. We considered these questionnaires over NEIVFQ as there is pre-existing literature using these questionnaires in other nations and thus it would provide a direct comparison of QoL of our patients from those of other countries.[23]

Responses for mobility, self-care, usual activity, pain, and depression were scored as no problem (1), mild problem (2), moderate problem (3), extreme problem (4), and incapable (5). The second component of EQ-5D measures self-rated health using a VAS. Participants were asked to rate their "health today" on a scale ranging from 0 ("worst imaginable health state") to 100 ("best imaginable health state"). Patients scored their health preoperatively and then postoperatively on a scale of 0–100. For analysis purposes, Indonesian value set for EQ5D was used and a composite score generated for profile obtained by collating all subscale scores for each patient.

Measuring condition specific QoL

IND-VFQ-33 questionnaire was used for activity measurement to assess visual health status.[21] IND-VFQ-33 questionnaire items are classified into three subscales: General functioning, psychosocial impact, and visual symptoms.

The questions were divided into three broad categories. Questions (1–21) assessed general functioning, Questions (22–26) assessed psychosocial impact, and Questions (27–33) assessed visual symptoms. Responses for Questions 1–21 were scored as no difficulty (1), mild difficulty (2), occasional difficulty (3), severe difficulty (4), and inability (5). Responses for Questions 22–33 were scored as no difficulty (1), mild difficulty (2), occasional difficulty (3), and severe difficulty (4).

Separate composite scores were generated for each of three individual subscales. Scores for Questions 1–21 (Subscale 1), Questions 22–26 (Subscale 2), and Questions 27–33 (Subscale 3) were thus analyzed.

The collected data were analyzed using IBM-SPSS (Statistical Product's and service solution, version 21.0) computer software. The results were tested for statistical significance using *t*-tests. $P < 0.05$ was considered statistically significant. Paired *t*-test was used to compare pre-operative and post-operative scores at the last follow-up (minimum 2 years).

Results

Before THOA certification of secondary center at Alwar, 56 surgeries were done in 3 years from 2013 to 2015 among patients examined at secondary center and referring them to higher tertiary center. After THOA certification, 80 patients were operated from November 2015 to December 2017. Of these, 65 (81.25%) completed minimum 2 years follow-up and were included in the QoL analysis. Out of 66 optical keratoplasties, 57 completed minimum 2-year follow-up while eight out of 14 TPK patients completed minimum 2-year follow-up [Table 1].

The mean age of patients was 51.5 years with a range from 24 to 85 years. Of the 80 participants, 40 operated eyes were right-sided and 40 were left-sided. The indications for surgery were corneal scar 34 (42.5%), pseudophakic bullous keratopathy 13 (16.2%), failed grafts 9 (11.2%), infective keratitis 8 (10.0%), corneal degeneration 7 (8.7%), perforated corneas 5 (6.2%), corneal dystrophy 2 (2.5%), and staphylomas 2 (2.5%). Sixty-six out of 80 operated cases were OPKs while 14 were TPKs. Sixty-six optical keratoplasties included two Descemet's stripping automated endothelial keratoplasty (DSAEK), one deep anterior lamellar keratoplasty, and 63 OPK.

There were five cases of pre-existing glaucoma in the present study. The incidence of secondary glaucoma increased from 6 (9.23%) in the immediate post-operative period to 13 (20%) in late post-operative period at the end of 2 years. Thirty-five (61.40%) participants of OPK group maintained clear graft at the past follow-up (minimum 2 years). Complications of keratoplasty surgery and additional procedures performed are described in Table 2.

Visual outcomes in logMAR at 2-year postoperatively were compared to pre-operative logMAR values. For purpose of analysis, patients were stratified according to their one-eyed status and by the type of surgery, OPK, or TPK [Table 3].

Thirty-one out of 80 participants were one-eyed or had vision <20/500 (<logMAR 1.3) in both eyes, including their better eye. Twenty-three of 31 of these patients completed minimum 2 years of follow-up post-surgery. Twelve of these 23 patients had vision better than 20/200 or logMAR 1 after surgery while eight patients had ambulatory vision and were able to do daily activities. Four one-eyed patients had worsening of vision or minimal improvement in vision at post-surgery.

As given in Table 3, after applying paired t-tests to pre-operative and post-operative logMAR scores, there was a statistically significant improvement in vision in all groups ($P < 0.001$) except TPK group ($P = 0.271$).

The EQ 5D utility scores for mobility, self-care, usual activity, pain/discomfort, and anxiety/depression were analyzed by comparing pre-operative and post-operative scores. All parameters of EQ 5D across all groups improved after surgery [Figure 1a] and differences were found to be statistically significant ($P < 0.05$).

VAS on a scale of 0–100 was analyzed by applying *t*-tests to pre- and post-operative scores. VAS difference was found to be statistically significant in all groups post-surgery [Figure 1b]. It suggested that patients had overall satisfaction post-surgery in all groups. There was a significant correlation of visual outcomes with EQ-5D and VAS scores in all groups [Table 3].

IND-VFQ-33 questionnaire was analyzed in three subscales: Subscale 1 included Questions 1–21 (General functioning), Subscale 2 included responses to Questions 22–26 (Psychosocial wellbeing), and Subscale 3 (Visual Function) included responses to questions 27–33 [Figure 2]. Applying *t*-tests to pre-operative and post-operative scores for all sub scales, it was found to be statistically significant in all groups [Table 4].

Correlation of visual outcomes with EQ-5D and VAS was carried out. For IND-VFQ-33 questionnaire, visual function (Subscale 3) was correlated with visual outcomes as only Subscale

Table 1 : Gender demographics and surgical procedure

	No. of patients	% (Percentage)	Patients with minimum 2 years follow-up *n*=65	
			No of patients	% Of patients undergoing quality of life analysis
Surgery procedure, patients *n*=80				
Optical PK	66	82.5	57	87.69
Therapeutic PK	14	17.5	8	12.30
Gender, all patients *n*=80				
Males	55	68.75	45	69.23
Females	25	31.25	20	30.76
n=80				
One-eyed	31	38.75	23	35.38
Non-one-eyed	49	61.25	42	64.61

Table 2: Complications and additional procedures

Complications	Number of cases	%	Additional procedures done (number)
Graft infiltrate and infections	11	16.9	Paramedian Tarsorrhaphy (11)
Secondary glaucoma	6 (Immediate) 13 (Late)	9.2 20.0	Medical management (10) Trabeculectomy with Mitomycin C (2) Glaucoma drainage device (1)
Persistent epithelial defect	8	12.3	Permanent Paramedian Tarsorrhaphy (3) Amniotic membrane transplantation (5)
Failed grafts	5	7.69	Repeat OPK (4) Evisceration (1)
Graft rejection	2	3.07	Repeat OPK (2)
Cataract	1	1.53	Phacoemulsification (1)
PCR	1	1.53	Vitrectomy (1)

Table 3: *P* value of difference between pre- and post-operative scores for EQ-5D, VAS, and their correlation

	Visual outcome pre- versus post- operative	EQ5D scores pre- versus post-operative	VAS scores pre- versus post-operative	Correlation of EQ5D with VAS	Correlation of EQ5D with visual outcome
Group 1 (*n*=23)	0.0016	0.0004	0.0009	0.0011	0.0001
Group 2 (*n*=42)	<0.001	<0.001	<0.001	<0.001	<0.001
Group 3 (*n*=8)	0.271	0.0166	0.0314	0.022	0.045
Group 4 (*n*=57)	<0.001	<0.001	<0.001	<0.001	<0.001
Group 5 (*n*=49)	<0.001	<0.001	<0.001	<0.001	<0.001

EQ-5D: Euroqol 5D, VAS: Visual analog score

3 part of questionnaire assessed visual function. Subscale 3 or visual function part of IND-VFQ-33 was also correlated with EQ-5D. We found that correlation of visual outcome and EQ 5D utility scores showed $P < 0.05$ in all groups. Similarly, correlation between visual outcome and VAS scores post-surgery showed statistical significance ($P < 0.05$) in all groups. When Subscale 3 (visual function) was correlated with EQ-5D utility scores, it was found to be statistically significant in all groups. Correlation between Subscale 3 (visual function) with post-operative visual outcomes at 2 years was also found to be statistically significant in all groups.

As shown in [Figure 1a], the baseline EQ 5D utility scores which were earlier in negative become significantly positive post-keratoplasty in one eyed patients.

Discussion

The rural population is more at risk of corneal blindness whereas accessibility remains a barrier for them as most tertiary hospitals are in urban areas.[6] Unlike most studies on QoL post-keratoplasty which were done at tertiary centers, our study was done at a secondary center. THOA was enacted in 1994 to provide a system of removal, storage, and transplantation of human organs for therapeutic purposes and for prevention of commercial dealings in human organs.[24] Before THOA certification of our secondary care center, only 56 surgeries were done in 3 years from 2013 to 2015 after referring patients to tertiary center at New Delhi. One of the factors for this low

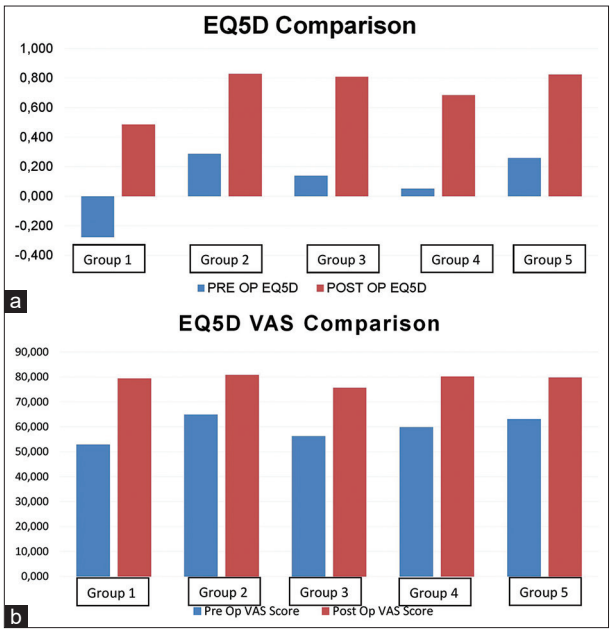

Figure 1: (a) Baseline EQ 5D utility scores and post-operative scores. (b) Pre-operative and post-operative changes in VAS scores

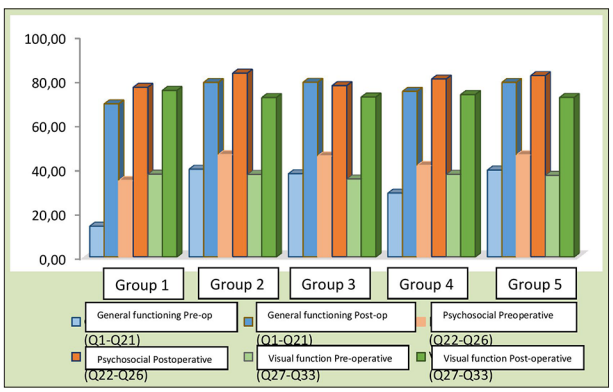

Figure 2: Pre- and post-operative IND-VFQ-33 comparison charts for general functioning, psychosocial, and visual functions

number was dropouts due to referral to a distant tertiary care center 165 km away from secondary center and also the loss of wages incurred due to traveling and treatment. Following THOA certification, 80 surgeries were done at Alwar secondary center from 2016 to 2017. Hence, it is evident that uptake of surgery increased once patients were operated at secondary center itself.

According to Brook *et al.*,[25] routine follow-up with a primary care provider after high-risk surgery was associated with a lower likelihood of 30-day readmission, particularly among patients with a complicated post-operative course. This underlies importance of good follow-up after keratoplasty surgery. Studies from India and United States have reported follow-up rates of 50–65% at 3–6 months.[26,27] The present study had a follow-up rates of 81.25% at 6 months. The eye care facility being closer to patients in our study contributed to high follow-up rate in our study.

Table 4: Statistical analyzes of IND-VFQ-33 in different categories of patients pre- and post- surgery (Correlation of visual function by IND-VFQ-33 and EQ 5D)

	Group 1	Group 2	Group 3	Group 4	Group 5
General functioning (Subscale 1)	0.001	0.001	0.001	0.001	0.001
Psychosocial function (Subscale 2)	0.001	0.001	0.001	0.001	0.001
Visual function (Subscale 3)	0.001	0.001	0.001	0.001	0.001
Visual function and EQ5D correlation	0.001	0.001	0.001	0.001	0.001
Visual function (Subscale 3) and vision correlation	<0.001	<0.001	<0.001	<0.001	<0.001

In this study, we have used EQ-5D and IND-VFQ-33, a validated questionnaire to study QoL in rural Indian population which has not been done so far.[23] Patients filled both questionnaires (EQ-5D and IND VFQ 33) together with a relaxation interval of 15 min to have an unbiased snapshot of the patients' perceptions for both questionnaires. This was done because both questionnaires rely on perception of patients' own well-being and their self-scoring might vary based time elapsed after procedure. This means that scoring was done by patient under similar circumstances for both questionnaires for better comparability.

We found that keratoplasty results in significant improvement in vision post-surgery except in TPK group. Out of 13 TPK cases, only two patients regained BCVA > 20/200 or logMAR 1, 12 (92.3%) patients achieved therapeutic success with elimination of infection and maintained structural integrity while one patient underwent evisceration. This contrasted with another study done at a tertiary center in North India by Raj *et al.*[28] where there was a statistically significant difference (P = 0.0001) in BCVA postoperatively for both optical and therapeutic grafts. In this study, 14 out of 34 patients (41.17%) of TPK cases regained BCVA >20/200, 30 (88.25%) patients achieved therapeutic success maintaining structural integrity, one underwent evisceration and three eyes got phthisical. In the present study, the number of TPK was less than OPK despite being closer to rural areas which was in contrast to the findings of Das *et al.*[11] who reported higher number of patients undergoing TPK from rural districts than urban areas. This could be explained by the high number of previous healed corneal scars due to keratitis in patients of rural areas who underwent OPK.

We also found statistically significant improvement in all parameters of EQ5D and IND-VFQ-33 post-surgery across all groups including TPK patients. The parameters in EQ-5D questionnaire such as mobility, self-care, usual activity, pain/discomfort, and anxiety/depression showed significant improvement across all groups. Similarly, all parameters of IND-VFQ-33 such as general functioning, psychosocial well-

being, and visual function showed significant improvement post-keratoplasty. An important observation is that although all groups showed significant change in QoL post-surgery, the difference is most marked in one-eyed patient group.

Type of corneal transplantation procedure has a definite impact on degree to which patient population may benefit according to studies by Puri *et al.*,[27] Yildiz *et al.*,[29] and Price *et al.*[30] Puri *et al.* found that DSAEK recipients reported a greater improvement in their overall QoL than keratoprosthesis and PK recipients. Although small in numbers, our study provides useful information in change in QoL of patients post-TPK. We found that there was no statistically significant change in visual outcome post-TPK at last follow-up post-surgery. This can be explained as the aim of surgery is relief from infection and pain in such cases and not visual improvement. Correlation of visual outcome and EQ 5D scores showed $P < 0.05$ in all groups. There was a significant improvement in mobility, self-care, daily activity, relief from pain, and anxiety along with VAS scores in TPK group. General functioning, psychosocial well-being, and visual function also showed statistically significant change ($P < 0.05$) in TPK group at the last follow-up (minimum 2 years) post-surgery. Although there was no visual improvement in TPK group, there was a significant improvement in other parameters of QoL. Patients in this group were satisfied without much improvement in vision.

Among OPK group, we found statistically significant improvement in vision at the last follow-up ($P < 0.001$). The mean BCVA in the present study improved from 2.13 logMAR preoperatively to 1.13 logMAR postoperatively at the last follow-up. This was similar to the findings of a study done by Raj *et al.*[28] where BCVA in optical keratoplasty group at 1 year improved from 1.39 logMAR preoperatively to 0.367 logMAR postoperatively which was statistically significant ($P = 0.0001$, $n = 111$).[26]

We also analyzed correlation of visual outcomes with different parameters of quality of life (QoL) such as EQ-5D, VAS, and visual function part of IND-VFQ-33 questionnaire. Correlation of visual outcomes with EQ-5D, VAS, and visual function (Subscale 3) showed statistical significance in all groups. Overall, there was improvement in QoL and satisfaction with improvement in vision in OPK group.

According to Belghmaidi *et al.*,[14] QoL before keratoplasty was worse in subjects with bilateral involvement of cornea and in those with cataract. Their results suggested that visual acuity in other eye was an important variable that predicts patient satisfaction. In this study, we analyzed QoL in one-eyed patients and non-one-eyed patients. It was found that visual outcomes at the last follow-up and its correlation with EQ-5D scores and IND-VFQ-33 (visual function scores) were statistically significant ($P < 0.001$) in both group of patients [Table 4]. Although there was improvement in QoL in both groups, it was more significant in one-eyed patients. This is mainly because one-eyed patients had a poorer pre-operative baseline visual acuity and QoL and are more dependent on others.

Limitations of the study include its relatively small sample size and recall bias. Another limitation of study could be Indonesian EQ-5D value set used for generating QoL scores as there is no Indian value set available currently. As discussed earlier, a greater number of patients especially in TPK group could be more conclusive.

Conclusion

This study highlights the impact of performing keratoplasty at more accessible secondary centers resulting in improvement of uptake, follow-up, and QoL of patients. This can be done by capacity building with training and addition of infrastructure at these centers. Cost-effectiveness of this model needs to be studied in developing countries like India with predominantly rural population.

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