Visual Outcome of Allogenic Penetrating Keratoplasty

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Abstract

Purpose: To examine the common indications, postoperative complications and visual outcomes of allogenic penetrating keratoplasty (PKP).

Methods: Participants were recruited from the Ophthalmology Department of Jordan University Hospital (JUH). The medical charts of all patients who underwent PKP at JUH from January 1, 2001 to December 31, 2009 were analyzed retrospectively through Quasi-experimental interventional design. All completed a three year follow up period.

Results: A total of 388 patients were included. Keratoconus (KC) (59% of patients), followed by corneal opacity other than KC scar (12%), and bullous keratopathy (8%) were the most common indications for PKP. KC was the most common cause in males (62%, $p < 0.05$), and females (53% $p < 0.05$). Best corrected visual acuity improved from (0.064 ± 0.12) preoperatively to (0.317 ± 0.28) three years postoperatively ($P < 0.05$). 67.5% of patients did not suffer any complication during follow up period. Most common reported complications were rejection (13.7%) and glaucoma development (3.6%). Twenty three patients (5.9 %) received trauma to the operated cornea which resulted in wound dehiscence in 8 patients.

Conclusion: KC is the leading indication for PKP in Jordan. PKP has provided better results concerning impaired vision, and showed a favorable success rate. Complications like rejection and glaucoma development still form a challenge to the treating physician. Trauma to the graft might lead to wound dehiscence.

Keywords: Complications, Corneal Transplantation Methods, Indication, Keratoplasty, Penetrating.

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Introduction

Ophthalmic pathologies play a major role in the development of severe complexities among the general population. It has been evaluated by the world Health Organization (WHO) that global causes of blindness mainly include corneal opacities. It has affected 5.1 percent of the total blind population, which accounts for around 1.9 million persons[1]. It is estimated that unilateral corneal disease is the cause of blindness in around 23 million people worldwide[2]. Other corneal pathologies leading to loss of vision include trachoma, onchocerciasis, ophthalmia neonatorum, and vitamin A deficiency[1]. Penetrating keratoplasty

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(PKP) is a surgical intervention, in which replacement of the impaired cornea with a donor cornea is performed. In PKP, all layers of cornea, including epithelium, Bowman layer, stroma, descemet membrane and endothelium, are surgically replaced[3].

Various studies from different parts of the world tried to study the various indications for PKP[4-9]. Keratoconus (KC), pseudophakic/ aphakic bullous keratopathy, corneal scar, keratitis, corneal perforation, corneal dystrophies, and rejected/failed grafts appeared as the most common indications, whereas some certain indications like trachomatic keratopathy appeared in certain populations[1,10]. It is said therefore that PKP has similar nature of indications across various regions of the world. Such indications constitute certain complexities, which usually result in using surgical intervention for therapy[7].

This study is parallel with the ophthalmic domain, where corneal and retinal complications are treated through advanced surgical techniques to try to improve visual acuity. PKP is considered as an advanced surgical intervention, which is commonly used in ophthalmic settings for addressing corneal complexities. Therefore, the study would contribute to enhance the visual outcomes for addressing visualization morbidities.

This study has aimed to evaluate indications, visual outcome before and after surgery, and post-operative complications related with PKP. Certain postoperative complications such as graft rejection and development of glaucoma were assessed during multiple follow-ups. Knowing that PKP exposes the patient to increased risk of wound dehiscence, spontaneously or because of blunt trauma, the expected rate and visual prognosis of traumatic wound dehiscence after PKP were also investigated in this study.

Methods

This interventional quasi-experimental study was carried out at the Ophthalmology Department of Jordan University Hospital (JUH). The study was conducted after obtaining approval from the Ethics Committee of JUH. Hospital records of all patients, who underwent allogenic PKP at JUH from January 2001 to December 2009, were retrospectively studied. Inclusion criteria included all patients who completed a follow up period of 3 years. For all these patients, important data including gender, age, and previous medical/surgical history were collected. Patients' medical records were retrospectively analyzed to evaluate the possible variables related to disease outcome and prognosis.

All corneas were imported through the National Eye Bank in Jordan (located in the same hospital). All corneas were previously examined for endothelial cell count (not less than 2200 cells/mm^2) and corneal clear zone (more than 8 mm). Donors were already reported as negative for HIV, S.VDRL, S.HCV, and S.HbsAg. Similarly, all corneas were approved for surgery by treating surgeon before ordering the cornea. Indication for surgery was clearly highlighted. Data regarding their detailed ophthalmic exam pre and post-surgical intervention was also collected. Under certain aseptic techniques, all surgeries were performed under general anesthesia. Details of surgical techniques were retrieved. Details of postoperative complications that occurred through the follow up period were collected. Routine blood screening and blood sugar levels were also investigated as a part of physical

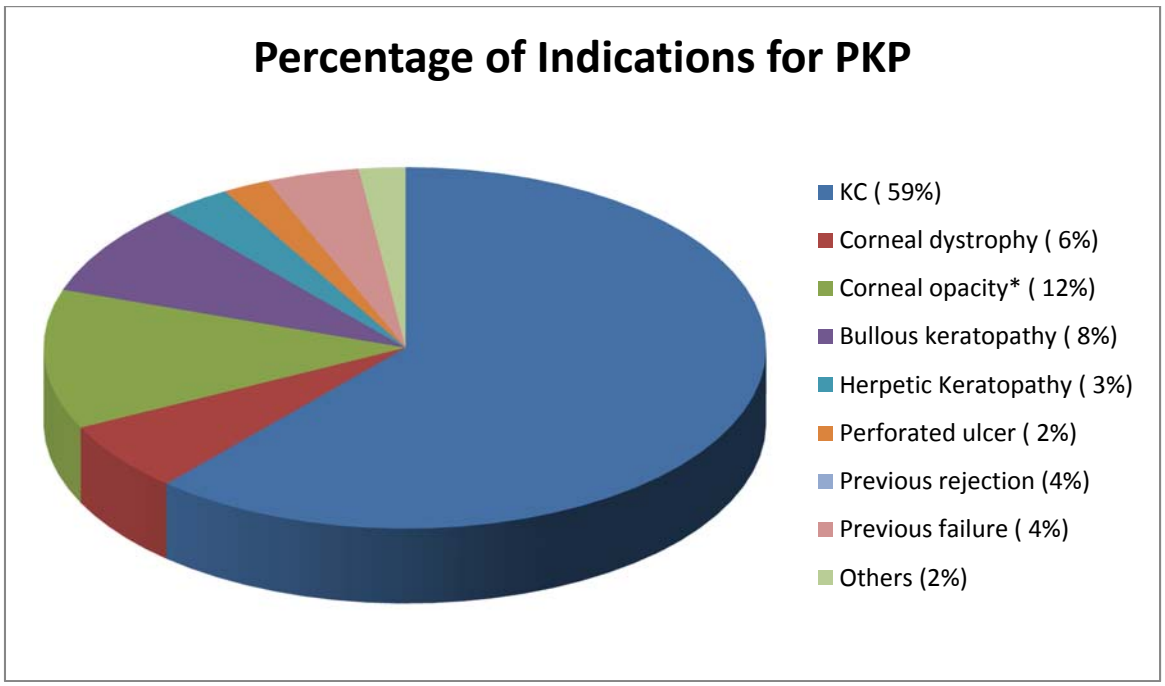

Figure 1. Indications for Penetrating keratoplasty (PKP), * other than corneal scar due to KC

exam. Follow up visits included best corrected visual acuity (BCVA), slit lamp biomicroscopy, applanation tonometry (when applicable) and fundus exam. BCVA was checked and compared preoperatively and postoperatively (i.e. at the end of the three year follow up period) with Snellen acuity charts. SPSS software (version 22; SPSS, Inc., Chicago, IL, USA) was used for data analysis. P values less than 0.05 were considered as statistically significant.

Results

Three hundred and eighty eight patients fitted the criteria to be studied. Ages ranged from 1-76 years (25 ±5.2 SD). Out of these patients, 94% had PKP in one eye and 6 % had PKP in two eyes. In this study, 235 (61%) of the patients were males and 153 (39%) were females. KC was the most common indication for PKP among all patients (59%). Presence of corneal opacity (other than central corneal scar caused by KC) was the second most common indication (12%). Reported Indications for PKP are summarized in Figure 1.

KC was the most common indication for PKP in both males and females; 62% (p-value=0.045), 53% (p-value=0.033), respectively. Table 1 summarizes the variable indications for PKP by gender. Corneal opacity was the second most common cause in both genders.

Table 1. Indications for PKP by Gender

Indication	Male	Female	Total
Keratoconus	146	82	228
Corneal Dystrophy	7	15	22
Corneal Opacity	24	22	46
Bullous Keratopathy	19	11	30
Herpetic Keratopathy	8	3	11
Perforated Ulcer	6	3	9
Previous Rejection	11	4	15
Previous Failure	8	8	16
Others	6	5	11
Total	**235**	**153**	**388**

Table 2. BCVA Levels prior to Penetrating Keratoplastym
***BCVA: Best-corrected visual acuity**

Pre BCVA*	Frequency	Percentage
≤ 0.1	296	76.3
≤ 0.2	34	8.8
≤ 0.3	23	5.9
≤ 0.4	12	3.2
≤ 0.5	11	2.8
≤ 0.6	4	1.0
≥ 6.6	4	1.0
Missing data	4	1.0
Total	**388**	**100.0**

Table 3. BCVA Levels after Penetrating Keratoplasty,
***BCVA: Best-corrected visual acuity**

Post BCVA*	Frequency	Percentage
≤ 0.1	113	29.1
≤ 0.2	22	5.7
≤ 0.3	38	9.8
≤ 0.4	44	11.3
≤ 0.5	47	12.1
≤ 0.6	24	6.2
≤ 0.7	31	8.0
≤ 0.8	25	6.4
≤ 0.9	12	3.1
≤ 1.0	12	3.1
≥ 1.0	20	5.2
Total	**388**	**100.0**

Multiple levels of visual acuity were recorded before undergoing PKP. According to the study, 296 patients (76.3%) had BCVA < 0.1 preoperatively while 4 patients (1 %) had BCVA equal or better than 0.6. Table 2 summarizes preoperative BCVA levels.

Table 4. Pairing of pre- and post- operative BCVA, *BCVA: Best-corrected visual acuity

Variables	Mean (± SD)	P-Value
Pre BCVA*	0.064 (0.1155)	<0.005
Post BCVA	0.317 (0.2826)	
Pair Pre-Post BCVA	- 0.2529 (0.2782)	

Table 5. Post-Operative Complications

Post-Operative Complication		**Frequency**	**Percent**
Valid	No Complications	262	67.5
	Failure	7	1.8
	Keratitis	3	0.77
	Hyphema	1	0.26
	Iris Incarceration	4	1.03
	Persistent epithelial defect	4	1.03
	Cataract formation	4	1.03
	Glaucoma	14	3.6
	Graft Vascularization	4	1.03
	Suture Abscess	2	0.5
	AC Membrane formation	1	0.26
	Rejection	53	13.7
	Recurrence of KC	5	1.3
	Endophthalmitis	1	0.26
	Trauma	23	5.93
	Total	388	100

Multiple visual outcomes were reported in patients following PKP. Twenty patients (5.2%) reported BCVA of 1.0 or better. These results are shown in table 3.

Preoperative BCVA increased from 0.064 (± 0.1155) to 0.317 (0.2826) by the end of the 3 year follow up period (Table 2). Data pairing of pre- and post- operative BCVA, showed a mean of -0.2529 which was statistically significant (P value < 0.005).

Various post PKP complications have been considered as the basic constituent for improved visual acuity level. Two hundred and sixty two patients (67.5%) did not report any of the mentioned complications. Fifty three patients (13.7%) suffered rejection of the allogenic graft. Twenty three patients (5.9%) suffered trauma directly to the grafted cornea. These were 18 males and 5 females ($p < 0.05$). Patients were distributed through all age groups, 3 patients were less than 20 years, 6 between 20 and 29, 6 between 30 and 39, 6 between 40 and 49 and 5 equal or more than 50 years of age. This caused wound dehiscence in 8 patients (all at the graft-host junction) which needed readmission to the operating room for resuturing. All traumas occurred within the first 6 months postoperatively except 2 patients who suffered wound dehiscence 24 and 27 months postoperatively. Table 5 summarizes the multiple post-operative complications reported.

Discussion

Among various populations, PKP is the most common prevalent technique for corneal transplantation[4-11] .In comparison with the rising trend of lamellar keratoplasty (Deep Anterior Lamellar Keratoplasty (DALK), Descemet Stripping Endothelial Keratoplasty (DSEK), and Descemet Membrane Endothelial Keratoplasty (DMEK)), PKP was the most prevalent technique for the corneal transplantation in Iran according to Zare *et al*.[5] These findings support our findings that PKP is still a favourable procedure in treating various corneal disease. Lamellar keratoplasty needs advanced surgical equipments and settings that might not be easily available in third world countries, making PKP an acceptable low cost procedure in such communities. Recently, according to Dong *et al*.[11] there is a decrease in the rate of PKP over the last eight years. The change in the technique has been observed regarding the corneal transplantation from the full-thickness PKP to anterior and posterior lamellar keratoplasty. PKP has been supplanted by the lamellar techniques particularly endothelial keratoplasty in USA over the past years, according to Eye Bank Association of America[3]. It has been observed that the relative ratio persisted to be constant over this period. Other investigations have revealed dissimilar outcomes[12,13,14]. As compared to PKP, patients undergone DSEK achieved more rapid and satisfied visual acuity[14, 15].

It has been observed that there is a continual increase in the number of DALK cases achieved for KC, particularly from the year 2011-2012[13], establishing about 30% of all corneal grafts for KC[16]. A growing trend for DALK was observed from in data from Canada [13, 14] during the same time period. Although, DALK accounted for only 0.6 percent of the corneal grafts. In comparison of with PKP, DALK has a longer surgical time and a steep learning curve, This might be the major purpose for the lack of rise in the trend of DALK in other parts of the world[14,16].

A study conducted by Vieira *et al*.[17] at a university hospital in Brazil, has evaluated the outcomes of penetrating corneal transplantation. It suggested that corneal transplantation is a challenging initiative that can lead to very deprived consequences under adverse circumstances. It has been agreed that PKP is the gold standard for surgical operations of many corneal pathologies. Lamellar keratoplasty has recently evolved as an alternative, which replaces the diseased corneal layer. While, innovations in the surgical instrumentations and techniques offers visual outcomes, which are comparable to PKP.

The outcomes and indications of different anterior lamellar surgery techniques developed for the treatment of stromal disorders have been reviewed by Arenas *et al*.[18]. Posterior lamellar keratoplasty techniques have also been focused including DSEK and DMEK. Additionally, therapeutic anterior lamellar keratoplasty produces comparable graft survival to PKP without an amplified risk of disease relapse for medically insensitive infectious keratitis[18]. PKP technique has been largely overtaken by the lamellar keratoplasty (LK) techniques, but PKP was the generally preferred techniques in the period when lamellar keratoplasty techniques were utilized in Turkey according to Bozkurt *et al*. [19].

Our study found that KC was the most common indication for PKP in our cohort. It was the indication of PKP in 59% of patients. The second most common indication was

corneal opacity other than KC scar (12%) then bullous keratopathy (8%). These three causes were interchangeably the top three indications for PKP over the world. While KC was the most common indication in certain populations (Zare *et al*.[5] 38.5%, Altay *et al*.[9] 34.1 %), it was only second to bullous keratopathy in others (Keenan *et al*.[12] 22.5 %) or third to bullous keratopathy and corneal scar (Tan *et al*.[6] 9.7 %). It seems that even in certain populations where KC is not that prevalent, only bullous keratopathy and corneal scars take the lead as the most common cause of PKP[4,6,7,8,12].A study done on a smaller sample size using the same cohort showed that most common indications for PKP were keratoconus (67.8%) followed by corneal opacity (11%)[20].

In our cohort, marked improvement in BCVA was observed by the end of the three year follow up period. BCVA improved from 0.064 (± 0.12) preoperatively to 0.317 (± 0.28) three years postoperatively ($P < 0.05$), which was statistically significant. Wagoner et al.[21] studied a Saudi cohort, a population which might be similar to our population; reported improvement in vision in (82.4%) of studied eyes. Visual outcomes were observed poor in many eyes with injuries and favourable in keratoconus and corneal dystrophies. Yorston et al [22] found that after an average follow up period of 27.3 months, grafts carried out for keratoconus had a better visual outcome than grafts performed for other corneal pathologies. Preoperatively, 12.4% of keratoconus and 48.5% of non-keratoconus patients were legally blind in their better eye. Postoperatively, only 1.1% of keratoconus patients and 25.7% of non-keratoconus patients were legally blind. In the same trend, Dandona et al.[23] found that the 5 year survival rate was highest if the corneal transplant was done for keratoconus (95.1%) and lowest if carried out for previous transplant failure (21.2%). In our study, we defined legal blindness using the visual acuity measure as that used by the U.S. Social Security Administration (SSA). Its definition of legal blindness is either: Reduced central best corrected visual acuity of 20/200 or less in the better seeing eye, or limitation of visual field in the better eye so as the widest diameter of the visual field subtends an angle no greater than 20 degrees.

PKP has a restricted part in the cure of blindness from corneal scarring, which can be due to measles, vitamin A deficiency and trachoma, for which there is a need of community based preventive measures[21]. According to Wagoner *et al*.[21], multiple levels of visual acuity were recorded before undertaking PKP (similar to what we had in our study). 2.8% of his patients suffered from legal blindness preoperatively. As compared to patients suffering the non-herpetic corneal scars, bullous keratopathy, and herpetic corneal scars, ideal visual acuity in relation to visual outcomes was observed in patients suffering keratoconus before operation. So, with the widely accepted concept that lamellar keratopathy might achieve more rapid and satisfied visual acuity than PKP[14,15,24,25].

PKP provides an appropriate long-term visual rehabilitation for keratoconus[26]. As any other surgical procedure, it is prone to complications. Hovlykke *et al*.[27] reported the results of PKP for their pediatric population over forty years of practice. They found that visual improvement and eye preservation was achieved in 70% of them. The complications of PKP might be very serious. 0.26% of our cohort ended up with endophthalmitis, and 0.77% with keratitis. Kunimoto *et al*.[28] reviewed 1,074

consecutive cases of endophthalmitis presenting to Wills Eye Hospital between 1989 and 2000. Out of these, only fourteen patients (1.3%) were with endophthalmitis after penetrating keratoplasty. Fortunately this devastating complication is very rare after PKP.

In our study, the most common reported complication was rejection in 13.7 of cases. Kuchle *et al.*[29] reported 13.5% incidence of allogenic graft rejection over the first two years of follow up. They specifically mentioned that special ophthalmological care should be offered to the patients suffering from dry eyes or atopic dermatitis to prevent rejection. As per Epstein *et al.*[30], the most imperative rejection factor was the size of the graft after corneal transplantation for keratoconus. Rao *et al*. reported higher allograft rejection rates (10.5%) in his series. He mentioned though that, in cases of bilateral PKP, corneal transplantation in the second eye does not seem to increase the risk of graft rejection in either eye. Inoue *et al*.[31] found that after a 10 year follow up period, 77.9% of grafts were rejection free. The risk factors after PKP for rejection were corneal vascularization, long operation time, and younger donor age. So rejection might occur many years after PKP and a long follow up period is needed.

Glaucoma was the second most common reported complication in our study. It developed in 3.6% of patients. Sandhu *et al.*[32] found that 29% of patients without prior glaucoma diagnosis required change in their medications to control intraocular pressure (IOP) after PKP. Increase in IOP was reported even after lamellar keratoplasty[33,34]. Many risk factors like bullous keratopathy[35], Irido-corneal-endothelial syndrome[36], pre-existing glaucoma[37], previous PKP[38], post-traumatic cases, and combined PKP and cataract extraction surgeries[36, 37] might increase the risk for glaucoma development. Appropriate therapy and careful monitoring are recommended to avoid the development of glaucoma in PKP patients.

There is a life-long risk in the patients post PKP for wound dehiscence. Eight of our sample (2.1%) suffered wound dehiscence at the graft-host junction due to trauma post PKP. Tran *et al*[39]. reviewed 26 patients who suffered surgical wound dehiscence after PK because of ocular blunt trauma. In all cases the rupture occurred at the graft-host junction. Rupture occurred as late as 20 years post PKP. In other series by Foroutan *et al*[40]. this risk was especially more during the first year post PKP. This condition was more common in the young male population because they are usually social and at higher risk to suffer trauma. Due to the small number of cases in our cohort, we were not able to do such a comparison. The adverse effects of trauma in the patients suffering PKP can be minimized by the use of protective eye shields and taking more preventive measures.

This study was performed in Jordan University hospital. Though this hospital hosts the National Eye Bank, but still this sample might not present the whole Jordanian population, a nation wide study might provide a better perspective. Although a three year period might be sufficient to judge the long term survival rate of grafts post PKP, still complications can occur much later than that. Studies with longer follow up periods might be needed.

In conclusion, our study revealed that KC is the main indication for PKP in Jordan University Hospital. Complications are not rare after this procedure though the improvement in

visual acuity is usually achieved with proper pre, intra and postoperative care. Certain complications like rejection and glaucoma development need further attention for early diagnosis and treatment. Risk of wound dehiscence after trauma persists after PKP and needs more preventive measures. This study may serve as a baseline for future studies about any changes in trends for PKP indications and complications in the Jordanian population.

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النتائج البصرية لزراعة القرنية

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الملخص

الغرض: دراسة المؤشرات المشتركة، مضاعفات ما بعد الجراحة والنتائج المرئية من زراعة القرنية.

الطريقة: تم تجنيد المشاركين من قسم العيون في مستشفى الجامعة الأردنية، تم تحليل السجلات الطبية لجميع المرضى الذين خضعوا لزراعة القرنية ما بين 1 يناير 2001 إلى 31 ديسمبر 2009 بأثر رجعي من خلال تصميم التداخلية شبه التجريبي. جميع السجلات تم متابعتها لمده 3 سنوات كحد أدنى.

النتائج: تم دراسة سجلات 388 مريضا. كانت القرنية المخروطية هي السبب الرئيس للزراعة عند 59٪ من المرضى، تليها عتامة القرنية (12٪)، واعتلال القرنية الفقاعي (8٪). كانت القرنية المخروطية السبب الأكثر شيوعا في الذكور 62٪، والإناث 53٪. حدة البصر تحسنت من (0.064 ± 0.12) قبل الجراحة إلى (0.317 ± 0.28) بعد العمل الجراحي بثلاث سنوات. لم يعان 67.5٪ من المرضى من أي مضاعفات خلال فترة المتابعة. وكانت معظم الاختلاطات شيوعا رفض (13.7٪) وحدوث الزرق (3.6٪). ثلاثة وعشرين مريضا (5.9٪) تلقوا ضربة على القرنية مما أدى إلى تفزر الجرح في 8 من المرضى.

الخلاصة: القرنية المخروطية هي أهم سبب لزراعه القرنية في الأردن. وقد وفرت زراعة القرنية نتائج أفضل فيما يتعلق بتحسين قوة البصر، وأظهرت نسبة نجاح مناسبة. المضاعفات مثل الرفض وحصول الزرق لا تزال تشكل تحديا للطبيب المعالج.

الكلمات الدالة: مضاعفات، طرق زراعة القرنية، الرفض، القرنية المخروطية.