Advanced Medical Journal, Vol.10, No.2, P.171-178,2025 https://doi.org/10.56056/amj.2025.357

Epithelialization of the anterior surface of the optic as a newly discovered problem of type I Boston Keratoprosthesis

Shafeeq Salman Shafeeq* Ahmed Yahya Jabary Didar Sddeq Anwar*****

Abstract

Background and objectives: The corneal disorders represented one of first 5 causes responsible of blindness all over the world. Failed keratoplasty commonly occurs in patients with poor prognosis. The Boston Keratoprosthesis (BKPro type-I) is the first option for managing these patients; however, many postoperative complications have been reported. Our aim was to determine the incidence of epithelialization of the anterior surface of the optic of type I Boston Keratoprosthesis in patients who underwent Prosthokeratoplasty.

Methods: A retrospective study was implemented in North Eye Center in Hawler city, Kurdistan region, Iraq. Data from sixty patients who underwent BKPro type-I from August 1, 2017, to March 31, 2023, were reviewed. Epithelialization of optical anterior surface was implemented through researcher in regard to finding epithelial layer affecting vision on slit lamp examination, with the visual acuity measurement pre and postoperatively.

Results: Postoperative complications were observed in 66.7% of patients following BKPro type-I, Epithelialization was present in 10% of all patients. The VA was moderate visual impairment in 83.3% of patients with epithelialization, while severe visual impairment in 16.7% of patients with epithelialization. There was a highly significant improvement in VA post Prosthokeratoplasty ($p<0.001$). No significant differences were observed between patients with postoperative epithelialization and patients without postoperative epithelialization regarding follow up periods ($p=0.2$). There was a significant association between late onset complications and postoperative epithelialization ($p=0.03$).

Conclusions: Boston type 1 keratoprosthesis is effective with restoring vision among patients with poor prognosis corneal blindness although elevated rate of postoperative complications.

Keywords: Corneal, Epithelialization, Keratoplasty Boston type 1 keratoprosthesis

*M.B.Ch.B., trainee at Kurdistan Higher council of Medical Specialties-Ophthalmology; Eye Teaching Hospital - Erbil-Kurdistan region/Iraq.
**M.B.Ch.B, F.I.B.M.S; (Ophth);Ophthalmologist-Eye Teaching Hospital-Erbil-Kurdistan region/Iraq .
***M.B.Ch.B, F.I.B.M.S; (Ophth);Ophthalmologist- North Eye center-Erbil-Kurdistan region/Iraq .
*Corresponding author:Contact email: drshafeeqs@gmail.com

Introduction

Globally, millions of peoples are blind, and the corneal diseases represented within first 5th disorders causing blindness.[1,2] In order to solve the problem in those patients, the corneal transplant surgeries; are performed. Common indications for corneal transplantation are corneal decompensation, keratoconus, and keratitis.[3] Despite promising outcomes, survival rates for high-risk patients undergoing traditional keratoplasty can be lower, and there has been a decrease in live corneal donations worldwide, affecting traditional keratoplasty rates.[4] Many obstacles are facing the Ophthalmologists regarding management of corneal disorders. For that, the Boston Keratoprosthesis (KPro) was designed to reform corneal tissues especially for patients with poor prognosis.[5] The common indications for KPro include failed corneal grafts, children, limbal stem cell deficiency, extreme trauma and herpes infection. [6,7,8,9] The KPro, composed of poly-methyl methacrylate (PMMA), demonstrates better biocompatibility with the corneal stroma, although its compatibility with corneal epithelium and endothelium is questionable.[10] Permanent keratoprosthesis are devices designed to restore eye function among patients with extreme corneal injuries or repeated corneal transplant failures, but they are associated with complications such as infection and tissue necrosis. [11,12] Several authors have been shown that earlier results of BKPro type-I implant retention rates reaching 80% and average of 70% of eyes were with acuity of (20/200) or higher after 2 years following.[13] Despite these findings, late complications pose a danger and may lead to vision loss.[4] Main late adverse outcomes of BKPro implant is the retro prosthetic membrane, with rates ranging from 18% to 55%.[14] Corneal melting is responsible for the exposure of the back plate, as well as leak of fluids from device. These complications have been reported with an incidence range of 11% to 25.9%.[15] Glaucoma is considered as the common cause of blindness after BKPro.[16] Glaucoma prevalence varies between 33.3% to 89.3%.[17] As other implantable prosthetic devices, infectious keratitis and endophthalmitis are the main complications of BKPro.[18] Generally, it was believed that the plastic frontal plating of the keratoprosthesis leads to uncovering of front plate. However, recent studies have reported the epithelial wall formation in front plate.[19] On histopathology analysis non-keratinized squamous epithelial tissue have been recognized. In addition to histopathological analysis, other studies implemented immunofluorescent staining showed cytokeratin and other inflammatory agents leading to expression of epithelialization of anterior surface of optic following BKPro type-I implantation. [3,20] In Iraq, blindness burden was (2.7%) and the main causes of vision loss were cataract (76.1%), diabetic retinopathy (12.9%), glaucoma (5%) and corneal diseases (1.6%).[21] Due to the scarcity of national literature discussing the issue of epithelialization following BKPro type-I implantation and the growing need for this surgical procedure in the country, we conducted this study to determine the incidence of epithelialization of the anterior surface of the optic in patients who underwent prosthokeratoplasty.

Patients and methods

A retrospective literature implemented at the North Eye Center in Hawler city, Kurdistan region, Iraq. The study reviewed the data of patients who underwent BKPro type-I from August 1, 2017, to March 31, 2023.The inclusion criteria were adult patients underwent BKPro type-I implantation after failed penetrating keratoplasty. Exclusion criteria were pediatric age, patients not candidate to BKPro type-I, patients with missing data and lost to follow up. Ethical considerations were implemented in

https://doi.org/10.56056/amj.2025.357

accordance with the Helsinki Declaration, including obtaining ethical approval from the Ethical Committee of Kurdistan Higher Council of Medical Specialties, securing the agreement of the North Eye Center authority, and ensuring the confidentiality of data. Sample size was 60 patients who underwent BKPro type-I. Information of patients were taken through researchers from files stored in the north eye center and written in sheet form. The sheet form had information on the general characteristics of patients (age, gender, and prosthokeratoplasty side), visual acuity (pre and postoperative), postoperative characteristics (follow-up periods, postoperative complications, types of complications, and onset of complications), and the incidence of epithelialization among the studied patients, Follow-up duration ranged from six months to five years, during which best-corrected visual acuity was measured, and slit lamp examinations were conducted. Visual acuity (BCVA) was categorized into four grades: good (6/6 to 6/12), minimal visual impairment (6/18), moderate visual impairment (<6/18 to 6/60), and severe visual impairment (<6/60). The data were analyzed by SPSS version 22 using statistical tests. The level of significance was regarded as significant when p value ≤0.05, Figure(1).

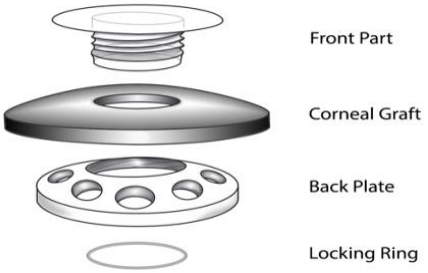

Figure (1): Assembly of the Boston Type I KPro device.

Results

Sixty patients underwent prosthokeratoplasty presented by average age of (49 years); 36.7% of them were in age group of 60 years and more. The male patients were more than females, Table (1).

Table (1): General characteristics of patients.

Variable	No.	%
Age <30 years	13	21.7
30-39 years	10	16.7
40-49 years	8	13.2
50-59 years	7	11.7
≥60 years	22	36.7
Gender Male	46	76.7
Female	14	23.3

The preoperative visual acuity (VA) for patients preoperatively was severe visual impairment for all of them. Postoperatively, the VA was good VA 3.3% of them, minimal visual impairment in 6.7% of them, moderate visual impairment in 46.7% of them and severe visual impairment in 43.3% of them. There was a highly significant improvement in VA post prosthokeratoplasty ($p<0.001$), Table (2). About half of studied patients had follow up less than one year duration, 33.3% of them had follow up for 1-3 years and 18.4% of them had follow up for more than 3 years. The postoperative complications were observed in 66.7% of patients following prosthokeratoplasty. Common postoperative complications were epithelialization of the anterior surface of the optic (15%), retroprosthetic membrane (12.5%), vitreous hemorrhage (12.5%), glaucoma (12.5%), fungal keratitis (7.5%), sever exposure of Boston KPro (7.5%), etc.The onset of postoperative complications was at 1st month in 45% of patients, at 1st year in 27.5% of patients and at 2nd year in 27.5% of patients, Table (3).

https://doi.org/10.56056/amj.2025.357

Table (2): Distribution of visual acuity pre and post Prosthokeratoplasty.

Variable	Preoperative		Postoperative		P
	No.	%	No.	%	<0.001[S]
Visual acuity					
Good VA	0	-	2	3.3	
Minimal visual impairment	0	-	4	6.7	
Moderate visual impairment	0	-	28	46.7	
Severe visual impairment	60	100.0	26	43.3	

S=Significant.

Table (3): Postoperative characteristics of patients.

Variable	No.	%
Follow up periods <1 year	29	48.3
1-3 years	20	33.3
>3 years	11	18.4
Postoperative complications Yes	40	66.7
No	20	33.3
Complications Epithelialization of the anterior surface of the optic	6	15.0
Boston KPro melt	1	2.5
Retroprosthetic membrane (RPM)	5	12.5
Edema of the Boston KPro	1	2.5
Glaucoma	5	12.5
Fungal keratitis	3	7.5
Hemorrhage in the anterior chamber (AC)	2	5.0
Vitreous hemorrhage	5	12.5
Pthisis	1	2.5
Retinal detachment	4	10.0
Sever exposure of Boston KPro	3	7.5
Endophthalmitis	1	2.5
Epithelial defect and filaments	1	2.5
Posterior capsular opacity (PCO)	1	2.5
Vitiritis	1	2.5
Onset of postoperative complications At 1st month		
At 1st month	18	45.0
At 1st year	11	27.5
At 2nd year and more	11	27.5
Total	40	100.0

Post-prosthokeratoplasty, the epithelialization was present in 10% of total patients. The VA was moderate visual impairment in 83.3% of patients with epithelialization, while severe visual impairment in 16.7% of patients with epithelialization, Table (4).

Table (4): Incidence of epithelialization among studied patients.

Variable	No.	%
Epithelialization Yes	6	10.0
No	54	90.0
Total	60	100.0
Visual acuity with epithelialization Moderate visual lmpairment	5	83.3
Severe visual impairment	1	16.7
Total	6	100.0

There was no relationship between epithelialization and pre-prosthokeratoplasty disease categories; non-autoimmune corneal diseases group (dystrophies, post-infections graft failures); presumed autoimmune diseases group (Stevens–Johnson syndrome, mucous membrane pemphigoid, graft-vs-host disease, atopy, uveitis) and Glaucoma group,Table(5)

https://doi.org/10.56056/amj.2025.357

Table (5): Distribution of pre-prosthokeratoplasty disease categories according to epithelialization incidence.

Variable	Epithelialization present				P
	Yes		No		
	No.	%	No.	%	
Pre-prosthokeratoplasty disease categories					0.2 NS
Non-autoimmune corneal diseases group	1	16.7	28	51.9	
Glaucoma group	3	50	17	31.5	
Presumed autoimmune diseases group	2	33.3	9	16.7	

NS=Not significant.

There was no relationship between epithelialization and each of patients age, gender and eye side, Table (6).

Table (6): Distribution of general characteristics according to epithelialization incidence.

Variable	Epithelialization present			P	
	Yes		No		
	No.	%	No.	%	
Age					0.5 NS
<30 years	2	33.3	11	20.4	
30-39 years	2	33.3	8	14.8	
40-49 years	0	-	8	14.8	
50-59 years	1	16.7	6	11.1	
≥60 years	1	16.7	21	38.9	
Gender					0.54 NS
Male	4	66.7	42	77.8	
Female	2	33.3	12	22.2	

NS=Not significant.

There was no relationship between epithelialization and follow up periods. The late onset was related to postoperative epithelialization complication, Table (7).

Table (7): Distribution of postoperative periods according to epithelialization incidence.

Variable	Epithelialization present				P
	Yes		No		
Follow up periods	No.	%	No.	%	
<1 year	1	16.7	28	51.9	0.2 NS
1-3 years	3	50.0	17	31.5	
>3 years	2	33.3	9	16.7	
Onset of postoperative complications complications					0.05S
At 1st month	0	-	18	52.9	
At 1st year	3	50.0	8	23.5	
At the 2nd year and more	3	50.0	8	23.5	

S=Significant, NS=Not significant.

Discussion

Recently, the Boston keratoprosthesis is regarded as the most common artificial cornea selected all over the world. Most frequently, it is indicated in patients with corneal blindness with poor prognosis for conventional corneal transplantation[22]. However, the procedure is associated with several postoperative complications which can affect visual outcomes.[23] In present study, mean age of patients who underwent BKPro was (49 years) with 36.7% of them were in age group of 60 years and more. This finding is close to results of Chew et al [7] retrospective study which documented that older age patients (≥60 years) were the predominant in subjecting to BKPro. Fung et alretrospective multi-center study revealed that pediatric BKPro is related by complication elevated rates as compared to adults. Our study found male gender patients were more than females (76.7% vs. 23.3%). This was in agreement with the results of Aldave et al international study conducted in different countries which reported that 70%

https://doi.org/10.56056/amj.2025.357

of BKPro surgeries were done for male patients. [24, 25,26] The study demonstrated a significant improvement in visual acuity (VA) post prosthokeratoplasty (p<0.001). Preoperatively, all patients had severe visual impairment, while postoperatively, 3.3% achieved good VA, 6.7% had minimal visual impairment, 46.7% had moderate visual impairment, and 43.3% still experienced severe visual impairment. These findings are lower than results of Wang et al retrospective case series study which reported that proportion of eyes with postoperative VA of 10/200 or better was 82.7% after 6 months, 82.8% after 12 months and 42.9% after 8 years. This inconsistency might be attributed to differences in grouping and indication and preoperative VA status between different studies. However, many authors revealed that postoperative VA of BKPro acquired by Snellen chart of 20/40 or better was detected 10-40% eyes. [27,28-32] In current study, about half of studied patients were followed up postoperatively in less than one year duration, 33.3% of them were followed up for 1-3 years duration and 18.4% of them were followed up for more than 3 years duration. El-Khoury et al retrospective review study documented that best duration of achieving better VA following BKPro is between 3 to 6 months and the follow up extended to years in order to assess the outcomes and complications. Our study showed postoperative complications in 66.7% of patients following BKPro. This finding is better than results of Gao et alstudy which reported that all studied patients who underwent Boston type 1 keratoprosthesis had postoperative complications and stated that BKPro is associated with serious postoperative complications. Present study found that the epithelialization was present in 10% of total patients who underwent Boston type 1 keratoprosthesis. This incidence rate is lower than epithelialization incidence rate of (54%) reported by Shapiro et alretrospective comparative study. [31,32,33] On histopathology analysis multilayered, non-keratinized squamous epithelial tissue, presumably of corneal epithelial origin was detected. In addition to histopathologic analysis, other studies implemented immunofluorescent staining showed cytokeratin[3] and other inflammatory agents leading to expression of epithelialization of anterior surface of optic following BKPro type-I implantation.[20]Current study showed a significant association between late onset and postoperative epithelialization complication of Boston type 1 keratoprosthesis (p=0.03). This finding is close to results of Nonpassopo et alstudy which documented that the post-BKPro epithelialization of anterior surface of the optic was presented later. [4]

Conclusions

The Boston type 1 keratoprosthesis is effective in restoring vision among patients with poor prognosis corneal blindness. However, we still have a road to travel until we have a truly effective, inexpensive and, most importantly, a long-term safe procedure with low rate of postoperative complications especially the epithelialization of anterior surface of the optic. Therefore, this study recommends conducting earlier examinations and implementing strict postoperative follow-up protocols for patients who undergo this procedure, emphasizing the necessity for further comprehensive research on this issue.

Conflicts of interest

Declared none.

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