



## Outcome of Boston Type I Keratoprosthesis in a Tertiary Eye Center in Erbil City

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### Abstract

**Background and objective:** The corneal diseases constituted the fourth leading cause of blindness in Iraq. Boston keratoprosthesis implanting is considered as effective surgical management of corneal diseases. The objective is to determine the visual outcome of Boston Type I keratoprosthesis in a tertiary eye center in Erbil city.

**Methods:** Present study was a retrospective cross-sectional study carried out in Tertiary Eye center (North Eye center) in Erbil city-Kurdistan region/Iraq through the period of seven years from 1<sup>st</sup> of May 2017, to 30<sup>th</sup> of April 2023 on sample of 37 patients underwent Boston Type I Keratoprosthesis surgery. All the surgeries and postoperative evaluation were implemented by Dr. Didar S. Anwar. Patients examined by slitlamp device both pre and postoperatively, all the findings were recorded on patients' sheet and the data were evaluated. Visual acuity was done by (Refractionist & optometrist).

**Results:** The mean age of patients was (50.1 years) with predominance of male gender. Preoperative visual acuity was poor (non-useful) for all studied patients. Postoperative visual acuity of patients was distributed as followings; poor (non-useful) in 37.8% of patients, poor (useful) in 13.5% of patients, borderline in 24.3% of patients and good in 24.3% of patients. There was a highly significant difference in visual acuity between pre and postoperative Boston Type I keratoprosthesis ( $p<0.001$ ), the visual acuity was significantly improved postoperatively. The postoperative complications were reported for 59.5% of patients; commonly retro prosthetic membrane.

**Conclusions:** The Boston Type I keratoprosthesis implantation is effective and relatively safe surgery with a prominent improvement in visual acuity.

**Keywords:** Boston Type I keratoprosthesis, Corneal disease, Visual acuity

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## Introduction

The corneal disease is the second leading reason for blindness following cataract. It is considered as one of five major causes of blindness all over the world.<sup>1</sup> In Iraq, corneal diseases are the fourth cause of blindness.<sup>2</sup> The corneal transplant is the final management of different complicated or severe corneal diseases, however, it carries a higher risk for some cases such as immunodeficiency, vascularization of cornea and severe injuries.<sup>1, 3</sup> In these cases, keratoprosthesis (KPro) helps in restoring vision with acceptable prognosis.<sup>4</sup> Boston keratoprosthesis (BKPro) grafting is regarded as effective surgical treatment of corneal diseases globally.<sup>5</sup> Recently, different KPros Types are developed, of which three Types are applied commonly (Osteo-Odonto KPro, Boston Type I KPro and Boston Type II KPro).<sup>6</sup> Boston Type I KPro was firstly developed at 1970s to become the widely used keratoprosthesis device globally. This technique utilizes the collar button architecture that included 3 divisions (front plate, corneal allograft and back plate) which all squeeze the corneal graft and protected by titanium locking ring. Special sutures are used to secure keratoprosthesis to host tissue.<sup>7</sup> The prognosis of Boston Type I KPro in various indications is dependable on comorbidity with other diseases and ocular status postoperatively.<sup>8</sup> Generally, the multiple graft failure is still regarded as the commonest indication for Boston Type I KPro which helps in reaching about 50–65% of 20/200 visual acuity achievement or better and approximately 80–87.8% a device retention rate.<sup>9</sup> Different literatures had been presenting short-term outcomes of Boston Type I KPro with about 80% retention rate and above than 70% of eyes achieved an appropriate visual acuity.<sup>10, 11</sup> In spite of these reports; several complications affecting visual acuity were recorded in long-term follow up.<sup>8</sup> In general, the visual acuity was

improved in majority of eyes following implantation with Boston Type I KPro. In many studies, post-Boston Type I KPro best corrected distance visual acuity ( $\geq 20/200$ ) was ranging between 44% to 85%.<sup>12, 13</sup> The indications of Boston Type I KPro play a major role in prediction of visual acuity postoperatively.<sup>8</sup> It was shown that 76% of eyes had achieved best corrected distance visual acuity ( $\geq 20/200$ ) post-Boston Type I KPro among patients with limbal stem cell deficiency after three years follow up.<sup>14</sup> In same direction, many authors documented that 64% to 67% of eyes had achieved best corrected distance visual acuity ( $\geq 20/200$ ) in patients with chemical injury.<sup>15</sup> On other hand, less than half of patients with in autoimmune associated- limbal stem cell deficiency diseases like Steven's Johnson syndrome and mucous membrane pemphigoid had achieved best corrected distance visual acuity ( $\geq 20/200$ ).<sup>16</sup> Others reported 60% of the eyes were visually corrected in herpes simplex keratitis, while patients with herpes zoster infection achieved best corrected distance vision only in 25% of eyes.<sup>17, 18</sup> The most common complication of Boston Type I KPro is retroprosthetic membrane with various incidence rates ranged between 18-55% especially for cases with infections or Aniridia.<sup>19</sup> The glaucoma is the commonest reason for blindness following Boston Type I KPro with prevalence of preexisting glaucoma between 33.3% to 89.3%.<sup>20</sup> The aim of present study was to determine the visual outcome of Boston Type I keratoprosthesis in a tertiary eye center in Erbil city.

## Patients and methods

The present study was a retrospective cross-sectional study carried out in Tertiary Eye center (North Eye center) in Erbil City-Kurdistan Region/Iraq through the period of seven years from 1<sup>st</sup> of May 2017, to 30<sup>th</sup> of April 2023. The studied population was all patients admitted to Tertiary Eye center for





Boston Type I Keratoprosthesis surgery. Inclusion criteria were adult (age $\geq$ 18 years) patients with different indications of Boston Type I Keratoprosthesis surgery (like corneal graft failure, bullous keratopathy, trauma, etc), available data and completing follow up. Exclusion criteria were younger age patients & patients who had less than 1 year of follow-up visits after the surgery. The study ethics were implemented in regard to the Helsinki Declaration by informed written and verbal consent of patients, approved by the Ethical Committee of Kurdistan Higher Council of Medical Specialties with approval code 1973 on 28.11.2023. A sample of 37 patients underwent Boston Type I Keratoprosthesis surgery was selected after eligibility to inclusion and exclusion criteria. Data were collected retrospectively by a prepared designed by the researcher and its validity will be approved by the supervisor. The collected data will be the following: general characteristics of patients (age and gender), clinical history of patients (chronic medical conditions, previous eye diseases, history of trauma and type of trauma), preoperative characteristics of patients (preoperative visual acuity, preoperative diagnosis and comorbid ocular), and postoperative characteristics of patients (postoperative complications, postoperative procedures and postoperative visual acuity). Evaluation of patients postoperatively had been done and, any complications or events happened was recorded on the patient's sheets. Visual acuity was done by (Refractonist & optometrist) from North Eye center through using Snellen chart when applicable, Finger count, hand motion and light projections to evaluate those with poor vision. The patient's information was entered and interpreted statistically by SPSS program-26. Fisher's exact test was applied to check the relationship of tables and p value of  $\leq 0.05$  was considered significant.

## Results

This study included 37 patients underwent Boston Type I keratoprosthesis surgery with mean age of (50.1 years); 40.5% of them were in age of 60 years and more. Male patients were more than females (73% vs. 27%). Table (1).

**Table (1):** General characteristics of patients.

Variable	No.	%
Age mean $\pm$ SD (50.1 $\pm$ 22.9 years)		
<30 years	8	21.6
30-39 years	7	18.9
40-49 years	3	8.1
50-59 years	4	10.8
$\geq$ 60 years	15	40.5
Gender		
Male	27	73.0
Female	10	27.0
Total	37	100.0

The common chronic medical conditions were absent in 78.4% of patients, while the hypertension was present in 8.1% of them and diabetes mellitus was present in 5.4% of them. The glaucoma is common previous eye disease in patients (35.1%), History of trauma was positive in 29.7% of patients; commonly explosion (45.5%) and direct trauma (27.3%). Table (2).



**Table (2):** Clinical history of patients.

Variable	No.	%
<b>Chronic medical conditions</b>		
No	29	78.4
Diabetes mellitus	2	5.4
Hypertension	3	8.1
DM & HT	1	2.7
DM & autoimmune disease	1	2.7
Others	1	2.7
<b>Previous eye disease</b>		
No	15	40.5
Corneal disease	4	10.8
Glaucoma	13	35.1
Uveitis	1	2.7
Others	1	2.7
Glaucoma & retinal disease	1	2.7
Retinal disease & uveitis	1	2.7
Retinal disease & others	1	2.7
<b>History of trauma</b>		
No	26	70.3
Yes	11	29.7
<b>Type of trauma</b>		
Explosion	5	45.5
Direct trauma with sharp object	3	27.3
Chemical injury	2	18.2
Others	1	9.1
Total	37	100.0

Preoperative visual acuity was poor (non-useful) for all studied patients. Corneal graft failure & bullous keratopathy was the prevalent preoperative diagnosis (48.6%), while prevalent co-morbid ocular disease was glaucoma (51.4%). Table (3)

**Table (3):** Preoperative characteristics of patients.

Variable	No.	%
<b>Preoperative visual acuity</b>		
Poor (non-useful)	37	100.0
<b>Preoperative diagnosis</b>		
Corneal graft failure	1	2.7
Bullous keratopathy	1	2.7
Corneal dystrophy	1	2.7
Trauma	1	2.7
Congenital corneal opacity	1	2.7
Others	2	5.4
Chemical injury & corneal graft failure	2	5.4





Corneal graft failure & bullous keratopathy	18	48.6
Corneal graft failure & corneal dystrophy	1	2.7
Corneal graft failure & trauma	6	16.2
Corneal graft failure & HSV keratitis	1	2.7
Corneal graft failure, HSV keratitis & bullous keratopathy	1	2.7
Corneal graft failure, neurotrophic keratopathy & trauma	1	2.7
<b>Co-morbid ocular disease</b>		
No	5	13.5
Glaucoma	19	51.4
HSV keratitis	2	5.4
Previous retinal detachment and/or atrophy	3	8.1
Diabetic retinopathy	1	2.7
Glaucoma & previous retinal detachment and/or atrophy	1	2.7
Glaucoma & AMD	3	8.1
Glaucoma & diabetic retinopathy	1	2.7
Glaucoma & others	2	5.4
<b>Total</b>	<b>37</b>	<b>100.0</b>

The postoperative complications were reported for 59.5% of patients; commonly retro prosthetic membrane (21.6%), posterior capsular opacity (8.1%) and high intraocular pressure (5.4%). The common postoperative procedures were Nd:YAG membranotomy

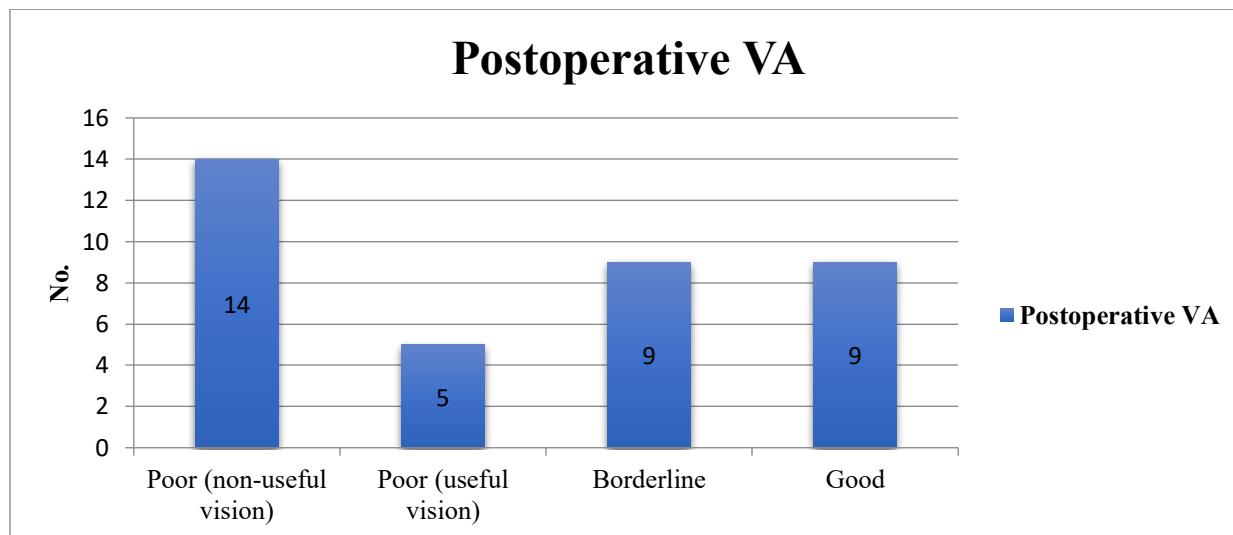
(18.9%) and Nd:YAG capsulotomy (8.1%). Postoperative visual acuity of patients was distributed as followings; poor (non-useful) in 37.8% of patients, poor (useful) in 13.5% of patients, borderline in 24.3% of patients and good in 24.3% of patients. Table (4) and Figure (1).

**Table (4):** Postoperative characteristics of patients.

Variable	No.	%
<b>Postoperative complications</b>		
No	15	40.5
Retro prosthetic membrane	8	21.6
Persistent epithelial defect	1	2.7
High intraocular pressure	2	5.4
Retinal detachment	1	2.7
Posterior capsular opacity	3	8.1
Keratitis & retro prosthetic membrane	1	2.7
Keratitis & persistent epithelial defect	1	2.7
Retro prosthetic membrane & persistent epithelial defect	1	2.7
Retro prosthetic membrane & high intraocular pressure	1	2.7
Retro prosthetic membrane & posterior capsular opacity	1	2.7
Vitreous hemorrhage & others	1	2.7
Keratitis, retro prosthetic membrane & vitreous hemorrhage	1	2.7
<b>Postoperative procedures</b>		
No	18	48.6



Nd:YAG membranotomy	7	18.9
Glaucoma tube shunt	1	2.7
Surgical membranectomy	1	2.7
Tarsorrhaphy	1	2.7
Nd:YAG capsulotomy	3	8.1
Others	2	5.4
Nd:YAG membranotomy & glaucoma tube shunt	1	2.7
Nd:YAG membranotomy & Nd:YAG capsulotomy	1	2.7
Nd:YAG membranotomy & others	2	5.4
Postoperative visual acuity		
Poor (non-useful vision)	14	37.8
Poor (useful vision)	5	13.5
Borderline	9	24.3
Good	9	24.3
Total	37	100.0



**Figure (1):** Postoperative visual acuity of patients.

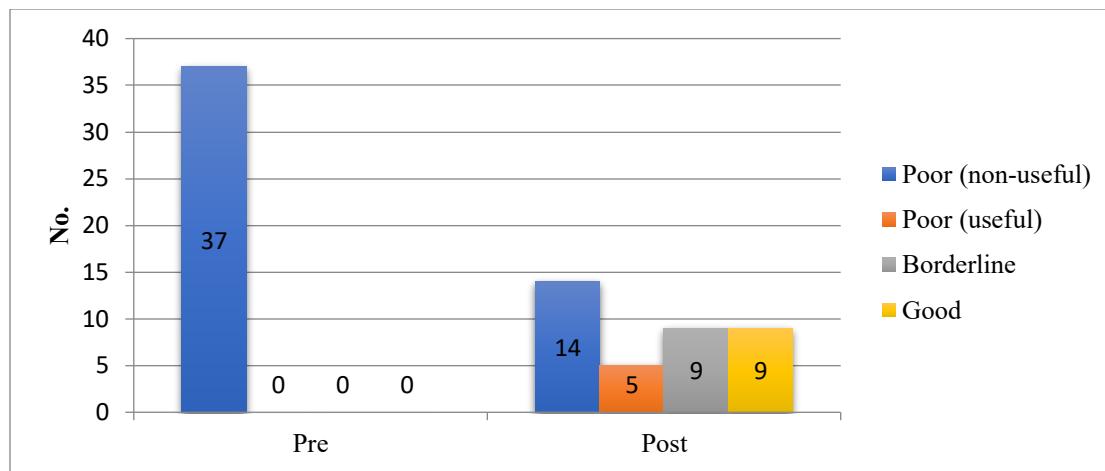
There was a highly significant difference in visual acuity between pre and postoperative Boston Type I keratoprosthesis ( $p<0.001$ ), the visual acuity was significantly improved postoperatively. Table (5) and Figure (2)

**Table (5):** Distribution of visual acuity pre and postoperatively.

Variable	Preoperative		Postoperative		P
	No.	%	No.	%	
<b>Visual acuity</b>					
Poor (non-useful vision)	37	100.0	14	37.8	<0.001 <sup>s</sup>
Poor (useful vision)	0	-	5	13.5	
Borderline	0	-	9	24.3	
Good	0	-	9	24.3	

S=Significant.





**Figure (2):** Visual acuity pre and postoperatively.

## Discussion

Although the advancement of Boston Type I keratoprosthesis technology, retention rate improvement and lowering its postoperative complication rates which helps in wide application of this surgical procedure, its common indication nowadays remains prior graft failure.<sup>11</sup> Current study showed that mean age of patients underwent Boston Type I KPro was (50.1 years) with predominance of male gender. These findings are in agreement with results of Shihadeh retrospective study which reported mean age of (51.7 years) for patients underwent Boston Type I KPro with predominance of male gender.<sup>21</sup> In our study, the hypertension and diabetes mellitus where the common chronic medical diseases of patients underwent Boston Type I KPro. These findings are close to results of Kamyar et al retrospective cohort study which reported that hypertension and diabetes mellitus affected outcomes of Boston Type I KPro.<sup>22</sup> Our study showed that glaucoma is common previous eye disease in patients underwent Boston Type I KPro (35.1%). Similarly, a study conducted by AlHilali reported higher prevalence of glaucoma as common previous eye disease in patients underwent Boston Type I KPro.<sup>23</sup> In our study, history of trauma was positive in

29.7% of patients underwent Boston Type I KPro; commonly explosion (45.5%) and direct trauma (27.3%). These findings are close to results of Patel et al study in United States of America which reported that about one third of patients underwent Boston Type I KPro had positive history of trauma.<sup>24</sup> In present study, the corneal graft failure & bullous keratopathy was the prevalent preoperative diagnosis (48.6%), while prevalent co-morbid ocular disease was glaucoma (51.4%). These findings are consistent with reports of Nonpassopon et al study which revealed that multiple graft failure was the predominant indication of Boston Type I KPro and glaucoma was the predominant co-morbid ocular disease.<sup>8</sup> The present study found that postoperative complications were reported for 59.5% of patients; commonly retro prosthetic membrane (21.6%), posterior capsular opacity (8.1%) and high intraocular pressure (5.4%). These findings are lower than results of Gao et al study which reported postoperative complications in 35% of patients underwent Boston Type I KPro.<sup>25</sup> This difference in complications rate might be attributed to differences in sample size and duration of follow up between different studies. Our study revealed that common postoperative procedures were Nd:YAG





membranotomy (18.9%) and Nd:YAG capsulotomy (8.1%). These findings coincide with results of Jardeleza et al study.<sup>26</sup> The current study found that preoperative visual acuity was poor (non-useful) for all studied patients, while postoperative visual acuity of patients were distributed as followings; poor (non-useful) in 37.8% of patients, poor (useful) in 13.5% of patients, borderline in 24.3% of patients and good in 24.3% of patients, there was a highly significant difference in visual acuity between pre and postoperative Boston Type I keratoprosthesis ( $p<0.001$ ), the visual acuity was significantly improved postoperatively. These findings are similar to results of different literatures such as Al Arfaj K, Wang et al study which all documented a significant improvement in visual acuity reached to about 60%.<sup>27,28</sup> In conclusion, the Boston Type I keratoprosthesis implantation is effective and relatively safe surgery with a prominent improvement in visual acuity. This study encouraged further national multi-centers studies on visual improvement of patients underwent Boston Type I KPro.

## Conflicts of interest

None

## Acknowledgment

Gratitude and thanks for the staff of Tertiary Eye Center.

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