



## PEDIATRIC ENDOTHELIAL KERATOPLASTY: CHALLENGES AND OUTCOME- A PROSPECTIVE STUDY AT A TERTIARY CARE EYE CENTRE

### Ophthalmology

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### ABSTRACT

**Purpose:** The purpose of this article is to highlight the challenges faced during non-descemet stripping endothelial keratoplasty (n-DSEK) and the outcome in pediatric patients.

#### METHODS

**Design:** Eight eyes of six children with corneal decompensation [Congenital hereditary endothelial dystrophy (05), failed Penetrating Keratoplasty (02) and toxic endothelitis (01)] who underwent n-DSEK, were prospectively followed for visual acuity, corneal thickness and complications. Intra operative challenges encountered during n-DSEK were also evaluated. All the patients were evaluated pre-operatively under slit-lamp. Refraction and initial visual acuity was documented. Postoperative follow up was done at day 1, 7, 30, 12 weeks and at 6 months. Subsequent, follow up was done at 12 and 18 months postoperatively.

**Results:** All patients completed 6 months of follow-up. Mean visual acuity (VA) in LogMar at 3 months and 6 months was 0.73 & 0.43 respectively. VA improved significantly and corneal thickness also reduced at 3 ( $p<0.05$ .) & 6 ( $p<0.05$ ) months post-operatively. 2 out of 8 eyes had lenticule dislocation at 7th postoperative day. They were managed successfully by re-bubbling. Intraoperative challenges faced were: while making incision, descematorrhexis, peripheral iridotomy, sheet glide insertion and air tamponade and were managed by using cohesive viscoelastic, deeper anesthesia and multiple suture placement respectively.

**Conclusions:** Inspite of multiple intra operative challenges the n-DSEK seems to be a promising surgical procedure in children with corneal endothelial decompensation.

### KEYWORDS

Pediatric Endothelial Keratoplasty, DSEK, Corneal endothelial decompensation

#### INTRODUCTION:

Pediatric Keratoplasty has been extremely formidable for the Ophthalmologists over the years as the surgery involves a peculiar set of age-related problems.

A consequential proportion of Pediatric patients undergo Penetrating Keratoplasty for Endothelial Dysfunction due to various causes like Congenital Hereditary Endothelial Dystrophy, Birth Trauma; making Penetrating Keratoplasty the standard of care for this predisposed age group. In the current scenario, Endothelial Keratoplasty has shown more promising results in comparison to traditional full thickness Penetrating Keratoplasty, in terms of smaller wounds, lesser sutures and quicker rehabilitation.<sup>1,2</sup> These unique set of advantages make Endothelial Keratoplasty a befitting option for Pediatric age group who are prone to Penetrating Keratoplasty related complications and Amblyopia.

Endothelial Keratoplasty in the form of DSEK is currently the gold standard treatment in adult patients with corneal endothelial dysfunction.<sup>3</sup> DSEK has also been reported in few Pediatric patients including a series on the treatment of Congenital Hereditary Endothelial Dysfunction patients.<sup>1,2-7</sup>

In this article, we report the challenges and the outcome of Endothelial Keratoplasty at our centre while managing the Pediatric cases of Endothelial dysfunction/ Corneal Opacities subjecting to various etiologies.

#### Aim & Objectives

##### Aim:

To assess the challenges and outcome in Pediatric Patients undergoing Endothelial Keratoplasty (DSEK)

##### Objectives:

1. To elucidate the challenges faced during the management of Pediatric patients who are eligible for Endothelial Keratoplasty.
2. To evaluate the postoperative gain in visual acuity and a substantial reduction of corneal oedema by measuring corneal

thickness on OCT in Pediatric patients who underwent Endothelial Keratoplasty.

#### Methodology:

This was a prospective non randomized interventional study done in a tertiary care eye centre of a government hospital in western Maharashtra; in patients from Pediatric age group (<12 years) from Jan-Dec 2018 undergoing Endothelial Keratoplasty. Written informed consent was taken from the parents/guardians of the Pediatric patients before the procedure.

Preoperatively, the patients were examined under slit lamp to assess the extent of corneal oedema clinically (Fig 1.1) and refraction was performed for each patient to check the baseline visual acuity. All children underwent IOP measurement, Pachymetry on Anterior segment OCT and systemic evaluation to rule out any syndromic association. Photographs of the corneal pathology were taken to document the findings. Subsequently, the patients were followed up postoperatively to determine the outcome of surgery. Patients were evaluated for Graft Survival in terms of graft-host junction adhesion, any detachment of lenticule or dislocation, clarity of host cornea and also refraction was performed to check Visual Acuity to analyze the gain in Best Corrected Visual Acuity following surgery. Anterior segment OCT and serial photographs on anterior segment imaging system were also taken to keep the records (Fig 1.2, 1.3, 1.4, 1.5). Lenticule adhesion and attachment were also measured on Anterior segment OCT at 1 week, 4<sup>th</sup> week, 12 weeks and 6 months postoperatively. Also, patients were thoroughly examined to check for any complication following surgery. Patients were closely monitored and followed up at regular interval.

#### Surgical Technique:

Endothelial Keratoplasty is a partial thickness corneal transplant procedure/lamellar keratoplasty involving replacement of diseased corneal endothelium with healthy donor corneal endothelium. At our centre, Endothelial Keratoplasty in the form of Descemet Stripping Endothelial Keratoplasty has been performed on 08 eyes of 06

Pediatric cases reported in this article.

n-DSEK in these Pediatric patients was done under General Anesthesia by the surgeon trained in Anterior Segment surgery. The corneo-scleral rims were obtained from the deceased donors at our Eye Bank and kept in Cornisol preservative media. Only the optical quality donor tissues with adequate corneo-scleral rims having higher endothelial cell count were utilized within 48-72 hrs of harvesting.

The steps involved in the Descemet Stripping Endothelial Keratoplasty surgery included: Donor tissue Preparation (the most critical step). Donor tissue mounted on an artificial anterior chamber and depth of the chamber maintained by air and BSS. The lenticule were prepared by the surgeon intra-operatively, lamellar dissection is done manually, using 300 u depth marked blade and Melle's lamellar dissectors. The dissection was done till a planar shaped donor lenticule with a uniform thickness of approximately 180 um and with a disc diameter approximately 3mm less than the diameter of recipient cornea was obtained. After dissection, donor tissue was gently removed from the artificial anterior chamber and placed endothelial side up and the tissue was punched with 7.5mm trephine block. The donor lenticule was preserved in the Cornisol medium for the interim duration while the recipient's eye was being prepared.

While preparing the recipient, the hazy host cornea was de-epithelized with a crescent blade to improve the visualization of the anterior chamber. Paracentesis incisions were given using 15-degree side port at 10 and 2'0 clock positions. Main port entry into the anterior chamber was made superiorly with 2.8 mm keratome and was extended up to 5.5mm. Anterior chamber depth was maintained by injecting the viscoelastic Helon into the anterior chamber. Peripheral iridectomy was made at 6'0 clock position after constricting the pupil by injecting Pilocarpine 2%. Viscoelastic was removed before inserting donor lenticule.

Donor Lenticule Implantation- Helon GV was placed in the centre of donor button on the endothelial side. Donor lenticule was placed on the Sheet glide covered with Helon GV and inserted into the anterior chamber through the main port using 26 G needle cystitome. The anterior chamber was inflated with air once the graft was inserted to firmly press the donor tissue up against the recipient cornea. While Anterior chamber was being filled with air, the surface of recipient cornea was massaged with a flat cannula to manipulate donor graft in position and move any entrapped fluid out of the donor-recipient interface. Partial decompression of the anterior chamber was done after 8-10 min to avoid a pupillary block. The main port was sutured with 3 interrupted 10-0 Monofilament nylon sutures. Eye pad and bandage was applied. In some of the patients even side port incisions were required to be closed by interrupted sutures. Post-operatively, patients were started on antibiotics, steroids and lubricants eye drops in the operated eye. The steroid eye drop was given at a frequency of 12 times a day for the first week and was subsequently tapered off in the following weeks. Antibiotic eye drop was given at a frequency of 4 times a day for 15 days. The sutures were removed after 1 month.

These patients were vigilantly followed up on Day 1, 7 and 30, 12 weeks and at 6 months. Visual acuity was recorded at every visit and the status of the graft was evaluated using the Slit lamp and Anterior Segment OCT findings documentation on every follow up.

## Results:

**Statistical Analysis-** Data analysis was done by using STATA 15.0 Statistical software.

- Qualitative data variables were expressed by using frequency and percentage (%)
- Quantitative data variables were expressed by using Mean, SD and Median.
- To find the significant difference between OCT at preoperative and post-operative thickness, Non Parametric test( Wilcoxon Sign Rank test) was used.
- To find the significant difference between Mean Visual acuity in Log Mar at preoperative and post operative period, Non Parametric test (paired t-test) was used.
- p-value < 0.05 was considered as significant.

A total of 8 eyes of 6 Pediatric patients were operated. The age of the patients ranged from 5-10 years (3 males & 3 females); who reported with endothelial decompensation at an early age. The common underlying cause was Congenital Hereditary Endothelial Dystrophy

(CHED) (n=5), Failed Penetrating Keratoplasty (n=2) and Toxic Endothelitis (n=1). 3 out of 6 patients were the product of the consanguineous marriage. All the eyes were phakic. 3 out of the 6 patients who were diagnosed as CHED had bilateral involvement of eyes. 2 eyes had a previous history of surgical intervention in the form of Penetrating Keratoplasty.

Demographic profile of the patients is given as under in table 1.

**Table 1: Demographic profile of patients who underwent Pediatric Endothelial Keratoplasty**

| S NO  | AGE    | SEX    | EYE (RE/LE) | DIAGNOSIS                     | COMORBIDITIES/ SURGICAL HISTORY                                                                                               |
|-------|--------|--------|-------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| EYE 1 | 9 yrs  | Male   | RE          | CHED                          | Nil                                                                                                                           |
| EYE 2 | 7 yrs  | Male   | RE          | CHED                          | Nil                                                                                                                           |
| EYE 3 | 8 yrs  | Female | LE          | CHED                          | Nil                                                                                                                           |
| EYE 4 | 9 yrs  | Male   | LE          | CHED                          | History of DSEK in RE 6 months back at this center. Presently, diagnosed to have SNHL in both ears (Harboyan Syndrome)        |
| EYE 5 | 7 yrs  | Male   | LE          | CHED                          | History of DSEK in RE 6 months back at this center                                                                            |
| EYE 6 | 9 yrs  | Female | RE          | CORNEAL OEDEMA POST FAILED PK | Patient had blunt trauma to RE at 7 yrs of age, underwent PK at age of 8 yrs, reported with failed graft at 9 yrs             |
| EYE 7 | 5 YRS  | Female | RE          | TOXIC ENDOTHELITIS            | Parents give history of fever at 2 years of age for which she required ICU admission for 15 days and was given parental drugs |
| EYE 8 | 10 YRS | Male   | LE          | CORNEAL OEDEMA POST FAILED PK | Diagnosed case of infective keratitis left eye who underwent PK at the age of 9 yrs                                           |

In this study, the graft was taken from the deceased donors aged between 20 to 35 yrs for a healthy endothelium. Endothelial donor count was evaluated pre-operatively. The mean donor graft endothelial count was  $2852 \pm 198$ . Surgery was uneventful in all the cases. There were various intra operative challenges encountered by surgeon which were dealt with certain modifications of standard technique. There was difficulty in making the first incision and main entry port because of rigid sclera and tough cornea. Therefore, to assist in incision the cohesive viscoelastics were used. The peripheral iridectomy was performed in all paediatric cases to avoid pupillary block glaucoma and extreme care was taken to avoid the iatrogenic touch of the crystalline lens. To avoid this complication intracameral pilocarpine was used to constrict the pupil along with insertion of helon Gv in anterior chamber, while using cutter for making iridectomy. Sheet glide was preferred over Busen glide in all these cases. There was constant shallowing of anterior chamber depth requiring deeper general anesthesia throughout the procedure. So in some cases, interrupted 10-0 sutures were placed over the main incision and side incisions.

On the first postoperative day, the cornea was edematous in all the cases. Lenticule was well adhered in all the cases. Postoperatively, intra ocular pressure was within normal limits in the operated eyes. 2 patients complained of excessive lacrimation and foreign body sensation on the first postoperative day due to epithelial defect. Postoperative recovery was slower in the patients of CHED in comparison to other patients who underwent DSEK, probably due to delay in initial reporting. By the time these patients had reported, the cornea was already quite thick and edematous, which was documented in anterior segment OCT preoperatively. Best corrected visual acuity was satisfactorily achieved up to 6/18 (logMar 0.5) (unaided) or better in 5 cases (62.5 %). 2 cases (25 %) even improved up to 6/12 (logMar 0.3)(unaided). Considering the fact that the children with CHED had reported late at our centre, the element of developmental amblyopia could not be ruled. Anterior segment OCT was performed at every follow-up visit to monitor the host corneal thickness and condition of lenticule as well as its thickness. Serial recording of AS-OCT revealed a gradual decrease in thickness of graft over 3 months duration which concurrently corroborated with the corneal clarity during the follow-up. Post operative follow up details of patients are given in table 2 and descriptive statistical analysis of OCT and visual acuity over 6 months is given in table 3.1 & 3.2 respectively.

**Table 2: Follow up of OCT and visual acuity of the operated cases**

| Eye                               | Pre op | DAY1 | DAY 7 | DAY 30 | 12 WEEKS | 6 MONTHS |
|-----------------------------------|--------|------|-------|--------|----------|----------|
| <b>OCT (um)</b>                   |        |      |       |        |          |          |
| 1                                 | 1003   | 944  | 1000  | 780    | 749      | 699      |
| 2                                 | 1005   | 1004 | 1050  | 988    | 784      | 647      |
| 3                                 | 1072   | 994  | 990   | 960    | 853      | 720      |
| 4                                 | 1004   | 949  | 993   | 767    | 758      | 691      |
| 5                                 | 1007   | 1004 | 990   | 987    | 811      | 648      |
| 6                                 | 1119   | 1009 | 897   | 889    | 883      | 702      |
| 7                                 | 1092   | 998  | 963   | 893    | 854      | 794      |
| 8                                 | 1108   | 1006 | 992   | 969    | 914      | 812      |
| <b>Visual acuity( in Log MAR)</b> |        |      |       |        |          |          |
| 1                                 | 1.3    | 1.3  | 1.68  | 1.08   | 1.0      | 0.5      |
| 2                                 | 1.68   | 1.68 | 2.0   | 1.18   | 0.8      | 0.5      |
| 3                                 | 1.08   | 1.08 | 1.08  | 1.0    | 0.6      | 0.3      |
| 4                                 | 1.3    | 1.3  | 1.48  | 1.08   | 0.6      | 0.5      |
| 5                                 | 1.68   | 1.68 | 1.68  | 1.3    | 0.8      | 0.5      |
| 6                                 | 2.0    | 2.0  | 1.48  | 1.08   | 0.6      | 0.3      |
| 7                                 | 2.0    | 1.68 | 1.3   | 1.08   | 0.8      | 0.3      |
| 8                                 | 2.0    | 2.0  | 1.68  | 1.3    | 0.6      | 0.5      |

**Table 3.1: Descriptive Statistics of OCT of the operated cases**

| OCT at         | OCT  |      |         |       |        | p-value |
|----------------|------|------|---------|-------|--------|---------|
|                | Min  | Max  | Mean    | SD    | Median |         |
| Pre- operative | 1003 | 1119 | 1051.25 | 51.49 | 1039.5 |         |
| Day 1          | 944  | 1009 | 988.50  | 26.37 | 1001   | 0.012   |
| Day 7          | 897  | 1050 | 984.38  | 42.83 | 991    | 0.049   |
| Day 30         | 767  | 988  | 904.13  | 89.28 | 926.5  | 0.012   |
| 3 mth          | 749  | 914  | 825.75  | 59.82 | 832    | 0.012   |
| 6 mth          | 647  | 812  | 714.13  | 60.69 | 700.5  | 0.012   |

By using Wilcoxon Sign rank test p-value was < 0.05 therefore there is significant changes in OCT at Day1 to 6th month with Baseline data.

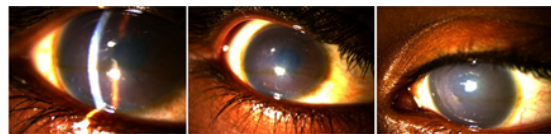
**Table 3.2: Descriptive Statistics of Visual Acuity of the cases**

| Visual Acuity at | Visual Acuity in LogMar |     |      |      |        | p-value  |
|------------------|-------------------------|-----|------|------|--------|----------|
|                  | Min                     | Max | Mean | SD   | Median |          |
| Pre- operative   | 1.08                    | 2   | 1.63 | 0.37 | 1.68   |          |
| Day 1            | 1.08                    | 2   | 1.59 | 0.34 | 1.68   | 0.351    |
| Day 7            | 1.08                    | 2   | 1.55 | 0.28 | 1.58   | 0.572    |
| Day 30           | 1                       | 1.3 | 1.14 | 0.11 | 1.08   | 0.004*   |
| 3 mth            | 0.6                     | 1   | 0.73 | 0.15 | 0.7    | < 0.001* |
| 6 mth            | 0.3                     | 0.5 | 0.43 | 0.10 | 0.5    | < 0.001* |

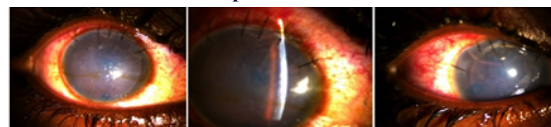
\*Significant p-value < 0.05 (Paired t-test was used)

A complication in the form of graft dislocation was observed in 2 out of 8 eyes in the first postoperative week which was managed successfully by Re-bubbling under General Anaesthesia. On the first postoperative

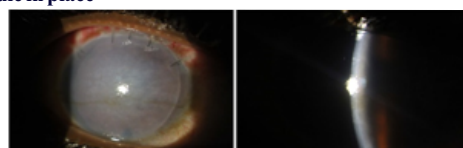
day, following Re-bubbling, the host cornea cleared drastically with the air bubble in the anterior chamber. Appropriate measures were ensured in subsequent surgeries to avoid such complications. The graft started clearing up only after 3 months but pristine clarity could never be attained. There were no cases of pupillary block. Follow up of all the cases have revealed no evidence of cataract.



**Fig 1.1: Pre-operative slit lamp photographs showing diffuse corneal oedema in a CHED patient**



**Fig 1.2: Post-operative follow up Day 7 of CHED patient showing gradual resolution of corneal oedema, Compact cornea and lenticule in place**



**Fig 1.3: Post-Operative follow up Day 30 of CHED patient showing some amount of corneal oedema but a Compact cornea and lenticule in place**



**Fig 1.4: Post-Operative follow up at 3 month showing clearer compact cornea with well attached lenticule**



**Fig 1.5: Post-Operative follow up at 6 months**

## DISCUSSION:-

A significant number of Pediatric patients undergo Keratoplasty for Endothelial Dysfunction due to various causes as listed in this article. As the visual recovery in this set of population is promptly warranted due to dreaded complication of amblyopia as a result of visual deprivation in the budding years, it makes Penetrating Keratoplasty the standard of care for this vulnerable age group.<sup>8-10</sup> The consorted preoperative, intraoperative and postoperative challenges make the surgery onerous.<sup>11</sup> Preoperatively, diligent co-operation of the patient is required for adequate clinical assessment of pathology which is a herculean task in children. Intra-operatively, it is grueling to handle tissue in children due to low scleral rigidity, pliable and smaller cornea, poor visibility due to edematous or ground glass appearance of the cornea, smaller size of donor tissue, sticky iris, risk of crystalline lens damage by instruments and more tenacious vitreous. Besides, at a younger age, eyes are immunologically pronounced leading to protracted and severe inflammatory responses.<sup>12,13-15</sup> Due to rapid healing, the sutures easily become loose making pavement for neovascularization. The incessant requirement of examination under general anesthesia is another major limiting factor in this age group.

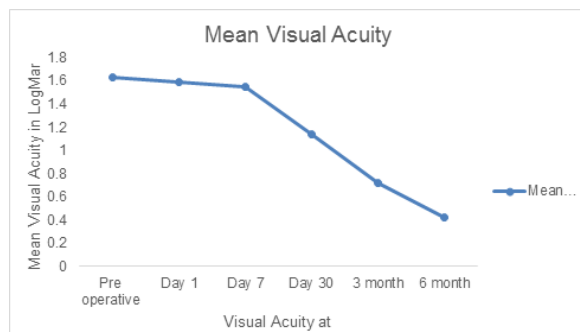
Postoperative management of the Pediatric patient is another impediment due to their vulnerability to trauma and frequent eye rubbing. Children seldom report symptoms timely which preclude prompt intervention and timely management of postoperative complications. Unique to Pediatric age group is a dire requirement for timely optical correction and amblyopia therapy for optimum visual gain.<sup>15-17</sup> It requires a conjoint effort of the surgeons and the parents in the endeavor of visual rehabilitation in children.

Presently, Endothelial Keratoplasty has gained popularity over traditional full thickness Penetrating Keratoplasty due to major advantages in terms of smaller wound size, lesser sutures and better visual prognosis, with a decline in the incidence of surgically induced astigmatism in these patients along with the speedy recovery.<sup>18,19</sup> Due to the lesser number of sutures involved in Endothelial Keratoplasty, the chances of suture-related complications like infections, astigmatism is reduced to minimal.<sup>20-22</sup> A smaller wound size facilitate better healing and reducing the risk of wound dehiscence. At this tertiary care center, Endothelial Keratoplasty was performed in the form of DSEK. Only a few Pediatric patients who underwent DSEK have been reported till date. Case reports have been published of performing DSEK in CHED patients.<sup>4,8,23,24</sup> The other article reported DSEK in a child whose visual recovery was poor due to amblyopia.<sup>25</sup>

In DSEK, surgery is performed through a short clear cornea tunnel, hence, vision-threatening intra-operative complications are rarely witnessed and can be easily managed. Besides, the structural integrity of the globe is maintained. Intra-operatively Challenges faced by the surgeon include difficulties with Descemet's stripping, inadequate visualization due to corneal opacity, making Peripheral iridotomy using vitrectomy cutter and the requirement for prolonged general anaesthesia due to the difficulty of maintaining an air bubble tamponade. Also, there was a hindrance in making entry port due to corneal pliability in children. To overcome these issues, various modifications of the standard surgical procedure were adopted. Anterior chamber shallowing due to constant push of vitreous was another challenge leading to raised intraocular pressure which had to be maintained preoperatively by giving iv Mannitol and maintaining hypotony by hyperventilation and use of injection Propofol under the supervision of a Pediatric anesthesiologist. After making entry, Anterior chamber was well formed by injecting Healon-GV, which facilitated the entry of sheet glide smoothly as well as reduced the difficulties of performing Peripheral iridotomy. Intracameral pilocarpine was used to constrict the pupil, thereby, preventing damage to the crystalline lens. Subsequently, Healon -GV was removed before placement of sheet glide into the anterior chamber. Sheet glide was preferred over busin glide in order to protect the underlying crystalline lens from accidental touch by instruments and also to prevent the iris prolapse.

Postoperatively, it was a herculean task to ensure compliance of children for supine position. The most common postoperative complication of graft dislocation was seen in 2 out of 8 eyes which were operated at our centre during the first postoperative week, which was managed successfully by Re-bubbling in the form of air injection. In this study, postoperative results were evaluated in terms of graft clarity and best corrected visual acuity. Best corrected visual acuity was satisfactorily achieved up to 6/18(0.5 log MAR) (unaided) or better in 5 cases . 2 cases even improved up to 6/12 (0.3 log MAR)(unaided). The element of developmental amblyopia could not be ruled out in children with congenital anomaly. Mean visual acuity showed a gradual improvement over a period of 6 months. (Graph 1)

**Graph 1: Mean Visual Acuity on follow up**

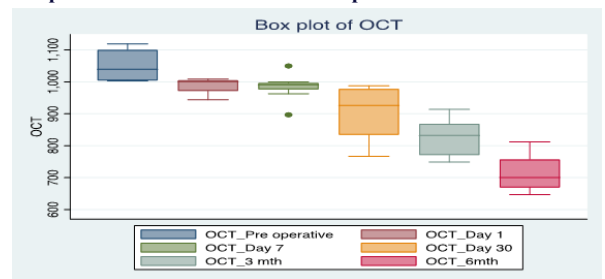


**Percentage change of visual acuity**

| Day 1 | Day 7 | Day 30 | 3 month | 6 month |
|-------|-------|--------|---------|---------|
| 2.45  | 5.06  | 30.21  | 55.52   | 73.93   |

Anterior segment OCT was performed at every follow-up visit to monitor the condition of lenticule as well as its thickness. Serial recording of AS-OCT revealed a gradual decrease in thickness of host oedematous cornea over 6 months duration which concurrently corroborated with the corneal clarity during the follow-up. (Graph 2)

**Graph 2: Mean OCT count on follow up**



**Percentage change of OCT over 6 months**

| Day 1 | Day 7 | Day 30 | 3 month | 6 month |
|-------|-------|--------|---------|---------|
| 5.97  | 6.36  | 14.00  | 21.45   | 32.07   |

## CONCLUSION:-

In this article, we have highlighted the challenges and the possible solutions which we preferably resorted to and outcome witnessed during the management of Pediatric patients with endothelial decompensation owing to various etiologies. It has been proven beyond doubts that an endothelial keratoplasty is a feasible option in Pediatric patients in comparison to Conventional Penetrating Keratoplasty. However, advancements in surgical techniques of Endothelial Keratoplasty may further augment the safety profile in the Pediatric patients making this technique a preferred option in cases of Endothelial decompensation.

## Informed Consent :

A written informed consent to publish clinical patient information and photographs was obtained from all the patient's parents.

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