

# Clinical profile and demographic distribution of Fuchs' endothelial dystrophy: An electronic medical record-driven big data analytics from an eye care network in India

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**Purpose:** To describe the demographics and clinical profile of Fuchs' endothelial corneal dystrophy (FECD) in patients presenting to a multi-tiered ophthalmology hospital network in India. **Methods:** This cross-sectional hospital-based study included 3,082,727 new patients presenting between August 2010 and December 2021. Patients with a clinical diagnosis of FECD in at least one eye were included as cases. The data were collected using an electronic medical record system. **Results:** Overall, 2570 (0.08%) patients were diagnosed with FECD. The majority of the patients were female (65.53%) and were predominantly adults (99.92%). The most common age group at presentation was during the seventh decade of life with 867 patients (33.74%). The overall prevalence was higher in patients from a higher socioeconomic status (0.1%) presenting from the urban geography (0.09%) and in retired individuals (0.4%). About half of the 5,140 eyes had mild or no visual impairment (<20/70) in 2643 eyes (51.42%) followed by moderate visual impairment (>20/70 to 20/200) in 708 eyes (13.77%). The average logMAR was 0.61 ± 0.81 at presentation. The most documented corneal signs were guttae (76.63%), corneal scar (23%) and stromal edema (21.73%). The most associated ocular comorbidity was cataract (47.32%) followed by glaucoma (5.39%). More than a tenth of the affected eyes required a surgical intervention of endothelial keratoplasty (15.58%). **Conclusion:** FECD more commonly affects females presenting during the seventh decade of life. Majority of the eyes had mild or no visual impairment and endothelial keratoplasty is warranted in a tenth of the affected eyes.

**Key words:** Big data, cornea, electronic medical records, Fuchs' endothelial dystrophy, India

Fuchs' corneal endothelial dystrophy (FECD) is characterized by the development of guttae in the Descemet membrane, resulting in endothelial dysfunction.<sup>[1]</sup> The morphological and functional abnormalities in the corneal endothelium results in corneal edema leading to vision impairment and pain due to the epithelial bullae in advanced cases. FECD was first described by Professor Ernest Fuchs in 1910 as "dystrophia epithelialis" where a slowly progressive corneal clouding more in the inferior cornea was associated with diurnal variation of symptoms in elderly patients.<sup>[2]</sup> While the late-onset form predominantly affects patients in the elderly age group above 40 years of age, the early-onset form can also affect younger populations.<sup>[3,4]</sup> The prevalence of FECD has been reported in varying degrees in the population ranging from 3.7%–11%. In United States, it is reported between 3.9%–6.62% of the population aged above 40 years;<sup>[3,4]</sup> in Iceland, it is reported to be 9.2% of the population above the age of 50 years;<sup>[5]</sup> and Japan reported a lower prevalence rate of 3.3%.<sup>[6]</sup> A greater prevalence of FECD has been reported in females than males in the literature.<sup>[2,3,5,7]</sup> A genetic inheritance of autosomal

dominant (AD) pattern has been described in the early-onset disease of two mutations in the *Col8A2* gene located on chromosome 1p34.3-p32 that encodes for the  $\alpha 2$  polypeptide of collagen type VIII.<sup>[8]</sup> Acquired corneal endotheliopathies accounted for 8.3% of severe visual impairment and blindness in eyes affected with corneal diseases.<sup>[9]</sup> Studies from India have shown that FECD accounted for 41.89% of the overall corneal dystrophies<sup>[10]</sup> and accounted for 20.4% of the endothelial keratoplasty that were performed.<sup>[11]</sup>

The purpose of the current study was to present the clinical and demographic profile of Fuchs' endothelial dystrophy at a large multi-tiered ophthalmology network in India using electronic medical record-driven analytics.

## Methods

**Study Design, Period, Location and Approval:** This cross-sectional, observational, hospital-based study included all patients presenting between August 2010 and December 2021

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to a multi-tiered ophthalmology network located in India.<sup>[12]</sup> The patient or the parents or guardians of the patient filled out a standard consent form for electronic data privacy at the time of registration. None of the identifiable parameters of the patient were used for analysis of the data. The clinical data of each patient who underwent a comprehensive ophthalmic examination was entered into a browser-based electronic medical records system (eyeSmart EMR) by uniformly trained ophthalmic personnel and supervised by an ophthalmologist using a standardized template.<sup>[13]</sup> The study adhered to the Declaration of Helsinki and was approved by the Institutional Ethics Committee (LEC 04-19-027).

**Cases:** A total of 3,082,727 new patients presented to the tertiary and secondary centers of the multi-tiered ophthalmology network during the study period. The eyeSmart EMR was screened for patients with a documented ocular diagnosis of Fuchs' endothelial dystrophy in one or both eyes. The diagnosis of FECD was made based on typical clinical features such as guttae in the central cornea, thickening of the Descemet membrane, pigments on the endothelial surface, with or without subepithelial changes, along with specular microscopy wherever applicable. Histology of the Descemet membrane showing excrescences or guttae was corroborative with the clinical diagnosis in those eyes that underwent keratoplasty. Figs. 1(a-d) and 2(a-f) show the representative photographs of some patients diagnosed with FECD. A total of 2570 patient records were identified using this search strategy and were labelled as cases. A total of 5140 eyes diagnosed with

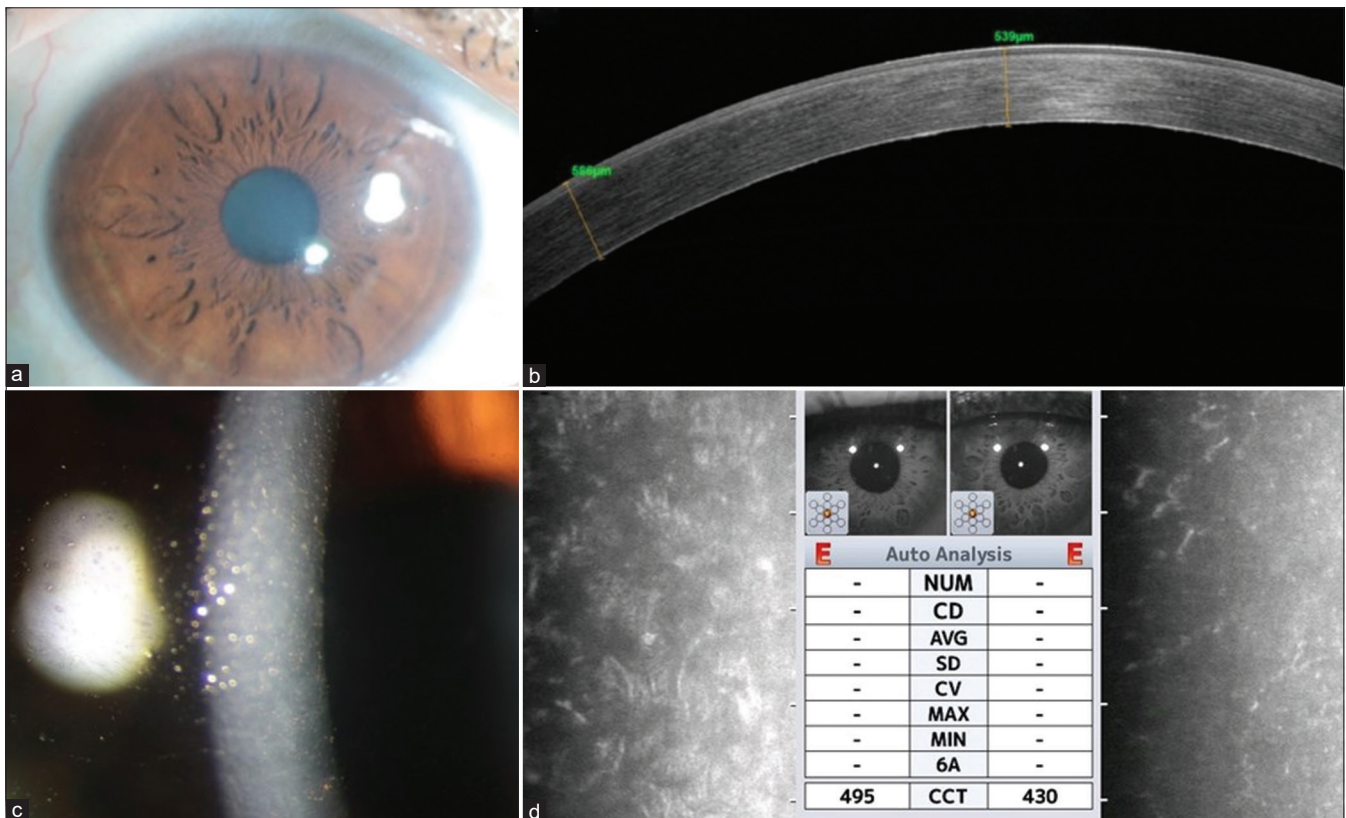
Fuchs' endothelial dystrophy in the above patients were further analyzed for clinical information.

**Data Retrieval and Processing:** The data of 2570 patients included in this study were retrieved from the electronic medical record database and segregated into a Microsoft Excel sheet. The columns included the data on patient demographics, clinical presentation, ocular diagnosis and treatment information and were exported for analysis. The Excel sheet with the required data was then used for analysis using the appropriate statistical software. Standardized definitions were used for occupation and socioeconomic status.<sup>[13]</sup> The visual acuity was classified according to the World Health Organization (WHO) guidelines.<sup>[14]</sup>

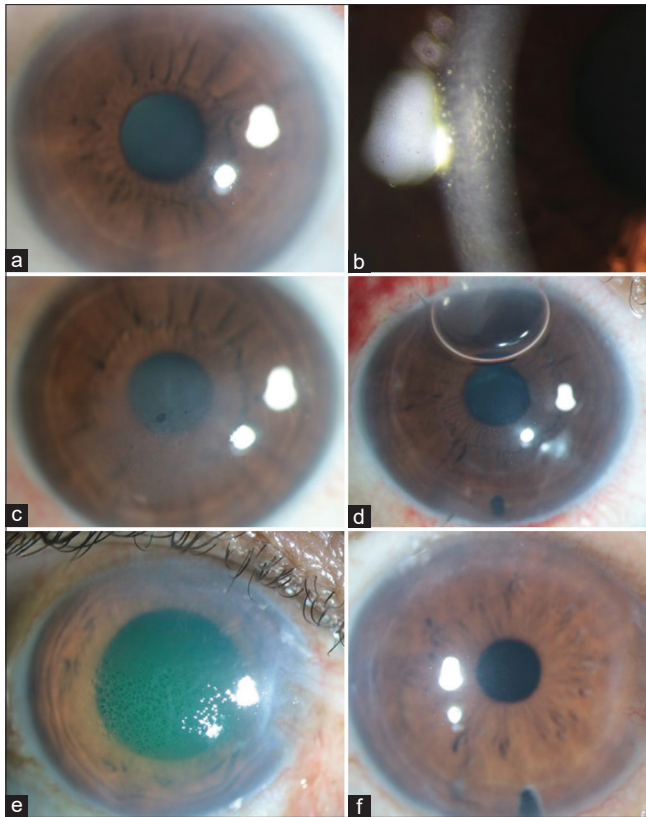
**Statistical Analysis:** Descriptive statistics using mean  $\pm$  standard deviation (SD) and median with inter-quartile range (IQR) were used to elucidate the demographic data. All tables for age, gender, visual acuity and clinical features were drawn by using Microsoft Excel (Microsoft Corporation 2018, Redmond, USA). Chi-squared test (StataCorp. 2015, Stata Statistical Software: Release 14, College Station, TX: StataCorp LP) was used for univariate analysis to detect significant differences in the distribution of demographic features between patients with FECD and the overall population.

## Results

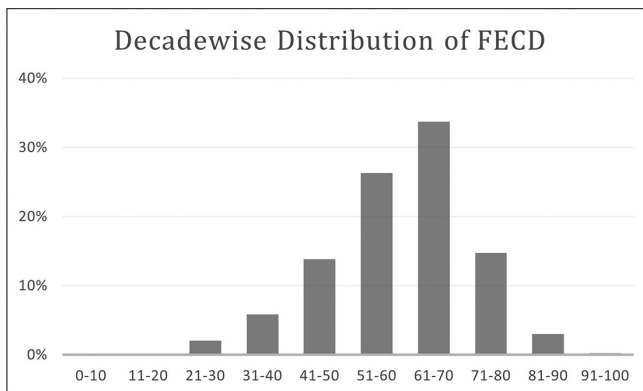
**Prevalence:** Of the 3,082,727 new patients who presented across the eye care network during the study period, 2570 patients



**Figure 1:** (a) Slit-lamp photograph of a 50-year-old female showing clear and compact cornea, with a BCVA of 20/30. (b) The high-resolution anterior segment optical coherence tomography shows a mild thickening of the Descemet membrane. (c) High magnification slit-lamp biomicroscopy view of the central cornea showing confluent guttae. (d) Specular microscopy in both the eyes of this patient had non-analyzable images due to the confluent nature of guttae



**Figure 2:** (a) Slit-lamp photograph of a 54-year-old female with clear and compact cornea on diffuse illumination, and (b) guttae on specular reflection of the central cornea. (c) Slit-lamp photograph of a 33-year-old (early-onset) female with FECD who presented with blurred vision, showed corneal edema involving the central visual axis and (d) underwent Descemet membrane endothelial keratoplasty with clear lens preservation. (e and f) Slit-lamp photograph of a 65-year-old male who developed corneal edema three years after cataract surgery and underwent Descemet membrane endothelial keratoplasty



**Figure 3:** Decade-wise distribution of patients with Fuchs' endothelial dystrophy

were diagnosed with FECD in at least one eye, translating into a prevalence rate of 0.08% (95%CI:±0.0008%) or 834/million patients seen in the clinics.

**Age:** The mean age of the patients was  $59.54 \pm 12.63$  years while the median age was 61 (IQR: 52–68) years. The most common age group of the patients was distributed

between 61 and 70 years ( $n = 867$ ; 33.74%) followed by 51 and 60 years ( $n = 676$ ; 26.3%). The distribution of patients in each age-decade is presented in Fig. 3. A comparison of clinical parameters in those who were under 40 years versus over 40 years is described in Table 1.

**Sex:** There were 886 male (34.47%) and 1684 female (65.53%) patients. The overall distribution of FECD was significantly greater in females (0.12%; 1684/1,423,295) when compared to males (0.05%; 886/1,659,432) and was statistically significant ( $P \leq 0.00001$ ). Among the patients diagnosed with FECD, the mean and median age were  $60.53 \pm 13.29$  and 63 (IQR: 53–69) years for men and  $59.01 \pm 12.2$  and 60 (IQR: 51–67) years for women, respectively. The overall mode was 66 years and 69 years in men and 66 years in women.

**Urban–Rural Distribution:** Of the 2570 patients with FECD, 1236 (48.09%) were from an urban locality, 752 (29.26%) were from a rural locality and 582 (22.65%) patients presented from the metropolitan region. The overall prevalence of FECD in the metropolitan community (0.16%; 582/358,434) was higher when compared to the urban (0.09%; 1236/1,341,267) or rural (0.05%; 752/1,383,026) community and was statistically significant ( $P \leq 0.00001$ ).

**Socio-economic status:** Of the 2570 patients with FECD, there were 230 patients (8.95%) from the lower socioeconomic class, 1860 (72.37%) from the lower-middle class, 293 (11.4%) from the upper-middle class and 187 (7.28%) from the upper class. The overall prevalence of FECD was significantly higher in the higher socioeconomic strata (0.1%; 2340/2,363,156) as compared to the lower socioeconomic strata (0.03%; 230/719,571) but was statistically significant ( $P \leq 0.00001$ ).

**Occupation:** Of the 2570 patients with FECD, 1263 (49.14%) were homemakers; 597 (23.23%) were professionals; 403 (15.68%) were retired individuals; 86 (3.35%) were agricultural workers; 75 (2.92%) were manual laborers; 14 (0.54%) were students and in the remaining 132 patients (5.14%), the occupational category was not available or applicable. The overall prevalence of FECD in retired individuals (0.4%, 403/99,637) was significantly higher ( $P < 0.00001$ ) in comparison to other professions.

**Presenting Visual Acuity:** In the 5140 eyes, 3074 eyes (59.81%) had mild or no visual impairment ( $< 20/70$ ), 781 eyes (15.19%) had moderate visual impairment ( $> 20/70$  to  $20/200$ ), 172 eyes (3.35%) had severe visual impairment ( $> 20/200$  to  $20/400$ ), 549 eyes (10.68%) had blindness ( $> 20/400$  to  $20/1200$ ), 71 eyes (1.38%) had blindness ( $> 20/1200$  to PL), 18 eyes (0.35%) had blindness (NLP), and in 475 eyes (9.24%), the visual acuity was undetermined or unspecified. The average logMAR was  $0.61 \pm 0.81$  at presentation. Family history was documented in 33 patients (1.28%).

**Corneal Findings:** Among the 5140 eyes, guttae was seen in 3939 eyes (76.63%), corneal scar in 1182 (23%), stromal edema in 1117 (21.73%), endothelial folds in 607 (11.81%), epithelial bullae in 548 (10.66%), epithelial microcysts in 207 (4.03%), corneal vascularization in 207 (4.03%) and sub-epithelial fibrosis in 90 (1.75%) eyes.

**Intraocular Pressure:** Among the 5140 eyes, 0–9 mmHg of intraocular pressure was seen in 148 eyes (2.88%), 10–21 mmHg in 4699 eyes (91.42%),  $> 21$  mmHg in 72 eyes (1.4%) and deferred in 221 eyes (4.3%).

**Table 1: Comparison of patients with age <40 years versus and >40 years with FECD**

Parameter	<40 years	%	>40 years	%	P
Total Patients	209	8.13%	2361	91.87%	NA
Sex					
Male	77	36.84%	809	34.27%	0.60
Female	132	63.16%	1552	65.73%	0.73
Age (in years)					
Average Age	33.18	5.86	61.87	10.18	NA
0-10	1	0.48%	NA	NA	NA
11-20	5	2.39%	NA	NA	NA
21-30	53	25.36%	NA	NA	NA
31-40	150	71.77%	NA	NA	NA
41-50	NA	NA	356	15.08%	NA
51-60	NA	NA	676	28.63%	NA
61-70	NA	NA	867	36.72%	NA
71-80	NA	NA	379	16.05%	NA
81-90	NA	NA	77	3.26%	NA
91-100	NA	NA	6	0.25%	NA
Socioeconomic status					
Lower	19	9.09%	211	8.94%	0.95
Lower-Middle	168	80.38%	1692	71.66%	0.29
Upper-Middle	13	6.22%	280	11.86%	0.03
Upper	9	4.31%	178	7.54%	0.10
Visual acuity					
Mild or No Visual Impairment 0	312	74.64%	2762	58.49%	0.002
Moderate Visual Impairment 1	37	8.85%	744	15.76%	0.001
Severe Visual Impairment 2	4	0.96%	168	3.56%	0.006
Blindness 3	15	3.59%	534	11.31%	<0.00001
Blindness 4	2	0.48%	69	1.46%	0.10
Blindness 5	0	0.00%	18	0.38%	NA
Undetermined or Unspecified	48	11.48%	427	9.04%	0.14
Ocular Comorbidities					
Cataract	38	9.09%	2394	50.70%	<0.00001
Glaucoma	6	1.44%	271	5.74%	0.0003
AMD	0	0.00%	27	0.57%	NA
BSK	0	0.00%	2	0.04%	NA
Vascular Occlusions	0	0.00%	14	0.30%	NA
Clinical Features					
Guttae	353	84.45%	3586	75.94%	0.16
Stromal Scar	84	20.10%	1098	23.25%	0.24
Stromal Edema	64	15.31%	1053	22.30%	0.006
Descemet Membrane Folds	24	5.74%	583	12.35%	0.0003
Epithelial Bullae	41	9.81%	507	10.74%	0.60
Epithelial Microcysts	10	2.39%	197	4.17%	0.09
Vascularization	8	1.91%	199	4.21%	0.03
Sub-Epithelial Fibrosis	16	3.83%	74	1.57%	0.001
Intraocular Pressure					
0-9 mmHg	4	0.96%	144	3.05%	0.02
10-21 mmHg	353	84.45%	4346	92.04%	0.25
>21 mmHg	1	0.24%	71	1.50%	0.04
Defer	60	14.35%	161	3.41%	<0.00001
Surgical Interventions					

Contd...

**Table 1: Contd...**

Parameter	<40 years	%	>40 years	%	P
Cataract	21	5.02%	1005	21.28%	<0.00001
DSEK	19	4.55%	522	11.05%	0.0001
DMEK	18	4.31%	252	5.34%	0.39
Penetrating Keratoplasty	4	0.96%	49	1.04%	0.88
Glaucoma	3	0.72%	18	0.38%	0.30
Others	8	1.91%	60	1.27%	0.28
ASP	0	0.00%	6	0.13%	NA
Endothelial Keratoplasty	37	8.85%	774	16.39%	0.0004
Cataract + Keratoplasty	11	2.63%	477	10.10%	<0.00001

**Ocular Comorbidities:** Among the 5140 eyes, an associated ocular comorbidity of cataract was seen in 2432 eyes (47.32%), glaucoma in 277 (5.39%), age-related macular degeneration in 27 (0.53%), vascular occlusions in 14 (0.27%) eyes and band-shaped keratopathy in 2 (0.04%) eyes.

**Surgical Treatment:** Among the 5140 patients, surgical intervention of endothelial keratoplasty (EK) was performed in 811 eyes (15.78%), and a combined procedure of cataract surgery and keratoplasty was performed in 488 eyes (9.49%). Of the total EKs, Descemet's stripping endothelial keratoplasty (DSEK) was performed in 541 eyes (10.53%) and Descemet membrane endothelial keratoplasty (DMEK) was performed in 270 eyes (5.25%). There were 1026 eyes (19.96%) that underwent cataract surgery, of which 49 (10%) required an endothelial keratoplasty at an average interval of  $361 \pm 288$  days. The detailed table describing the surgical interventions and the visual acuity is detailed in Table 2. The average follow-up of the patients was  $361 \pm 579$  days with an average of  $4 \pm 6$  visits.

## Discussion

This study sought to describe the clinical profile and demographic distribution of Fuchs' endothelial corneal dystrophy (FECD) in a large cohort of patients presenting to a multi-tiered hospital network in India using electronic medical records-driven big data analytics. The primary purpose of the study was to determine the relative proportion and demographic profile of the FECD in the clinical care setup. The overall prevalence of FECD was 0.08% in patients who presented between 2018 and 2021 (four-year period).

The clinical diagnosis of FECD is based on guttae seen on slit-lamp biomicroscopy. The nature and extent of guttae that occur in FECD is varied and the impact of guttae on vision and their correlation with visual acuity is complex.<sup>[15]</sup> Additionally, the severity of FECD disease and the progression of the condition to a stage of clinical corneal edema can vary. Many patients with FECD may not have visual complaints and are either diagnosed with the condition incidentally in the clinics or when the visual acuity is affected at a later age coinciding with cataract development. In a study by Barrera-Sanchez M *et al.*<sup>[16]</sup> on 102 eyes of 51 Mexican-mestizo population, a majority of eyes (57.8%) with FECD were asymptomatic and keratoplasty was required in 17.6% of eyes. In our study, we found that the disease caused mild or no visual impairment in half (59.81%) of the affected eyes and only over a tenth (16.81%) of the eyes required a keratoplasty.

The disease is known to be commoner in females. Except for a few,<sup>[17]</sup> most studies have reported a male/female ratio of 2.5:1 to 3.5:1.<sup>[17,18]</sup> A similar observation was noted in this study where female preponderance was seen in 65.53%. In comparison to nationwide epidemiological study in Taiwanese population,<sup>[17]</sup> which identified low socioeconomic status as a risk factor for FECD, our study found a significantly higher prevalence in higher socioeconomic status. We did not see any association with ocular allergic conditions that was found in the same study.

FECD is known to occur in two forms: early-onset and late-onset variants.<sup>[19,20]</sup> The distinction of the two forms is not always possible as genetic testing is not a routine practice. Also, the exact age of onset of the disease and evolution of the condition in the longitudinal follow-up is not possible. Hence, we compared the clinical and demographic parameters in younger versus older patients taking 40 years as an age divide [Table 1]. The females were more commonly affected in both < 40 and > 40 years (63.16% versus 65.73%, respectively), although the difference was not statistically significant. Visual acuity impairment was notably more significant in those older than 40 years, due to associated cataract in the above 40 years age group. Corneal edema, Descemet membrane folds, vascularization and subepithelial fibrosis were significantly more in those above 40 years. The need for EK was significantly higher in the > 40 years age group.

Cataract surgery alone is considered in FECD when patient has no clinical symptoms suggestive of endothelial compromise and cornea is compact without evident anterior stromal changes and Descemet membrane thickening.<sup>[21]</sup> However, the risk of FECD disease progression exists post cataract surgery. We found that of the 1026 eyes that underwent cataract surgery, 49 (10%) needed EK later.

This is the largest series of FECD patients in an Indian population. The study lends insight into the sociodemographics, clinical presentation, visual impairment, and treatment aspects of FECD in a large cohort of patients. FECD can vary from mild, asymptomatic to a severe form with corneal edema. Furthermore, the condition has ethnic differences in the mode of presentation. Our study found that 16.81% of FECD required keratoplasty. Of those patients with FECD that had cataract surgery alone, ~10% eventually needed keratoplasty after a few years. This information is important and can be used in clinical practice for prognostication and decision-making on cataract surgery alone in those with guttae but no clinically apparent

**Table 2: Surgical distribution of patients with Fuchs endothelial dystrophy and visual acuity**

Surgical Intervention	Eyes	%	Pre-Op*	Post-Op*
Cataract	1026	19.96%	0.88±0.84	0.44±0.62
Endothelial	811	15.78%	1.01±0.85	0.68±0.74
Keratoplasty	541	10.53%	1.11±0.89	0.79±0.78
DSEK	270	5.25%	0.78±0.71	0.46±0.58
DMEK				
Penetrating Keratoplasty	53	1.03%	1.98±1.08	1.18±0.85
Cataract + Keratoplasty	488	9.49%	0.98±0.87	0.60±0.70
Glaucoma	21	0.41%	0.47±0.33	0.73±0.82
Others	68	1.32%	0.96±1.07	0.82±0.95
ASP	6	0.12%	2.45±1.29	2.50±0.87

\*Visual acuity in LogMAR

corneal edema. The strength of the study is the complete utilization of the digital data entry in a structured manner by trained ophthalmologists and automated extraction methods for data analysis. Our study does have few limitations due to its hospital-based method of selection of subjects, which may have introduced a certain level of ascertainment bias. Another limitation to the study is that the diagnosis of FECD was based on clinical criteria and not on genetic screening methods recommended in the IC3D classification.

In conclusion, this study aimed to describe the epidemiology and clinical presentation of Fuchs' endothelial dystrophy in three million new patients presenting to a multi-tiered ophthalmology hospital network in India. The findings show that Fuchs' endothelial dystrophy more commonly affects females presenting during the seventh decade of life. Most of the eyes had mild or no visual impairment and endothelial keratoplasty was warranted in a tenth of the affected eyes.

#### Author contributions

The corresponding author states that authorship credit of this manuscript was based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. All listed authors met conditions 1, 2, and 3. All persons designated as authors qualify for authorship, and all those who qualify are listed. Each author has participated sufficiently in the work to take public responsibility for appropriate portions of the content.

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Nil.

#### Conflicts of interest

There are no conflicts of interest.

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