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Although the focus of Asian Journal of Ophthalmology mainly was on glaucoma with close ties to the South-East Asian Glaucoma Interest Group (SEAGIG) in the past, the journal now focuses on the entire spectrum of Ophthalmology. This resulted in collaboration with the Asia Pacific Ophthalmic Trauma Society (APOTS).

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Managing suspected temporal arteritis without a temporal artery biopsy

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We would like to report 2 cases of suspected temporal arteritis which were managed without routine temporal artery biopsy.

Temporal Arteritis, otherwise known as Giant Cell Arteritis or Cranial Arteritis, is a large vessel vasculitis that primarily affects the cranial arteries and commonly presents with symptoms such as headache, fever, malaise, jaw claudication, polymyalgia rheumatica, or visual symptoms (diplopia, blurred vision, amaurosis fugax or visual loss). Because delays in treatment can result in blindness, timely corticosteroid treatment is paramount. However, the risk of significant corticosteroid side effects necessitates an accurate diagnosis. The gold standard diagnostic test for temporal arteritis, the temporal artery biopsy (TAB), is known to be highly specific for a diagnosis of temporal arteritis, but is only positive in up to 82% of temporal arteritis cases (with sensitivities reported as low as 20%.¹ This figure has been shown to decrease even further (12%) following corticosteroid therapy.

Although it is a relatively minor procedure, the risks of TAB are not trivial and include facial nerve injury, infection, haemorrhage, incisional alopecia, scar widening and foreign body reaction to entrapped hairs.² Furthermore, the need for theatre time and skilled personnel in a procedure with a significant number of false negatives makes TAB questionable.

Case 1

An 83 year-old male presented with diplopia due to right esotropia of about 25 prism dioptres. He had no headache, jaw claudication, or other visual symptoms such as reduced visual acuity or visual field defect. Ocular movements were consistent with a right cranial nerve VI paresis. Visual acuity was 6/9 in each eye.

He had a history of glaucoma and was not on any medication after previous Selective Laser Trabeculoplasty. He also had a history of atrial fibrillation, hyperlipidaemia, hypertension, sleep apnoea, coronary artery stent and bilateral cataract surgery. Carotid artery duplex did not show any haemodynamically significant stenosis.

His erythrocyte sedimentation rate (ESR) on presentation was 90 and C-reactive protein (CRP) was 50.5. His clinical presentation suggested a moderate likelihood of Temporal Arteritis. Temporal artery biopsy was discussed and the patient elected to not have it as he had an upper respiratory tract infection and wished to avoid

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any invasive procedures. A trial of Prednisone was commenced at 75mg daily. ESR after 17 days was 4 and CRP was 0.4. When he was seen on day 25, his diplopia had resolved, hence the prednisone dose was reduced. However, on day 35, ESR had increased to 93 and CRP was 14.6. Hence, prednisone was recommenced at 75mg daily. He had no further symptoms.

In this case, the diplopia consistent with right cranial nerve VI paresis may be due to ischaemic necrosis of the extraocular muscles or ischaemia of the nerve itself³.

Although the symptoms and biochemical changes were highly suggestive of Temporal Arteritis, a rheumatological review was sought to exclude other possible causes of this clinical picture. The patient was subsequently commenced on a tapering corticosteroid regimen. To date, no other causes have been found for this patient's elevated ESR and CRP.

Case 2

An 82 year-old man presented with blurred vision of his right eye and eye ache/headache. His past medical history included diabetes, hypertension and hyperlipidaemia.

On examination, vision of the right eye was 6/18; in the left eye 6/9. Humphrey visual field test showed a small inferior paracentral visual field defect (Figure 1). ESR at presentation was 5, CRP 0.4. Fundus examination showed swelling and haemorrhage of the superior optic disc, likely consistent with AION (Figures 2 and 3). Temporal artery biopsy was suggested, but the patient declined as it was "not going to make him better". He was commenced on prednisone 50mg daily.

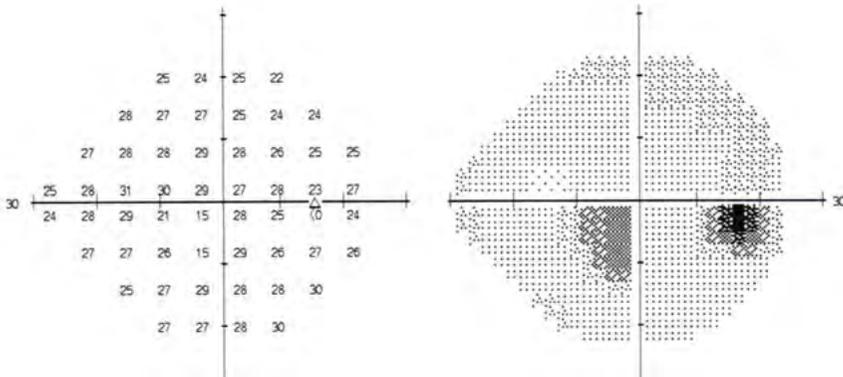


Figure 1: Right eye Humphrey Visual Field Test at presentation

On Day 22 his right eye vision had improved to 6/12, he no longer complained of visual loss in the right eye, and visual field testing was normal. The optic disc haemorrhage appeared to be resolving. On Day 43 the haemorrhage had resolved. He had no headaches or visual symptoms. Vision was 6/12 in both eyes due to cataracts. Prednisone was reduced and eventually ceased. After 4 months, visual

acuity was 6/9 part in each eye, there was no disc haemorrhage, cup/disc ratios were 0.4 in the right eye and 0.5 in the left eye. Humphrey visual field test was normal.

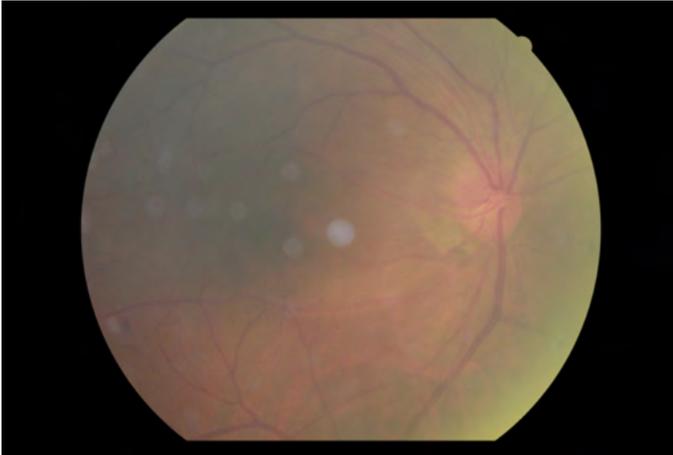


Figure 2: Day 1 – swelling of superior optic disc.

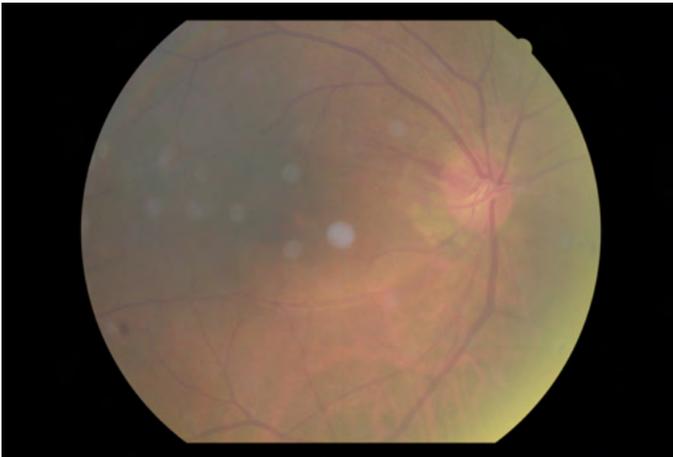


Figure 3: Day 3 – optic disc margin haemorrhage.

This patient had right AION. This may be arteritic or non-arteritic. The dramatic improvement with prednisone suggests an arteritic process, although ESR and CRP were normal. Carotid dopplers showed no haemodynamically significant stenosis in the carotid arteries.

Corticosteroids would have been commenced regardless of the aetiology of AION.⁴

Discussion

Even if TAB were performed, a high index of suspicion would have led to commencement of corticosteroid therapy regardless of the biopsy result. The only drawback

in not conducting a TAB appears to be the lack of additional conclusive evidence supporting a diagnosis of temporal arteritis.

The two cases presented here illustrate how a trial of corticosteroid therapy is a reasonable and practical option for patients who prefer not to have a TAB. The strength and duration of corticosteroid therapy will still be guided by clinical progress as well as biochemical markers such as ESR and CRP. As the result of TAB does not significantly alter the management of suspected TA, perhaps it is time to review and form a consensus on the indications for temporal artery biopsy for suspected temporal arteritis.

References

1. Davies C, Frost B, Eshan O, McLain A, Shandall A. Temporal artery biopsy... Who needs one? *Postgrad Med J*. 2006;82(969):476–8.
2. Winkler A, Wudel J. Medscape - Temporal Artery Biopsy 2012 [9th September 2012]; Available from: <http://emedicine.medscape.com/article/1520091-overview#a17>.
3. Barricks M, Traviesa D, Glaser J, Levy I. Ophthalmoplegia in cranial arteritis. *Brain*. 1977;100(2):209-21.
4. Hayreh SS. Vascular disorders in neuro-ophthalmology. *Current Opinion in Neurology* February. 2011;24(1):6-11.

Femtosecond laser-assisted anterior lamellar keratoplasty (FSALK) versus microkeratome-assisted anterior lamellar keratoplasty (MALK) for the treatment of anterior corneal dystrophy.

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Abstract

Purpose: To compare the visual outcome of femtosecond laser-assisted anterior keratoplasty (FSALK) and microkeratome-assisted anterior lamellar keratoplasty (MALK) in anterior corneal dystrophy.

Methods: retrospective comparative chart review of 7 eyes that underwent FSALK and 7 eyes that underwent MALK. The primary outcome was the visual outcome of both procedures. The secondary outcome was the recurrence of the corneal dystrophies.

Results: Mean follow-up time was 30 ± 14 (7-51) months for the FSALK group and 127 ± 28 (80-127) months for the MALK group. In the FSALK group the preoperative best spectacle-corrected visual acuity (BSCVA) improved from 20/63 to 20/25 at 36 months. In the MALK group there was 1 eye with documented BSCVA over 36 months follow-up; it improved from 20/160 preoperatively to 20/32 at 36 months. Uncorrected visual acuity (UCVA) at 36 months improved from 20/100 preoperatively to 20/63 in the FSALK group and from 20/200 preoperatively to 20/63 in the MALK group. Five eyes with Reis-Bucklers showed a clinical recurrence at a mean of 142 ± 13 (125-152) months. Two eyes with granular dystrophy showed a clinical recurrence at 23 and 80 months of follow-up. One eye in the MALK group had epithelial ingrowth. One eye in the FSALK group with compromised ocular surface due to 2 previous penetrating keratoplasty, suffered bacterial keratitis that ended up with corneal scarring.

Conclusion: Both procedures improve visual outcome for anterior corneal dystrophy. FSALK has theoretical advantages over MALK; however, larger prospective studies are needed to prove this.

Keywords: Corneal dystrophy; femtosecond; microkeratome; anterior keratoplasty.

Introduction

Corneal dystrophies are defined as primary, inherited, bilateral disorders of the cornea affecting transparency, leading to varying degrees of visual disturbances.¹ Clinically, corneal dystrophies are said to be of early onset, axially symmetric, slowly progressive or stationary, free from vascularization, and not associated with other systemic conditions. Known exceptions are the unilateral presentation in Meesman

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and lattice dystrophy, vascularization in gelatinous drop-like keratopathy, and delayed presentations in the case of Fuchs Dystrophy.^{1,2}

Corneal dystrophies with primarily anterior involvement such as Bowman's layer, granular, and lattice dystrophies share similar clinical presentation with visual disturbances. The recurrent erosions are mainly associated with Bowman's layer dystrophy in the early years of life and to a less extent with the granular and lattice dystrophies.³

When diminished vision is such that intervention is required, lamellar keratoplasty (LK) and penetrating keratoplasty (PK) have been the procedures of choice.^{4,5} LK has many advantages over PK. Avoiding full thickness trephination minimizes potential intraoperative complications and allows faster visual recovery. Maintaining the host endothelium prevents endothelium rejection. Furthermore, LK allows multiple lamellar (anterior, stromal, endothelial) corneal transplantations to be performed from one donor cornea.⁶

The major limitation of LK is the technical challenge of performing manual dissections: the resulting stromal irregularities between the donor and the recipient interface could affect visual outcome. Improvements in automated microkeratomes and artificial anterior chambers minimize these difficulties.⁷ Use of the femtosecond (FS) laser optimizes the LK technique by augmenting the precision of lamellar dissections and side cuts. The smooth interface should in theory improve visual results.^{8,9} Femtosecond-assisted lamellar keratoplasty (FSALK) also has less chance of causing a microperforation, and allows visualization of the cornea during lamellar dissection that allows the procedure to be stopped if technical incidents occur.

We designed this retrospective study to compare the visual outcome of microkeratome-assisted anterior lamellar keratoplasty (MALK) and FSALK in the treatment of anterior corneal dystrophy. Secondary outcomes were corneal dystrophy recurrence, graft survival and complications associated with these procedures.

Materials and Methods

This was a retrospective study of the patients with anterior corneal dystrophy that were followed up between July 1997 and July 2010. The study was conducted at a corneal tertiary referral center in the south west of England and it was approved by the institutional review board and followed the tenets of the Helsinki declaration.

We retrieved the notes of 133 patients with the term "corneal hereditary dystrophy" using the hospital based audit department coding system. Only the notes of patients with the diagnosis of RB, granular, and lattice dystrophies were reviewed.

Inclusion and Exclusion criteria

Inclusion criteria were corneal dystrophies involving Bowman's layer (Reis-Bucklers) or the anterior cornea (lattice and granular), and eyes that had either MALK or FSALK as a surgical treatment for the corneal dystrophy. Exclusion criteria were follow-up of less than 6 months, eyes that did not have FSALK or MALK as part of the corneal dystrophy management, extensive missing data, and patients with any

other condition that could significantly affect their visual acuity (e.g. advanced age related macula degeneration, severe glaucoma).

Surgical technique

All procedures were performed under topical anesthesia. Anterior segment ocular coherence tomography (OCT: Visante OCT, model 1000, Carl Zeiss Meditec, Dublin, CA, USA) was used in all patients to assess the depth of the corneal pathology that needed to be removed. To prepare the donor corneal graft, corneoscleral donor tissue was mounted on an artificial anterior chamber maintainer. In the MALK cohort, a 200 μ m Hansatome plate (Bausch and Lomb, Irvine, CA) was used to form the donor and the recipient corneal graft. Graft diameter was the same in both donor and host, ranging from 8 to 9 mm. Only in one patient with high myopia (-9D) secondary to a previous penetrating keratoplasty (PK), the donor lenticule was made smaller by 1 mm (donor: 8mm, host: 9mm) to overcome the steep cornea. In the FSALK cohort, the donor graft was created using an Intralase FS laser (AMO, Santa Ana, CA, USA). The software of the laser was regularly updated throughout the duration of the study (frequency range: 15 to 60 kilohertz). The following settings were used for the donor graft: donor lenticule thickness, 145 to 230 μ m. Lenticule thickness was adjusted in relation to the depth of the lesions as shown on the OCT findings.

Donor lenticule diameter ranged from 7.8 to 8.7 mm. Lamellar cut energy was 0.95 to 1.2 microjoules; side cut energy was 1 to 1.3 microjoules; side cut angle 70° in 6 eyes and 120° in one eye; lamellar spot and line separation 6 to 12.

Only 1 donor lenticule had the same thickness as the recipient corneal lenticule. Additional thickness was added to the donor lenticule to compensate for edema in 6 grafts, ranging from 20 to 30 μ m.

A recipient corneal lenticule was created using similar FS laser settings, however; the host lenticule was set to be smaller in diameter than the donor lenticule (range 0 to 0.2 mm). The host lenticule was then removed and replaced by the donor lenticule. Five patients in the FSALK cohort and 1 patient in the MALK cohort had additional phototherapeutic keratectomy (PTK) surgery on the stromal bed of the host cornea before applying the donor lenticule to improve the visual outcome or to remove residual corneal pathology. Laser ablation was performed using the Technolas 217C (Bausch & Lomb, Rochester, NY). The ablation was performed with 6 to 7 mm diameter without a transition zone and with a depth of an average of 70 μ m (range: 50 to 100).

All grafts in the FSALK cohort were sutured in place with 10/0 nylon; 6 grafts had interrupted sutures, and 1 graft had overlay sutures. In the MALK cohort 3 grafts were placed without suturing, 3 with interrupted sutures, and one graft with overlay sutures. Patients were placed on topical antibiotic and steroid drops for 1 month; the topical steroids were tapered over a few months.

The removal of sutures was carried out at 6 ± 5 (1-15) weeks for the FSALK group and at 5 ± 0.5 (4-5) weeks for the MALK group.

Data collection

Baseline demographic information was collected for each eye of the patient recruited in the study. Numerical results were presented as mean±standard deviation, range. Surgical procedures that were performed before the study period were determined. The first anterior lamellar keratoplasty (ALK) during the study period was referred to as the index surgery. The following refractive data were collected before the index surgery and at 1,3,6, 12, 24±3, 36±3 months postoperatively: uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction spherical equivalent (MRSE), mean K readings. These refractive outcomes were also documented 3 months after any further refractive surgery. Graft failure was diagnosed as a stromal opacification due to recurrence of the original disease or as a result of microbial keratitis, causing a loss of 2 lines or more of BSCVA.

Simple recurrence of the dystrophy was documented as the heterogeneous haze of the cornea, with distinct patterns resembling the original dystrophy with or without subjective symptoms. Stromal haze related to the excimer laser was usually homogeneous over the entire ablation zone in most eyes and was also less dense than a recurrence. The complications related to the index surgery were noted. Stromal rejection was diagnosed if there were sub-Bowman infiltrates on the donor tissues, which resemble that of adenoviral infection without conjunctival injection and with positive response to topical corticosteroid therapy (Figure 1).

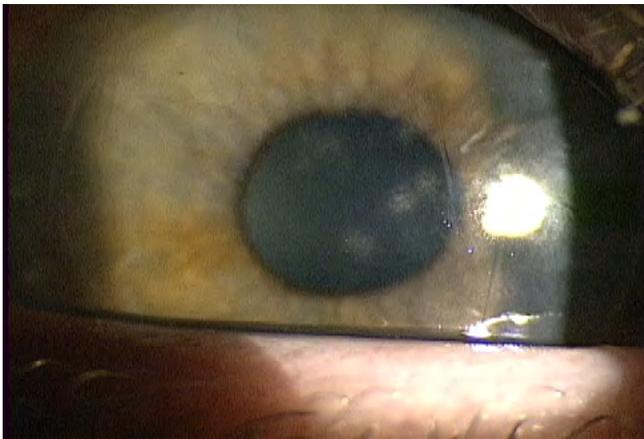


Fig. 1. One eye in the Femtosecond laser-assisted anterior lamellar keratoplasty cohort showing signs of corneal graft stromal rejection with sub-Bowman's infiltrate in the donor tissue, which resemble that of adenoviral epidemic keratoconjunctivitis.

Statistical analysis

We used XLSTAT 2010 Mac software (Addinsoft, NY, USA) for statistical analysis. Visual acuity data converted to the logarithm of the minimum angle of resolution (logMAR). The following conversion to logMAR was used for vision worse than 20/400: counting fingers = 1.6, hand movements = 2.0.¹⁰ The distribution of data was examined using the Shapiro-Wilk test of normality. Friedman test was applied to the comparisons of refractive outcome between different moments for each

group. For quantitative variables, the student t-test or the Mann-Whitney *U* tests were used, as appropriate, to compare the outcome between groups. Student t-test was used for paired comparison. To evaluate differences in proportions, the Chi-square test or Fisher exact test was employed as needed. Kaplan-Meier survival analysis was performed to estimate the probability of corneal dystrophies recurrence. Log-rank test was used to compare the recurrence rate between the different corneal dystrophy. *P* values less than 0.05 were considered significant.

The safety index is determined as the mean postoperative BSCVA/mean preoperative BSCVA (in Decimal fraction). Efficacy index is determined as the mean postoperative UCVA/mean preoperative BSCVA (in Decimal fraction).

Results

We reviewed the notes of 25 eyes with anterior corneal dystrophy. We excluded the eyes that had no surgical intervention as part of their management (3 eyes), or that had surgical intervention not in the inclusion criteria (penetrating keratoplasty, deep anterior lamellar keratoplasty, phototherapeutic keratoplasty) (6 eyes), or with extensive missing data (2 eyes). Fourteen eyes (7 FSALK, 7 MALK) from 9 patients were included for further analysis: some patients had a FSALK for one eye and MALK for the other eye, hence the comparison between both groups was carried out per eye rather than per patient. The baseline factors including age, BSCVA, UCVA, topographic keratometry, and MRSE did not differ significantly between groups. Despite the similarity between the 2 groups, the MALK group had significantly longer follow up (Table 1). Most of the corneal dystrophies were RB in both groups (5/7 in the FSALK and 6/7 in the MALK group) and the rest were granular dystrophy with no case of lattice dystrophy included.

Three eyes in the FSALK group had previous PK and the rest (4/7 eyes) were naïve. In the MALK group 5/7 eyes were naïve and one eye had previous PK then DALK, one eye had 1 PK, and one eye had PK then laser-assisted in situ keratomileusis (LASIK) then trabeculectomy.

Table 1: Patients characteristics and baseline data for microkeratome-assisted anterior lamellar keratoplasty (MALK) and femtosecond-assisted anterior lamellar keratoplasty (FSALK) groups.

Patients characteristics and baseline data	FSALK No	MALK No	P value*
Number of eyes	7	7	
Laterality			
Right	4	4	1.0
Left	3	3	
Corneal disease			0.51
Reis-Bucklers dystrophy	5	6	
Granular dystrophy	2	1	
Lattice dystrophy	0	0	
Age at the index surgery†	37±7(25-45)	41±13(25-62)	0.59
Age at the first surgery†	32±11(17-45)	35±12(25-52)	0.59
Age at the start of the recurrent erosion syndrome†	11±11(3-25)	4±2(3-7)	0.24
Age at the start of visual deterioration†	21±3(16-26)	20±5(16-29)	0.81
BSCVA before surgery†	0.3±0.1(0.1-0.6)	0.4±0.3(0.2-0.9)	0.4
UCVA before surgery†	0.7±0.2(0.5-1.0)	0.8±0.4(0.4-1.3)	0.3
Topographic K reading†	45±4.2(40.5-52.25)	43.0±2.5(40.5-49)	0.43
MRSE†	-3±3.3(-10 to 0.3)	-1±(-7 to 1.5)	0.35
Follow-up in months	30±14(7-51)	127±28(80-127)	<0.0001
Family history			
Yes	5	6	
No	1	1	
Unknown	1	0	
Indication for index surgery			
Visual			
Recurrent erosion syndrome	7 0	7 0	
<p>BSCVA: best spectacle corrected visual acuity, UCVA: uncorrected visual acuity, MRSE: manifest refraction spherical equivalent. *P values were obtained by Chi-square or Fisher's exact test as needed for qualitative variables, and by student t-test or Mann-Whitney U test for quantitative variables. † mean ± standard deviation (range)</p>			

None of the eyes in the FSALK group had further surgery. In the MALK group one naïve eye had lifting of the graft with washing of the stromal bed to clean epithelial ingrowth, 4 days after the index surgery, then the graft had to be replaced 14 months later due to the epithelial ingrowth. The eye underwent LASIK surgery followed by photorefractive keratectomy (PTK), 38 and 155 months respectively, after the index surgery to correct residual refractive error. One eye had PK one year following the index surgery to correct high astigmatism related to a previous PK that was performed before the index surgery, and another eye had two PTK procedures following the index surgery to correct high astigmatism related to a previous PK.

BSCVA progression over 36 months:

The patients in the FSALK group started to show improvement in the mean BSCVA at 6 months and achieved their best BSCVA at 24 months (Figure 2), however; this improvement did not reach significant difference at any point comparing to preoperative BSCVA.

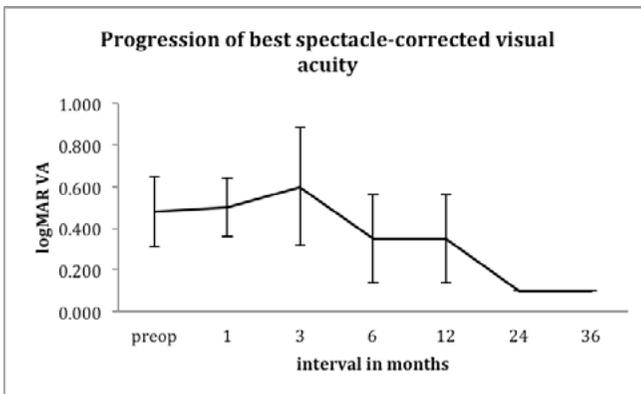


Fig. 2. Progression of best spectacle-corrected visual acuity postoperatively in the FSALK group. The improvement was evident at 6 months postoperatively with maximum improvement at 24 months postoperatively ($P=0.138$, Friedman's test).

In the FSALK group 4/7 eyes had BSCVA < 20/40 (mean 20/63, range 20/32 to 20/80) preoperatively and the BSCVA improved to a mean of 20/40 at 6 and 12 months, and 20/25 at 24 and 36 months of follow-up. At 12 months of follow-up 3/5 eyes gained an average of 2.5 ± 1 (2-4) lines of BSCVA, 1 eye neither gained nor lost preoperative lines, one eye lost 2 lines of preoperative BSCVA. At 24 months of follow-up, 3/3 eyes gained an average of 2.5 ± 2.2 (0.5-5) lines of BSCVA. At 36 months of follow-up, 3/4 eyes gained an average of 3 ± 1.7 (2-5) lines, 1 eye lost 4 lines of preoperative BSCVA due to graft failure as a result of bacterial keratitis secondary to chronic epithelial defect.

In the MALK group, 2/7 eyes had BSCVA < 20/40 preoperatively, 1 eye had BSCVA of 20/32 and another eye with BSCVA of 20/40, and 3 eyes had no preoperative BSCVA documentation. Over 36 months of follow-up, 1 eye only had documentation of BSCVA and it showed improvement of 6, 7, and 7 lines at 12, 24, and 36 months respectively. BSCVA improved from 20/160 preoperatively to 20/63 at 6 months, 20/40 at 12 months, and 20/32 at 24 and 36 months of follow-up.

UCVA progression over 36 months:

Both groups showed improvement of UCVA over the 36 months follow-up, without significant difference between the two groups.

In the FSALK group, the mean UCVA started to improve at 6 months postoperatively with maximum improvement at 24 months postoperatively ($P=0.053$) (Figure 3).

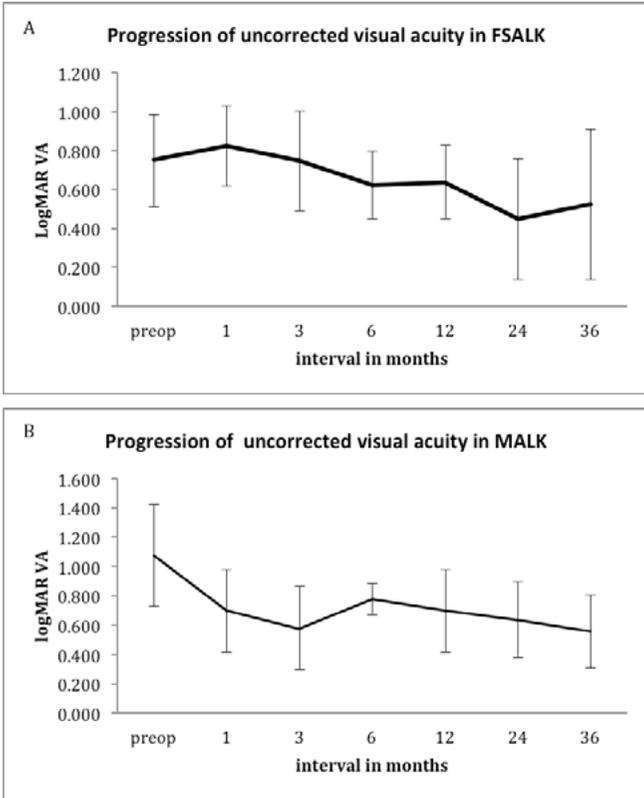


Fig. 3. Progression of uncorrected visual acuity postoperatively in the FSALK and MALK.
A. In the FSALK the improvement was evident at 6 months with maximum improvement at 24 months postoperatively ($P=0.053$ Student t test).
B. In the MALK group the improvement was evident at 1 month with maximum improvement at 3 and 36 months postoperatively ($P=0.004$, Friedman’s test).

All the eyes in the FSALK group had preoperative UCVA of <20/40 (mean 20/100, range 20/63 to 20/200). The UCVA improved to a mean of 20/80 at 6 and 12 months, 20/50 at 24 months, and 20/63 at 36 months of follow-up. At 12 months of follow-up, 3/6 eyes gained an average of 4.5 ± 1.5 (3-6) lines of UCVA, 2 eyes lost 2 lines of preoperative UCVA and 1 eye neither gained nor lost preoperative lines. At 24 months of follow-up, 5/6 eyes gained an average of 3.2 ± 1.9 (2-6) lines of UCVA and 1 eye lost 1 line of preoperative UCVA. At 36 months of follow-up, 4/4 eyes gained an average of 2 ± 1.4 (1-4) lines.

In the MALK group, the UCVA showed significant improvement at 24 and 36 months postoperatively ($P=0.03$ and $P=0.02$ respectively). The improvement in UCVA was evident at the first month postoperatively and it reached the maximum at 3 and then at 36 months postoperatively (Figure 3).

In the MALK group, all the eyes had preoperative UCVA $<20/40$ (mean 20/200, range 20/63 to counting fingers). Postoperatively, the UCVA improved to a mean of 20/125 at 6 months, 20/100 at 12 months, 20/80 at 24 months, and 20/63 at 36 months of follow-up. At 12 months of follow-up, 5/7 eyes gained an average of 3.8 ± 1.7 (1-5) lines of UCVA, 1 eye lost 3 lines due to epithelium ingrowth and another eye lost 1 lines of preoperative UCVA due to high astigmatism related to previous PK that was done before the index surgery. At 24 months of follow-up, 5/5 eyes gained an average of 4.4 ± 2.3 (1-6) lines. At 36 months of follow-up, 5/5 eyes gained an average of 5 ± 3 (1-7) lines.

The safety index for FSALK group was 1.25, 1.57, and 1.25 at 12, 24, and 36 month postoperatively. The efficacy index for FSALK was 0.62, 0.8, and 0.8 at 12, 24, and 36 months postoperatively.

We could not assess the safety/efficacy index for the MALK group, as there was only 1 eye with postoperative documented BSCVA.

Manifest refraction spherical equivalent (MRSE)

FSALK group showed emmetropic shift towards slight myopia over 36 months postoperatively (Figure 5), although, the shift was not statistically significant ($P=0.42$ for FSALK, Friedman's test).

We did not assess the MRSE value for MALK group, as there was only one eye in the MALK group that had BSCVA documentation over 36 months.

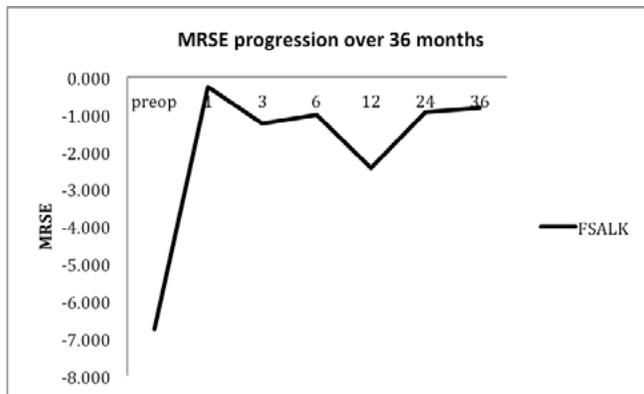


Fig 5. Progression of manifest refraction spherical equivalent for FSALK group with emmetropic effect towards slight myopia.

Keratometric reading

In the FSALK group there was a reduction of the mean keratometric (K) reading postoperatively, and this reduction was mainly in the eyes ($n=5$) that had associated PTK treatment (Figure 6), as for the other 2 eyes that had mainly FSALK, there was no change in the mean K reading ($K=49.5$ preoperatively vs $K=49.5$ at 36 months postoperatively).

In the MALK group, K reading showed no statistical difference comparing to preoperative measures at any point.

Evidence of recurrence was noted in 1 eye in the FSALK group and 6 eyes in the MALK group; however, the MALK group had a significantly longer follow-up period (127 vs. 30 months). We have added both groups for dystrophy recurrence assessment, as the surgical procedure in both groups should not affect the recurrence interval. Over a mean follow-up of 79 ± 54 months, Kaplan-Meier survival analysis shows a mean time to recurrence of 72 ± 11 (95% CI 50.1-94.6) months (Figure 7). One eye in the FSALK group with granular dystrophy had a recurrence at 23 months. In the MALK group 6/7 eyes had recurrences of the dystrophy: 5 of them were RB dystrophy with a mean recurrence interval at 142 ± 13 (125-152) months. The one eye that was treated with MALK procedure for granular dystrophy had a recurrence at 80 months. Granular dystrophy had a significantly shorter time to recurrence compared with RB dystrophy ($P=0.016$. Log-rank test).

One graft in the FSALK failed at 32 months postoperatively due to bacterial keratitis resulting from persistent epithelial defect. One graft in the MALK group failed due to epithelial ingrowth.

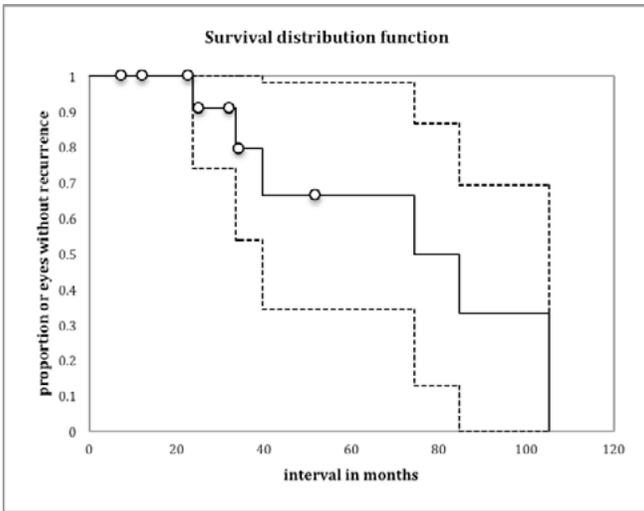


Fig. 7. Kaplan-Meier survival analysis for the recurrence of the corneal dystrophy postoperatively. Mean recurrence time was 72 ± 11 (95% CI 50.1-94.6). The percentages of clear cornea after 2, 3, and 4 years following the index surgery, were 90%, 79%, and 66% respectively. Solid line is the mean data and the dotted lines are the upper and lower bound of the 95% confidence interval.

Complications:

One naïve eye that underwent a MALK had epithelium ingrowth under the corneal graft, which was treated with lifting of the graft and washing the stromal bed 7 days postoperatively. As the epithelium cells were still evident under the graft, it was replaced 14 months later with another anterior lamellar graft, resulting in UCVA of 20/50. This eye had further LASIK surgery 24 months later with resulting UCVA of 20/20. One MALK eye experienced stromal rejection 7 months postoperatively and it was controlled with topical steroid treatment. One MALK eye experienced slipped lenticule 1 week postoperatively, as the graft was fashioned to be 1 mm smaller than the host bed to overcome high myopia (-7D) that resulted from a previous PK surgery. The lenticule was sutured back to the host and the sutures were removed after 1 month.

One eye that had 2 PK for RB dystrophy, followed by FSALK, suffered bacterial keratitis 32 months after the FSALK resulting in corneal scar and graft failure.

Discussion

Anterior lamellar keratoplasty is considered to be convenient for anterior corneal dystrophy and less invasive than the full thickness graft used as the conventional treatment. The fact that the dystrophy recurs after corneal grafting multiplies the risks of the full thickness graft.^{11,12}

Invasive procedures can cause an acceleration of the dystrophy. However, once a cornea has been grafted, the dystrophy often appears to be more anteriorly situated¹³; hence, the ALK is a suitable procedure for both naïve eyes and eyes that have undergone previous surgery.

Anterior lamellar keratoplasty was performed in the early days with microkeratome (MALK). When the femtosecond technology became available, we started to use FSALK, and it is now the main treatment for anterior corneal dystrophy in our practice. We found no significant difference in visual outcome between the MALK and FSALK groups; however, there is growing evidence of the high precision and reproducibility of femtosecond laser-assisted lamellar corneal incisions.¹⁴ This focusable infrared laser is capable of cutting corneal tissue of various depths with minimal corneal collateral tissue damage measured to be in the order of 1 μm . These capabilities are also less hampered by optical haze, compared with other lasers using visible wavelengths, and thus more capable of cutting opacified corneas.¹⁵

Evidence of dystrophy recurrence was noted in 50% of cornea over a mean follow-up of 79 ± 54 months, with an average recurrence at 72 months. The granular dystrophy recurrence was noted to recur relatively early, with 2 cases recurring at 23 and 80 months. RB dystrophy, on the other hand, showed signs of recurrence late, at 142 ± 13 (125-152) months. Dinh *et al.* noted the recurrence of RB dystrophy in 10 of 17 PTK procedures after a mean of 12.3 (range 5.6-19.8) months; in 7 of 13 PTKs performed for granular dystrophy after a mean of 31.9 (range 22.5-48.4) months; and in 1 of 7 eyes with lattice dystrophy, 5.4 months post PTK.¹⁶ They suggested that the granular dystrophy was the slowest to recur. However, in our series, granular dystrophy recurred significantly earlier than RB. In the case series of Lyons *et al.*, consisting of 20 PK and 11 lamellar keratoplasties for granular dystrophy, the granular dystrophy recurrence was observed in almost all grafts within a range of 13 to 36 months after surgery, and the recurrence-free interval was not longer after PK than lamellar grafts.¹⁷

The FSALK group showed a trend of BSCVA improvement over 36 months of follow-up; however, it was not statistically significant. The BSCVA improved from 20/63 preoperatively to 20/40 at 6 months and reached maximum at 24 months postoperatively with BSCVA of 20/25. Abou Shousha M *et al.* describe a series of FSALK patients, who achieved their best BSCVA at 8 months.¹⁸ This series consisted of naïve eyes (no previous corneal surgery) with mainly anterior corneal scar as an indication for surgery, and the surgery was sutureless. In comparison, our FSALK cohort comprised 3 eyes that had previous PK surgery and 4 naïve eyes. Furthermore,

all the eyes in our FSALK series had sutures that were removed at an average of 6 weeks postoperatively, which would explain the slower visual rehabilitation.

In the MALK group we employed a microkeratome head with 200 μ m slit to cut the recipient and donor head. Published data have shown that all microkeratome heads cut somewhat more thickly than expected¹⁹, mainly because corneal tissue is squeezed through the slit while being dissected, and that could explain the less need for the associated PTK to remove residual host stromal opacity (5 eye in FSALK vs 1 eye in MALK) and the earlier improvement with UCVA in the MALK group compared to the FSALK group. The UCVA in the MALK group showed an improvement from 1 month postoperatively and it was significant at 2 and 3 years postoperatively ($P=0.03$, 0.02 respectively). In the series of 10 eyes with microkeratome-associated ALK reported by Hashemi and Dadgostar, the UCVA improved from a logMAR of 1.20 preoperatively to 0.88 at the last mean follow-up of 10 months (comparable to Snellen VA of 20/300 preoperatively to 20/160 postoperatively).²⁰ Our MALK cohort showed comparable UCVA improvement from 20/200 preoperatively to 20/100 at 12 months and 20/63 at 36 months of follow-up.

There was a significant flattening of the corneal surface in the FSALK group postoperatively and this could be related to the fact that 5/7 eyes in this group underwent further PTK procedure along with the ALK to overcome the high K reading and also to remove any residual stromal opacities.

One eye in the MALK developed epithelial ingrowth that needed the graft to be replaced eventually. Previous reports have suggested that patients undergoing primary LASIK with a microkeratome, rather than a femtosecond laser, are at higher risk for developing epithelial ingrowth²¹, and we postulated that the same could happen in the case of ALK, as the corneal wound morphology in microkeratome keratoplasty, allowing inoculation of epithelium in the stromal interface, apply in both LASIK and ALK. The one graft failure in the FSALK group was due to bacterial keratitis in an already compromised ocular surface due to 2 previous PK surgeries.

In comparison to PK, both MALK and FSALK are non-penetrating procedures that are relatively safe, as most of the complications that could be encountered postoperatively, are dealt with medical approaches as in the case of donor rejection that was controlled with only topical steroid drops. Even when we had to replace the graft, like in the case of epithelial ingrowth or recurrence of the corneal dystrophy, we could achieve that with another lamellar graft, hence avoiding all complications associated with full thickness graft (eg; endothelial rejection, expulsive suprachoroidal hemorrhage).¹² It is difficult to compare the visual outcome of our ALK to PK as almost half of the eyes that underwent ALK (6/14 eyes) already had a previous PK. However, Major astigmatism ($\geq 5D$) that has significant effect over visual outcome, could be induced in 18% of eyes with PK.¹² In comparison, both of our groups, when there was no associated PTK procedure, no change in the K reading was encountered postoperatively.

Limitation of the retrospective design of the study is that it did not yield information about exactly when the dystrophy recurred (either symptomatically or morphologically), as examination at the study visit only revealed morphological

signs of recurrence at the point in time. It would be appropriate to identify onset of clinical recurrence when the patients report the symptoms, and with assessing the morphological recurrence at a regular interval in a longitudinal study design. In addition, the small number of eyes in this study makes it difficult to draw any definitive conclusions from our final results. Furthermore, the follow-up time in the 2 groups differed by approximately 97 months, in large part as a function of when FSALK was introduced at the authors' institution. However, this concern was addressed with cumulative incidence function analysis and by adding both groups in the analysis of the corneal dystrophy recurrence.

Both eyes of the bilateral cases were included in the study to increase the sample size. This could contribute to a bias because of a correlation effect in statistical analyses.

Our study showed a reduction in the K reading in FSALK with PTK group and a stable K reading in the MALK and the FSALK without PTK groups postoperatively, however; the surgically induced astigmatic correction was not calculated in our study and it would be beneficial to include it in future studies, especially in eyes with high preoperative astigmatism.

The anterior segment OCT was used to assess the depth of the lesion and hence the depth of lamellar dissection, however; in the case of FSALK, there was residual stromal opacity in some cases that needed further photoablation. In future studies, the extent of lamellar dissection below the predetermined OCT depth of corneal opacity should be documented and to be set at an extra depth to remove all anterior stromal opacity.

This case series represent a heterogeneous group of eyes with varying corneal dystrophies, surgical histories, and surgical techniques, which makes meaningful analysis of outcomes difficult. These drawbacks could be avoided in future studies with naïve eyes to better assess the visual results of anterior lamellar keratoplasty.

Despite these limitations, our series suggest that both FSALK and MALK procedures improve visual outcome, with negligible operative risk and postoperative graft rejection. There is still no consensus regarding the recurrence rate of anterior corneal dystrophies.

We described in our series the surgical treatment of anterior corneal dystrophy using FSALK, which provides many advantages over the conventional PK and MALK^{22,23}, and, in theory, the smooth interface made by the FALK should provide better visual quality. However, a prospective study design with larger patient samples is required before establishing a definitive role for FSALK in the treatment of anterior corneal stromal dystrophy.

References

1. Bron AJ. Genetics of corneal dystrophies. *Cornea* 2000;19:699-711.
2. Klintworth GK. Advances in the molecular genetics of corneal dystrophies. *Am J Ophthalmol* 1999;128:747-754.
3. Waring III GO, Rodrigues MM, Laibson PR. Corneal Dystrophies. 1. Dystrophies of the epithelium, Bowman's layer and stroma. *Surv Ophthalmol* 1978;23:71-122.

4. Pandrowala H, Bansal A, Vemuganti GK, *et al.* Frequency, distribution, and outcome of keratoplasty of corneal dystrophies at a tertiary eye care center in south India. *Cornea* 2004;23:541-456.
5. Kawashima M, Kawakita T, Den S, *et al.* Comparison of deep lamellar keratoplasty and penetrating keratoplasty for lattice and macular corneal dystrophies. *Am J Ophthalmol* 2006; 142:304-309.
6. Vajpayee RB, Sharma N, Jhanji V, *et al.* One donor cornea for 3 recipients: a new concept for corneal transplantation surgery. *Arch Ophthalmol* 2007;125:552-554.
7. Vajpayee RB, Vasudendra N, Titiyal JS, *et al.* Automated lamellar therapeutic keratoplasty (ALTK) in the treatment of anterior to mid-stromal corneal pathologies. *Act Ophthalmol Scand* 2006;84:771-773.
8. Hoffart L, Proust H, Matonti F, *et al.* Keratoplastis lamellaire anterieure assistee par laser femtoseconde. *J Fr Ophthalmol* 2007;30:689-694
9. Kezirian GM, Stonecipher KG. Comparison of the intralase femtosecond laser and mechanical keratomes for laser in situ keratomileusis. *J Cataract Refract Surg* 2004;30:804-811.
10. Schulze-Bonell K, Feltgen N, Burau H, *et al.* Visual acuities "hand Motion" and "counting Fingers" can be quantified with the freiburg visual acuity test. *Invest Ophthalmol Vis Sci* 2006;47:1236-1240.
11. Caldwell DR. Postoperative recurrence of Reis Bucklers' corneal Dystrophy. *Am J Ophthalmol* 1978;85:567-568.
12. Williams KA, Muehlberg SM, Wing SJ, *et al.*, on behalf of all contributors. The Australian corneal graft registry, 1990-1992 report. *Aust NZ J Ophthalmol* 1993;21:1-48.
13. Dausch D, Landes M, Klein R, *et al.* Phototherapeutic keratectomy in recurrent corneal epithelial erosion. *Refract Corneal Surg* 1993;9:419-424.
14. Medeiros FW, Stapleton WM, Hammel J, *et al.* Wafefront analysis comparison of LASIK outcomes with the femtosecond laser and mechanical microkeratomes. *J Refract Surg* 2007;23:880-887.
15. Mian SI, Soong HK, Patel SV, *et al.* In vivo femtosecond laser-assisted corneal surgery. *Curr Opin Ophthalmol* 2007;18:295-299.
16. Dinh R, Rapuano CJ, Cohen EJ, *et al.* Recurrence of corneal dystrophy after excimer laser phototherapeutic keratectomy. *Ophthalmology* 1999;106:1490-1497.
17. Lyons CJ, McCartney AD, Kirkness CM, *et al.* Granular corneal dystrophy. Visual results and pattern of recurrence after lamellar or penetrating keratoplasty. *Ophthalmology* 1994;101:1812-1817.
18. Abou Shousha M, Yoo SH, Kymionis GD, *et al.* Long-term results of femtosecond Laser-Assisted sutureless anterior lamellar keratoplasty. *Ophthalmology* 2011;118:315-323.
19. Springs CL, Joseph MA, Odom JV, *et al.* Predictability of donor lamellar graft diameter and thickness in an artificial anterior chamber system. *Cornea* 2002;21:696-699.
20. Hashemi H, Dadgostar A. Automated lamellar therapeutic keratoplasty with fibrin adhesive in the treatment of anterior corneal opacities. *Cornea* 2011;30:655-659.
21. Henry CR, Canto AP, Galor A, *et al.* Epithelial ingrowth after LASIK: clinical characteristics, risk factors, and visual outcomes in patients requiring flap lift. *J Refract Surg* 2012;28:488-492.
22. Hoffart L, Proust H, Matonti F, *et al.* Keratoplastis lamellaire anterieure assistee par laser femtoseconde. *J Fr Ophthalmol* 2007;30:689-694
23. Kezirian GM, Stonecipher KG. Comparison of the intralase femtosecond laser and mechanical keratomes for laser in situ keratomileusis. *J Cataract Refract Surg* 2004;30:804-811.

Pattern ERG as a predictor in ocular hypertensive

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Abstract

Purpose: To report the repeatability of Pattern Electrotretinogram (PERG) and its findings in ocular hypertension (OHT) and normal eyes.

Methods: A cross-sectional study where PERG responses were compared between the study group comprising of 80 eyes of 80 patients with intraocular pressure (IOP) > 21 mmHg and the control group with 80 eyes of 80 normal individuals (IOP ≤ 21 mmHg). The optic disc and the visual fields were normal with a visual acuity of ≥ 0.8 in both groups. PERG was recorded twice for each individual in the control group by a single operator on 2 consecutive days to assess the repeatability.

Results: The mean age in the study and control groups was 50.05 ± 10.03 and 54.8 ± 7.66 years ($p=0.44$) respectively. The mean IOP was 26.55 ± 3.9 mmHg for the study group as opposed to 14.45 ± 2.9 mmHg for the controls ($p<0.001$). The central corneal thickness and the cup-disc ratio was similar between the groups ($p>.05$). The P50-N95 amplitude ($p=0.01$) and the P50 latency ($p<0.001$) was statistically significantly different between both the groups. The intra-class correlation coefficient (ICC) showed poor agreement for all parameters except for N35-P50 0.8 to 16 degree check size amplitude ratio (PERG ratio).

Conclusion: Increase in P50 latency emerges as a new candidate for early glaucoma indicator in addition to reduction in P50-N95 amplitude. PERG parameters suffer from high test-retest variability. Deterioration in PERG recordings should be interpreted with caution. The variability is lesser for the PERG ratio which may be more meaningful while monitoring for change over time.

Keywords: Glaucoma, Ocular Hypertension, Pattern Electrotretinogram, PERG, Repeatability.

Introduction

Ocular hypertension (OHT) is defined as elevated intraocular pressure (IOP) without any glaucomatous visual field defects or optic disc changes. Elevated IOP is a major modifiable risk factor for glaucoma. Glaucoma is characterized by chronic retinal ganglion cell (RGC) loss. A sizable fraction (25%–35%) of RGCs is already lost when visual field defects become apparent in automated visual field testing.¹

The retinal response to pattern stimulation, the pattern electroretinogram (PERG), predominantly reflects RGC activity.²⁻⁶ Reduction in the PERG amplitude had been reported in patients with OHT.⁷⁻¹⁴ Knowledge of the variability of PERG is extremely important especially when we want to judge its deterioration. This variability has been studied before.^{6,15-16} PERG testing is essentially objective and theoretically more repeatable than subjective testing because it is minimally affected by motor response and learning effects. The aim of our study is to find whether a difference in the PERG recordings between OHT and normal patients exists and also to ascertain

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that this difference is outside the test-retest variability of the PERG machine. To the best of our knowledge both these things together have not been done before.

Materials and methods

This was a cross sectional study and an informed consent was obtained from all subjects. For the study group, we included 80 eyes of 80 consecutive patients diagnosed as ocular hypertension (OHT) from October 2012 to April 2013. Inclusion criteria were: IOP (measured with Goldmann applanation tonometry at two different times) >21 mmHg, open angles on 4-mirror gonioscopy without indentation, normal and reliable visual field test results as described below and normal optic disc at clinical examination and on photographs. Our control group also consisted of 80 eyes of 80 random patients recruited during the same period with similar age range. The inclusion criteria were similar except for the IOP which was ≤ 21 mmHg. Exclusion criteria were visual acuity <0.8 , spherical correction outside $\pm 5.0D$, cylinder correction outside $\pm 3.0D$, secondary glaucoma (e.g., pigment dispersion or pseudoexfoliation syndrome), and diabetic retinopathy or any other condition capable of causing visual field loss or optic disc damage. Pressure lowering treatment was not an exclusion criterion. Treatment was actively recommended only to patients with IOP >28 mmHg which is the standard practice at our institute.

A complete ophthalmic examination including best corrected visual acuity, IOP measurement with Goldmann applanation tonometer, pachymetry, gonioscopy, indirect ophthalmoscopy, slit lamp biomicroscopy, visual fields with Humphrey Visual Field Analyzer II (Carl Zeiss Meditec, Dublin, CA) and PERG recording was done. The PERG was recorded twice for each individual in the control group by a single operator (JJ) on 2 consecutive days at approximately the same time of the day in order to find out the test-retest variability. All other examinations were performed by one of the two authors (PRD and JJ).

Visual field

All the tested eyes had a pupil diameter ≥ 3 mm and corrective lenses were placed on the lens holder to evaluate the visual field. Visual field examination was performed using 24-2 SITA Standard strategy by HVF analyzer. Only patients with reliable visual fields (false positive, false negative $<33\%$, fixation losses $<20\%$) were included. A normal visual field was defined by the absence of each of these responses: a cluster of 3 points lower than $p < 5\%$ or a cluster of 2 points lower than $p < 1\%$ on a pattern deviation plot, or PSD with $p < 5\%$. All visual field examinations were done not more than 1 month prior to doing the first PERG.

PERG Recording

For PERG recording, we followed the International Society for Clinical Electrophysiology of Vision (ISCEV) standard guidelines.¹⁷ RETIport 21 (version: 19-99-04-7.2E; Roland Consult, Brandenburg, Germany) machine was used to perform the PERG under photopic condition at a distance of 1 meter from the 19" monitor. The stimulus

was a high contrast (99%) black and white stimulus with a mean luminance of 80 cd/m^2 and a chequerboard size of 0.8° or 16° . The stimulus frequency was 15.005 Hz, cycle time of 0.6664 seconds and a plot time of 400 milliseconds. Responses from both eyes were measured simultaneously. Before testing, the electrode impedance was monitored automatically and an on-screen indicator signaled an acceptable impedance ($<10 \text{ k}\Omega$). Retinal potentials were recorded with corneal DTL electrodes and gold cup electrodes at the outer ipsilateral canthus served as reference.¹⁸ Signals were amplified and filtered with a 2-channel bio signal amplifier. During each examination, two PERG measurements were taken, and the mean of the traces was used to yield the raw PERG amplitude. The glaucoma program calculated the PERG ratio (response amplitude to 0.8° checks divided by the response amplitude to 16° checks). The spectrum in the software was used for getting the P50-N95 marker. Fig. 1 and Fig. 2 show the representative PERG traces of normal control and ocular hypertensive eyes respectively.

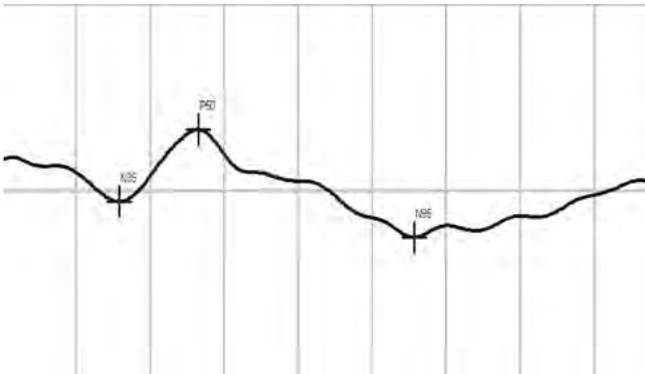


Fig. 1. A representative Pattern Electroretinogram recording of a normal control eye.

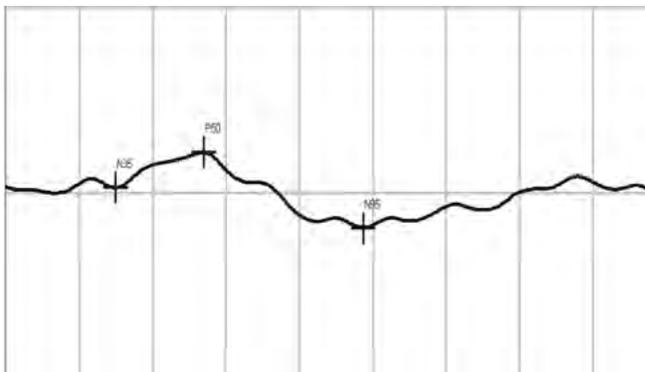


Fig. 2. A representative Pattern Electroretinogram recording of an eye with ocular hypertension.

Statistical Analysis

Descriptive and inferential statistics were performed using STATA version 12 for Windows (StataCorp LP, Texas). Mann-Whitney U test for continuous variables and Chi Square test for categorical variables was used to compare the baseline

parameters between the groups. The 95% confidence limits of variability for all PERG parameters were calculated from the Bland-Altman plot (BAP) method. The intra-class correlation coefficients (ICC) were also calculated for all PERG parameters.

RESULTS

Forty eyes of 80 patients were diagnosed during the study period with ocular hypertension. Twelve patients had a positive family history of glaucoma (1st degree relative having glaucoma). Twenty-two of the 80 eyes were on topical medication. Sixteen of these were on a β-blocker and the remaining 6 on a prostaglandin analogue. Another 80 eyes of 80 patients were recruited as controls during the same period. Table 1 shows the demographic data and PERG parameters of the included patients.

Table 1. Baseline demographics and pattern electroretinogram readings

Parameters	OHT	Controls	p value
Age (years)	50.05±10.03	54.8±7.66	0.44
Male:Female	11:9	8:12	0.34
IOP (mmHg)	26.55±3.9	14.45±2.9	<0.001
CCT	543.95±36.86	530.5±48.9	0.15
CDR	0.45±0.15	0.35±0.07	<0.001
P50-N95amp	2.5±0.82	3.55±1.29	<0.001
P50-N95lat	94.5±9.02	94.8±9.39	0.82
N35lat16	23.62±4.6	22.15±3.4	0.15
N35lat0.8	34.5±3	34.4±8.07	0.17
P50lat16	51.9±5.74	43.35±2.53	<0.001
P50lat0.8	57.7±8.2	52.05±8.52	<0.001
N35-P50amp16	4.7±1.8	5.93±2.87	0.03
N35-P50amp0.8	2.04±1.27	2.2±1.53	0.99
PERG ratio (right)	0.365±0.089	0.284±0.183	0.04
PERG ratio(left)	0.397±0.278	0.49±0.175	0.08

*P50-N95amp =P50-N95 amplitude

†P50-N95lat = P50-N95 latency

‡N35lat16 = N35 latency with 16 degree check size

§N35lat0.8 = N35 latency with 0.8 degree check size

||P50lat16 = P50 latency with 16 degree check size

**P50lat0.8 =P50 latency with 0.8 degree check size

††N35-P50lat16 =N35-P50 latency with 16 degree check size

‡‡N35-P50lat0.8 =N35-P50 latency with 16 degree check size

The age, gender and central corneal thickness was similar between the two groups. The mean IOP in the OHT group was 26.55 ± 3.9 mmHg compared to 14.45 ± 2.9 mmHg in the control group ($p < 0.001$). The P50-N95 latency (P50-N95lat), N35 latency with 16 degree check size (N35lat16), N35 latency with 0.8 degree check size (N35lat0.8) and the N35-P50 amplitude with 0.8 degree check size (N35-P50amp0.8) was similar in both the groups ($p > 0.05$). The P50-N95 amplitude (P50-N95amp), P50 latency with both 16 and 0.8 degree check size (P50lat16, P50lat0.8) and N35-P50 amplitude with 16 degree check size (N35-P50amp16) was statistically significantly different between the groups ($p < 0.05$) as shown in **table 1**.

Table 2 shows the 95% confidence limits of variability for all PERG parameters calculated from Bland-Altman plots. Only P50 latency with 16 degree check size (P50lat16) had a difference beyond the 95% confidence limits between the two groups. Table 2 also shows the ICC for the PERG parameters. The ICC showed poor agreement for all the PERG parameters except for the PERG 0.8 to 16 degree check size amplitude ratio for the right [PERG ratio (right)] and the left eye [PERG ratio (left)] which was 0.69 and 0.68 respectively.

Table 2. Test-retest variability for pattern electroretinogram parameters

Parameters	Control 1 st Run	Control 2 nd Run	p value	Bland-Altman 95% limit	ICC
P50-N95amp	3.55 ± 1.29	3.25 ± 1.22	0.33	-2.835, 3.437	0.184
P50-N95lat	94.8 ± 9.39	90.85 ± 10	0.13	-19.603, 27.503	0.222
N35lat16	22.15 ± 3.4	22.95 ± 3.88	0.24	-11.692, 10.092	-0.16
N35lat0.8	34.4 ± 8.07	29.35 ± 5.75	0.002	-14.081, 24.181	0.024
P50lat16	43.35 ± 2.53	43.8 ± 3.03	0.34	-8.047, 7.047	-0.181
P50lat0.8	52.05 ± 8.52	50.5 ± 9.95	0.16	-24.227, 27.327	-0.009
N35-P50amp16	5.93 ± 2.87	5.87 ± 1.8	0.32	-6.708, 6.826	-0.039
N35-P50amp0.8	2.2 ± 1.53	2.7 ± 2.2	0.35	-5.271, 4.257	0.166
PERG ratio (right)	0.284 ± 0.183	0.466 ± 0.314	0.06	-0.841, 0.713	0.692
PERG ratio (left)	0.49 ± 0.175	0.425 ± 0.255	0.08	-0.553, 0.667	0.676

*P50-N95amp = P50-N95 amplitude

†P50-N95lat = P50-N95 latency

‡N35lat16 = N35 latency with 16 degree check size

§N35lat0.8 = N35 latency with 0.8 degree check size

||P50lat16 = P50 latency with 16 degree check size

**P50lat0.8 = P50 latency with 0.8 degree check size

††N35-P50lat16 = N35-P50 latency with 16 degree check size

‡‡N35-P50lat0.8 = N35-P50 latency with 0.8 degree check size

§§ICC = Intra-class correlation coefficient

Discussion

We already know that the conversion rate from untreated OHT to glaucoma is only ~1% per year.¹⁹ Accordingly, most patients with OHT never have glaucoma and thus do not need treatment. Hence, a method to identify these high risk patients is essential to avoid over treatment. Wanger *et al.*²⁰ reported a significant reduction in the amplitude of PERG in OHT patients. Weinstein GW *et al.*²¹ found a selective reduction in the second negative wave (N-95) in glaucomatous patients and concluded that this wave (N-95) is related to early optic nerve dysfunction. Arai M *et al.*¹² further strengthened this concept when they showed that decrease in the amplitude of the second negative wave (N-95) is a warning sign of development of glaucoma in ocular hypertensives. In our study also we found that the P50-N95 amplitude was statistically significantly less in the OHT group than the controls. However, the difference was not beyond the 95 % limits of test-retest variability of the machine. The previous studies do not mention the test-retest variability of their machines. In addition, the P50lat16 and the P50lat0.8 was more in the OHT group while the N35-P50amp16 was greater in the normal patients. The P50lat16 was the only PERG parameter which had a between group difference greater than the retest variability. This makes it a possible candidate for early indicator of glaucoma. The ICC for all PERG parameters in our study showed poor to fair agreement except for the PERG ratio. Bowd *et al.*²² in their study demonstrated a within-trial and between trial ICC of 0.85 and 0.88 respectively. However, they did not calculate the ICC for each PERG parameter as we have done in our study. Bach M *et al.*²³ described that an individual with a large 0.8° PERG will also have a large 16° PERG and hence it is useful to compute the PERG ratio to reduce the inter-individual variability. Our study finding is in agreement with this. This low variability for the PERG ratio maybe extremely important while monitoring for change over time. Refractive errors decrease the small check size amplitudes more than large check size amplitudes, mainly due to reduction of the visual acuity.²⁴ In our study, we overcame this shortcoming by including only those patients with a best corrected visual acuity ≥ 0.8 . But, this issue somewhat limits the general applicability of the PERG for early glaucoma detection.

This study has its limitations. We had a relatively small sample size and the PERG measurements were all one time measurements. A better way of doing this study would have been to follow-up all these patients and look for PERG changes over time and amongst those who convert to glaucoma. This would throw light on the predictive accuracy of PERG. This study is currently under way. Another confounder was the fact that treatment of OHT eyes was allowed in our study. Ventura LM *et al.*²⁵ have showed that abnormal PERG recorded in the early stages of glaucoma may often improve after IOP reduction. However, treating eyes with OHT is a real life situation that we encounter very often and hence it was not considered as exclusion criteria. Our current study gives us insight into what PERG parameters would have a low variability which could be used for comparison over time. To the best of our knowledge this is the only study which looks into PERG difference between OHT and normal patients with calculation of the retest variability of the PERG

machine. It is extremely important to find parameters with difference outside this range in order to be sure of a real change over time. The increase in the P50 latency has emerged as a new candidate parameter to check for possible conversion of OHT eyes to glaucoma in future. This needs further confirmation by longitudinal studies with larger sample sizes.

Conclusion

Increase in P50 latency emerges as a new candidate for early glaucoma indicator from our study in addition to reduction in P50-N95 amplitude which is already known. PERG parameters suffer from high test-retest variability and hence deterioration in PERG recordings should be interpreted with caution. The changes in the PERG parameters need to be greater than the inherent variability of the machine. The variability is lesser for the PERG ratio which maybe more meaningful while monitoring for change over time.

References

1. Kerrigan-Baumrind LA, Quigley HA, Pease ME, Kerrigan DF, Mitchell RS. Number of ganglion cells in glaucoma eyes compared with threshold visual field tests in the same persons. *Invest Ophthalmol Vis Sci* 2000;41:741-748.
2. Holder GE. Pattern electroretinography (PERG) and an integrated approach to visual pathway diagnosis. *Prog Retin Eye Res* 2001;20:531-561.
3. Maffei L, Fiorentini A. Electroretinographic responses to alternating gratings before and after section of the optic nerve. *Science* 1981;211:953-954.
4. Zrenner E. Physiological basis of the pattern electroretinogram. *Prog Retin Res* 1989;9:427-464.
5. Ventura LM, Porciatti V. Pattern electroretinogram in glaucoma. *Curr Opin Ophthalmol* 2006;17:196-202.
6. Pfeiffer N, Tillmon B, Bach M. Predictive value of the pattern electroretinogram in high-risk ocular hypertension. *Invest Ophthalmol Vis Sci* 1993;34:1710-1715.
7. Walker WM. Ocular hypertension: Follow-up of 109 cases from 1963 to 1974. *Trans Ophthalmol Soc UK* 1974; 94: 525-534.
8. Porciatti V, Falsini B, Brunori S, Colotto A, Moretti G. Pattern electroretinogram as a function of spatial frequency in ocular hypertension and early glaucoma. *Doc Ophthalmol* 1987;65:349-355.
9. Bach M, Speidel-Fiaux A. Pattern electroretinogram in glaucoma and ocular hypertension. *Doc Ophthalmol* 1989;73:173-181.
10. Parisi V, Manni G, Gandolfi SA, Centofanti M, Colacino G, Bucci MG. Visual function correlates with nerve fiber layer thickness in eyes affected by ocular hypertension. *Invest Ophthalmol Vis Sci* 1999;40:1828-1833.
11. Arai M, Yoshimura N, Sakaue H, Chihara E, Honda Y. A 3-year follow-up study of ocular hypertension by pattern electroretinogram. *Ophthalmologica* 1993;207:187-195.
12. Gonzalvo Ibanez FJ, Fernandez Tirado FJ, Almarcegui Lafita C, Polo Llorens V, Sanchez Perez A, Honrubia Lopez FM. Predictive value of the pattern-electroretinogram in glaucoma (in Spanish). *Arch Soc Esp Oftalmol* 2001;76:485-491.
13. Bayer AU, Maag KP, Erb C. Detection of optic neuropathy in glaucomatous eyes with normal standard visual fields using a test battery of short-wavelength automated perimetry and pattern electroretinography. *Ophthalmology* 2002;109:1350-1361.
14. Ventura LM, Porciatti V, Ishida K, Feuer WJ, Parrish RK 2nd. Pattern electroretinogram abnormality and glaucoma. *Ophthalmology* 2005;112:10-19.
15. Bach M, Hoffmann MB. Update on the pattern electroretinogram in glaucoma. *Optom Vis Sci* 2008;85:386-395.

16. Bach M, Unsoeld AS, Philipppin H, Staubach F, Maier P, Walter HS, Bomer TG, Funk J. Pattern ERG as an early glaucoma indicator in ocular hypertension: a long-term, prospective study. *Invest Ophthalmol Vis Sci* 2006;47:4881-4887.
17. Holder GE, Brigell GM, Hawlina M, Meigen T, Veagan, Bach M. ISCEV standard for clinical pattern electroretinography-2007 update. *Doc Ophthalmol* 2007;114:111-116.
18. Chapter in a book: Bach M, Hoffmann MB. The origin of the pattern electroretinogram (PERG). In: Heckenlively J, Arden G, editors. *Principles and Practice of Clinical Electrophysiology of Vision*. Massachusetts: Cambridge MIT Press; 2006. pp.185-196.
19. Kass MA, Heuer DK, Higginbotham EJ, Johnson CA, Keltner JL, Parrish RK 2nd, Wilson MR, Gordon MO. The Ocular Hypertension Treatment Study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma. *Arch Ophthalmol* 2002;120:701-713; discussion 829-830.
20. Wanger P, Persson HE. Pattern reversal electroretinogram in ocular hypertension. *Doc Ophthalmol* 1983;61:27-31.
21. Weinstein GW, Arden GB, Hitchings RA, Ryan S, Calthorpe CM, Odom JV. The pattern ERG in ocular hypertension and glaucoma. *Arch Ophthalmol* 1988;106(7):923-8.
22. Bowd C, Tafreshi A, Vizzeri G, Zangwill LM, Sample PA, Weinreb RN. Repeatability of pattern electroretinogram measurements using a new paradigm optimized for glaucoma detection. *J Glaucoma* 2009;18(6):437-442.
23. Bach M. Electrophysiological approaches for early detection of glaucoma. (review) *Eur J Ophthalmol* 2001;11(suppl 2):41-49.
24. Bach M, Mathieu M. Different effect of dioptric defocus vs. lightscatter on the pattern electroretinogram (PERG). *Doc Ophthalmol* 2004;108:99-106.
25. Ventura LM, Porciatti V. Restoration of retinal ganglion cell function in early glaucoma after intraocular pressure reduction: a pilot study. *Ophthalmology* 2005;112:20-27.

Soft prosthetic contact lens practice in Indian scenario

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Aim: The aim of this study is to investigate the prescribing trend of prosthetic soft contact lens (PSCL) in a tertiary eye care center in India.

Design: Retrospective.

Methods: The electronic medical records of 223 patients who were prescribed PSCL for various indications for a period of 1 year in a tertiary eye care center were investigated. PSCL were classified to the following types: Type A - black pupil with clear iris, type B - no pupil with tinted iris, type C - clear pupil with tinted iris; and type D - black pupil with tinted iris. Parameters investigated were age, gender, indication for PSCL, prescribed base curve, diameter, type and iris tint of PSCL, number of trials required to achieve desirable cosmesis or fit, duration of use of PSCL and number of PSCLs dispensed from off the shelf.

Result: A total 223 patients were prescribed PSCL for a period of 1 year, of which 221 patients were prescribed PSCL for one eye and only 2 patients for both the eyes. The mean age of the patients was 29.15 years (SD ± 12.65). Majority of the patients were male (64.57%). Type D PSCL was prescribed for 183 eyes (81.33%), type C PSCL for 38 eyes (16.88%) and type A PSCL for only 4 eyes (1.77%).

Among type D PSCL users 81.96% eyes were fitted with various shades of brown colour iris tint. The main categories for prescribing type D soft PSCLs were corneal abnormalities 89.61% (164 eyes). The most common base curves prescribed among type D PSCL users were 8.6 and 8.7 mm and most common diameters prescribed were 13.8 and 14 mm.

The major categories for prescribing type C PSCLs were corneal abnormalities (55.26%; 21 eyes) and pupil or iris abnormalities (34.21%; 13 eyes).

Only four patients (four eyes) were prescribed with type A PSCL and the only reason was leukocoria due to cataract.

In type D PSCL users, 67.21% (123 eyes) were prescribed stock lenses but for type C PSCL users, 84.21% (32 eyes) and for type A 100% (4 eyes) required customization.

Conclusions: Majority of disfigured eyes requiring PSCL are due to corneal abnormality, which can be satisfied with off the shelf PSCL. Sizeable numbers of eyes require customized PSCL for better cosmesis and fitting.

Keywords: base curve, diameter, prosthetic soft contact lens, iris tint

Introduction

Prosthesis is an artificial device to replace externally or internally a missing body part or disfigured part. One should note that prosthetic contact lens and cosmetic contact lens are not the same. Cosmetic contact lenses or decorative lenses are used to change the colour or appearance of a normal eye whereas prosthetic contact lenses are used to improve the appearance of a disfigured eye,¹ or to improve

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visual function in diseased eyes,² and for occlusion therapy.³ Common indications for prosthetic contact lenses are albinism, amblyopia, aniridia, diplopia, fixed or dilated pupil, heterochromia,⁴ iridectomy, iris coloboma, photophobia,⁵ scarred or opacified cornea and so on. The types of prosthetic soft contact lenses (PSCLs) are determined by pupil colour and iris tint. PSCL has three zones: the central pupillary area, the tinted iris and the clear peripheral zone which is called the annulus. PSCLs are available in four types and used for different purposes: Type A (black pupil with clear iris; Fig. 1a), type B (no pupil with tinted iris; Fig. 1b), type C (clear pupil with tinted iris; Fig. 1c) and type D (black pupil with tinted iris; Fig. 1d). Types D and B PSCLs are usually prescribed for non-seeing or blind eyes and type A PSCL for patching therapy or for cosmetic reasons. Type C PSCL is used to improve visual function by controlling light entrance in an eye and spherical power can be incorporated in clear pupil area. In India very few manufacturers manufacture PSCLs and they are usually available in light, medium or dark brown iris tint. This is due to the fact that most of the Indian eyes have naturally brown iris colour and rarely require different colours of prosthetic iris tint. Very few studies have been published worldwide and as per our best knowledge no study has been done exclusively on prosthetic contact lens in India. The aim of this study is to understand PSCL practice better and be a quick guide to choose proper PSCL.

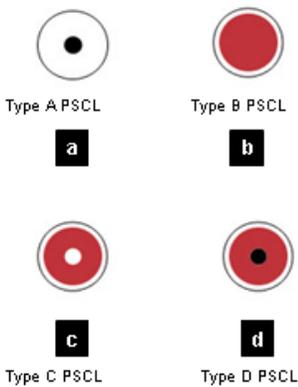


Fig. 1. Various types of prosthetic soft contact lenses: (a) type A; (b) type B; (c) type C; (d) type D.

Materials and Methods

For a period of 1 year (January 2013 to December 2013), 223 patients were prescribed PSCL. Data were collected retrospectively after institutional review board and ethics approval. Data were documented: age, sex, common reasons for prescribing PSCL, types of PSCL prescribed, colour of iris tint used, selection of base curve and diameter of the PSCL, number of trials required to achieve desirable cosmesis or fit, period (months) of use of prosthetic lens among old PSCL users and number of prosthetic lenses dispensed from off the shelf. PSCL were classified to

the following types: Type A - black pupil with clear iris, type B - no pupil with tinted iris, type C - clear pupil with tinted iris; and type D - black pupil with tinted iris. Data were analyzed using Microsoft Excel 2007©. Patients who had undergone PSCL trial during the particular period but not purchased the lens due to unsuccessful fit or unwillingness for purchasing the lenses were excluded from this study.

Results

A total of 223 patients (225 eyes) were prescribed PSCL and majority were male (64.57%). Mean age was 29.15 years (SD \pm 12.65) and the age range was between 6 and 78 years. Type D PSCL was prescribed for the maximum number of eyes (81.33%) and type A PSCL for least number of eyes whereas type B PSCL was not prescribed for any eye (Fig. 2).

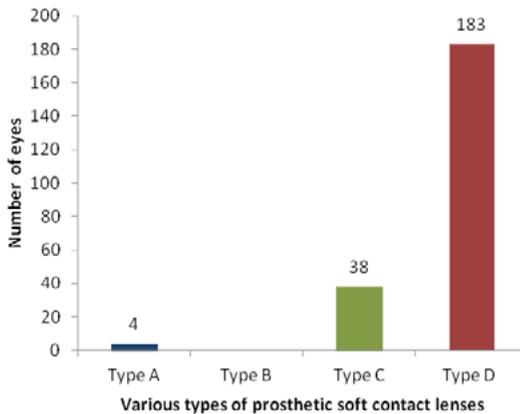


Fig. 2. Number of eyes prescribed with various types of PSCLs.

The leading causes for prescribing prosthetic contact lenses invariable of the type of lens were corneal abnormality, cataract, iris or pupillary abnormality and leukocoria. A detailed analysis was performed for each type of PSCL to gather further information.

Type D PSCL

Unilaterally, 183 patients (183 eyes) were prescribed type D PSCL and almost two-thirds were male. The categories of eye diseases for prescribing type D PSCLs were corneal abnormalities 89.61% (164 eyes), lens abnormalities 4.91% (9 eyes), pupil or iris abnormalities 3.82% (7 eyes), leukocoria 1.09% (2 eyes) and anterior chamber abnormalities 0.54% (1 eye) (Fig. 3). Further categorization of abnormalities and the number of eyes prescribed with type D PSCLs are shown in Fig. 3.

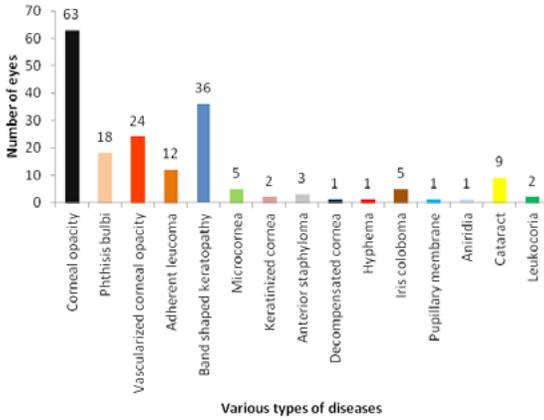


Fig. 3. Various eye diseases and number of eyes prescribed with prosthetic type D contact lenses.

Tint of the prosthetic contact lens varied on the basis of the condition and the colour match with the fellow eye. The common tints used in prosthetic contact lenses for Indian eyes were light brown iris (LB), medium brown iris (MB) and dark brown iris (DB). Almost 81.96% of eyes were fitted with LB, MB or DB type D iris tint. Rest of the disfigured eyes (18.4%) required customized iris tint for better cosmesis. The common prosthetic lens fitted had 8.6 or 8.7 mm base curve (BC) and 13.8 or 14.00 mm diameter (DIA). Few cases required modifications in BC or DIA to achieve optimal fit after trial lens evaluation. Various colours of iris tint and the number of eyes prescribed with type D PSCL are shown in Fig. 4.

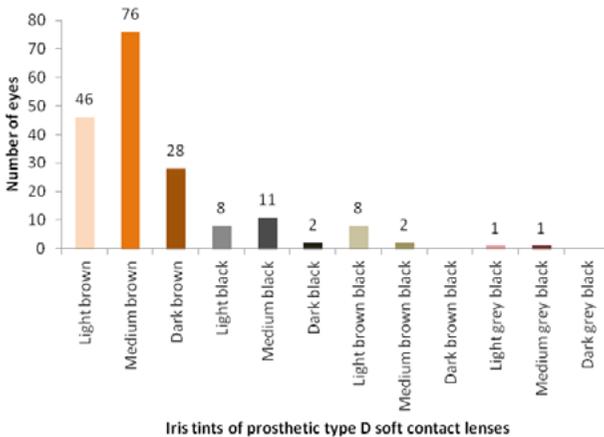


Fig. 4. Various PSCL iris tints and the number of eyes prescribed with type D PSCL.

Almost half of the eyes (50.8%) were newly fitted with type D PSCL. For new cases, the average number of trials required was 1.32 (SD \pm 0.69; range 1–4 times) for achieving better cosmesis and 1.36 (SD \pm 0.73; range 1–5 times) for desirable fit. Among the old type D PSCL users, the average wearing period was 42.70 months (SD \pm 41.70; range 2–240 months). Tables 1 and 2 show the distribution of various BCs and DIAs prescribed for type D PSCLs.

Table 1: Various BCs prescribed for type D prosthetic contact lenses (n=183)

BC (in mm)	Number of eyes (%)
8.1	1 (0.54)
8.3	7 (3.82)
8.6	91 (49.72)
8.7	65 (35.51)
8.9	13 (7.1)
9.0	1 (0.54)
9.1	3 (1.63)
9.3	2 (1.09)

BC, base curve.

Table 2: Various DIAs prescribed for type D prosthetic contact lenses (n=183)

DIA (in mm)	Number of eyes (%)
13.8	21 (11.47)
14.0	155 (84.69)
14.5	1 (0.54)
15.0	6 (3.27)

DIA, diameter.

Type C PSCL

Type C prosthetic contact lens was prescribed for 36 patients (38 eyes) of whom 22 were male and 14 female. Only two patients were prescribed with type C prosthetic contact lens for both eyes; rest was fitted unilaterally. The main categories for prescribing type C PSCLs were corneal abnormalities (55.26%; 21 eyes), pupil or iris abnormalities (34.21%; 13 eyes), lens abnormalities (2.63%; 1 eye) and others (7.89%; 3 eyes). Further categorization of abnormalities and the number of eyes prescribed with type D PSCLs are shown in Fig. 5.

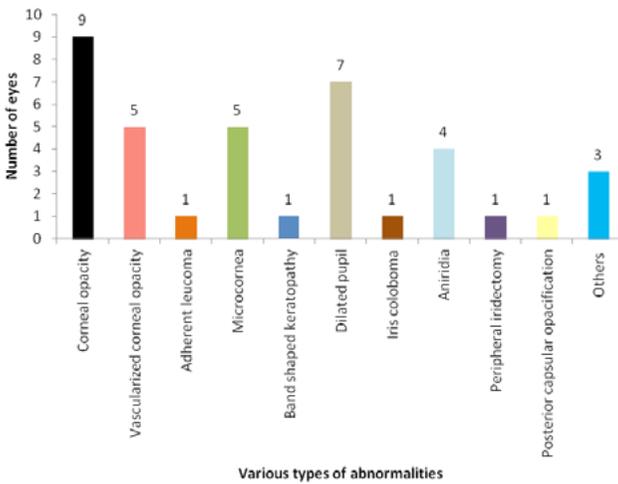


Fig. 5. Various types of abnormalities and the number of eyes prescribed with type C PSCL.

Different shades of brown colour iris tint were prescribed for all type C PSCLs and are shown in Fig. 6 along with the number of eyes prescribed with type C PSCL.

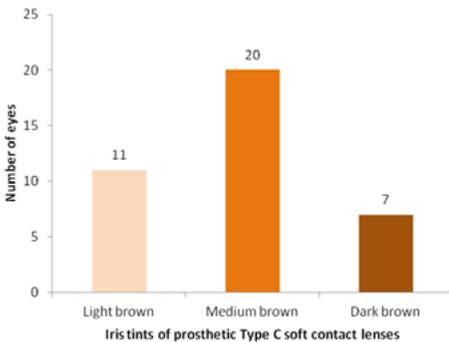


Fig. 6. Various tints prescribed for type C prosthetic contact lens user.

Type C prosthetic contact lens was prescribed for 19 new patients and 17 old patients. The average number of trials required for new patients to achieve better cosmesis was 1.05 (SD ± 0.22; range 1–2 times) and to achieve best desirable fitting

was 1.1 (SD \pm 0.30; range 1–2 times). Among the old prosthetic contact lens users the average wearing period was 39.11 months (SD \pm 29.31; range 8–98 months).

Type A PSCL

Only four male patients (four eyes) were unilaterally prescribed type A PSCL and the only reason was cataract and all were new patients.

Off the shelf vs. customized PSCL

Among type D PSCL users, 67.21% (123 eyes) were prescribed stock lenses and rest of them required customization for various reasons. But for type C PSCL users, 84.21% (32 eyes) customization as most of the eyes required refractive error correction along with cosmetic correction. All the type A prosthetic contact lenses needed customization because of various pupil sizes in the affected eye compared to fellow eye and the customization of pupil size was limited due to manufacturer's techniques. Table 3 shows the number of eyes for which lenses were dispensed from the stock and the number of eyes which required modified lenses.

Table 3: Off the shelf vs. customized PSCL comparisons

Type of PSCL	Number of eyes prescribed from Stock lenses/off the shelf (%)	Number of eyes required Customization (%)
A	0 (0.0)	4 (100)
B	0 (0.0)	0 (0.0)
C	6 (15.78)	32 (84.21)
D	123 (67.21)	60 (32.78)

Discussion

Patient with disfigured eyes have limited options for cosmetic solution in India. They can wear sunglasses, undergo prosthetic shell implantation,⁶ and corneal tattooing,⁷ or wear prosthetic contact lenses for cosmetic purpose. Approximately 120,000 corneal blindness cases are reported in India by the National Programme for Control of Blindness and only 60,000 cases benefit from penetrating keratoplasty; the rest 50% vision cannot be improved due to posterior segment diseases.⁸ Approximately 20,000 cases of corneal blindness are added newly in each year.⁹ In a study, Dandona and Dandona projected a growth in the prevalence of corneal blindness mostly in unilateral cases, from 0.66% (year 2001) to 0.84% (year 2020).¹⁰ Childhood blindness and visual loss due to corneal diseases cause significant impact on the child's development, education, future jobs and quality of life.¹¹ In India, ocular trauma, corneal ulcer, hereditary corneal dystrophy, vitamin deficiency and failed ocular surgery lead to various degrees of corneal opacity. Disfigured eyes have significant impact on a person's social life like lack of eye contact, emotional impact and withdrawal from education. Disfigured eye can

create anxiety or poor self-image and problems in employment.¹² A proper PSCL, prosthetic rigid gas permeable prosthetic contact lens, scleral prosthetic lens or enucleation of the disfigured eye and fitting of a prosthetic shell can serve as alternate options and can improve a person's self-confidence. PSCL is reasonably cheap when compared to other options. In their study, Meshel and Jessen reported that a large number of patients have disfigured eyes but only 5-10% is being treated with ocular prosthesis.¹³ In India uses of prosthetic contact lenses are limited and mostly soft prosthetic contact lenses are fitted in the disfigured eyes. The soft prosthetic contact lenses available in the Indian market are usually made up of high water content (67–70%) hydrogel materials though these lenses are prescribed as conventional modality with an advisable follow-up period of 6 months to 1 year.

In most of the contact lens studies, females¹⁴⁻¹⁸ are the predominant contact lens users internationally as well as in India,¹⁹ but our study results showed that the predominant users of prosthetic soft contact lens are males (64.5%); this is probably due to eye injuries as mostly males are involved in outdoor activities compared to females.²⁰⁻²² Most of the disfigured eyes are fitted with brown colour prosthetic iris tint as Asians have dark brown colour iris.²³ The leading cause for prescribing PSCL was corneal pathology or corneal abnormality which is due to eye injuries, complex ocular surgeries and congenital abnormalities. Our study results showed that 185 eyes (82.2%) were fitted with PSCLs due to corneal abnormality, similar to a study done in Japan where 89.5% (40 eyes) were fitted with PSCLs due to various corneal abnormalities.²⁴

Type D PSCL prescribed majority for disfigured eyes to mask the opacity, compare to other type of PSCL and majority of them prescribed from stock lenses, probably type D PSCL does not required additional refractive error correction unlike type C PSCL or not frequently required any kind of pupil size correction like type A PSCL. All the type A prosthetic contact lenses needed customization because of various pupil sizes in the affected eye compared to fellow eye and the customization of pupil size was limited due to manufacturer's techniques. Additionally few disfigured eyes could not be fitted with type A prosthetic lenses due to poor cosmesis as the white opacity could not be masked from pupillary area. Such cases were fitted with type D PSCL to mask leukocoria. None of the patient prescribed occludable PSCLs for patching therapy may be it is not a popular treatment of choice in India.

Information about patients' occupation, complication with prosthetic contact lens and quality of lifestyle improvement after using PSCL is lacking in this retrospective analysis and can be planned prospectively for further study. This is a retrospective study and despite several missing information still we identified several parameters for prescribing trends in PSCLs.

Conclusion

Majority of disfigured eyes requiring PSCL are due to corneal abnormality, which can be satisfied with off the shelf PSCL. Sizeable numbers of eyes require customized PSCL for better cosmesis and fitting.

References

1. Yildirim N, Basmak H, Sahin A. Prosthetic contact lenses: adventure or miracle. *Eye Contact Lens*. 2006;32(2):102–103.
2. Olali C, Mohammed M, Ahmed S, Gupta M. Contact lens for failed pupilloplasty. *J Cataract Refract Surg*. 2008;34(11):1995–1996.
3. Collins RS, Mcchesney ME, Mccluer CA, Schatz MP. Occlusion properties of prosthetic contact lenses for the treatment of amblyopia. *J AAPOS*. 2008;12(6):565–568.
4. Mcdermott ML, Chandler JW. Therapeutic uses of contact lenses. *Surv Ophthalmol*. 1989;33(5):381–394.
5. Rajak SN, Currie AD, Dubois VJ, Morris M, Vickers S. Tinted contact lenses as an alternative management for photophobia in stationary cone dystrophies in children. *J AAPOS*. 2006;10(4):336–339.
6. Raizada K, Rani D. Ocular prosthesis. *Cont Lens Anterior Eye*. 2007;30(3):152–162.
7. Pitz S, Jahn R, Frisch L, Duis A, Pfeiffer N. Corneal tattooing: an alternative treatment for disfiguring corneal scars. *Br J Ophthalmol*. 2002;86(4):397–399.
8. MoH & FW(NPCB). Rapid assessment of Avoidable Blindness- India. Report-2006-07
9. Saini JS, Reddy MK, Jain AK, Ravindra MS, Jhaveria S, Raghuram L. Perspectives in eye banking. *Indian J Ophthalmol*. 1996;44(1):47–55.
10. Dandona R, Dandona L. Corneal blindness in a southern Indian population: need for health promotion strategies. *Br J Ophthalmol*. 2003;87(2):133–141.
11. Dandona L, Gilbert CE, Rahi JS, Rao GN. Planning to reduce childhood blindness in India. *Indian J Ophthalmol*. 1998;46(2):117–122.
12. Linberg JV, Tillman WT, Allara RD. Recovery after loss of an eye. *Ophthal Plast Reconstr Surg*. 1988;4(3):135–138.
13. Meshel LG, Jessen W. Ocular prostheses. *J Am Optom Assoc*. 1998;69(9):550.
14. Morgan PB, Efron N, Helland M, *et al*. Demographics of international contact lens prescribing. *Cont Lens Anterior Eye*. 2010;33(1):27–29.
15. Morgan PB, Efron N, Woods CA. An international survey of contact lens prescribing for presbyopia. *Clin Exp Optom*. 2011;94(1):87–92.
16. Tajunisah I, Ophth M, Reddy SC, Phuah SJ. Knowledge and practice of contact lens wear and care among medical students of University of Malaya. *Med J Malaysia*. 2008;63(3):207–210.
17. Morgan PB, Efron N. A decade of contact lens prescribing trends in the United Kingdom (1996–2005). *Cont Lens Anterior Eye*. 2006;29(2):59–68.
18. Woods CA, Jones DA, Jones LW, Morgan PB. A seven year survey of the contact lens prescribing habits of Canadian optometrists. *Optom Vis Sci*. 2007;84(6):505–510.
19. Thite N, Noushad B, Kunjeer G. Contact lens prescribing pattern in India--2011. *Cont Lens Anterior Eye*. 2013;36(4):182–185.
20. Nirmalan PK, Katz J, Tielsch JM, *et al*. Ocular trauma in a rural south Indian population: the Aravind Comprehensive Eye Survey. *Ophthalmology*. 2004;111(9):1778–1781.
21. Khan S, Maqbool A, Abdullah N, Keng MQ. Pattern of ocular injuries in stone pelters in Kashmir valley. *Saudi J Ophthalmol*. 2012;26(3):327–330.
22. Sinha S. Pattern of trauma to anterior segment of eyes in a tertiary eye care centre of Jharkhand. *J Indian Med Assoc*. 2008;106(5):289–290.
23. Obianwu HO, Rand MJ. The relationship between the mydriatic action of ephedrine and the colour of the iris. *Br J Ophthalmol*. 1965;49:264–270.
24. Kanemoto M, Toshida H, Takahiro I, Murakami A. Prosthetic soft contact lenses in Japan. *Eye Contact Lens*. 2007;33(6 Pt 1):300–303.

Diabetic Macular Edema Estimation Using Slit Lamp Biomicroscopy Versus That Using Oct

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Purpose: Comparison of Diabetic macular edema estimation using slit lamp biomicroscopy versus that using OCT.

Materials and Methods: We performed a retrospective analysis of 121 patients (154 eyes) with established Type 2 diabetes mellitus, divided into three groups. Group I consisted of 62 eyes with NPDR, Group II, 27 eyes with PDR and Group III, 66 eyes with CSME. Diagnosis of CSME was made as per ETDRS protocol, using slit lamp stereoscopic biomicroscopy. DME was defined on OCT as central foveal thickness greater than 250 μ m. OCT scanning was performed through the macula of each eye after pupillary dilatation.

Results: The mean age of patients included was 60.70 \pm 9.20 years and 61.98% were males. Only 66 eyes were classified as having DME clinically as opposed to 109 eyes by OCT, leading to a significant sub-estimation of 39.44% eyes. The mean macular thickness in the CSME patients identified by slit lamp biomicroscopy was 399.59 \pm 105.31 μ m. The mean central macular thickness in the sub-estimated cases was 290.58 \pm 28.92 μ m overall, 290.10 \pm 26.19 μ m in the PDR group and 290.95 \pm 31.46 μ m amongst NPDR patients.

Conclusion: Mild macular thickening on OCT may not correspond to overt edema clinically and has been termed sub-clinical macular edema by some authors. We report a sub-estimation of DME in 39.44% eyes in our study. The emerging importance of monitoring of these vulnerable patients and early detection of their conversion to overt CSME must be realised. In conclusion, assessment of diabetic macular edema with OCT is probably more objective and reliable.

Keywords: Diabetic Macular Edema, OCT, Slit lamp biomicroscopy, subestimation, CSME

Introduction

Officially crowned as *The diabetes capital of the world*, India houses a massive 62 million diabetics, making every fifth diabetic in the world, an Indian.¹⁻³ Out of these, 34.6% are estimated to have diabetic retinopathy.⁴⁻⁷ It is fast gaining the status of the number one cause of avoidable blindness all over the world and this, amongst the working population of any nation, takes a heavy toll on its social and economic productivity. Macular edema is the leading cause of visual impairment in patients with diabetic retinopathy and its importance as a major public health issue is gaining recognition.⁸⁻¹² It can develop at any stage of diabetes and there are various factors that determine the visual outcome in these cases, including central foveal involvement, perifoveal capillary blood flow velocity, capillary occlusion in the foveal zone and central foveal thickness.^{13,14} Hence, there is an urgent need for early detection, regular monitoring and timely treatment of macular edema in these vulnerable patients.

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As the traditional methods of assessment of macular thickening evolved from slit lamp biomicroscopy to conventional stereo fundus photography, these methods remained both largely subjective as well as relatively imperceptive to small changes in retinal thickness. Thus, there was continued scouting for newer, better techniques to quantify retinal thickness.¹⁵

Optical Coherence Tomography is an objective, non-invasive technique that has been widely used over the past two decades and has proved invaluable in the diagnosis and evaluation of several macular conditions such as Central Serous Chorioretinopathy, clinically significant diabetic macular edema (CSME), cystoid macular edema, epiretinal membranes, and macular holes.¹⁶⁻¹⁸ It has undergone several modifications over time, to emerge as a highly reproducible, patient friendly diagnostic imaging technology. It generates real time, high resolution cross sectional tomographic images and operates on the principle of low coherence interferometry. Past studies on patients with diabetic retinopathy uphold that central foveal thickness determined using OCT equate well with visual acuity and has proved to be a valuable asset in monitoring of macular thickening pre and post laser therapy.¹⁸⁻²⁰ As per the current established protocol by ETDRS, the decision of using focal laser photocoagulation for clinically significant macular edema (CSME) relies solely on the subjective presence or absence of macular thickening by slit-lamp fundus stereo biomicroscopy.²¹ But, lately OCT has come to assume a pivotal role in the assessment of diabetic macular edema and is deemed to be more objective and reliable. However, it is imperative that we evaluate whether the retinal thickness measurements generated by OCT are in concordance with the subjective assessment by the traditional techniques.²² We also need to evaluate whether the use of an OCT will aid in greater accuracy of establishing diabetic macular edema as opposed to the standard techniques in use.

In this study, we seek to compare estimation of Diabetic macular edema using slit lamp biomicroscopy with that using Cirrus SD OCT.

Methods

A retrospective analysis of data of 121 patients (154 eyes) was obtained from the records of all diabetic patients who visited our outpatient clinic between January 2012 to May 2014. The inclusion criteria was any established case of diabetes mellitus, between 40 and 80 years, diagnosed to have diabetic retinopathy. Diabetes was established by physician diagnosis, laboratory reports and treatment history. Patients with significant media opacities that would hinder with OCT signal and those with pre existing macular pathologies like epiretinal membrane, macular hole or ARMD changes as well as other causes of macular edema were excluded from the study. Clearance was obtained from Institutional Ethics Committee.

All cases identified were further divided into three groups. Group I with 61 eyes having Non proliferative diabetic retinopathy, Group II consisting of 27 eyes with Proliferative diabetic retinopathy and Group III included 66 eyes with clinically significant macular edema. Diagnosis of CSME was made using slit lamp stereoscopic biomicroscopy by an experienced ophthalmologist. Clinically Significant

Macular Edema was defined as per the Early-Treatment Diabetic Retinopathy Study (ETDRS) protocol²³ as presence of retinal thickening or hard exudates associated with adjacent retinal thickening within 500µm of the center of the fovea or zone of retinal thickening 1 disc diameter or larger, any part of which lies within 1 disc diameter of the center of the macula. Diabetic Macular Edema was defined on OCT as central foveal thickness greater than 250µm.^{24,25} OCT scanning was performed for each eye after pupillary dilatation using tropicamide 1% and phenylephrine hydrochloride 2.5% eyedrops, by a single ,experienced ophthalmologist.

OCT works on the principle of low coherence interferometry that analyses the time delay of light reflected from various retinal microstructures located at various depths and generates a high resolution image. We used a widely available Carl Zeiss SD-OCT unit in our study.

The Central Foveal Thickness (CFT) considered here was the average thickness of retina within the central 1 mm area, marked at the point of intersection of six radial scans, procured using *the fast macular thickness map protocol* and an automated value was displayed by the OCT machine using the *retinal map analysis* function.

Descriptive statistical methods (mean, standard deviation) as well as two sample, two sided students unpaired 't' test, a statistical package SPSS version 17.0 was used to do the statistical analysis and p value <0.05 was considered as significant.

Results

The mean age of patients included was 60.70 ± 9.20 years and 61.98% were males. Only 66 eyes were classified as having DME clinically as opposed to 109 eyes by OCT, leading to a significant sub-estimation of 39.44% eyes.

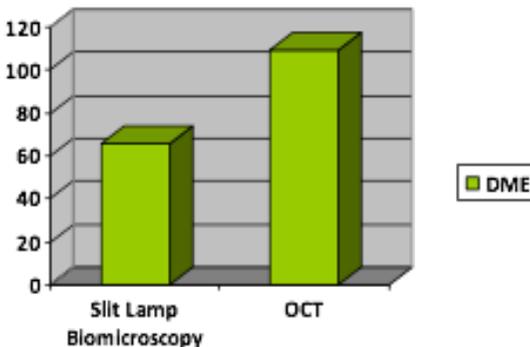


Fig. 1. The number of patients classified as DME by Slit lamp biomicroscopy Vs that by OCT.

Out of these sub-estimated 43 eyes, diagnosed as DME by OCT, 24 (55.81%) had NPDR and 19 (44.18%) had PDR. The mean macular thickness in the CSME patients identified by slit lamp biomicroscopy was $399.59 \pm 105.31 \mu\text{m}$ while those identified by OCT was $356.58 \pm 99.32 \mu\text{m}$.

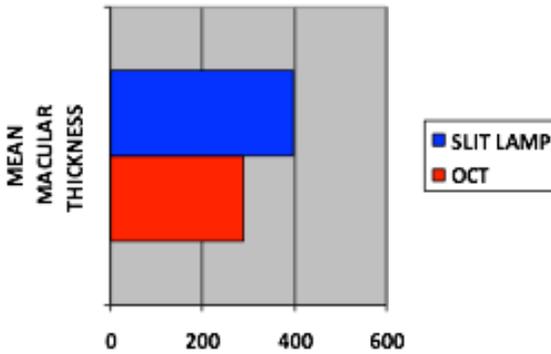
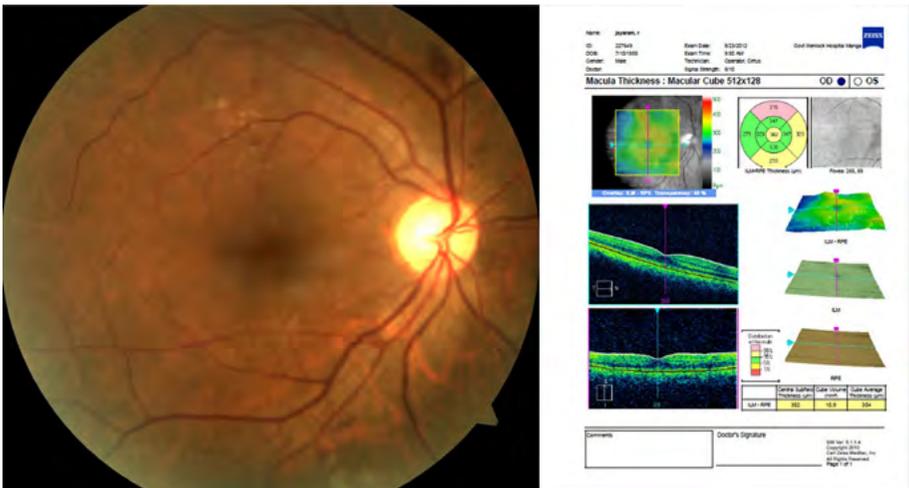


Fig. 2. As is evident, a much higher macular thickness is required to be recognised as DME by slit lamp biomicroscopy as opposed to OCT.

This was found to be statistically significant at $p=0.007$ ($p<0.05$, CI at 95%). The mean central macular thickness in the sub-estimated cases was $290.58 \pm 28.92 \mu\text{m}$ overall, $290.10 \pm 26.19 \mu\text{m}$ in the PDR group and $290.95 \pm 31.46 \mu\text{m}$ amongst NPDR patients.

Discussion

All subjects, in whom retinal thickening or hard exudates were observed at the macula during slit lamp biomicroscopy, also exhibited a corresponding increase in macular thickness on OCT. However, there were instances when OCT detected macular thickening in the absence of any clinically detectable macular edema.



This was perhaps more common when the type of edema was diffuse rather than focal or when there were no tell-tale hard exudates. We found that the central foveal thickness had to be substantially greater to be clinically identified as CSME. The

mean macular thickness in the CSME patients identified by slit lamp biomicroscopy was $399.59 \pm 105.31 \mu\text{m}$ while those identified by OCT was $356.58 \pm 99.32 \mu\text{m}$. This difference was found to be statistically significant with p value < 0.05 . This led to a significant sub-estimation of 39.44% eyes by slit lamp biomicroscopy as opposed to that by OCT.



A similar study conducted by Koleva-Georgieva in 2010, evaluating the role of OCT in detecting early macular edema in diabetics, shared the same observations.²⁶

Such cases have been described in the past as sub-clinical DME.^{27,28} The term was coined by Brown who reported up to 25% of subclinical cases.²⁷ In another study by Browning, 58 to 90% of cases were found to be sub-estimated.²⁹ Bhavsar and Subramaniam reported an interesting observation that a sizeable number of subjects with subclinical macular edema eventually progressed to CSME as compared to the control population.²⁸

It has been previously reported that while all three standard methods of slit-lamp biomicroscopy, fluorescein angiography and OCT have been found to be complementary for diagnostic purposes, OCT is a more objective and less invasive technique for follow up of diabetic macular edema.³⁰

There have been several studies by Udaondo *et al.*,³¹ Song *et al.*,³² Takatsuna *et al.*,³³ and Vemala *et al.*³⁴ that have explored the utility of OCT in various dimensions of macular edema such as comparison with Indirect ophthalmoscopy in diagnosis of DME, monitoring the efficacy of new innovative treatment for BRVO by following macular edema with OCT and exploring the various levels of efficacies of intravitreal triamcinolone, bevacizumab and laser photocoagulation as treatment for DME. However, very little attention has been paid to the new concept of predicting susceptibility to CSME in patients, early detection of DME in them as well as comparison with the standard subjective methods of evaluation that are still the protocol.

Limitation of our study is lack of records of other parameters due to retrospective

collection of data. There are many more parameters that can be analysed and their respective relationship with macular thickness can be explored, like visual acuity, HbA1C levels, duration of diabetes *etc.* Also, we didn't draw comparisons with healthy subjects or a baseline control group.

In conclusion, we found that OCT was a useful and sensitive technique for quantitative measurement of retinal thickness in patients with diabetes. Our study fully supports previous suggestions that early changes in retinal thickness can be detected by OCT despite normal findings in slit lamp biomicroscopy, thus facilitating early detection and timely management of such patients.

References

1. Kumar A, Goel MK, Jain RB, Khanna P, Chaudhary V. India towards diabetes control: Key issues. *AMJ* 2013; 6: 524-531.
2. Kaveeshwar SA, Cornwall J. The current state of diabetes mellitus in India. *AMJ* 2014; 7: 45-48
3. Joshi S, Joshi SR, Mohan V. Methodology and feasibility of a structured education program for diabetes education in India: The National Diabetes Educator Program. *Indian J Endocrinol Metab.* 2013; 17: 396-401
4. Yau JW, Rogers SL, Kawasaki R, Lamoureux EL, Kowalski JW, Bek T *et al.* Meta-Analysis for Eye Disease (META-EYE) Study Group. Global prevalence and major risk factors of diabetic retinopathy. *Diabetes Care* 2012; 35: 556-564
5. Namperumalsamy P, Kim R, Vignesh TP, Nithya N, Royes J, Gijo T *et al.* Prevalence and risk factors for diabetic retinopathy: a population-based assessment from Theni District, south India. *Br J Ophthalmol* 2009; 93:429-434
6. Dandona L, Dandona R, Naduvilath TJ, McCarty CA, Rao GN. Population based assessment of diabetic retinopathy in an urban population in southern India. *Br J Ophthalmol* 1999; 83:937-940
7. Raman R, Rani PK, Reddi Rachepalle S, Gnanamoorthy P, Uthra S, Kumaramanickavel G *et al.* Prevalence of diabetic retinopathy in India: Sankara Nethralaya Diabetic Retinopathy Epidemiology and Molecular Genetics Study report 2. *Ophthalmology* 2009; 116:311-318
8. Nicholson BP, Schachat APA. A review of clinical trials of anti-VEGF agents for diabetic retinopathy. *Graefes Arch Clin Exp Ophthalmol* 2010; 248: 915-930
9. Klein R, Klein BEK, Moss SE. Visual impairment in diabetes. *Ophthalmology* 1984; 91: 1-9
10. Soheilian M, Garfami KH, Ramezani A, Yaseri M, Peyman GA. Two-year results of a randomized trial of intravitreal bevacizumab alone or combined with triamcinolone versus laser in diabetic macular edema. *Retina* 2012; 32:314-321.
11. Klein R, Klein BEK, Moss SE. The Wisconsin epidemiologic study of diabetic retinopathy. IV. Diabetic macular edema. *Ophthalmology* 1984; 91: 1464-1474
12. Gillies MC, Islam FMA, Zhu M, Larsson J, Wong TY. *Br J Ophthalmol.* Oct 2007; 91: 1323-26.
13. Gardner TW, Larsen M, Girach A, Zhi X: Protein Kinase C Diabetic Retinopathy Study (PKC-DRS2) Study Group. Diabetic macular oedema and visual loss: relationship to location, severity and duration. *Acta Ophthalmol* 2009, 87:709-713.
14. Sakata K, Funatsu H, Harino S, Noma H, Hori S: Relationship of macular microcirculation and retinal thickness with visual acuity in diabetic macular edema. *Ophthalmology* 2007, 114:2061-2069.
15. Nussenblatt RB, Kaufman SC, Palestine AG, Davis MD, Ferris FL. Macular thickening and visual acuity. *Ophthalmology* 1987; 94:1134-1139.
16. Hee MR, Izatt JA, Swanson EA, Huang D, Schuman JS, Lin CP *et al.* Optical coherence tomography of the human retina. *Arch Ophthalmol.* 1995; 113:325-332.
17. Puliafito CA, Hee MR, Lin CP, Reichel E, Schuman JS, Duker JS *et al.* Imaging of macular diseases with optical coherence tomography. *Ophthalmology.* 1995; 102:217-229.
18. Hee MR, Puliafito CA, Duker JS, Reichel E, Coker JG, Wilkins JR *et al.* Topography of diabetic macular edema with optical coherence tomography. *Ophthalmology* 1998; 105:360-370
19. Hee MR, Puliafito CA, Wong C, Duker JS, Reichel E, Rutledge B *et al.* Quantitative assessment of macular edema with optical coherence tomography. *Arch Ophthalmol.* 1995; 113: 1019-1029.

20. Otani T, Kishi S, Maruyama Y. Patterns of diabetic macular edema with optical coherence tomography. *Am J Ophthalmol.* 1999; 127: 688–693.
21. Early Treatment Diabetic Retinopathy Study Research Group. Photocoagulation for diabetic macular edema: early treatment diabetic retinopathy study report number 1. *Arch Ophthalmol* 1985; 103:1796-1806
22. Strom C, Sander B, Larsen N, Larsen M, Lund-Andersen H. Diabetic Macular Edema Assessed with Optical Coherence Tomography and Stereo Fundus Photography Invest. *Ophthalmol. Vis. Sci.* 2002 ;43:241-245
23. Early Treatment Diabetic Retinopathy Study Research Group. ETDRS report number 7: Early Treatment Diabetic Retinopathy Study design and baseline patient characteristics. *Ophthalmology* 1991; 98:741–756.
24. Chan CKM ,Mohamed S, Shanmugam MP, Tsang CW, Lai TYY, D Lam DSC. Decreasing efficacy of repeated intravitreal triamcinolone injections in diabetic macular oedema. *Br J Ophthalmol.* 2006; 90:1137–1141.
25. Davis MD, Bressler SB, Aiello LP, Bressler NM, Browning DJ, Flaxel CJ. Comparison of Time-Domain OCT and Fundus Photographic Assessments of Retinal Thickening in Eyes with Diabetic Macular Edema. *Invest Ophthalmol Vis Sci.* 2008; 49: 1745–1752.
26. Koleva-Georgieva DN, Sivkova NP. Optical coherence tomography for the detection of early macular edema in diabetic patients with retinopathy. *Folia Med Plovdiv;* 52: 40-48.
27. Brown JC, Solomon SD, Bressler SB, Schachat AP, Di Bernardo C, Bressler NM. Detection of diabetic foveal edema: Contact lens biomicroscopy compared with optical coherence tomography. *Arch Ophthalmol.* 2004. 122: 330-335.
28. Bhavsar KV, Subramanian ML. Risk factors for progression of subclinical diabetic macular oedema. *Br J Ophthalmol.* 2011; 95(5): 671–674.
29. Browning DJ, McOwen MD, Bowen RM Jr, O'Marah TL. Comparison of the clinical diagnosis of diabetic macular edema with diagnosis by optical coherence tomography. *Ophthalmology* 2004 ;111: 712–715.
30. Baskin DE. Optical coherence tomography in diabetic macular edema. *Curr Opin Ophthalmol.* 2010; 21: 172-177.
31. Udaondo P, Diaz-Llopis M, Garcia-Delpech S, Salom D, Romero J. Intravitreal plasmin without vitrectomy for macular edema secondary to branch retinal vein occlusion. *Arch Ophthalmol.* 2011; 129:283–287.
32. Song JH, Lee JJ, Lee SJ. Comparison of the short-term effects of intravitreal triamcinolone acetate and bevacizumab injection for diabetic macular edema. *KJO* 2011; 25:156–160
33. Takatsuna Y, Yamamoto S, Nakamura Y, Tatsumi T, Arai M, Mitamura Y. Long-term therapeutic efficacy of the subthreshold micropulse diode laser photocoagulation for diabetic macular edema. *Jpn J Ophthalmol.* 2011; 55:365–369
34. Vemala R, Koshy S, Sivaprasad S. Qualitative and quantitative OCT response of diffuse diabetic macular oedema to macular laser photocoagulation. *Eye* 2011; 25:901–908

Five year refractive outcome of LASIK for myopia and myopic astigmatism in Vietnam

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Abstract

Purpose: To assess the long-term refractive outcome of laser in situ keratomileusis (LASIK) for myopia and myopic astigmatism

Design: An observational, single center, multisurgeon case series

Methods: This study was a follow up study of 128 patients contacted to return for repeat investigation post refractive surgery. It included 245 eyes of 128 patients who underwent LASIK for myopia or myopic astigmatism at the Ho Chi Minh City Eye Hospital, Vietnam in 2008. Surgical parameters as well as patient data at presentation, three months and five years after surgery were analyzed. The main outcome was spherical equivalent (SE) within $\pm 0.5D$ at 5 years.

Results: At the fifth year follow up, 80% of eyes were within $\pm 0.5D$ and 98% of eyes were within $\pm 1.0D$ of emmetropia. No eyes underwent laser enhancement prior to the last visit although the retreatment criteria was met in 45 eyes (18.4%). The mean SE decreased from 0.16 ± 0.33 at 3 months to -0.07 ± 0.50 at 5 years for the whole cohort. Patients with severe myopia were most susceptible to myopic regression and had a less predictable refractive outcome. The overall UCVA of 20/20 or better and of 20/40 or better were obtained in 68.2% and 95.1% of eyes. Fourteen eyes (5.7%) improved 1 line of BCVA. Forty two eyes (17.1%) lost 2 lines of BCVA which were unrelated to laser complications.

Conclusion: Although there was myopic regression over time, LASIK provided excellent 5 year refractive outcome for myopia and myopic astigmatism. Almost 20% of patients meet criteria for retreatment but do not seek a retreatment in this Vietnamese population.

Keywords: LASIK, refractive outcome, myopia, myopic astigmatism

Introduction

Myopia is the most common eye condition worldwide, which affects up to 80% of people in some Asian populations.^{1,2} For most patients, glasses and contact lenses are the most convenient way of correcting myopia. The most commonly performed operative procedure for myopia is LASIK (Laser In situ Keratomileusis). This is a relatively safe procedure with quick visual recovery. More than 28 million LASIK surgeries have been performed globally with a patient satisfaction rate regarding refractive efficacy of over 95%.^{3,4}

Since the foremost aim of LASIK surgery is to correct refractive error in order to reduce dependence on eye glasses or contact lenses, its long term refractive

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outcome is of great concern.³ Most published reports of refractive efficacy are limited to 1 year with only a few reports beyond 5 years.⁵⁻¹² These studies in general report that postoperative refraction does remain stable beyond 5 years.⁷

In Vietnam, LASIK was first introduced in 2000. The long term follow up for postoperative outcomes has not been well studied in our setting. Locally a final postoperative visit occurs at 3 months with patients then they are lost to follow up. Thus, the aim of this study was to assess the long term (5 year) refractive outcome of uneventful LASIK for myopia and myopic astigmatism in Vietnamese patients. These results were compared to the 3 month results at all levels of myopia. As a secondary aim, the study also looked into the association between the 5 year refraction and predictors of regression.

Materials and methods

Patient population

This study involved contacting and recruiting patients who underwent LASIK surgery at the Ho Chi Minh City Eye Hospital (HCMCEH) in 2008.

The criteria for LASIK eligibility at the HCMCEH since 2008 were: patients aged 18 or older with manifest spherical equivalent (SE) refraction less than or equal to -12.0 diopters (D), astigmatism less than or equal to -6.0 D, difference between best corrected visual acuity (BCVA) and uncorrected visual acuity (UCVA) equal or more than 2 lines, and stable refraction for at least 6 months before surgery. The exclusion criteria for surgery were: any past or present ocular diseases or systemic diseases that might lead to abnormal wound healing, insufficient corneal thickness for laser ablation (total corneal thickness < 475 μ m), evidence of keratoconus or keratoconus suspect, untreated retinal breaks, and women who were pregnant or 12 months postpartum.

Inclusion criteria for our study were: 1. Resident in Ho Chi Minh City, 2. Underwent uneventful LASIK for myopia and myopic astigmatism, 3. Complete postoperative information up to 3 months. Of the 3922 patients who underwent LASIK in 2008, 772 met these criteria. Reasons for study exclusion of 3150 patients were due to them living outside Ho Chi Minh City, having other refractive errors or incomplete 3 month follow up data. Patients were contacted by letters inviting them to participate and/or phone messages. Of the 772 individuals, 148 patients (19.2%) agreed to participate and scheduled a free follow up assessment. Twenty patients were excluded from the analysis for not completing all the required tests (3 patients) or having unreliable data in any studied parameters (17 patients) at the 5 year visit. Our study then was left with 245 eyes of 128 patients which were analyzed.

Informed consent was obtained from all patients for their initial surgery and this follow up study.

Patient management

Preoperative Examination

Prior to the surgery, all patients underwent detailed examination included UCVA, BCVA (Auto Chart Projector, Shin Nippon), manifest and cycloplegic refraction (Welch Allyn retinoscope and Inami refraction lens case), contrast sensitivity (FACT, Stereo Optical), corneal topography (Orbscan, Technolas Perfect Vision), corneal pachymetry (AL2000, Tomey), preoperative intraocular pressure testing (IOP) (Schiotz, Germany), and slitlamp biomicroscopy examination (Topcon, Japan).

Surgical Procedure

LASIK procedures were performed by surgeons of the HCMCEH, using the same technique and protocol. Eyelids were retracted with a speculum. After the eye was positioned beneath the laser, alignment marks were placed on the cornea. Superior-hinged flap was created by M2 automated microkeratome (Moria) or Hansatome (Bausch and Lomb), based on nomograms provided by the manufacturer. The flap was reflected and excimer laser ablation was then performed with Ladarvision, WaveLight Allegretto (Alcon), or Technolas 217z (Technolas Perfect Vision) laser systems. After ablation, the interface was irrigated with balanced salt solution and then replaced. The striae test was performed to check flap adhesion before removing speculum.

Postoperative Evaluation

Following surgery, topical antibiotic (Ofloxacin 0.3%, Santen) was used for the first week. Corticosteroid eye drops (Pred Forte 1%, Allergan) was prescribed for 1 week. Nonpreservative artificial tear was used for up to 3 months.

Patients underwent postoperative examinations at 1 day, 1 week, 1 month, 3 months and 5 years (this study) after the initial procedure by independent examiners. Slit lamp examination and UCVA were performed at all examinations. Manifest refraction, BCVA and contrast sensitivity were assessed from the 1 week recheck. At 5 years, IOP and corneal thickness were remeasured by using ocular response analyzer (Reichert) and pachymeter (AL2000, Tomey). Flap thickness measurement was done with the optical coherence tomography (OCT1000, Carl Zeiss). Chorioretinal degenerative signs were recorded. Residual stromal bed thickness was calculated by using preoperative pachymetry minus predicted flap thickness minus calculated ablation depth.

Variable measurements

Outcome

Spherical equivalent of BCVA at 5 years was the primary outcome of interest. It was examined as a continuous variable and then grouped into 2 groups based on its value within $\pm 0.5D$ range.

Exposed (predictor) variables of interest:

Levels of myopia (based on manifest SE) were grouped into 3 levels: mild (0 to -3.0D), moderate (-3.12 to -6.0D), and severe (more than -6.0D). Regression was defined as a 0.5D or more myopic shift occurring between follow up visits without laser enhancement. The 3 month regression was further categorized into whether or not regressed at 3 months to predict for the 5 year refractive outcome. Operative machine (Ladarvision, Allegretto and Technolas) was also included. Safety index = $BCVA_{\text{postoperative}} / BCVA_{\text{preoperative}}$; Efficacy index = $UCVA_{\text{postoperative}} / BCVA_{\text{preoperative}}$. Corneal haze was graded from 0 to 4 in which grade 0 (clear cornea) and 1 (trace haze) were then grouped as insignificant, and the remaining grades were significant haze group. Degree of lens opacity was graded according to the LOCS III system after pupil dilatation. A gradable cataract was defined as grade 3 or more in nuclear or cortical cataract, or a grade 2 or more posterior subcapsular cataract¹³. Age at surgery, preoperative pachymetry value, flap thickness, optic zone, ablation depth and residual stromal bed thickness were all examined by regression analysis for any association with postoperative SE at 5 years.

Other variable description:

Undercorrection was defined as an SE of -0.5D or more at the first reassessment of postoperative refraction (at 1 week visit). Retreatment criteria, after the first 3 months, included any of the following parameters: manifest SE of -0.5D or more, UCVA of 20/32 or less, stable myopic refraction between consecutive visits, and patient dissatisfaction with the visual result including sufficient residual stromal bed thickness. Snellen acuity, noted in decimal, was converted to the logarithm of the minimum angle of resolution (LogMAR) equivalent for analysis and back to lines for interpretation. Changes in visual acuity and refraction at 3 months and 5 years were compared between three levels.

Statistical analysis

All variables were assessed through univariate analysis. Bivariate analysis was conducted to compare differences in some measurements according to level of myopia (t test or chi square test). In order to predict SE at 5 year range within $\pm 0.5D$, multivariate analysis was used to assess the role of the given exposure variables in predicting the refractive outcome. Logistic regression was used to select the best subset of predictors. Data was entered using Excel 10 and analyzed using SAS 9.4 at 0.05 level of significance.

Results

Demographics of patients and surgical related parameters

In this study, 245 eyes of 128 patients that underwent LASIK surgery for myopia and myopic astigmatism were analyzed. There was no age difference of the patients within mild, moderate and severe myopia group ($p = 0.33$). Demographics of the patients are listed (Table 1).

Table 1 Demographics of patients included in this study

Gender (%)	
Male	63 (25.7)
Female	182 (74.3)
Myopia levels (%)	
Mild ($\leq 3.0D$)	51 (20.8)
Moderate (-3.12 to $-6.0D$)	128 (52.2)
Severe ($> 6.0D$)	66 (27)
Mean age \pm SD, range, years	25.0 ± 6.3 (18.0 to 43.0)
Mean SE \pm SD, range, D	-4.99 ± 2.3 (-12.0 to -0.75)
Mean corneal thickness \pm SD, range, μm	524.97 ± 31.1 (475 to 609)
SD = standard deviation; SE = spherical equivalent; D = diopters	

All eyes were targeted for emmetropic correction. Technolas 217z was used in 193 (78.8%) operations while Ladarvision and Allegretto were used in 29 (11.8%) and 23 (9.4%) cases, respectively. Diameter of the ablated area was 6.5 ± 0.1 mm in the optical zone, and 6.6 ± 0.4 mm when the transitional zone was included. The mean ablation depth was 91.7 ± 29.3 μm . Laser ablation left an average residual stromal bed thickness of 310 ± 36.5 μm . Postoperative corneal thickness was 463.8 ± 39.9 μm . At 5 years, gradable cataracts were present in 7 cases (2.9%). Clear corneas were found in 88.2% of patients postoperatively, while haze graded 1 and grade 2 were only in 26 cases (10.6%) and 3 cases (1.2%), respectively. IOP at the 5th year visit was 14.1 ± 2.7 mmHg.

Refractive outcome, predictability and stability

The manifest refraction of -4.99 ± 2.27 D preoperatively was improved to 0.16 \pm 0.33 D at 3 months. The manifest refraction at 5 years was slightly reduced to -0.07 ± 0.50 D compared to the 3 month average. Refractive results declined over time in all three levels of myopia (Table 2).

Table 2 Spherical equivalent (SE) refraction over 5 years stratified by levels of myopia

	No of eyes	Preop SE*	SE at 3 months	SE at 5 years*
		Mean ± SD	Mean ± SD	Mean ± SD
Mild (<3.0D)	51	-2.19 ± 0.59	0.18 ± 0.28	0.06 ± 0.45
Range, D		-0.75 to -3.0	-0.25 to +1.00	-1.00 to +1.00
Median		-2.25	0.25	0.00
Moderate (-3.12 to -6.0D)	128	-4.58 ± 0.79	0.19 ± 0.26	0.01 ± 0.42
Range, D		-3.12 to -6.0	-0.38 to +1.00	-1.25 to +0.75
Median		-4.56	0.25	0.00
Severe (> -6.0D)	66	-7.94 ± 1.60	-0.25 ± 0.46	-0.32 ± 0.60
Range, D		-6.13 to -12.0	-1.38 to +1.75	-3.13 to +0.75
Median		-7.44	0.00	-0.25
All levels	245	-4.99 ± 2.27	0.16 ± 0.33	-0.07 ± 0.50
Range, D		-12.00 to -0.75	-1.38 to +1.75	-3.13 to +1.00

SE = spherical equivalent; SD = standard deviation; D = diopters
 *Test differences between means of myopia level: p < 0.0001

The overall percentage of myopic regression increased from 16% at 3 months to 30% at the 5 year visit. Eyes in the severe myopia group had the highest percentages of myopic regression over time and means of SE at 3 months and at 5 years were significantly different by level of myopia (Fig.1).

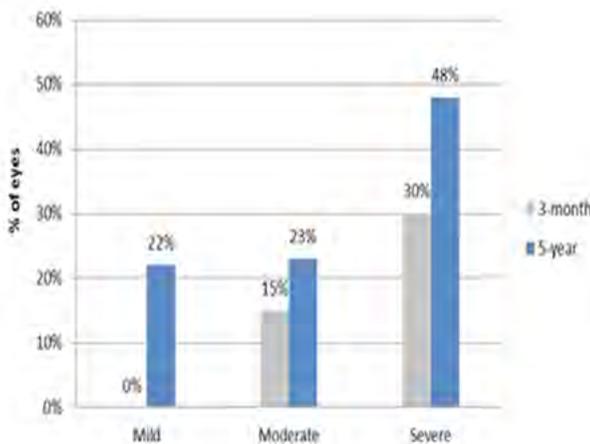


Fig 1. Myopic regression in different levels of myopia

At 5 years, the mean regression in each level of myopia were -0.12D (mild), -0.18D (moderate) and -0.4D (severe). Regarding to the refractive predictability, the overall prevalence of eyes achieving SE within $\pm 0.5D$ declined by more than 10 percentage point after 5 years (from 93% to 80%), whereas prevalence of SE within $\pm 1.0 D$ remained almost the same at 99% during the period (Table 3).

Among three types of operative machine, the rate of regression at 5 years after Ladarvision (62%) was two times higher than Technolas (24%) and Allegretto (30%).

Table 3 Prevalence of eyes within $\pm 0.5 D$ or $\pm 1.0 D$ of target correction stratified by levels of myopia

	Within $\pm 0.5 D$		Within $\pm 1.0 D$	
	At 3 months	At 5 years	At 3 months	At 5 years
Mild	96%	80%	100%	100%
Moderate	95%	84%	100%	99%
Severe	89%	70%	95%	94%
All levels	93%	80%	99%	98%

Factors associated with the 5 year SE within $\pm 0.5 D$

Demographics of the eyes achieving SE within $\pm 0.5D$ at 5 years following LASIK had a mean age of 24.9 ± 6.3 , mean SE of -5.01 ± 2.27 . The myopia level distribution was 19% (mild), 55.4% (moderate) and 25.6% (severe). Technolas 217z, Ladarvision and Allegretto were used in 81.5%, 8.2% and 10.3% of cases, respectively.

Among various variables, age at surgery was the only factor having association with 5 year SE within $\pm 0.5D$ after adjustment (Table 4). Specifically the younger patients tended to regress more than older patients.

Table 4 Associations between the 5 year SE predictability within ± 0.5 D and exposed variables

	Adjusted OR (95%CI)
Age at surgery	0.93 (0.88, 0.98)
Myopia level	1.17 (0.43, 3.17)
Preoperative corneal thickness	0.99 (0.96, 1.03)
Flap thickness	0.96 (0.91, 1.01)
Optic zone	4.04 (0.32, 51.28)
Ablation depth	0.99 (0.95, 1.03)
Machine type	1.14 (0.64, 2.02)
Regression at 3 month	1.14 (0.43, 3.02)
Residual stromal bed thickness	1.00 (0.98, 1.04)
Cataract	2.07 (0.26, 16.37)
Haze	(0.22, 1.10)

Visual outcome, efficacy and safety

At the fifth year post-operation, the efficacy index was 0.96 and the safety index was 1.07. Both were lower than its parameters at 3 months which were 1.24 and 1.29. The preoperative UCVA was 1.12 ± 0.21 (range, 0.40 to 1.70), improved to -0.07 at 3 months, and reached 0.03 at 5 years after surgery. The overall final UCVA of 20/20 or better and of 20/40 or better were obtained in 68.2% and 95.1% of patients, respectively. About 50% of the eyes with severe myopia retained UCVA of 20/20 or better at the last checkup (Fig. 2).

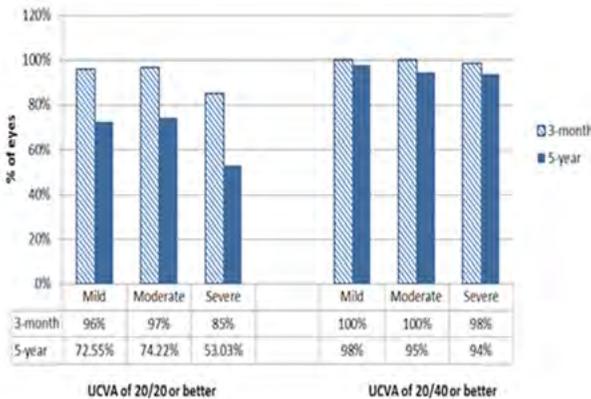


Fig 2. UCVA outcomes at 3 months and 5 years postoperation in different levels of myopia

The 5 year BCVA was unchanged in 82 eyes (33.5%), improved 1 line in 14 eyes (5.7%) and dropped 1 to 2 lines in 149 eyes (60.8%). In the 42 eyes (17.1%) that lost 2 lines of BCVA, the reasons were due to progressive cataract (7%) and myopic chorioretinal degeneration (93%).

No eye underwent laser enhancement prior to the last visit although the indication for retreatment was met in 45 eyes (18.4%) at the fifth year.

There were 4 cases that the patient underwent LASIK on one eye only. The other eyes progression of myopia was almost the same with the operated one (difference of 0.25D)

Discussion

In this study, we showed a mild myopic regression at the 5 year refractive outcome of uneventful LASIK for myopia and myopic astigmatism at HCMCEH.

Refractive outcome, predictability and stability

After surgery, the mean SE changed, from 0.16 ± 0.33 D at 3 months to -0.07 ± 0.50 D at 5 years, indicating a myopic shift over time. The overall percentage of eyes having myopic regression doubled over the period. This was seen more in the severe group with two to three times more than that of the other two groups. This tendency has been confirmed in a number of other prospective case series studying the mechanism of post LASIK regression.¹⁴ However, Liu Z LY, in a seven year study with moderate to severe myopia found that eyes did not regress in refraction between 1 and 7 years postoperatively.⁹

Regarding to the predictability of refractive surgery, we found that 80% of eyes retained within ± 0.5 D of target correction and 98% were within ± 1.0 D at the fifth year. Our 0.5D refractive predictability result was similar to those of previous researches which range from 60% to 89%.⁹⁻¹¹ In terms of the 1.0D refractive predictability, although several studies showed comparable figures to us,^{6,7,9-11} some six to eleven year follow up reports revealed a predictability of around 50%.^{5,12,15} When looking at each group, severe myopic eyes had a less predictable outcome (70%) than eyes with mild to moderate myopia (from 84%). These results were comparable with findings in a 13 year follow up study.¹¹

Factors associated with the 5 year SE within ± 0.5 D

In previous studies, myopic regression mechanisms were reported due to nuclear sclerosis of the lens, corneal steepening due to the thinning, corneal hydration, stromal synthesis, and compensatory epithelial hyperplasia.¹⁴ In addition, higher achieved correction and change in corneal power were also found to be associated factors of regression.⁷ This study, after adjusting for a number of factors, we observed a significant association between age at surgery and the 5 year SE within ± 0.5 D of target correction. Our result implied that with each year increase in age, patients face a 5% possibility of having their 5 year SE outside the 0.5 range, OR = 0.93 (0.88, 0.98).

Visual outcome, efficacy and safety

In the long term, our results indicated that both efficacy and safety index of uneventful LASIK followed a downtrend. However, its safety parameter remained higher than 1.0. This outcome was reinforced by the same results of the 10 years⁷ and 15 years follow up studies (M.Elbahrawy *et al.*, the XXXII Congress of ESCRS 2014).

At the fifth year, almost all eyes (95%) could be independent of spectacles with the UCVA of 20/40 or better. Our findings were close to the results of some studies (between 78% to 100%),^{6,7,9-11} but it more than double that in three reports (33% to 46%) which conducted on moderate to extreme myopia^{5,12} (M. Elbahrawy *et al.*, the XXXII Congress of ESCRS 2014). In our study, about three fourths of eyes in the mild and moderate group retained their UCVA of 20/20 at 5 years whereas this amount in the severe group was just over a half. When we compare these results with the figures at 3 months, a 20-30% decrease was noted in each level of myopia regarding to the probability of obtaining UCVA of 20/20 or better over time.

BCVA was unchanged in 33.5% of eyes, and about 5.7% of eyes gained 1 line at 5 years. According to Applegate, the improvement in BCVA may be due to the change in the plane of correction, from the spectacle to the cornea, which induced a retinal image magnification effect. Other long term studies also reported positive final BCVA of their patients.^{5-7,9,10,12} Among three levels of myopia in our study, the moderate group achieved the highest rate in BCVA improvement.

To the best of our knowledge, this is the first study in Vietnam to evaluate the 5 year refractive outcome in LASIK patients in terms of regression and SE range within 0.5D of target correction. We also attempted to look at predictors of myopic regression across a number of clinical variables. To us, the 3 month landmark is very important as it is not only the least time for postoperative refraction stabilization¹⁶ but also the last time most of our patients returned for reassessment. The outcomes were described in separate levels of myopia, which is clinical relevant in postoperative LASIK studies.

However, this study had several limitations. This was a follow-up study by invitation. The 5-year follow up group was only 128 of 3922 patients who had LASIK at our center (3.3%). There was a large loss to follow up due to patients living outside Ho Chi Minh City and were unable to be reexamined. Of the 772 patients eligible to be recruited, only 128 agreed (17%). This small study group does result in recruitment bias for our results. Further, our study involves treatment by a number of different LASIK machines which may have themselves have different long term refractive stability outcomes. Despite this, the type of operative machine (Allegretto, Technolas and Ladarvision) showed no significant difference in postoperative SE nor safety and efficacy^{17,18}.

In conclusion, our findings showed that although there was a regression in postoperative results over time, uneventful LASIK for myopia and myopic astigmatism provided a good long term refractive outcome at 5 years after surgery. About 95% of eyes could be independent of their glasses (UCVA of 20/40 or better) and nearly 70% retained emmetropia (UCVA of 20/20 or better). 17% of eyes lost 2 lines

of BCVA due to progressive cataracts and myopic retinal degeneration. Approximately 80% and 98% of eyes were within $\pm 0.5D$ and $\pm 1.0D$ at 5 years. Severe myopia was most susceptible to myopic regression and had less predictable outcome as compared to mild and moderate myopia.

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References

1. Lee YY LC, Sheu SJ, Lin JL. Factors Associated with Myopia in Young Adults. *IOVS*. 2013;54(2):1026-1033.
2. Pan C-W RD, Saw S-M. Worldwide prevalence and risk factors for myopia. *Ophthalmic & Physiological Optics*. 2012(32):3-16.
3. Solomon K.D LEFdc, Helga P. Sandoval, Joseph M. Biber, Brian Groat, Kristiana D. Neff, Michelle S.Ying, John W.French, Eric D.Donnenfeld, Richard L.Lindstrom. LASIK World Literature Review. *Ophthalmology*. 2009;116(4):691-701.
4. Stuart A. A look at Lasik Past, Present and Future. *Eyenet: American Academy of Ophthalmology*; 2009:39-44.
5. George D. Kymionis NST, Nikolaos Astyrakasis, *et al*. Eleven-year follow up of laser in situ keratomileusis. *J Cataract Refract Surg*. 2007;33:191-196.
6. Ide T *et al*. Outcome of a 10-year follow-up of laser in situ laser keratomileusis for myopia and myopic astigmatism. *Taiwan Journal of Ophthalmology*. 2014:1-7.
7. Jorge L. Alio OM, Dolores Ortiz, *et al*. Ten Year Follow-up of Laser in Situ Keratomileusis for Myopia of up to -10 Diopters. *American Journal of Ophthalmology*. 2008;145(1):46-54.
8. Kato NTI, Hori-Komai Y, Sakai C, Tsubota K. Five-Year Outcome of LASIK for Myopia. *Ophthalmology*. 2008;115(5):839-844.
9. Liu Z LY, Cheng Z, *et al*. Seven-year follow up of LASIK for moderate to severe myopia. *J Refract Surg*. 2008;24(9):935-940.
10. M O'Doherty MOK, C Kelleher. Five year follow up of laser in situ keratomileusis for all levels of myopia. *Br J Ophthalmol*. 2006;90:20-23.
11. Mohamed Dirani TC, Joanne Yau, *et al*. Long-term refractive outcomes and stability after excimer laser surgery for myopia. *J Cataract Refract Surg*. 2010;36:1709-1717.
12. Sekundo W. BK, Mattausch P, *et al*. Six-year follow-up of laser in situ keratomileusis for moderate and extreme myopia using a first-generation excimer laser and microkeratome. *J Cataract Refract Surg*. 2003;29:1152-1158.
13. Hassan Hashemi MK, Mohammad Miraftab, Kazem Mohammad, Akbar Fotouhi. The Association Between Refractive Errors and Cataract: The Tehran Eye Study. *Middle East Afr J Ophthalmol*. 2011;18(2):154-158.
14. Arturo S. Chayet KKA, Miguel Montes, *et al*. Regression and Its Mechanisms after Laser In Situ Keratomileusis in Moderate and High Myopia. *Ophthalmology*. 1998;105(7):1194-1199.
15. Zalentein WN TT, Holopainen. Seven-year follow-up of LASIK for myopia. *J Cataract Refract Surg*. 2009;25(3):312-318.
16. Gerard Sutton ML, Christopher Hodge. Laser in situ keratomileusis in 2012: a review. *Clinical and Experimental Optometry*. 2014;97:18-29.

17. Daphne CY Han JC, Hla Myint Htoon, *et al.* Comparison of outcomes of conventional WaveLight Allegretto Wave and Technolas excimer lasers in myopic laser in situ keratomileusis. *Clinical Ophthalmology* 2012;6:1159-1168.
18. Melissa D. Bailey KZ. Outcomes of LASIK for Myopia with FDA-Approved Lasers. *Cornea*. 2007;26(3):246-254.

Usefulness of the Non-Contact Tonometry in Out-Patient Screening

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Abstract

Purpose: Goldmann applanation tonometry (GAT) is considered the gold standard for Intraocular Pressure (IOP) measurement. It has the disadvantages of being a contact device, need for a slit-lamp, non-portability and need of a skilled examiner. Many hospitals are using a Non Contact Tonometry (NCT) as a screening device to save clinician time, however the usefulness is not proved in terms of reliability. This study was aimed to determine the usefulness of the Air-puff tonometer (TONOREF NIDEK II, NIDEK CO., LTD., JAPAN) over a GAT in a tertiary care center.

Design: Cross-sectional Study

Methods: This was a cross-sectional, non interventional observational study conducted on 224 eyes (right eye) from 224 patients. All patients underwent the IOP measurement with both methods and a central corneal thickness (CCT) measured. The data was analyzed using SPSS 20.0 software.

Results: The mean age of the patients was 40.3 ± 11.29 years. There was a statistically significant difference ($p < 0.001$) between the mean NCT and GAT readings which persisted even after correction for central corneal thickness. The correlation between NCT and GAT using Pearson's correlation coefficient was strong irrespective of the corrections for their corneal thickness ($r = 0.751$ and 0.718 for uncorrected and corrected values respectively). The correlation of the individual clinicians for the readings varied from moderate to strong. The ROC curve showed the best sensitivity and specificity to occur at around 13 to 14 mmHg.

Conclusion: NCT seems to overestimate the IOP at low ranges as compared to the GAT and underestimate at higher ranges. The crossover of the values is seen between 12 to 13 mmHg. The clinician should do an individualized analysis of his/her GAT measurements to the readings of the NCT machine at the clinic to obtain clinician specific nomogram.

Keywords: Air Puff, Applanation, Corneal Thickness, Goldmann, Non Contact, Tonometry,

Introduction

Intra ocular pressure (IOP) refers to the pressure exerted by the intraocular contents on the coats of the eyeball.¹ Normal range of IOP is maintained due to the equilibrium which exists between aqueous humor formation, its outflow and its episcleral venous pressure. IOP measurement is an integral part of eye examination especially in patients in the older age group and in patients with glaucoma or suspect glaucoma. Raised IOP is the only risk factor that can be modified in patients with glaucoma and a precise measurement is very important in its management. Measurement of IOP

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can be done using various methods which includes contact techniques (Goldmann applanation, Schiøtz Indentation, Rebound and Dynamic contour tonometry) or the non contact techniques (Air puff and Pulsair tonometry).²⁻⁴

Goldmann applanation tonometry (GAT) is considered the gold standard³ for recording intra-ocular pressure and is based on the principle of Imbert-Fick law^{5,6} which states that the pressure within an infinitely thin, dry, smooth-walled, flexible sphere is equal to the external force required to flatten the surface of the sphere divided by the area flattened. The IOP is recorded based on the amount of pressure applied to applanate the area.⁴⁻⁶

Non-contact tonometry (NCT) measures the IOP by firing an air puff at the cornea. This air puff flattens the cornea and the IOP is calculated based on the time taken for the increasing velocity of the air-puff to flatten the cornea.^{7,8} The main advantages of NCT are that it is a non-invasive procedure and does not require use of anaesthetic drops, does not require Fluorescein staining, easy to perform, comfortable procedure and has minimal risk of infection and it takes less time to perform the procedure with added advantage of its usefulness in children.^{1,7-9}

Central corneal thickness (CCT) affects the IOP when measured by GAT with thick and thin corneas, measuring false high and low IOP respectively.¹⁰⁻¹⁴ A thinner cornea requires less force to applanate and might give us IOP values on a lower side, thicker corneas would need more force and may give us artificially high IOP reading.¹¹⁻¹³ Also there is proven evidence for diurnal variation of the IOP.¹⁵⁻¹⁷ Goldmann himself discussed the influence of variations of central corneal thickness on IOP measured by applanation, he felt that significant variations in CCT occurred rarely and hence assumed a "normal" CCT of 520 μm for his instrument.⁶

Patients and Methods

This was a cross sectional non interventional observational study conducted at a tertiary care center in South India. Both the IOP measurement procedures were explained to the patients and were enrolled after informed consent. This study was approved by the Institutional Review Board (IRB Min No: 8673).

Data of 50 patients fitting the inclusion and exclusion criteria, on whom NCT was measured by the primary investigator (CESJ) on patients of the two clinicians were collected, which was then used for the sample size calculation. A sample of minimum 109 subjects for each clinician were needed to be studied, to detect a mean difference of 1.21 mmHg between the two measurement of IOP with a 5% error and 80% power.

All patients registered for an out-patient visit to see two selected clinicians aged between 20 to 60 years were enrolled after informed consent. In patients with both eyes fitting the inclusion criteria, the right eye was chosen as the study eye. Patients with corneal pathology, shallow anterior chamber as assessed by torchlight and slit-lamp examination, intraocular surgeries in the past 6 months, ocular surface infections, one eyed patients and astigmatism of more than 3D were excluded from the study. Patients with systemic conditions who could not sit at the slit lamp for the recording of IOP were also excluded. The data from our study was further

sub-categorized and analyzed based on the GAT readings as group 1 (≤ 13 mmHg), group 2 (14-21 mmHg) and group 3 (≥ 22 mmHg) respectively.

Methodology

The participants had their NCT readings taken using Nidek Tonoref (TONOREF NIDEK II, NIDEK CO., LTD., JAPAN) by the primary investigator (CESJ). The participants were seated comfortably with their chin on the chin-rest and asked to fix at the target shown and the IOP readings were taken. The machine displayed the average of three IOP measurements taken, which was considered as the NCT reading. CCT was measured with TOPCON (SP 3000P, Non Contact Specular Microscope) according to the instruction manual. The machine displays an average of 3 readings. NCT and the CCT were not given to the clinicians to avoid bias.

After the NCT and CCT measurements patients underwent refraction and torch-light examination by experienced optometrists. A drop of Tropicamide (0.8%) with Phenylephrine (5.0 %) was instilled in each eye and patient sent to the clinician. The clinicians examined the patients and a GAT (Haag Streit AT 900[®]), performed on the dilated eye. The GAT was calibrated every morning by standard protocol. The patients were explained about the procedure and a proparacaine drop (0.5%) and the tear film stained with Fluorescein strips 1% (Fluorescein Sodium Ophthalmic Strips USP, Fluro Strips).¹⁸ Goldmann applanation prism was positioned and IOP measurement of the right eye was taken by asking the patient to look ahead with the left eye.⁹ The readings were noted in the medical record, the patient was sent back to the primary investigator (CESJ) where they underwent a post dilated NCT and CCT measurements as before.

To avoid a diurnal variation affecting the readings, all the IOP measurements for a participant were completed within 90 minutes¹⁵⁻¹⁷ Patients in whom the IOP readings were not done within the time zone as defined in the study were excluded. The data regarding the GAT values were extracted from the medical records by the primary investigator (CESJ) after the completion of the study for analysis.

Data entry was transcribed into a Microsoft Excel 2010 document and analyzed with SPSS software (Version 20.0). Pearson's correlation coefficient and the Paired t test were done to compare the different set of readings by the two methods. Descriptive statistics was calculated using mean difference and Bland-Altman Plots. The categorical variables were analyzed using frequency and percentages.

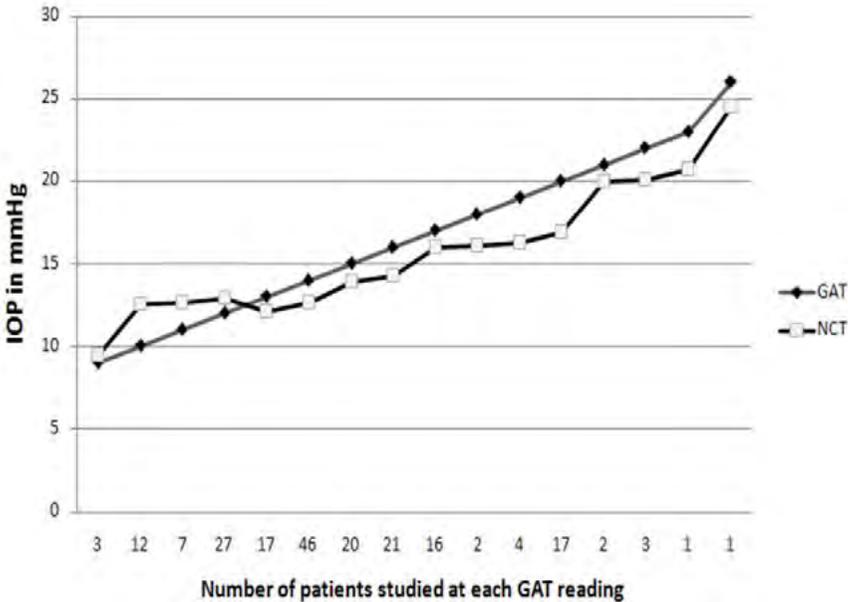
Results

A total of 235 patients participated in the study, of which 11 patients were excluded (10 in whom all the IOP measurements could not be completed in 90 minutes and 1 patient who did not stay through the study protocol) from the study. 224 patients (right eye, $n = 224$) remained for the final analysis. The sample included 119 (53.1%) males and 105 (46.9%) females. The mean age of the patients was 40.3 ± 11.29 years (range 20 to 60 years). Table 1 shows the mean values and the standard deviation of the various IOP and the CCT measurements. The mean IOPs between the clinicians

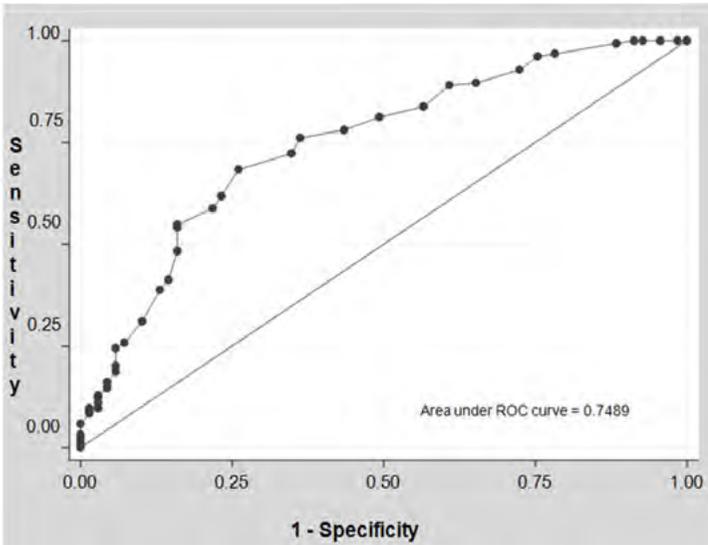
in the different subsets were not statistically significant.

The pre dilatation (Pr D) and the post dilatation (Ps D) readings were analyzed for the agreement. There was a statistically significant difference ($p < 0.001$) between the mean NCT (Ps D) and GAT which persisted even after correction for corneal thickness. The correlation between NCT (Ps D) and GAT using Pearson's correlation coefficient was strong ($0.751, p < 0.001$). The same values corrected for corneal thickness also had a strong correlation ($0.718, p < 0.001$). The correlation was moderate if only the GAT values were corrected for corneal thickness (Table 2). However the correlation of the individual clinicians for the readings varied from moderate to strong (Table 3). When looking for correlation for various IOP levels measured with GAT, there was a strong correlation only in the group above 22 mmHg. Below 13 mmHg the correlation was very poor (Table 4).

The graph in Figure 1 shows that from 13 mmHg, the NCT values were lower than the GAT values and vice versa below 13 mmHg. The ROC curve drawn also showed the best sensitivity and specificity of around 70% occurred at around 13 to 14 mmHg (Fig 2). Figure 3 shows the distribution of GAT and NCT (Ps D) readings with the Bland Altman Plot.

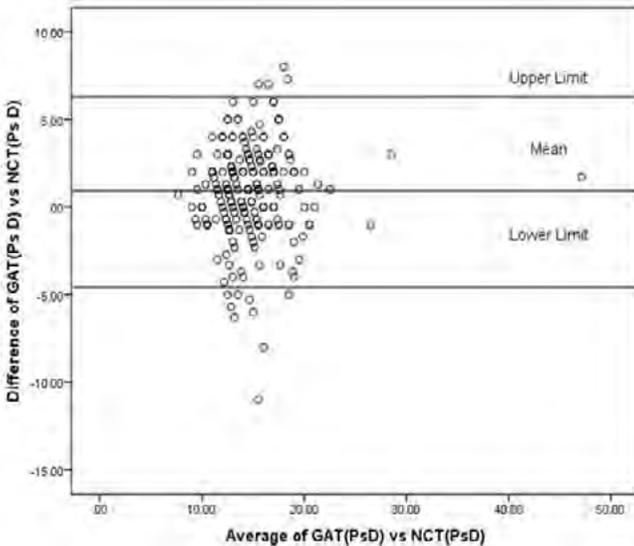


*NCT (Ps D) - Non contact tonometry (Post dilatation), [†]GAT - Goldmann Applanation Tonometry
 Fig 1. Mean NCT (Ps D)* readings at each GAT[†]value



*GAT (Ps D) - Goldmann Applanation Tonometry (Post dilatation), †NCT (Ps D) - Non contact tonometry (Post dilatation)

Fig 2. ROC curve of GAT (Ps D)* vs NCT (Ps D)†



*GAT (Ps D) - Goldmann Applanation Tonometry (Post dilatation), †NCT (Ps D) - Non contact tonometry (Post dilatation)

Fig 3. Bland-Altman Plot of GAT (Ps D)* vs NCT (Ps D)† showing distribution of patients

Discussion

Quick accurate measurements of IOP in the clinic setting will hasten patient throughput and is something most clinicians are looking for. GAT is the gold standard tonometer for IOP measurements but this takes time and has associated problems of the need for a skilled examiner, staining with fluorescein and the chance of spread of infection.⁵ NCT measurement is quick and easy and circumvents the above problems.

This study was initiated to look for the correlation and agreement of the IOP readings taken by NCT and GAT in a clinical setup and on patients from the Indian subcontinent. If NCT is found useful then it can be substituted for GAT in evaluation of patients in an eye clinic. Though various studies have been published in the literature, there are always variations that can occur with the different machines in measuring the NCT.

In this study we chose two clinician's measurement to make it more relevant in a multi-clinician set up. Since there are clinical work flows where patients are seen after dilatation by the clinician we decided to do GAT only after dilatation. However, to see the change in NCT with dilatation, we took the post dilated readings too (Table 2 and 3). To evaluate the possible error due to instillation of eye-drops for dilatation which could change corneal hydration and give a false reading, the CCT readings were taken before and after the dilatation and the differences were found not to be statistically significant (Table 1).

The IOP measured by the GAT as we know is affected by CCT.¹⁰⁻¹⁴ Comparison between the mean differences between the NCT (Pr D) vs GAT (0.067 ± 2.958) and the NCT (Pr D) vs cGAT (0.749 ± 4.27) showed an increase in the latter. The fact that the mean cGAT moves away from the mean NCT, compared to uncorrected GAT values suggest that NCT is also affected by CCT in a similar fashion. Though the CCT influences the measured NCT values as studied by Tonnu *et al*¹³, the correction factor is not well established. Since no correction nomogram were available to correct the NCT for the measured CCT, we applied the same correction formula as described by Ehlers *et al*¹⁴ for GAT, to compute the corrected IOP as measured by the NCT. The fact that the differences became smaller when the NCT was corrected with the same correction formula, suggested NCT too is affected in a similar manner as that of GAT (Table 1).

Though the correlation between the NCT and the GAT above 13 mmHg was moderate to good, the Bland Altman plot shows a wide variation. The Bland-Altman plot which gives the bird's eye view of the entire data set shows great variations are possible from patient to patient in terms of the agreement between values at different IOP levels (Fig 1 and 3).

If the pattern shown in figure 1 was reversed and the NCT over estimated the IOP measured with GAT at higher values the chances of missing higher IOPs would have been less making it more useful in the clinical setting. The ROC curve showed that the NCT had a poor sensitivity and specificity (around 70%) even at 13 to 14 mmHg making it a poor test to measure IOP. To make it more useful each clinician should probably study their own correlation pattern of NCT vs GAT readings (Table 3).

To the best of our knowledge this is the first study that looked at two clinicians doing the comparisons simultaneously. This makes comparisons difficult and complicated.

In conclusion, there is only a moderate correlation between NCT and the GAT readings. Measurement by NCT seems to overestimate at low ranges and underestimate at higher ranges and the crossover of the values is seen between 12 to 13 mmHg. The correlation between NCT and GAT reading is best when both the readings are corrected for corneal thickness. The clinician should do an individualized analysis of the readings got from their clinic NCT machine and his/her GAT measurements so that a clinician specific nomogram is derived.

NCT in our study is still far from the ideal tool to be the only measuring device for IOPs in the clinic. The good correlation at higher IOP ranges makes it more useful to screen for patients with high tension glaucoma and patients with high IOP in the immediate post operative settings.

References

1. Farhood QK. Comparative evaluation of intraocular pressure with an air-puff tonometer versus a Goldmann applanation tonometer. *Clin Ophthalmol Auckland NZ*. 2013;7:23-7.
2. Shalini Mohan, Satyaprakash Tiwari, Arvind Jain, Jaya Gupta, Surendra Kumar Sachan. Clinical comparison of Pulsair non-contact tonometer and Goldmann applanation tonometer in Indian population. *J Optom*. Apr 2014; 7(2): 86–90.
3. Kniestedt C, Punjabi O, Lin S, Stamper RL. Tonometry through ages. *Surv Ophthalmol*. 2008; 53:568-591
4. Carlos Gustavo V. De Moraes, Tiago S. Prata, Jeffrey Liebmann, and Robert Ritch. Modalities of Tonometry and their Accuracy with Respect to Corneal Thickness and Irregularities. *J Optom* 2008;1:43-49
5. Jennifer V. Basaiawmoit, Tarun Arora, Lt. Col. Dr. Sanjay K. Mishra. Tonometry: Guildelines for Glaucoma Investigations. All India Ophthalmological Society (2012)
6. Goldmann H. Applanation Tonometry. Transactions Second Glaucoma Conference. New York, Josiah Macy, Jr Foundation. 1957
7. Masood Alam Shah, Khalid Bin Saleem, Talat Mehmood. Intraocular pressure emasurement Goldmann applanation tonometer vs non-contact airpuff tonometer *J Ayub Med Coll Abbottabad* 2012;24(3-4)
8. Abdulrahman M. Al-Amri. Comparison of the CT80 Non-Contact Tonometer and Goldmann Applanation Tonometer. *Med. J. Cairo Univ.*, 2011 Dec;79(2):9-11
9. Moses RA. The Goldmann applanation tonometer. *Am J Ophthalmol*. 1958;46:865-869
10. Thomas R, Korah S, Muliylil J. The role of central corneal thickness in the diagnosis of glaucoma. *Indian J Ophthalmol*. 2000 Jun; 48(2):107-11.
11. Shimmyo M, Ross AJ, Moy A, Mostafavi R. Intraocular pressure, Goldmann applanation tension, corneal thickness, and corneal curvature in Caucasians, Asians, Hispanics, and African Americans. *Am J Ophthalmol*. 2003 Oct; 136(4):603-13.
12. Gupta V, Sony P, Agarwal HC, Sihota R, Sharma A. Inter instrument agreement and influence of central corneal thickness on measurements with Goldmann, pneumo-tonometer and noncontact tonometer in glaucomatous eyes. *Indian J Ophthalmol*. 2006; 54:261-265
13. PA Tonnu, T Ho, T Newson *et al*. The influence of central corneal thickness and age on intraocular pressure measured by pneumotometry, noncontact tonometry, the Tono-Pen XL, and Goldmann applanation tonometry. *Br J Ophthalmol* 2005; 89:851-854.
14. Ehlers N, Bramsen T, Sperling S. Applanation tonometry and central corneal thickness. *Acta Ophthalmol* 1975;53:34-43

15. Fogagnolo P, Capizzi F, Orzalesi N, Figus M, Ferreras A, Rossetti .Can mean central corneal thickness and its 24-hour fluctuation influence fluctuation of intraocular pressure? *J Glaucoma*. 2010 Aug; 19(6):418-23.
16. L Mosaed S, Chamberlain WD, Liu JH, Medeiros FA, Weinreb RN. Association of central corneal thickness and 24-hour intraocular pressure fluctuation. *J Glaucoma*. 2008 Mar; 17(2):85-8
17. Chakraborty R, Read SA, Collins MJ. Diurnal variations in axial length, choroidal thickness, intraocular pressure and ocular biometrics. *Invest Ophthalmol Vis Sci*. 2011;11:5121-5129
18. Moses RA. Fluorescein in applanation tonometry. *Am J Ophthalmol*. 1960;49:1149-1155

Retained orbito-sinal wooden foreign body as an unsuspected cause of epistaxis

Vikram Wadhwa, Swati Tandon, Chandala Chitguppi, Jaffer Husein Sura, Samuel Rajan, Anju Chauhan

Abstract

We describe an unusual case of a orbito-sinal wooden stick lodged in ethmoid sinus in a 42 year old male with epistaxis which was undetected for 3 months. The foreign body (FB) was removed successfully by endoscopic approach without complications.

Keywords: Orbitosinal, Epistaxis, Wooden, foreign body, Endoscopy, Trans-orbital

Introduction

Penetrating injuries of the paranasal sinuses (PNS) due to foreign bodies are rare.¹ A variety of foreign bodies like glass fragments, metal, and wood splinters can be retained in the nasal cavity and PNS following penetrating injuries of the maxillo-facial region.²

Among all the foreign bodies in the PNS, 75 per cent are found in the maxillary sinus, less than 20 percent in frontal sinus, with rare involvement of ethmoid & sphenoid sinuses.³ Transorbital ethmoidal foreign bodies are extremely rare.

We present here a rare case of transorbital penetrating wooden stick injury of the ethmoid sinus which went undiagnosed for three months.

Case report

A 42-year-old male patient presented to otolaryngology department of our hospital with history of recurrent epistaxis from left nasal cavity for the last two months not controlled by conservative management. On careful history taking, he mentioned an accidental fall from his bicycle three months back during which he had injury to left orbit due to a wooden stick.

According to the patient, the wooden stick was removed by an ophthalmic surgeon using external approach immediately after the accident as an outpatient procedure, the details of which were not available with the patient. There were no visual complaints or diplopia. The patient was asymptomatic for 1 month thereafter, when he complained of recurrent bleeding from left nasal cavity. By the time the patient presented to us, the external wound of eye had healed (Fig.1) and his only complaint was recurrent epistaxis.

No significant finding was observed on examination of the left eye except for a 0.5 cm scar medial to left medial canthus. On nasal examination, the anterior rhinoscopy was normal. On nasal endoscopic examination, a piece of wooden stick was seen in the left nasal cavity medial to middle turbinate and in the ethmoid

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Fig. 1. clinical photograph of patient showing scar mark near left medial canthus

sinus (Fig. 2).



Fig. 2. Nasal endoscopy of left nasal cavity (M- Middle turbinate, S-Septum, FB-Foreign body)

A Contrast enhanced CT scan of the PNS and orbit was performed which showed damage to lamina papyracea and ethmoid sinuses with surrounding tissue inflammation. No obvious foreign body was seen on CT scan (Fig. 3). There was no involvement of extraocular muscles or fat on CT, though tissue inflammation around medial rectus was seen. MRI scan of PNS and orbit was planned, but due to poor affordability of the patient, it could not be done.



Fig. 3. Contrast enhanced CT scan of PNS and orbit (coronal section) showing destruction of lamina papyracea with inflammation in left ethmoid sinus without any intraorbital injury (R- Right orbit, L-Left orbit)

The patient was taken up for endoscopic removal of foreign body under general anesthesia. On endoscopy, wooden stick was visualized in the ethmoid sinuses and was removed in two pieces.

A complete ethmoidectomy was done to ensure no foreign body was left behind. There was no evidence of granuloma formation in the surrounding region, probably foreign body was inert, but the surrounding mucosa was inflamed. On examination of the two wooden pieces, they were 4 cm in length and were not rotten. Culture of foreign body was not done. Postoperatively, patient was given oral antibiotics for 2 weeks and suction clearance of nasal cavity was done to remove all crusts. The patient was followed up for 2 months, during which he remained completely asymptomatic. On subsequent endoscopic examination, no foreign body was seen.



Fig. 4. FB (Wooden piece) on removal

Since, a complete ethmoidectomy was done, no foreign body was left behind.

Discussion

The trajectory taken by the penetrating foreign bodies can be quite peculiar. In our case, the wooden stick after piercing the medial region of the eye travelled medially to breach the medial wall of the orbit and finally come to lie in the left ethmoid sinus and nasal cavity medial to middle turbinate. The possible trajectory of the FB is shown in Fig. 5.

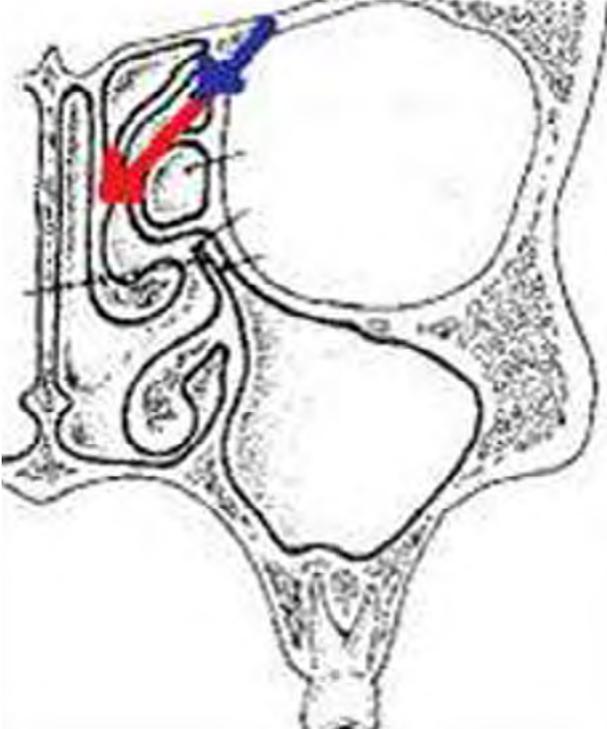


Fig. 5. Picture denoting the possible trajectory of the FB (Red line indicates the external part of the FB which was removed by the ophthalmic surgeon and the blue denotes the retained part of the FB removed endoscopically).

Wooden foreign bodies are quite peculiar compared to other foreign bodies. They may follow relatively minor trauma, as in our case. They are notorious for remaining quiescent for a long time, before presenting with a variety of complications.⁴ It is important to remember that wooden foreign bodies often break during attempted removal.⁴ The associated wound may be small and self-sealing.⁵ In our case the wooden stick broke into two pieces probably during removal by the ophthalmic surgeon and the internal piece remained undetected for 3 months and the external wound had healed completely making it difficult to detect. The external part of the FB was removed by the ophthalmic surgeon while the internal part was retained.

Complications associated with organic sinonasal foreign bodies include delayed-onset orbital granuloma, cellulitis, orbital abscess, chronic draining sinus.^{4,6} It was

surprising to note that inspite of a wooden FB being retained for 3 months the patient had no complaints other than recurrent epistaxis. The exact cause for the absence of the above mentioned complications is not known.

CT scan is the examination of choice for a suspected penetrating intra orbital FB.⁷ It is helpful to detect the FB, complications & extent of injury. In our case, CT scan revealed damage to the lamina papyracea and ethmoid sinus on the left side but no obvious FB was seen. In review of literature, there have been occasional reports of intranasal wooden foreign bodies during the chronic stage being detected on CT.⁸ But majority of the previous reports suggest that wood is often not detected on CT scan⁹ It is recommended that MRI scan should be performed after a negative CT scan in case of wooden foreign bodies.⁹ In our case, since the FB was already visualised in the nasal cavity and due to cost issues, we did not perform a MRI scan.

Endoscopic removal gives an advantage of good illumination, magnification and visualisation of critical areas and a scarless surgery. The slippage of FB into the airway can be prevented by using a choanal pack during removal. Blind attempts should not be done as it may lead to incomplete removal of FB.

Conclusion

In conclusion, we would like to emphasize that wooden foreign bodies may often present a confusing clinical picture. Their removal should be done cautiously and complete removal should always be confirmed as they are tending to break easily. It is imperative to consider a retained FB in the differential diagnosis in all cases of past trauma with unexplained symptoms. High index of clinical suspicion, careful history taking and complete physical examination cannot be replaced by radiological investigations especially in a case of intranasal wooden foreign body.

References

1. Wu MR, Shih CT, Yeh CW. Transorbital penetrating injury of the paranasal sinuses. *J Laryngol Otol.* 1998; 112: 1202-4.
2. Mohiuddin SA, Rahiman S, Sultana S. Multiple glass pieces in paranasal sinuses. *Indian J Dent Res.* 2011; 22: 847-9
3. Krause HR, Rustemeyer J, Grunert RR. Foreign body in paranasal sinuses. *Mund Kiefer Gesichtschir.* 2002; 6: 40-44.
4. Goldberg MF, Paton D. Ocular emergencies. In : Peyman GA, Sanders DR, Goldberg MF, ed. *Principle and practice of ophthalmology*, Philadelphia: WB Saunders; 1980. p. 2466.
5. Banerjee A, Das A, Agarwal PK, Banerjee AR. Late spontaneous extrusion of a wooden intraorbital FB. *Indian J Ophthalmol.* 2003; 51: 83-4.
6. Webb BD, Pereira KD, Fakhri S. Nasal foreign body as the cause of a subperiosteal orbital abscess in a child. *Ear Nose Throat J.* 2010; 89: E 11-3.
7. Vipul Arora, Usha R Kim, Shashikant Shetty, Akash D Shah. Atypical presentation of an unusual foreign body. *Indian J Ophthalmol.* 2010 Jul-Aug; 58(4): 338-339.
8. VK Anand, Phiji Philip George, Aparna Irodi, Shailesh M Prabh, Rajan Sundaresan. Missed intranasal wooden foreign bodies on computed tomography. *Indian J Radiol Imaging.* 2014; 24(1) : 72-74.
9. Takasaki K, Enatsu K, So E, Takahashi H. Fifty-four wooden toothpicks in the nasal cavity. *Otolaryngol Head Neck Surg.* 2005; 132: 669-70.



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