

Keratorefractive surgery practice in a tertiary eye care center in central India

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印度中部某三级眼科护理中心的角膜屈光手术实践

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摘要

目的: 研究印度中部患者的特征和角膜屈光手术 (KRS) 实践。

方法: 回顾性研究 2017-06/2022-04 在印度中部某三级眼科护理中心行 KRS 的患者 410 例。记录患者的人口统计学资料, 如年龄、性别、居住地 (城市或农村)、屈光不正、手术原因、最佳矫正视力、手术类型、术后随访和并发症。

结果: 410 例患者中, 324 例接受 KRS (79.0%)。其中, 200 例 (61.7%) 行激光辅助原位角膜磨镶术 (LASIK), 124 例 (38.3%) 行屈光性角膜切除术 (PRK)。研究组最终由 179 名女性和 145 名男性组成。患者平均年龄为 (25±3.5) 岁。大多数患者来自城市地区 ($n=250, 77.2%$)。右眼和左眼的平均术前显性屈光度分别为 -4.5 ± 2.1 和 -4.9 ± 2.0 。LASIK 患者双眼平均手术时间为 (15±2) min, PRK 患者双眼平均手术时间为 (17±3) min。未出现上皮向内生长、皮瓣愈合并发症或感染, 且无患者需行增强手术。角膜厚度不理想 ($n=28, 32.6%$) 是排斥手术最常见的原因。随访 1a, 3 名接受 LASIK 手术的患者出现回退 ($-0.5D\pm 1D$), 屈光度校正分别为 $-6.75D, -8.5D, -7.0D$ 。

结论: LASIK 是印度中部人群矫正屈光不正的主要手术。虽然 PRK 手术的数量很少, 但 LASIK 和 PRK 都具有良好的视力预后。高度近视选择 LASIK 时应考虑近视消退。

关键词: 准分子激光角膜切削术 (PRK); 印度中部; 角膜屈光手术; 准分子激光原位角膜磨镶术 (LASIK)

Abstract

• AIM: To study the patient characteristics and keratorefractive surgery (KRS) practice in central India.

• METHOD: The retrospective study was conducted on 410 patients who underwent KRS from June 2017 to April 2022 at a tertiary eye care center in central India. Demographic data of the patients presenting for the spectacle free vision like age, sex, residence in the form of urban or rural area, refractive error, cause for spectacle-free vision, best-corrected visual acuity, types of procedure, postoperative follow-up and complications were recorded.

• RESULTS: Among the 410 patients who presented for spectacle-free vision, 324 patients were considered for KRS (79.0%), and 200 patients (61.7%) underwent the laser-assisted *in situ* keratomileusis (LASIK) procedure, whereas 124 patients (38.3%) underwent the photorefractive keratectomy (PRK) procedure. The final study group comprised 179 female and 145 male. The mean age of the patients was (25±3.5) years. A majority of patients were from urban areas ($n=250, 77.2%$). The mean preoperative manifest refraction in the right and left eyes was -4.5 ± 2.1 and -4.9 ± 2.0 , respectively. The mean surgical time in the LASIK patient was (15±2) min and (17±3) min for both eyes in PRK. None of the patients exhibited epithelial ingrowth, flap healing complications, or infection, and none of them required enhancement. Suboptimal corneal thickness ($n=28, 32.6%$) was the most common reason for rejection. At the end of the 1-year follow up, 3 patients who underwent the LASIK procedure exhibited regression ($-0.5 D\pm 1 D$), with a refractive error correction of $-6.75 D, -8.5 D, \text{ and } -7.0 D$, respectively.

• CONCLUSION: LASIK is the predominant procedure for the correction of refractive error in the central Indian population. Although the number of PRK procedures was small, both LASIK and PRK exhibited excellent visual outcome. Myopic regression should be considered when choosing LASIK for high myopia.

• KEYWORDS: photorefractive keratectomy (PRK); central India; keratorefractive surgery; laser-assisted *in situ* keratomileusis (LASIK)

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INTRODUCTION

Refractive error (RE) is the leading cause of visual impairment^[1]. Myopia is the most common RE observed in the general population^[2–3], and as high as 70%–90%, with a prevalence of 84% reported in Taiwan^[3–4]. Patients with myopia are dependent on spectacles or contact lenses for clear vision. Refractive surgery is an attractive alternative for vision correction secondary to RE for patients seeking spectacle independence.

Refractive surgery has undergone significant changes with the development of excimer laser. Laser vision correction has been widely accepted as a useful technique for effective visual outcomes in the correction of RE.

Modalities available for RE correction include laser *in situ* keratomileusis (LASIK), small incision lenticule extraction (SMILE), laser subepithelial keratomileusis^[5], phakic iris-claw lens^[6], photorefractive keratectomy (PRK)^[7], bioptics^[8], implantable contact lenses (ICLs)^[9], and clear lens extraction (CLE)^[10]. Of these, LASIK, PRK, and SMILE are the preferred modalities for RE correction. REs are not amenable to correction due to the thin cornea being treated with ICL or CLE. However, the method of RE correction is chosen only through a thoughtful discussion between the surgeon and patient.

LASIK is currently the most popular technique for RE correction. It involves the creation of the corneal flap and ablation of the stroma equivalent to the RE. It has postoperative little pain and discomfort and early recovery after the procedure. PRK procedure involves removal of epithelium either with alcohol assisted debridement or with the excimer laser. PRK is associated with pain, discomfort and delayed visual recovery after the procedure. It is associated with stromal haze formation which may remain for a longer time. LASIK has its own complications in the form of buttonhole flaps and free caps during the procedure. Flap displacement, epithelial ingrowth and dry eye may occur in the postoperative period.

The success of the refractive procedure depends on the preoperative evaluation. A meticulous evaluation prevents intraoperative and postoperative complications.

Various centers have reported inconsistent results for RE correction by LASIK and PRK in various RE grades^[11–14]. None of the studies has focused on the patient characteristics and keratorefractive surgery (KRS) practice in the central Indian population. Therefore, the present study evaluated the baseline data on the demographics of patients undergoing KRS.

MATERIAL AND METHODS

The present retrospective record review study was conducted in a tertiary eye care center in central India after obtaining

institutional ethics clearance (No. 2243EC/Pharmac/GMC/NGP). The study followed the tenets of the Declaration of Helsinki. The records of the patients who underwent refractive surgery between June 2017 and April 2022 were retrieved. The demographic profile, RE, spectacle power, refractive workup, type of refractive surgical plan, complications, and follow-up of the patients were recorded. Preoperative workup included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refraction, slit lamp biomicroscopy examination, intraocular pressure measurement by applanation tonometry, indirect fundus examination under dilated pupil, pupillometry, Scheimpflug camera tomography (Sirius, CSO, Italy), aberrometry. All ocular aberrations were measured for a pupil diameter of 4 mm. All operative procedures were performed using the wavefront-guided VISX Star S4 Custom Vue machine (Johnson and Johnson Vision, Santa Ana, CA, USA). Eye tracker and iris registration were used in the treatment of all eyes. Manifest refraction was chosen for the treatment of all eyes. Ablation was performed based on aberration-free protocol. The treatments were aimed at emmetropia except in a few eyes with a target refraction of -0.25 D~ -0.5 D.

Surgical Technique A single surgeon (AM) performed all the procedures. Both LASIK and PRK were performed under topical 0.5% proparacaine hydrochloride drops.

Laser *in situ* keratomileusis procedure An 8-mm suction ring was applied to the limbus. A microkeratome (Moria, France) was placed on the right track and activated to pass across the cornea in a forward and reverse manner with the flap hinge on the nasal side. The vacuum was released, and the flap was lifted. The flap thickness was decided through pachymetry. Residual bed thickness was kept at 290 μ m. The flap thickness was adjusted to 130 μ m or 90 μ m depending on the RE correction and central corneal thickness. The ablation of the stroma was performed using an excimer laser. The optical zone was kept between 5.5 mm and 6 mm. The stromal bed was washed thoroughly with the help of a balanced salt solution. The flap was repositioned on the stromal bed. Postoperatively, moxifloxacin eyedrops were prescribed four times a day for 10d. Additionally, 1% prednisolone acetate eye drops were prescribed four times a day for 5d, which were tapered every 5d until 3wk. Lubricating eye drops were prescribed four times until 6mo.

Photorefractive keratectomy procedure Corneal epithelium was removed after soaking with 20% alcohol for 30s. Excimer laser was used to ablate the corneal surface with an optic zone of 6.5-mm diameter. The stromal bed was soaked with 0.2% mitomycin C (10s per dioptric power to be corrected). The surface was irrigated with balanced salt solution before 0.3% moxifloxacin and 1% prednisolone acetate eyedrops were instilled. Then, bandage contact lenses were applied for 3d. Systemic anti-inflammatory tablets were prescribed for 3d, whereas local moxifloxacin eyedrops were

prescribed four times a day for 15d. Additionally, 1% prednisolone acetate eye drops tapering over 2mo and lubricating drops four times a day for 6mo were prescribed.

Statistical Analysis The data were entered in an Excel[®] sheet [Software version 14.1.0 (110310)/2011] (Microsoft Corporation, Redmond, WA, USA), and statistical analysis was performed using SPSS version 13.0 (SPSS Inc, Chicago, IL, USA). Snellen visual acuity measurements were converted to LogMAR for statistical analysis. Continuous variables are presented in the form of mean and standard deviation (SD), whereas categorical variables are presented in the form of percentages.

Postoperative Examinations Patients were instructed to follow up for the examination on 1d, 1wk, 1 and 3mo postoperatively. The examination included slit - lamp biomicroscopy, UCDVA, CDVA, autorefractometry, manifest refraction and tonometry. Patients having corneal haze was evaluated as recommended by Fantès *et al*^[15] (0: 1/4 no haze; 0.5: 1/4 trace haze on oblique illumination; 1: 1/4 corneal cloudiness not interfering with the visibility of fine iris details; 2: 1/4 mild effacement of fine iris details; 3 and 4: 1/4 details of the lens and iris not discernible). The bandage contact lens was removed after 7d in PRK operated patients and day 1 postoperative patient in LASIK operated patients.

RESULTS

Of the 410 patients who consulted for spectacle-free vision between June 2017 and April 2022, 324 patients were considered for KRS (79.0%), and 86 patients were rejected due to various reasons. Of these patients, 200 patients underwent LASIK (61.7%), whereas 124 patients underwent PRK (38.3%). The final study group comprised 179 female and 145 male (F:M=1.2:1). The mean age of the patients at the time of surgery was 25 ± 3.5 years (range: 18–39 years). A majority of patients were from urban areas ($n = 250$, 77.2%). The urban-to-rural ratio was 3:1. The mean preoperative manifest refraction in the right and left eye was -4.5 ± 2.1 (range: 2 to 3.0 and -1 to -8.50 D) and -4.9 ± 2.0 (range: 2 to 3.5 and -1 to -8.50 D), respectively. The mean preoperative manifest cylindrical refraction in the right eye and left eye was -1.2 ± 0.9 (range: 0.5–3.5) and -1.1 ± 0.8 (range: 0.5–3.25), respectively. The range of RE correction in PRK was 0.75 D–3.00 D and it was from 4.00 D to 8.50 D in LASIK patients. The pattern of RE in the study is elaborated in Table 1. The mean surgical time in the LASIK patient was (15 ± 2) min and (17 ± 3) min for both eyes in PRK. The surgical time was calculated from the application of the speculum to the completion of the procedure in both eyes. Postoperative pain was analysed after surgery in 2 groups on the visual analogue scale on a scale of 1–10 (1=no pain and 10=worst pain).

Two patients had a RE of -8.0 and corneal thickness was $510 \mu\text{m}$. In these two patients, the optic zone diameter was 5.5 mm to keep the residual bed thickness of $290 \mu\text{m}$. No glare and halos were seen in these two patients post LASIK. The mean preoperative visual acuity was -1.1 ± 0.7 LogMAR

Table 1 Pattern of refractive error

Type of refractive error	Number of patients
Myopia	252
Compound myopic astigmatism	47
Myopic astigmatism	21
Hypermetropia	2
Compound hypermetropia astigmatism	1
Hypermetropic astigmatism	1
Total	324

in both eyes, whereas the mean postoperative visual acuity in both eyes was 0.0 ± 0.1 LogMAR. The mean pachymetry was $531 \pm 27 \mu\text{m}$ (range: 610–485) μm in the right eye and $533 \pm 27 \mu\text{m}$ (625–490) μm in the left eye. The optical zone in LASIK was $6.50 \pm 0.32 \mu\text{m}$ and the PRK group was $6.13 \pm 0.30 \mu\text{m}$. The residual bed thickness in the LASIK group was $299 \pm 0.22 \mu\text{m}$ (excluding flap thickness) and $310 \pm 0.10 \mu\text{m}$ in the PRK group. The mean residual spherical error in the LASIK group is $0.20 \text{ D} \pm 0.15 \text{ D}$ and $0.15 \text{ D} \pm 0.11 \text{ D}$ in the PRK group ($P = 0.12$). 90% of eyes in the LASIK group were $\pm 0.9 \text{ D}$ and 89% of eyes in the PRK group were in the range of $\pm 0.11 \text{ D}$. UDVA was 20/20 in 98% of eyes in LASIK and 97% in the PRK group. Pain score in the PRK group postoperatively was 5.23 ± 0.11 and 1.23 ± 0.12 in the LASIK group ($P = 0.02$). 98% of patients were satisfied in LASIK and 80% in the PRK group on the first postoperative day. On the 7th postoperative day, 99.2% of patients were satisfied in both the groups.

The three main reasons for which patients presented to us for KRS were the need for spectacle independence, cosmetic reasons, and job purposes (Table 2). Most of the patients presented due to the need for independence from spectacles ($n = 231$, 71.3%). PRK was done on three patients for the purpose of job.

Retinal barrage was performed in three patients before considering them for KRS. Anterior stromal haze was observed in both eyes of one patient undergoing the PRK procedure that persisted for 9mo. Preoperative RE for the right of the patient was -4.50 D sphere and -3.50 D cylinder, whereas that for the left eye was -3.00 D sphere and -4.00 D cylinder. In patients who underwent LASIK, two patients exhibited interface haze that persisted for 1mo, 1 patient exhibited micro striae, and one patient exhibited an epithelial defect, which persisted for 5d. At the end of the 1-year follow up, 3 patients exhibited regression ($-0.5 \text{ D} \pm 1 \text{ D}$). These patients underwent the LASIK procedure. The RE correction in these patients was -6.75 D , -8.5 D , and -7.0 D . None of the patients exhibited epithelial ingrowth, flap healing complications, or infection, and none of them required enhancement at the 1-year follow up.

Suboptimal corneal thickness ($n = 28$, 32.6%) was the most common reason for rejection of patients for KRS, followed by high myopia ($n = 20$, 23.3%), unstable refractive power ($n = 16$, 18.6%), and keratoconus ($n = 11$, 12.8%; Table 3).

Table 2 Reasons for presentation of patient for keratorefractive surgery

Reasons	Number of patients (%)
Dependency on spectacle	231 (71.3)
Cosmetic	66 (20.4)
Job purpose	27 (8.3)
Total	324

Table 3 Reasons for rejection of patient for keratorefractive surgery

Reasons for rejection	Number of patients (%)
Suboptimal central corneal thickness	28 (32.6)
High myopia (>11.0D)	20 (23.3)
Spectacle not stable	16 (18.6)
Keratoconus	11 (12.8)
Herpetic keratitis history	6 (7.0)
Collagen diseases	3 (3.5)
Anxiety about procedure	2 (2.3)
Total	86

DISCUSSION

LASIK and PRK are the two most commonly performed procedures for RE correction. The safety and efficacy of both the procedures have been established in numerous studies^[16-17]. However, the success of both procedures depends on a proper preoperative evaluation.

The present study exhibited an urban to rural ratio of 3:1. This disparity could be due to the lack of awareness of refractive surgery in the rural population. A Medline search could not demonstrate any study exhibiting such differentiation.

The proportion of female who underwent KRS was higher than that of male in the present study, with a female to male ratio of 1.2:1. We could not elucidate the exact reason for the female preponderance; however, it could be due to the higher prevalence of myopia ≥ 5 D in the female population^[18]. Another reason could be that females are more prone to undergo KRS for cosmetic reasons.

The present study considered manifest RE in the range of 1 D ~ -8 D sphere and 0.5 D ~ 3.5 D cylinder and exhibited superior postoperative visual outcome (0.0 ± 0.1 LogMAR) at the 1-year follow up. This finding is concurrent with that of Duffey and Leaming^[19] who reported the range of RE in the US between +3.00 D and -8.00 D. Chua *et al*^[20] studied 18-year LASIK outcomes for myopia in 53731 Asian eyes and demonstrated the safe and effective refractive predictability of LASIK. Yuen *et al*^[21] demonstrated the long-term efficacy of the LASIK procedure in low, moderate, and high myopia.

PRK has also exhibited promising results in all types of REs and has been preferred to LASIK even in high myopes^[22]. The development of the trans-PRK procedure ensured a single-step procedure with superior outcomes^[23-24]. However, single-step PRK is possible with an Amaris excimer laser (Schwind eye-tech solution). All the KRSs were performed with the VISX Star S4 Custom Vue machine in the present

study. Therefore, we had to perform PRK in two steps. Literature has exhibited comparable results in terms of postoperative best-corrected visual acuity, safety, and efficacy in a 3.5-month follow-up period in trans-PRK versus 2-step PRK^[24-25].

In PRK, the size of the optic zone was 6.5 mm. Small optic zone size (<6.0 mm) is associated with glare and halos in the scotopic condition^[26-27] and large optical zone is predicted to have less initial overcorrection and less myopic regression^[28]. The range of RE correction in PRK patients in our study was 0.75 D ~ 3.00 D. Therefore 6.5 mm optic zone adjustment was possible. In LASIK patients, the range of RE was 4 D ~ 8.50 D. Two patients had a RE of -8.0 D and corneal thickness was 510 μ m. To compensate for the residual bed thickness of 290 μ m optic zone was kept in these two patients. No glare and halos were seen in these patients post LASIK.

We studied the surgical time in both groups. The surgical time in the PRK group (17 ± 3 min) was marginally longer than in the LASIK group (15 ± 2 min). 15 ± 2 min and for both eyes in PRK. We could not elucidate the exact reason for this. But it could be due to alcohol debridement of epithelium and the use of mitomycin C after the procedure and copious irrigation by balanced salt solution for the removal of mitomycin C after its application. To the best of our knowledge, no comparison of surgical time between LASIK and PRK was noted in the literature. However, Kaluzny *et al*^[29] compared the surgical time between trans-PRK and alcohol assisted PRK and found out surgical time in trans-PRK was 35% less than alcohol assisted PRK.

The postoperative pain in the PRK group (5.23 ± 0.11) was more than that in the LASIK group (1.23 ± 0.12 , $P = 0.02$). The removal of epithelium in PRK could be the cause of pain in PRK as epithelium is covered by the flap in LASIK cases. Kaluzny *et al*^[29] have also shown that PRK patients exhibited more pain scores. Our observation on pain was in contrast to Aslanides *et al* and Fadlallah *et al*^[30-31] who have shown less pain in eyes undergoing trans-PRK.

The mean residual spherical error in both groups was correlating and no statistical difference was seen (LASIK group was $0.20 \text{ D} \pm 0.15 \text{ D}$ and PRK group was $0.15 \text{ D} \pm 0.11 \text{ D}$, $P = 0.12$). 90% of eyes in the LASIK group were $\pm 0.9 \text{ D}$ and 89% of eyes in the PRK group were in the range of $\pm 0.11 \text{ D}$. Similar to any other surgical procedure, KRS has potential complications. Although corneal haze may occur after PRK, the introduction of mitomycin C has reduced its occurrence^[32]. In the present study, one patient undergoing PRK exhibited anterior stromal haze in both eyes, which persisted for 9mo. The preoperative RE of the patient was a -4.50 D sphere and -3.50 D cylinder in the right eye and a -3.00 D sphere and -4.00 D cylinder in the left eye. The persistent corneal haze in this patient could be due to the large cylindrical value of RE. Various factors contributing to the corneal haze include poor compliance to the prescribed medicines, poor follow up, and large preoperative RE. The patient has been prescribed loteprednol etabonate eye drops, which were tapered over

9mo. The patient improved to 20/30 at the end of 9mo. Among the LASIK-operated cases, 2 patients demonstrated interface haze, which persisted for 1mo. The haze responded to local steroids, and no recurrence was observed in both cases in the follow-up period.

At the 1-year follow up, 3 patients exhibited myopic regression; however, no action was taken because the residual stromal bed in these patients was (285 – 290) μm . Preoperative RE in these patients was on the higher side (-6.75 D, -8.5 D, and -7.0 D). A long-term study reported that myopic regression occurs between 3mo and 15a after LASIK^[32]. Kymionis *et al*^[33] also observed myopic regression in a 11-year follow-up period in patients who underwent LASIK for myopia. Most of the myopic regression has been observed in patients who underwent LASIK for high myopia^[32-33]. Myopic regression could be helpful if it develops in the pre-presbyopic age group for spectacle-free near vision. However, both the patient and surgeon should be aware of myopic regression, particularly in case of high myopic LASIK.

Another crucial complication of LASIK is epithelial ingrowth, which may lead to decreased vision if it approaches in the pupillary area. The incidence of this complication is between 0% and 20%^[34]. However, we did not encounter this complication in our study.

Patients undergo KRS for various reasons. The most common reason in the present study was the need for independence from spectacles ($n = 117$, 55.7%), followed by cosmetic reasons ($n = 66$, 31.4%), and job purpose ($n = 27$, 12.9%). PRK was done in three patients which was requirement for the job (1.4%, 3/210).

Although LASIK and PRK are safe procedures for spectacle-free vision, certain limitations exist for considering patients for the procedure. For long-term safety and efficacy of the procedure, factors that can harm vision in the long course must be identified. In the present study, 86 (29.1%) out of 296 patients were rejected due to various reasons. Literature suggests that the rejection rate varies from 21% to 34%^[35-38]. The most common reason for rejection in our study was suboptimal corneal thickness ($n = 28$, 32.6%). Sharma *et al*^[38] also reported suboptimal corneal thickness (55.1%) as the main cause of rejection for KRS. Various authors have reported different reasons for rejection. Mahfouth *et al* and Hori-Komai *et al*^[36-37] reported high myopia (>11.0 D) as the most common reason for rejection. Alsulami *et al*^[35] reported unstable refraction as the most common reason for not proceeding to KRS in the Saudi population. Variations in the rejection rate and reasons for rejection could be due to differences in the geographical location and strategies exercised to collect the data.

The present study is the first to investigate the efficacy of LASIK and PRK and explore causes of rejection for KRS in the central Indian population, and it may serve as a guide for refractive surgeons.

The present study has certain limitations. The retrospective

nature of the study introduces bias. Additionally, the comparison between LASIK and PRK could not be performed due to the disparity in the number of patients in both groups. LASIK was considered by the surgeon as the choice of the procedure unless there was a demand for PRK (job purpose). Being a retrospective study randomisation of the patients was not possible. A single surgeon was involved in the operative procedure in one center. Therefore, a comparison was not possible with other surgeons and centers. Future prospective studies to evaluate the results of both procedures would further strengthen the findings of this study.

CONCLUSION

LASIK is the predominant procedure for RE correction in the central Indian population. Both LASIK and PRK exhibited excellent visual outcomes, although the total number of PRK procedures was small in the study. Myopic regression should be considered while opting for LASIK for high myopia. Finally, the most common reason for rejection is the suboptimal corneal thickness.

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