

THESIS

**OUTCOMES OF REFRACTIVE LASER SURGERY AT EAGLE
EYE LASER CENTRE, NAIROBI: A RETROSPECTIVE CASE
SERIES**

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AWARD OF DEGREE OF MASTER OF MEDICINE IN
OPHTHALMOLOGY**

DECLARATION

I declare that this thesis is my original work and has not been presented for the award of a degree in any other university.

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LIST OF ABBREVIATIONS

| | | |
|--------------------|---|---|
| BCVA | – | best corrected visual acuity |
| BSCVA | – | best spectacle corrected visual acuity |
| D (dioptre) | – | unit of lens power; reciprocal of the second focal length |
| DC | – | (diopter cylinder) refractive correction as measured in cylinders |
| DS | – | (diopter sphere) refractive correction as measured in spheres or spherical equivalent |
| DLK | – | diffuse lamellar keratitis |
| Epi-LASIK | – | epipolis laser in situ keratomileusis |
| FDA | – | Food and Drug Administration |
| FLEx | – | femtosecond lenticule extraction |
| LASEK | – | laser subepithelial keratomileusis or laser epithelial keratomileusis or laser-assisted subepithelial keratectomy |
| LASIK | – | laser <i>in situ</i> keratomileusis |
| MRSE | – | manifest refraction spherical equivalent |
| PRK | – | photorefractive keratectomy |
| ReLEx | – | refractive lenticule extraction |
| RSBT | – | residual stromal base thickness |
| SMILE | – | small incision lenticule extraction |
| Trans PRK | – | transepithelial photorefractive keratectomy |
| UCVA | – | uncorrected visual acuity |

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ABSTRACT

Study title

Outcomes of refractive laser surgery at Eagle Eye Laser Centre, Nairobi: A retrospective case series.

Study objective

To evaluate the outcomes of refractive laser surgery at Eagle Eye Laser Centre, Nairobi, Kenya from 6th October 2010 to 31st December 2016.

Methodology

The study was a retrospective case series on the outcomes of refractive laser surgery in 785 eyes followed up over a 6-month period. Different degrees of refractive errors ranging from +4.75DS to -10.00DS were treated. 449 eyes underwent LASIK, 304 eyes underwent PRK and 32 eyes underwent presbyLASIK. Operated patients were evaluated at week 1, month 1, month 3 and month 6 follow up visits. Retreatments were also done where necessary. The postoperative results were categorized in terms of efficacy, stability and safety.

Results

At 6 months, combining both LASIK and PRK, a postoperative UCVA of 6/6 or better was achieved in 85.6% of the eyes. There was no statistically significant difference between the two procedures. However, visual recovery was noted to occur faster following LASIK as compared to PRK. A postoperative MRSE of within 0.50DS was achieved in 93.5% of the eyes in both groups, with no statistically significant difference between these two procedures. Both procedures were stable with minimal regression at final follow up visit. Both procedures were also safe with less than 2% of the operated eyes losing 2 or more Snellen lines of BCVA, and recording few intraoperative and postoperative complications.

Conclusion

Both LASIK and PRK are effective, stable and safe surgical methods for correction of refractive errors. However, recovery of vision is faster following LASIK as compared to PRK regardless of the refractive error. Research on long term efficacy, stability and safety, and patient satisfaction following keratorefractive surgery should be carried out to increase the available knowledge on keratorefractive surgery.

CHAPTER 1: INTRODUCTION, BACKGROUND AND LITERATURE REVIEW

1.1 Introduction and background

Surgical correction of refractive errors involves alteration of the cornea or lens, the two main structures responsible for refraction in the eye. The main goal of refractive surgery is to reduce dependence on spectacles or contact lenses for routine daily activities.^{1,2} Keratorefractive procedures create a new corneal radius of curvature thereby changing its refractive power.³

Since the introduction and development of the excimer laser, there has been remarkable progress in refractive surgery techniques, safety, efficacy, and predictability of surgical outcomes.^{3,4}

Laser refractive procedures are among the most common elective surgical procedures done worldwide. Of these, photorefractive keratectomy (PRK) and laser *in situ* keratomileusis (LASIK) are the most common.^{1,3,4} LASIK is done in as many as 71% to 92% of all patients who undergo keratorefractive surgery.³ However, surface ablation techniques such as photorefractive keratectomy (PRK) are still widely available and a sizeable number of surgeons continue to prefer PRK.⁴⁻⁶

Newer surgical techniques have recently evolved for more customized and precise correction. Such procedures include refractive lenticule extraction (ReLEx), which has become increasingly popular, with more than 80,000 eyes having undergone successful treatment to date.⁷

The number of keratorefractive procedures being performed has increased rapidly over the last 30 years.³⁻⁷ Moreover, there has been an increase in awareness of refractive surgery and the number of people taking up refractive surgical procedures in developing countries. Analysis of the outcomes of these procedures including efficacy, safety and stability is key in understanding the suitability of these procedures particularly in regions with limited resources.

1.2 Literature review

1.2.1 Laser keratorefractive procedures

Laser keratorefractive procedures correct myopia, hyperopia and astigmatism within a range of +6 to -14 dioptres (D).^{1,2} Refraction should be stable, and within 0.50 DS for a year or more before surgery.¹ Patients should not have used soft contact lenses for at least 2 weeks, and rigid gas permeable contact lenses for at least 3 weeks, before surgical assessment.²

Laser refractive procedures include:

1. Surface ablation procedures: photorefractive keratectomy (PRK), laser subepithelial keratomileusis (LASEK), epipolis laser *in situ* keratomileusis (Epi-LASIK), and trans-epithelial photorefractive keratectomy (Trans-PRK).
2. Lamellar procedures: Laser *in situ* keratomileusis (LASIK) using microkeratome or femtosecond laser.
3. Refractive lenticule extraction (ReLEx) procedures: femtosecond lenticule extraction (FLEx), and small incision lenticule extraction (SMILE).

LASEK, Epi-LASIK and Trans-PRK are not available at Eagle Eye Laser Centre. Femtosecond laser and ReLEx procedures are currently not available in Kenya.

1.2.2 Factors affecting outcomes of laser refractive surgery

1.2.2.1 Laser effects

The effects of laser on the cornea are dependent on the laser's wavelength and ablation zone. These parameters are variable and machine dependent. In recent years, efficacy has been increased by using computer-controlled enhancements such as pupil tracking and anatomical registration.^{1,2}

Surface ablation procedures and LASIK use excimer laser to remove a discrete volume and depth of corneal tissue.^{1,2} This process, known as photoablation, is done using a 193 nm Argon-Fluoride excimer laser.

The size of the ablation zone is determined by the pulse duration and frequency. It is dictated by the Munnerlyn formula.^{1,8} Deeper and wider ablation zones are used in the

correction of larger errors, but take longer to heal. This leads to higher regression rates and less predictable outcomes.^{9,10} Smaller ablative zones are associated with complications such as glare, halos and starbursts.¹¹ High laser energy causes increased stromal tissue temperature, which worsens corneal haze, particularly in surface ablation procedures.¹² Comparative studies have reported less incidence of haze, and better outcomes, when using intraoperative mitomycin C (0.02%) during surface ablation procedures.^{2,13,14}

1.2.2.2 Corneal factors

1.2.2.2.1 Corneal biomechanics

The biomechanical and wound healing properties of the cornea determine the efficacy and stability of refractive surgery.^{9,10} The intensity and overall pattern of wound healing following keratorefractive procedures depend on the ablation zone, refractive procedure, patient wound healing properties, and modification of the normal wound healing processes.

Surface ablation techniques generally have a longer duration of epithelial and stromal healing, and subsequently longer regression periods.¹⁰ Modification of wound healing may be needed to reduce the accompanying cellular response following surgery. This may be done using steroids, non-steroidal anti-inflammatory drugs (NSAIDs), mitomycin C or target specific modulators such as transformin growth factor beta.¹³⁻¹⁶

1.2.2.2.2 Corneal imaging

Corneal topography, keratometry and pachymetry are important in determining whether the patient qualifies for refractive surgery and which procedure suits them best.^{6,17,18}

Generally, corneal ectasia is considered a contraindication for excimer laser procedures, and detection of ectasia (including forme fruste keratoconus) may disqualify patients from surgery.^{17,18} Pre- or intra-operative residual stromal bed thickness (RSBT) is important in determining the choice of refractive surgery. If RSBT is projected to be less than 250 micrometers following surgery, a surface ablation procedure may be a better option.^{1,18} However, Kymionis et al concluded that in patients with thin corneas

(preoperative central corneal thickness of between 470 and 498 micrometers), LASIK was still safe and predictable for myopic refractive corrections.¹⁹

Incorporation of wavefront analysis parameters creates ablation profiles that are customized for individual patients, thus improving post-operative outcomes and reducing optical aberrations.^{1,20,21} Oshika et al reported greater total aberrations after custom LASIK compared with custom PRK, suggesting that flap creation may cause more aberrations.^{20,21}

1.2.2.3 Pupil size

Pupil size greater than the effective optical zone decreases the overall visual quality.^{1,21-23} Current lasers incorporate larger optical and transition zones, enabling surgery to be done on patients with larger pupils with a decrease in the incidence and severity of night vision complications.²³ However, some studies suggest that large daytime pupil size is much less critical than previously supposed, with no correlation between night vision complications and pupil size.^{23,24}

1.2.2.4 Intraocular pressure (IOP)

Both LASIK and PRK may induce a gradual forward shift of the cornea. Eyes with higher intraocular pressure are more predisposed to the anterior shift of the cornea. This reverses the photoablative effect, particularly in myopes, and may also put the patient at risk of post-surgical ectasia.^{25,26}

Keratorefractive surgery may also have an influence on IOP. During flap creation in LASIK, the IOP is transiently but significantly elevated, potentially aggravating optic nerve damage.^{1,2} Furthermore, refractive laser procedures reduce corneal thickness resulting in falsely low IOP readings postoperatively.^{1,27} Long-term postoperative topical steroids may cause a marked elevation of IOP in steroid responders.¹ For these reasons, postoperative monitoring of IOP may become more difficult.

1.2.2.5 Patient factors

Photoablative procedures are elective procedures and careful pre-operative evaluation is critical before any patient is scheduled for surgery. Various occupational requirements, awareness, availability, cost and personal preferences affect the specific choices for correction in any individual patient.^{1,27}

Laser refractive surgery can be done at any age, as long as the patient and their eye is healthy, and the refraction is stable for at least 1 year.^{1,27-32} However, Hersh et al reported that older age is a risk factor for retreatment following LASIK. In their study, more than 10% of the patients above the age of 40 who underwent LASIK required retreatment.³³ In a separate study to assess the outcomes of PRK in patients with an average age of 38 years, Hersh et al concluded that an individual's likelihood of having an uncorrected visual acuity of 20/40 or better decreases by approximately 8% with every additional year of age.³⁴

Patients with well controlled and mild systemic disease (including atopy, collagen vascular disease, diabetes mellitus and human immunodeficiency virus), with no ocular involvement, may be suitable candidates for laser refractive surgery.^{1,28} LASIK is preferred in these patients due to a faster healing time as compared to PRK.¹ Active infection or intra-ocular inflammation is a contraindication for laser refractive surgery, and a history of herpetic keratitis is of particular concern as application of the laser can potentially stimulate herpes simplex virus re-activation.^{1,2,27} Laser refractive surgery is also contraindicated in pregnant or nursing women, due to the hormone-related increase in corneal curvature, unstable refraction, and increased risk of postsurgical ectasia.²⁸

Due to the absence of a flap, PRK is preferred in patients who have undergone previous corneal surgery, and in patients predisposed to trauma such as those in the military and in sports.^{1,2,27}

1.2.3 Assessment of outcomes of laser refractive surgery

A standard guideline for reporting refractive surgery outcomes was proposed by Waring et al and further revised by Kock et al.^{35,36} They include assessment of efficacy, stability, and safety of each of the procedures.

1.2.3.1 Efficacy

Efficacy is assessed by determining the postoperative uncorrected visual acuity (UCVA), reported as the proportion of patients achieving a postoperative UCVA of equal to or better than 6/6 (or 20/20), and/or 6/12 (or 20/40); and the proportion of patients with a manifest refraction spherical equivalent (MRSE) of within 0.50 and/or 1.00 DS of the intended correction.

1.2.3.1.1 Outcomes for myopia

a) Low to moderate myopia (spherical equivalent of less than -6.00 DS)

Studies assessing the outcomes of PRK and LASIK on low to moderate myopia reported more than 60% of the patients achieving UCVA of 20/20 or better after at least 6 months of follow up in both groups.^{27,37-39} UCVA of 20/40 was achieved in around 90% of eyes in both groups.^{27,37,39-41} Studies differ as to which one of the two procedures produces higher proportions of eyes with UCVA of 20/20 or better.^{37,40}

MRSE of within 0.50 DS of the targeted correction was achieved by more than 60% of eyes in most of the PRK studies, and by more than 70% of eyes in most of the LASIK studies.^{27,38-40} MRSE of within 1.00 DS of the intended correction was achieved in more than 90% of all cases in both the PRK and the LASIK groups.^{27,39,40} Lee et al reported higher values of MRSE of within 0.50 DS and 1.00 DS of the intended correction in the PRK group, while Dirani et al reported higher values for LASIK.^{37,40}

A higher proportion of patients achieved UCVA of 20/20 or better following use of wavefront guided laser platforms as compared to conventional laser ablation, for the treatment of low to moderate myopia using LASIK.²⁷

b) High myopia (Spherical equivalent of more than -6.00 DS)

Laser refractive surgery for high myopia has been associated with more unpredictable outcomes, particularly in higher levels of myopia.^{27,39-45}

In several reviews of eyes with high myopia that underwent PRK, less than 50% of the eyes achieved a UCVA of 20/20 or better, with worse outcomes being reported in higher errors.^{40,43,44} The corresponding outcome in the LASIK studies was slightly higher.^{27,39,40,42-45} UCVA of 20/40 or better was higher in both groups ranging from 60% to 90%.^{27,39-42,44-45}

MRSE of within 0.50 DS was attained in less than 70% of the eyes postoperatively in both of the PRK and LASIK studies.^{27,39,44,45} MRSE of within 1.00 DS of the intended correction was about 80% in both PRK and LASIK groups.^{27,39,40}

In a meta-analysis comparing the efficacy of PRK and LASIK for myopia, Shortt et al reported that more LASIK patients had a UCVA of 20/20 after a year. Additionally, significantly more LASIK patients were within 0.50 DS of the target refraction.³

1.2.3.1.2 Outcomes for hyperopia

Laser correction of hyperopia remains a challenge in refractive surgery despite significant technological advances.^{22,46}

For low to moderate hyperopia (up to +5.00 DS), results from several studies have shown that both PRK and LASIK are of largely of similar efficacy. In both groups, most studies showed UCVA of 20/20 or better being achieved in more than 50% of the eyes, while UCVA of 20/40 or better was achieved in about 90% of the eyes.^{22,27,46,47}

MRSE of within 0.50 DS of the intended correction was achieved in more than 60% of the patients in both groups, with slightly higher values in the PRK group.^{22,27,47} MRSE of within 1.00 DS was achieved in more than 70% of patients in both groups with slightly higher values recorded for the LASIK group.^{27,47}

The outcomes were slightly higher in terms of UCVA and MRSE following wavefront guided LASIK correction for hyperopia, as compared to conventional laser.²⁷

Correction of high hyperopia is however less predictable and the cutoff appears to be around +5.00 DS.^{22,27,46} However, Tabarra et al concluded that LASIK is safe and effective in the treatment of hyperopia from +0.50 to +11.50 DS. In their study, 44% of the eyes achieved UCVA of 20/20 or better, and 97.5% of them achieved 20/40 or better. MRSE of within 1.00 DS of the intended correction was reported in 84% of the eyes.⁴⁸

1.2.3.2 Stability

Stability is measured by determining the change in MRSE over a defined time interval. It dictates the predictability of the final result after a given follow up period. MRSE itself takes about 3 to 6 months to stabilize, depending on the size of the error corrected. During the first post-operative months, corneal wound healing causes a partial reversal of the photoablative effects resulting in a return toward the original refractive error. This phenomenon is known as regression, and it is a natural component of the healing process.^{1,27,41}

Refractive stability must be achieved before any decision is made regarding possible retreatment of the correction.¹

In both PRK and LASIK, stabilization takes longer in higher corrections, both for myopia and hyperopia.^{9,10,40,44} Myopic regression rates of less than 1% have been reported in most studies of low to moderate myopia, with rates of about 3% in higher myopic corrections.^{41,45} Higher regression rates have been reported in hyperopic corrections as compared to myopic corrections^{1,27,46} Stability measures reported in LASIK studies are superior to those in PRK studies, with higher rates of retreatment in PRK corrections.^{40,44,49}

In both procedures, re-treatment rates vary from 1 % to 11%, based on surgical experience, patient demands, type and degree of refractive error and regression rates.¹

1.2.3.3 Safety

The safety of refractive surgery is determined using the percentage of patients with a postoperative loss of 2 or more Snellen lines of best corrected visual acuity (BCVA), and the incidence of surgical complications.

1.2.3.3.1 Loss of best corrected visual acuity (BCVA) or best spectacle corrected visual acuity (BSCVA)

In both PRK and LASIK the number of eyes losing 2 or more lines of BCVA increases with greater refractive corrections.^{27,40} The percentage is higher following PRK than LASIK in similar corrections.^{3,22,27,41}

In several studies less than 2% of those with low to moderate myopia develop a loss of BCVA of 2 or more Snellen lines following PRK or LASIK. The number is higher in high myopia (about 4%), and even higher in hyperopia (about 6%).^{27,39,41,47}

Loss of BCVA may result from intraoperative or postoperative complications, and may also be attributed to the learning curve associated with the different techniques.³⁹

Moreover, patients with high errors may have difficulty visualizing the fixation light of the excimer laser, resulting in eccentric ablation and decentration.³⁹

1.2.3.3.2 Incidence of surgical complications

Intraoperative complications occur more frequently in LASIK, and subsequent postoperative complications are almost always related to events that occur during surgery. Many complications unique to LASIK are microkeratome-related, including flap complications (incidence of up to 10%), and intraoperative epithelial defects (incidence of up to 10%).^{27,39,50,51}

Dry eye is more common after LASIK than after surface ablation, with reports of up to 48% of all patients experiencing it to varying degrees.⁵⁰ Surface ablation procedures are less likely to cause dry-eye syndrome because they avoid flap formation and ablate the more superficial nerve endings.¹

Diffuse lamellar keratitis (DLK) is a nonspecific, post-LASIK, sterile inflammatory response to a variety of mechanical and toxic insults. It has an incidence ranging from 0.4% to 19%, and occurs more frequently with femtosecond laser keratomes than microkeratomes.^{27,51,52} Clinically significant epithelial ingrowth occurs if the epithelium is advancing toward the visual axis or triggers overlying flap melting. It occurs in about 2% of LASIK surgeries.^{11,53} Post-surgical corneal ectasia occurs more commonly following LASIK, particularly with higher corrections, at an incidence of less than 1%.^{12,54}

Surface ablation procedures have a higher intensity of postoperative discomfort, corneal haze, and a longer duration of visual recovery, particularly in the treatment of higher refractive errors.^{4,5,12,27} Visually significant haze occurs in 2 to 6% of patients postoperatively.²⁷ Greater amounts of correction and smaller ablation zones may result in a higher incidence of postoperative corneal haze. The severity of the haze is time dependent, peaking in intensity at 1-2 months and gradually diminishing over the following 6-12 months. Late-onset corneal haze may occur several months or even a year or more postoperatively. Judicious use of adjunctive mitomycin C has markedly reduced the incidence of haze.^{1,2,13,14}

Optical aberrations, residual refractive errors, regression and subsequent retreatment may occur following all forms of laser refractive surgery. Higher rates of retreatment are reported following PRK as compared to LASIK.^{44,49} Hersh et al reported that the

rate of retreatment following LASIK was higher in larger corrections, pre-existing astigmatism and in older patients.³³ Incorporation of wavefront analysis parameters improves post-operative outcomes by reducing optical aberrations.^{1,20,21}

Infectious keratitis has been reported in up to 1.5% of refractive surgeries with a higher risk in surface ablation as compared to LASIK, due to longer durations of healing.^{1,44,55}

Other complications common to all laser refractive procedures include laser and steroid induced reactivation of herpes simplex keratitis, glaucoma and cataracts.¹

CHAPTER 2: JUSTIFICATION

2.1 Study Rationale

There has been an increase in awareness of refractive surgery and the number of people taking up refractive surgical procedures in developing countries.

Currently, only a few studies have been reported from developing countries that conclusively describe the outcomes of keratorefractive surgery. To date, there is no published data available on the numbers and outcomes of keratorefractive surgeries done in Kenya. It was therefore important to carry out an audit to establish whether the outcome of these procedures is suitable and acceptable in regions with limited resources.

2.2 Objectives

2.2.1 Broad objective:

To evaluate the outcomes of refractive laser surgery in Eagle Eye Laser Centre, Nairobi, Kenya from 6th October 2010 to 31st December 2016.

2.2.2 Specific Objectives:

1. To assess the visual outcomes of the refractive laser procedures
2. To determine the stability of the correction following refractive laser surgery
3. To determine the complications associated with the refractive laser procedures
4. To compare LASIK and PRK in terms of visual outcomes, stability and safety

CHAPTER 3: MATERIALS AND METHODS

3.1 Study design

Retrospective case series.

3.2 Study setting

The study was conducted at Eagle Eye Laser Centre, Nairobi, Kenya. Eagle Eye Laser Centre is a subsidiary of Hurlingham Eyecare Services (HECS) Holdings, and is located in two branches within Nairobi – Lavington and Ngong Road.

The centre provides eye treatment services including eye surgery, and was chosen because it is one of the four largest centres in the country that provide keratorefractive surgery. More than 400 patients had undergone keratorefractive surgery between the inception of keratorefractive surgical procedures in 2010, and the end of the study period in 2016. All surgeries were performed by 4 surgeons, and patients were reviewed preoperatively and postoperatively as described below (see 3.9 Data collection procedure).

3.3 Study period

6th October 2010 to 31st December 2016.

3.4 Study population

All patients who underwent refractive laser surgery in Eagle Eye Laser Centre, over the study period.

3.5 Sample size

The following formula was used to calculate the required sample size for the study:

$$n = \frac{NZ^2P(1 - P)}{d^2(N - 1) + Z^2P(1 - P)}$$

Where

- n = sample size
- N = size of the target population = 50 x 6 years = 300 (according to the registry book, about 50 eyes undergo primary laser refractive surgery in Eagle Eye Laser Centre per year. The study period was 6 years i.e. between 6th October 2010 and 31st December 2016).

- Z = confidence interval. Typical levels of confidence for surveys are 95%, in which case Z was set to 1.96
- P = the estimated proportion of population value, in this case estimated failure rate = 30%
- d = margin of error = 2.1%

$$n = \frac{300 \times 1.96^2 \times 0.30 (1 - 0.30)}{0.021^2(300 - 1) + 1.96^2 \times 0.30 (1 - 0.30)}$$

$n = 258$ eyes

Thus to correct for finite population, the following formula was used:

$$\frac{N' \times X}{X + N - 1}$$

Where:

- N' = population size (assumed to be 100,000 if the actual value is unknown)
- X = previous sample size calculated

$$\frac{100,000 \times 258}{258 + 100,000 - 1}$$

After correcting for finite population, $n = 257.3$

Then, the following formula was used for the study to have an adequate power of 80%.

$$n^1 = \frac{n}{1 + \frac{n}{N}}$$

Where:

- n = sample size after population correction
- N = previous sample size calculated

$$n' = \frac{257.3}{1 + \frac{257.3}{258}}$$

Therefore, the minimum sample size required for this study to have adequate power of 80% was 129 eyes.

3.6 Inclusion criteria

Any patient who underwent refractive laser procedures in Eagle Eye Laser Centre within the study period.

3.7 Exclusion criteria

1. Patients who underwent cataract surgery and had refractive laser surgery as an enhancement procedure during the study period.
2. Patients who had had previous refractive surgery (corneal or lenticular) prior to the study period.

3.8 Outcome measures

A reliable refraction was key in the assessment of primary outcome measures.

3.8.1 Primary outcomes:

1. Post-operative uncorrected visual acuity (UCVA) at week 1, month 1, month 3, and month 6 follow up visits.
2. Manifest refraction spherical equivalent (MRSE) 6 months after surgery.

3.8.2 Secondary outcomes:

1. Proportion of patients with postoperative loss of 2 or more lines of best corrected visual acuity (BCVA) on the Snellen chart after 6 months.
2. Incidence of intraoperative and post-operative complications.

3.9 Materials

A pre-designed questionnaire was used to collect the data (see Appendix 1).

3.10 Data collection procedure

The patient's name, age, date of surgery/follow-up visit, and hospital number were obtained from the clinic and theatre records. This information was then used to retrieve the medical records of all patients who underwent the procedures and entered into the pre-designed questionnaire.

All patients were evaluated preoperatively where uncorrected visual acuity (UCVA), refraction, best corrected visual acuity (BCVA), slit-lamp biomicroscopy, pachymetry and any other necessary tests were done.

All surgeries were performed by 4 surgeons (KK, DI, WK, HG) using the same technique and protocol. Refraction was confirmed by the surgeon prior to the procedure. A 193 nm Allegretto Wave Eye© laser was used. Calibration was done at the beginning of each surgical session. Ablation was achieved using a beam with a fluence of 150 mJ/ cm² at an ablation rate of 6 Hz. The optical zone and the ablation depth were dependent on the refractive error to be corrected. Intraoperative mitomycin C was used on eyes with a refractive error of -6.00DS and above (high myopia) that underwent PRK. For LASIK, a 130 micron Schwind-Eye Tech-Solutions© microkeratome was used to create the flap. Maximum ablation depth was calculated so that the remaining corneal stromal bed was more than 290 micrometers thick after surgery.

PresbyLASIK was done in the non-dominant eye of patients with presbyopia leaving the operated eye slightly myopic so as to facilitate near vision.

Postoperatively, patients were evaluated at week 1, month 1, month 3 and month 6 follow up visits. During these visits, uncorrected visual acuity (UCVA), refraction, best corrected visual acuity (BCVA), slit-lamp biomicroscopy and any other necessary tests were done.

Retreatments were also done if required. The patients were put on a topical steroid antibiotic eye drop which was tapered over 4 weeks. Thereafter, artificial tears and lubricants were administered for 8-12 weeks.

3.11 Data analysis

The data was entered into Microsoft Excel 2010. Double entry of data into Excel was done to reduce errors. Stata IC 12 was used for data analysis.

Descriptive analysis was used determine the frequencies and proportions of the variables, which were presented in tables or graphs where appropriate. The normality of the data was assessed using histograms. If not normally distributed, transformation of the data was attempted, when appropriate, to find the best possible normal fit. The mean with standard deviations was reported when the data was normally distributed

and medians when it was not, or where it was appropriate. Students' t-test was used to study the statistical significance of differences between pre- and post-operative measurements at each follow up visit. Statistical significance was set at a p-value of <0.05 with a confidence interval of 95%.

Pearson coefficient was used to determine correlations between outcome measures and demographic characteristics and presenting features of the patients. The strength of these correlations was further tested using univariate regression analysis. For each outcome variable, based on the univariate analysis, any associations with a p-value of <0.05 was included in a multivariate analysis. This was then used to build a model for factors affecting the final surgical outcomes.

3.12 Ethical consideration

Ethical permission was sought and granted from Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee. Permission was also sought and granted from Eagle Eye Laser Centre, Nairobi.

Patient details and identity were kept anonymous at all times through the use of coded questionnaires with matching codes on the patient's file. The information on the questionnaire was only accessible to the investigator, who upheld confidentiality and maintained adherence to data protection standards. Data was encrypted to facilitate confidentiality. The coded questionnaires were destroyed after data was analyzed. The investigator had no conflict of interest.

CHAPTER 4: RESULTS

The study included 785 eyes of 397 patients who underwent preoperative examination and keratorefractive surgery at Eagle Eye Laser Centre, Nairobi, between 6th October 2010 and 31st December 2016.

4.1 Preoperative statistics

Table 1: Summary of preoperative statistics (N = 397 patients)

| Characteristics | Mean (SD) |
|--|-----------------------------|
| Age (years) | 34.4 (7.9), range 19 - 58 |
| *Total number of patients | 397 |
| Average spherical correction (DS) | -3.37 (2.14) |
| Average cylindrical correction (DC) | -0.96 (0.79) |
| Average spherical equivalent correction (DS) | -3.61 (2.17) |
| Average pachymetry (μm) | 511 (35.9), range 420 – 653 |

*Males = 168 patients, females = 229 patients; Male:female ratio = 1:1.4

4.1.1 Demographics (n = 397 patients)

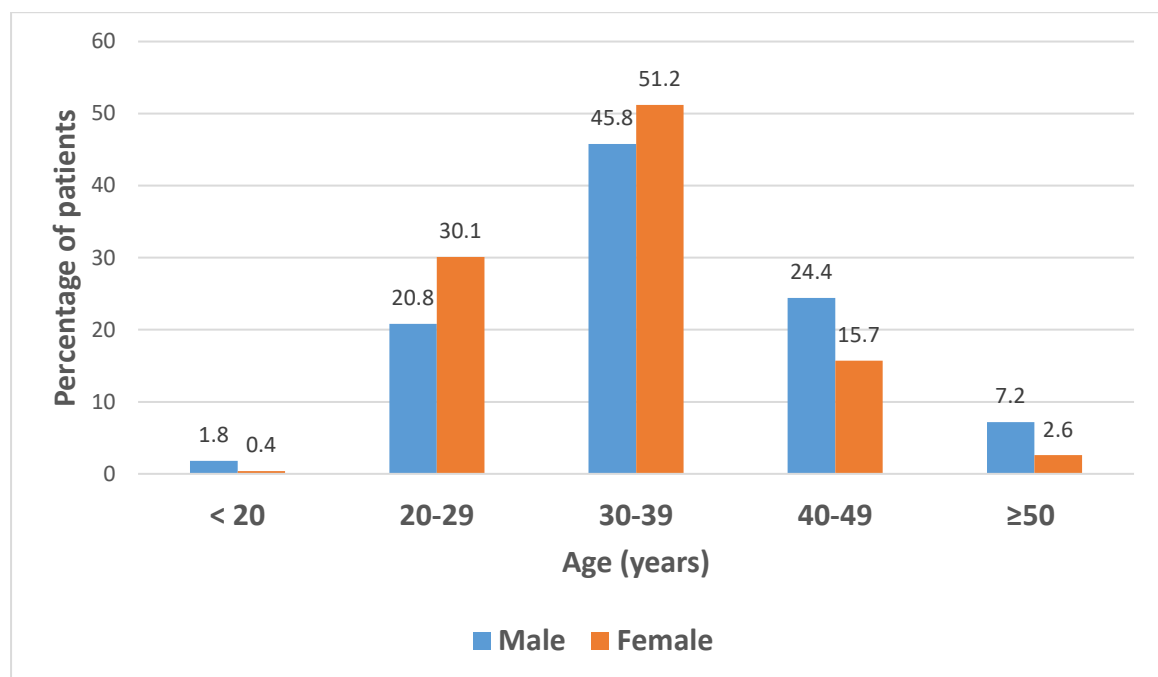


Figure 1: Percentage of patients that underwent surgery based on age and sex

Mean age of all patients: 34.4 years (SD 7.9)

- Mean age of males: 35.9 years (SD 8.6)
- Mean age of females: 33.4 years (SD 7.2)

Median age of all patients: 33.0 years (IQR: 29 – 39 years)

4.1.2 Preoperative best corrected visual acuity (BCVA)

Table 2: Preoperative BCVA (n = 785 eyes)

| Preoperative BCVA | n(%) |
|-------------------|------------|
| ≥ 6/6 | 753(95.9) |
| ≥ 6/12 | 784(99.9) |
| < 6/12 | 1(0.1) |
| Total | 785(100.0) |

99.9% of all eyes had a preoperative BCVA of ≥ 6/12.

4.1.3 Preoperative refractive error

Table 3(a): Preoperative refractive error (spherical and cylindrical components) (N = 785 eyes)

| Refractive error | Mean | Range |
|------------------|----------------|---------------------|
| Sphere | -3.37DS (2.14) | +4.75DS to -10.00DS |
| Cylinder | -0.96DC (0.79) | -0.25DC to -5.25DC |

Range of refractive errors based on spherical equivalent: +4.75DS to -10.00DS

Table 3(b): Types of preoperative refractive errors (n = 785 eyes)

| Refractive error | n(%) |
|-----------------------|-----------|
| Myopic astigmatism | 482(61.4) |
| Myopia | 286(36.4) |
| Hyperopic astigmatism | 12(1.5) |
| Hyperopia | 5(0.7) |
| Total | 785(100) |

More than 97% of the eyes had preoperative myopia and myopic astigmatism.

Table 3(c): Preoperative refractive error (spherical equivalent categories) (n = 785 eyes)

| Spherical equivalent category | n(%) |
|-------------------------------------|-----------|
| High myopia (-6.00DS and above) | 138(17.6) |
| Low-moderate myopia (below -6.00DS) | 630(80.2) |
| Hyperopia (all levels) | 17(2.2) |
| Total | 785(100) |

Mean preoperative spherical equivalent:

- High myopia: -6.96DS (SD 2.8)
- Low-moderate myopia: -3.61DS (SD 3.7)
- Hyperopia: +2.15DS (SD 1.0)

4.1.4 Preoperative pachymetry (N = 785 eyes)

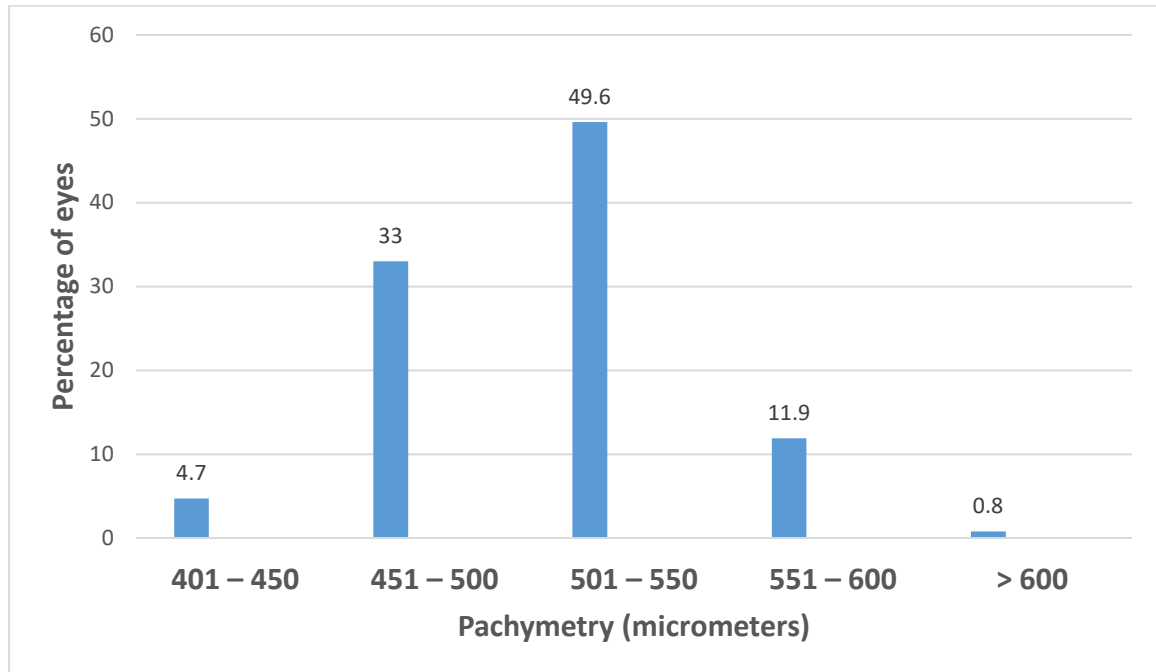


Figure 2: Percentage of eyes based on preoperative pachymetry.

Mean pachymetry: 511.0 micrometers (SD 35.9)

Median pachymetry: 510.0 micrometers (IQR: 486.5 to 535.0 micrometers)

4.2 Operative data

4.2.1 Refractive surgical procedures carried out (N = 785 eyes)

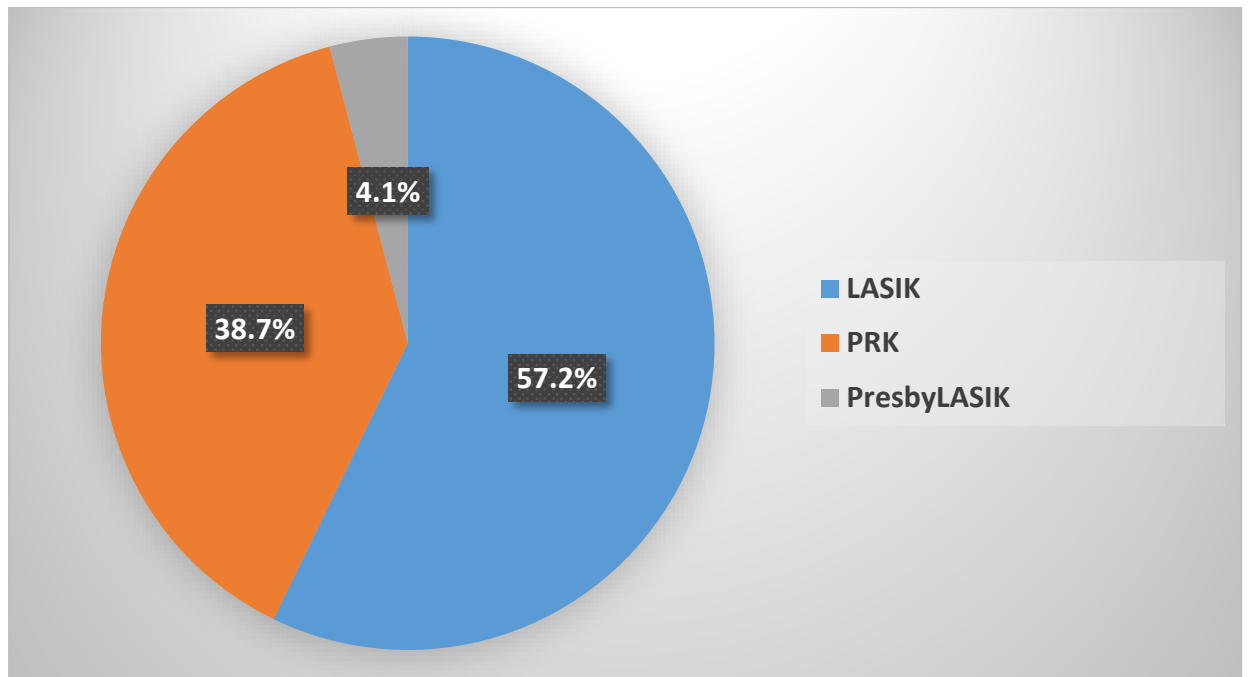


Figure 3: Percentage of eyes that underwent the different surgical procedures. More than half the number of eyes underwent LASIK.

4.2.2 Choice of refractive procedure

Table 4: Surgical procedure vs preoperative refractive error – LASIK and PRK (n = 753 eyes)

| Refractive error | Procedure | | P value |
|---------------------|-------------|-----------|---------|
| | LASIK, n(%) | PRK, n(%) | |
| High myopia | 42(9.4) | 89(29.3) | <0.001 |
| Low-moderate myopia | 397(88.4) | 209(68.8) | <0.001 |
| Hyperopia | 10(2.2) | 6(1.9) | 0.769 |
| Total | 449(100) | 304(100) | |

A higher proportion of eyes with preoperative high myopia underwent PRK as compared to LASIK ($p < 0.001$).

Table 5: Surgical procedure vs preoperative pachymetry – LASIK and PRK (n = 753 eyes)

| Pachymetry | Procedure | | P value |
|--------------|-------------|-----------|---------|
| | LASIK, n(%) | PRK, n(%) | |
| 401 - 450µm | 6(1.3) | 30(9.9) | <0.001 |
| 451 – 500µm | 96(21.4) | 151(49.7) | <0.001 |
| 501 - 550µm | 279(62.1) | 95(31.3) | <0.001 |
| 551 - 600µm | 64(14.3) | 26(8.6) | 0.023 |
| > 600µm | 4(0.9) | 2(0.7) | 0.785 |
| Total | 449(100) | 304(100) | |

A higher proportion of eyes with a preoperative pachymetry of less than 500 micrometers underwent PRK as compared to LASIK (p<0.001).

Table 6: Surgical procedure vs preoperative refractive error and pachymetry (N = 753 eyes)

| Pachymetry | Procedure | | | | | |
|--------------|-------------------|---------------------------|-----------------|-------------------|---------------------------|-----------------|
| | LASIK (N = 449) | | | PRK(N = 304) | | |
| | Refractive error | | | Refractive error | | |
| | High myopia, n(%) | Low-moderate myopia, n(%) | Hyperopia, n(%) | High myopia, n(%) | Low-moderate myopia, n(%) | Hyperopia, n(%) |
| 401 – 450 µm | 0(0) | 4(1.0) | 2(20.0) | 9(10.1) | 21(10.0) | 0(0) |
| 451 – 500 µm | 4(9.5) | 91(22.9) | 1(10.0) | 35(39.3) | 114(54.5) | 2(33.3) |
| 501 – 550 µm | 33(78.6) | 240(60.5) | 6(60.0) | 38(42.7) | 53(23.4) | 4(66.7) |
| 551 – 600 µm | 5(11.9) | 58(14.6) | 1(10.0) | 7(7.9) | 19(9.1) | 0(0) |
| > 600 µm | 0(0) | 4(1.0) | 0(0) | 0(0) | 2(3.0) | 0(0) |
| Total | 42(100) | 397(100) | 10(100) | 89(100) | 209(100) | 6(100) |

Both pachymetry and refractive error determined the choice of refractive surgical procedure for emmetropic correction as shown above.

4.2.3 PresbyLASIK

32 eyes underwent presbyLASIK. 7 eyes had preoperative high myopia, 24 had low-moderate myopia and 1 had hyperopia. Preoperative pachymetry ranged from 420 to 576 micrometers. In these patients, one eye underwent emmetropic correction. In eyes that underwent presbyLASIK, not only were the preoperative refractive error and

pachymetry values considered, but also the presence of presbyopia, ocular dominance and patient's preference.

4.3 Postoperative data

Operated patients were evaluated at week 1, month 1, month 3 and month 6 follow up visits. The postoperative results were categorized in terms of follow up data, efficacy, stability and safety.

4.3.1 Follow up data

Table 7, Figure 4: Postoperative follow up data (N = 785 eyes)

| Follow up visit | Procedure | | | Total (N = 785) n(%) |
|-----------------|----------------------|---------------------|----------------------------|----------------------|
| | LASIK (N = 449) n(%) | PRK (N = 304), n(%) | PresbyLASIK (N = 32), n(%) | |
| Week 1 | 387(86.3) | 286(94.8) | 29(90.6) | 702(89.4) |
| Month 1 | 292(65.0) | 210(69.1) | 28(87.5) | 530(67.5) |
| Month 3 | 211(47.0) | 168(55.3) | 18(56.3) | 397(50.6) |
| Month 6 | 156(34.7) | 107(35.2) | 17(53.1) | 280(35.7) |

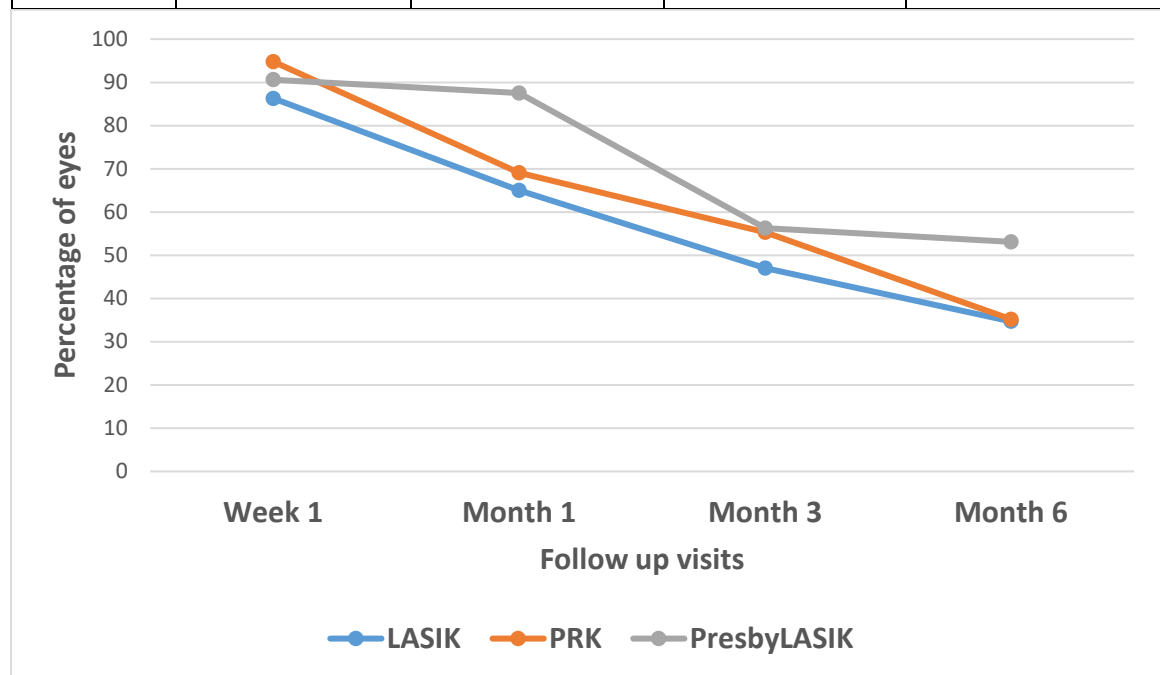


Table 7, Figure 4: Percentage of eyes that were reviewed postoperatively over a 6-month follow up period. At 6 months, the proportion of eyes that were reviewed postoperatively was less than 36% following PRK or LASIK.

4.3.2 Efficacy

4.3.2.1 Postoperative uncorrected visual acuity (UCVA)

4.3.2.1.1 Postoperative uncorrected visual acuity (UCVA) for both LASIK and PRK (N = 753 eyes)

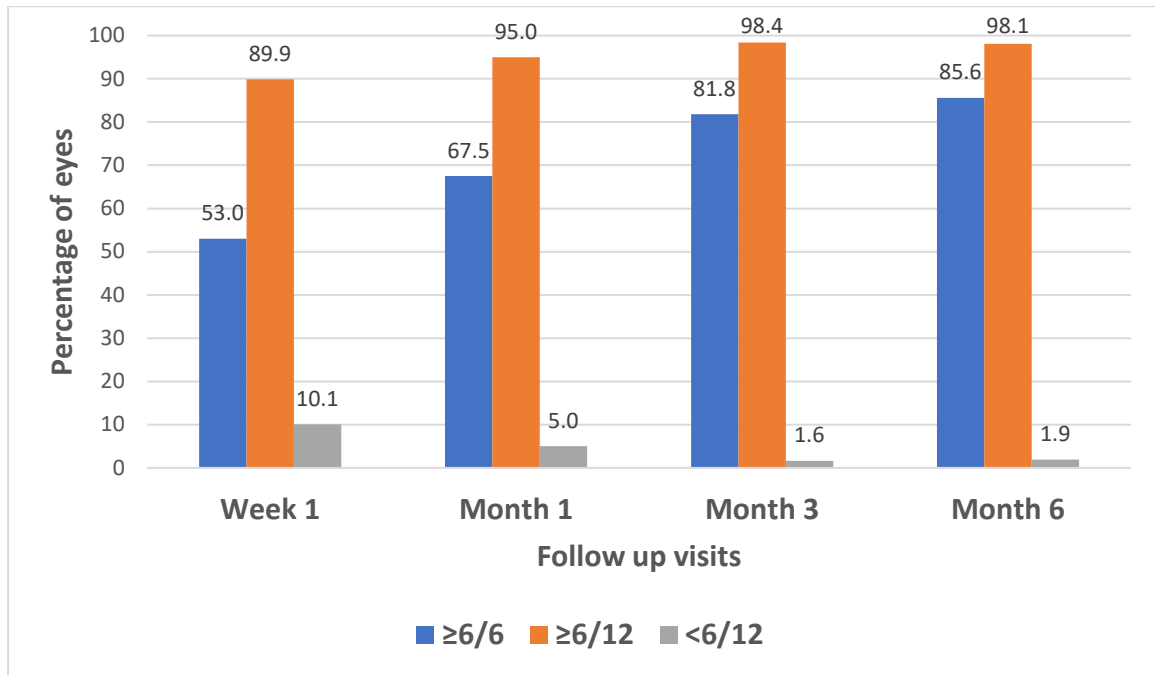


Figure 5: Percentage of eyes that had a postoperative UCVA of 6/6 or better, 6/12 or better, and worse than 6/12 over a 6-month follow up period. By 6 months 85.6% of the operated eyes had a visual acuity of 6/6 or better.

4.3.2.1.2 Postoperative uncorrected visual acuity (UCVA) for LASIK (N = 449 eyes)

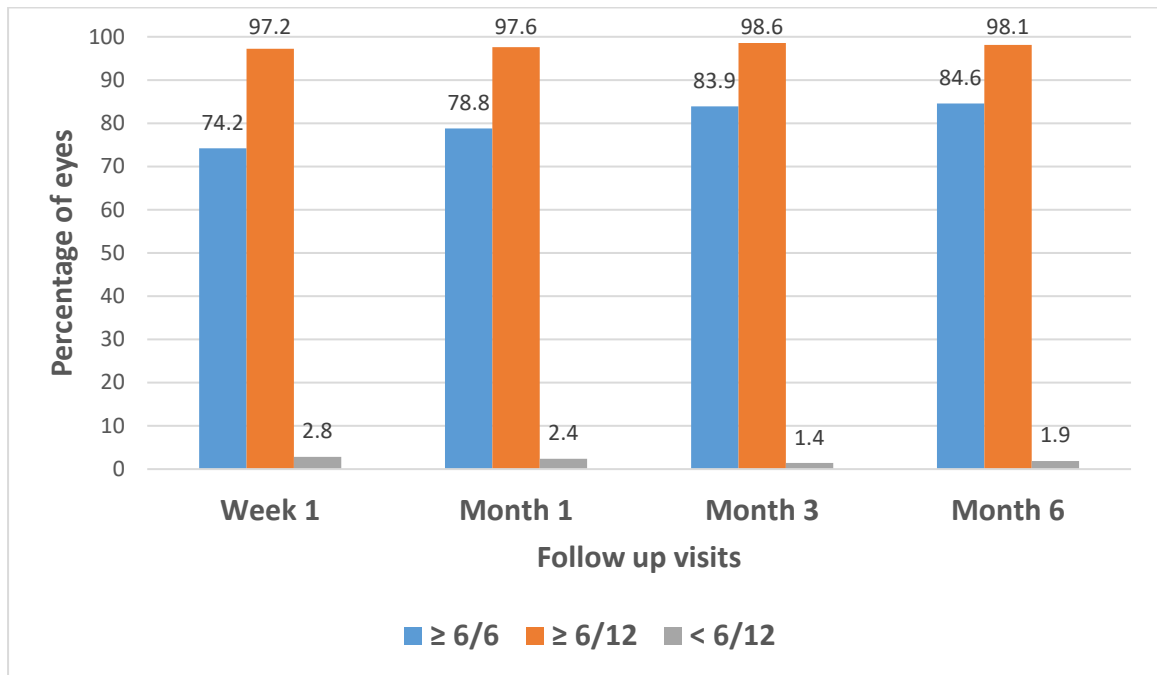


Figure 6: Percentage of eyes that had a postoperative UCVA of 6/6 or better, 6/12 or better, and worse than 6/12 following LASIK over a 6-month follow up period. By 6 months 98.1% of the operated eyes had a visual acuity of 6/12 or better.

4.3.2.1.3 Postoperative uncorrected visual acuity (UCVA) for PRK (N = 304 eyes)

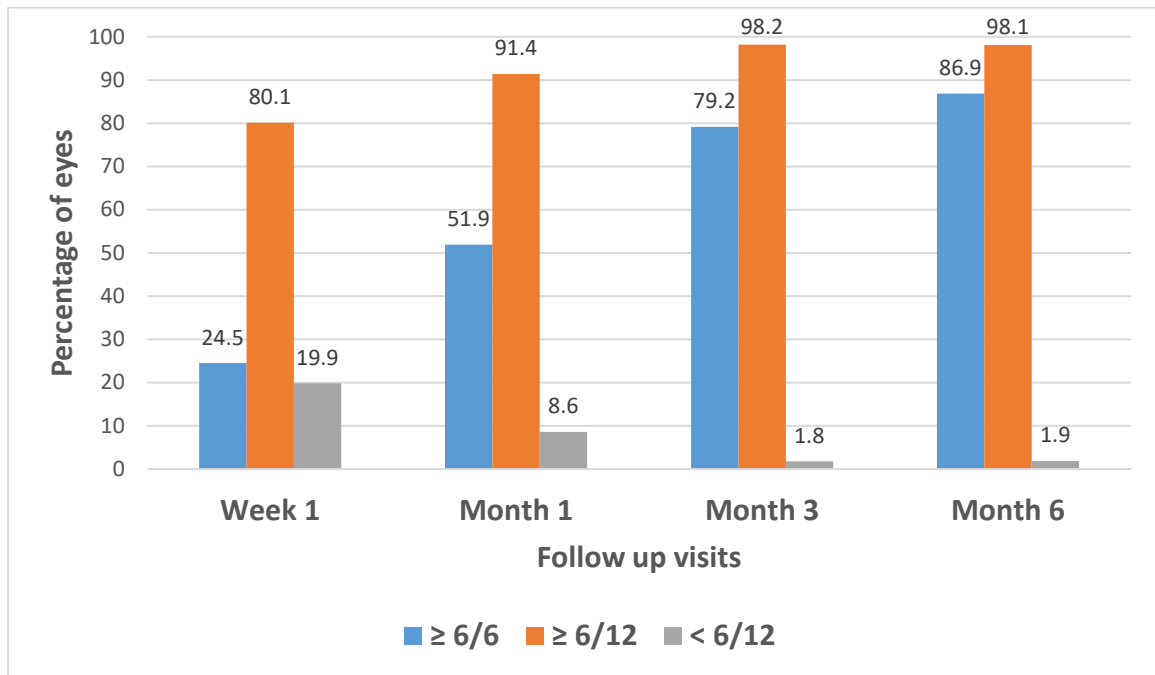


Figure 7: Percentage of eyes that had a postoperative UCVA of 6/6 or better, 6/12 or better, and worse than 6/12 following PRK over a 6-month follow up period. By 6 months 98.1% of the operated eyes had a visual acuity of 6/12 or better.

4.3.2.1.4 Postoperative uncorrected visual acuity (UCVA) based on refractive error categories

Table 8: Postoperative UCVA after LASIK based on refractive error categories

| UCVA per follow up visit | Procedure – LASIK | | |
|--------------------------|----------------------------|-------------------------------------|--------------------------|
| | High myopia (N = 42), n(%) | Low-moderate myopia (N = 397), n(%) | Hyperopia (N = 10), n(%) |
| Week 1 | | | |
| ≥ 6/6 | 17(56.7) | 264(75.6) | 6(75.0) |
| ≥ 6/12 | 29(96.7) | 339(97.1) | 8(100) |
| <6/12 | 1(3.3) | 10(2.9) | 0(0) |
| Total | 30(100) | 349(100) | 8(100) |
| | | | |
| Month 1 | | | |
| ≥ 6/6 | 12(57.1) | 214(80.8) | 4(66.7) |
| ≥ 6/12 | 19(90.5) | 260(98.1) | 6(100) |
| < 6/12 | 2(9.5) | 5(1.9) | 0(0) |
| Total | 21(100) | 265(100) | 6(100) |
| | | | |
| Month 3 | | | |
| ≥ 6/6 | 14(66.7) | 160(85.6) | 3(100) |
| ≥ 6/12 | 19(90.5) | 186(99.5) | 3(100) |
| < 6/12 | 2(9.5) | 1(0.5) | 0(0) |
| Total | 21(100) | 187(100) | 3(100) |
| | | | |
| Month 6 | | | |
| ≥ 6/6 | 11(78.5) | 119(85.0) | 2(100) |
| ≥ 6/12 | 14(100) | 137(97.9) | 2(100) |
| < 6/12 | 0(0) | 3(2.1) | 0(0) |
| Total | 14(100) | 140(100) | 2(100) |

Following LASIK, more than 78% of all eyes achieved a final visual acuity of 6/6 or better after 6 months of follow up regardless of the preoperative refractive error.

Table 9: Postoperative UCVA after PRK based on refractive error categories

| UCVA per follow up visit | Procedure – PRK | | |
|--------------------------|----------------------------|-------------------------------------|-------------------------|
| | High myopia (N = 89), n(%) | Low-moderate myopia (N = 209), n(%) | Hyperopia (N = 6), n(%) |
| Week 1 | | | |
| ≥ 6/6 | 19(23.1) | 50(25.1) | 1(20.0) |
| ≥ 6/12 | 66(80.5) | 158(79.4) | 4(80.0) |
| <6/12 | 16(19.5) | 41(20.6) | 0(0) |
| Total | 82(100) | 199(100) | 5(100) |
| | | | |
| Month 1 | | | |
| ≥ 6/6 | 32(54.2) | 76(51.3) | 1(33.3) |
| ≥ 6/12 | 53(89.8) | 136(91.9) | 3(100) |
| < 6/12 | 6(10.2) | 12(8.1) | 0(0) |
| Total | 59(100) | 148(100) | 3(100) |
| | | | |
| Month 3 | | | |
| ≥ 6/6 | 40(75.5) | 93(80.8) | 0(0) |
| ≥ 6/12 | 52(98.1) | 113(98.3) | 0(0) |
| < 6/12 | 1(1.9) | 2(1.7) | 0(0) |
| Total | 53(100) | 115(100) | 0(100) |
| | | | |
| Month 6 | | | |
| ≥ 6/6 | 23(85.2) | 68(89.5) | 2(50.0) |
| ≥ 6/12 | 25(92.6) | 76(100) | 4(100) |
| < 6/12 | 2(7.4) | 0(0) | 0(0) |
| Total | 27(100) | 76(100) | 4(100) |

Following PRK, more than 85% of all eyes achieved a final visual acuity of 6/6 or better after 6 months of follow up regardless of the preoperative refractive error.

4.3.2.1.5 PresbyLASIK

The postoperative UCVA in eyes that underwent presbyLASIK was assessed separately.

Table 10(a): Postoperative UCVA at final follow up visit following presbyLASIK (n = 32 eyes)

| Postoperative UCVA at final follow up visit | n(%) |
|--|----------------|
| ≥ 6/6 | 10(31.3) |
| ≥ 6/12 | 30(93.8) |
| < 6/12 | 2(6.2) |
| Total | 32(100) |

Table 10(b): Postoperative uncorrected near visual acuity at final follow up visit following presbyLASIK (n = 32 eyes)

| Postoperative uncorrected near vision at final follow up visit | n(%) |
|---|----------------|
| N5 | 27(84.4) |
| ≥ N10 | 32(100) |
| Total | 32(100) |

Note that the aim of this procedure was to correct the eyes for near vision and not emmetropia and hence the near vision assessment table (Table 10(b)).

4.3.2.2 Postoperative manifest refractive spherical equivalent (MRSE)

4.3.2.2.1 Postoperative manifest refractive spherical equivalent (MRSE) for both LASIK and PRK after 6 months (N = 263 eyes)

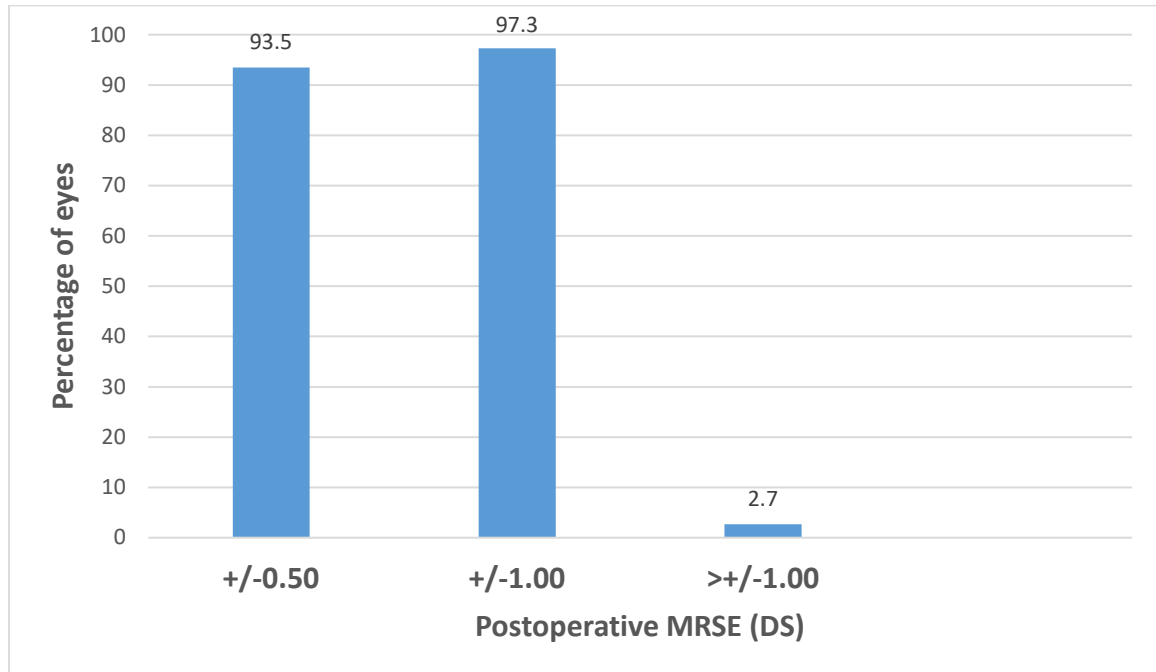


Figure 8: Percentage of eyes with a postoperative MRSE of within 0.50, 1.00 and above 1.00 after a 6-months follow up period. 93.5% of all the eyes that underwent emmetropic correction were within 0.50DS of the targeted correction.

4.3.2.2.2 Postoperative manifest refractive spherical equivalent (MRSE) comparing LASIK and PRK (N = 156 for LASIK and 107 for PRK)

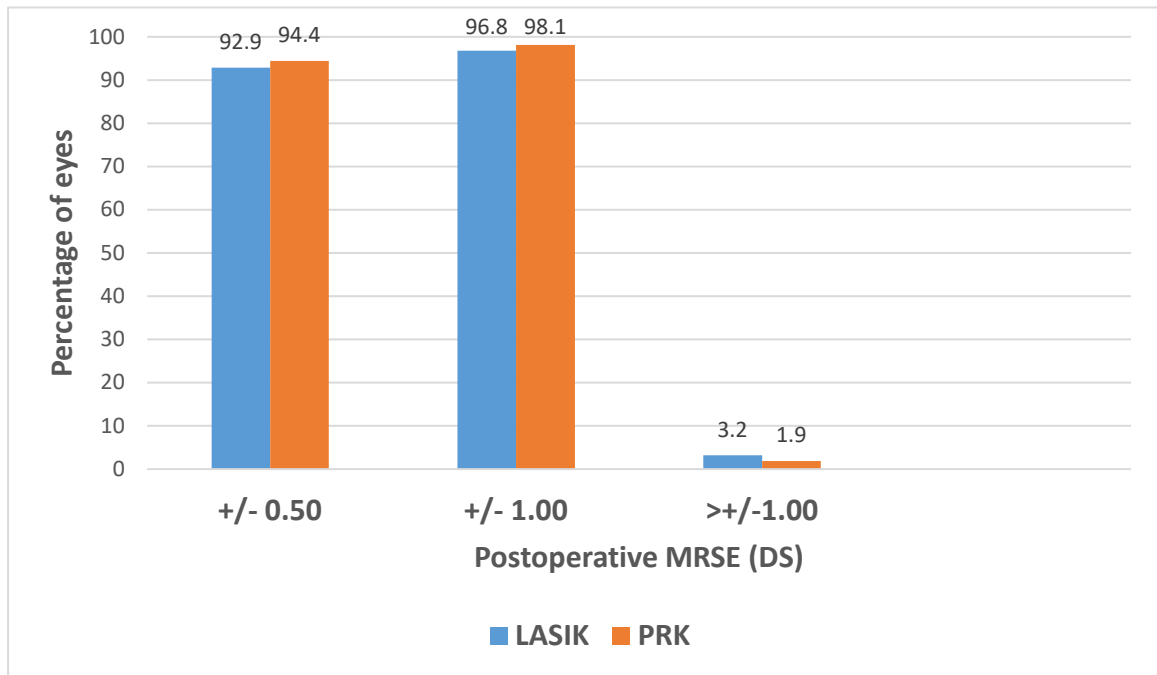


Figure 9: Percentage of eyes with a postoperative MRSE of within 0.50, 1.00 and above 1.00 after a 6-months follow up period for both LASIK and PRK. In both procedures an MRSE of within 0.50 was achieved in more than 92% of the eyes.

4.3.2.2.3 Postoperative manifest refractive spherical equivalent (MRSE) based on refractive error categories

Table 11: Postoperative MRSE at 6 months after LASIK based on refractive error categories (N = 156 eyes)

| MRSE | Procedure – LASIK | | |
|-------------------|-------------------|---------------------------|-----------------|
| | High myopia, n(%) | Low-moderate myopia, n(%) | Hyperopia, n(%) |
| Within +/- 0.50DS | 12(85.7) | 131(93.6) | 2(100) |
| Within +/- 1.00DS | 13(92.8) | 136(97.1) | 2(100) |
| Above +/- 1.00DS | 1(7.2) | 4(2.9) | 0(0) |
| Total | 14(100) | 140(100) | 2(100) |

The proportion of eyes that achieved a postoperative MRSE of within 1.00DS were lower in the high myopia group.

Table 12: Postoperative MRSE at 6 months after PRK based on refractive error categories (N = 107 eyes)

| MRSE | Procedure – PRK | | |
|-------------------|--------------------------|----------------------------------|------------------------|
| | High myopia, n(%) | Low-moderate myopia, n(%) | Hyperopia, n(%) |
| Within +/- 0.50DS | 24(88.9) | 75(98.7) | 2(50.0) |
| Within +/- 1.00DS | 25(92.6) | 76(100) | 4(100) |
| Above +/- 1.00DS | 2(7.4) | 0(0) | 0(0) |
| Total | 27(100) | 76(100) | 4(100) |

The proportion of eyes that achieved a postoperative MRSE of within 1.00DS were lower in the high myopia group.

4.3.3 Stability

4.3.3.1 Stability assessment based on procedure

Table 13: Postoperative MRSE at Month 3 and Month 6 follow up visits following LASIK (n = 101 eyes)

| MRSE | Procedure - LASIK | | P value |
|-------------------|-------------------|---------------|---------|
| | Month 3, n(%) | Month 6, n(%) | |
| Within +/- 0.50DS | 93(92.1) | 91(90.1) | 0.897 |
| Within +/- 1.00DS | 97(96.0) | 97(96.0) | 1.000 |
| Above +/- 1.00DS | 4(4.0) | 4(2.0) | 1.000 |
| Total | 101(100) | 101(100) | |

2 eyes regressed from a postoperative MRSE of within 0.50DS to an MRSE of within 1.00DS. This difference was however not statistically significant.

Table 14: Postoperative MRSE at Month 3 and Month 6 follow up visits following PRK (n = 79 eyes)

| MRSE | Procedure - PRK | | P value |
|-------------------|-----------------|---------------|---------|
| | Month 3, n(%) | Month 6, n(%) | |
| Within +/- 0.50DS | 77(97.5) | 75(94.9) | 0.855 |
| Within +/- 1.00DS | 78(98.7) | 79(100) | 0.921 |
| Above +/- 1.00DS | 1(1.3) | 0(0) | 0.057 |
| Total | 79(100) | 79(100) | |

2 eyes regressed from a postoperative MRSE of within 0.50DS to an MRSE of within 1.00DS. This difference was however not statistically significant.

4.3.4 Safety

4.3.4.1 Loss of 2 or more Snellen lines of BCVA (N = 263 eyes)

Table 15: Postoperative loss of 2 or more Snellen lines of BCVA after 6 months (n = 263 eyes)

| Loss of 2 or more Snellen lines of BCVA | n(%) |
|--|-----------------|
| Loss of 2 or more Snellen lines of BCVA | 12(4.5) |
| No loss of Snellen line | 251((95.5) |
| Total | 263(100) |

Loss of 2 or more Snellen lines of BCVA was reported after subjective refraction at month 6 follow up visit.

4.3.4.2 Intraoperative complications

All the recorded intraoperative complications occurred during LASIK and presbyLASIK.

They occurred in 9 eyes. These complications were recorded as irregular flap (4 eyes), buttonhole formation (2 eyes), free cap (2 eyes) and amputated flap (1 eye). 8 of these complications occurred during LASIK while 1 occurred during presbyLASIK.

4.3.4.3 Unfavourable postoperative outcomes

Table 16: Unfavourable postoperative outcomes (N = 785 eyes)

| Unfavourable outcome | n(%) |
|---|-----------------|
| None | 725(92.4) |
| Residual refractive error | 24(3.1) |
| *Persistent dry eyes | 21(2.7) |
| *Persistent corneal haze | 6(0.7) |
| Optical aberrations | 4(0.5) |
| Elevated intraocular pressure | 2(0.3) |
| Ectasia | 1(0.1) |
| Dislodged flap | 1(0.1) |
| Sands of the Sahara and epithelial ingrowth | 1(0.1) |
| Total | 785(100) |

7.6% of all operated eyes had unfavourable outcomes after 6 months of follow up.

*Persistent dry eyes and persistent corneal haze were defined after a time duration of 6 months postoperatively.

Table 17: Unfavourable postoperative outcomes per procedure (N = 60 eyes)

| Unfavourable outcome | LASIK, n(%) | PRK, n(%) | PresbyLASIK, n(%) |
|---|--------------------|------------------|--------------------------|
| Residual refractive error | 14(40.0) | 8(36.4) | 2(66.7) |
| *Persistent dry eyes | 13(37.2) | 8(36.4) | 0(0) |
| *Persistent corneal haze | 2(5.7) | 4(18.2) | 0(0) |
| Optical aberrations | 4(11.5) | 0(0) | 0(0) |
| Elevated intraocular pressure | 1(2.8) | 1(4.5) | 0(0) |
| Ectasia | 0(0) | 1(4.5) | 0(0) |
| Dislodged flap | 1(2.8) | 0(0) | 0(0) |
| Sands of the Sahara and epithelial ingrowth | 0(0) | 0(0) | 1(33.3) |
| Total | 35(100) | 22(100) | 3(100) |

Residual refractive errors were the commonest unfavourable outcome in all procedures.

*Persistent dry eyes and persistent corneal haze were defined after a time duration of 6 months postoperatively.

4.3.5 Retreatment

Table 18: Retreatment (n = 23 eyes)

| Refractive error | Procedure | | | Total, n(%) |
|-------------------------|--------------------|------------------|--------------------------|--------------------|
| | LASIK, n(%) | PRK, n(%) | PresbyLASIK, n(%) | |
| High myopia | 3(23.1) | 3(37.5) | 0(0) | 6(26.1) |
| Low-moderate myopia | 8(61.5) | 5(62.5) | 2(100) | 15(65.2) |
| Hyperopia | 2(15.4) | 0(0) | 0(0) | 2(8.7) |
| Total | 13(100) | 8(100) | 2(100) | 23(100) |

Retreatment rates per procedure:

- 2.9% of total LASIK surgeries done
- 2.6% of total PRK surgeries done
- 6.3% of total presbyLASIK surgeries done

CHAPTER 5: DISCUSSION

We documented the outcomes of keratorefractive surgery in 785 eyes over a 6 month follow up period. Different degrees of refractive errors ranging from +4.75DS to -10.00DS were treated (Table 3(a)).

397 patients underwent surgery, with a slight female preponderance (Table 1). The ages of the patients ranged from 19 to 58 years, with most patients being in the 30 to 39 year age group. The average age at surgery was 34.4 years (Table 1, Figure 1). Similar demographic data concerning age and sex was recorded in a meta-analysis of refractive surgery by Ang et al.⁴¹ The slight female preponderance particularly in the younger age groups may be explained by the fact that women are generally more conscious about their aesthetics and may prefer to be free of spectacles earlier in life. With regard to age, at around the average age of surgery from our study, most patients are generally financially stable and able to afford the elective procedure. Patients who underwent presbyLASIK ranged in age from 40 to 58 years, as it is at this age that presbyopia starts.

Preoperatively, almost all eyes had a BCVA of 6/12 or better following either spectacle or contact lens correction (Table 2). The majority of refractive errors were myopia and myopic astigmatism, which comprised more than 97% of the types of preoperative refractive errors (Tables 3(b) and 3(c)). In a study done in Kenya in 2013, Bastawrous et al concluded that myopia and myopic astigmatism were the commonest refractive errors among adults aged 50 and above.⁵⁶ This may explain the higher proportions of patients with myopia and myopic astigmatism in the population.

Based on pachymetry, almost half the number of eyes had central corneal thickness values of between 501 and 550 micrometers. The mean pachymetry was 511.0 micrometers (SD 35.9) (Table 1, Figure 2). In a local study, Gelaw et al reported mean pachymetry readings of 518.68 micrometers (SD \pm 32.92) in adults, which is in keeping with our data.⁵⁷

The choice of refractive surgical procedure was determined by the preoperative refractive error and the preoperative pachymetry. Bearing this in mind, LASIK was preferred whenever possible, because it has less discomfort and a shorter duration of healing. More than half the eyes underwent LASIK (Figure 3). It was however noted that a higher proportion of eyes with a preoperative pachymetry of less than 500

micrometres underwent PRK as compared to LASIK ($p < 0.001$) (Table 4). Similarly, a higher proportion of eyes with preoperative high myopia underwent PRK as compared to LASIK ($p < 0.001$) (Table 5). So as to reduce the risk of postoperative ectasia, Moisseiev et al and Santhiago et al preferred PRK over LASIK in eyes with low pachymetry values and in eyes with higher errors, and recommended PRK over LASIK in these conditions.^{3,6}

The number of eyes that were reviewed postoperatively decreased successively though the follow up visits. However, it was noted that a higher proportion of eyes was reviewed following PRK as compared to LASIK for the first 3 months (Table 7, Figure 4). Similar follow up trends were noted in other comparative studies, particularly by Dirani et al and Alio et al.^{40,44} Vestergaard et al suggested that lower patient satisfaction may lead to more frequent clinic visits following PRK as compared to LASIK.⁴³ This might have also been the case in our study, as PRK takes longer to heal and patients may have had a stronger need to be reviewed.

Efficacy is assessed by determining the postoperative uncorrected visual acuity (UCVA) of equal to or better than 6/6, and/or 6/12; and the proportion of patients with a manifest refraction spherical equivalent (MRSE) of within 0.50 and/or 1.00D of the intended correction.

In our study, combining both LASIK and PRK, a postoperative UCVA of 6/6 or better was achieved in 85.6% of the eyes after 6 months of follow up (Figure 5). These results are similar to a meta-analysis of outcomes of PRK and LASIK done by Sakimoto et al.²⁷ In our study, the above figure was arrived at despite a 65% drop out rate in terms of follow up. However, it was assumed that most patients who were not reviewed up to the 6-month follow up period had good vision and may not have found a reason to be followed up.

On comparing LASIK and PRK in terms of postoperative UCVA, we found that there was no statistically significant difference between the two procedures at 6 months. Studies differ as to which one of the two procedures produces better postoperative UCVA results – Lee et al concluded that PRK did better, while Dirani et al documented better results after LASIK.^{37,40} However, we found that recovery of vision was faster

following LASIK as compared to PRK regardless of the refractive error (Figure 6 and 7). Similar outcomes concerning vision recovery were documented by Dirani et al.⁴⁰

With regards to MRSE, several studies have concluded that a postoperative MRSE of within 0.50DS of the targeted correction was achieved in about 50% to 70% of eyes following LASIK or PRK. Better outcomes are achieved with lower refractive errors.^{27,38-40} Combining both LASIK and PRK, our study had a postoperative MRSE of within 0.50DS of 93.5% at 6 months (Figure 8). This is much higher than most studies and may be attributed to a good preoperative and postoperative refraction which were key to our success. As indicated earlier, the surgeons prefer to do their own refraction prior to surgery.

On comparing LASIK and PRK, there was no statistically significant difference between these procedures in terms of targeted correction at 6 months regardless of the preoperative refractive error (Tables 11 and 12). Lee et al documented a similar outcome in terms of MRSE on comparing the two procedures.³⁷ However, Dirani et al concluded that a higher proportion of eyes achieved a better MRSE after LASIK as compared to PRK, for similar refractive error categories.⁴⁰

In eyes that underwent presbyLASIK, not only were the preoperative refractive error and pachymetry values considered, but also the presence of presbyopia, ocular dominance and patient's preference. Sakimoto et al concluded that the most important factors for obtaining good outcomes with this technique is proper patient selection and adequate counselling before the procedure. Furthermore, they concluded that the outcomes for presbyLASIK are dependent on the ability to reach the target refraction accurately and on the patient's ability to adjust to anisometropia.²⁷ Based on our results, presbyLASIK can be used to achieve reasonable distance and near vision (Tables 10(a) and 10(b)). However, a separate study may be recommended to assess patient satisfaction following presbyLASIK.

Stability of the correction was established by comparing the manifest refractive spherical equivalent (MRSE) at month 3 follow up visit and month 6 follow up visit after the initial surgical procedure. Only the eyes of patients who came for both month 3 and month 6 follow up visits were included in the assessment of stability. Eyes which underwent enhancement (23 eyes) during this period were not included in the

assessment of stability. Eyes which underwent presbyLASIK were also not included in the assessment of stability, as stability is dependent on MRSE values.

In our study, both LASIK and PRK underwent a slight regression between month 3 and month 6 follow up visits, with a 2% drop in the postoperative MRSE of within 0.50DS (Tables 13 and 14). This difference was however not statistically significant. Dirani et al and Alio et al concluded that surface ablation techniques had higher regression rates compared to LASIK.^{40,44} A meta-analysis by Ang et al reported equal regression rates of up to 3% in both LASIK and PRK with more regression seen in higher errors.^{41,45} Studies with longer follow up periods may be needed to establish the possibility of further regression following refractive surgery.

The safety of refractive surgery is determined by assessing the proportion of patients with a postoperative loss of 2 or more Snellen lines of visual acuity, and the incidence of surgical complications. Eyes that underwent presbyLASIK were not included in the postoperative assessment of loss of Snellen lines as their intended correction was not emmetropia.

In our study, 1.6% of all the eyes that underwent emmetropic correction lost 2 or more lines of BCVA (Table 15). Based on procedure, 6 eyes in both the LASIK and the PRK group lost 2 or more lines after 6 months. Based on preoperative refractive error, 5 of these eyes were in the high myopia group, 6 in the low-moderate myopia group and 1 had preoperative hyperopia. 9 of the 12 eyes which lost 2 Snellen lines postoperatively had postoperative complications, including residual refractive error and persistent dry eye. One of the eyes developed ectasia following PRK and had a final visual acuity of 6/36 at the last follow up visit. It underwent crosslinking 11 months postoperatively. Postoperative loss of 2 Snellen lines was not accounted for in 2 eyes. The numbers were too few to draw a statistically significant comparison based on procedure or refractive error, but they appear not to be influenced by either. Several studies have shown that the percentage loss in BCVA is higher following PRK than LASIK in similar corrections.^{3,22,27,41} These proportions range from 1% to as high as 27% for higher refractive errors as reported in a meta-analysis by Ang et al.⁴¹

Intraoperative complications occurred in 9 eyes (1.2% of all operated eyes) and were all flap related. However, all the eyes recovered from these complications and recorded good vision postoperatively. 8 eyes had a visual acuity of 6/6 or better at the final follow

up visit. The one eye which had undergone presbyLASIK and developed intraoperative complications, had a near visual acuity of N5 at final follow up visit. In studies of more than 1000 eyes that underwent LASIK, Schallhorn et al reported a total incidence of intraoperative flap complications of 0.3% to 5.7%.⁵⁰

As regards postoperative unfavourable outcomes, Sakimoto et al, Ang et al and Schallhorn et al concluded that most postoperative complications after keratorefractive surgery are not vision threatening.^{27,40,51} In our study, we found that residual refractive errors were the most common of these unfavourable outcomes, occurring in 3.1% of all surgeries (Table 16). Of these, 23 out of 24 eyes (95.8%) underwent retreatment (Table 18). Retreatment was in done after a mean duration of 88.4 days (SD = 32.5; range 42 to 144 days) following the initial surgery. In our study, the criteria for retreatment included an unsatisfactory uncorrected visual acuity after 1 month following LASIK or PRK, and an unsatisfactory near visual acuity in presbyLASIK eyes. Following enhancement, 18 eyes (78.3%) achieved a final postoperative UCVA of $\geq 6/6$, while the rest achieved a final UCVA of $\geq 6/12$. Both presbyLASIK eyes had a final near vision of N5. Residual inadvertent errors and subsequent retreatment rates vary from 1% to 11%, based on surgeon experience, patient demands, and higher corrections.^{1,27,43} Sakimoto et al reported higher rates of retreatment following PRK as compared to LASIK.²⁷ In our study, the numbers of eyes that underwent retreatment do not vary much between the procedures, or in terms of preoperative refractive errors. These numbers were however were too few to draw statistically significant comparisons. Persistent dry eyes were seen in more LASIK eyes as compared to PRK eyes. Dry eye is more common after LASIK than after surface ablation, with reports of up to 48% of all patients experiencing it to varying degrees.^{27,50} 6 eyes developed persistent corneal haze (4 following PRK and 2 following LASIK) (Table 17). Surface ablation procedures have a higher likelihood of visually significant postoperative corneal haze, particularly in the treatment of higher refractive errors, with reports of up to 6% developing this complication.^{4,5,12,27} 2 of the eyes which underwent surgery developed elevated intraocular pressure. This was thought to be due to steroid response. In less than 1% of cases, long-term use of postoperative topical steroids may cause an elevation of intraocular pressure in steroid responders.¹ Furthermore, refractive laser procedures reduce corneal thickness resulting in falsely low IOP readings postoperatively.²⁷ Sands of the Sahara and epithelial ingrowth developed in 1 eye following presbyLASIK

(Table 17). Sands of the Sahara (diffuse lamellar keratitis) has an incidence ranging from 0.4% to 19%, and occurs more frequently with femtosecond laser keratomes than microkeratomes.^{27,51,52} Clinically significant epithelial ingrowth occurs in about 2% of LASIK surgeries.^{11,53} The total number of unfavourable outcomes are few compared to other studies. Most residual refractive errors occurred in the earlier years of initiation of keratorefractive surgery at the facility and might be attributed to a learning curve. Natural regression may have also played a part in contributing to some of the unfavourable outcomes including residual errors and optical aberrations.

CHAPTER 6: CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

6.1 Conclusions

1. Both LASIK and PRK reported good visual outcomes postoperatively after 6 months of follow up. However, recovery of vision was faster following LASIK as compared to PRK. PresbyLASIK also provides reasonable distance and near vision after 6 months of follow up.
2. Both LASIK and PRK are stable with minimal regression between 3 and 6 months of follow up.
3. Both LASIK and PRK are associated with few unfavourable outcomes, most of which are not vision threatening. Residual refractive errors were the commonest of these unfavourable outcomes.
4. Both LASIK and PRK are effective, stable and safe surgical methods for correction of refractive errors with statistically insignificant differences in terms of efficacy, stability and safety between the two procedures.

6.2 Recommendations

Based on our study, both LASIK and PRK are suitable elective surgical procedures for correcting refractive errors. However, cost, awareness and availability of these procedures should be improved so as to provide patients with more treatment options for refractive errors. Research on long term efficacy, stability, safety and patient satisfaction following keratorefractive surgery should also be carried out to increase the available knowledge on keratorefractive surgery.

6.3 Limitations

The main limitation of the study was that not all patients were examined between 1 week and 6 months postoperatively. However, we assumed that patients who were lost to follow up were usually those with good vision, and did not feel the need to return. Efficacy, stability and safety results may have been better analysed if all eyes had been examined at each follow-up visit.

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Appendix 1: Questionnaire

Demographics

1. Hospital ID/ File number:.....
Code:.....
2. Age:.....years
3. Sex: Male Female

Relevant history

1. Co-morbidities
 - a) Ocular pathology:
 - RE
None Present , specify.....
 - LE
None Present , specify.....
 - b) Systemic pathology:
 - None Diabetes Connective tissue disease Others , specify.....
2. Previous correction:
 - None/not specified Spectacles Contact lenses PCIOL

Pre-operative examination

1. UCVA:
 - RE.....
 - LE.....
2. BCVA:
 - RE.....
 - LE.....
3. Refractive error:
 - RE: sphere....., cylinder/axis....., spherical equivalent.....
 - LE: sphere....., cylinder/axis....., spherical equivalent.....

4. Pachymetry (CCT):

- RE:micrometers
- LE:micrometers

5. Keratometry:

- RE: K1....., K2....., Average K.....
- LE: K1....., K2....., Average K.....

6. Corneal topography:

- RE: Normal [] Abnormal [], indicate abnormality.....
- LE: Normal [] Abnormal [], indicate abnormality.....

Surgery

1. Date of Surgery: RE / / LE / /

2. Procedure:

- RE: PRK []
 LASIK []
- LE: PRK []
 LASIK []

3. Intraoperative complications:

- RE:
 1. None (both LASIK and PRK) []
 2. Flap complications (LASIK) []
 3. Intraoperative epithelial defects (LASIK) []
 4. Other, specify.....
- LE:
 1. None (both LASIK and PRK) []
 2. Flap complications (LASIK) []
 3. Intraoperative epithelial defects (LASIK) []
 4. Other, specify.....

Post-operative data

1. Complications (indicate eye: RE/LE/BE):

| | Week 1 | Month 1 | Month 3 | Month 6 | Year 1 |
|-----------------------------------|---------------|----------------|----------------|----------------|---------------|
| Flap complications (LASIK) | | | | | |
| DLK (LASIK) | | | | | |
| Optical aberrations | | | | | |
| Under/over-correction | | | | | |
| Regression | | | | | |
| Dry eye | | | | | |
| Corneal haze (0 to 4) | | | | | |
| Infectious keratitis | | | | | |
| Epithelial ingrowth | | | | | |
| Ectasia | | | | | |

Other (specify).....

2. Surgical interventions of complications (indicate eye: RE/LE/BE):

1. Flap reattachment (LASIK) []
2. Retreatment/ Enhancement: Yes [], No []; if yes, Repeat LASIK [], or Repeat PRK []
3. Other surgical procedure, specify.....

3. Follow up data

- RE

| | UCVA | BCVA | MRSE (WITHIN +/-0.50DS) (6 months) | MRSE (WITHIN +/- 1.00 DS) (6 months) | LOSS OF ≥ 2 SNELLEN LINES OF BCVA (6 months) |
|----------------|-------------|-------------|---|---|---|
| Week 1 | | | | | |
| Month 1 | | | | | |
| Month 3 | | | | | |
| Month 6 | | | | | |

- LE

| | UCVA | BCVA | MRSE (WITHIN +/-0.50DS) (6 months) | MRSE (WITHIN +/- 1.00 DS) (6 months) | LOSS OF ≥ 2 SNELLEN LINES OF BCVA (6 months) |
|----------------|-------------|-------------|---|---|---|
| Week 1 | | | | | |
| Month 1 | | | | | |
| Month 3 | | | | | |
| Month 6 | | | | | |

Appendix 2: Budget

| Item | Quantity | Unit Cost | Total Cost |
|---|----------------------|-----------------|---------------|
| Proposal/Ethical approval | | | |
| Proposal writing and printing (35 pages) | 6 copies | | 1,000 |
| Binding Proposal | 6 copies | | 150 |
| Ethics | 1 | | 2,000 |
| Internet | | | 1,000 |
| | | Subtotal | 4,150 |
| Data Collection | | | |
| Printing of Questionnaires | 4 pages | | 50 |
| Photocopy of Questionnaires | 4 pages (400 copies) | | 800 |
| Stationery –pens, rubbers etc. | | | 500 |
| Flash Disk 16GB Hp | 1 | | 2,000 |
| Box files for filing questionnaires | 10 | | 400 |
| | | Subtotal | 3,750 |
| Transport | | | |
| | | Subtotal | 2,000 |
| Contracted services | | | |
| Statistician | 1 | Subtotal | 40,000 |
| Printing costs and binding of final book | | | |
| Finished book printing (approx. 60 pages) | 8 copies | | 2,400 |
| | 20 coloured pages | | 400 |
| Binding | 8 copies | | 800 |
| | | Subtotal | 3,600 |
| TOTAL | | | 53,500 |

Appendix 3: Annex

RSBT: residual stromal base thickness

- *Central corneal thickness - thickness of flap - depth of ablation = RSBT*

Munnerlyn formula: $t = S^2D/3$

- where t is the depth of ablation in micrometers, S is the optical zone diameter in millimeters, and D is the total refractive correction

Hanna's (1992) classification of sub-epithelial corneal haze

- 0: totally clear
- 0.5: a faint corneal opacity seen only by oblique indirect illumination
- 1: an opacity of minimal density seen with direct and diffuse illumination
- 2: an easily visible opacity
- 3: a denser opacity that significantly decreases visualization of intraocular structures such as the iris and retina
- 4: an opaque cornea

Appendix 4: Ethical approval: KNH-UON ERC



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Email: uonknh_erc@uonbi.ac.ke
Website: <http://www.erc.uonbi.ac.ke>
Facebook: https://www.facebook.com/uonknh_erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC



KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/303

12th October, 2017

Dr. Cliff Mwangi Muturi
Reg. No.H58/80978/2015
Dept. of Ophthalmology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Muturi

REVISED RESEARCH PROPOSAL – OUTCOMES OF REFRACTIVE LASER SURGERY AT EAGLE EYE LASER CENTRE, NAIROBI: A RETROSPECTIVE CASE SERIES (P324/06/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 12th October 2017 –11th October 2018.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal.*)
- Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

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Yours sincerely,



PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chairperson, KNH-UoN ERC
The Dean, School of Medicine, UoN
The Chair, Dept. of Ophthalmology, UoN
Supervisors: Dr. Kahaki Kimani, Prof. Dunera Rahel Ilako

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Appendix 5: Permission to access medical records – Eagle Eye Laser Centre

Eagle Eye Lavington Executive Clinic
Ramisi Road, Off James Gichuru Road
Tel: 020 3860748, 3860749, 264 2153,
264 2154, 264 2142
Cell: 0717471429



5th Avenue Building, 3rd Floor, Ngong Road
P.O.Box 76386 - 00508, Nairobi, Kenya
Tel: 020 271 3403, Fax: 020 272 394
Cell: 0715 186 034, 0737 385 36
Email: info@eagleeye.co.ke
Web: www.eagleeye.co.ke

24th August 2017

To Whom It May Concern,

RE: PERMISSION TO ACCESS MEDICAL RECORDS AT EAGLE EYE LASER CENTRE.

This is to confirm that Dr.Cliff Muturi who is a postgraduate student at the department of ophthalmology, University of Nairobi, has been granted permission to access data on outcome of refractive laser surgery at Eagle Eye laser Centre.

This is also to state that although the two supervisors of Dr.Muturi are directors at Eagle Eye Laser Centre, they will in no way interfere with the collection, analysis and interpretation of the data.

Yours Sincerely,

Dr.Kahaki Kimani.
Director.

