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Comparison Of Photorefractive Keratectomy Versus Femtosecond Lasik For Correction Myopia

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Abstract

This study aimed to compare and determine the differences in visual acuity, complications and higher order aberration (HOAs) in eyes with stable myopia undergoing either photorefractive keratectomy (PRK) or femtosecond Lasik (Fs Lasik) flaps were created with an intended thickness of 100 µm, diameter of 8.4 to 9.0 mm, superior hinge, at one month postoperatively. Prospective study, randomized pilot study, refractive surgery was performed on 40 eyes: 20 eyes with PRK and 20 eyes with Fs Lasik. Primary outcomes measures were uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) and complications. Higher order aberration was as a secondary measurement. At one month postoperative in Fs Lasik eyes more improvement UDVA, CDVA was statically different between group at 1 month 25% of PRK group losing a line or more from preoperative while 10%of Fs group lost only 1 line .35% of Fs group gained a line by a month compared of 10%of PRK group .Types of complications different between groups: eight eyes in Fs Lasik group experiencing complications including diffuse lamellar keratitis (DLK) with no loss of UDVA or CDVA. There were slightly significant differences between groups in any HOAs, spherical and coma aberrations were increased compared with preoperative conditions. At 1-month follow-up, Fs Lasik group demonstrated clinically and statistically significant better visual acuity and higher order aberrations HOA than the PRK group with differences in experienced complications.

Keywords:: Photorefractive Keratectomy ; Femtosecond Lasik ; Refractive Surgery

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1.0. Introduction

The development of physiologic optics and methods of objective measurement of ocular parameters was essential for concepts of refractive surgery to evolve [1]. The measurement of the anterior surface of the cornea by Scheiner in 1619 [2] and the development of keratometry by Von Helmholtz in 1867, quantified parameters of the cornea and thus enabled concepts of the alteration of corneal shape for correction of astigmatism to be proposed [2,3] .

In 1894, William Bates described two cases in which non-perforating incisions were made in the cornea to correct astigmatism [4,5]. Refractive errors have major health and economic burdens, for example as regards visual requirements at work. It has been calculated that 2.54 billion dollars are spent each year in the USA merely for the inspection and correction of myopia [7-9]. There are numerous reasons why the correction of the human eye does not yield “supervision”, as one might expect. Changes of aberrations related to variation in the accommodative status, pupil size, wave length (color) of light, and aging have been known for a long time [19, 24] .

Basically, two different types of laser refractive surgery procedures are performed: surface or stromal/lamellar ablation [6,7, 11] . In Photorefractive keratectomy (PRk) they reshaping the cornea by a surface photo ablation , following epithelial removal by laser or by mechanical or alcohol assisted scraping; excimer laser photo ablation of the stroma is performed, removing the epithelium , and in the 1990s LASIK (laser assisted in situ keratomileusis) become the most common laser refractive procedure used worldwide [8,10, 21] .

The rapid improvement in vision and lack of postoperative pain associated with LASIK has made this the preferred option with patients compared with PRK, which has greater postoperative discomfort and prolonged recovery of visual acuity [12, 17] . A thicker-than-expected flap not noticed by the surgeon can lead to corneal ectasia following Lasik [13]. Cutting a thinner LASIK flap is less invasive to the nerves within the corneal stroma, decreasing the severity and duration of dry eye, possibly by preserving corneal sensation and blinking rate [7, 9] .

Several other techniques have also been introduced, such as EpiLASIK and LASEK, but these are merely modifications of PRK. In EpiLASIK, a special microkeratome, epikeratome, dissects the epithelium from the Bowman’s layer instead of mechanical scraping, while in LASEK the central epithelium is exposed to alcohol, after which an epithelial button can be removed [7,10] .

In order to improve the safety and the efficacy of the first step of the LASIK procedure, the refractive surgeon can now use a new tool which has quickly become the gold standard in lamellar refractive surgery. This is the femtosecond laser which allows the carving of a lamellar corneal flap using a laser rather than a blade. This procedure is named IntraLASIK or ‘bladeless LASIK’ [7,11, 13] .

The femtosecond laser is a Nd:YAG laser operating in the infra-red wavelength range (1053nm) that can create flaps by performing a lamellar dissection within the corneal stroma [13]. Flap creation is the most common use of the laser. A raster pattern is used to create a circle of separation horizontally at a predefined diameter and once accomplished a circumference cut is used, leaving a gap for the hinge. The location and width of the hinge, depth and width of the flap are all defined by the user [7,13, 18] .

Recently, most surgeon interest in PRK because of increasing Concerns of complications associated with LASIK flap creation, including dry eye, corneal ectasia, and flap tears [18,19, 27]. The vast majority of studies comparing PRK with LASIK were conducted using mechanical microkeratomes before the introduction of the femtosecond laser for flap creation or wavefront-guided surgery [22,23].

2.0. Methods and Materials

Randomized study, refractive surgery was performed on 40 eyes : 20 with PRK and 20 with Fs LASIK, in Alhokama Eye Center and Almagrabi hospital, between October 2010 and April 2011. The Mean age of patient, 10 men and 10 women, was 25.4±48 years (range: 19-41). 20 patients (40 eyes) with stable myopia (-0.75 to -7.00 [D]) and astigmatism (0.25 to 1.25 D) were enrolled in the study. Five patients excluded from this study had clinically significant lens opacities, previous corneal or intraocular surgery, keratoconus, unstable refraction, autoimmune disease, immunosuppressive therapy, or were pregnant or breastfeeding. Contact lenses were discontinued 2 weeks prior to screening for soft contact lens wearers and 6 weeks prior to screening for rigid gas permeable lens wearers.

All patients had a preoperative examination including assessment of uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), tonometry, slitlamp examination of the anterior segment, and dilated fundus examination. Manifest and cycloplegic refractions were repeated on 2 separate visits to ensure reliability and stability. Corneal topography and thickness were measured using the Pentacam. All flaps were created with the IntraLase LDV femtosecond laser at 60 kHz in a raster pattern, the flaps were created with an intended thickness of 100 µm, diameter of 8.4 to 9.0 mm, superior hinge.

Postoperatively, each eye undergoing thin-flap LASIK received 1 drop of gatifloxacin 0.3% (Zymar; Allergan Inc, Irvine, CA), prednisolone acetate 1% (Pred Forte, Allergan Inc), ketorolac tromethamine 0.4% (Acular LS, Allergan Inc.), and a bandage soft contact lens (Softlens Plano T, Bausch and Lomb, Rochester, NY). The prednisolone acetate was continued hourly during the first preoperative day and 4 times daily for an additional 6 days. The gatifloxacin was continued 4 times daily for 1 week. In eyes undergoing PRK all eyes had their corneas by butting alcohol or trans epi PRK . This was followed by 1 drop of a gatifloxacin 0.3% (Zymar), prednisolone acetate 1% (Pred Forte), ketorolac tromethamine 0.4% (Acular LS) and a bandage soft contact lens (Softlens Plano T). Ketorolac tromethamine was continued 4 times a day for 3 days and then discontinued. Gatifloxacin and prednisolone acetate were continued 4 times a day for 1 week with a subsequent steroid taper over 2 to 3 months per surgeon preference. Mitomycin C was not administered to any patient in the study at any time. Both bandage soft contact lenses were removed simultaneously once re-epithelialization was complete, typically on postoperative days 3 to 5.

Primary outcome measures were UDVA, CDVA, and complications while HOAs were measured and trended within groups as secondary measures. After the study was completed, the results were compiled and the data unmasked for statistical analysis. Refractive error, visual acuity, and HOAs were treated as continuous variables and analyzed was done using Microsoft Excel (Microsoft and Graphpad instate3).

3.0. Results:

Mean preoperative measurements of UDVA, CDVA, sphere, and cylinder are shown in Table 1. of 20 patients (40 eyes) completed the study at postoperative 1 months. One eye in the thin-flap LASIK group required PRK retreatment following a flap tear and both eyes from this patient were therefore removed from analysis of visual acuity, contrast sensitivity, and HOAs as the retreatment prevented the ability to distinguish results between the 2 surgical methods. The eyes from this patient were still included in the analysis of complications.

Table 1. Preoperative group comparisons

	PRK	Fs
n	20	20
M	12	8
F	8	12
Age	25.9 ± 5.87 (19 to 41)	26.9 ± 4.85 (20 to 35)
CCT	550.3 ± 28 (498 to 585)	556 ± 26 (503 to 598)
Sphere	(-3.75 ± 1.85) (-6.50 to -1.50)	(-4.00 ± 2.00) (-7.00 to -0.75)
Cylinder	(-0.75 ± 0.39) (-0.25 to -1.25)	(-0.80 ± 0.70) (-0.50 to -1.00)
UDVA (20/X)	448.50 ± 260.50	456 ± 255.30
CDVA (20/X)	(15 to 25)19± 2.50	(15 to 25)19± 2.50

3.1.Visual acuity , Stability, Efficacy, and Predictability

Table 2 shows visual acuity outcomes stability, efficacy, and predictability outcomes at 1 month postoperatively. Statistically significant differences were found between PRK and thin-flap LASIK in UDVA at 1 month postoperatively, with thin-flap LASIK eyes showing more improvement in UDVA. CDVA was statistically different between groups at 1 month, with 25% of the PRK group losing a line or more from preoperative values, while 10% of eyes in the thin-flap LASIK group lost only 1 line at 1 month. No eyes in the thin-flap LASIK group lost more than 1 line. Also, 35% of eyes in the thin-flap group gained a line by 1 month compared with only 10 % of eyes in the PRK group.

Table 2. Postoperative comparisons of visual acuity efficacy and safety

	PRK	Fs
UDVA (20 / X)	(24 ± 6.56)	(20.65 ± 4.78)
SE	(- 2.95 to 1.00)	(-2.25 to 1.50)
Sphere	(-1.50 to 0.75)	(- 0.75 to 0.25)
Cylinder	(0 to 1.00)	(0 to 0.75)
20/15 or better	5 % (1)	25 % (5)
20/20 or better	40 % (8)	80 % (16)
20/25 or better	75 % (15)	95 % (19)
20/35 or better	95 % (19)	100 % (20)
20/45 or better	100 % (20)	
Loss 2 line	2	0
Loss 1 line	3	2
No loss	13	11
Gain 1 line	2	7

3.2. Higher-order aberrations:

Fig.1 At postoperative 1 month , 18 (90%) eyes in each group completed pentacum corneal topography analysis. Total root-mean square (RMS) HOAs, coma, trefoil, and spherical aberrations are compared in Figure 1. There were slightly significant differences between groups in any HOAs throughout the study with all *P* values total HOAs (*P* , 0.006), spherical (*P* , 0.002), and coma (*P* = 0.008 at 1 months) aberrations were significantly increased compared with preoperative conditions. Trefoil showed no significant change throughout the study in either group (*P* = 0.298).

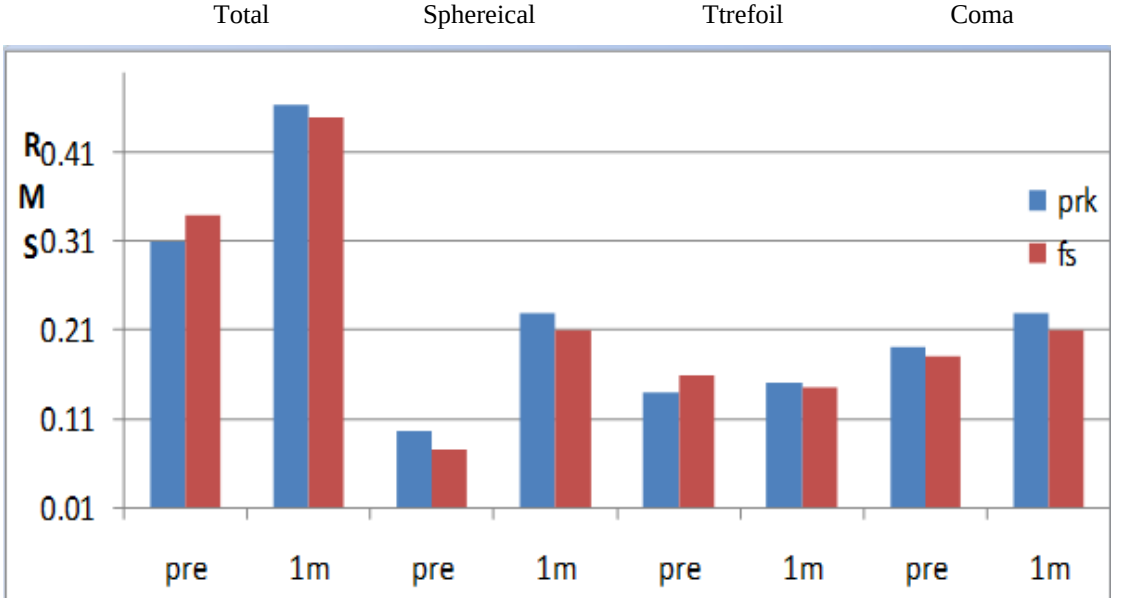

Fig.1 Higher order aberrations

3.3. Complications:

Table 3. Two eyes in the PRK group had mild haze appearing as early as 1 week postoperatively Haze remained in only 1 eye , but was classified as minimal and had no effect on UDVA or CDVA. Eight eyes (40%) in the thin-flap LASIK group experienced complications. In the thin-flap LASIK group and flap debris (1 eye) diffuse lamellar keratitis (DLK, 1 eye), with no loss of UDVA or CDVA . As a result of the retreatment with the counter surgical technique, the ability to accurately compare visual acuity, contrast sensitivity, and HOAs between the 2 surgical methods was limited and both eyes from this patient were removed from analysis of these measures, but were still included in the analysis of complications.

Table 3 Complications

Complications	PRK n of eyes	Fs n of eyes
Painful	3	2
Dry eye	7	4
Mild haze	4	0
Photophobia	0	4
Difficulties driving night	6	4
Diffuse lamellar keratitis (DLK)	0	1
Flap debris	0	1
Flap tears	0	2

4.0. Discussion:

The present study confirms that PRK and thin-flap LASIK are effective surgeries for the correction of low to moderate myopia. Although thin-flap LASIK showed superior visual results in the early postoperative period there was no statistically significant difference in outcomes of UDVA, CDVA, or total RMS HOAs between PRK and thin-flap LASIK by 1 month.

The UCVA at the 1-month postoperative visit showed 80 % of the Fs eyes at 20/20 or better compared with 40% of the PRK eyes (*P<.0001)*.CDVA was statistically different between groups at 1 month, with 25 % of the PRK group losing a line or more from preoperative values, while 10% of eyes in the fs LASIK group lost only 1 line at 1 month(P<.005) .No eyes in the fs LASIK group lost more than 1 line. Also, 35% of eyes in the Fs group gained a line by 1 month compared with only 10 % of eyes in the PRK group.(P<0.0001).

A loss of CDVA has been associated with the development of corneal haze in other studies, but as mentioned above none of the patients with visual regression developed haze. Findings in other studies showing that the biomechanics of eyes that have received thin-flap LASIK treatment are indistinguishable from those of PRK have led to suggestions that thin-flap LASIK is the best approach to LASIK [14, 22]. Although the present study find statistically significant differences between thin-flap LASIK and PRK in terms of visual quality at 1 month, complications dealing with flap integrity in the thin-flap LASIK group were present which are not complications found in PRK. Although PRK remains a viable option for those unable to undergo LASIK, the use of thinner flaps may eliminate some of the complications seen with traditional LASIK.

Larger studies are needed to better compare the complication rates of both methods and to determine how effective thin-flap LASIK will be in achieving the benefits of PRK and LASIK while avoiding the risks associated with each method. While thinner LASIK flaps attempt to preserve the biomechanical stability of the corneal stroma, at the same time, the flap itself becomes less stable, as was noted withthe 2 flap tears and other complications occurring in the thin-flap LASIK group in this study.

A study by Espandar and Meyer showed that most complications in flaps created by IntraLase femtosecond laser occurred at the hinge, which is where the 2 flap tears that occurred in this study. A thinner flap hinge would be biomechanically less stable and would increase the likelihood of intraoperative flap tear occurrence as well. Six of the 9 eyes with complications in the thin-flap LASIK group had microstriae, which are caused by the flattening of a weak corneal flap unable to maintain its curvature over the small area of stroma removed during ablation. The biomechanics of the flap and hinge, however, cannot be evaluated by the design of this study as analysis was done based on intended flap thickness, which has been shown to vary with the IntraLase FS60 femtosecond laser [14].

The study could have been strengthened had intraoperative pachymetry or OCT been performed. Creating a flap with increased integrity would help prevent microstriae from forming and would also provide for a stronger hinge that would be less susceptible to flap tear. Possible ways to optimize flap integrity include modification of hinge and side-cut angle creation, as well as improved planarity and microdisruption of flap edges. This will allow improved adhesion of the flap to the underlying stroma [20, 25]. Continued improvements in laser technology may allow for safer creation of thinner flaps, helping to provide evidence for superior outcomes in thin-flap LASIK, permitting the biomechanical stability of PRK with the visual recovery of LASIK. Custom flap formation that minimizes weak areas susceptible to tearing will be helpful in achieving this difficult balance between corneal and flap integrity [15, 16] .

In [16] study 42% of the PRK group lost a line or more of CDVA and 22% of the fs LASIK group lost 1 line at 1 month postoperatively while in [14] study 24 % and 9%. Imola Ratkay and et al performed PRK or IntraLASIK 1 month postoperatively, 60% of the fs patients had an UCVA of 20/20 or better By comparison, 29 % of eyes in the PRK group achieved UCVA of 20/20 or better. Dr Ratky said there were no buttonhole flaps or infections, no

significant epithelial defects, decentered flaps, or foreign body under the flap associated with IntraLASIK [16, 26]. She noted 4 cases of diffuse lamellar keratitis and 3 cases of photophobia. PRK was associated with greater pain, and a higher incidence of halos, and haze. This was particularly true among patients with more than six diopters of myopia. Postoperative increases in total HOAs, sphere, and coma were noted in our study, as also seen by [16, 14], although they noted that the increase in sphere and coma aberrations was significantly higher in the PRK group at 1 and 3 months postoperatively

5.0. Conclusion:

Conclusions: At the 1-month follow-up, Fs group demonstrated clinically and statistically significant better visual acuity and HOA than the PRK group with differences in experienced complications. There is also a need for further independent, contralateral studies to verify these results, particularly to compare results obtained with the femtosecond laser versus mechanical microkeratomes that are capable of creating thin, planar (SBK) flaps.

From this study of comparing fs with PRK, we conclude that this new procedure offers refractive surgeons and patients many of the advantages of both LASIK and PRK, with the quicker visual recovery and comfort associated with LASIK and the theoretical biomechanical changes and tear function of PRK. Proponents of surface procedures argue that it is unfair to compare the results between a flap-based and surface ablation procedure before the 3-month visit. However, they may be missing what is important from the patient's perspective. Sub-Bowman keratomileusis would seem to be more practical for the patient with less pain, quicker visual recovery, fewer medications, and an overall superior experience.

In future study we will try to complete the follow up for long term after stabilities of both surgery to get more information and to decide which procedure is more efficacy and safety.

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