

A prospective comparison of off-flap epi-LASIK and P.R.K for correction of myopia

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الخلاصة

تم في هذه الدراسة مقارنة النتائج العملية لكلا التقنيتين (ابي ليزر منزوعة الغلاف) وتقنية (بي- ر- ك) في معالجة قصر البصر بواسطة الأكرامير ليزر باستخدام مئة عين لخمس مريض مصاب بقصر البصر أجريت لهم عملية تصحيح قصر البصر بواسطة الأكرامير ليزر باستخدام تقنية الأبي ليزر لعين وتقنية (بي- ر- ك) للعين الأخرى تم استخدام جهاز القشط الميكانيكي (MORIA) في تقنية الأبي ليزر وتم استخدام الكحول بتركيز (18%) لمدة (25) ثانية في تقنية (بي- ر- ك) لفصل الطبقة الطلائية للقرنية تم إجراء عملية التصحيح بالأكرامير ليزر باستخدام جهاز نوع (نايدك-اليابان) تم تسجيل زمن شفاء الطبقة الطلائية للقرنية بشكل كامل , مقاييس عتمة أو غشاوة القرنية , مقاييس الألم وحدة البصر في كلتا التقنيتين ونتائج البحث كانت درجات قصر البصر تتراوح بين اثنان إلى ستة ونصف وحدة بؤرية , معدل زمن شفاء الطبقة الطلائية للقرنية كان أطول قليلا باستخدام تقنية (بي- ر- ك) التقليدية 94% من المرضى في كلتا الطريقتين كانت درجة الرؤيا لديهم 6/ 6 بعد ستة أشهر من إجراء عملية التصحيح مقاييس الألم ودرجة العتمة أو الغشاوة للقرنية كانت متشابهة تقريبا في كلتا الطريقتين استنتج ان كلا الطريقتين في علاج قصر البصر بالأكرامير ليزر كانت فعالة ومؤثرة وكانت النتائج متقاربة من حيث الألم ودرجة الغشاوة التي تحدث بعد عملية التصحيح ولكن عدم استخدام الكحول في تقنية الابي ليزر يؤدي إلى تلافي التأثيرات السمية المؤذية للكحول على قرنية العين

Abstract

Purpose: To compare the clinical post operative results of off-flap epi-LASIK and photorefractive keratectomy (P.R.K) for the correction of myopia

Methods: In Al-Hillah teaching Hospital (Laser Unit), 100 eyes of 50 patients with myopia in which off-flap epi-LASIK was done to one eye and photorefractive keratectomy (P.R.K) was done to other eye, in epi-LASIK mechanical separation of the corneal epithelium was performed with MORIA epikeratome and alcohol assisted separation with 25 seconds application of 18% alcohol (P.R.K technique). Ablation was performed with NIDEK CXIII laser.

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The patients were seen daily until epithelial healing and at one, three, and six months, time to epithelial healing, haze grades and pain scales were recorded

Results: pre operative myopic spherical refraction was $(-3.90 \pm 1.45$ diopters) range $(-2.00$ to -6.50 diopters) , the mean time to epithelial healing was slightly longer after (P.R.K) $(4.9 \pm 0.6$ days) compared to epi-LASIK $(4.20 \pm 0.56$ days) .

Of both techniques (P.R.K and epi-LASIK) treated eyes 94% achieved 6/6 after six months; the grades of pain and haze were nearly similar in both off-flap Epi-LASIK and P.R.K

Conclusions: Off-flap epi-LASIK and P.R.K offer effective correction of myopia with comparable results regarding postoperative pain and haze

Key words: comparison, P.R.K, off-flap epi-LASIK

Introduction

Laser in situ keratomileusis (LASIK) has been the most popular procedure for treatment of refractive errors since its introduction and carries its popularity despite advances in surface ablation techniques , however, flap related complications ,corneal ectasia ,and the need to retain sufficient thickness in the stromal bed have led to further researches and advances in surface ablation techniques. Laser epithelial keratomileusis (LASEK) and epi-LASIK are the most recent surface ablation techniques, and are referred to as, advanced surface ablations, as they probably have beneficial effects on corneal wound healing ⁽¹⁾. Surface ablations have become popular for patients with moderate to high refractive errors and thinner corneas, or corneal thickness in which conservation of tissue is a factor ⁽²⁾

Epi-LASIK as an alternative surface ablation procedure, however, has been reported to involve slower healing and visual recovery than that of traditional lasik surgery. ⁽³⁾

Photorefractive keratectomy (P.R.K), the sculpting of de-epithelialized corneal surface to alter refractive power, underwent extensive preclinical investigation before it was applied to sighted human eyes. Results of early animal studies provided evidence for normal wound healing in laser-ablated corneas .MC Donald and co-

workers treated the first sighted human eyes in 1988, while more lasik procedures continue to be performed than P.R.K, P.R.K. is an attractive alternative in specific indications ,such as very low refractive corrections , epithelial basement membrane disease (often called map-dot-fingerprint dystrophy), thin corneas and or treatment of some lasik flap complications such as button holed flaps. ⁽⁴⁾

Patients and methods

One hundred eyes of 50 patients with myopia (16 were men and 34 were women) with the mean age of (27 ± 7) years, range (20-44 years) were involved in this prospective comparative study . Written informed consent was obtained from all patients and all patients were informed about the details and risks of the surgery. The refractive errors were treated with off-flap epi-LASIK of one eye and P.R.K. (photorefractive keratectomy) in the other eye.

The preoperative examinations included: manifest and cycloplegic refraction, uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), anterior segment examination, applanation tonometry, fundoscopy, corneal topography, mesopic pupil size measurement , wavefront analysis and pachymetry .

Inclusion criteria were age above 18 years old, stable refraction of one year and normal corneal topography. Exclusion criteria were dry eye, patients with unstable refraction , blepharitis, glaucoma, collagen vascular diseases, diabetes mellitus, previous refractive surgery and evidence of keratoconus. All surgeries were done by the same surgeon, and both eyes were treated at the same surgical session. All surgeries were performed under sterile conditions in an operating room ,topical anesthesia (proparacain 0.5%) was used to anaesthetize the cornea ,a drape and eye lid speculum were inserted after sterilization of eyelids with (10%) povidone iodine , the cornea was irrigated with cool (4C) balanced salt solution (BSS).

In epi-LASIK treated eyes ,the epikeratome (MORIA, France) preassembled hand piece was applied to the operative eye with its central circular opening centered around the limbus , then suction was activated , the operative eye was irrigated with (BSS) solution during passage of epikeratome .Depressing a foot pedal caused the oscillating

block to run parallel to the horizontal corneal plane , separating the epithelial sheet, producing nasal hinged epithelial of (9.0 mm) diameter ,then suction was released and the epikeratome was removed from the eye . the epithelial flap was completely removed by forceps.

In P.R.K treated eyes ,the epithelium was incised with an (8.5) mm trephine placed centrally and (18%) alcohol was applied for (25) seconds ,then the epithelium was detached and removed . As the patient focused on a fixation target , laser ablation was performed with excimer laser (NIDEK CXIII. Japan) .The corneal surface and the entire conjunctival fornix were irrigated with cool (BSS), a drop of tobramycin (0.3%) and dexamethasone (0.1%) were instilled and a bandage contact lens was placed over the cornea with sterile forceps . The eyelid speculum and drape were removed , then the patient was examined with slit lamp biomicroscopy before discharge .

Patients were examined daily until complete epithelial healing and the therapeutic contact lens was removed ,then at one, three and six months postoperative intervals , the post operative medication consist of topical tobramycin and dexamethasone eye drops 4 times / day ,diclofenac tablets 50 mg was prescribed and the patients were advised to take it orally once or twice / day if required , topical tobramycin was discontinued following complete epithelial healing , dexamethasone was administered 4 times/day for one month followed by fluorometholone eye drops (0.1%) 4 times / day for another one to two months depending on haze level , all medications were discontinued after 3 months , all patients also given artificial tears (Sodium Hyaluronate , Alcon) for use 4 times /day for a maintenance of tear film and a regular ocular surface .

Corneal haze development was objectively evaluated according to the system reported by Fantes et al ⁽⁵⁾ : 0 completely clear , 0.5 trace haze seen with careful oblique illumination with slit lamp biomicroscopy,1 more prominent haze but not interfere with

visibility of iris details ,2 mild obscuration of iris details ,3 moderate obscuration of iris details and lens

pain scores within 2 days after surgery were included in subjective evaluation that was done by patients according to predetermined scale ranging from 0to 3 as follows : 0 no pain or discomfort, 1 mild pain, 2

obvious pain not require analgesics, 3 obvious pain that require analgesics

statistical analysis was performed using SPSS 15 software. The comparisons were done with the chi-square test for categorical variables . Statistical significance was considered at $P < 0.05$.

Results

The mean pre operative myopic spherical equivalent refraction was (-3.90 ± 1.45 diopters) range (-2.00 to -6.50 diopters). the mean astigmatism was (1.25 ± 0.65 diopters), (range: 0.5 to 2.25 diopters)

Post operative visual acuity ranged between ($6/18$ to $6/9$) by Snellen's chart test during first month after epi-LASIK and P.R.K (34 eyes, 68%) . visual acuity showed variation even in the same eyes on different days until epithelial healing , this variation vary with extent of epithelial healing , epithelial edema and presence of epithelial debris under the contact lens seemed to affect visual acuity during this period , nearly all eyes had achieved ($6/12$) or better visual acuity after contact lens removal . after one month ,68% of epi-LASIK treated eyes achieved $6/6$ or better while 64% of P.R.K treated eyes achieved $6/6$ visual acuity table I ($p > 0.05$) not significant

After 6 months all eyes which are treated by both techniques achieved $6/9$ or better visual acuity (table I)

The mean time to epithelial healing was (4.20 ± 0.56 days) after epi-LASIK and (4.9 ± 0.6 days) after P.R.K

Most patients reported mild to moderate pain(85 eyes), while 15 eyes reported sever pain (table II) during first two days , epi-LASIK treated eyes seemed to have less pain than P.R.K treated eyes , otherwise , both epi-LASIK and P.R.K treated eyes did not differ significantly in terms of pain ($p > 0.05$) (table II).

Our results showed no significant difference in occurrence of haze between epi-LASIK and P.R.K ($p > 0.05$) table III , and no eye in both groups showed more than grade +1

Table (I): Visual acuity after off-flap epi-LASIK that performed in eye and P.R.K in the other eye of 50 myopic patients

	EPILASIK				P.R.K.				P Value
	6/9 or less		6/6 or better		6/9 or less		6/6 or better		
preoperative	3	6%	47	94%	3	6%	47	94%	
One month	16	32%	34	68%	18	36%	32	64%	> 0.05
Three months	6	12%	44	88%	7	14%	43	86%	> 0.05
Six months	3	6%	47	94%	3	6%	47	94%	> 0.05

Table (II): grades of postoperative ocular pain within two days after excimer laser ablation in both techniques.

	EPILASIK		P.R.K.		P. Value
Grade 1	29	58%	23	46%	> 0.05
Grade 2	15	30%	18	36%	> 0.05
Grade 3	6	12%	9	18%	> 0.05
Grade 4	0	0	0	0	

Table (III): incidence of haze after 1,3 ,6 months in 100 eyes of 50 patients , in which off-flap epi-LASIK is done to one eye and P.R.K. is done to other

Follow up	EPILASIK				P.R.K.				P. Value
	0.5		1		0.5		1		
One month	24	48%	10	20%	27	54%	12	24%	> 0.05
Three months	22	44%	6	12%	24	48%	8	16%	> 0.05
6 months	8	16%	0	0	10	20%	0	0	> 0.05

Discussion

Since its introduction in 1983 ,excimer photorefractive keratectomy (P.R.K) has undergone numerous modifications in surgical technique and instrumentation ⁽⁶⁾

Over the past few years ,a tendency toward performing surface ablation procedures has emerged ⁽⁷⁾. Thin, steep ,or flat corneas and deep set eyes are preferably treated with surface ablation , so that the flap related complications of LASIK can be avoided ⁽⁸⁾

Epi-LASIK is the most recent development in surface ablation and it involves the use of a mechanical separator to create an epithelial flap .

the cornea is not exposed to alcohol ,and hence alcohol- related toxicity to the epithelium and underlying stroma is avoided ^(1,3,9) ,in addition, mechanical separation of the epithelium has been proposed to provide a more proper plane of cleavage . Pallikaris et al ⁽⁹⁾ demonstrated that the level of separation was beneath the level of basement membrane with preserved hemidesmosomes in epi-LASIK. In the same study , the level of separation after LASEK (P.R.K preserving flap procedure) was within the basement membrane between lamina Lucida and Lamina densa , which implies some damage to the basement membrane. In addition ,damage to the basal epithelial cells has been observed by both light microscope and electron microscope evaluation in LASEK, while the basal cells were only minimally damaged after epi-LASIK ⁽⁹⁾ , these findings suggest less damage to basement membrane and basal epithelial cells after epi-LASIK than P.R.K.

In our study ,in off-flap epi-LASIK compared to P.R.K. techniques, the cornea was revealed to have rapid recovery with a more regular and smooth surface. this finding may be due to the removal of the epithelial flap ,which triggers epithelium regrow process resulting in a smooth corneal surface⁽⁵⁾ , in addition, the healing response in off-flap epi-LASIK is not a duplication of what happens in P.R.K. In P.R.K the surgeon removes the epithelium with a blade . Compared with P.R.K ,the removal of epithelial flap with the use of an epikeratome in off- flap epi-LASIK results in a smooth corneal surface with regular borders ⁽¹⁾ , offering advantages with respect to comfort , visual recovery and haze formation .

Most of the patients in both techniques experienced pain (mild to moderate) during the first two days , eyes with P.R.K. seemed to have more discomfort and pain, but there was no significant difference in post operative pain between two techniques table II ($p>0.05$), O'Doherty et al⁽¹⁰⁾ reported pain after epi-LASIK ,P.R.K. or LASEK for myopia .patients who underwent epi-LASIK were found to have less pain in the first few hours , after which all patients had similar level of ocular pain. Torres et al ⁽¹¹⁾ found that the postoperative pain after epi-LASIK and P.R.K. to be similar on postoperative day one, but epi-LASIK demonstrated significantly more pain than P.R.K. on days three and six. The explanations for the difference are that we use cooled BSS to

irrigate eyes in our study that relieved pain and variability of pain threshold among the patients.

The results of off-flap epi-LASIK and P.R.K. were relatively similar related to visual acuity after operation (table I) and it is ranged between 6/18 and 6/9 until the epithelial healing. After removal of contact lens and complete epithelial healing occurred, almost all eyes had achieved 6/12 or better visual acuity, similarly O'Doherty⁽¹⁰⁾ et al reported comparable visual and refractive results after epi-LASIK and other surface ablation techniques.

Postoperative corneal haze is one of the major obstacles that prevent widespread acceptance of surface ablation by patients and surgeons. It is mainly relative to the surface irregularity of ablated stroma. Our study showed no significant difference in the incidence and degree of haze between off-flap epi-LASIK and P.R.K. treated eyes (table III) $p > 0.05$, other studies have shown lower levels of haze after LASEK or epi-LASIK in comparison with conventional P.R.K.^(10,14). The difference in haze formation may be attributable to the different healing response resulting from the removal of epithelial flap.

Our study shown that non of both techniques seems to offer a major advantage to the other in clinical results except that the major motive in the development of epi-LASIK technique has been to avoid the toxic effect of alcohol on the anterior stroma ,also epi-LASIK has been proposed to provide better cleavage plane underneath the epithelial basement membrane .^(1, 3, 9) on the other hand in P.R.K., alcohol application provides separation in a plane within the epithelial basement membrane between Lamina Lucida and Lamina densa.^(9, 15, 16)

Conclusions

The results of our study imply that P.R.K and epi-LASIK are both effective in the correction of low or moderate myopia in virgin eyes and are safe as both techniques does not weaken the cornea significantly and additionally , there is no corneal flap to worry about , so there are no problems related to flap creation and no problems related to healing of the flap

References

- 1- Pallikaris IG ,Katsanevaki VJ, Kalyvianaki MI, Naoumidi II. Advances in subepithelial excimer refractive surgery techniques: epi-LASIK. *Curr Opin Ophthalmol.*2003;14:207-212.
- 2- Duffey RJ, Leaming D. US trends in refractive surgery :2003; ISRS /AAO survey.*J Refrac Surg.* 2005;21:87-91.
- 3- Pallikaris IG, Kalyvianaki MI , Katsanevaki VJ, et al. Epi-LASIK:preliminary clinical results of an alternative surface ablation procedure. *J Cataract Refract Surg.*2005; 31:879-885.
- 4- Srinivasan R. Ablation of polymers and biological tissue by ultraviolet lasers, Trokel SL, Srinivasan R, Braren B. Excimer laser surgery of the cornea. Refractive surgery . American Academy of ophthalmology, Basic and clinical science course .2005-2006;sec13:87-134
- 5- Fantes FE, Hanna KD,Waring GO, et al . Wound healing after excimer laser keratomileusis (photorefractive keratectomy) in monkeys *Arch Ophthalmol.* 1990 ; 108:665-675.
- 6- Trokel SL , Srinivasan R, Braren B. Excimer laser surgery of the cornea, *Am J Ophthalmol.* 1983;96:710-15 .
- 7- Solomon KD, Fernandes de Castro LE, Sandoval HP,et al . Refractive surgery survey. *J Cataract Refract Surg.* 2004;30:1556-1569.
- 8- Pallikaris IG ,Katsanevaki VJ, Panagopoulou SI. Laser in situ keratomileusis intraoperative complications using one type of microkeratome .*Ophthalmology.* 2002;109:57-63.
- 9- Pallikaris IG,Noumidi II, Kalyvianaki MI, Katsanevaki VJ. Epi-LASIK: comparative histological evaluation of mechanical and alcohol- assisted epithelial separation . *J Cataract Refract Surg.* 2003; 29:1496-1501
- 10- O'Doherty M, Kirwan C,O,Keeffe M, et al. Postoperative pain following epi-LASIK,LASEK and PRK for myopia. *J Refrac Surg.*2007; 23: 133-138 .
- 11- Torres LF ,Sancho C, Tan B, et al . Early postoperative pain following Epi-LASIK and photorefractive keratectomy : a prospective, comparative, bilateral study. *J Refract Surg.* 2007;23 :126-132.

- 12-Serrao S, Lombardo M, Mondini F. Photorefractive keratectomy with and without smoothing :a bilateral study. *J Refract Surg.* 2003;19: 58-64 .
- 13- Netto MV , Mohan RR, Sinha S ,et al . Stromal haze , myofibroblasts, and surface irregularity after PRK. *Exp Eye Res.* 2006; 82: 788-797.
- 14- Javier JA , Lee JB , Oliveira HB, Chang JH, Azar DT. Basement membrane and collagen deposition after laser subepithelial keratomileusis and photorefractive keratectomy in the leghorn chick eye . *Arch Ophthalmol.* 2006; 124: 703-709.
- 15- Lee JB, Javier JA, Chang JH, Chen CC , Kato T, Azar DT. Confocal and electron microscopic studies of laser subepithelial keratomileusis (LASEK) in the white leghorn chick eye . *Arch Ophthalmol.* 2002;120;1700-1706.
- 16- Azar DT, Ang RT , Lee JB, Kato T, Chen CC ,Jain S, Gabison E, Abad JC . Laser subepithelial keratomileusis : electron microscopy and visual outcomes of flap photorefractive keratectomy . *Curr OPin Ophthalmol.*2001;12: 323-328.