LASEK FOR MYOPIA: FIRST RESULTS

VANDORSELAER T.,**, HERMIAT J.J.***, SCHRAEPEN P.*, TRAU R.*, TASSIGNON M.J.**

SUMMARY

Purpose: To evaluate the efficacy and safety of laser-assisted subepithelial keratectomy (LASEK) for the treatment of myopia and astigmatism (low, moderate and high).

Material and Methods: Laser-assisted subepithelial keratectomy was performed by 3 surgeons in 45 eyes using an INPRO Gauss Excimer laser (31 eyes) or a NIDEK EC-5000 Excimer Laser (14 eyes). The mean follow-up is 9 months (3-15 months). Preoperative best-corrected visual acuity (BCVA) and corneal topography were measured. The postoperative parameters were: uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), spherical equivalent refraction (SER), defocus equivalent refraction (DER), and corneal topography.

Results: The mean preoperative sphere and cylinder were –4.09 diopters (D) ± 1.94 D (range –1.25 D to –9.75 D) and –0.67 D ± 0.55 D (range 0 D to –2.50 D) respectively. No eye lost 2 or more lines of BCVA. The UCVA was ≥ to 20/20 in 56 % of the cases and 20/40 or better in 100 % of the cases. No eye developed corneal haze that affected visual acuity. No major complications were recorded.

Conclusions: LASEK treatment is a safe and effective technique for treatment of low to high myopia. This surgical technique is less invasive and more effective than LASIK because of the lack of flap- and microkeratome-related complications.

RÉSUMÉ

But: Evaluer l'efficacité et la sécurité de la kératectomie sous-épithéliale assistée par laser (LASEK) pour le traitement de la myopie et de l'astigmatisme (faible, modérée, forte).

Matériel et Méthodes: La technique du LASEK a été appliquée par 3 chirurgiens sur 45 yeux à l'aide du laser à excimères INPRO Gauss (31 yeux) ou du laser à excimères NIDEK EC-5000 (14 yeux). Le suivi postopératoire moyen est de 9 mois (3-15 mois). La meilleure acuité visuelle et la topographie étaient mesurées en pré-opératoire. Les paramètres postopératoires étaient l'acuité visuelle non-corrigée et corrigée, la réfraction en équivalent sphérique, la réfraction en ''défocus équivalent'' ainsi que la topographie.

Résultats: La sphère et le cylindre préopératoires moyens étaient de –4.09 dioptries (D) ± 1.94 D (de –1.25 D à –9.75 D) et de –0.67 D ± 0.55 D (de 0 D à –2.50 D) respectivement. Aucun œil n'a perdu 2 lignes ou plus de la meilleure acuité visuelle corrigée préopératoire. La vision postopératoire non-corrigée était ≥ à 20/20 dans 56 % des cas et ≥ à 20/40 dans 100 % des cas. Aucun des yeux n'a développé un voile cornéen affectant la vision. Il n'y a eu aucune complication sérieuse au cours de l'étude.

Conclusions: Le LASEK est une technique sure et efficace pour le traitement de myopies faibles à fortes. Cette technique chirurgicale est moins invasive que le LASIK car elle évite les complications liées au volet et au microkératome.

SAMENVATTING

Doel: Het evalueren van de doeltreffendheid en de veiligheid van LASEK voor de behandeling van myopie en astigmatisme (lage, matige, hoge).

Methoden: 45 ogen werden behandeld door 3 chirurgen met de Inpro Gauss excimer laser (31 ogen) of met de Nidek EC 5000 excimer laser (14 ogen). Steeds werd de LASEK methode toegepast. De gemiddelde follow-up is 9 maanden (3-15 maanden). Preoperatieve best- en ongecorrigeerde visus en pre- en postoperatieve cornea topografie werden systematisch geregistreerd.

Resultaten: De gemiddelde preoperatieve sfeer en cilinder bedroegen –4,09 Dioptrie (D) ± 1,94 D (van

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* *Department of Ophthalmology, University of Antwerp.*
** *Department of Ophthalmology, CHU St Pierre, University of Brussels.*
*** *Department of Ophthalmology, CHU de la Citadelle, University of Liège.*

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–1,25 D tot –9,75 D) en –0,67 D ± 0,55 D (van 0 D tot –2,50 D) respectievelijk. In geen enkel geval daalde de best-gecorrigeerde visus met meer dan 2 lijnen. De ongecorrigeerde visus was 20/20 of meer in 56 % van de gevallen en 20/40 of meer in 100 % van de gevallen. Geen enkele cornea ontwikkelde een waas waardoor de visus werd beïnvloed. Geen ernstige complicaties werden vastgesteld.
Conclusie: LASEK behandeling is een veilige en doeltreffende behandeling voor lage tot hoge myopieën. Deze heelkundige behandeling is minder invasief dan LASIK en vermijdt de complicaties veroorzaakt door de flap en/of door de microkeratoom.

KEY-WORDS

Excimer Lasers, InPro, Nidek, myopia, LASEK, subepithelial keratectomy

MOTS-CLÉS

Lasers excimères, InPro, Nidek, myopie faible à modérée, LASEK, kératectomie sous-épithéliale.

INTRODUCTION

Photorefractive keratectomy (PRK) is a refractive procedure using an Excimer laser to ablate the surface of the cornea (41). This technique was progressively replaced by laser in situ keratomileusis (LASIK) because of its superiority on pain, speed in visual recovery and absence of corneal haze (10, 27, 28, 31).
However, numerous complications have been reported with this technique (1, 2, 4, 9, 24, 26, 34, 38, 39).
Laser-assisted subepithelial keratectomy (LASEK) is a modified PRK, first described by Camellin in 1999 (oral presentation) (6). In LASEK, Excimer laser stromal ablation is performed under a hinged flap of corneal epithelium. The repositioned epithelium is expected to reduce stromal changes and postoperative haze. Additionally, pain seems to decrease dramatically by the presence of the epithelial flap and the use of a bandage contact lens in order to keep the flap in place.

PATIENTS AND METHODS

In this prospective study, 45 eyes of 27 consecutive patients were treated by 3 surgeons with LASEK from September 2001 to September 2002 and followed for 3 to 15 months.
Preoperative best-corrected visual acuity (BCVA), postoperative uncorrected visual acuity (UCVA) and BCVA, pre- and postoperative topography were systematically recorded. The preoperative myopic spherical equivalent refraction (SER) ranged from –1.75 to –9.75 diopters (D) of which 33 % from –1.00 to –3.00 D; 47 % from –3.25 to –6.00 D and 20 % of –6.25 D and higher. The mean patient's age was 33 years (range, 20 to 58 years).
Each patient was informed about laser refractive surgery in general and LASEK compared to LASIK in particular. Patients were required to read and sign an informed consent form.

Laser-assisted Subepithelial Keratectomy Procedure

Tetracaïne hydrochloride 0.5 % drops were used for topical anaesthesia. A preincision of the corneal epithelium was made using a 8.00 mm

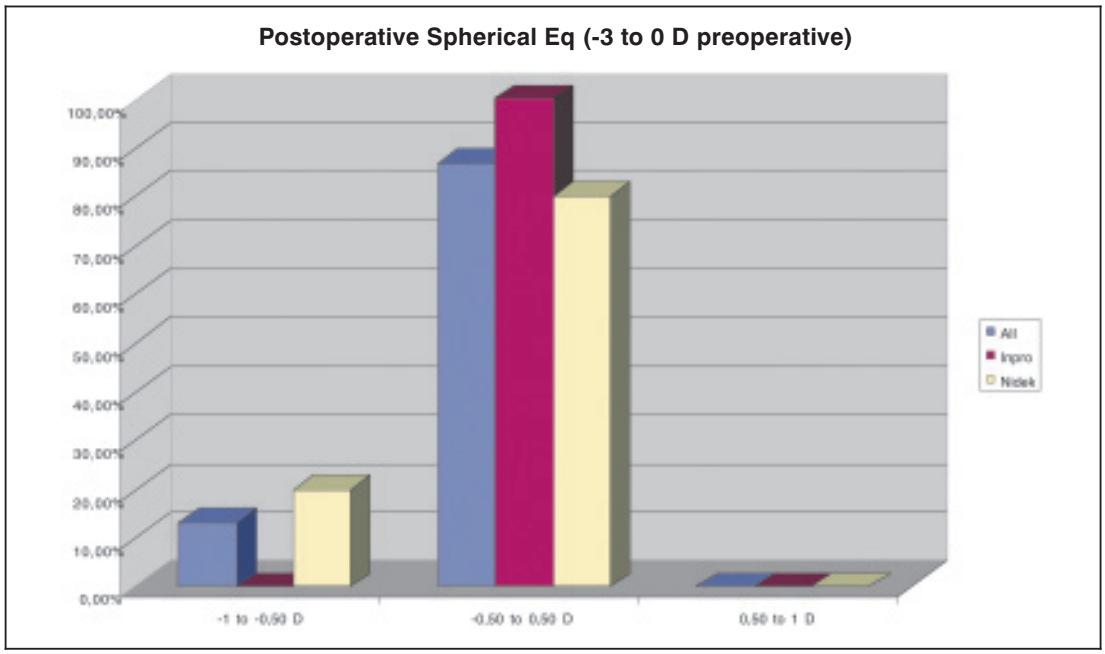

Fig 1. Postoperative SER (at 3 months) for preoperative SER between –1.25 and –3 D.

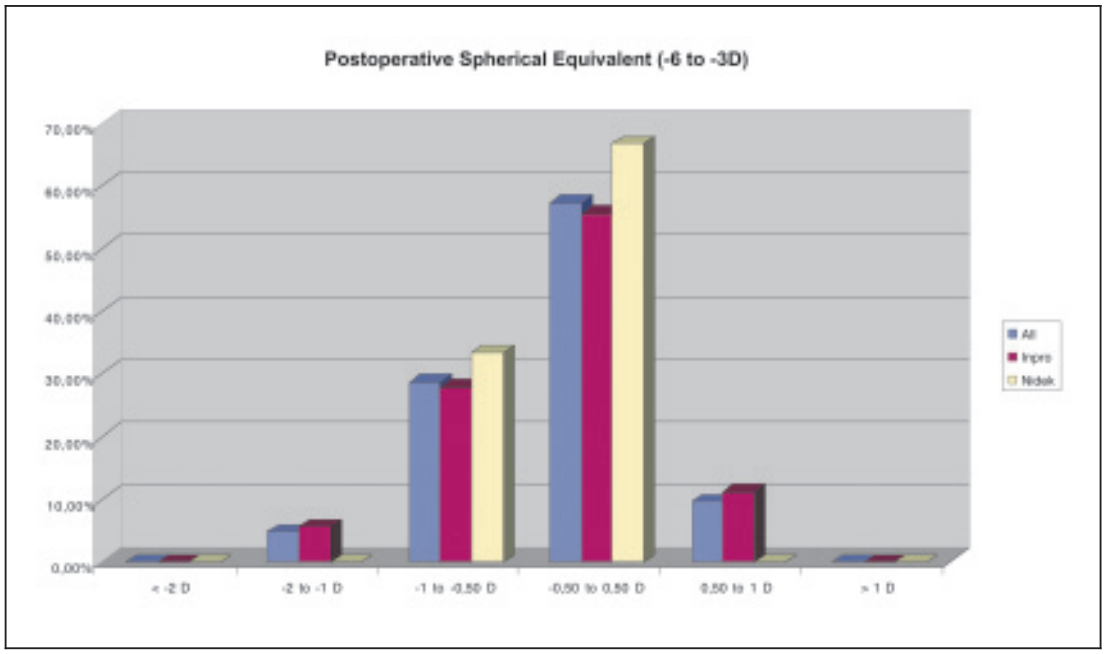

Fig 2. Postoperative SER (at 3 months) for preoperative SER between –3.25 and –6 D.

trephine centered on the visual axis. A 20 % alcohol solution was then placed on the cornea inside the trephine cone and left in place for 20 seconds. The alcohol was removed using a cellulose sponge. The cornea was irrigated with BSS. The epithelial flap was gently removed using a hockey knife. The epithelium was scraped and enrolled at the 12 o'clock position. Myopia and astigmatism were treated using the INPRO Gauss Excimer Laser (31 eyes) or the NIDEK EC 5000 Excimer Laser (14 eyes). Treatment diameter were 6.5 mm for the INPRO and 5.5 mm for the NIDEK. Astigmatism was treated in plus-cylinder format for the INPRO and minus-cylinder format for the NIDEK. Immediately after treatment, the stroma was irrigated with BSS and the epithelial flap was repositioned using an irrigating cannula. A therapeutic lens (Soflens®) was placed on the cornea. Topical Ofloxacin (Trafloxal®) and Ketorolac Tromethamin (Aculare®) were instilled on the corneal surface before the bandage contact lens was put in place. Postoperatively, patients were instructed to apply Trafloxal® each hour and Aculare® 4 times daily until the epithelium was healed. After corneal reepithelialization was completed, chloramphenicol and dexamethasone phosphate (Deicol®) were administered 4 times daily for 1 month. Patients were examined at 1 and 4 days, 1 week, and 1 month. At each examination, UCVA, BCVA andslitlampbiomicroscopywerechecked.Manifest refraction and corneal topography were performed at 1 month.

RESULTS

One day postoperatively, slitlamp examination showed an oedematous epithelial flap under the bandage soft contact lens. The central epithelium was healed in 100 % of the eyes by day 4. The percentage of eyes with UCVA of 20/40 or better was 100 % at 1 week. At 3 months UCVA was 20/40 or better in 100 % of eyes and 20/20 or better in 56 % of eyes.

In the low myopia group (0 D to –3 D) (n = 15), postoperative SER at 3 months was between –0.50 and +0.50 D in 87 % of the cases and between –1 and +1 in 100 % of the cases (Fig. 1). UCVA of 20/20 or better was achieved in 80 % of the cases at 1 week.

In the moderate myopia group (–3.25 D to –6 D) (n = 21), postoperative SER at 3 months was between –0.50 and +0.50 D in 57 % of the cases and between –1 and +1 in 95 % of the cases (Fig. 2). UCVA of 20/20 or better was achieved in 50 % of the cases at 1 week.

In the high myopia group (> –6.25 D) (n = 9), postoperative SER at 3 months was between –0.50 and +0.50 D in 22 % of the cases and between –1 and +1 in 78 % of the cases (Fig. 3). UCVA of 20/20 or better was achieved in 22 % of the cases at 1 week.

Patients with a preoperative SER between 0 and –6.0 D had better UCVA at 3 months than those with a preoperative SER of –6,25 D or higher.

At 3 months, 60 % of the eyes were within ± 0.5 D and 93 % were within 1.0 D of the spherical equivalent intended correction (Fig. 4 and 5). The mean defocus equivalent refraction (DER) (Fig. 6) was 0.84 D ± 0.50 (range, 0 to 2 D). There was no clinically significant haze. One eye lost 1 line of BCVA, other eyes did not loss any line, 3 eyes won 2 lines of BCVA and one eye won 4 lines of BCVA (Fig. 7).

Both lasers (InPro and Nidek EC-5000) achieved comparable results. There is a slight tendency of undercorrection for the Nidek laser compared to the InPro. DER is slightly better for the InPro which is most probably due to the shorter time of treatment, inherent to the delivery system. Nevertheless, considering the small number of patients in both series, these differences are negligible.

DISCUSSION

LASEK is an alternative technique for treatment of myopia, astigmatism and hyperopia.

The advantages of this new surface treatment over PRK are less postoperative discomfort, reduction of postoperative haze and shorter visual recovery time.

Moreover, LASEK and PRK do not present flap or microkeratome complications (40) e.g.: buttonhole (23, 29), decentered flap, incomplete flap (17), free cap, corneal perforation (44), poor flap adherence (14), striae (42), flap melt (7), late traumatic flap dislocation (26), interface problems like epithelial ingrowth (43, 46), blood or debris, diffuse lamellar keratitis (DLK)

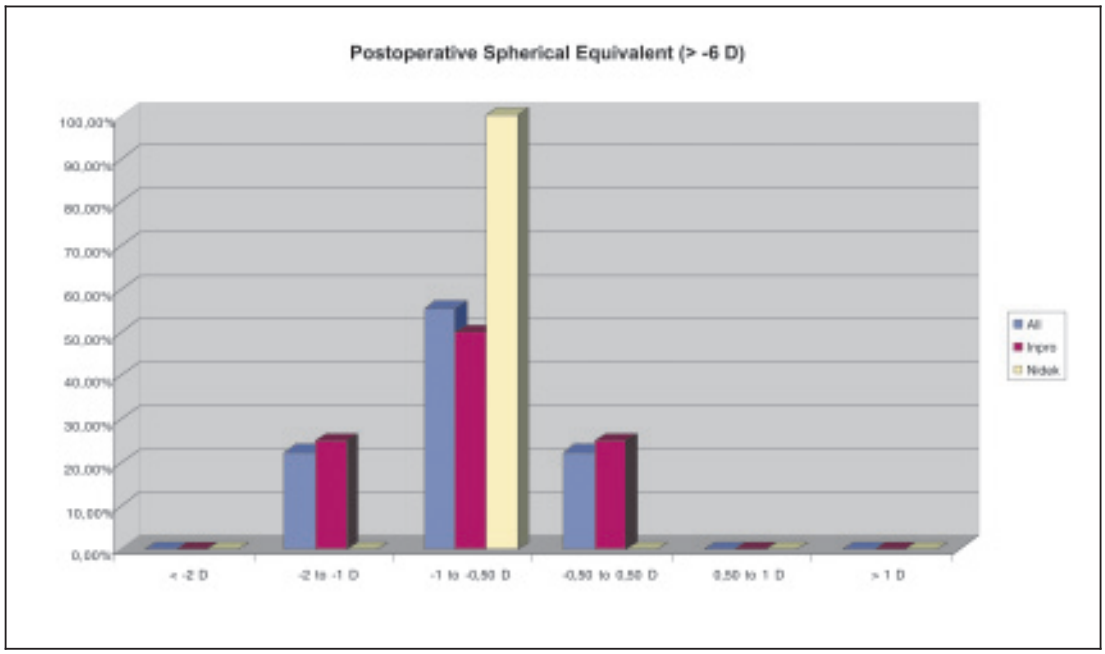

Fig 3. Postoperative SER (at 3 months) for preoperative SER between –6.25 and –10 D.

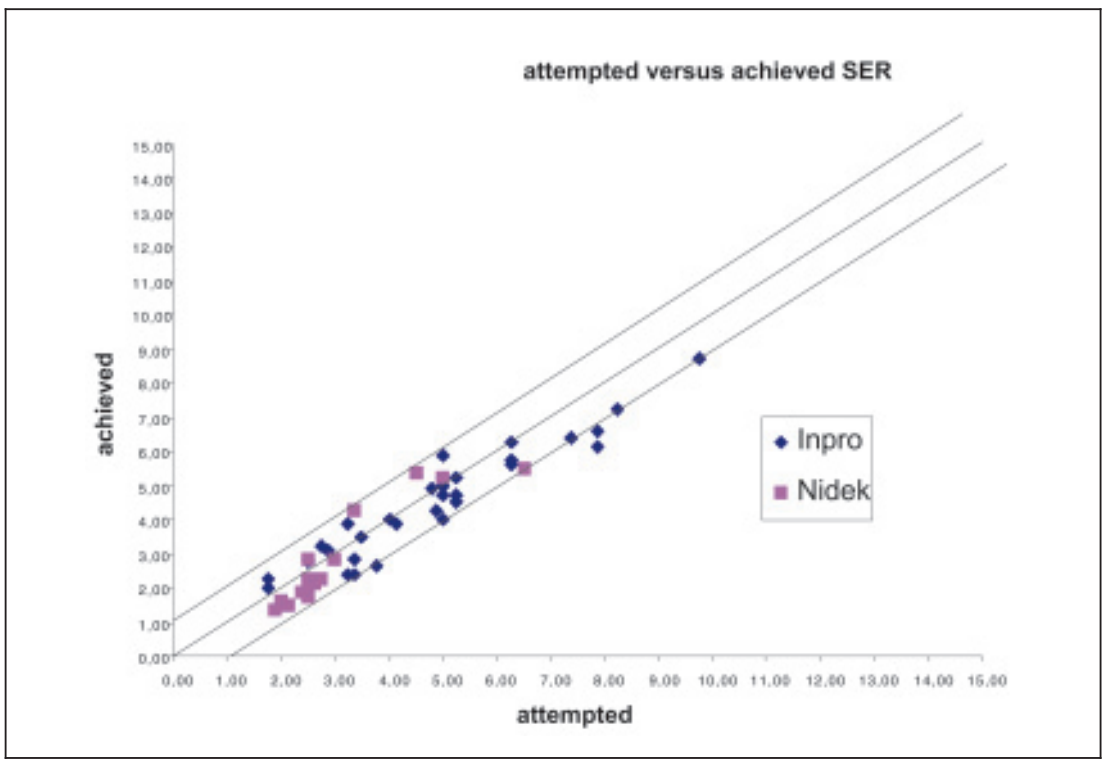

Fig. 4. Attempted versus achieved SER (at 3 months). 43 of the 45 eyes were within 1 D of the attempted spherical equivalent refraction.

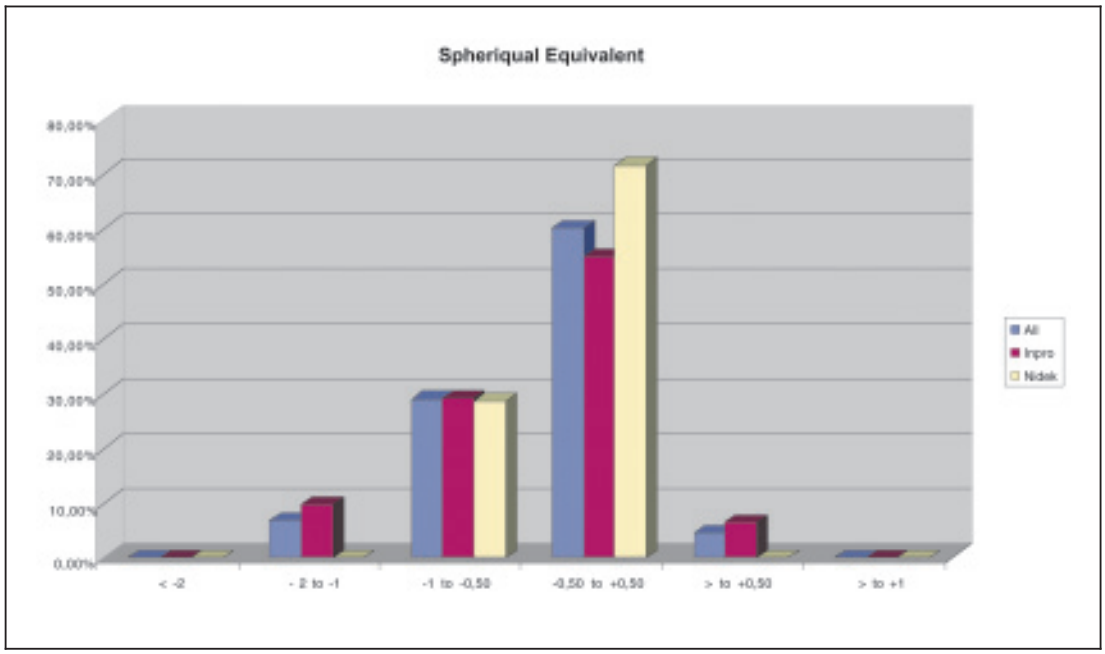

Fig. 5. Postoperative SER at 3 months for all cases (preoperative SER between –1.25 and –10).

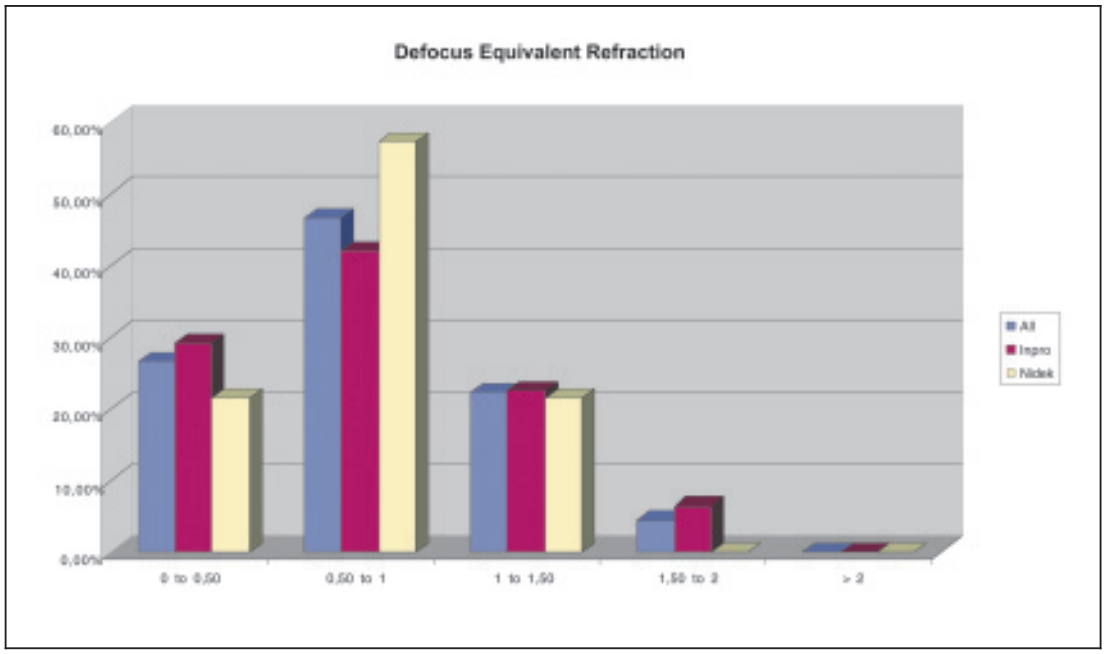

Fig. 6. Postoperative DER at 3 months.

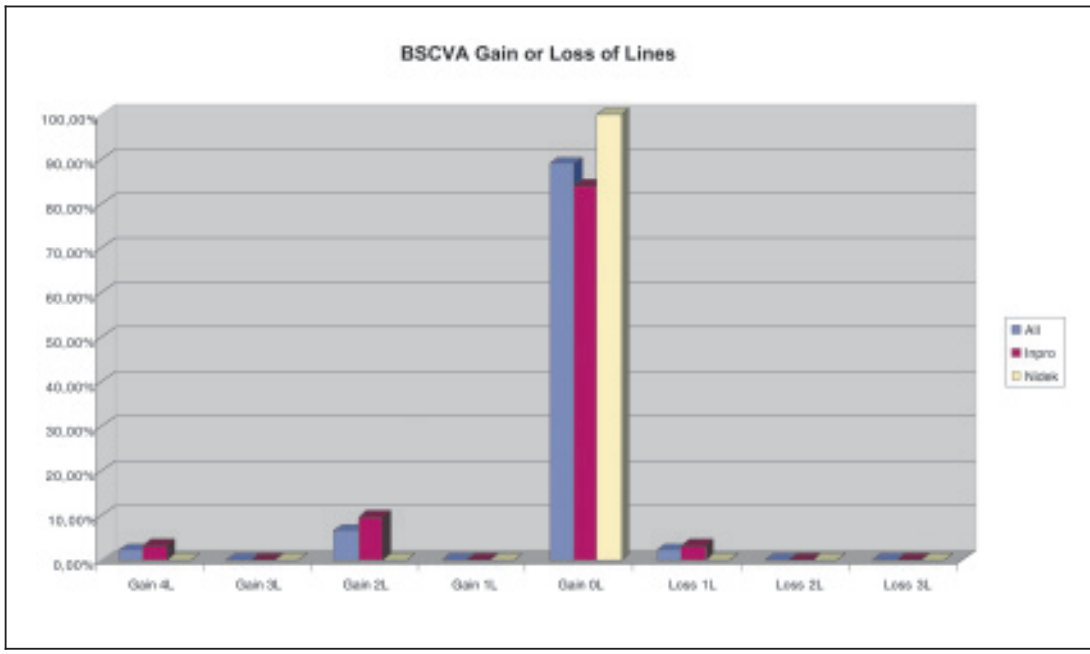

Fig. 7. BCVA gain and loss of lines at 3 months.

(37), secondary DLK (16, 47), deep infections (12, 30), no potential risks for postoperative corneal ectasia (2, 5, 13, 18, 20, 33, 45). Above these advantages, PRK leaves more residual tissue for eventual retreatment (21, 22, 32, 35).

Furthermore, surface ablation techniques (LASEK, PRK) may offer even more accurate results than LASIK when combined with customized wavefront ablation technology (48).

LASEK however presents postoperative pain, though less than PRK but more than LASIK. Lee et al. (22) compared postoperative pain in a study in which PRK was performed in 1 eye and LASEK in the fellow eye. The LASEK eyes had lower postoperative pain scores than the PRK eyes and most patients preferred LASEK procedure. However, in a similar comparative study, Litwak et al. (25) obtained higher pain score in the LASEK group than in the PRK group. In a non-comparative study, Anderson et al. (3) had no postoperative pain in 87 % of their cases. In our clinical experience, postoperative pain was experienced to be lower after LASEK than after PRK in those patients who had both eyes treated with both different techniques.

In contrast to LASIK, vision is blurred during the first 4 to 7 postoperative days (3, 22, 25, 36). This is the same delay as in PRK and is related to epithelial healing.

The major advantage of LASEK over PRK is the epithelial flap overlying the superficial ablated zone which seems to play a protective bandage role (35, 49) with decreased damage to stromal keratocytes as a result. The epithelial flap seems to play a role on the expression of different growth factors such as hepatocyte growth factor, keratocyte growth factor, epithelial growth factor and transforming growth factor β (19). As a result, less pain, less haze and better visual rehabilitation can be obtained after LASEK compared to PRK (3, 8, 22, 25, 35, 36). Gabler et al. (11) demonstrated that after 15 to 30 seconds of exposure to 20 % ethanol, the epithelium remains intact and most corneal epithelial cells are still alive. The basal epithelial layer was maintained in a compact and regular arrangement with ultrastructurally normal desmosomes and hemidesmosomes.

Hamberg-Nyström et al. (15) suggest that the epithelial factors have the largest effect on the stroma within the first 24 hours of the injury.

Therefore, immediate postoperative coverage of the stromal wound surface with a vital and intact epithelium represents most probably a key issue in the suppression of a wound reaction after LASEK.

All comparative studies between PRK and LASEK showed significantly less haze in the LASEK group (22, 25, 35). Shahinian et al. (36) found no significant corneal haze even when treating up to –14 D of myopia.

No corneal haze affecting visual acuity was reported in any LASEK study.

Scerrati (32) compared LASIK and LASEK. Postoperative corneal topography, BCVA and contrast sensitivity were recorded. Results of LASEK were superior to those of LASIK.

The most common complication of LASEK is loss of the epithelial flap during surgery. In these cases, the procedure may be converted into PRK.

Some authors (17, 38, 48, 49) describe a higher incidence of recurrent corneal erosion after LASEK. We had no recurrent corneal erosion in our series. Longer follow-up is necessary to rule out this issue.

CONCLUSION

LASEK treatment is a safe and effective technique for treatment of low to high myopia. Camellin described LASEK as a technique combining the advantages of both LASIK and PRK, leaving the complications of both techniques aside.

Our experience correlates with Camellin's statement. LASEK presents obvious advantages over PRK: less or no haze, less regression, less discomfort.

However, LASEK remains unable to equal the comfort advantages of LASIK (short visual recovery time, absence of pain).

LASEK reaches as accurate results as LASIK in case of low to high myopia. Because of the absence of the flap complications and the dramatic reduction in haze and regression with the new generation of Excimer lasers, the risk/benefit ratio after LASEK is superior compared to LASIK and PRK for low to high myopia.

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Address for correspondance
Prof. dr. M.J. Tassignon
Dept. of Ophthalmology
U.Z. Antwerpen
Wilrijkstraat, 10
B-2650 Edegem
marie-jose.tassignon@uza.uia.ac.be