GAUSSIAN BROAD-BEAM EXCIMER LASER: CLINICAL AND EXPERIMENTAL RESULTS

SCHRAEPEN P., ESKINA E.**, GOBIN L.*, TRAU R.*, TIMMERMANS J.P.***, TASSIGNON M.J.**

RÉSUMÉ

But: Evaluation des résultats à moyen terme (1-3 ans), obtenus après un seul traitement au laser Excimer à faisceau large et répartition Gaussienne de l'énergie pour le traitement de la myopie. Etude comparative au microscope électronique à balayage après ablation par un système *"flying spot"* (Bausch & Lomb) et un système Gaussien (InPro).

Méthode: Les 1035 yeux consécutifs étudiés ont été répartis en 4 groupes suivant la myopie, en *équivalent sphérique*: *myopie faible* jusqu'à -3.00 D (183 yeux), *myopie modérée* de -3.25 D à -6.00 D (540 yeux), *myopie forte* de -6.25 D à -10.00 D (210 yeux) et *myopie très forte* de -10.25 D à -20.00 D (102 yeux).

Quatre paires d'yeux de banque de cornée ont été traitées avec *"flying spot"* à un œil et système Gaussien à l'autre.

Résultats: Un *équivalent sphérique* à ±1 D de l'emmétropie a été obtenu dans respectivement 99.1%, 98.9%, 83% et 21% des groupes 1, 2, 3 et 4.

L'*acuité visuelle sans correction* obtenue est de 10/10 ou plus dans 65%, 51% et 19% des groupes 1, 2 et 3. L'*acuité visuelle sans correction* était de 5/10 ou plus dans 86% et 75 % dans les groupes 3 et 4.

L'équivalent sphérique défocalisé était de 1.0 ou moins dans 98%, 93%, 62% et 7% des groupes respectifs.

Le microscope électronique à balayage montrait une surface d'ablation lisse et homogène pour le laser profil Gaussien.

Conclusion: Le système de délivrance Gaussien à faisceau large donne des résultats comparables aux résultats obtenus par laser *"flying spot"* pour les myopies jusqu'à -10 D. Les avantages du système Gaussien sont: surface d'ablation homogène, temps de traitement court, faible taux de *haze*, fiabilité et facilité d'entretien de l'appareil propre au système de délivrance optique. Il s'agit d'une alternative intéressante par rapport aux systèmes de délivrance mécaniques plus complexes.

SAMENVATTING

Doel: Bepalen van de resultaten op middellange termijn (1-3 jaren) na eenmalige behandeling voor myopie met een Gaussiaans excimer laser systeem met brede straal. Studie van het cornea oppervlak met behulp van scanning electronenmicroscopie na laserbehandeling met een *flying spot* laser systeem (Bausch & Lomb) en een Gaussiaans laser systeem (InPro).

Methoden: De 1035 opeenvolgend bestudeerde ogen werden ingedeeld in vier groepen in functie van de behandelde myopie, uitgedrukt in *sferische equivalenten*: *zwakke myopie* tot -3.00 D (183 ogen), *matige myopie* van -3.25 D tot -6.00 D (540 ogen), *hoge myopie* van -6.25 D tot -10.00 D (210 ogen) en *heel hoge myopie* van -10.25 D tot -20.00 D (102 ogen).

Vier post-mortem ogen van twee donoren werden behandeld met het *flying spot* laser systeem aan één oog en het Gaussiaans laser systeem aan het andere oog.

Resultaten: Wij bekwamen een postoperatief *sferische equivalent* van ±1 D emmetropie in respectievelijk 99.1 %, 98.9 %, 83%, 21 % van de ogen van groepen één, twee, drie en vier.

.....

* *Department of Ophthalmology, University Hospital Antwerp, Antwerp, Belgium*
** *Sphere Eye Clinic, Moscow, Russia*
*** *Laboratory of Cell Biology and Histology, University of Antwerp, Antwerp, Belgium*

received: 09.03.05
accepted: 30.08.05

De *niet-gecorrigeerde visus* was 10/10 of beter in 65%, 51% en 19% van respectievelijk groepen 1, 2 en 3. De *niet-gecorrigeerde visus* was 5/10 of beter in 86% en 75% van respectievelijk groepen 3 en 4.

De *defocus equivalent refraction* was 1.0 of minder in 98%, 93%, 62% en 7% in de respectievelijke groepen.

Het scanning elektronenmicroscopisch onderzoek toonde een zacht en homogeen ablatie-oppervlak voor de Gaussiaanse laser.

Besluit: Het Gaussiaans laser systeem met brede straal geeft even goede resultaten voor myopieën tot -10 D in vergelijking met *flying spot* laser systemen bij PRK. De voordelen van dit systeem zijn: homogeen ablatie-oppervlak, korte behandelingsduur, beperkt voorkomen van *haze*, betrouwbaarheid en eenvoud van het onderhoud van het toestel eigen aan het optische systeem. Het vormt een interessant alternatief voor de mechanische, gecompliceerde laser systemen.

ABSTRACT

Purpose: To evaluate the mid-term (1-3 years) results of the Gaussian broad-beam excimer laser Delivery System (DS) after single treatment for the correction of myopia. To study the corneal surface with scanning electron microscopy (SEM) after excimer laser ablation using a *flying spot* delivery system (Bausch & Lomb) and a Gaussian Delivery System (GDS) (InPro).

Methods: The 1035 consecutive eyes studied were split in four groups with respect to the treated myopia, expressed in *spherical equivalent*: *low myopia* up to -3.00 D (183 eyes), *moderate myopia* from -3.25 D to -6.00 D (540 eyes), *high myopia* from -6.25 D to -10.00 D (210 eyes) and *very high myopia* from -10.25 D to -20.00 D (102 eyes).

Four post-mortem eyes of two donors were treated using the *flying spot* DS on one eye and the GDS on the other eye.

Results: We achieved postoperative *spheriqual equivalent* within ±1 D of emmetropia in respectively 99.1%, 98.9%, 83% and 21% of the eyes of group 1, 2, 3 and 4.

UCVA was 10/10 or better in respectively 65%, 51% and 19% of group 1, 2 and 3. UCVA was 5/10 or better in respectively 86% and 75% of group 3 and 4.

The *defocus equivalent refraction* was 1.0 or less in respectively 98%, 93%, 62%, and 7% of the four groups.

On SEM, the corneal surface presented a smooth and polished profile for the GDS.

Conclusions: The Gaussian Delivery System gives comparable results to the *flying spot* laser system for surface laser ablation in myopic eyes up to -10 D. Advantages of this system are: smooth ablation surface, short treatment time, low haze rate, high reliability and easy maintenance of the device due to the optical DS. It is an interesting alternative for the more complex mechanical DS.

KEY WORDS

Excimer laser, PRK, Gaussian Delivery System, Myopia, Corneal Surface

MOTS-CLÉS

Laser excimer, PRK, Système de délivrance Gaussien, Myopie, Surface cornéenne

INTRODUCTION

Since the pioneering work of Trokel et al. (27) in 1983 the excimer laser has proven to be a useful tool to remove tissue from the human cornea in a controlled and precise way, allowing refractive changes of the cornea. Trokel et al. (27) also defined the optical wavelength and energy to achieve this goal. These parameters have remained unchanged ever since with a wavelength of 193 nm in all excimer lasers currently used and laser pulse energy in the range of 100 to 200 mJ/cm^2.

The various excimer lasers available for *photorefractive keratotomy* (PRK) differ essentially from each other by their delivery system (DS). These DSs determine to a large extent the morphological characteristics of the treated cornea, as demonstrated with the *scanning laser ophthalmoscope* (SLO) (29). They all aim at achieving a smooth, homogeneous ablation surface with the largest possible optical zone.

Initially, the first excimer lasers had a broad-beam DS and were used for surface treatment. The shape of the ablated zone was obtained by a diaphragm system, which opened progressively, creating a deeper ablation at the centre than at the periphery of the cornea (18). However, the excimer laser beam itself is quite inhomogeneous with 'hot' and 'cold' spots which, when added to the stepwise settings of the diagram, resulted in a rather irregular corneal surface.

Therefore, several systems trying to homogenize the beam energy on the cornea were subsequently introduced: oscillating slits, rotating slits, ablatable masks (16), interposition of prisms (rotating or not) and different lenses on the laser's pathway (17).

More recent systems use a small-beam coupled with a galvanometric scanning DS in an attempt to achieve a homogeneous distribution of energy on the cornea. They necessitate a smaller laser cavity, fewer optics, high repetition rates, and overlapping pulses. However, despite the much smaller ablated surface per pulse (0.8 to 2.0 mm) and the high repetition rate, the treatment time takes several minutes,

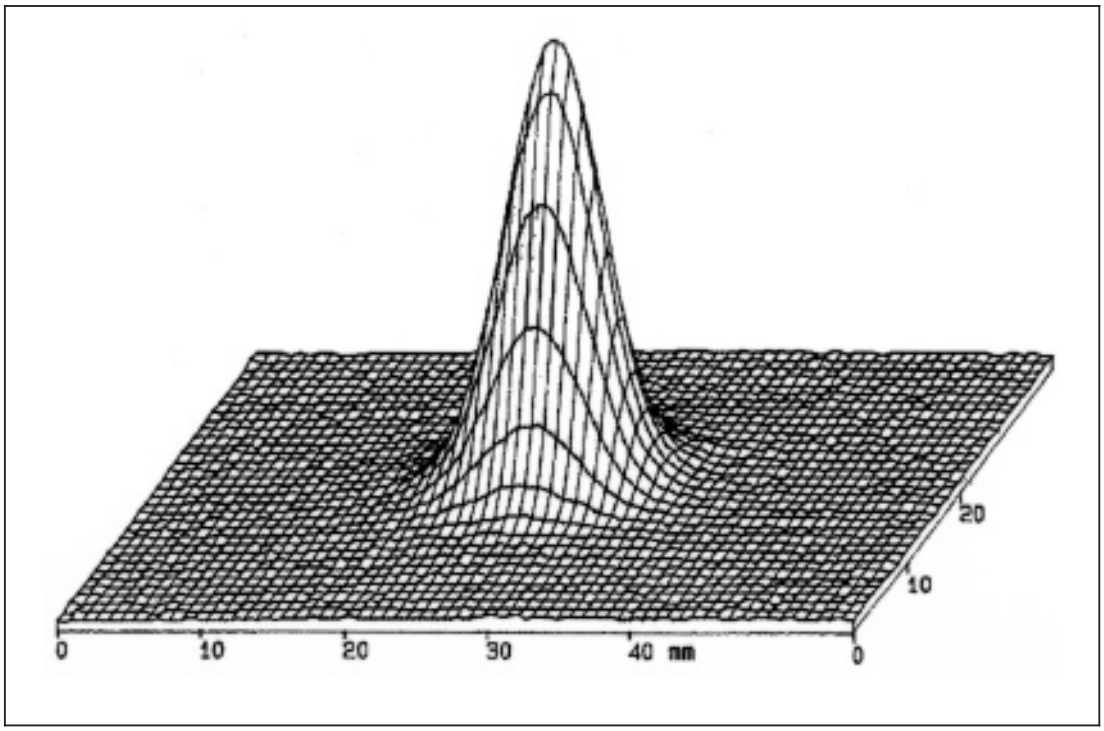


Fig. 1: Gaussian energy repartition with a peak energy in the centre and a progressively decreasing energy at the periphery.

making it difficult – if not impossible – for the patient to maintain a good fixation during the treatment. To solve this problem, tracking devices were introduced, which again increased the complexity of the mechanical parts of these DSs.

Laser in situ keratomileusis (LASIK) is one solution to atone the surface irregularities caused by the mechanical DSs, by covering them with a corneal flap. However, this flap technique creates an additional optic interface and may also cause significant intraoperative complications (12), including damage caused by intraocular pressure rise, partial flaps, buttonholed flaps, thin or irregular flaps, free flaps, flap folds, epithelial growth of different types and severity in the interface, infections and the more recently described ectasia (6). All these complications may have a negative impact on the quality of vision. For these reasons, a return to surface ablation has been observed recently. However, all currently available delivery systems are not suitable for surface treatment. Moreover, 'mechanical' DSs are delicate, expensive, subject to mechanical failures and they need intensive maintenance to ensure reliability.

For all these reasons the quest for an ideal DS continued and in 1996 Semchishen developed an entirely new concept of DS (24), replacing the mechanical components by a purely optical device. This device allows a homogeneous Gaussian repartition of the laser energy on the corneal surface, with peak energy in the centre and a progressively decreasing energy at the periphery (fig. 1).

The different steps of manufacturing can be summarized as follows:

The rough surface is manufactured on an UV quartz plate. At one side of the plate, first a metallic sublayer is deposited and then a photoresistant layer. By using photolithography windows are created in the photoresistant layer. These windows are holes of which the diameters vary according to the random law, around the mean value D_{av} (diameter average). In the same way, the distances T_i between the centres of the rings also vary according to the random law, around the mean value T_{av}.

Although the distribution of the diameters and the distances is at random, it follows a well-defined statistical law (fig. 2), where U_i are the linear diameters of the metallic sublayer elements after the windows have been created (fig. 3 a).

At the second stage, the quartz plate is subjected to etching through the windows in the metallic sublayer (fig. 3 b). To simplify the figure's construction, it is assumed that the tilt angels α_i of all microfaces, caused by etching under the metallic film, are equal to $\alpha_i = \alpha_O = 45°$. Fig. 3 b illustrates the relief profile in the cross-section. The heights of the profile ridges are:

$H_i = 1/2\ U_i\ [(1/2\ U_i)_{min} \leqslant H_i \leqslant (1/2\ U_i)_{max}]$ and the linear dimensions of the horizontal parts and the tilted parts' bases are D_i and $1/2\ U_i$ respectively.

At the third stage a polishing etchant was used. The process of surface polishing was accompanied with (i) formation of tilted parts of surface with the linear dimensions of the bases $I_i = 1/2\ (D_i + U_i)$, (ii) decrease of heights of the profile ridges due to smoothening of sharp peaks, (iii) diminishing the difference between heights of individual roughnesses due to the difference in velocities of etching large and small ridges. Thus, the tilts of roughnesses σ_i can be varied by changing the time of polishing, while the linear dimensions of the bases I_i remain practically unchanged (fig. 3 c).

According to the random law, light passing through such a plate will have a Gaussian angular energy distribution. The energy obtained in a focal plane of an imaging lens has a Gaussian distribution according to the following formula:

$$I_i(\rho,\varphi) \approx \frac{P_0\,\Phi^2(0)}{2\,\Pi\,\sigma^2 f^2\,(n-1)}\ \exp\left[-\frac{1}{2(n-1)^2\sigma^2}\,(\rho/f)^2\right]\quad (\rho/f \leqslant 0{,}25)$$

where ρ, φ are the polar coordinates in the focal plane and P_O is the total power of radiation reaching the rough surface. The multiplier $\Phi^2(0)$ takes into account the Fresnel attenuation of the transmitted radiation at two boundaries of the rough plate. The geometry of arrangement of the optical scheme is represented on fig. 4.

All beams scattered by the plate in the direction characterized by angles β and φ converge into point D_i, the location which is de-

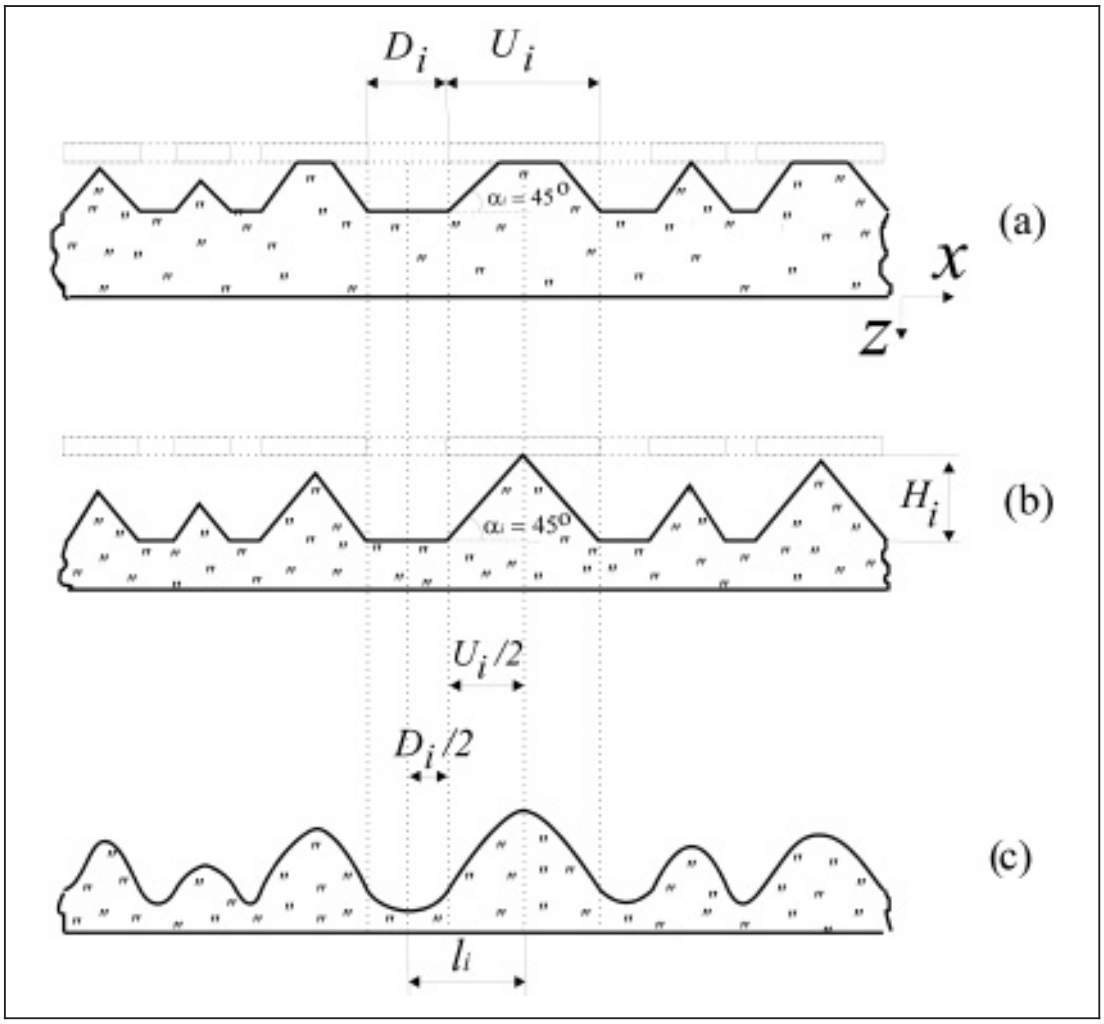


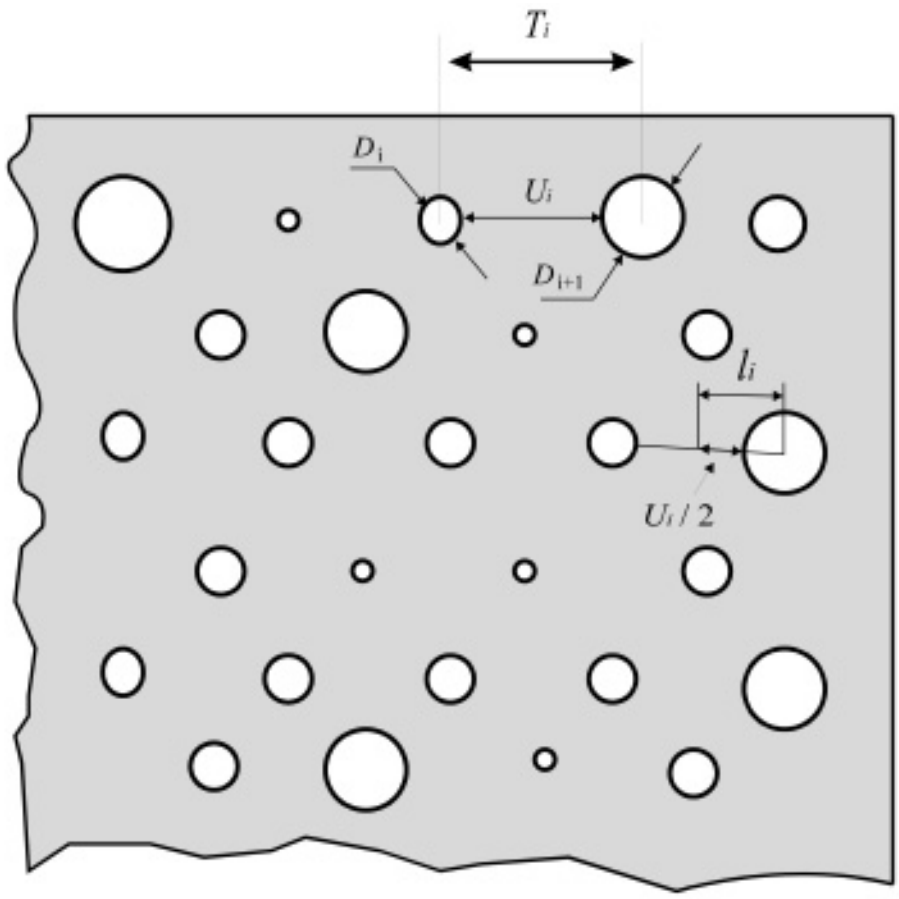
Fig. 2: Method of fabrication of rough surface with controlled statistic. Quartz plate + metal film + photoresist.

termined by the beam BD passing through the lens centre B. The radiation intensity in the focal plane of the lens does not depend on φ *and is a smooth function of the parameter* ρ *at an arbitrary distribution of intensity over the cross-section of the incident beam. This means that the rough plate-lens complex is capable of transforming any distribution of incident beam intensity into the homogenized radiation with circular symmetry in the focal plane.*

The advantages obtained by this conceptual innovation are: a large ablation zone, a smooth corneal surface, very progressive edges limiting optical aberrations and a short treatment time preventing fixation loss and corneal dehydration (3).

This Gaussian system has the additional advantage of being virtually maintenance-free since no mechanical or moving parts are used.

The purpose of this study is double: to evaluate the refractive results of surface treatments with the Gaussian broad-beam excimer laser according to the guidelines of G. Waring (33), and to examine, by means of SEM, the corneal surface of post-mortem donor eyes after treatment with a Gaussian broad-beam delivery system, as compared to a *flying spot* delivery system.



D_i , T_i - sampling according to the random low around the mean values $D_{av.}$, T_{av} from intervals

$$D_{min} \leq D_i < D_{max} , \quad T_{min} \leq T_i < T_{max} .$$

1) $U_i = T_i - (D_i + D_{i+1}/2)$ ⎫
2) $l_i = (D_i + U_i)/2$ ⎬ are distributed according to the Gauss low
3) $H_i = U_i/2$ ⎭

Fig. 3: Dielectric plate with “rough surface”.

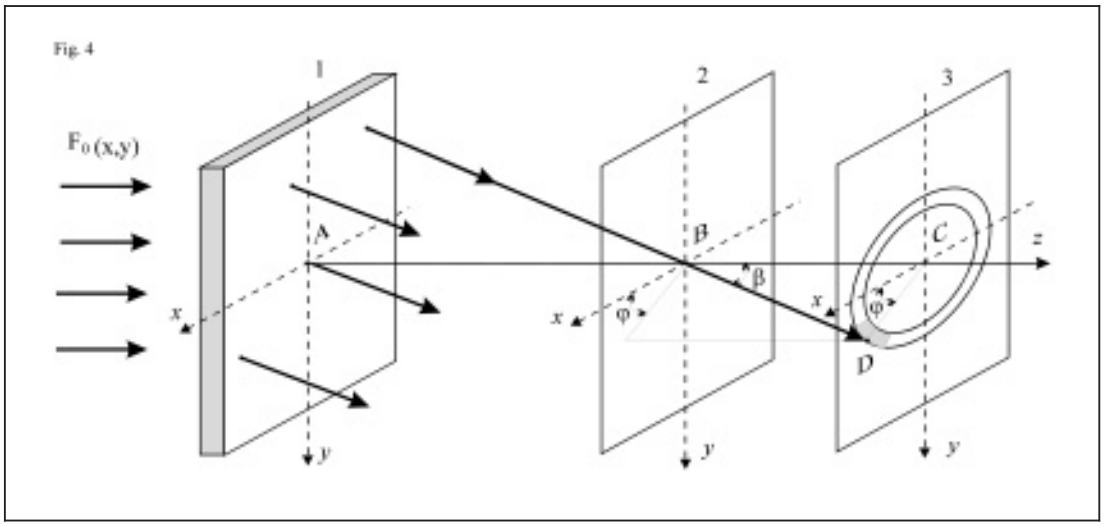


Fig. 4: Geometry of arrangement of the rough plate (1), the lens (2) and the lens focal plane (3).

MATERIALS AND METHODS

Clinical study

The clinical part of the study is the result of a collaboration between the Sphere Eye Clinic in Moscow (Russia) and the University Hospital of Antwerp (Belgium).

The excimer laser used by both centres for this study is based on a cavity manufactured by Lambda-Physik (model 200i) (fig. 5, fig. 6). Its main characteristics are a wavelength of 193 nm, a pulse frequency of 20 Hz, pulse energy at the centre of 210 mJ/cm^2 and pulse duration of 23 nsec.

The main inclusion criteria were correction for myopia, calculated in spherical equivalent. The associated astigmatism was -0.5 D ±0.9 D. A postoperative follow-up of 1 to 3 years is available.

The preoperative examination is based on a standard protocol including: *uncorrected* (UCVA) and *best spectacle-corrected visual acuity* (BSCVA), optimal refraction, binocular vision, corneal topography and slit-lamp examination.

Surgical procedure

Two drops of Ketorolac were given before treatment. Topical anaesthesia was achieved with Oxybuprocain monodosis. During surgery the eye was kept open by a speculum. The fixation was achieved by a double mechanism: active fixation of the patient by looking at a green LED located in the centre of the microscope, and control by the surgeon through a coaxial binocular microscope with a grating system. The contralateral eye was occluded.

After mechanical removal of the epithelium, laser ablation was performed on a useful optical zone of 6.5 mm, surrounded by a transition zone of up to 8 to 9 mm.

The ablation time varied from 3.00 sec (60 pulses) for 1 D correction to 18.25 sec (365 pulses) for 10 D correction.

Postoperatively a therapeutic contact lens was placed on the cornea for 4 days. Topical treatment was prescribed consisting of Ketorolac three times a day and Ofloxacin every hour for the first 48 hours, tapered to five times a day during the first postoperative week.

Daily postoperative examination was performed until complete closure of the epithelium, allowing removal of the contact lens. Corticosteroids and NSAID administration (2-3 times daily) were started at week 1 and continued for 3 to 4 months postoperatively. Further examinations were scheduled on a monthly basis until complete stabilization of the refraction was achieved and at every six months consecutively. Patients were instructed to avoid UV exposure during this period.

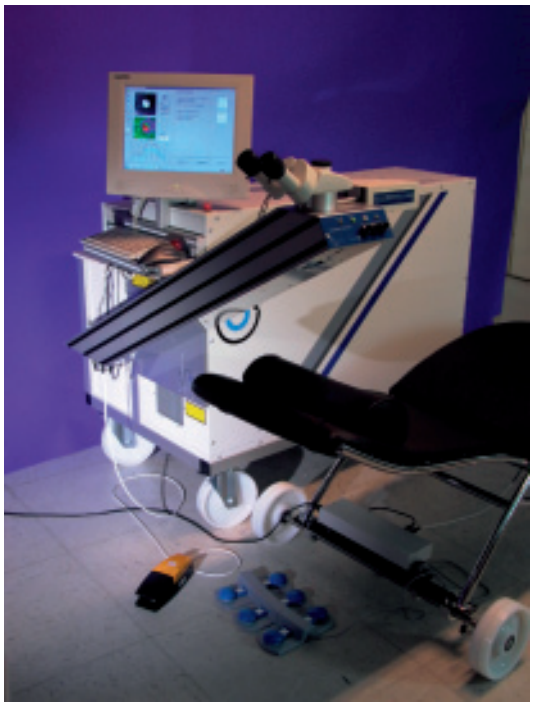


Fig. 5: Overview of the Inpro excimer laser with the Gaussian Delivery System.

Patients were invited to have a yearly standard examination, including UCVA and BSCVA, objective refraction, corneal topography and slit-lamp examination. The *achieved* versus *attempted refraction* was also taken into consideration. The available data of one to three years follow-up were considered for this paper.
To rate the haze we used the 0 to 5 scale of Braunstein (4): 0 = no haze; 1 = mild haze, but not affecting vision nor refraction; 2 = moderate haze, influencing refraction but not BSCVA; 3 = opacity, influencing refraction and BSCVA; 4 = difficult anterior chamber examination; 5 = impossible anterior chamber examination.

Scanning electron microscopy

The experimental part of this study is the result of a collaboration between the University Hospital of Antwerp and the Laboratory of Cell Biology and Histology of the University of Antwerp.
Four post-mortem donor eyes obtained from the cornea bank of the University Hospital of Antwerp (Belgium) were treated using a *flying spot* delivery system on one eye and the GDS on the contralateral eye. Only eyes presenting healthy corneas but rejected because of systemic disorders, which were incompatible with the national selection criteria, were used for the purpose of this study.
Both laser settings were installed to treat the same amount of myopia on both eyes: -4 D and -6 D. In order to check the ultrastructural effects of both lasers on the corneal surface, the treated corneas were prelevated from the globe, fixed in 2.5 percent *glutaraldehyde* and 0.1 percent *Na-cocodylate buffer*, dehydrated in an *acetone*-series, critical point dried, gold sputtered and finally examined in a SEM 515 microscope at 20 kV.

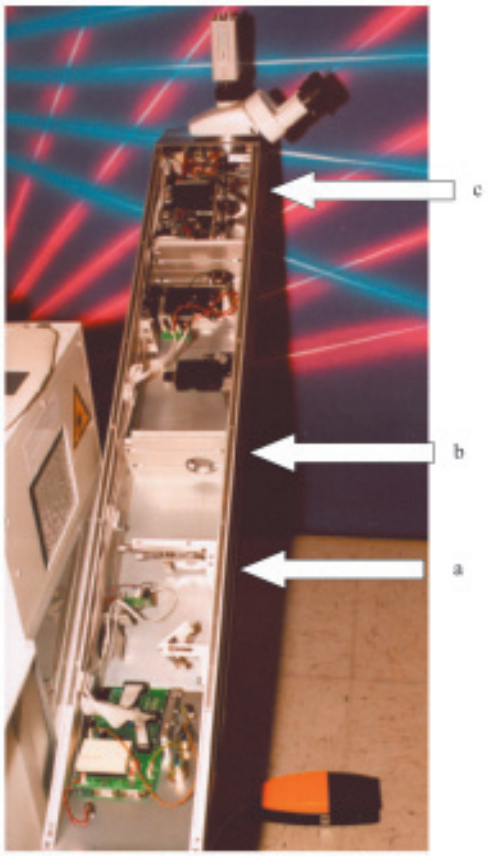


Fig. 6: Detail of the Gaussian Delivery System (GDS): a. dielectric plate; b. lens; c. X-Y motor to move the ablation zone.

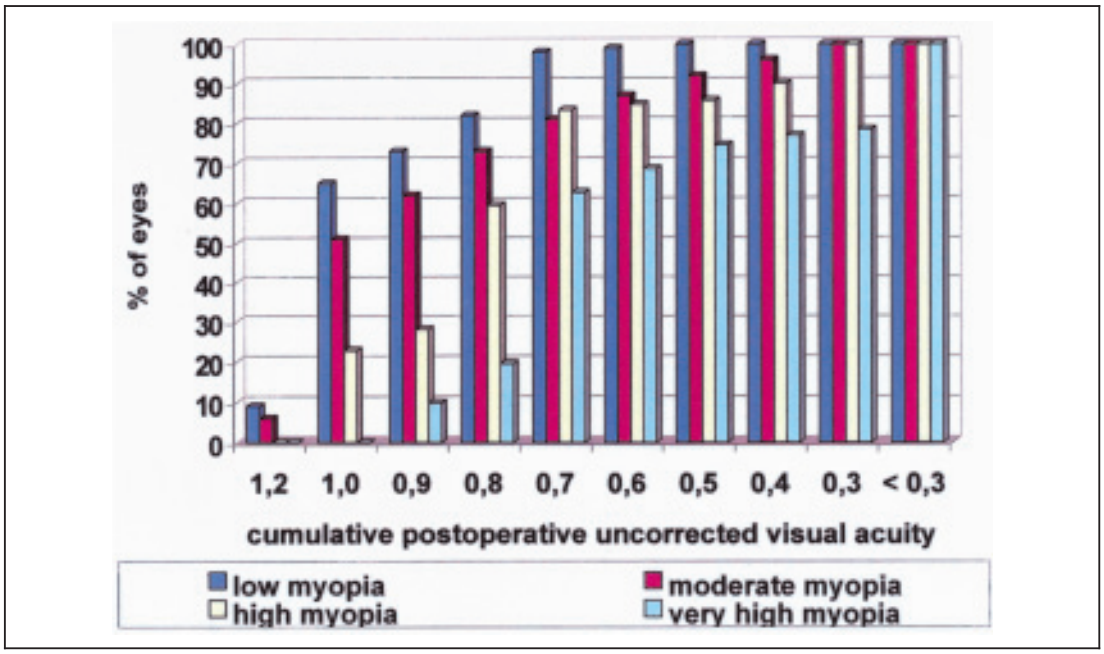


Fig. 7: The postoperative uncorrected visual acuity (UCVA) was 1.0 or better in 119 eyes (65 %) of the first group, in 275 eyes (51 %) of the second group and in 47 eyes (15 %) of the third group.

RESULTS

Clinical study

Patients were classified into four groups according to their initial myopia, expressed in *spherical equivalent*: *low*, *moderate*, *high* and *very high myopia*. The results are summarized in table 1.

Postoperative UCVA at one to three years postoperatively was 1.0 or better in 119 eyes (65%) of the first group, in 275 eyes (51%) of the second group and in 48 eyes (19%) of the third group. None of the patients of the *very high myopia* group achieved a UCVA of 1.0. However, 76 eyes (75%) of this fourth group had a postoperative UCVA of 0.5 or better (fig. 7).

The achieved postoperative *spherical equivalent* (SE) was within ±0.5 D of emmetropia in 95.6% of eyes in the *low myopia* group, in 85.4% of eyes in the *moderate myopia* group, in 54.3% of eyes in the *high myopia* group and in 5% of eyes in the *very high myopia* group (fig. 8). The postoperative SE was within ±1.0 D of emmetropia in 99.1%, 98.9%, 83% and 21% respectively of the *low, moderate, high* and *very high myopia* group.

When comparing the *attempted* and *achieved spherical equivalents* (fig. 9), undercorrection was more often present in the third group compared to the first two groups (mean postoperative SE: -0.97 D ± 0.94 D). In the fourth group practically all eyes were undercorrected (mean postoperative SE: -3.41 D ± 2.03 D).

A useful parameter is the *defocus equivalent refraction*, introduced by Holladay (12), and defined as the absolute value of the *spherical refraction* added to the absolute value of half the cylindrical refraction. This parameter gives a more realistic value of the astigmatic component than the *spherical equivalent*. For example, a patient with a *spherical refraction* of -1 D and a *cylindrical refraction* of +2 D has a *spherical equivalent* of 0, but a *defocus equivalent* of 2.0. In our study the *defocus equivalent refraction* (fig. 10) was 1.0 or less in 98.2%, 92.8 percent, 62% and 7.5% of cases in groups 1, 2, 3 and 4 respectively.

When comparing preoperative *best spectacle-corrected visual acuity* (BSCVA) with the postoperative BSCVA, no loss of two or more Snellen lines was observed (fig. 11).

No major complications were recorded. A haze two or three developed in 4.5% of the cases in

Table 1: *Clinical results of GDS treatment in myopia*

	Low myopia (→ -3 D) (n = 183)		**Moderate myopia (-3.25 D → -6 D) (n = 540)**		**High myopia (-6.25 D → -10 D) (n = 210)**		**Very high myopia (-10.25 D → -20 D) (n = 102)**	
	Preoperatively	**Postoperatively**	**Preoperatively**	**Postoperatively**	**Preoperatively**	**Postoperatively**	**Preoperatively**	**Postoperatively**
UCVA	0,13 ± 0,01	0,89 ± 0,18	0,05 ± 0,01	0,84 ± 2.32	0,04 + 0.02.	0,76 + 0.25	0,01 + 0.02	0,56 + 0.4
BSCVA	0,93 ± 0,16	0,95 ± 0,1	0,92 ± 0,12	0,89 ± 0,09	0,85 ± 0.16	0,85 ± 0.13	0,64 ± 0.17	0,65 ± 0.3
SE	-1.93 ± 0,72	-0,08 ± 0,37	-4,59 ± 0,85	-0,25 ± 0,53	-7.80 ± 1.07	-0.97 ± 0.94	-12.25 ± 1.8	-3,41 ± 2.03
DER	1.93 ± 0,72	0,25 ± 0,29	4,59 ± 0,85	0,43 ± 0,4	7.80 ± 1.07	1,02 ± 0.89	12.25 ± 1.8	3.48 ± 1.90.
0 ± 0.5 D		95.6%		85.4%		54.3%		5%
0 ± 1.0 D		99.1%		98.9%		83.3%		21%
0 ± 2.0 D		100%		95%		89.1%		40%
0 ± 3.0 D				100%		99.3%		61%
0 ± 4.0 D						100%		74%
Haze ⩾ 2		0		4,5%		2,4%		12,7%
Regression		0,5%		14,0%		14,0%		36,0%
Subjective aberration		0		0		7,0%		29,4%

UCVA: Uncorrected visual acuity **BSCVA:** Best spectacle-corrected visual acuity **SE:** Spherical equivalent
DER: Defocus equivalent refraction

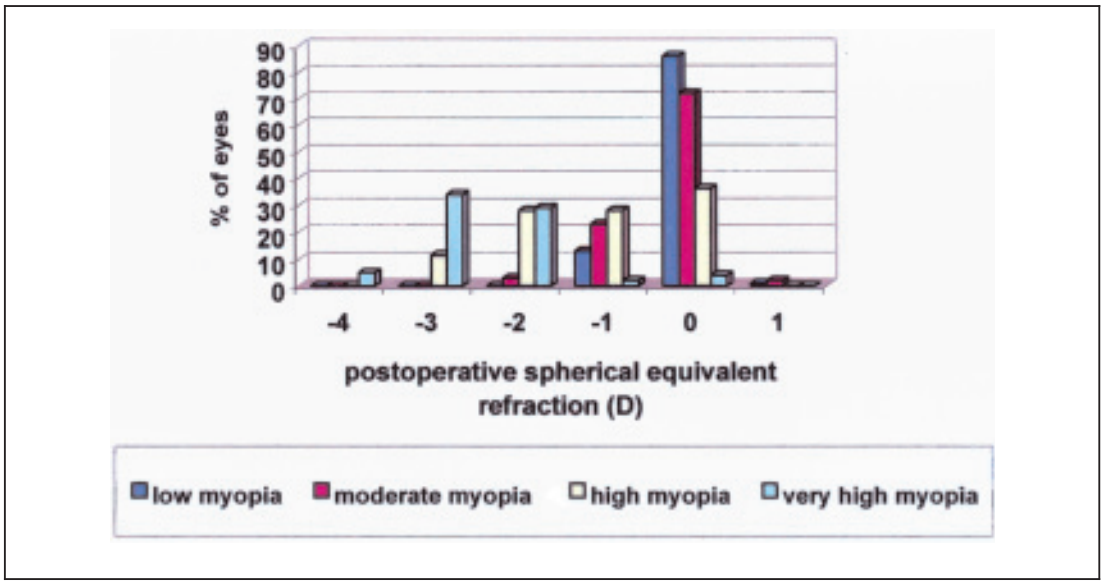


Fig. 8: The achieved postoperative spherical equivalent was within ±0.5 D of emmetropia in 95.6% of eyes in the *low myopia* group, 85.4% in the *moderate myopia* group, 54.3% in the *high myopia* group and 5% in the *very high myopia* group.

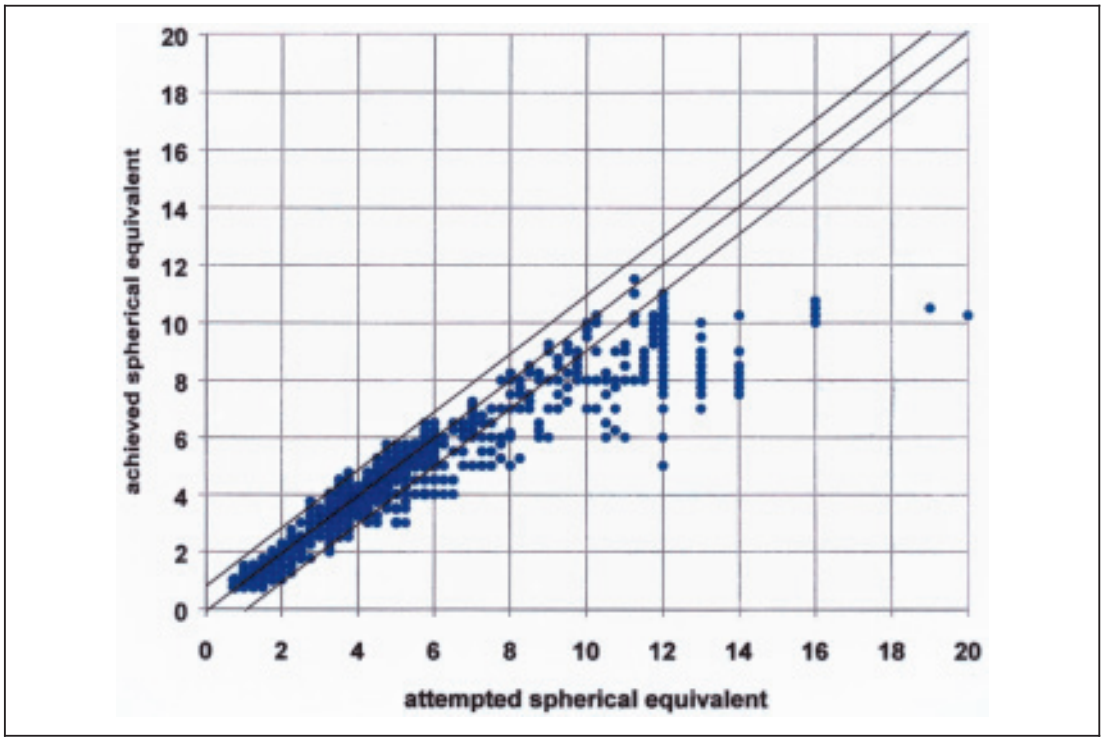


Fig. 9: The *attempted* versus the *achieved spherical equivalent*. Undercorrection was more often present in the third and fourth group.

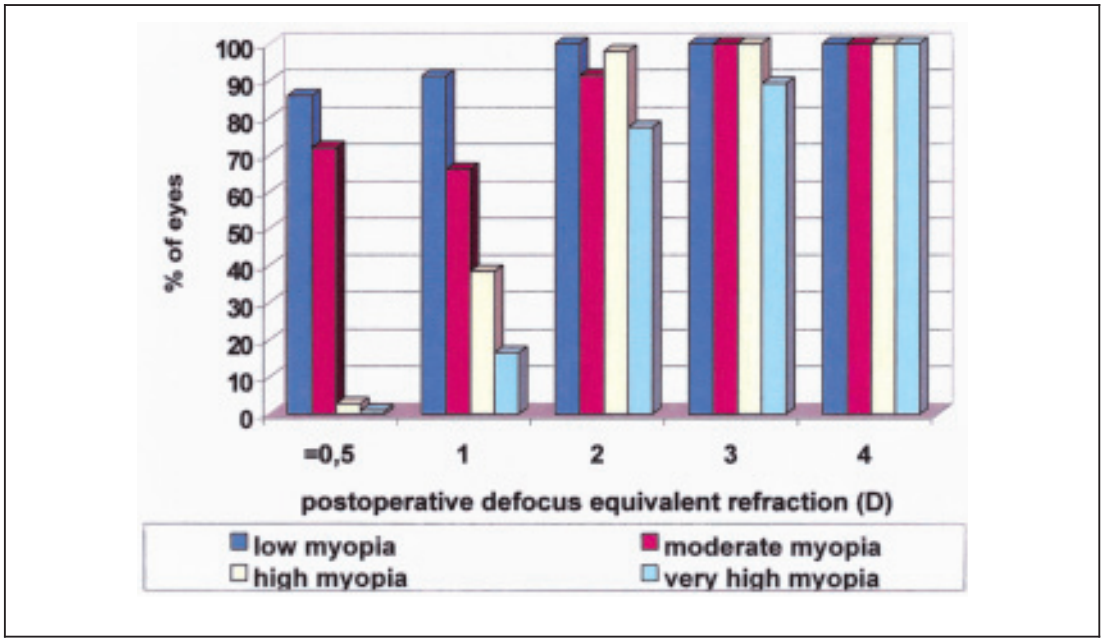


Fig. 10: The *defocus equivalent refraction* is 1 or less in 98.2%, 92.8%, 62% and 7.5% of cases in group 1, 2, 3 and 4 respectively.

group 2, in 2.4% of the cases in group 3 and in 12.7% of the cases in group 4 (table 1). No

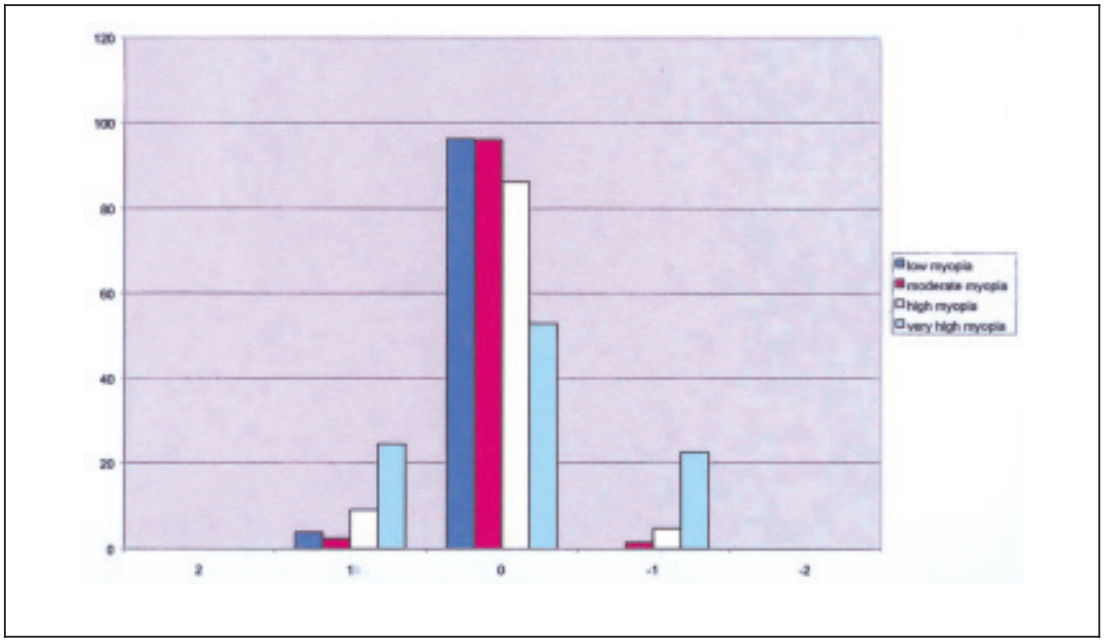


Fig. 11: Loss or gain in Snellen lines of *best spectacle-corrected visual acuity* (BSCVA).

haze higher than three was observed. A refractive regression was observed in 0.5 percent of the cases in the first group, in 14% of the cases in the second group, in 20% of the cases in the third group and in 36% of the cases in the fourth group during the course of this study. Only in the *high* and *very high myopia* group subjective aberration-linked complaints were reported (7% and 29% respectively).
Table 1 summarizes the different parameters studied for the four groups of myopia.

Scanning electron microscopy

The corneal surface after PRK for -4 D shows a beaten bronze aspect (fig. 12 a-b) using the *flying spot* DS. The corneal surface after PRK using the GDS for -4 D, corresponding to 52 μm ablation, shows a progressive transition zone (fig. 12 c-d). When -6 D, corresponding to 65.4 μm ablation, was performed the central corneal zone remained large, but the transition zone became slightly more pronounced (fig. 12 e-f).

DISCUSSION

The patients were classified and studied according to the guidelines of G. Waring (33), i.e. classification of myopia into four categories (up to -3 D, from -3.25 D to -6 D, from -6.25 D to -10 D and from -10.25 D to -20 D), analysis of the post-operative UCVA, postoperative refraction, *achieved* versus *attempted spherical equivalent* and postoperative *defocus equivalent refraction* and loss or gain in BSCVA. These guidelines should facilitate comparison with other studies.
Using the ExiMed 200 UV excimer laser, Kim et al. (14) reported in a three-year follow-up study ±1 D of emmetropia in 60% of the myopia cases between -1 D and -6 D. Using the VisX Excimer laser, Salz et al. (20) reported for the same myopia group ±1 D of emmetropia in 84%. In a study of Amano and Shimizu (2) 100%, 75% and 52% of the *low* (up to -3 D), *medium* (from -3 D to -6 D) and *high myopia* group (from -6 D to -14 D) respectively, were within 1 D of attempted correction after a two-year follow-up. Tuunanen and Tervo (16), who used the VisX excimer laser, reported that 87% in the *low*, 50% in the *medium* and 29% in the *high myopia* group were within 1 D of intended refraction.
An important study with 3218 eyes treated with the Nidek EC-5000 excimer laser (Shah et al. (25)) reported ±1 D of emmetropia in 97.2%, 96.7%, 94.1%, 91.1%, 88.1% and 78.2% of -1 D, -2 D, -3 D, -4 D, -5 D and -6 D myopia cases respectively, after one year.
Our study showed ±1 D of emmetropia in 99%, 98%, 83% and 21% of the *low*, *moderate*, *high* and *very high myopia* group, respectively.
Apart from assessing refractive results, it is important to evaluate the anatomical results after PRK. 'Haze' is a subepithelial opacification that occurs in the majority of patients after PRK, mostly without any symptoms. This opacification is the clinical expression of the healing process of the cornea (21).
Many scales of gradation have been proposed for haze. We have used the scale proposed by Braunstein (4), which is one of the most commonly used.
Many factors may contribute to the development of haze. One important factor is the initial refractive error, and consequently the ablation depth (5). Patients with myopia up to -6 D may develop grade one or two haze, three to twelve weeks postoperatively. This type of haze will vanish in most cases between the twelfth and eighteenth postoperative month (22).
The frequency of grade two or three haze is relatively low for *low* and *moderate myopia* (between 0 and 4.9%) (1, 7, 9, 13, 15, 19, 23). In our series we found 0% in the *low myopia* group, 4.5% in the *moderate myopia* group, 2.4% in the *high myopia* group and 12.7% in the *very high myopia* group.
Haze may cause regression resulting in a decrease of UCVA. Tengroth et al. (26) reported important refractive regression in all patients with grade three or grade four haze.

The *laser in situ keratomileusis* method (LASIK) confers some advantages in comparison to PRK, including less haze, less postoperative pain and earlier visual recovery. However, creating a flap may be associated with significant intraoperative complications, such as intraocular pressure rise with optic nerve or retinal damage, partial flaps, buttonholed flaps, thin or irregular flaps, and free flaps (12). The most threat-

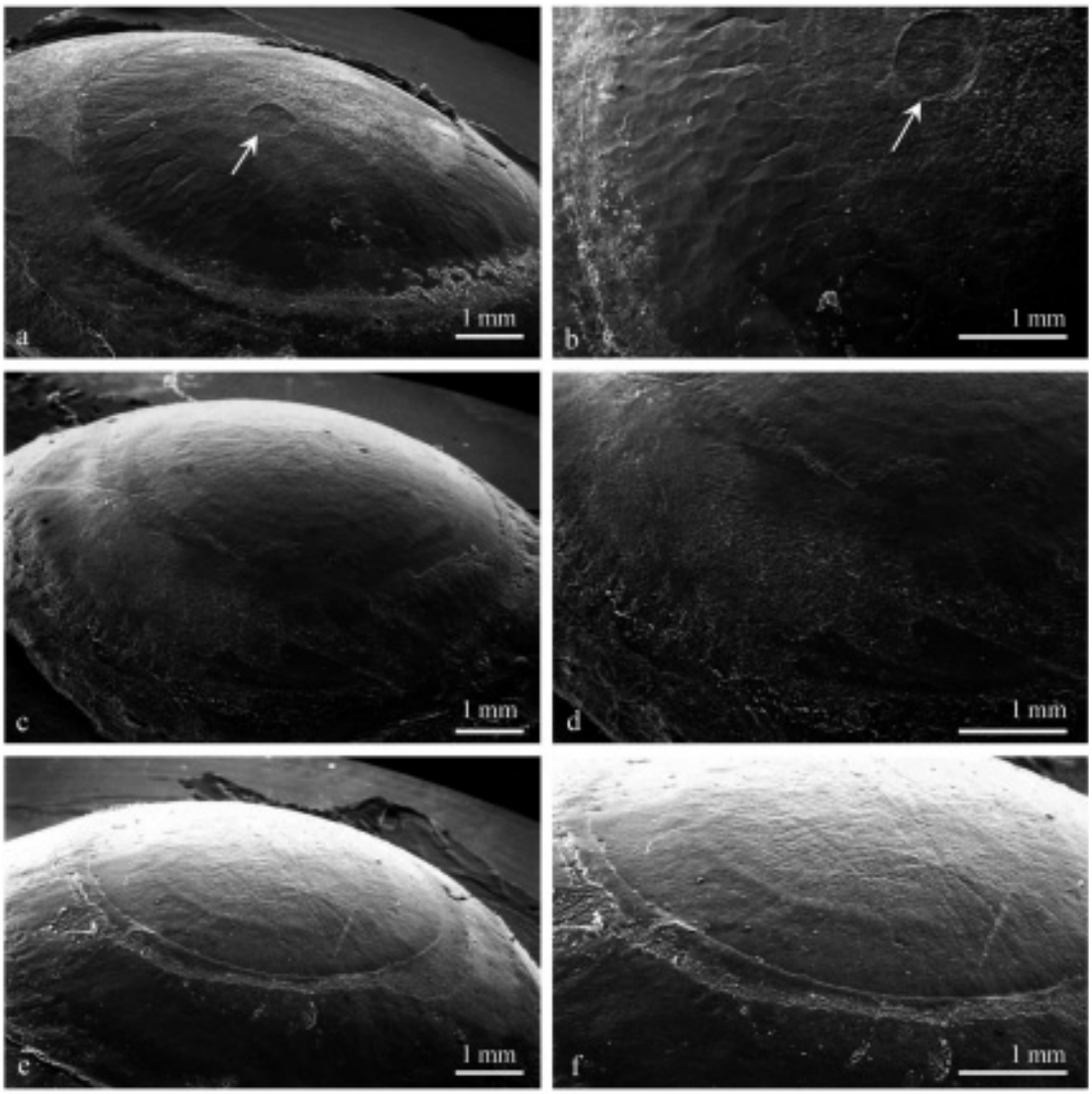


Fig. 12a.: SEM image of the surface of a human cornea after -4 D treatment using a *flying spot* DS. (arrow = artifact)
12b.: Same eye as a at a higher magnification. (arrow = artifact)
12c.: SEM image of the surface of a human cornea after -4 D treatment using a GDS
12d.: Same eye as c at a higher magnification.
12e.: SEM image of the surface of a human cornea after -6 D treatment using a GDS.
12f.: Same eye as e at a higher magnification.

ening postoperative complication of LASIK is keratectasia (6). These complications are a significant drawback for the LASIK procedure, affecting the final outcome significantly. Several studies have reported flap complication rates of 0.3 to 10%, depending on the microkeratome used and on the surgeon's experience (7-8, 10, 30-32).

Laser-assisted subepithelial keratectomy (LASEK), as developed by Massimo Camellin, is a technique in which the epithelium flap is detached after application of an alcohol solution and repositioned after laser ablation. The technique appears to constitute a good combination of PRK and LASIK advantages, allowing a faster visual recovery and less pain and inflammatory reaction, while avoiding all flap-related complications (6).

The smoothness of the ablated surface is recognized as the most important factor in the prevention of haze, regression and contrast sensitivity loss. The size and the profile of the ablated zone (progressive transition from the centre of the cornea to the edges of the ablation zone) are the main factors in preventing and decreasing the occurrence of halos, glare and optical aberrations. For both aspects the GDS gives excellent results as studied on SEM.

Each laser presents some limits in modifying the corneal curvature, partially due to the optical parameters of the laser and partially due to the corneal parameters. Based on our refractive results and because of the considerable amount of regression observed in the *very high myopia* group, we consider the limit for the GDS at -10 D.

It should be kept in mind that the GDS is based on physical optical principles and on a broad beam, allowing short treatment times and requiring no *eye tracker*. Since no moving mirrors, prisms or lenses are used maintenance costs are low. Low costs and high reliability, as demonstrated in this study, constitute the main advantages of the GDS.

REFERENCES

(1) ALIO J.L., ARTOLA A., CLARAMONTE P.J., AYALA M.J., SANCHEZ S.P. – Complications of photorefractive keratectomy for myopia: two year follow-up of 3000 cases. J. Cataract Refract. Surg. 1998, 24, 619-626

(2) AMANO S., SHIMIZU K. – Excimer laser photorefractive keratectomy for myopia: two-year follow-up. J. Cataract Refract. Surg. 1995, 11, S253-S260

(3) BEAUDUIN P., GOBIN L., TRAU R., TASSIGNON M.J. – PRK avec le laser excimer InproGauss: analyse statistique des résultats. Bull. Soc. belge Ophtalmol. 2002, 284, 65-71

(4) BRAUNSTEIN R.E., JAIN S., MCCALLY R.I., STARK W.J., CONNOLLY P.J., AZAR D.T. – Objective measurement of corneal light scattering after excimer laser keratectomy. Ophthalmology. 1996, 103, 439-443

(5) CAUBER E. – Cause of subepithelial corneal haze over 18 months after photorefractive keratectomy for myopia. Refract. Corneal Surg. 1993, 9, 65-70

(6) CLARINGBOLD T.V. – Laser-assisted subepithelial keratectomy for the correction of myopia. J. Cataract Refract. Surg. 2002, 28, 18-22

(7) EPSTEIN D., FAGERHOLM P., HAMBERG-NYSTROM H., TENGROTH B. – Twenty-four month follow-up of excimer laser photorefractive keratectomy for myopia. Ophthalmology. 1994, 101, 1558-1563

(8) FARAH S.G., AZAR D.T., GURDAL C., WONG J. – Laser in situ keratomileusis: literature review of a developing technique. J. Cataract Refract. Surg. 1998, 24, 989-1006

(9) FICKER L.A., BATES A.K., STEELE A.D., LYONS C.J., MILLIKEN A.B., ASTIN C. – Excimer laser photorefractive keratectomy for myopia: 12 month follow-up. Eye. 1993, 7, 617-624

(10) GIMBEL H.V., VAN WESTENBRUGGE J.A., PENNO E.E., FERENSOWICZ M., FEINERMAN G.A., CHEN R. – Simultaneous bilateral laser in situ keratomileusis: safety and efficacy. Ophthalmology. 1999, 106, 1461-1467

(11) HOLLADAY J.T., LYNN M.J., WARING G.O., GEMMILL M., KEEHN C.G., FIELDING B. – The relationship of visual acuity, refractive error and pupil size after radial keratotomy. Arch. Ophthalmol. 1991, 109, 70-76

(12) JACOBS J.M., TARAVELLA M.J. – Incidence of intraoperative flap complications in laser in situ keratomileusis. J. Cataract Refract. Surg. 2002, 28, 23-28

(13) KIM J.H., HAHN T.W., LEE Y.C., JOO C.K., SAH W.J. – Photorefractive keratectomy in 202 myopic eyes: one year results. Refract. Corneal Surg. 1993, 9, S11-S16

(14) KIM J.H., SAH W.J., KIM M.S., LEE Y.C., PARK C.K. – Three-year results of photorefractive keratectomy for myopia. J. Refract. Surg. 1995, 11, 248-252

(15) MAGUEN E., SALZ J.J., NESBURN A.B., WARREN C., MACY J.I. – Results of excimer laser

photorefractive keratectomy for the correction of myopia. Ophthalmology. 1994, 101, 1548-1556
(16) MALONEY R.K., FRIEDMAN M., HARMON T., HAYWARD M., HAGEN K., GAILITIS R.P., WARING G.O. 3rd. – A prototype erodible mask delivery system for the excimer laser. Ophthalmology. 1993, 100, 542-549
(17) O'DONNELL C.B., KEMNER J., O'DONNELL F.E. Jr. – Ablation smoothness as a function of excimer laser delivery system. J. Cataract Refract. Surg. 1996, 22, 682-685
(18) OTHENIN-GIRARD P. – Excimer laser: history, development and comparison of equipment. Bull. Soc. belge Ophtalmol. 1997, 266, 11-20
(19) POP M., ARAS M. – Multizone photorefractive keratectomy: six months results. J. Cataract Refract. Surg. 1995, 21, 633-643
(20) SALZ J.J., MAGUEN E., NESBURN A.B., WARREN C., MACY J.I., HOFBAUER J.D. – A two-year experience with excimer laser photorefractive keratectomy for myopia. Ophthalmology. 1993, 100, 873-882
(21) SEILER T., WOLLENSAK J. – Complications of laser keratomileusis with the excimer laser. Klin. Monatsbl. Augenheilkd. 1992, 200, 648-653
(22) SEILER T., WOLLENSAK J. - Results of a prospective evaluation of photorefractive keratectomy at 1 year after surgery. Ger. J. Ophthalmol. 1993, 2, 135-142
(23) SEILER T., HOLSCHBACH A., DERSE M., JEAN B., GENTH U. – Complications of myopic photorefractive keratectomy with the excimer laser. Ophthalmology. 1994, 101, 153-160
(24) SEMCHISHEN V.A., MROCHEN M., SEMINOGOV V.N., PANCHENKO V.Y., SEILER T. – Light beam shaping and homogenization (LSBH) by irregular microlens structure for medical applications. SPIE Proc. 1998, 3251, 28-33
(25) SHAH S., CHATTERJEE A., SMITH R.J. – Predictability of spherical photorefractive keratectomy for myopia. Ophthalmology. 1998, 105, 2178-2184
(26) TENGROTH B., EPSTEIN D., FAGERHOLM P., HAMBERG-NYSTROM H., FITZSIMMONS T.D. – Excimer laser photorefractive keratectomy for myopia: clinical results in sighted eyes. Ophthalmology. 1993, 100, 739-745
(27) TROKEL S.I., SRINIVASAN R., BRAREN R. – Excimer laser surgery of the cornea. Am. J. Ophthalmol. 1983, 96, 710-715
(28) TUUNANEN T.H., TERVO T.T. – Results of photorefractive keratectomy for low, moderate, high myopia. J. Refract. Surg. 1998, 14, 437-446
(29) VAN DE VELDE F.J., TASSIGNON M.J., TRAU R. – Scanning laser retinoscopy: a new technique for evaluating optical properties of the cornea after refractive surgery. SPIE Proc. 1997, 3192, 187-194
(30) WALKER M.B., WILSON S.E. – Lower intraoperative flap complication rate with the Hansatome microkeratome compared to the automated corneal shaper. J. Refract. Surg. 2000, 16, 79-82
(31) WANG Z., CHEN J., YANG B. – Posterior corneal surface of topografic changes after laser in situ keratomileusis are related to residual corneal bed thickness. Ophthalmology. 1999, 106, 406-410
(32) WARING G.O. III, CARR J.D., STULTING R.D., THOMPSON K.P., WILEY W. – Prospective randomized comparison of simultaneous and sequential bilateral laser in situ keratomileusis for the correction of myopia. Ophthalmology. 1999, 106, 732-738
(33) WARING G.O. III – Standard graphs for reporting refractive surgery. J. Refract. Surg. 2000, 16, 459-466.

.....

Reprint requests:
Marie-José TASSIGNON (MD, PhD),
University Hospital Antwerp,
Department of Ophthalmology,
Wilrijkstraat 10, 2650 Edegem, Belgium,
tel. +32 3 821 33 77, fax +32 3 825 19 26,
e-mail: marie-jose.tassignon@uza.be