

Limits of refractive laser surgery of the cornea

F. Fankhauser II

Univ.-Augenlinik Dresden

Summary

Present knowledge regarding the physiological-optical, biomechanical and technical limitations of refractive laser surgery of the cornea recommends limits of maximum correction of myopia (6 dpt if done by PRK, 10 dpt if done by LASIK), hyperopia (5 dpt) and corneal astigmatism (3 dpt). Individual factors may increase or decrease these limits in selected cases. Major refractive corrections may not be achievable on the cornea alone but may involve the entire optical System of the eye.

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Most refractive eye diseases can be corrected or at least reduced with refractive laser surgery. There are, however, three basic limitations:

- 1 Physiological- optical limits:
 - minimal size of ablation zone which differs between day and night
 - depth of the ablation zone (which is correlated to the size)
 - configuration of the ablation zone (e.g. multizone ablation).
- 2 Biomechanical limits:
 - Reduction of mechanical stability of the cornea which may lead to iatrogenic keratectasia
- 3 Technical precision of the ablation:
 - Hydration of cornea
 - Induced elastic vibrations
 - Eye movements of the patient during laser treatment

Size of the ablation zone and scotopic width of the pupil are the most important limiting factors for maximum sight in the dark

Pupil size varies naturally from 2 to 4 mm. Hence the theoretically maximum visual acuity will be 2.0 to 4.0. The retinal resolution probably could provide a maximum visual acuity of 2.5 to 3.0. With pupil diameters of 2.5 mm or less this maximum resolution is limited by diffractive effects. These are produced by inclinations of the light at the pupillary rim.

With pupil sizes larger than 4 mm the Stiles-Crawford effect (reduced sensitivity of the retina for oblique rays) supports the perception of small patterns. This effect results in a theoretical visual acuity larger than 3.0 (higher than the physiological resolution of the retina).

Due to the nonlinear effect of high order refractive errors of the transparent media, theoretical and manifest visual acuity are not correlated:

	emmetropia	1 dpt		5 dpt	
pupil diameter	> 2.0 mm	2 mm	4 mm	2mm	4mm
maximum possible visual acuity	2.0	1.0		0.125	
real visual acuity			approx. 0.6		0.09

By means of refractive laser surgery the optical conditions of the eye are intended to be corrected towards emmetropia. However, the ablation zone is of major importance. Using a common ablation zone of 4 mm diameter visual acuity of 2.0 may be reached at emmetropia. If the pupil is dilated (common in scotopic conditions), the zone of full refractive correction and the transition zone overlap. Hence the manifest visual acuity decreases at pupil sizes greater than 4 mm (see yellow line in fig. 2).

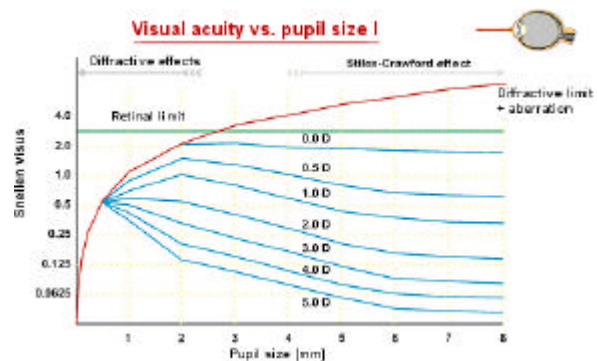


Fig. 1: Physiological-optical limits of the maximum possible visual acuity at ideal conditions. The maximum possible visual acuity varies as a function of the pupil size. It is supported by the Stiles-Crawford effect and limited by the maximum retinal resolution, diffractive effects and aberrations of lower and higher order.

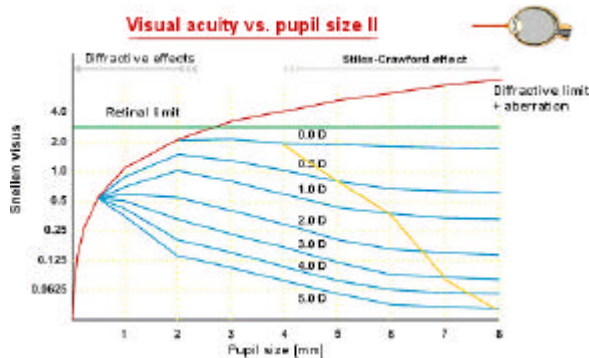


Fig. 2 Reduction of the maximum possible visual acuity at pupil sizes larger than 4 mm (yellow line) due to the limited size of the ablation zone after refractive laser surgery of the cornea

Biomechanical limits: multizone ablation reduces loss of tissue

There is a critical relation between the size of the ablation zone and the depth of this zone. The ablation zone becomes deeper the higher the needed correction and the larger the required ablation zone are:

$$p [\mu] = D [\text{dpt}] \times (d [\text{mm}])^2$$

With p: depth of ablation; D: correction; d: diameter of ablation zone

Two risks arise with increasing depth:

- Mechanical destabilization of the cornea
- Clinically significant scar formation from disturbed healing which always cause a regression.

Multizonal ablation tries to keep the overall depth as minimal as possible. Fig. 3 indicates multizonal versus monozonal ablation at an intended correction of 10 dpt starting at an initial corneal refraction of 48 dpt:

- With monozonal ablation of 6 mm diameter 120 μ of tissue must be removed.
- With multizonal ablation the full correction is performed only in a 4 mm wide ablation zone. This requires only 75 μ of tissue to be ablated, saving 45 μ as compared to monozonal ablation.

Within the 5 mm zone only 50 % of full correction is achieved (43 dpt) and in the 6 mm zone only 20 % of full correction is achieved (46 dpt).

Outside the ablation zone of 6 mm the initial corneal refraction of 48 dpt is still active.

This example demonstrates that superpositioned images can only be avoided with pupil sizes less than 4 mm. Above this diameter first the 50 % corrected image is superpositioned on the emmetropic image, then the three images of the fully corrected area, the 50 % cor-

rected area and the 20 % corrected area are superpositioned. More far out the additional image of the uncorrected cornea is added. This scenario explains sufficiently the complaints of patients under scotopic conditions.

Multizonal vs. monozonal ablation (10 dpt)

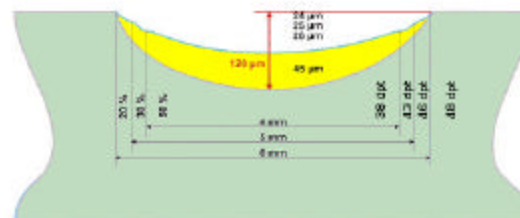


Fig. 3 Schematic setting off multizonal ablation and monozonal ablation for 10 dpt using PRK.

Risk of keratectasia especially with LASIK

Ablating too much tissue can cause changes of the curvature of the cornea within its central area (Fig. 4). Ablation depths of more than 30% display an exponential relationship between ablation depth and percentage of change for the curvature:

Ablation depth	> 50 %	75 %
Change of curvature in central area	4 dpt	> 15 dpt

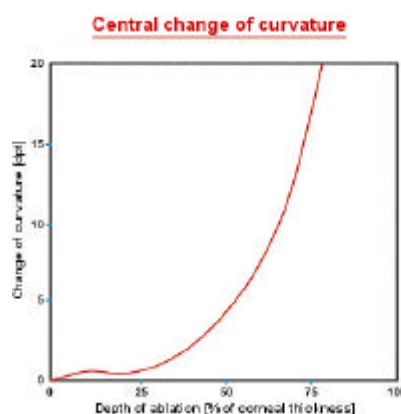


Fig. 4 Change of central corneal curvature in dpt relative to ablation depth in % of complete corneal thickness. Thinning the cornea more than 25 % yields a strong increase of the central curvature in the manner of a keratectasia.

This may lead to keratectasia which not only over-compensate the effect of the refractive surgery but also mechanically destabilizes the cornea irreversibly. The risk of too deep ablation - especially with strong myopia - and the related destabilization of the cornea is relatively small with PRK, because this procedure provides sufficient residual thickness. Deep ablations are risky due to the significant scar formation, which may make PRK impracticable at higher amounts of myopia.

With LASIK there is another situation (Fig. 5), because the first step is the cut of a corneal flap of 120 - 150 μ thickness. This flap does not provide any mechanical stability for the immediate postoperative time. Its sole purpose is the covering of the ablation zone and the preservation of Bowman's membrane. With LASIK the ablation is performed in the frontal and middle third of the stroma. The mechanical load must be supported by the residual stroma. Too low residual thickness of the stroma induces the risk of iatrogenic postoperative keratectasia.

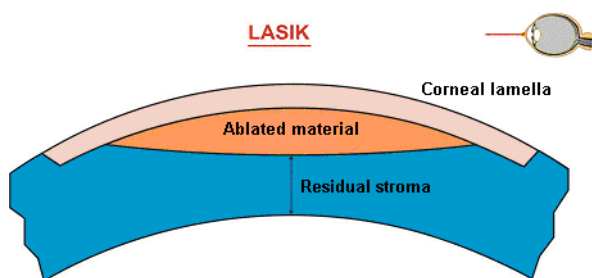


Fig. 5 Principle scheme of LASIK distinguishing corneal lamella, ablated stroma and load bearing residual stroma.

Two examples of maximum correction of myopia by LASIK shall be explained. The relatively thick cornea (560 μ) in Fig. 6 with a recommended thickness of the flap (150 μ) are favorable assumptions. It is known that a reduction of the mechanical strength by more than a factor of 2.3 significantly increases the risk of keratoconus. Hence this is taken into account:

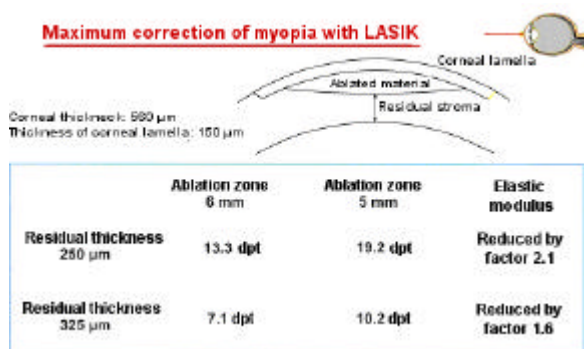


Fig. 6 Maximum correction of myopia with LASIK in the favorably case of a relatively thick cornea (560 μ)

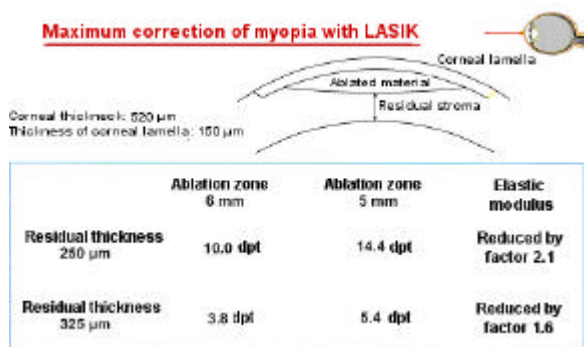


Fig. 7 Maximum correction of myopia with LASIK in the less favorably case of a thinner cornea than in fig. 6 (520 μ)

From this consideration it is recommend not to perform LASIK for myopia larger than 10 dpt - or at least be very careful. With PRK the maximum achievable corrections are limited by reactive built up of scars during healing.

Great risk for haze and scars with PRK for more than 6 dpt correction

Built up of scars after PRK was examined extensively in the past. Risk of excessive stimulation of biological wound healing causing scars which harm the visual acuity is increased with increasing amount of ablated tissue. Practically this leads to a maximum correction of myopia with PRK of 6 dpt.

Precision of ablation: multiple error sources

Consider the following laser parameters: A laser pulse ablates about 0.25 μ of tissue which corresponds to a central correction of 0.002 dpt. This number cheats a high precision of the method, which is levelled by biological factors. Too much or too little correction is a function of hydration of the cornea and can vary between 10 to 15 %. To avoid this deviation from the desired correction the corneal hydration must be carefully monitored (not only the laser parameters). Moreover, in Bowman's membrane the ablation rate is 30 % less than in the stroma. Theoretically this may lead to 12 % of under-correction, but this is already taken into account by the ablation algorithms of standard surgical laser equipment.

Additional limits are:

- Lacking precision of the corneal topography. This is important specifically for the correction of astigmatism. Most topography systems can not measure directly in the central optical zone. Hence they do not really measure the refraction of this zone, but interpolate from the paracentral area.
- Measurement of the corneal topography highly depends on the cooperation of the patient with good fixation on the target light. In the past the centering of the laser ablation zone depended exclusively on the cooperation of the patient. Fast eye-trackers leveled this requirement significantly. Fast eye-trackers are now standard in modern laser systems.
- A large number of the devices in use are not equipped with eye-trackers. Hence the fixation during surgery is still essential.

- For LASIK the cutting accuracy of the microkeratom is decisively important to preserve the desired critical thickness of the stroma. Generally the corneal lamella is 130 to 160 μ of thickness. The practical accuracy is 10 - 25 %. This fluctuation is also a reason why with LASIK the maximum correction should not be larger than 10 dpt. Interferometric measuring methods will soon be available to check the thickness after the cut and even during the laser ablation. These systems recently got clinical approval but are not available yet.

Tight limits for correction of hyperopia

For the correction of hyperopia or hyperopic astigmatism the recommended limit is 5 respective 3 dpt. Since the central area of the cornea must become more concave a significant amount of tissue must be removed paracentral. The ablation zone must be large enough to provide a sufficiently large central zone. If the central optical zone becomes too small the same effect of overlapping images (as described for myopia) may happen. In addition formation of clinically significant haze and central scars may be stimulated.

Even observing these limits irreversible development of scars (saltmannoidic plaques) may occur in the central refractive area which was not treated at all. The formation of this biological stimulation is unclear up to now. It is currently assumed that this reaction is stimulated by the loss of Bowman's membrane caused by hyperopic PRK. Since these scars also occur with hyperopic LASIK additional biological factors must be significant.

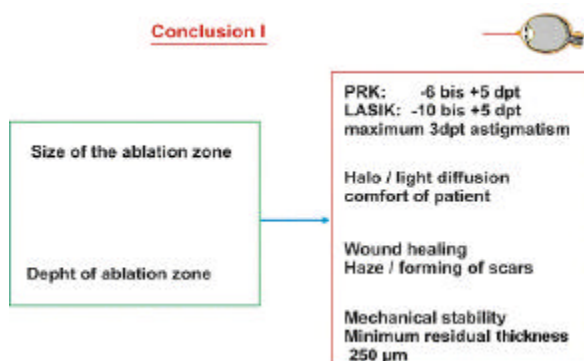


Fig. 8 Conclusions with instrumental and procedural precision as well as consideration of the fact that often an optimal refractive correction of the wrongsightedness is not possible with corrections at cornea alone. The complete optical system of the eye must be included.

Conclusion

Both for correcting hyperopia as well as myopia the size of the ablation zone and the corre-

sponding depth must be observed (Fig. 8). Hence the Kommission für Refraktive Chirurgie KRC (Commission for Refractive Surgery) recommends upper limits for myopic PRK (6 dpt) and for myopic LASIK (10 dpt) and for hyperopic PRK and hyperopic LASIK (5 dpt) at the respective astigmatism of 3 dpt. Attention must be paid to the fact that the patients' comfort is not reduced by postoperative halos and induced scattered light. Moreover the healing process must be stimulated excessively. Otherwise significant irreversible scar formation may occur. The mechanical stability of the cornea must be observed by providing a minimal residual thickness of 250 μ in the case of LASIK.

The instrumental precision is essential: The quality of the laser beam, the precision of the microkeratomes, the precision of instruments for corneal topography and eye-tracking systems. Current technical developments such as the topography- and wavefront guided ablation and the most recent generation of microkeratomes increase the instrumental precision and decrease the standard deviation of errors. Combined with laser systems providing a freely guidable laser beam these developments enable an individually adapted refractive correction for each patient. The correction of all errors of the refractive system becomes feasible. Related to this is the potential increase of visual acuity, but also the elimination of unwanted side effects, for example the dazzle from backlighting or reduced sight under scotopic conditions.

Finally the procedural precision must not be underestimated. In particular the hydration level of the cornea must be considered and the standardized processes must be adapted to the practical situation. Optimal motivation of the patient for cooperation and perfect fixation are of superior importance. Correction of higher ametropia can not be performed at the cornea alone. Additional refractive procedures, for example, phakic intraocular lenses, intracorneal stromatic ring segments (INTACS), laser thermokeratoplastic (LPTK) or the extraction of the clear natural lens.

Address of author:

Dr. med. F. Fankhauser
 Univ.-Augenklinik
 Martinistr. 52
 D-20246 Hamburg