

The Evolution of the Optical Zone in Corneal Refractive Surgery.

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Outline

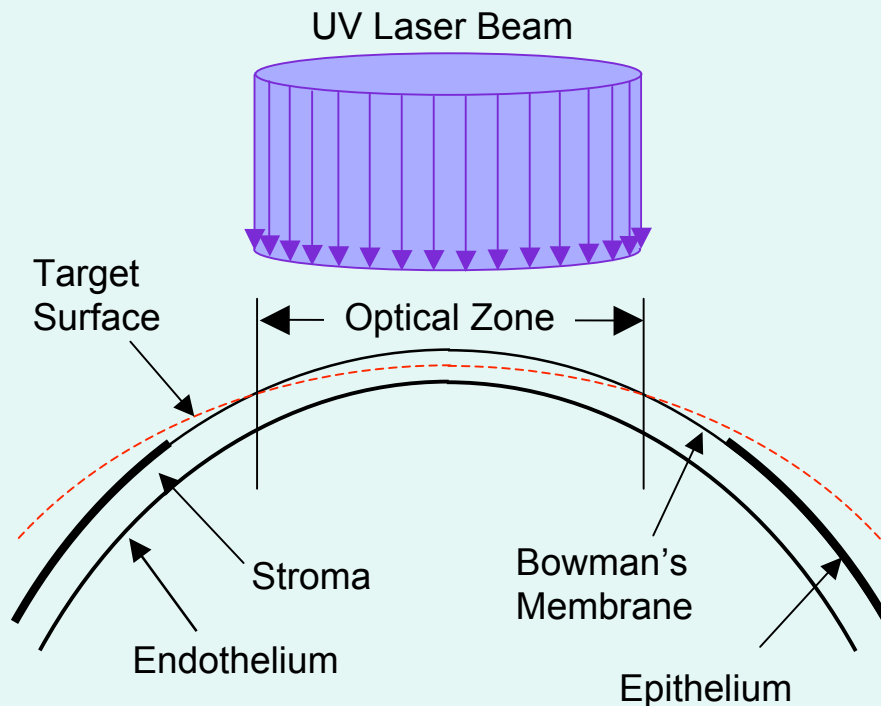
- Theoretical and Operational Definitions
- PRK with Early Large-Beam Lasers
- Small-Beam Scanning Lasers
- PRK vs. LASIK
- Wavefront-Guided Treatments
- Optimizing Residual Aberrations
- Future Developments

What is the Optical Zone?

- **Theoretical definition:** the part of the corneal ablation area that receives the full intended refractive correction.
- **Operational definition:** the part of the corneal ablation area that receives the treatment that is designed to produce the full intended refractive correction.
- **Effective Optical Zone:** the part of the corneal ablation area that actually conforms to the theoretical definition.

Early PRK Algorithms

PRK Ablation for Myopia



Munnerlyn Formula for myopia correction

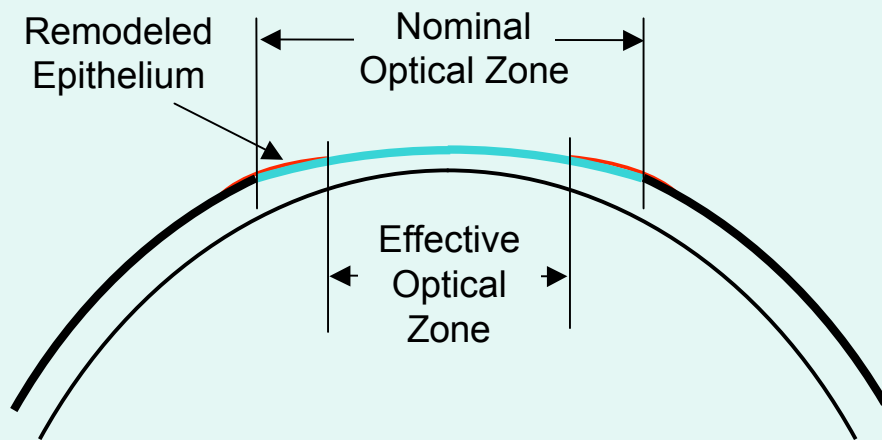
- Assumed spherical corneal surface
- Assumed uniform etch rate
- Ablation target was spherical surface of lower curvature
- Optical zone assumed equal to ablation zone

Problems with the Simple Spherical Model

- Epithelial Remodeling
- Central Islands
- Beam Inhomogeneity
- Radial Ablation Efficiency Function
- Biomechanical Effects
- Induced Spherical Aberration

Epithelial Remodeling

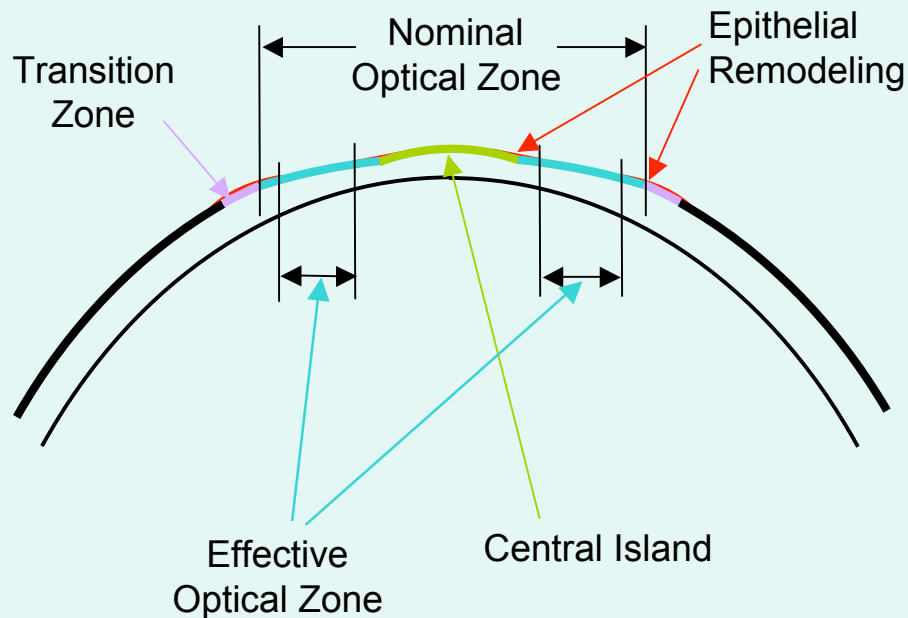
Epithelial Regrowth after PRK for Myopia



- Curvature discontinuity at ablation edge promotes epithelial remodeling.
- Remodeling extends into intended optical zone.
- Remodeling induces spherical aberration, reduces effective optical zone size.
- **Attempted solution:**
Ablate an annular “transition” or “blend” zone at the edge of the optical zone to minimize curvature discontinuity.
- Transition zones reduce but do not eliminate remodeling.

Central Islands

Central Island Profile



- **Causes:**

- Fluid pools on central surface, interferes with ablation.
- Debris plume interferes with central ablation.

- **Solutions:**

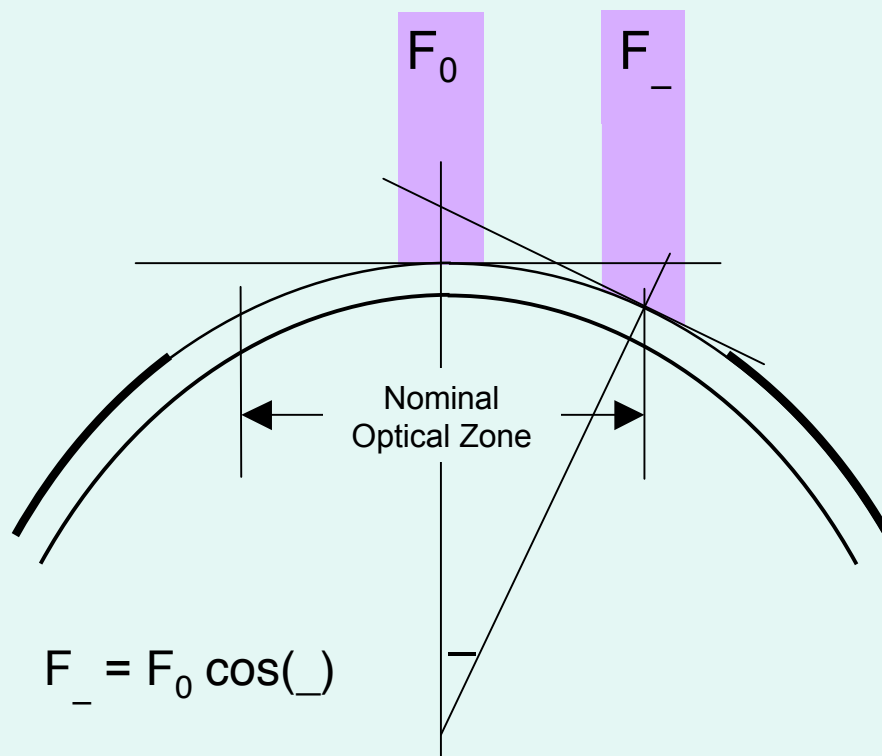
- Extra central pulses.
- Pause treatment, sop up fluid with sponge.
- Use small-beam scanning laser.
- Remove debris plume before each pulse.

Beam Inhomogeneity

- Early large-beam lasers used complicated optical schemes to make the laser beam uniformly intense over its entire area. These schemes were not always successful.
- Beam inhomogeneities, particularly dimming toward the beam perimeter, contribute to underablation near the edge of the optical zone.
- **Solution:** Switching to small-beam scanning algorithms effectively solves the problem.

Radial Ablation Efficiency Loss

Effects of oblique beam incidence



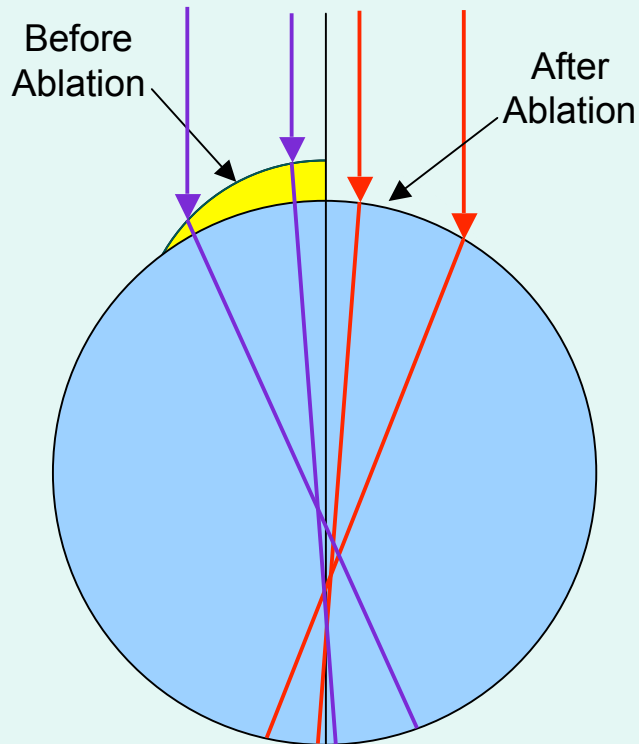
- Larger beam area, lower fluence.
- Higher reflectance, lower fluence.
- Dim edges of beam fall below ablation threshold, effective beam size shrinks.
- Ablation calibrations done on flat plastic don't show these effects.

Biomechanical Effects

- Ablation of stromal tissue releases tension on the cut stromal fibers, which then retract from the corneal center and thicken the stromal layer toward the edge of the optical zone.
- These changes flatten the center of the nominal optical zone and steepen the edges, contributing to an oblate contour, increasing spherical aberration and shrinking the effective optical zone.

Induced Spherical Aberration

Effect of True Spherical Ablation



- The Munnerlyn formula for spherical myopic ablation should make the cornea more prolate and reduce positive spherical aberration.
- The actual result is a more *oblate* cornea with *increased* spherical aberration.
- **Conclusion:** the theoretical reduction in spherical aberration due to the Munnerlyn equation is relatively minor, overwhelmed by opposing effects of healing, biomechanical changes and ablation efficiency losses.

The Effective Optical Zone

Myopia Treatments

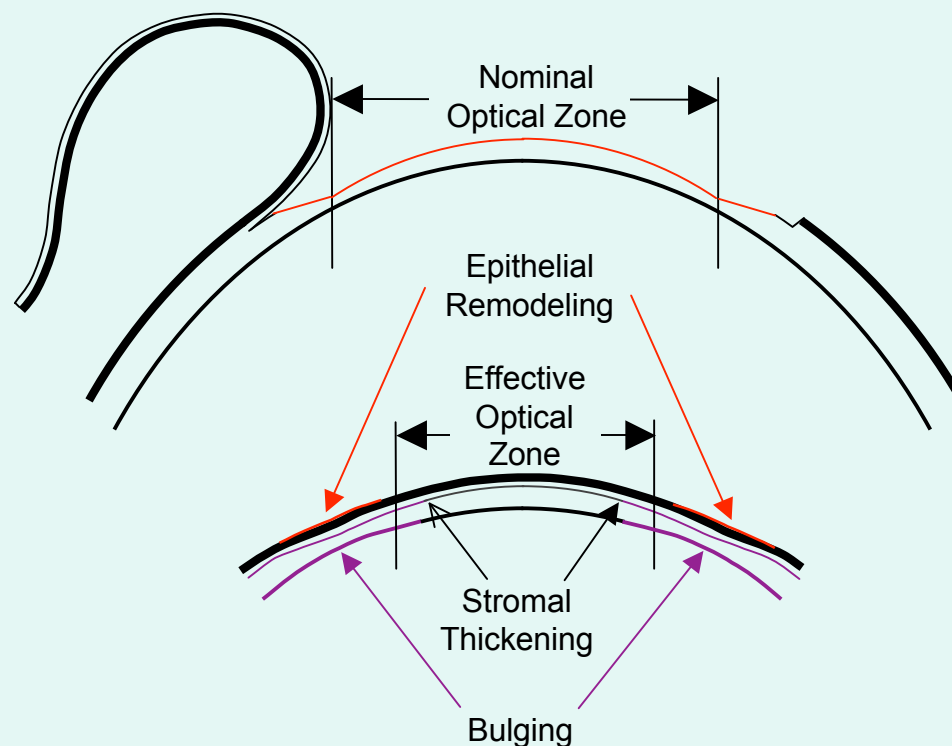
- Epithelial remodeling, radial ablation efficiency losses and biomechanical effects all reduce the effective ablation in the outer portion of the nominal optical zone.
- These effects shrink the actual zone of full refractive correction, i.e., the *effective* optical zone.
- They also distort attempted cylindrical ablations by flattening the cornea along the astigmatic axis, introducing an unintended spherical correction component and reducing the cylindrical correction.

The Effective Optical Zone

Hyperopia Treatments

Undercorrections caused by multiple mechanisms:

- Epithelial remodeling fills in annular ablation, induces negative spherical aberration.
- Cornea bulges out at diameter of maximum ablation depth.
- Cut fibers retract toward the center, thickening the stroma and flattening the central zone.
- Low efficiency reduces maximum ablation depth.
- All changes shrink the effective optical zone.



Small Beam Scanning Lasers

- Scanning lasers have largely replaced large beam lasers that relied on variable apertures to shape the ablation.
- Scanning beams provide smoother, more precise ablations, and allow elimination of central islands.
- Scanned ablations are also more flexible, making it easy to compensate for peripheral underablation by adding extra pulses to the affected regions.

LASIK vs. PRK

The use of LASIK instead of PRK has little effect on most of the factors that reduce effective peripheral ablation depth:

- Epithelial remodeling is reduced but not eliminated.
- Biomechanical effects tend to be worse because the flap results in additional stromal weakening.

Wavefront-Guided Treatments

- Recent developments in aberrometry allow us to incorporate the measurement of higher order aberrations into corneal refractive surgery.
- Small beam scanning lasers are able, in principle, to correct higher order aberrations.
- Successful wavefront-guided treatments require algorithms that compensate for ablation artifacts and anticipate healing and biomechanical factors.
- Operational definitions of wavefront-guided optical zones should include explicit control of higher order aberrations within the zone.

Optimizing Residual Aberrations

- Eliminating all higher-order aberrations is probably not the best strategy to optimize visual function. For example, some controlled aberrations can improve depth of focus with minimal degradation of image quality.
- The brain can adapt to long-term aberration patterns. In some cases, removing aberrations can therefore impair visual function.
- An operational definition of the optimal optical zone can specify aberrations to be preserved as well as those to be removed.

Future Developments

- We have come a long way since the early days of PRK toward understanding the ablation artifacts, healing factors and biomechanical effects that need to be taken into account to make the effective optical zone agree with the theoretical one.
- **Remaining challenges:**
 - Develop accurate calibration techniques to assure that the achieved corneal ablation depth map equals the one intended;
 - predict optimal aberration patterns and correction parameters in individual eyes; and
 - characterize refractive variability in individual eyes to establish fundamental limitations in defining the optical zone.
- In the past, operational definitions of the optical zone typically have been validated by test ablations on flat plastic. In the future, the goal should be to validate them by direct wavefront measurements of the cornea.

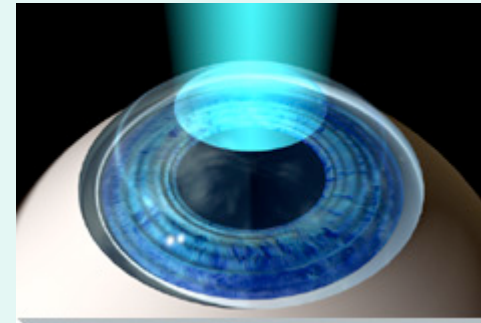
Conclusions

- We have made a lot of progress toward making corneal refractive surgery safe and effective, but there is still more room for improvement.
- The rapid development of corneal refractive surgery is an excellent example of how the collaborative efforts of manufacturers, scientists, clinicians, and FDA reviewers can lead to major improvements in the safety and effectiveness of medical devices.

Corneal Refractive Surgery

- **PRK**

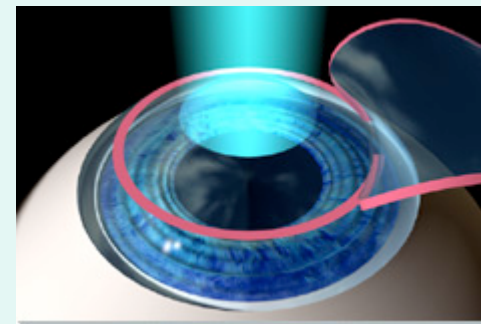
- Remove Epithelium
- Ablate with Excimer Laser
- Epithelium Regrows



PRK

- **LASIK**

- Cut 130-180 micron Flap
- Ablate with Excimer Laser
- Replace Flap



LASIK

FDA Perspective

- FDA's mission is to regulate medical products for safety and effectiveness.
- The goal of efforts to improve ablation algorithms is to maximize the safety and effectiveness of corneal refractive surgery to the patient.