

Page 3 - Herbert J. Nevyas, M.D.

profiles near the area where the dark blue and light blue areas meet. Please explain what causes this "scalloped" appearance.

5. Since your ablation equations do not appear to follow Munnerlyn's equations for generating a spherical correction on the cornea, it is unclear how you have verified that your ablation pattern and depth for any particular correction will actually produce the desired effect, i.e., the required dioptric change. For instance, using your high myopia ablation algorithm to produce a -12 D correction, please demonstrate how you have verified that removing 98.75 microns of tissue in the manner specified (single zone, multipass) produces a -12 D correction. What difference would it make if one removes 90 microns or 110 microns? How have you verified the other ablation parameters for ablations in both the low myopia and high myopia algorithms?
6. Regarding the total tissue removed, there appears to be a disconnect between your theoretical ablation algorithms (Amendment 1, page 40) and the ablation parameters in Amendment 3. For instance, on page 40 of your Amendment 1, a -6.0 D ablation should remove 61.8 microns of tissue, while a -7.0 D ablation should remove 70.6 microns. On the other hand, on page 7 of Amendment 3 you show that a -6.75 D ablation has a maximum ablation depth of 77 microns (greater even than the -7.0 predicted in Amendment 1). Please explain these differences.
7. In response to Deficiency # 2.d. about etch rate, you indicated that the etch rate was 0.194 microns per pulse in PMMA and 0.25 microns per pulse in tissue.
  - a. Our description of this deficiency probably was unclear. Please provide the etch rate *curve*, showing the laser energy per pulse versus the tissue (or PMMA) removed. Relate PMMA removed to tissue removed (this would be a ratio, for instance).
  - b. The etch rate of 0.194 microns per pulse in PMMA and 0.25 microns per pulse in tissue produces a ratio of 1.29. However, when the tissue ablation on page 7 of Amendment 3 is divided by the PMMA ablation taken from the PMMA ablation profiles, this ratio appears to vary with the number of pulses delivered, ranging from 1.25 at an ablation of -1 D to 1.48 at an ablation of -6.75 D. Please explain this discrepancy.

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