

Relate the amount of PMMA removed per pulse to the amount of tissue removed per pulse (this would be a ratio, for instance).

12. The formulation of the equation for the device ablation algorithm in Section 3.4.1.3.A "Ablation Patterns" is inadequate. Your description of the theoretical ablation algorithm appears to be internally inconsistent and lacks mathematical clarity. Please address the following:

- a. Why were 2 definitions provided for the same mathematical quantity  $c1()$ , and  $c2()$  as "curvatures" of the uncorrected and corrected cornea respectively, and simultaneously as "distances from an arc to a chord"? This information appears incorrect for the following reasons:

Curvature is a mathematically defined quantity. It is defined as the angular velocity of the tangent to the curve as the tangent traverses and therefore describes the given curve. In the rectangular coordinate (as provided in your submission) an angle  $\phi$  is defined as the angle between the tangent and the curve, and this angle  $\phi$  is the arc-tangent of the first derivative of the spatial coordinates of the curve with "x" as the independent variable. In fact, the diagram you submitted illustrates "2 intersecting curves, labeled by the sponsor as  $c1()$ , and  $c2()$ , which represent a 2 dimensional cross section of the uncorrected and corrected cornea." It is illogical for them to be described as anything else. There cannot be 2 intersecting curves and "distances to an arc to a chord" at the same time as you described.

The final equation [now labeled as (4)] does not appear to be one which can be related to ablation of the cornea because it is an equation which contains only spatial coordinates and no dependence on D (the dioptric power), or n (the index of refraction of the cornea). The statement that  $d(y)$  represents the depth at any spherical coordinate Y appears logically inconsistent because the equation is formulated in rectangular coordinates, and the equation has no Y dependence. In order to derive the ablation equation, one has to use the geometry of the 2 intersecting curves to set up an equation for the depth between the 2 curves as a function of Y where Y is defined as the lateral distance from optical axis of the cornea. At this point one has to get the dependence of D, and n into the geometrical equation by making appropriate substitutions from the equation for the power of a lens which is an independent equation. The result of these operations is a very complicated expression which is simplified by applying the binomial expansion to it. At this point a further simplification is made by finding the depth of cut on the corneal optical axis. This means let  $Y=0$ . The resulting simple equation is for  $t(\text{on axis depth}) = \text{optical zone diameter squared times dioptric change divided by eight times the difference between the indices of refraction of the cornea and air. This is the so-called Munnerlyn equation.}$