

performed using a non-approved Excimer Laser ("black box laser"). This Excimer Laser was not formally approved by the U.S. Food and Drug Administration, Medical Device Division. From subsequent reports, the laser engine was a Schwind Compex 201, which is not approved for human use in the United States.

The Excimer Laser ablation that was carried out by Dr. Anita Nevyas-Wallace using the unapproved Excimer Laser was subsequently found post-operatively to be significantly decentred based on computer-assisted corneal topographic analysis. In addition, Ms. Cheryl Fiorelli sustained a marked overcorrection with a significant hyperopic astigmatic refractive result. On the fourth day post-operative (3/24/97), Ms. Fiorelli was complaining of subjective and qualitative disturbances in her visual acuity. Her visual acuity without correction in the right eye measured 2100 pinholing to 20/70. The subjective refraction right eye: (+6.75 -2.25: axis 118 equaled 20/70). On follow-up exam, this major over-correction had a slight regression and on 3/31/97 the subjective refraction measured right eye: (+4.75: -2.25: axis 125 equaled 20/80-). The corneal topographic analysis disclosed a significantly decentred Excimer Laser ablation in the right eye.

On May 12, 1997, the visual acuity without correction right eye measured 20/70 pinholing to 20/40 with a significant halo. There was the previously noted supero-nasal decentration of the ablation.

On May 15, 1997, Dr. Anita Nevyas-Wallace attempted a retreatment of Ms. Fiorelli's right eye in an effort to reduce the disturbing subjective qualitative symptoms of halos and decreased vision resulting in part from the supero-nasal decentration. On 5/19/97, four days status post, the LASIK retreatment in the right eye, the visual acuity without correction in the right eye measured 20/100 pinholing to 20/70. Ms. Fiorelli was still seeing subjective halos in the right eye and complaining of subjectively diminished visual acuity especially at the mid-range distance of about five feet. Her subjective refraction in the right eye: (+4.75 -1.25 x 110 equals 20/60-3).

Ms. Fiorelli's subjective disturbances following the LASIK treatment with the unapproved Excimer Laser with significant decentration persisted through the summer of 1997. On July 7, 1997, the visual acuity without correction measured 20/70 with the hyperopic astigmatic refraction. It was felt that the decreased best corrected visual acuity was in part due to flap striae and due to the decentred ablation as well as the overcorrection. Dr. Anita Nevyas-Wallace then had developed several treatment plans in an effort to improve the poor quality and quantity of vision with yet another laser retreatment. On July 10, 1997, Ms. Fiorelli underwent a third LASIK retreatment to her right eye. On August 25, Ms. Fiorelli was still not driving at night and still complained of subjective halos and poor vision from the right eye. Her visual acuity without