

My LASIK Disaster



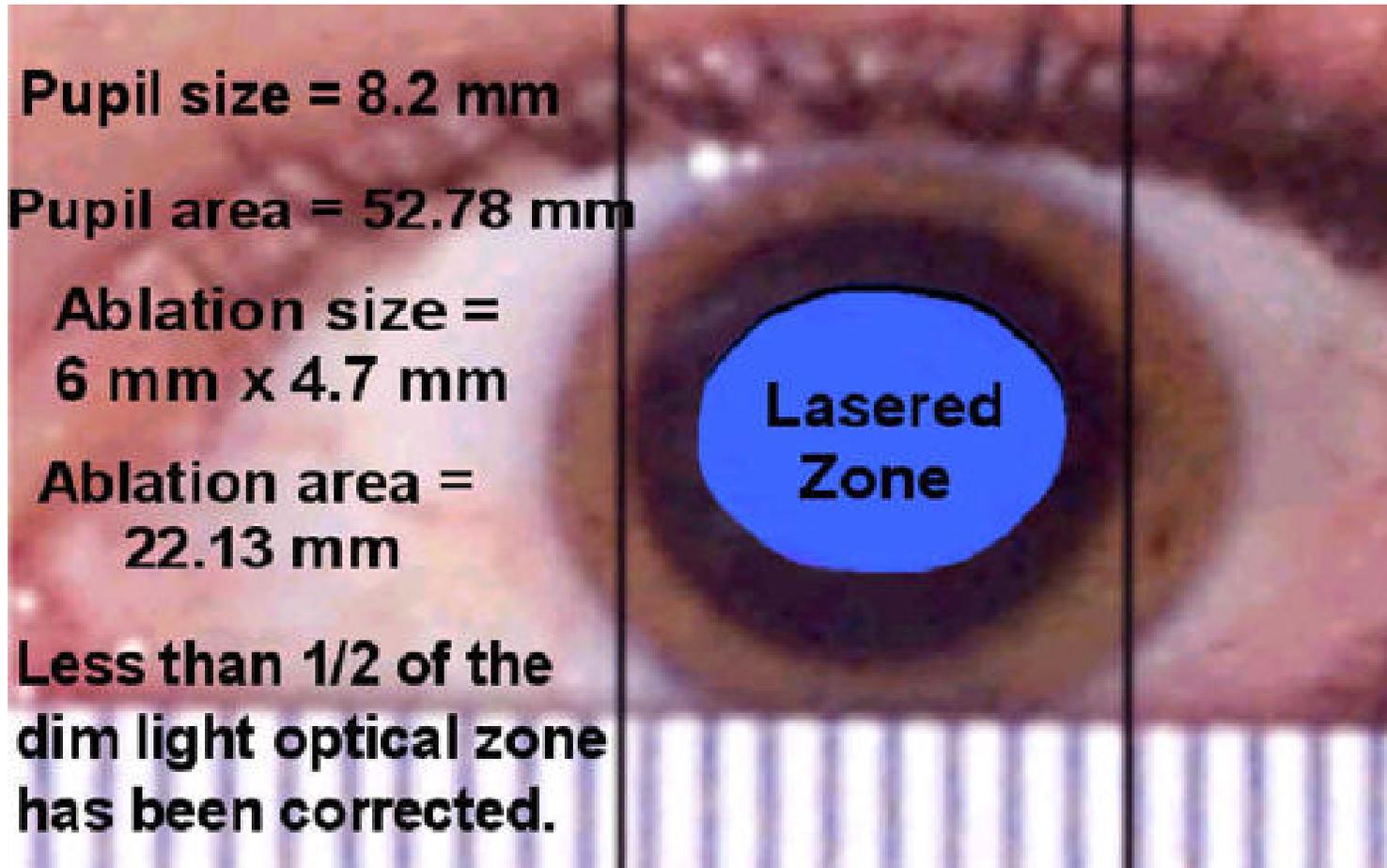
by Sandy Keller,
the original owner of LASIKdisaster.com

My Contraindications

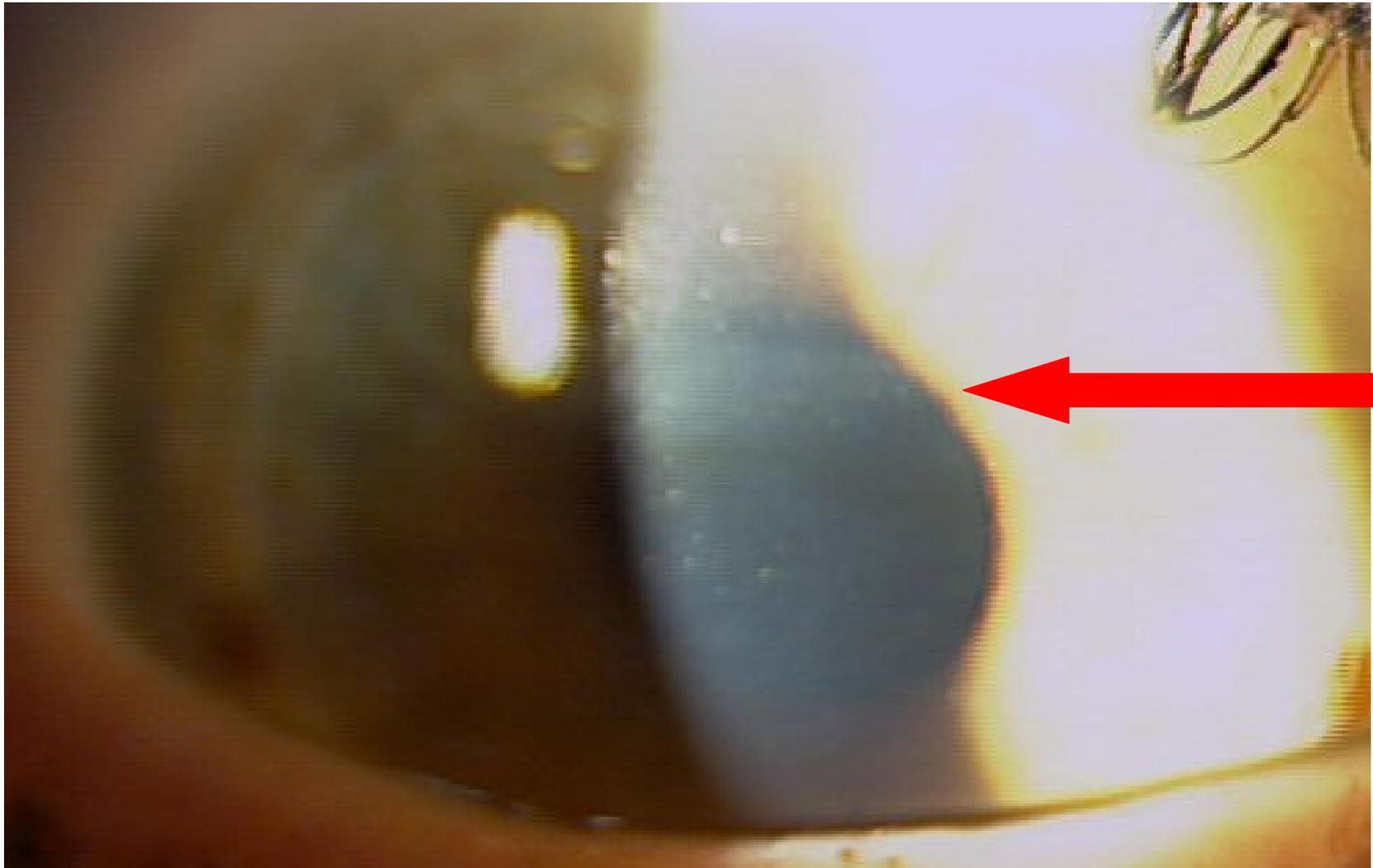
- 8+ mm scotopic pupil size
 - Dry Eyes
- Corneal warpage from 25 years of RGP use



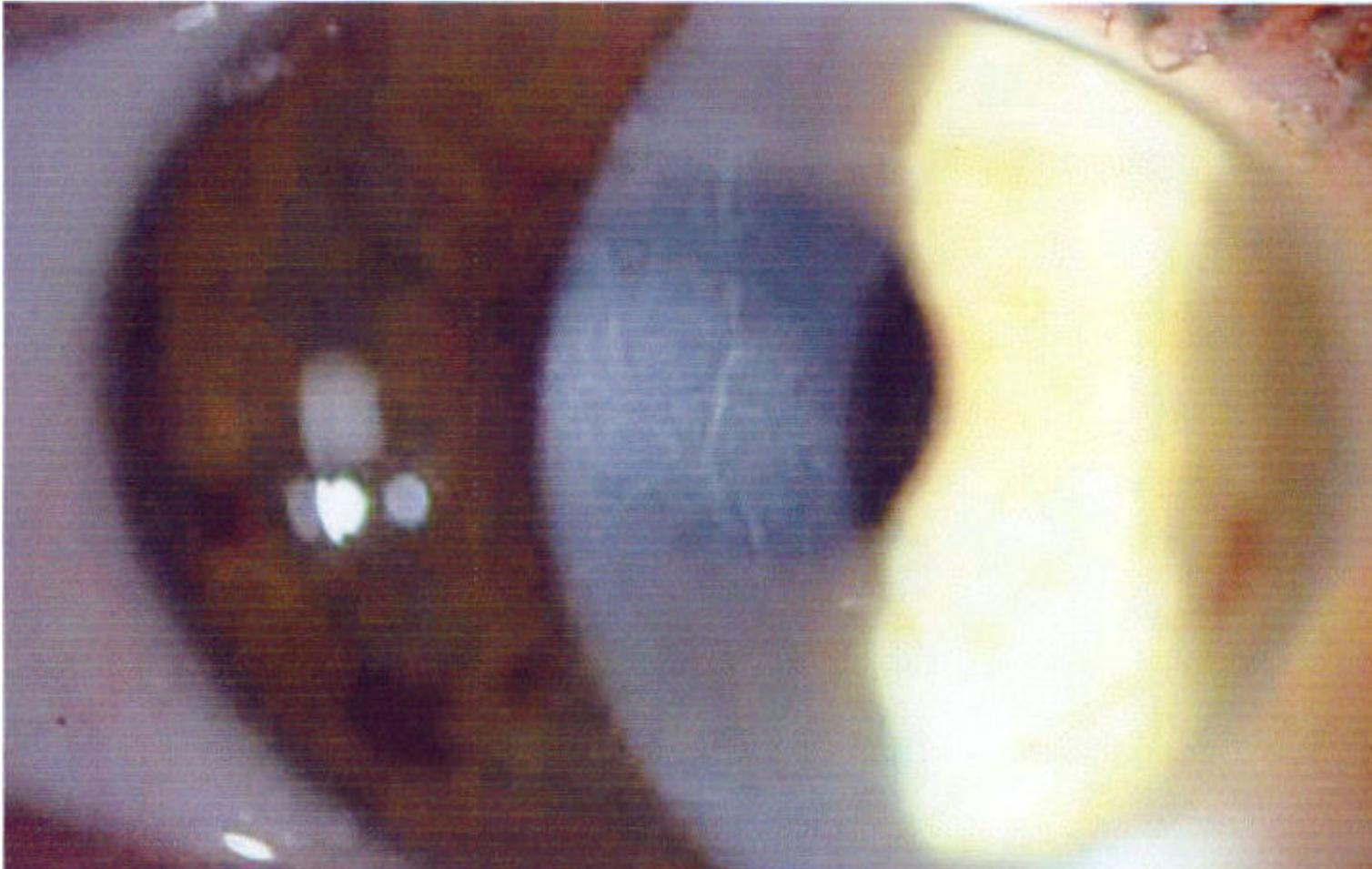
Disparity between my dark-adapted pupil size and the optical zone lasered



The blade jammed in my first eye, leaving a ridge within the optical zone still visible to this day.

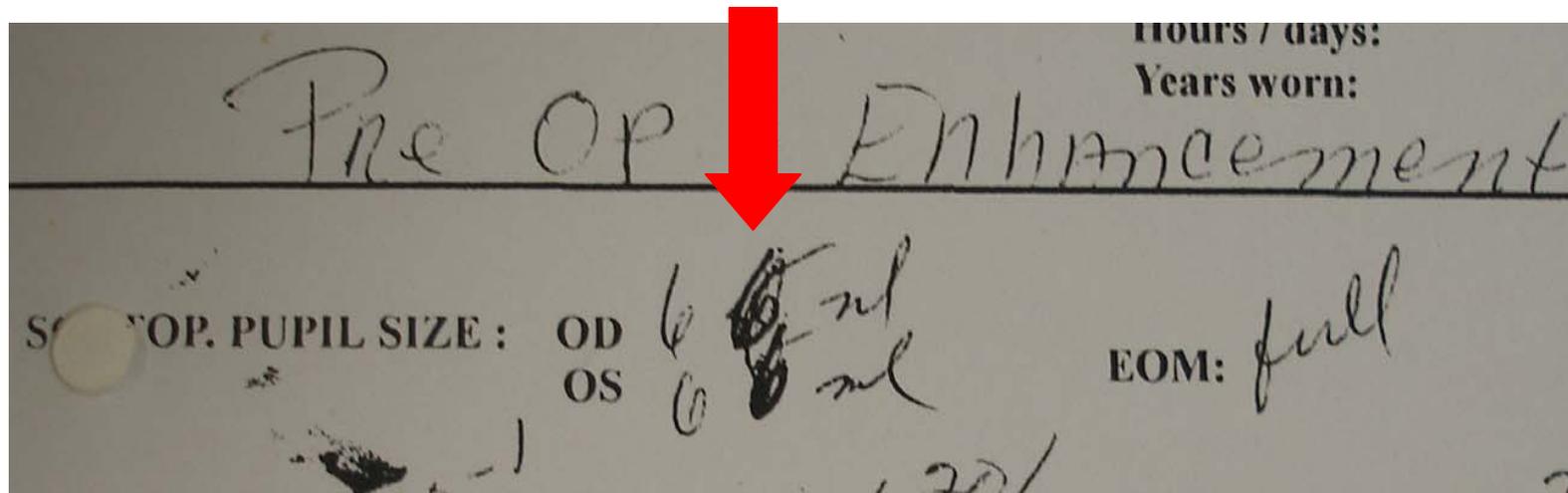


Grade IV DLK developed
Severe haze and flap wrinkles resulted



My Medical Record Was Altered

- My pupil size was never measured until the “enhancement” surgery two months post-op, and then those measurements were altered on my chart by my surgeon.



The MAUDE Report I Personally Filed



U.S. Food and Drug Administration



CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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Adverse Event Report

BAUSCH & LOMB INC. HANSATOME - 115 VOLT UNIT KERATOME, AC-POWERED

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Catalog Number 507-0036-01

Device Problem Other (for use when an appropriate device code cannot be identified)

Event Date 09/27/1999

Event Type Injury **Patient Outcome** Other;

Event Description

Information was received that a refractive surgery was performed in 1999. It was stated the patient developed diffuse lamellar keratitis (dlk), "wrinkles" in the corneal flap, induced irregular astigmatism and compromised night vision. A review of the company's files showed no record of the event being reported either by the surgeon(s) or the user facility. No information on the patient was found in company's database.

Manufacturer Narrative

H3/h6: serial number of the hansatome unit was not identified. No record of the reported event was found in the company's database for either the user facility, the surgeon (s) who performed the surgery or the patient.

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Brand Name HANSATOME - 115 VOLT UNIT

Type of Device KERATOME, AC-POWERED

Baseline Brand Name HANSATOME-115 VOLT UNIT

Baseline Generic Name ALK UNIT

Baseline Catalogue Number 507-0036-01

Baseline Device Family 86HNO-KERATOME, AC-POWERED

Baseline Device 510(K) Number [K913697](#)

Baseline Device PMA Number

Baseline Shelf Life Information Yes

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Disposition: “No record of the event...no information on the patient was found”

Date FDA Received 05/24/2001

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 507-0036-01

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? No

Was the Report Sent to FDA? No



Date Manufacturer Received 05/01/2001

Was Device Evaluated By Manufacturer? No



Is The Device Single Use? No

Is the Device an Implant? No

Is this an Explanted Device?

Type of Device Usage Reuse

Night Vision Result - Extreme Glare



My Vision Today

- This is how I see without rigid contact lenses, nearly nine years after my LASIK eye surgery.



My Call to Action

- Requirement that informed consent forms mention the risk of possible suicidal ideation following serious complications or visual aberrations post-refractive surgery
- Regulation of refractive surgery co-management by optometrists, including education, certification of competency, and setting limitations to allow payment only for services actually rendered
- Consequences for failure to report adverse events