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LASIK for myopia and myopic astigmatism with the CustomVis solid state laser (213nm) PULZAR Z1

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Purpose

- To evaluate the clinical efficiency, predictability and safety of a new high speed, 0.6 mm Gaussian shaped flying spot, 213nm solid state laser for the correction of myopia and myopic astigmatism.
- Laser in Situ Keratomileusis (LASIK) was done in all cases.
- All surgeries performed at four sites.
- Data collection done by ophthalmic assistant

CustomVis™ Pulzar™ Z1

A Solid State Laser Engine

213nm Wavelength

0.6mm Flying Beam Spot

An Intra Operative Gazetrak™

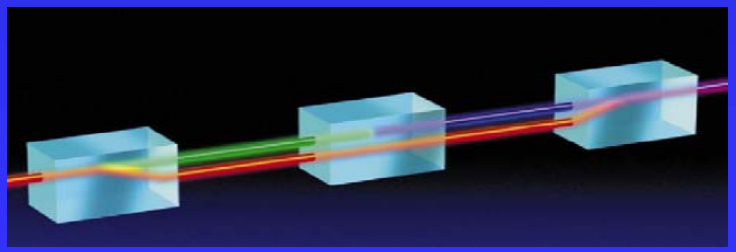
ZCAD Surgical Planning Application

Fast Closed Loop Eye Tracking System

Registration Matched 1:1 with Corneal Position

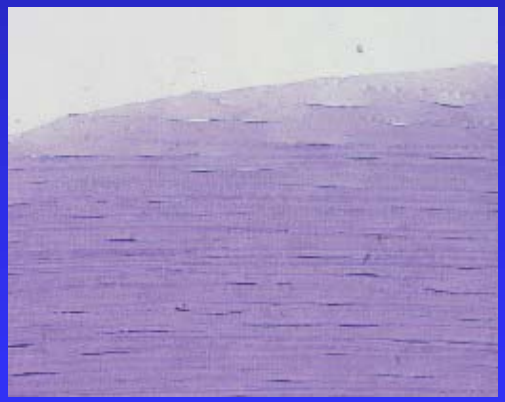
Solid State Laser Source

- Diode-pumped Nd:YAG laser
- Three non-linear crystals generate the 213nm wavelength
- Eliminates need for toxic gases and storage
- Energy efficient; no high voltage requirements
- Low maintenance



213nm Wavelength

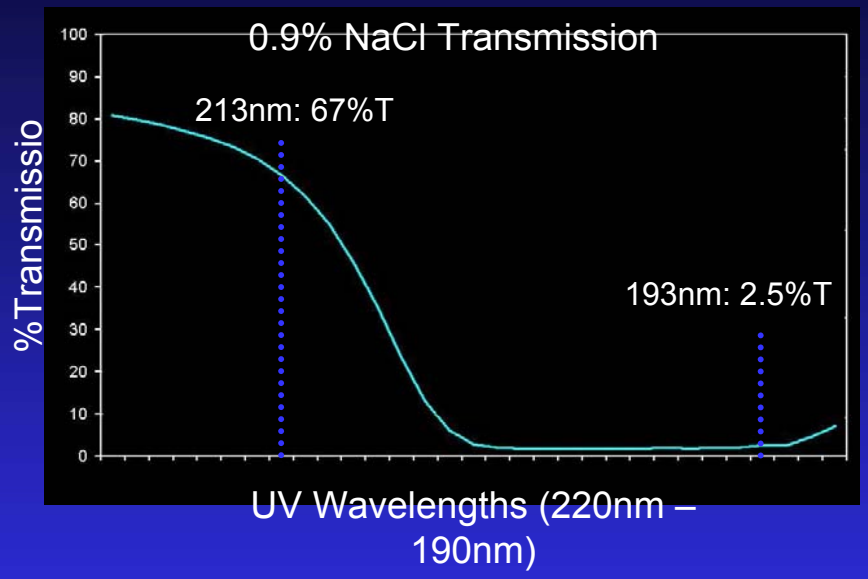
- Clean & Smooth Ablated Surfaces
- Possibly Free from Hydration Monitoring
- Closer to absorption peak of corneal collagen
- Better pulse to pulse energy stability

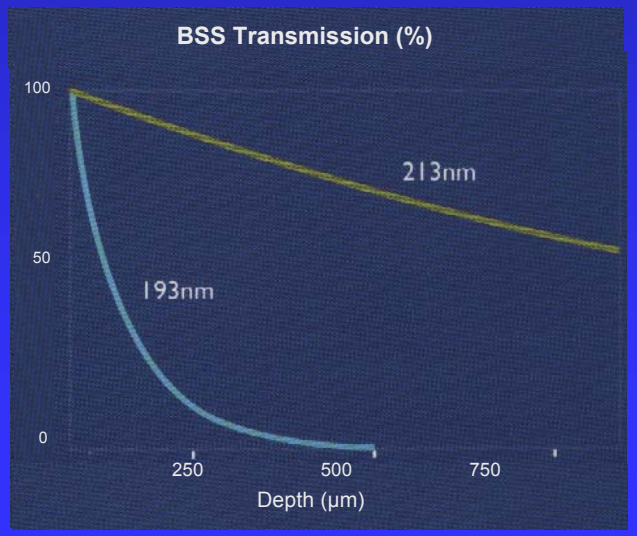


SEM of 213nm ablated surface

UV Spectrum

(Jain et al., 2004; unpublished data)





213nm has a significantly higher transmission through 0.9% NaCl and BSS than 193nm

Pulzar Z1 Laser Beam

- 0.6mm Gaussian Flying Beam Spot

  Allows precise customized ablation profiles

- Rapid Pulse Rate of 300 – 400 Hz

  Ensures quick treatment time

- Solid state laser engine source

  Improved pulse to pulse energy stability

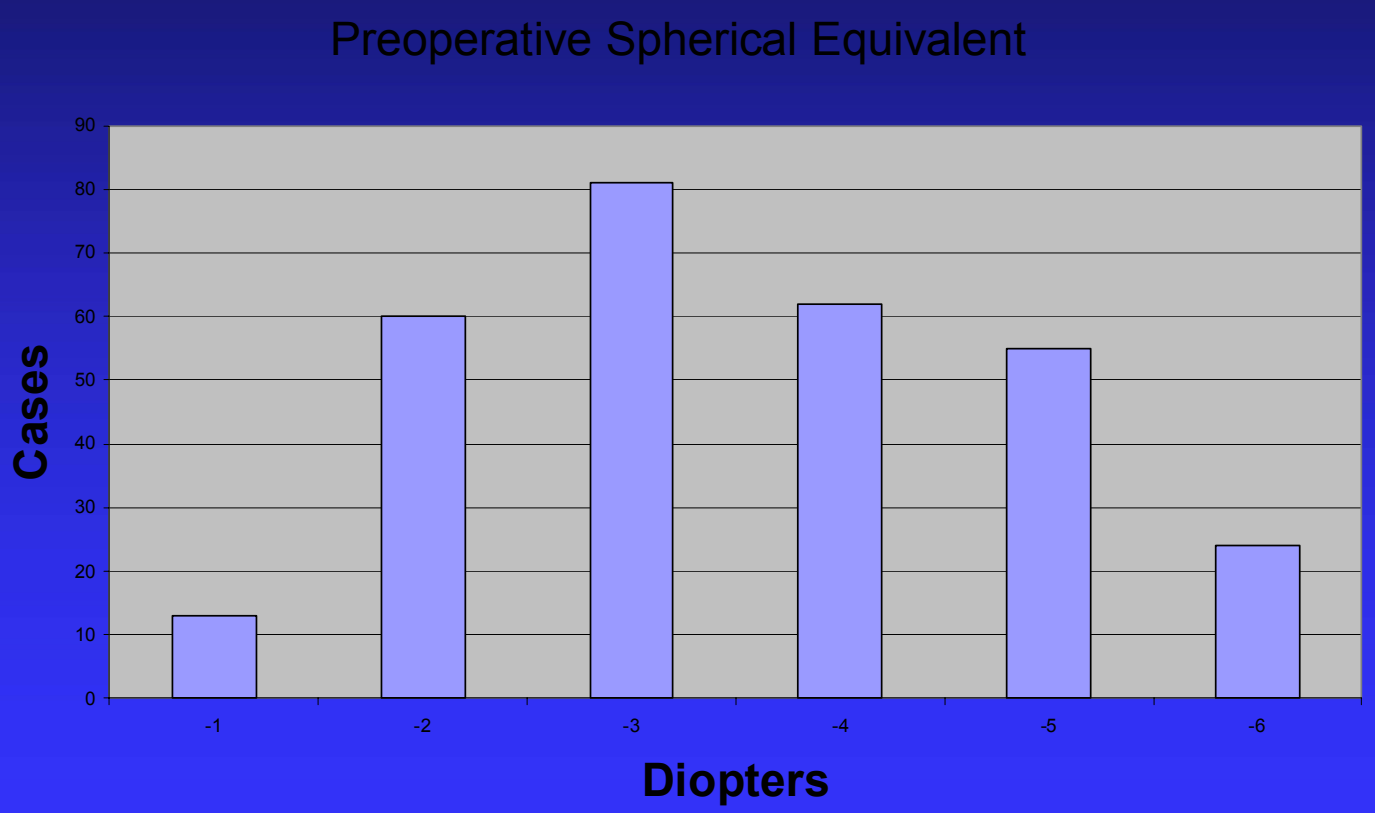
- High transmissibility through water

  Minimal thermal heating of the cornea

Patients

- 295 eyes with myopia and myopic astigmatism underwent Laser Vision Correction.
- Pre-operative spherical correction was from -0.5 D to -6.00 D and astigmatism was up to -5.00 D.
- All patients were operated at four different international sites.
- LASIK was done in all cases.

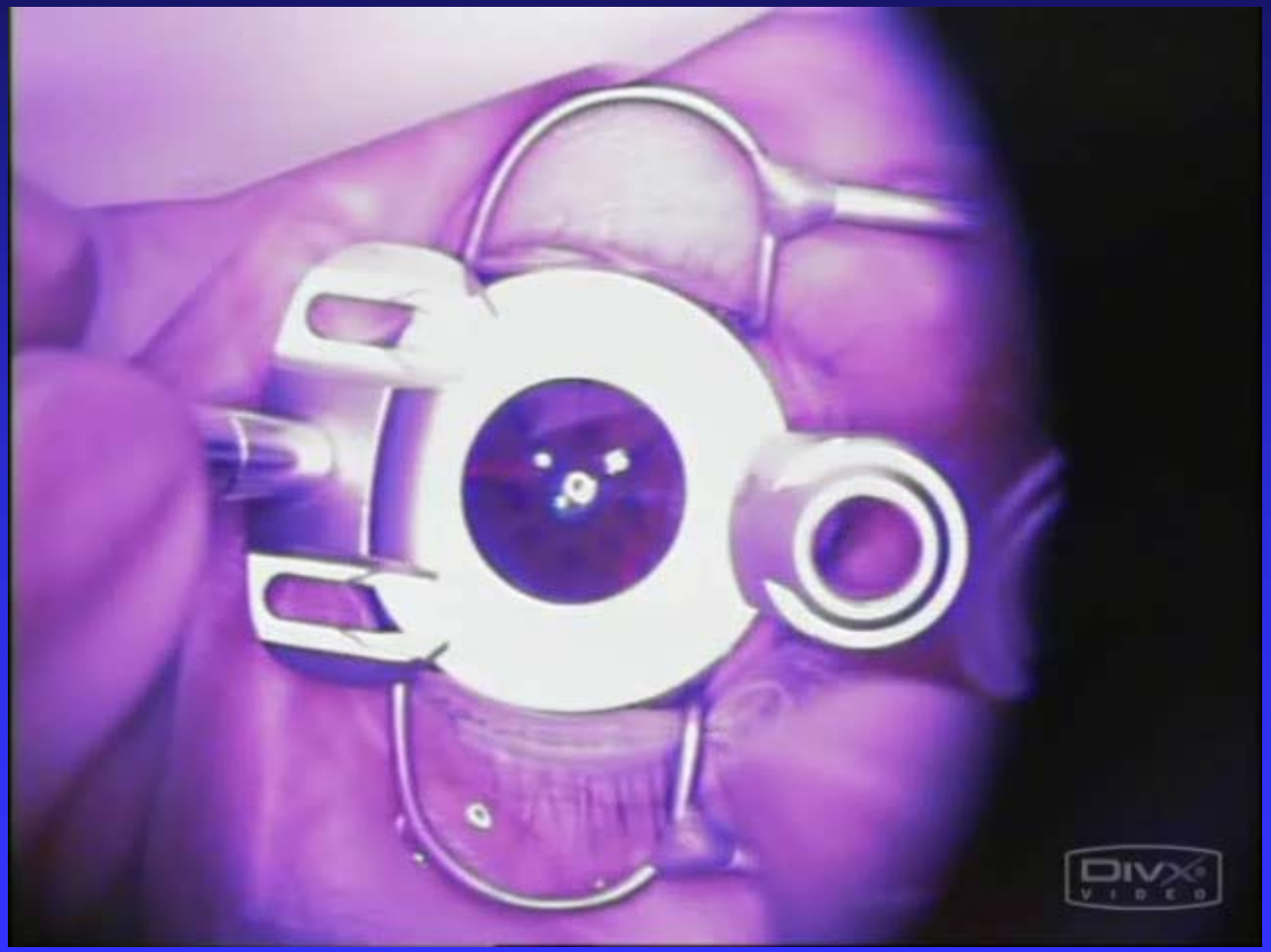
Uncorrected Preoperative Myopic Spherical Equivalent



Results

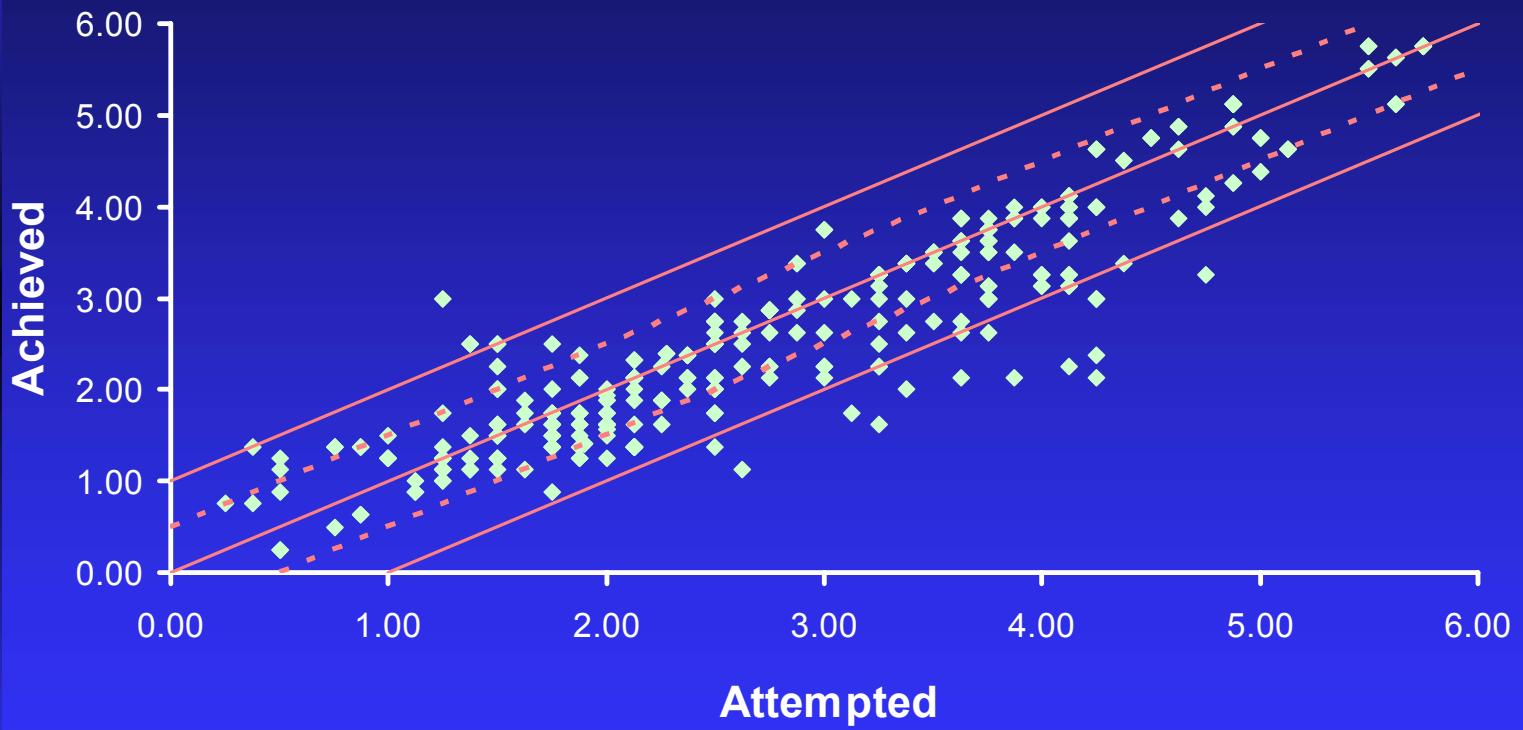
- All patients were evaluated after 3 month
- The post – operative mean SE was -0.19 D
- 75% of patients were within ±0.5 D and 95% were within ±1 D of intended refractive correction.
- Uncorrected Visual Acuity – 67% were 6/6 or better and 98% were 6/12 or better.
- 37% gained 1 line in their best spectacle corrected visual acuity and 87 % lost no lines.

Surgical Video



Myopia and Myopic Astigmatism (SE ≤ 6D)

3 month follow-up (n=295)



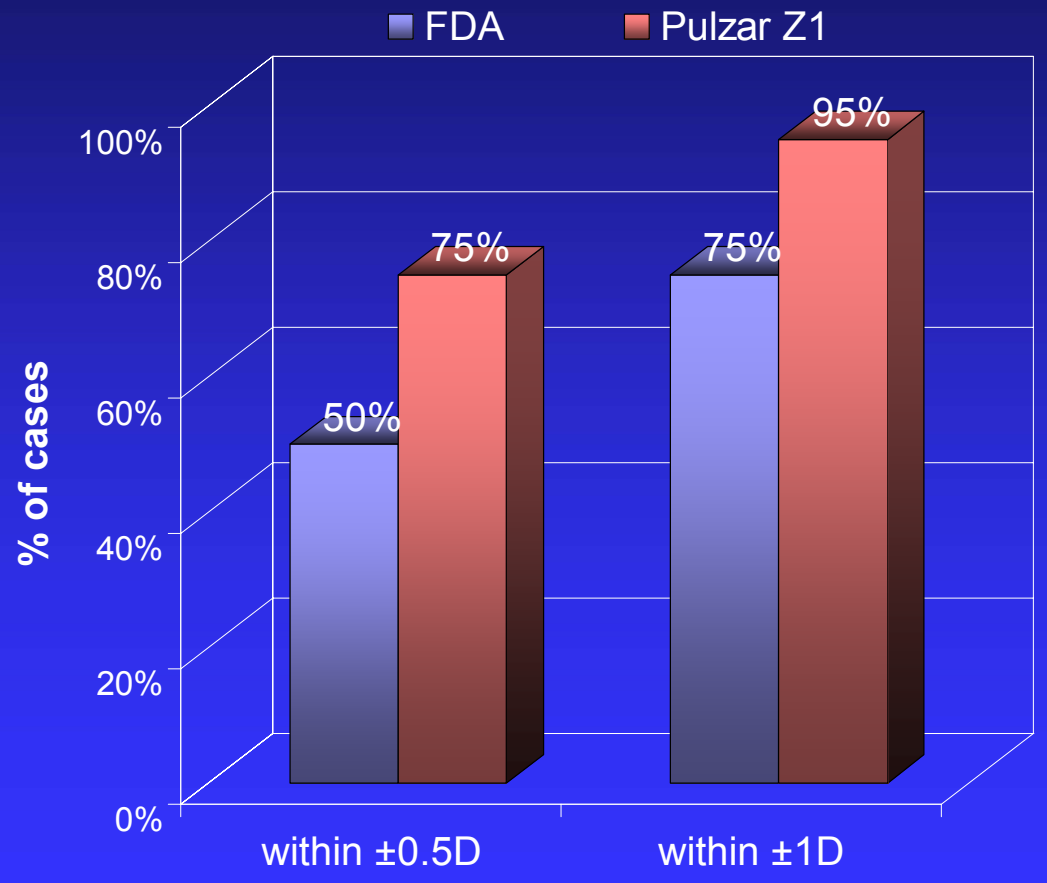
Note: The graph has some overlapping points

Also includes initial R & D phase data

Myopia and Myopic Astigmatism

Attempted vs. Achieved Correction

3 month follow-up (n=295)



Conclusions

- The Clinical Data supports the safety, predictability and effectiveness of PULZAR Z1 Solid State Refractive Laser (213nm) in Myopias and Myopic astigmatisms
- CustomVis™ Pulzar laser system is a good alternative to conventional Excimer systems