SMILE Onboarding: shortening the learning curve and early results

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Challenges in Adopting SMILE

- Challenging economic environment in Europe affecting Laser Vision Correction Market

- LASIK is well established, safe and effective

- Why learn a new technique?

- Learning Curve

- Patient Safety

- Reputation

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The New SMILE On Boarding Process

Each training step is a precondition for the following one and no step can be skipped!

Clinical Smile training
- Clinical training course incl. surgeries
- Performed at Zeiss training center in India

LONDON VISION CLINIC

London Vision Clinic course
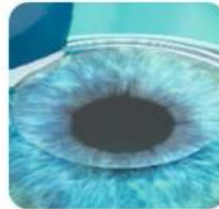- ReLEx SMILE
- PRESBYOND

Online Training for Visumax Basics and Flap

Onsite Training session flap
- Theory
- Hands-on
- Wetlabs (min.10 eyes each surgeon)
- First flap surgeries (min. 6 eyes each surgeon)
- Follow up

Following flap surgeries
- Continuous application support
- Minimum 50 eyes each surgeon
- CAS decides to proceed with Smile training

Onsite Training session Smile
- Theory
- Hands-on
- Wetlabs (min.10 eyes each surgeon)
- First Smile surgeries (min. 6 eyes each surgeon)
- Follow up

Following Smile surgeries
- Continuous application support
- Minimum 50 eyes each surgeon
- CAS decides if clinical endpoints are reached

Final debriefing
- All surgeons confident and results are good?
- Decision on end of initial application training process, or additional training sessions.

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Purpose of the study and methods

Purpose: The purpose of this study was to demonstrate the safety and efficacy of an integrated training programme for adopting SMILE, A Control Group of Femto-LASIK patients was used as comparison

Equipment: Zeiss Visumax Laser System (Carl Zeiss Meditec, Germany)

Methods: Retrospective case series.

The study population consisted of two groups of patients.

All included eyes had CDVA of at least 6/6 prior to surgery

Patients underwent one of either:

 SMILE surgery (242 eyes of 121 patients)or Femto-LASIK (445 eyes of 225 patients)

The setting for the study was within a private eye hospital group in the UK.

Unaided distance and near visual acuity (UDVA, DCNVA), spherical equivalent refraction and

fluorescein enhanced tear break up time were evaluated pre- and post-operatively.

Patient satisfaction data was gathered via an automated questionnaire.

Methods: Structured Training

- Supervised by Zeiss Clinical Applications Team UK: Anna Bielawska
- Theory based training with material provided by Zeiss
- MCQs to assess learning
- Attendance at London Vision Clinic SMILE Course: Prof Reinstein and Glenn Carp
- Wet Lab training
- Supervised surgical training in an approved Zeiss Training Facility
- Certificate of Surgical Competency
- Unsupervised surgery supported by Zeiss Clinical App Specialist
- Visumax optimisation throughout

Results: Unaided Visual Acuity

	LASIK	SMILE
N	445	242
PreOp SE	-3.89 ± 2.03 D	-5.16 ± 2.25 D
Monocular UDVA at least 6/12	444/445 (99.8%)	218/218 (100%)
Monocular UDVA at least 6/6	393/445 (88.3%)	199/218 (91.3%)
Binocular UDVA at least 6/6	199/211* (94.3%)	116/121 (95.9%)

p>0.05 between groups for all parameters
24 monovision eyes excluded from monocular acuity analysis in SMILE group
* Binocular acuity recorded for 211 of 225 patients

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Predictabilty, Ocular Surface, Patient Satisfaction

	LASIK	SMILE
SE refraction within ±1	439/445 (98.7%)	214/218 (98.2%)
SE refraction within ±0.50	391/445 (87.9%)	197/218 (90.4%)

p>0.05 between groups for all parameters

Fluorescein tear break up time was examined in a subgroup
of the SMILE sample (N = 50)

Mean TBUT Preop = 6.40 ± 1.83 seconds ± SD
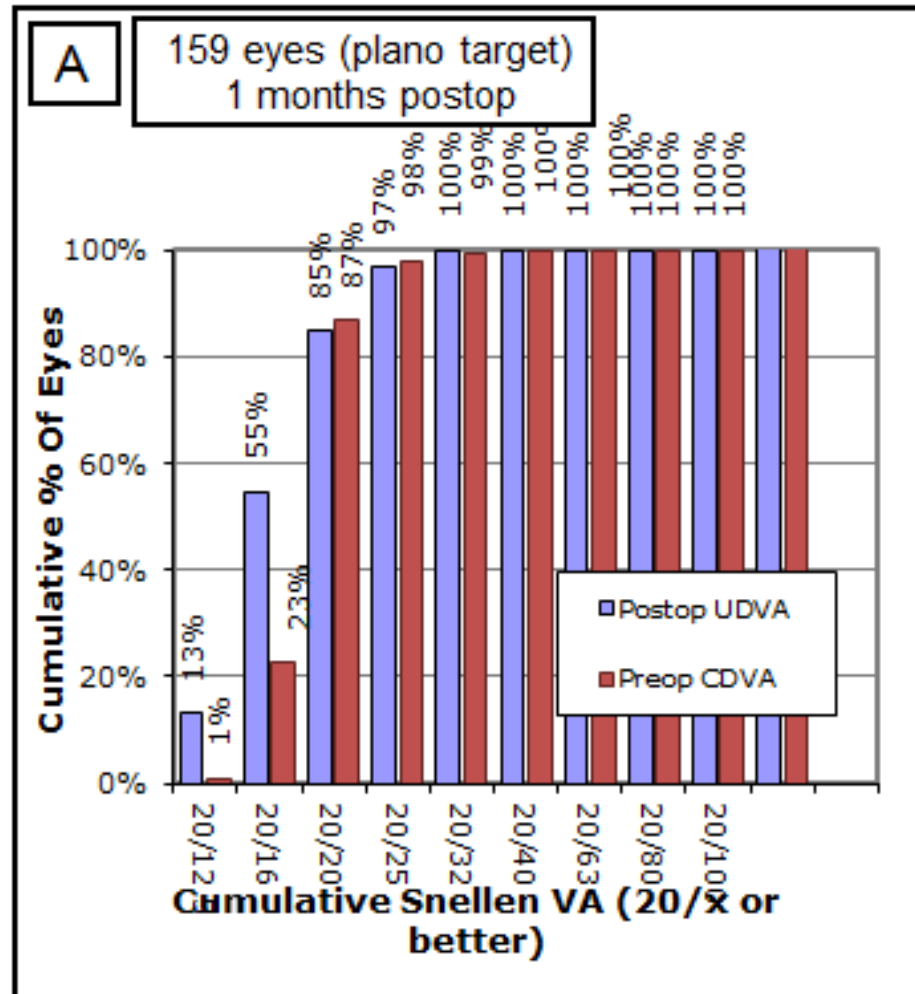
Mean TBUT Post-op = 5.76 ± 1.86 seconds ± SD

Patient reported satisfaction with both procedures was high.

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Waring Graphs Subgroup analysis 159 eyes with complete data at 1 month

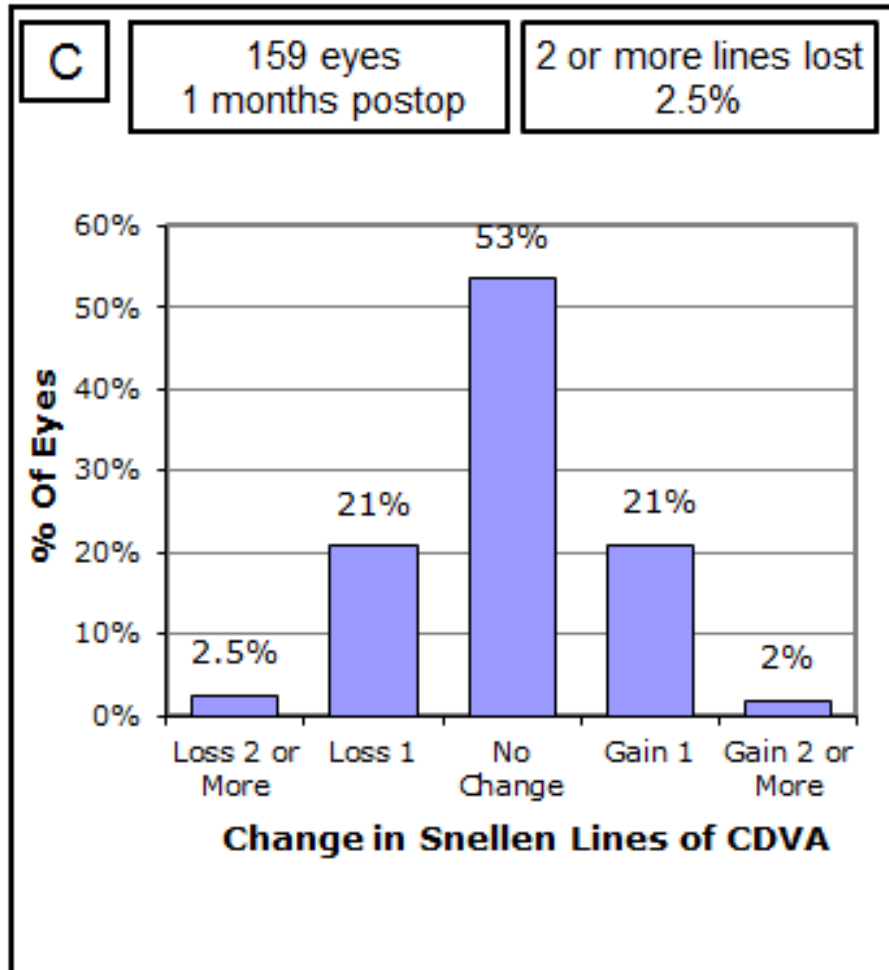# High levels of UCDVA: Improves further at 3 months
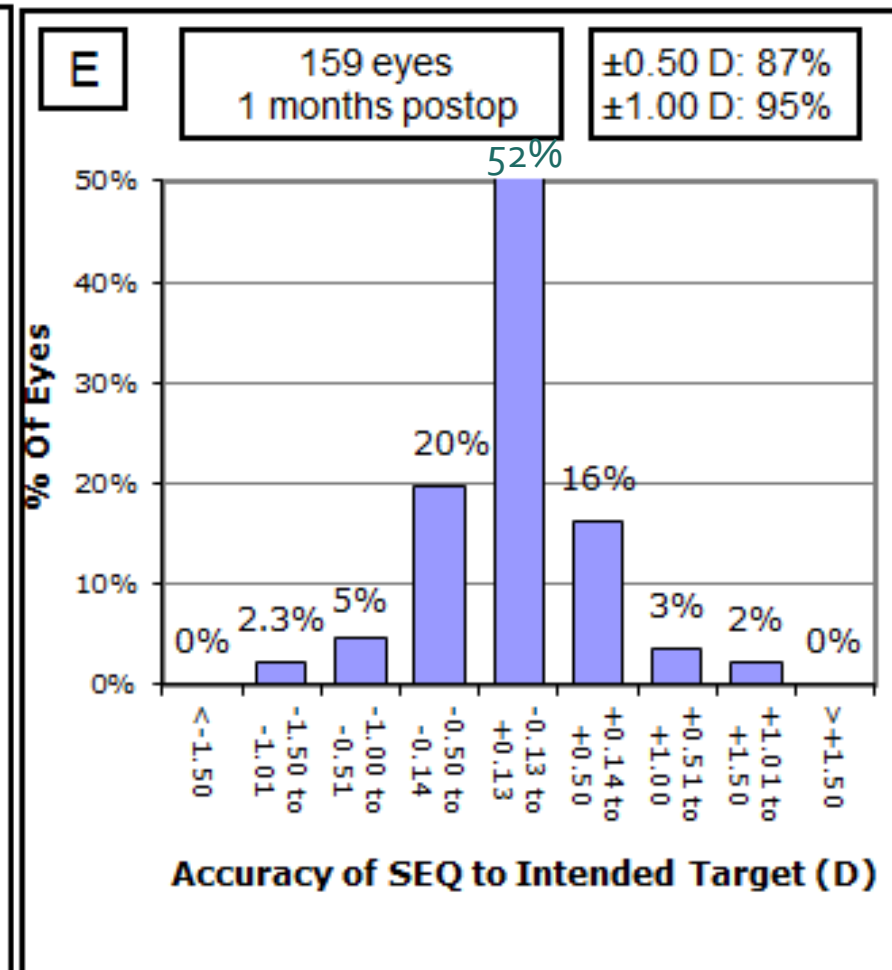

Uncorrected Distance Visual Acuity
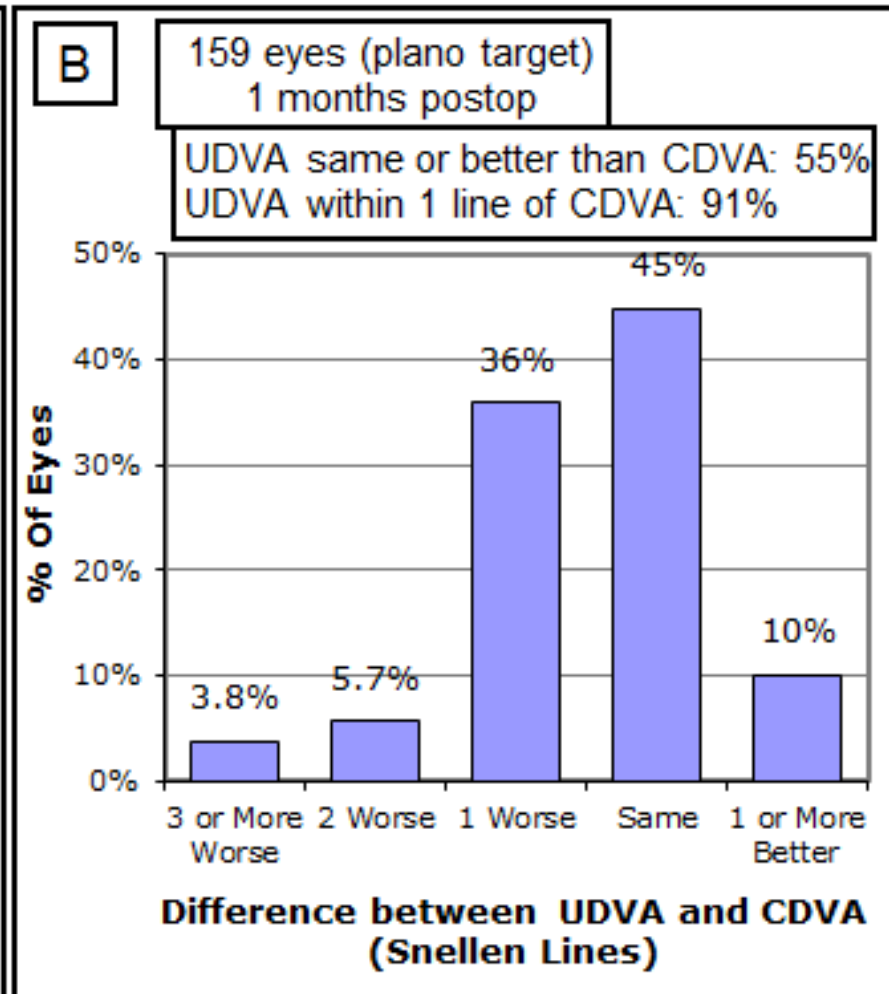
Uncorrected Distance Visual Acuity vs. Corrected Distance

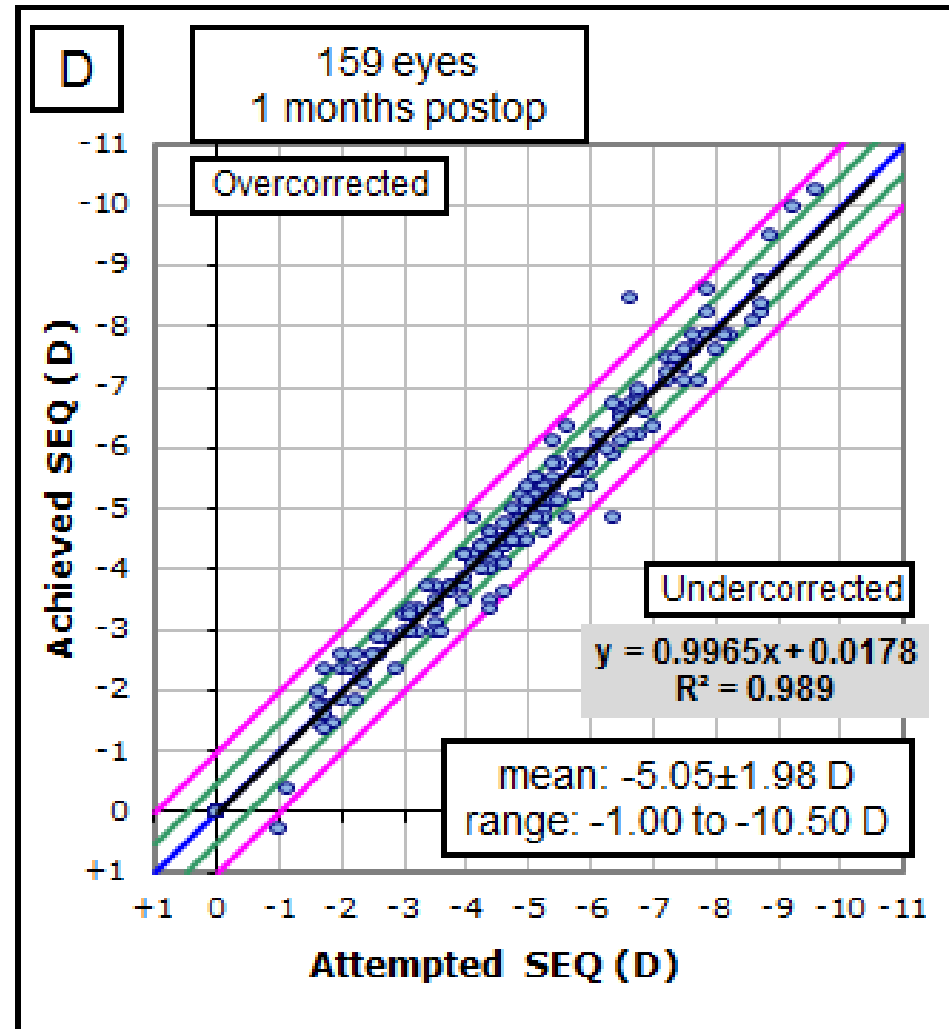# At 3 months there is further improvement in vision: data to follow
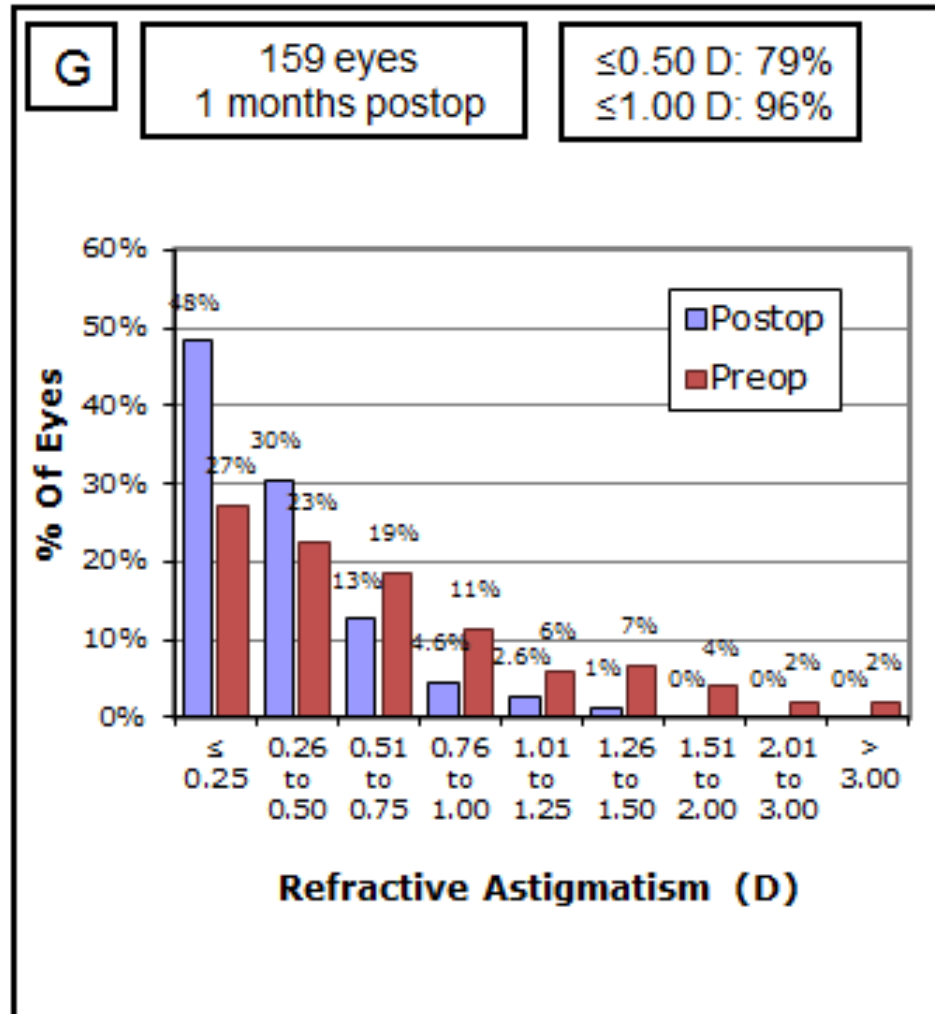

Change in Corrected Distance Visual Acuity

Spherical Equivalent Refraction Accuracy
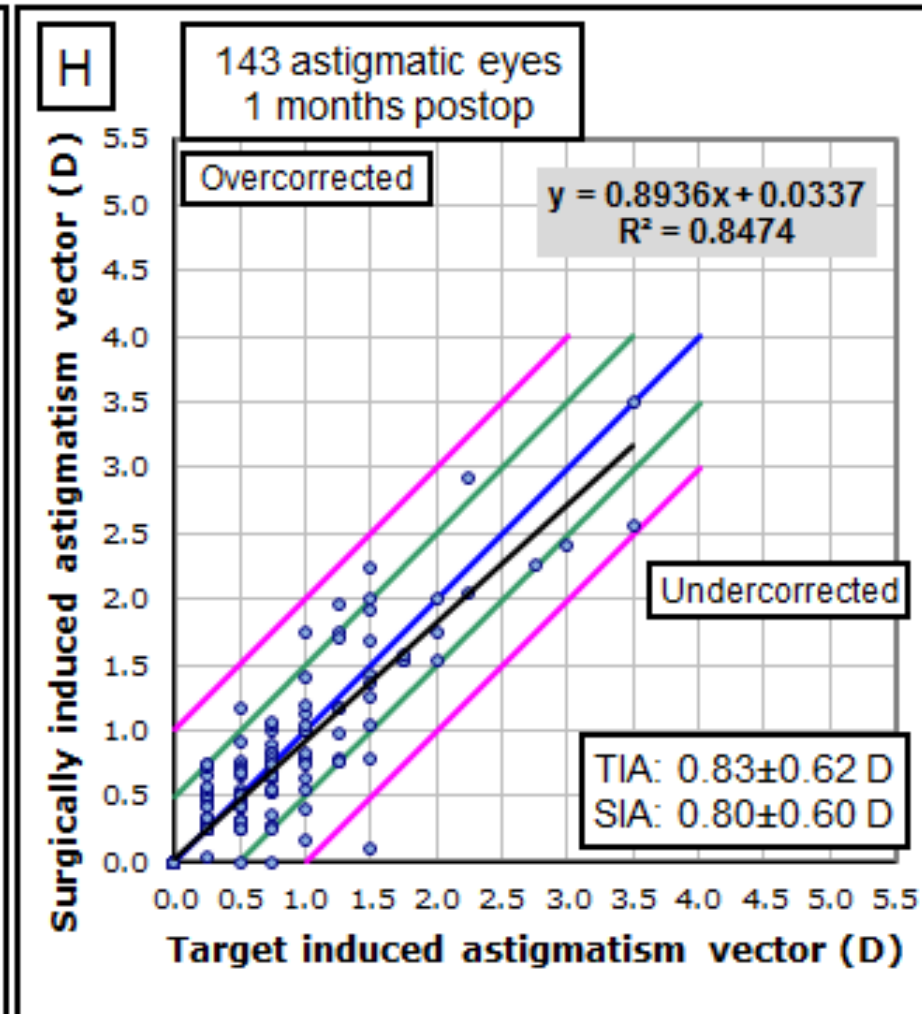
Highly predictable

**Spherical Equivalent Refraction
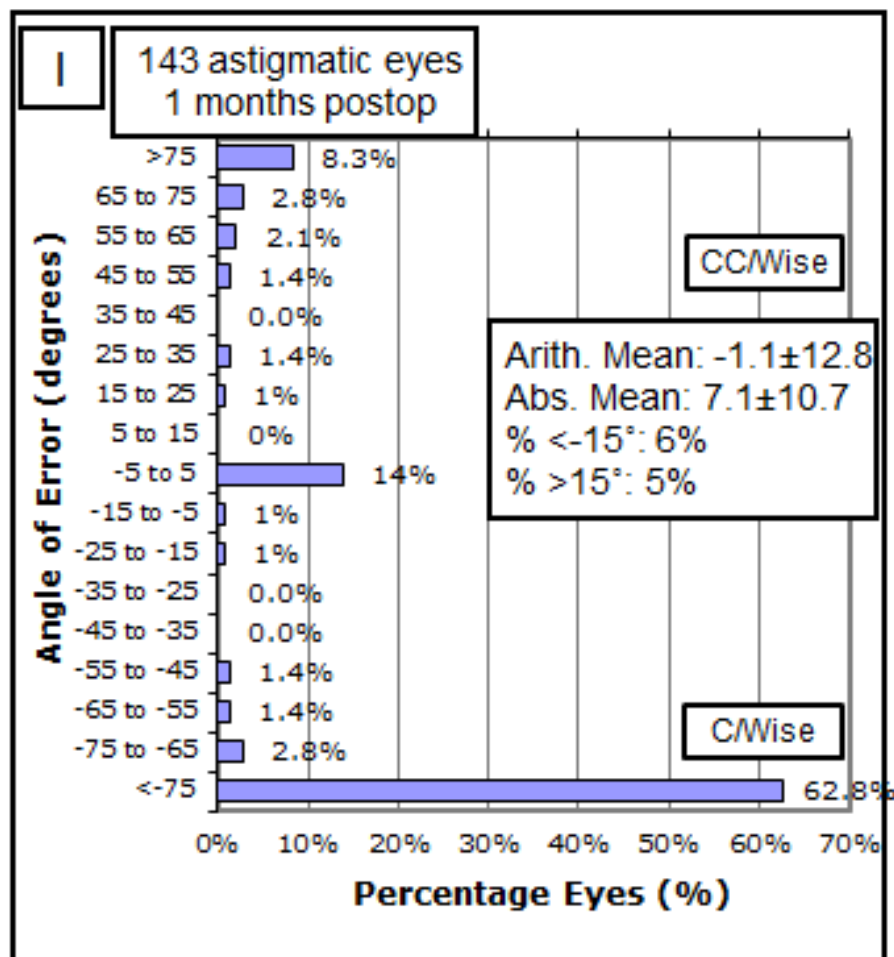Attempted vs Achieved**

Astigmatism correction is good

Refractive Astigmatism

Target Induced Astigmatism vs Surgically Induced Astigmatism

Refractive Astigmatism Angle of Error

In conclusion…

- The learning curve in adopting any new technique is well recognised in all surgical fields

- The challenge is to ensure high quality results with minimal complications and high patient satisfaction

- This study demonstrates that a structured training programme can produce excellent visual results within a safe an ethical environment for patients

- We believe such a programme should be the template for adopting SMILE

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Thank you very much
for your kind attention