Quality Control in Refractive Surgery

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Introduction

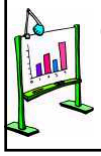
- Personal experience as application specialist for refractive excimer lasers since 1987. (Meditec, Schwind, Nidek)
- PRK & LASIK Nomogram development based on systematic outcomes analysis.
- Excimer Laser Surgery and refractive surgery in general well suited for a systematic approach on quality control.

Why Quality Control?

- Verify current nomogram settings and make adjustments if necessary.
- Reduce enhancement rate.
- Use for marketing and advertisement.
- Discover trends and technical problems in order to react more rapidly.
- Fulfill requirements of ophthalmic societies.
- Increase confidence level about refractive procedures offered in your center.

How to collect your data?

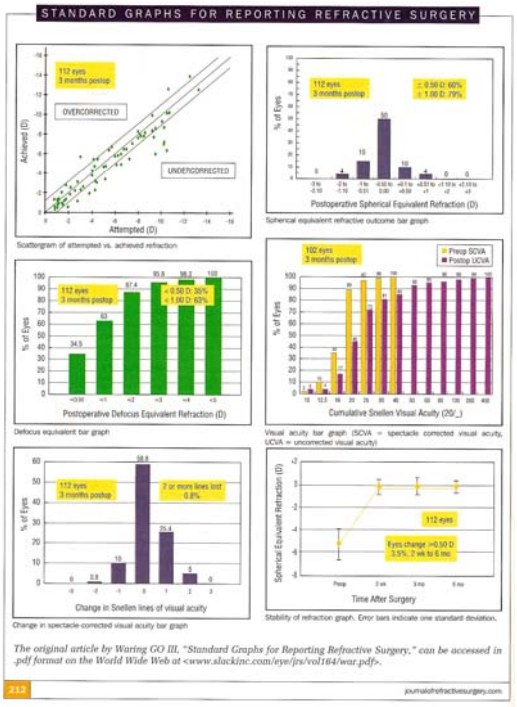
- Patients files 
- Excel Spread Sheet  
- Database Software (Access; Filemaker; etc.) 
- Outcomes Analysis Software (Datagraph; ASSORT; Refr. Consultant; etc.)



How to analyze refractive data?

- Standard Refractive Outcomes (JRS)
  - Stability / Safety / Predictability / Efficacy
- Additional Outcome Parameters
  - Astigmatism Outcomes: **SIRC** - **S**urgically **I**nduced **R**efractive **C**hange (='Vector Analysis'); Double Angle Scatter Plot
  - Defocus Equivalent / Contrast Sensitivity in mesopic conditions / pre OP BSCVA vs. post OP UCVA
- Wavefront Based Outcomes
  - Defocus + Cyl ('aberrometer refraction')
  - Higher Order RMS / Spherical Aberration (Z12) / Coma / Trefoil

Standard Outcomes



www.slackinc.com/eye/jrs/vol164/war.pdf

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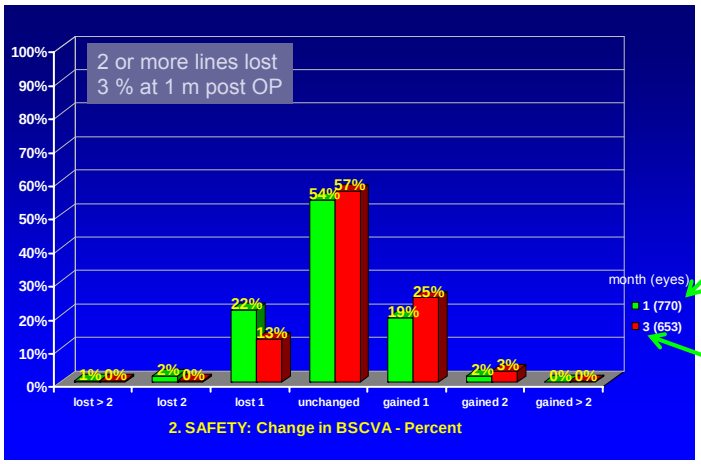
Standard Refractive Outcomes: Safety

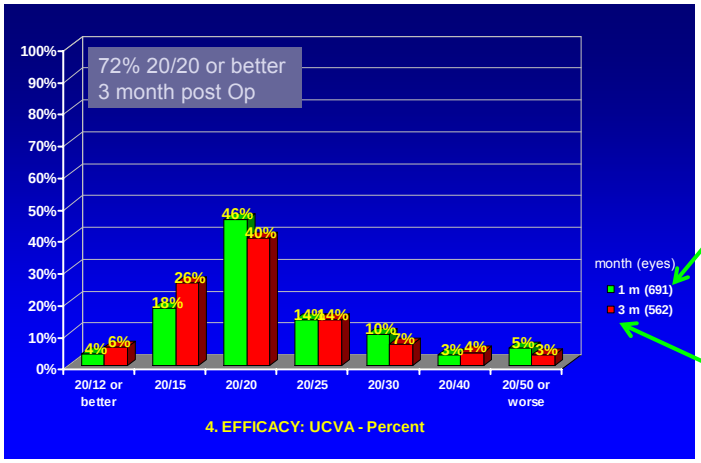


Number of eyes per Follow up visit.

Follow up time interval

DATAGRAPH MED

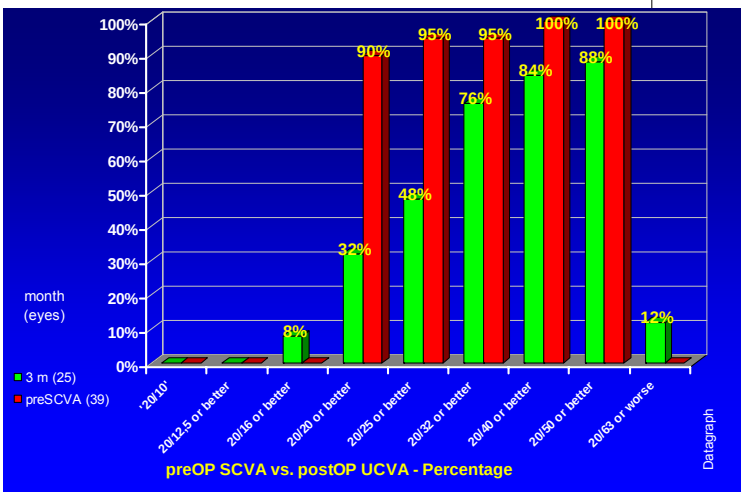
Standard Refractive Outcomes: Efficacy



Number of eyes per Follow up visit.

Follow up time interval

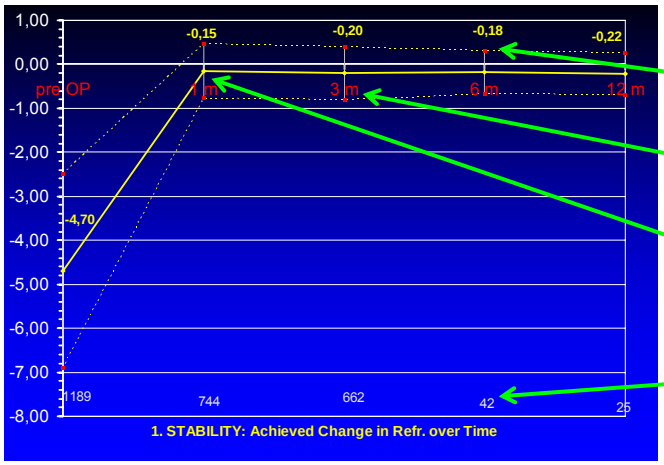
Standard Refractive Outcomes: Cumulative UCVA vs. preOP SCVA



Number of eyes at Follow up visit.

PreOP SCVA

Standard Refractive Outcomes: Stability (SEQ)



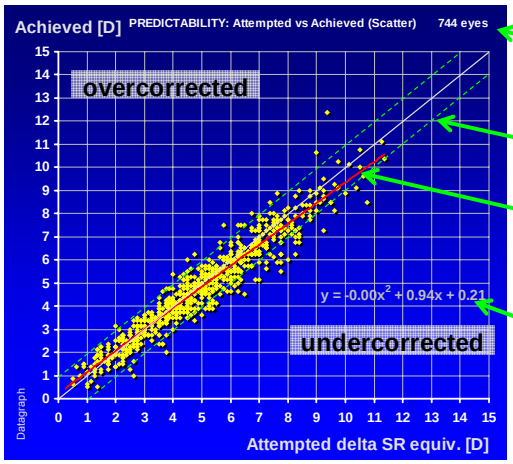
± 1 StDev

Follow up time interval

Mean value of SEQ

Number of eyes per Follow up visit.

Standard Refractive Outcomes: Predictability (SEQ)



Number of eyes at follow up

±1 D 'happiness' Zone

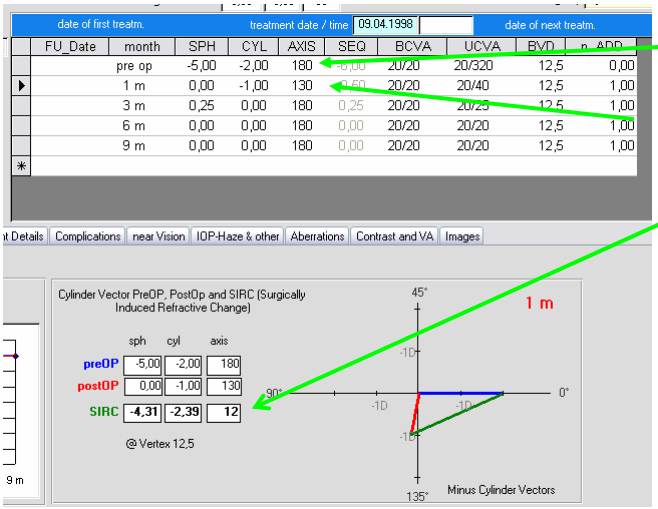
Trend line

$y = -0.00x^2 + 0.94x + 0.21$

Regression Formula: 'Achieved = 0.94*Attempted' (~6% undercorrection)

Astigmatism Outcomes: must be based on Vector Analysis!

SIRC (Surgically Induced Refractive Change)



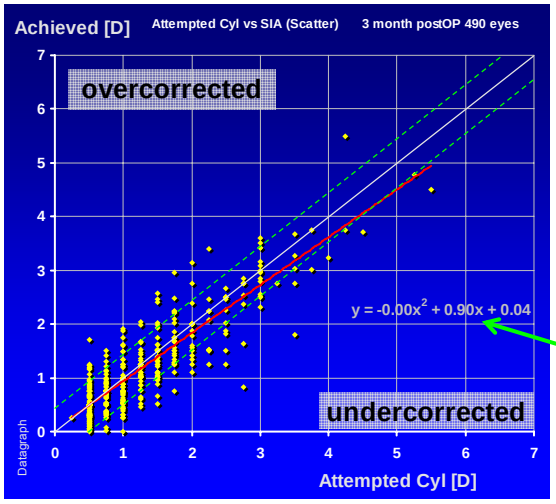
PreOP: -5/-2 x 180°

1 month: Plano/-1 x 130°

SIRC: -4.31/-2.39 x 12°

'The cylinder was actually overcorrectd and the axis has been misaligned by 12°!'

Astigmatism Outcomes: SIA (based on Vector Analysis)



-2/-1@180°

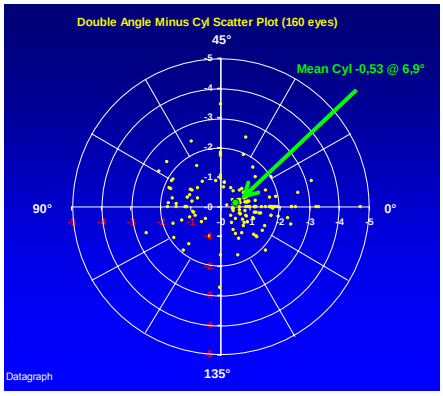
0/-0.5 x 180°
0.5 D Cyl
Undercorrection!

0/-0.5 x 90°
(-0.5/+0.5x180°)
0.5 D Cyl
Overcorrection!

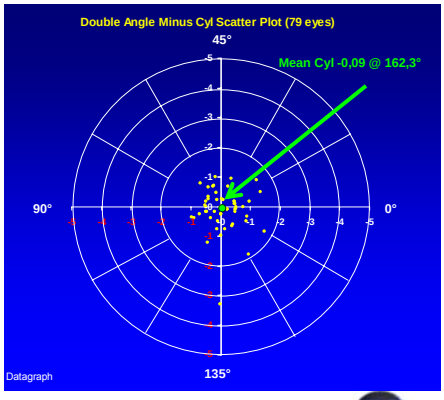
y = 0.90 * x
(~10% undercorrection)

Astigmatism Outcomes: Double Angle Scatter Plot

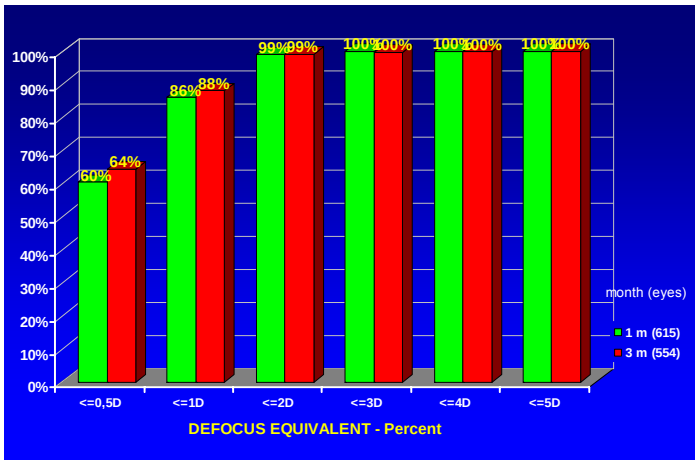
PreOP Cyl & Axis



PostOP Cyl & Axis



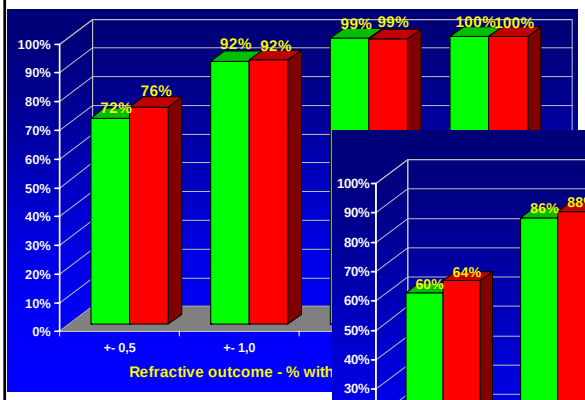
Additional Outcomes: Defocus Equivalent



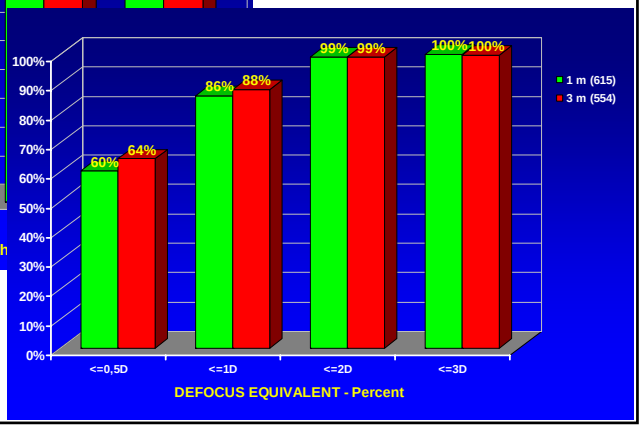
SEQ
=
SPH + ½ CYL

DEQ
=
|SEQ|+|½ CYL|

Defocus Equivalent vs. Refractive Outcome

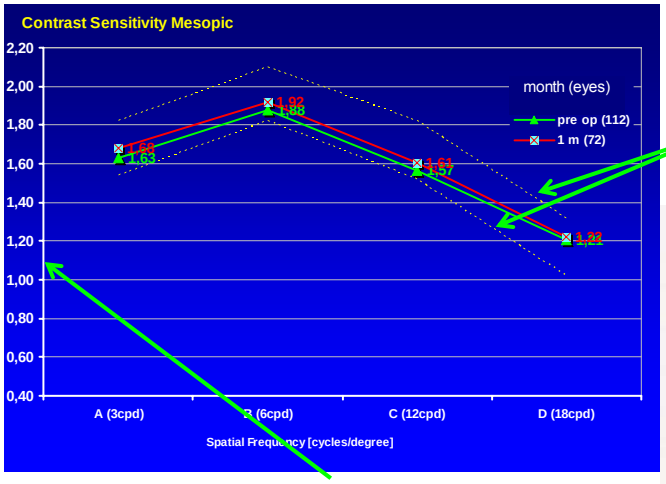


-5.0/+10.0 x 90°
SEQ ➔ Plano
DEQ ➔ +5

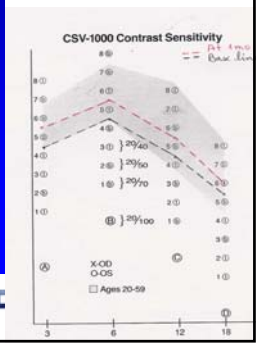


DEQ ~ ‚Blur Circle'

Additional Outcomes: Mesopic Contrast Sensitivity



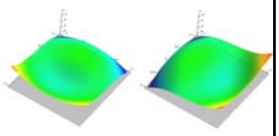
Normal Population Range (Vector Vision CSV 1000)

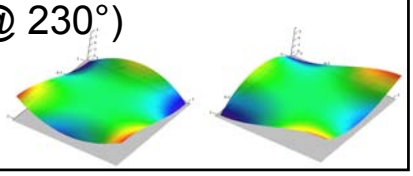


VA in LogMar Scale

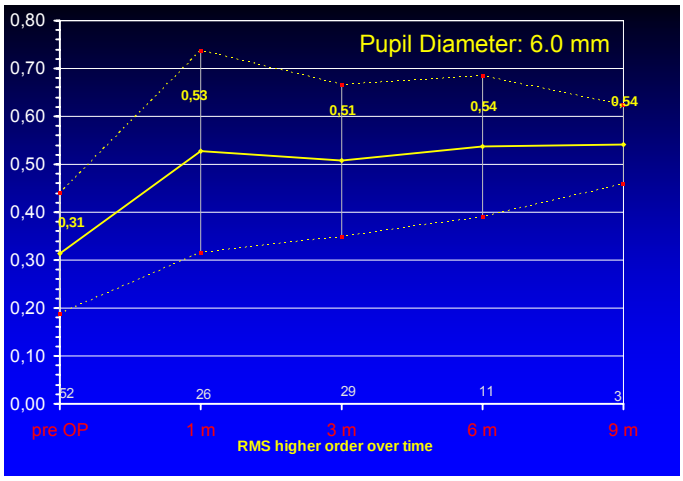
Wavefront based Outcomes

- „Work in progress“ !
- Important parameters: HO RMS, spherical Aberration and Coma
- Report on same (6mm) pupil dian or convert to diopters
- Presenting horizontal and vertical Coma individually? → Vector calculation to present magnitude and axis in [D]! (0.5 D Coma @ 230°)





Wavefront based Outcomes – Higher Order RMS [µm ±StDev]



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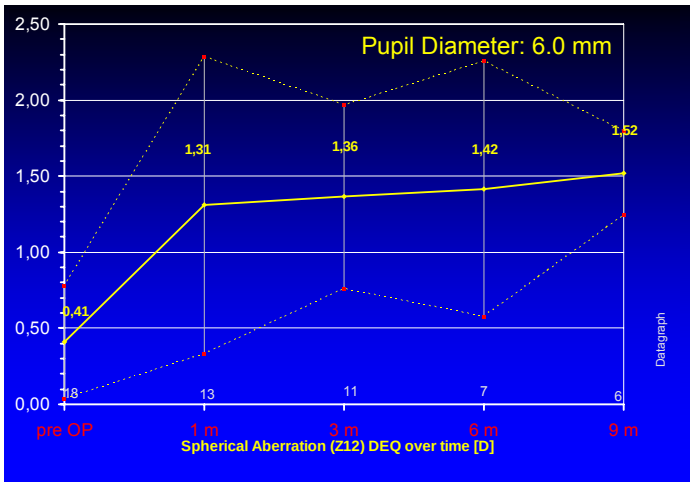
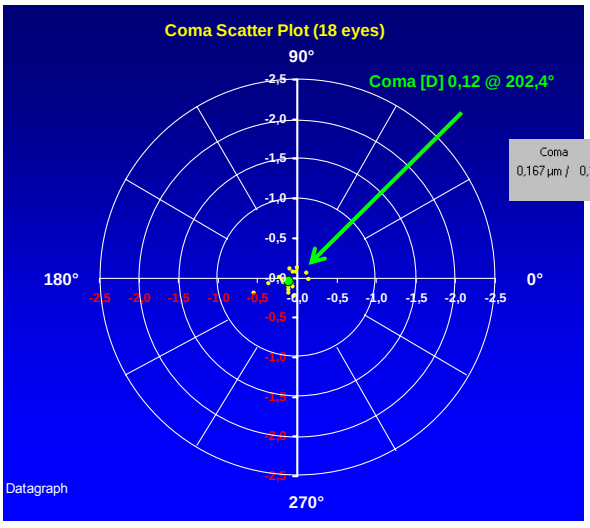
Wavefront based Outcomes – Spherical Aberration [µm] or [D]

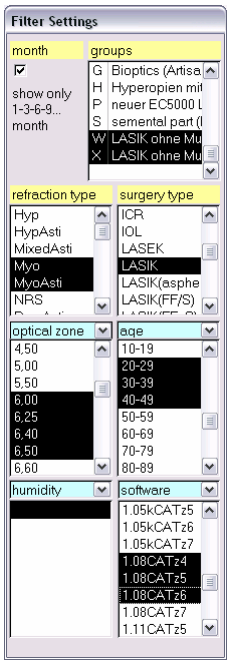


Coma as Vector- Scatter Plot



Making Outcome-based Nomogram Adjustments

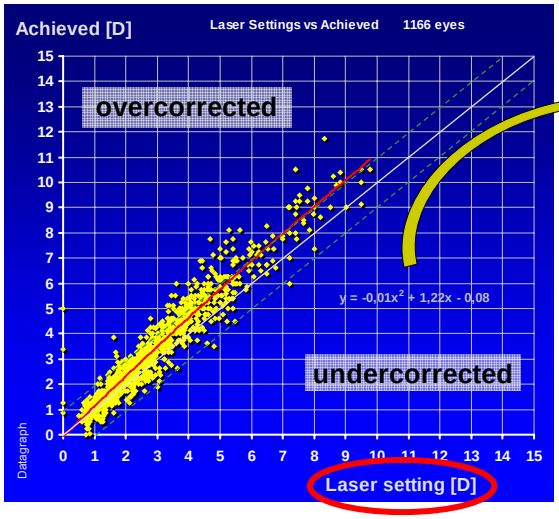
- Comparison of **Laser Settings vs. Achieved** change in refraction (and not Attempted vs. Achieved).
- Reduce random errors as far as possible as nomograms can only compensate *systematic* errors!
- Must be specific for major laser parameters like OZ, TZ, ablation profile type as well as for refraction types.



Nomograms for Individual Patient Groups

- Data must be filtered on certain parameters:
- Refraction Type (Myp/MyoAsti/Hyp/HypAsti…)
- Surgery Type (PRK; LASIK; LASEK; Custom…)
- Optical Zone Diameter
- Others (age, laser software version; humidity…)

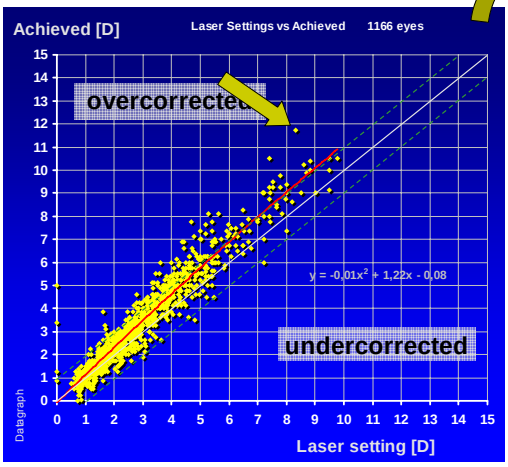
Nomogram Improvements – Laser Settings vs. Achieved



$y = -0{,}01x^2 + 1{,}22x - 0{,}08$

reduce attempted SEQ by 22%!

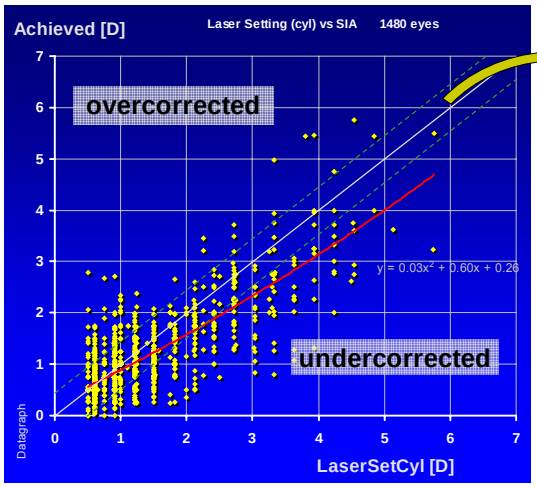
Identify and exclude outliers



refractive data analysis

treatmentID	Name	Attempted	Achieved	Delta
W-0092-R-0		9.375	12.375	3.000
X-0425-R-0		10.750	8.500	2.250
X-0550-L-0		7.750	5.500	2.250
W-0170-L-0		8.250	6.250	2.000
W-0170-R-0		8.000	6.000	2.000
X-0103-R-0		6.500	4.500	2.000
X-0474-R-0		9.250	7.250	2.000
X-0550-R-0		7.750	5.875	1.875
W-0087-R-0		7.000	5.125	1.875
B-0886-R-0		5.750	7.500	1.750
X-0521-L-0		3.750	2.000	1.750
W-0087-L-0		6.875	5.125	1.750
W-0098-R-0		7.625	5.875	1.750
W-0088-R-0		7.250	5.625	1.625
X-0815-R-0		9.000	10.625	1.625
X-0333-L-0		2.625	1.000	1.625
W-0220-L-0		6.250	4.625	1.625

Laser Setting CYL vs. Surgical Induced change in Astigmatism



1. High Scatter! (further analysis necessary!)
2. 40 % systematic undercorrection

Nomograms: General Comments

1. Reduce Scatter by Standardized Surgery and OR Environment
2. Exclude Outliers from Data Analysis
3. Exclude Enhancements (separate nomogram)
4. Choose appropriate follow up interval (≥ 3 m)
5. Create Formula („*-10%*“) / Lookup Table or use Nomogram Software

Summary

- Improving the results of refractive surgery procedures must be based on an individual quality control system.
- Nomograms can compensate for systematic errors, but not for random errors.
- Modern outcomes analysis software allows constant monitoring of your results.
- Conventional Outcomes will be extended by HO-RMS, Spherical Aberration and Coma.

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Thank You!

www.datagraph-med.com

The *Journal* publishes articles from around the world, where standards for measuring visual acuity vary. This table will help readers interpret visual acuity findings in familiar units.

Visual Acuity Conversion Chart*

Distance			LogMAR Acuity Chart				Near				
Snellen Equivalent Feet 20/	Meter 6/	Decimal	Line Number	LogMAR*	Spatial Frequency (cyc/deg)	% Central Visual Efficiency	Jaeger Standard	Inches (14/)	Centimeters (35/)	Revised American Point-Type	"M" Notation
10	3.0	2.00	-3	-0.30	60.00	100	-	7.0	17.5	-	0.20
12.5	3.8	1.60	-2	-0.20	48.00	100	-	8.8	21.9	-	0.25
16	4.8	1.25	-1	-0.10	37.50	100	-	11.2	28.0	-	0.32
20	6.0	1.00	0	0.00	30.00	100	1	14.0	35.0	3	0.40
25	7.5	0.80	1	0.10	24.00	95	2	17.5	43.8	4	0.50
30	9.0	0.67	-	0.18	20.00	91	3	21.0	52.5	5	0.60
32	9.6	0.63	2	0.20	18.75	90	4	22.4	56.0	6	0.64
40	12.0	0.50	3	0.30	15.00	85	5	28.0	70.0	7	0.80
50	15.0	0.40	4	0.40	12.00	75	6	35.0	87.5	8	1.0
60	18.0	0.33	-	0.48	10.00	67	7	42.0	105.0	9	1.2
63	18.9	0.32	5	0.50	9.52	65	8	44.1	110.3	10	1.3
70	21.0	0.29	-	0.54	8.57	63	-	49.0	122.5	-	1.4
80	24.0	0.25	6	0.60	7.50	60	9	56.0	140.0	11	1.6
100	30.0	0.20	7	0.70	6.00	50	10	70.0	175.0	12	2.0
114	34.2	0.18	-	0.76	5.26	44	11	79.8	199.5	13	2.3
125	37.5	0.16	8	0.80	4.80	40	12	87.5	218.8	14	2.5
150	45.0	0.13	-	0.88	4.00	32	-	105.0	262.5	-	3.0
160	48.0	0.13	9	0.90	3.75	30	13	112.0	280.0	21	3.2
200	60.0	0.10	10	1.00	3.00	20	14	140.00	350.0	23	4.0

Courtesy Jack Holladay, MD, modified from full Holladay table. For full table, visit www.JournalofRefractiveSurgery.com
**Log minimum angle of resolution; bold values are standard LogMAR progression*
Note: 20/2000 is equivalent to count fingers @ 2 feet; 20/20000 is equivalent to hand motion @ 2 feet

Resources
1. Sloan LL. New test charts for the measurement of visual acuity. Am J Ophthalmol 1959;48:808-813.
2. Report of Working Group 39, Committee of Vision, National Academy of Sciences. Recommended standard procedures for the clinical measurement and specification of visual acuity. Adv Ophthalmol 1980;41:103-143.
3. Keeney AH, Durerson HL Jr. Collated near-vision test card. Am J Ophthalmol 1958;46:592-594.
4. Keeney AH. Ocular Examination: Basis and Techniques. 2nd ed. St. Louis, MO: CV Mosby Co; 1976.
5. Newell FW. Ophthalmology: Principles and Concepts. 7th ed. St. Louis, MO: CV Mosby Co; 1992.
6. Frisen L. Clinical Tests of Vision. New York, NY: Raven Press; 1990.
7. Holladay JT. Proper method for calculating average visual acuity. J Refract Surg 1997;13:388-391.