Quality Control in Refractive Surgery

Stefan Pieger*, M.Sc.

- Ingenieurbüro Pieger GmbH, Wendelstein, Germany

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 - Surgically Induced Refractive Change** (=‘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
Standard Refractive Outcomes: Safety

2 or more lines lost
3 % at 1 m post OP

Number of eyes per Follow up visit.
Follow up time interval
Standard Refractive Outcomes: Efficacy

- 72% 20/20 or better
- 3 month post Op

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. **STABILITY**: Achieved Change in Refr. over Time

   - Mean value of SEQ
   - Number of eyes per Follow up visit.

   **Follow up time interval**

   **± 1 StDev**

Standard Refractive Outcomes: Predictability (SEQ)

- **Attempted vs Achieved (Scatter)**

  - **Regression Formula**: \( y = -0.00x^2 + 0.94x + 0.21 \)

  - **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)**

<table>
<thead>
<tr>
<th>PreOP: -5/-2 x 180°</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month: Plano/-1 x 130°</td>
</tr>
<tr>
<td>SIRC: -4.31/-2.39 x 12°</td>
</tr>
</tbody>
</table>

‘The cylinder was actually overcorrected and the axis has been misaligned by 12°’!

**SIA (based on Vector Analysis)**

\[ y = -0.00x^2 + 0.90x + 0.04 \]

\[ y = 0.90 \times x \]

\(-0.5/-1@180°\)

\(0/-0.5 x 180°\)

\(0/-0.5 x 90°\)

\(-0.5 + 0.5x 180°\)

\(0.5 D Cyl\)

Undercorrection!

Overcorrection!

\[ y = 0.90 \times x \]

\((-10\%\) 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

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 diameter 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]
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…)

12
Nomogram Improvements – Laser Settings vs. Achieved

\[ y = -0.01x^2 + 1.22x - 0.08 \]

Identify and exclude outliers
Laser Setting CYL vs. Surgical Induced change in Astigmatism

Achieved [D] Laser Setting (cyl) vs SIA 1480 eyes

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.

Thank You!

www.datagraph-med.com