Nomograms

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Main reason for re-treatments in refractive surgery are over- or under-correction in sphere and cylinder.
Published literature

- Even Nomograms are known to be of high clinical relevance in performing refractive procedures, the number of publications investigating the theoretical benefits and pitfalls are rather limited.

The problems of data distribution and noise propagation are not reported!
Purpose

To investigate the relevance of pre-operative data distribution in nomogram calculations, especially in small groups of eyes (typically 100 eyes)

Are we able to get better outcomes in future, if we are analyzing pre- and post-operative outcomes from the past?
Methods

• Generate simulated patient data
  – with different distributions of preoperative sphere and cylinder
  – with known systematic errors for sphere and cylinder

• Establish a fitting algorithm based on sphere and cylinder with Taylor polynomials
  \[
  \text{Sphere} = A_s \cdot \text{SPH} + B_s \cdot \text{SPH}_\text{-} + C_s \cdot \text{CYL} + D_s \cdot \text{CYL}_\text{-} + E_s \cdot \text{CYL} \cdot \text{SPH} + F_s
  \]

• The axis of cylinder is ignored here for simplification

• Least square solver for fitting and statistical analysis is used (SVD)
Simulation of patient data

Data distribution

Number of eyes

Attempted sphere

Achieved sphere

Systematic error

Sphere = \( A_s \cdot \text{SPH} + B_s \cdot \text{SPH}_\ldots + C_s \cdot \text{CYL} + D_s \cdot \text{CYL}_\ldots + E_s \cdot \text{CYL} \cdot \text{SPH} + F_s \)

Gaussian zero mean noise

Noise

Achieved sphere

Attempted sphere

Achieved sphere

Attempted sphere
Fit model reconstruction

Sphere = \( A_s \cdot \text{SPH} + B_s \cdot \text{SPH}_\ldots \)
+ \( C_s \cdot \text{CYL} + D_s \cdot \text{CYL}_\ldots \)
+ \( E_s \cdot \text{CYL} \cdot \text{SPH} + F_s \)

How accurate can we reconstruct the simulated systematic error in the presence of noise?
Establish a fitting model

\[ \text{Sphere} = A_s \times \text{SPH} + B_s \times \text{SPH}_0 + C_s \times \text{CYL} + D_s \times \text{CYL}_0 + E_s \times \text{CYL} \times \text{SPH} + F_s \]

- No noise
- Equal distribution for attempted sphere
Establish a fitting model

Sphere \[= As \cdot \text{SPH} + Bs \cdot \text{SPH}_\text{lin} + Cs \cdot \text{CYL} + Ds \cdot \text{CYL}_\text{lin} + Es \cdot \text{CYL} \cdot \text{SPH} + Fs\]

- No noise
- Equal distribution for attempted sphere

Linear and parabolic components

Systematic errors
Establish a fitting model

Sphere = As*SPH + Bs*SPH + Cs*CYL + Ds*CYL + Es*CYL * SPH + Fs

- No noise
- Equal distribution for attempted sphere

Constant deviation

Fitting errors or systematic error (e.g. flap cut)
Establish a fitting model

Sphere = \( A_s \cdot \text{SPH} + B_s \cdot \text{SPH}_1 + C_s \cdot \text{CYL} + D_s \cdot \text{CYL}_1 + E_s \cdot \text{CYL} \cdot \text{SPH} + F_s \)

- No noise
- Equal distribution for attempted sphere

Possible coupling between sphere and cylinder

Systematic error that introduces scatter
Noise

statistical outcomes / predictability

Source: www.fda.gov
Comparing different fit models

**linear reconstruction**

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**Without noise**

- Achieved sphere [D]
- Attempted sphere [D]

\[ Sph_{ST} = 0.788 \times Sph_{SOLL} - 1.33 \]

- \( R^2 = 0.964 \)
- \( \text{CHI} = 0.19 \)

Sphere = 1.2*SPH + 0.04*SPH_ ... + 0.5*CYL + 0.02*CYL_

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**With noise ±0.3 D**

- Achieved sphere [D]
- Attempted sphere [D]

\[ Sph_{ST} = 0.79 \times Sph_{SOLL} - 1.17 \]

- \( R^2 = 0.963 \)
- \( \text{CHI} = 0.21 \)

Noise does not affect the stability of a linear model fit
Comparing different fit models

linear reconstruction

Noise does not affect the stability of a linear + parabolic model fit
Comparing different fit models
sphere and cylinder reconstruction

\[ \text{Sph}_{\text{IST}} = 1.2 \times \text{Sph}_{\text{SOLL}} + 0.04 \times \text{SPH}_{\text{SOLL}} + 0.5 \times \text{Cyl}_{\text{SOLL}} + 0.02 \times \text{CYL}_{\text{SOLL}} \]

\[ R^2 = 1 \quad \text{CHI}^2 = 10^{19} \]

\[ \text{Sphere} = 1.2 \times \text{SPH} + 0.04 \times \text{SPH}_{\text{SOLL}} + 0.5 \times \text{Cyl} + 0.02 \times \text{CYL}_{\text{SOLL}} \]

Noise affects the stability of higher components in an combined sphere and cylinder model fit.
Summary fit models

- Even with noise, the general systematic errors (linear and parabolic) can be reconstructed.
- Noise only affects higher components in combined sphere and cylinder fit models (like - Cyl$^2$)
- However, so far we used only equally distributed refractions over a typical refractive range from -0.75D to -10D

Are we able to predict the assumed model, if the data used for analysis are not equally distributed?
Simulate patient data
sphere and cylinder distribution

Data are derived from four FDA – studies performed for myopia and myopic astigmatism
Comparing different preoperative distributions

**Sphere**

- Equal distribution
- Cluster distribution
- Typical distribution

**Cylinder**

- Equal distribution
- Cluster distribution
- Typical distribution
Comparing different preoperative distributions

- **Model fit + Noise**

  - **Equal distribution**
    - Gleichverteilit
    - 
  - **Cluster distribution**
    - Gruppenverteilung
    - 
  - **Typical distribution**
    - Typische Verteilung
    - 

  

- **Increase in prediction error**

  - **Equal distribution**
    - Increasing cylinder 0.0 D to 5.0D
    - 
  - **Cluster distribution**
    - Increasing cylinder 0.0 D to 5.0D
    - 
  - **Typical distribution**
    - Increasing cylinder 0.0 D to 5.0D
    - 

- **Comparing different preoperative distributions**

- **Erreichte Sphärenkorrektur [dpt]**

- **Angestrebte Sphärenkorrektur [dpt]**

- **Differenz [dpt]**

- **Typische Verteilung**

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- **Angestrebte Sphärenkorrektur [dpt]**

- **Differenz [dpt]**
Summary of simulations

• Use equally distributed data for nomogram analysis
• Analysis of cross coupling between sphere and cylinder is mainly affected by uncertainties in the measurements
• The use of only linear and parabolic terms provides highest stability for model fitting
Clinical relevance

- 3 groups treated with the Allegretto wave
  - Group A: miss calibrated energy detector
  - Group B: replaced energy detector
  - Group C: applied nomogram based on data from group B
- Clinical data were routinely tracked
- No group or data matching
Representing refractive results
scatter plots

Erreiche Sphärenkorrektur [d]

Achieved sphere [D]

Attempted sphere [D]

\[ \text{Sph}_{\text{IST}} = 0.788 \times \text{Sph}_{\text{SOLL}} - 1.33 \]

\[ R^2 = 0.964 \]

\[ \text{CH}^2 = 0.19 \]

95% predictability

Numerical fit
Representing refractive results

Histogram / box plots

Difference = residuals from numerical fit
Scatter plots

group A

achieved sphere [D]

35 eyes

attempted sphere [D]
Scatter plots

Group C

84 eyes

achieved sphere [D] vs. attempted sphere [D]
Histogram / Percentiles

90% of eyes within ~ ±1D
Simulate patient data
statistical outcomes / predictability

Source: www.fda.gov
Summary clinical relevance

• Nomograms are useful for tracking and monitoring clinical outcomes
• Nomogram improve the predictability of the outcomes even based on small data sets
• However, a certain percentage of eyes is not covered by the benefits of a specific nomogram (about 3% – 15% of the eyes)
Nomograms in quality management

Track data → Analyze data

Continuous improvement of outcomes

Perform treatment ← Plan treatment
Are we able to get better outcomes in future, if we are analyzing pre- and post-operative outcomes from the past?

"The only certain thing about the future is that it will surprise even those who have seen the furthest into it." - E J Hobsbaum, historian
Thank you!