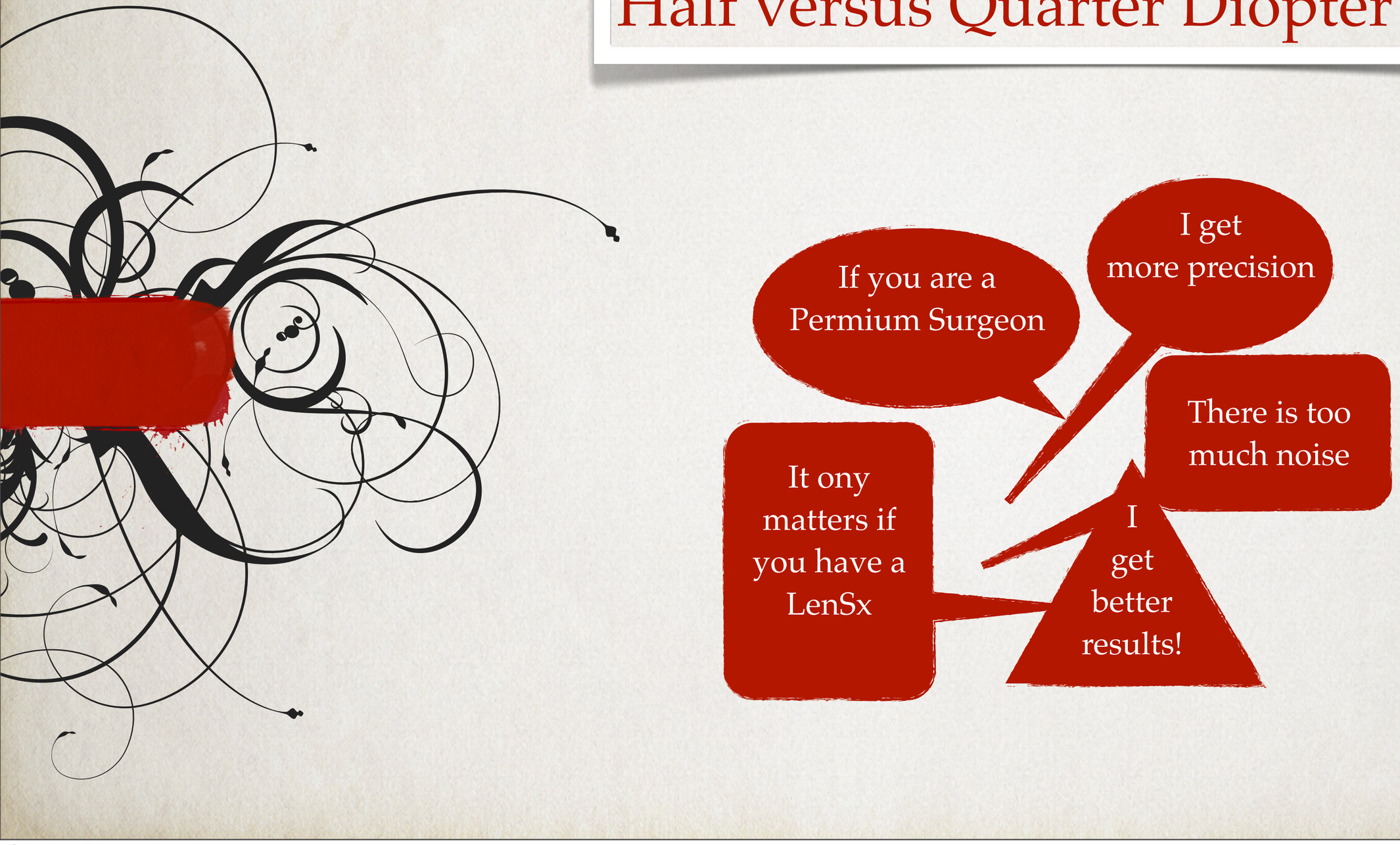
# Half versus Quarter Diopter Steps
# A Mathematical Model

James S. Lewis, MD

# Half versus Quarter Diopter Steps

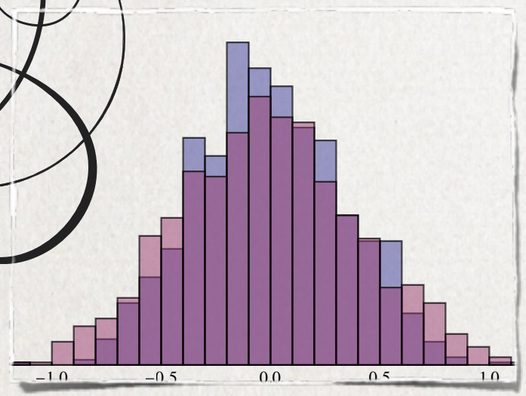


# Half versus Quarter Diopter Steps

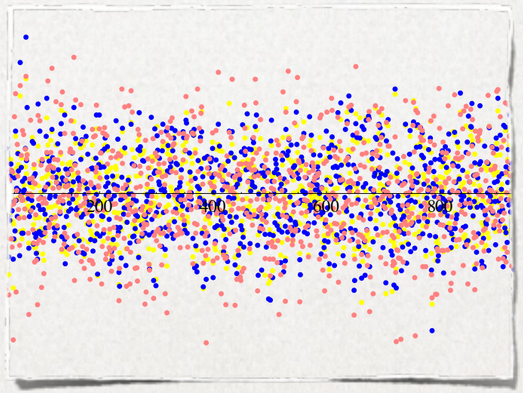
```
n = 100000; (* datapoints*)
iolpowerformulaerror = .3; (*formula error sd*)

de = .25 ; (*denomination error sd*)
me = de/2;  (*manufacturer error  sd*)

de2 = .5 ; (*denomination error sd*)
me2 = de2/2;  (*manufacturer error  sd*)

residualuncorrectedastigmaticerror = .2; (*astigmatism error*)

tol = .625; (*tolerance*)
Manipulate[
 j = SphericalPlot3D[{tol, tol, tol}, {θ, 0, 1.2 Pi}, {ϕ, 0, 1.2 Pi}];
  (*acceptable sphere of values*)

 k = SphericalPlot3D[{1.5, 1.5, 1.5}, {θ, 0, Pi}, {ϕ, 0, Pi}];

 spe = RandomVariate[NormalDistribution[0, iolpowerformulaerror], n];
 axe = Table[RandomReal[{1, 360}], {n}];
 men = Table[RandomReal[{-me, me}], {n}];
 ase =
  RandomVariate[NormalDistribution[0, residualuncorrectedastigmaticerror],
   n];
 den = RandomVariate[NormalDistribution[0, de/2], n];
 men2 = Table[RandomReal[{-me2, me2}], {n}];
 den2 = RandomVariate[NormalDistribution[0, de2/2], n];


 g =(*results without noise*)Table[{spe[[i]], ase[[i]]*Sin[axe[[i]]/2 Pi],
    ase[[i]]*Cos[axe[[i]]/2 Pi}, {i, n}];
 e = spe + den + men;
 f = spe + den2 + men2;
 meanE = Mean[e];
 sdE = StandardDeviation[e];
 meanF = Mean[f];
 sdF = StandardDeviation[f];
 q =(*results with noise*)Table[{e[[i]], ase[[i]]*Sin[axe[[i]]/2 Pi],
    ase[[i]]*Cos[axe[[i]]/2 Pi}, {i, n}];
 r =(*results with noise 2*)Table[{f[[i]], ase[[i]]*Sin[axe[[i]]/2 Pi],
    ase[[i]]*Cos[axe[[i]]/2 Pi}, {i, n}];

 bn = ListPointPlot3D[g, PlotRange -> {{-1.5, 1.5}, {-1.5, 1.5}, {-1.5, 1.5}},
    PlotStyle -> Yellow];
 cn = ListPointPlot3D[q, PlotRange -> {{-1.5, 1.5}, {-1.5, 1.5}, {-1.5, 1.5}},
    PlotStyle -> Blue];
 dn = ListPointPlot3D[r, PlotRange -> {{-1.5, 1.5}, {-1.5, 1.5}, {-1.5, 1.5}},
    PlotStyle -> Pink];

 b = ListPlot[spe, PlotRange -> {-1.5, 1.5}, PlotStyle -> Yellow];
 c = ListPlot[e, PlotRange -> {-1.5, 1.5}, PlotStyle -> Blue];
 d = ListPlot[f, PlotRange -> {-1.5, 1.5}, PlotStyle -> Pink];
 {Histogram[{e, f}, 20],
  SmoothHistogram[{e, f}],
  Show[{b, c, d}],
  Show[{k, bn, cn, dn, j}]
  },


 {iolpowerformulaerror, .1, .6},
 {residualuncorrectedastigmaticerror, .3, .5},
 SaveDefinitions -> True]
```

# Half versus Quarter Diopter Steps

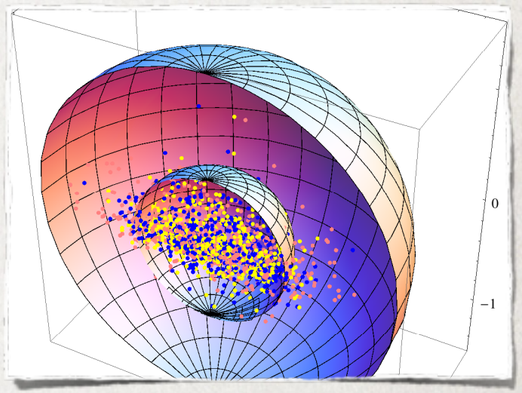
http://www.jameslewismd.com/acos




Compare Steps




Scatterplot




Astigmatism

# Lifecycle of an IOL

Power Determination

**19.24**

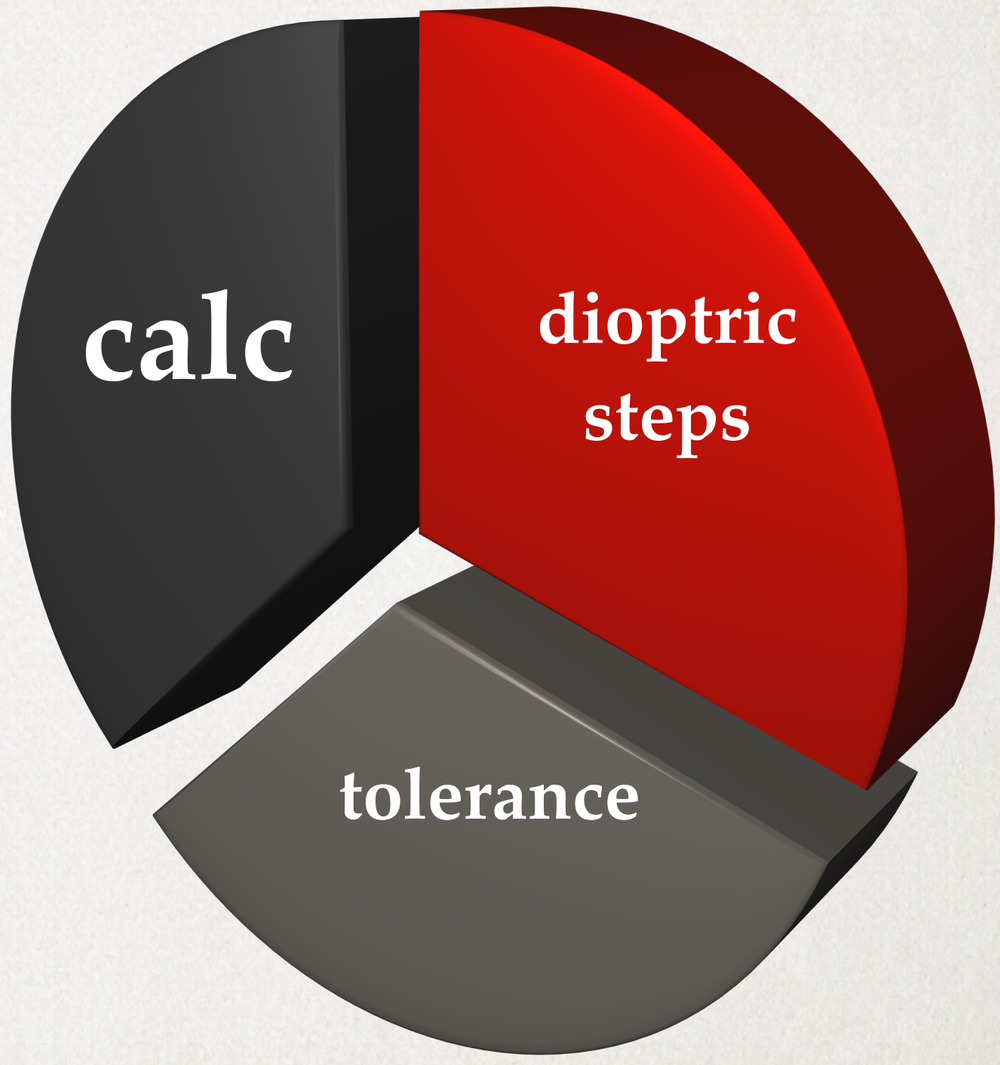
FDA Tolerance

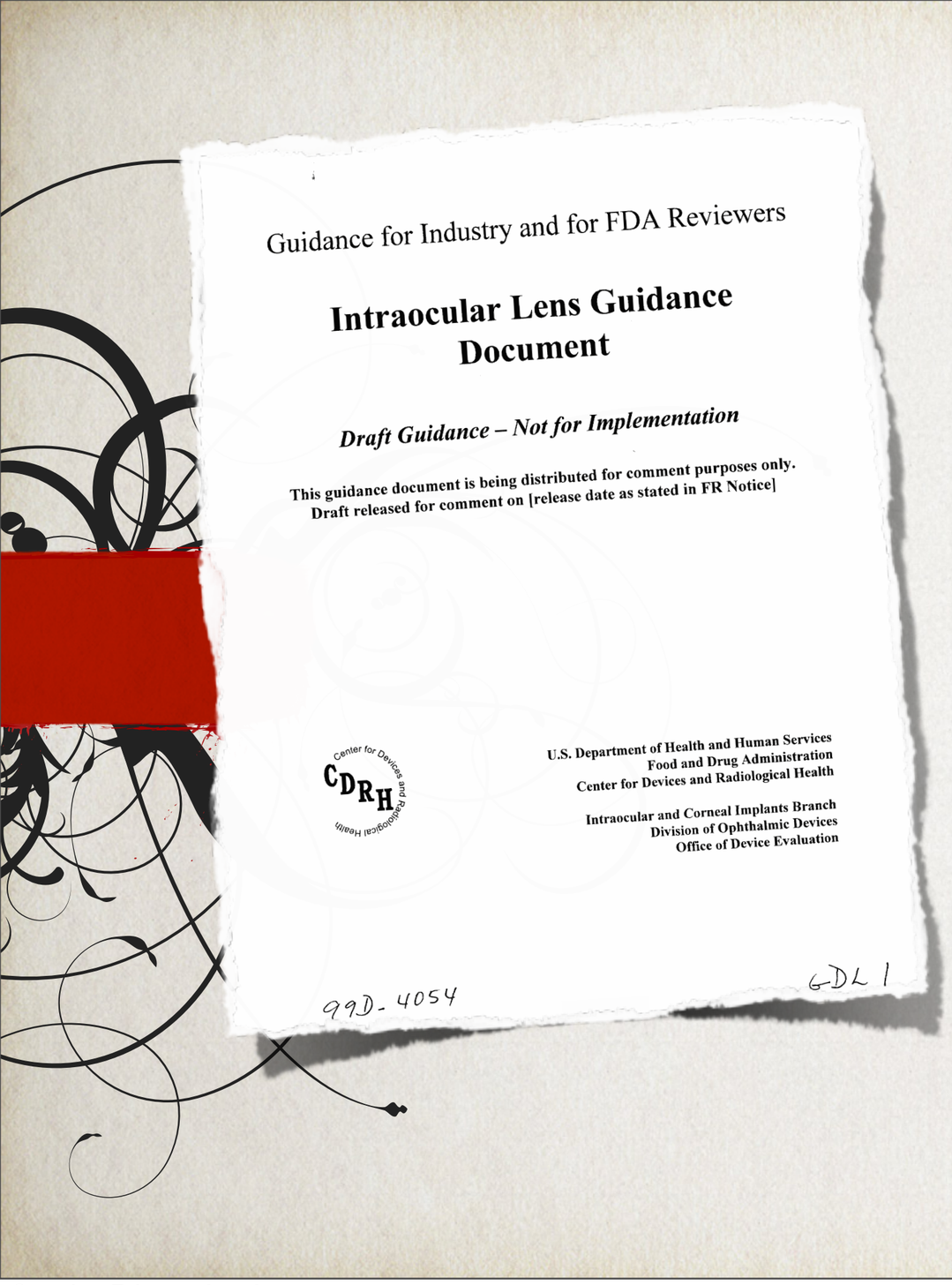
Need an 18.65 but I rounded up and there were only .5 D steps

**19.00**

**IOL is 0.59 higher than desired**

# Dissecting the Problem





Guidance for Industry and for FDA Reviewers

**Intraocular Lens Guidance Document**

***Draft Guidance – Not for Implementation***

**This guidance document is being distributed for comment purposes only.**
**Draft released for comment on [release date as stated in FR Notice]**

Center for Devices and Radiological Health
CDRH

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**

**Intraocular and Corneal Implants Branch**
**Division of Ophthalmic Devices**
**Office of Device Evaluation**

99D-4054

GDL 1

# Manufacturing Tolerances

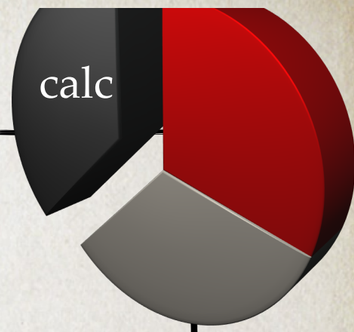

**Table 1 - Tolerances on dioptric power**

| Nominal dioptric power range (D) | Tolerance on dioptric power (D) |
|---|---|
| 0 to ≤ 15 | ± 0.3 |
| > 15 to ≤ 25 | ± 0.4 |
| > 25 to ≤ 30 | ± 0.5 |
| > 30 | ± 1.0 |

The Softec PS has a tolerance of 0.125 D.
Tetraflex has a tolerance of 0.10 D

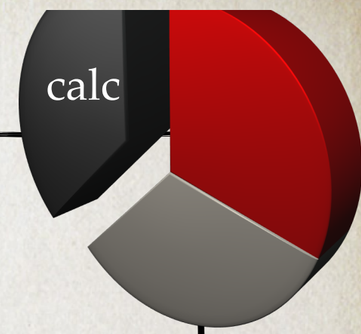

# Dioptric Steps


- **Bausch + Lomb**
  - Crystalens
- **Lenstec**
  - Softec HD
  - Tetraflex




*f*

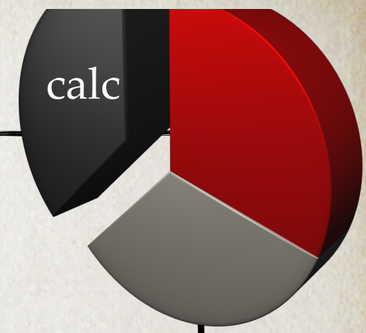
is the map from patient data to the IOL power resulting in the intended **TARGET** post-operative spherical refraction




# *f* idealized IOL power formula

*g*

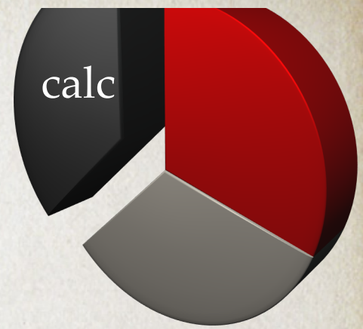
is the map from patient data to the IOL power designed to achieve the intended **TARGET** post-operative spherical refraction




$f$ idealized IOL power formula

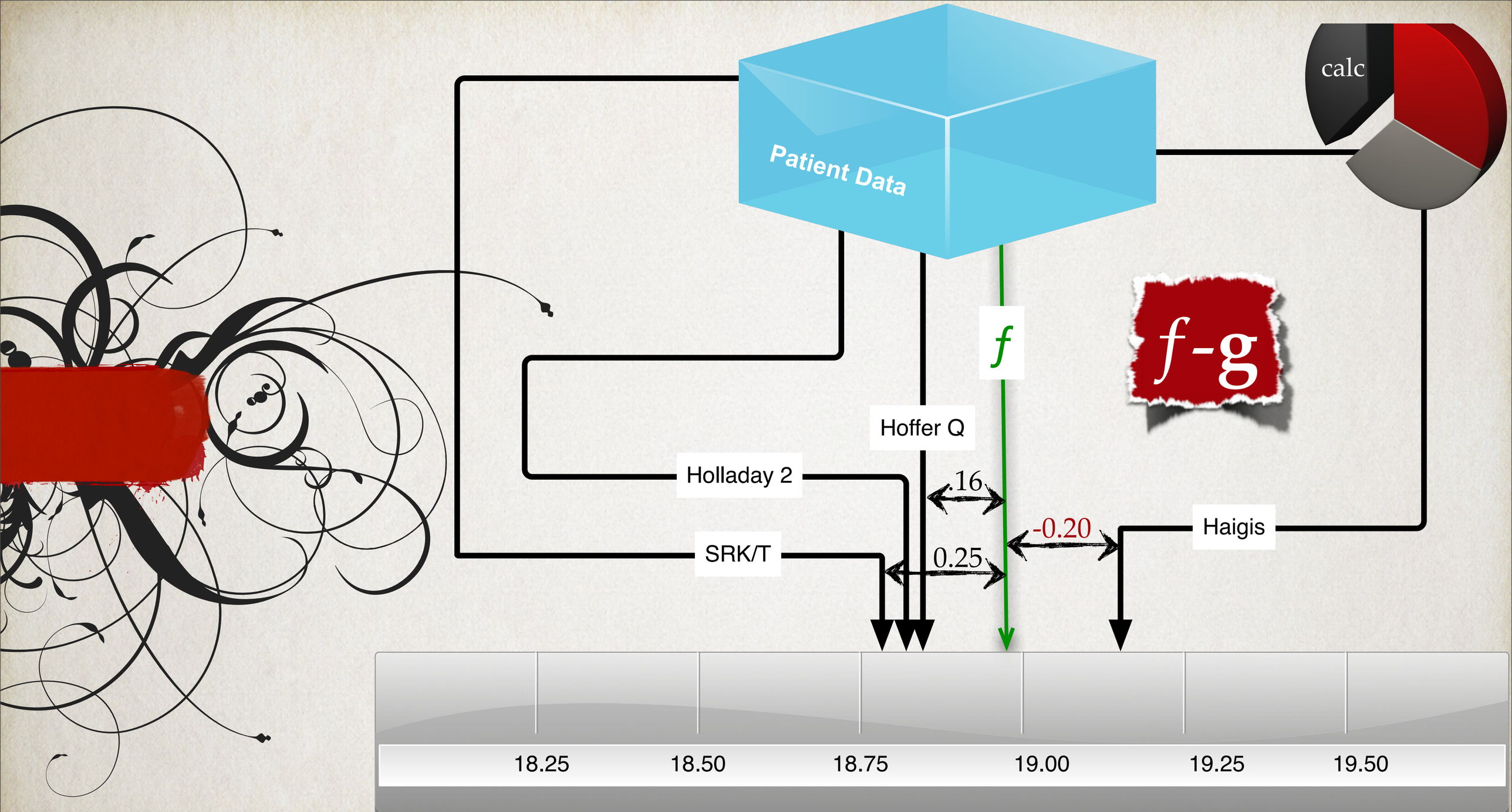
$g$ actual IOL power formula

$f$-$g$ the “error” in our IOL calculations

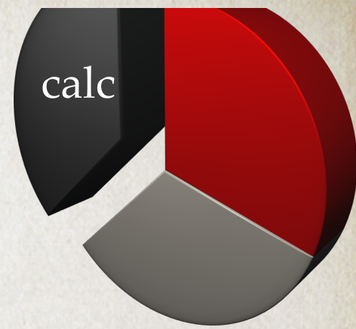


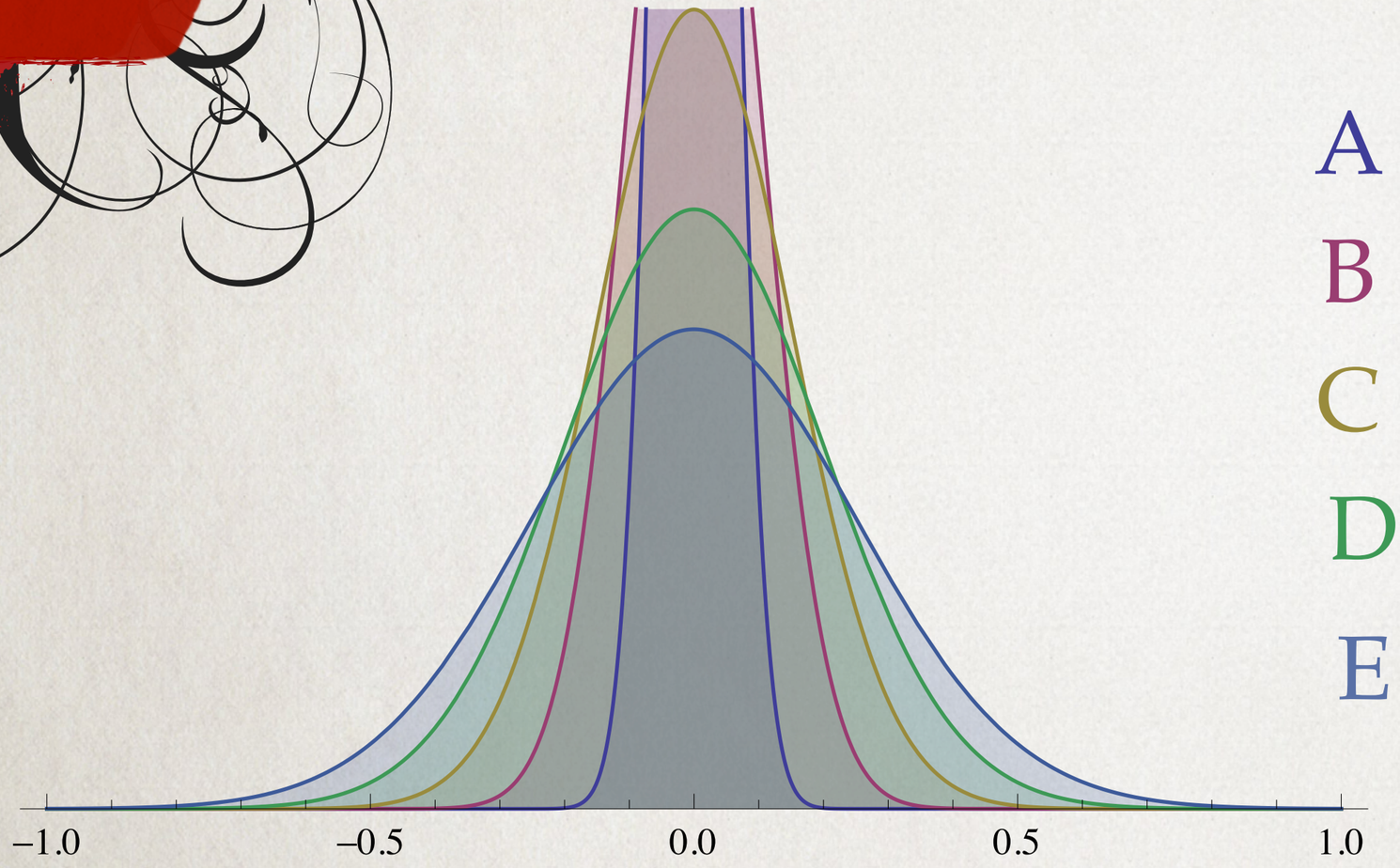

# IOL Power Calculations

| | *g* | | | | *f* |
|---|---|---|---|---|---|
| TARGET | Hoffer Q | Holladay 2 | Haigis | SRK/T | |
| +0.50 | 18.32 | 18.28 | 18.68 | 18.23 | 18.46 |
| 0.00 | **18.82** | **18.78** | **19.18** | **18.73** | **19.06** |
| -0.50 | 19.32 | 19.28 | 19.68 | 19.23 | 19.56 |


Patient Data
calc
f
f-g
Hoffer Q
Holladay 2
SRK/T
16
0.25
-0.20
Haigis
18.25
18.50
18.75
19.00
19.25
19.50

# Post-Op Refractive Distribution



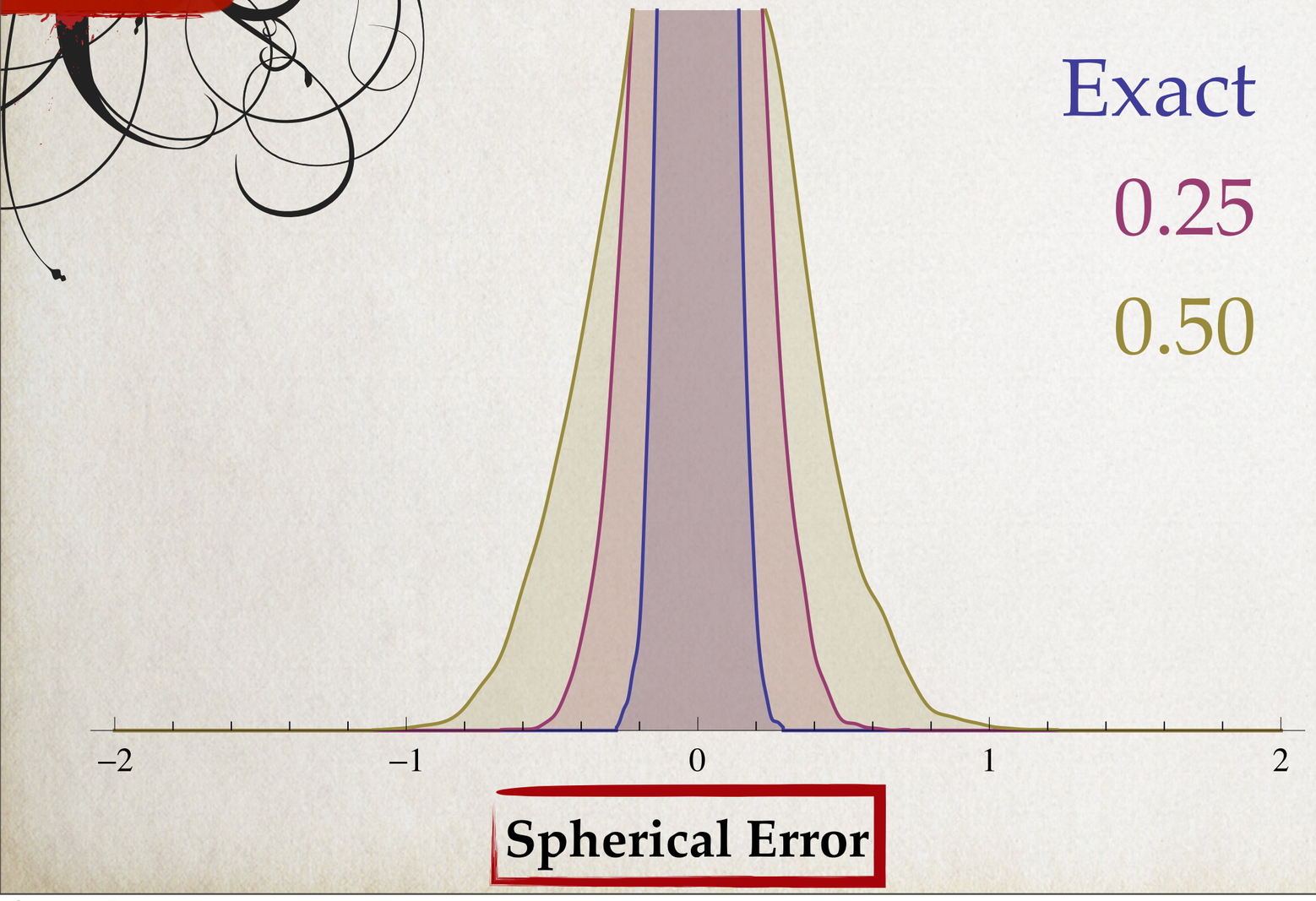

**Spherical Error**

| | | |
|---|---|---|
| A | 95% ± .10 | 99% ± .15 |
| B | 95% ± .20 | 99% ± .30 |
| C | 95% ± .30 | 99% ± .45 |
| D | 95% ± .40 | 99% ± .60 |
| E | 95% ± .50 | 99% ± .75 |

*assuming your exact IOL is available
zero tolerance, infinite steps

95% ± .10  99% ± .15

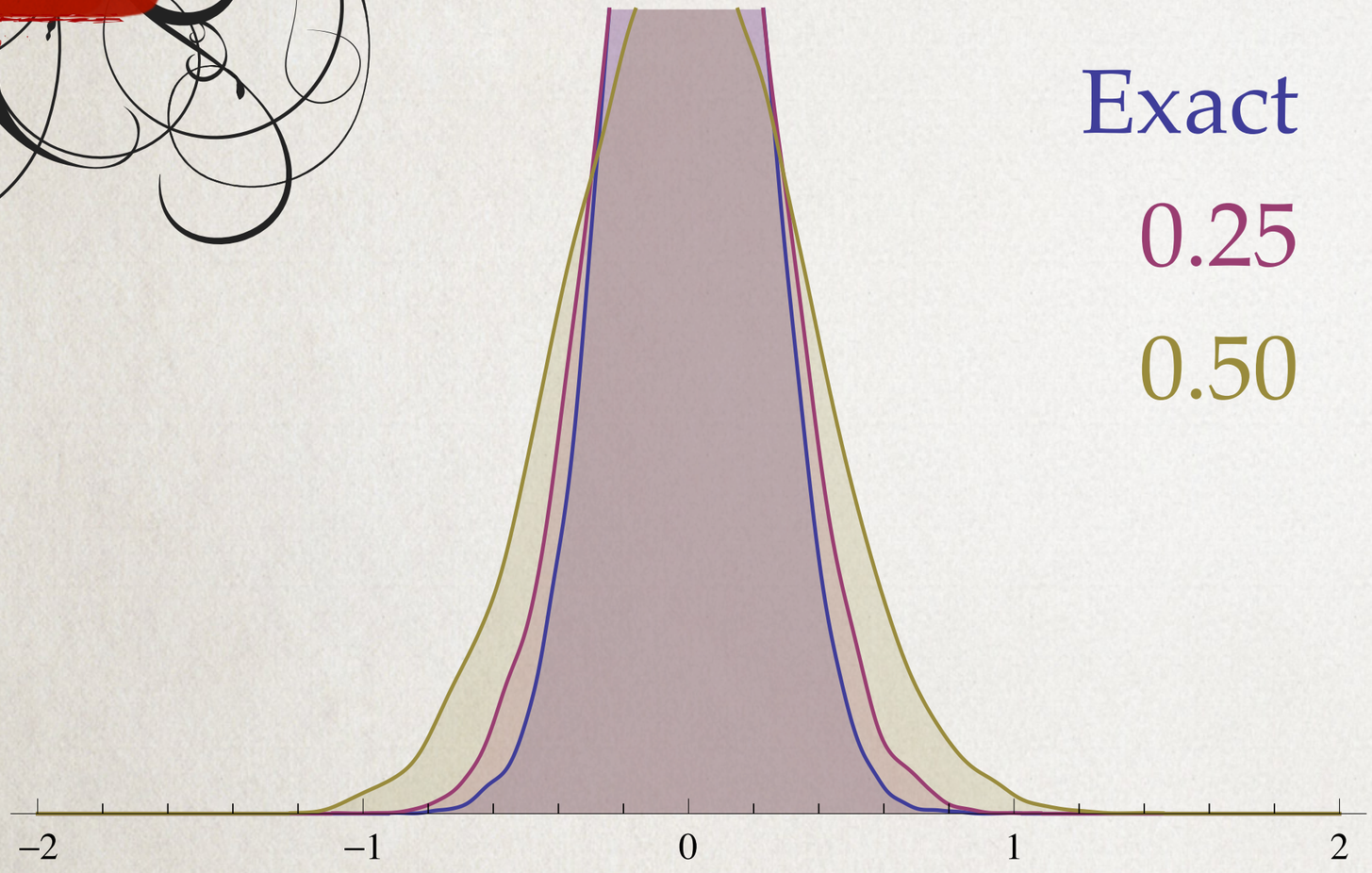
# A: Do They Need Quarter Diopter Steps?




| | |
|---|---|
| Exact | *Exact IOL Power Available* |
| 0.25 | *Quarter Diopter Steps* |
| 0.50 | *Half Diopter Steps* |

95% ± .30  99% ± .45

# C: Do They Need Quarter Diopter Steps?



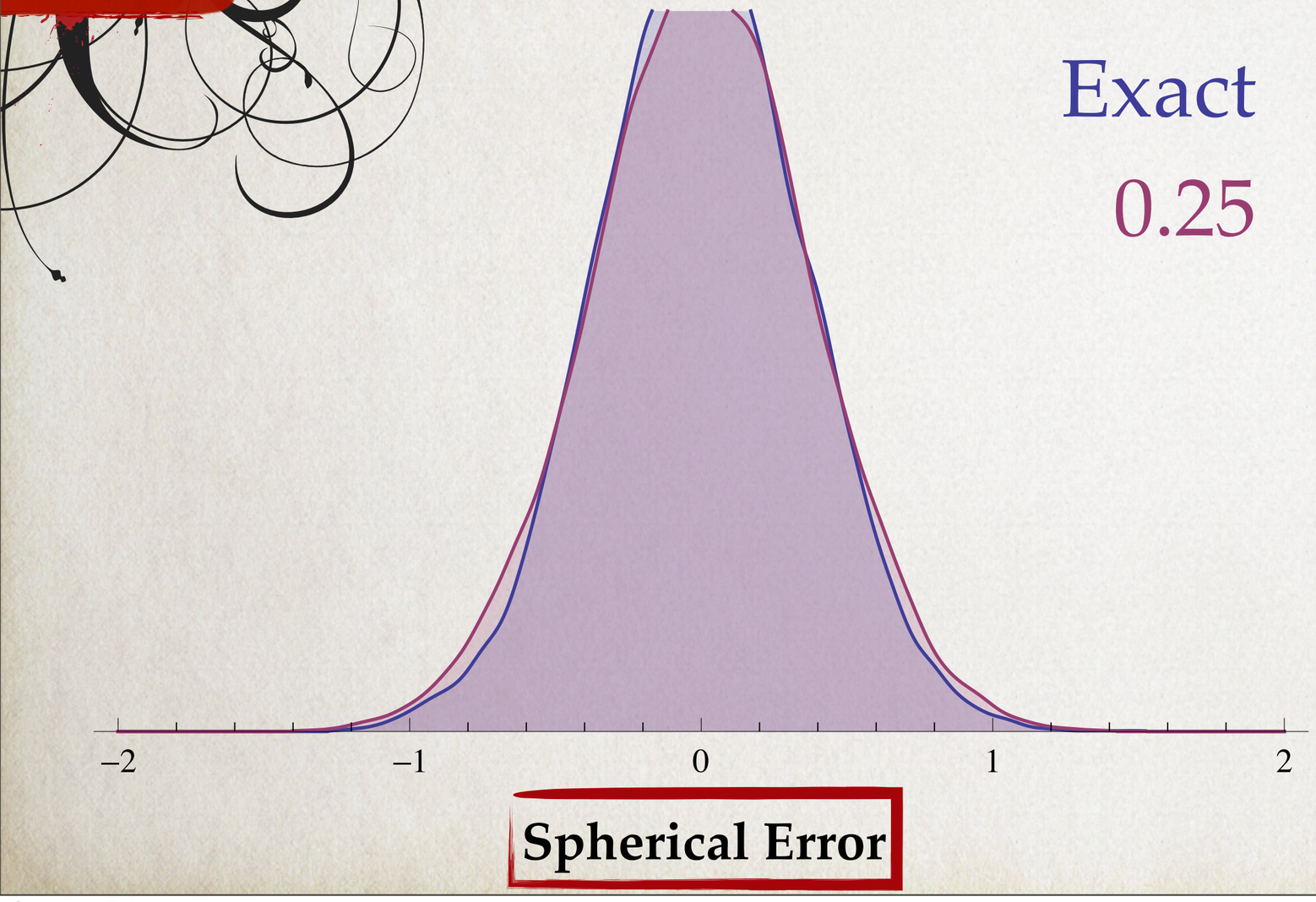

Exact *Exact IOL Power Available*

0.25 *Quarter Diopter Steps*

0.50 *Half Diopter Steps*

95% ± .50  99% ± .75

# E: Do They Need Quarter Diopter Steps?

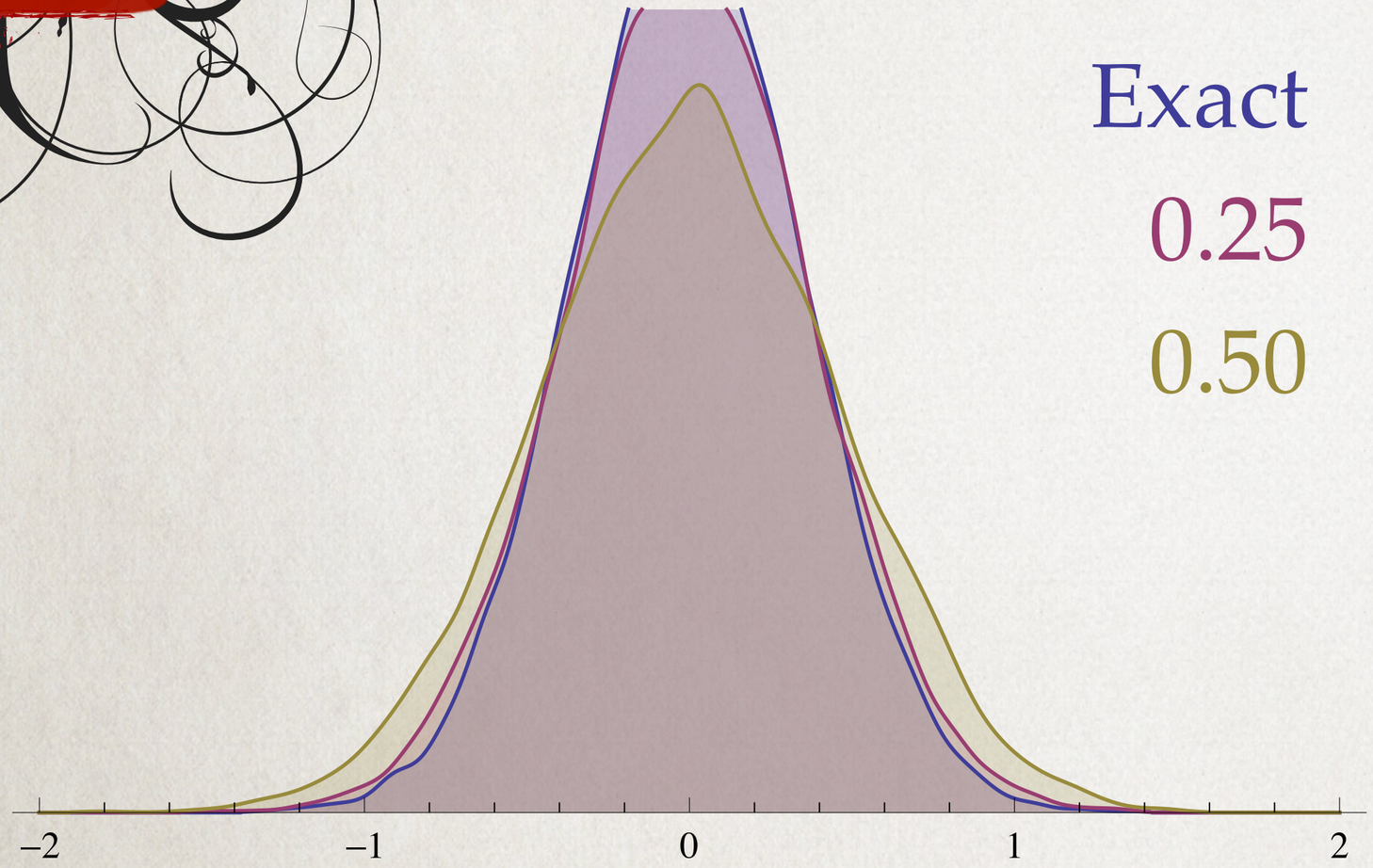



Exact *Exact IOL Power Available*

0.25 *Quarter Diopter Steps*

95% ± .50  99% ± .75

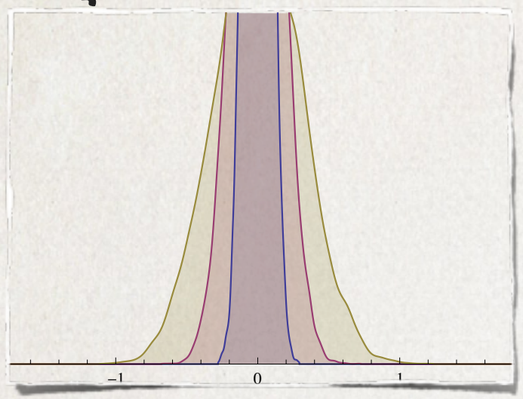
# E: Do They Need Quarter Diopter Steps?



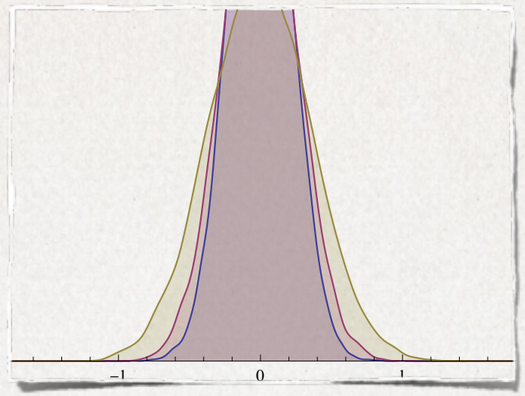

Exact *Exact IOL Power Available*

0.25 *Quarter Diopter Steps*

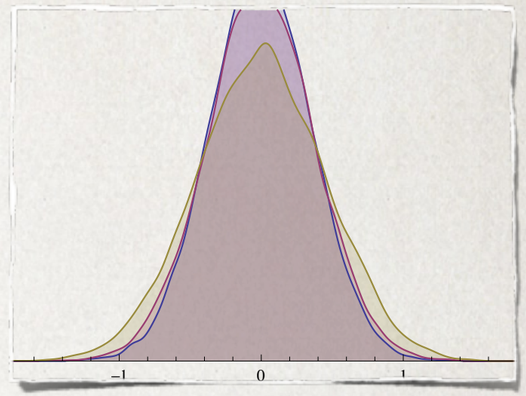
0.50 *Half Diopter Steps*




Surgeon A




Surgeon C



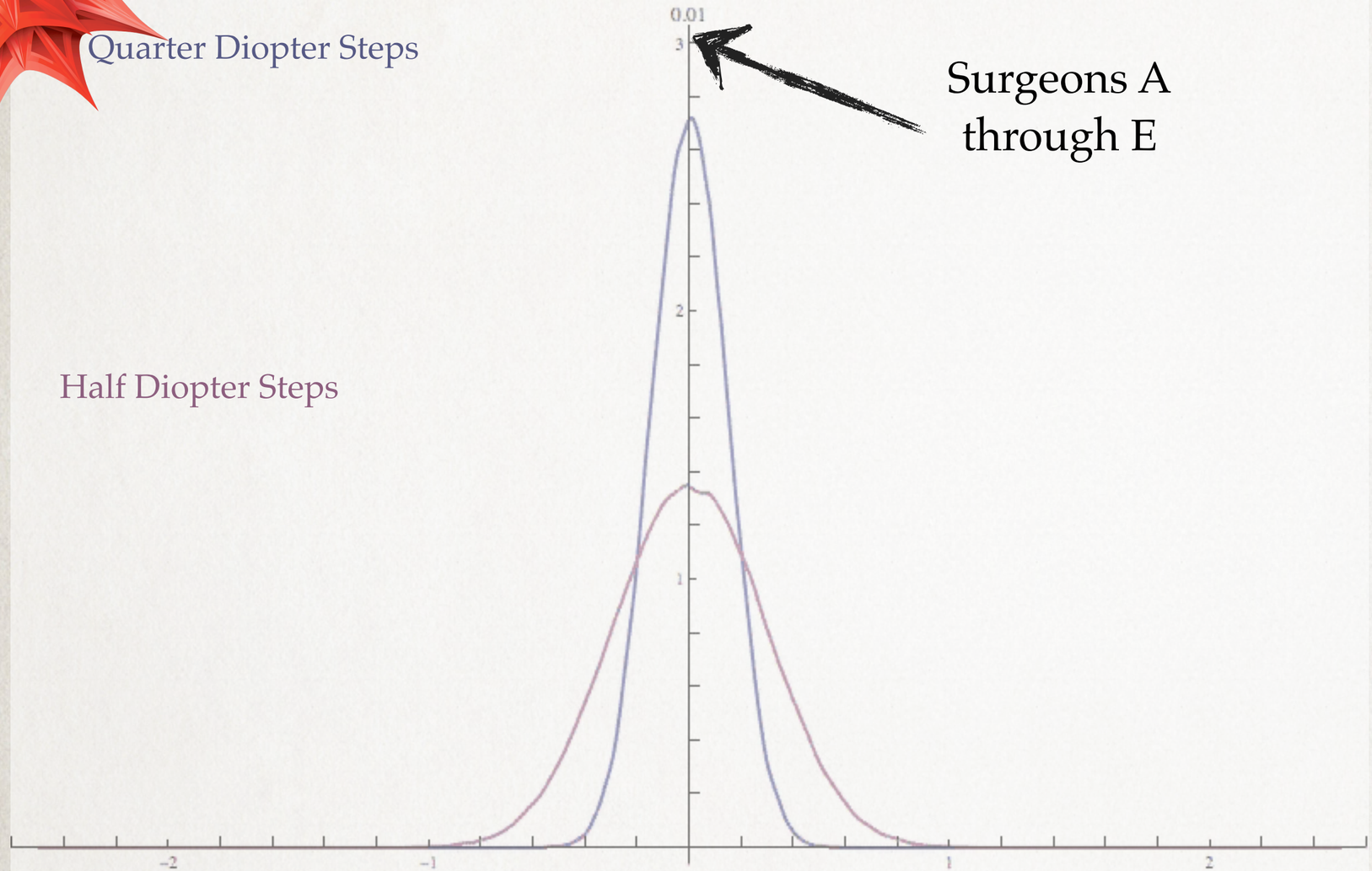

Surgeon E

- Surgeon A:  Clinical results are degraded by both Quarter and Half Diopter Steps
- Surgeon C:  Clinical results are acceptable with Quarter Diopter Step but degraded by Half Steps
- Surgeon E:  Clinical results are **not degraded** by Quarter or Half Diopter Steps

100,000 iterations for each of 1000 increments

Quarter Diopter Steps

Half Diopter Steps




Surgeons A through E

**Spherical Error**

# Quarter Diopter Steps Alternatives

- Exact Labeling
  - **TECHNOMED EASYCARE 600**
    (Technomed, Baesweiler, Germany)
    - Expense, Delay, Rigidity
    - Neuhann, Hoffer, many others
- Inventory Optimized Lens Selection
  - FDA and labeling issues
  - Web-based exact power lookup

# Inventory Optimized

Collect all lenses labeled
18.5 and 19.0 and determine
exact power from web

Need an 18.65
for a lens with
only 0.5 D steps

18.63

NEW

Select
Best
Match

IOL is 0.02
lower than
desired

18.63

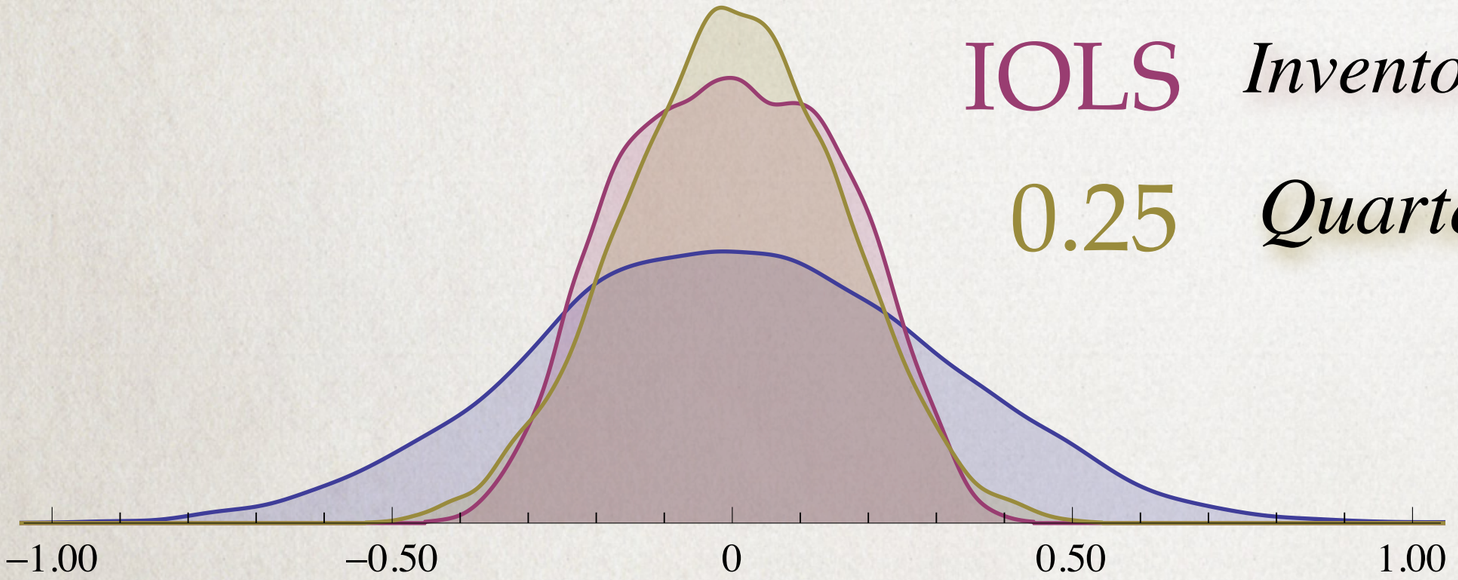
0.50

# A: "Upgrade my Half Diopter Steps"

0.50 *Half Diopter Steps*

IOLS *Inventory Optimized Lens Selection*

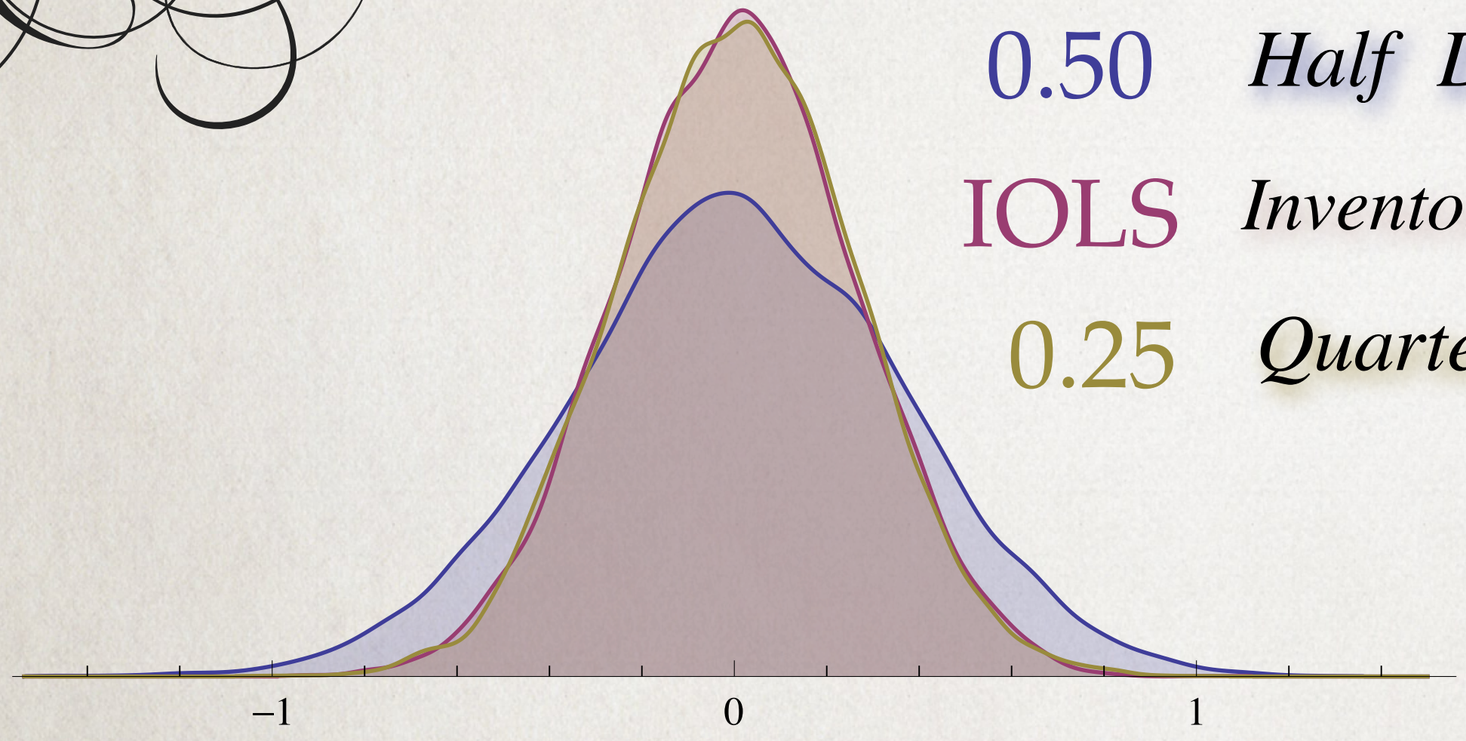
0.25 *Quarter Diopter Steps*




**Spherical Error**

0.50

# C: "Upgrade my Half Diopter Steps"




0.50 *Half Diopter Steps*

IOLS *Inventory Optimized Lens Selection*

0.25 *Quarter Diopter Steps*

# Conclusion

- **Quarter diopter steps** yield <u>improved clinical results</u> over Half Diopter steps when 99% of your patients are within 0.50 diopters of target.
- Conversely, Quarter Diopter Steps <u>have no value if 95%</u> of your patients aren't within 0.50 diopters of target.
- **Inventory Optimized Lens Selection** is as good an upgrade as quarter diopter steps