Early Experience with a Presbyopic Corneal Inlay

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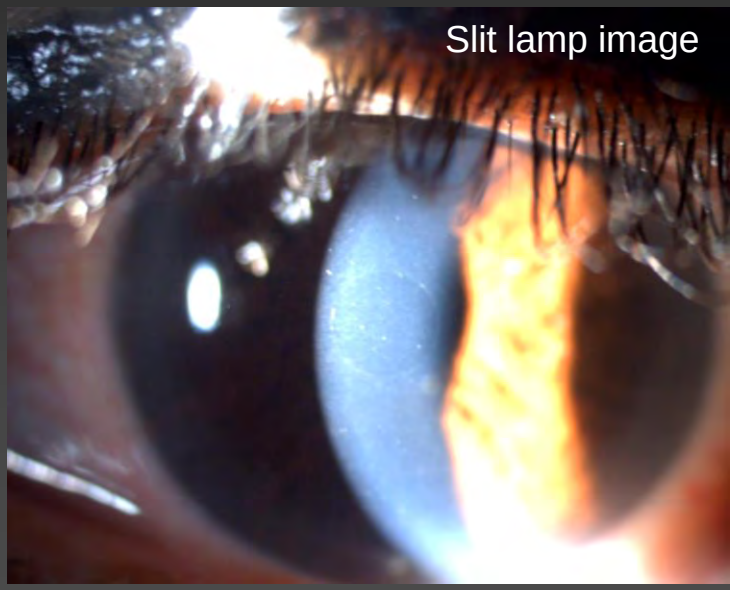
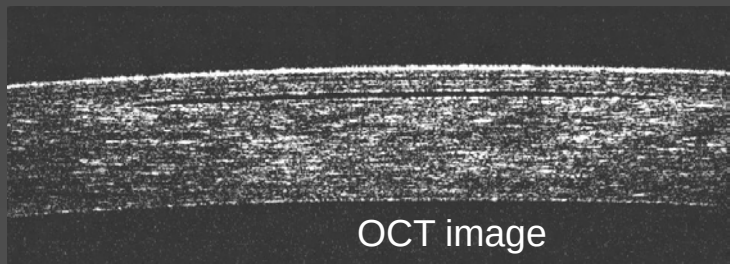
Finanancial Disclosure:

- **ReVision Optics**
- **Foresight**
- **QLT**
- **Nu-Lens**

PRESBYLENS® Corneal Inlay

- Additive procedure alters the anterior corneal curvature
- Micro-porous, optically clear hydrogel
  - Same index of refraction as cornea
  - Allows transmission of oxygen, water, and nutrients
  - Biocompatible
- Intended for use in patients…
  - Age: 45 +
  - Emmetropic presbyopes: 20/25 or better UCDVA
  - Near add requirement: 1.5 D - 2.5 D
- Easy surgical implantation and removal
  - Implanted under a corneal flap or in a pocket

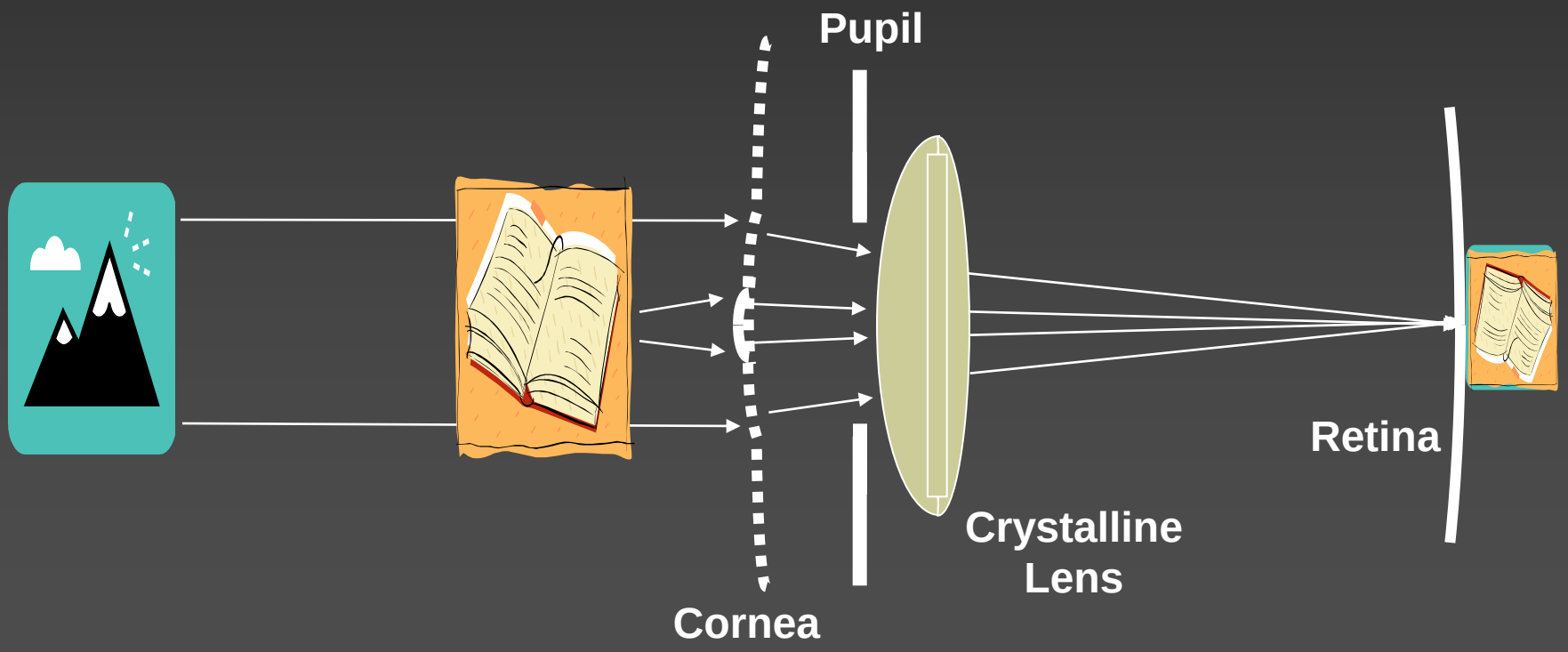




PRESYBLENS® Optical Design

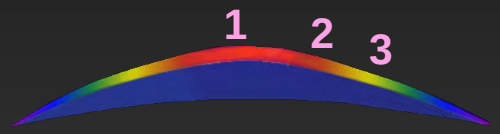
- Inlay steepens central cornea
- Dilated pupil allows for distance image focus
- Pupil constriction creates pseudo-accomodation during…
  - Accomodative response
  - Light constriction

Model Eye

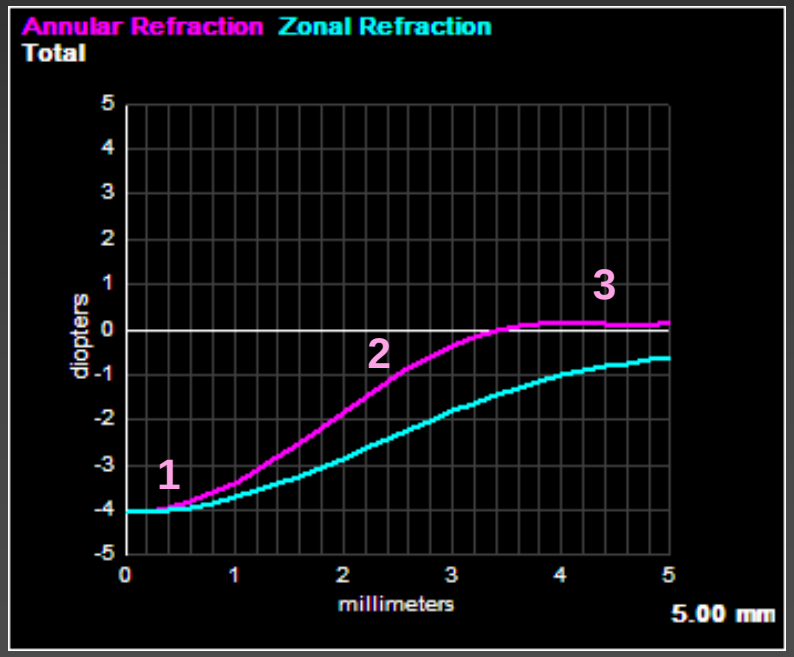


Optical Diagnostics

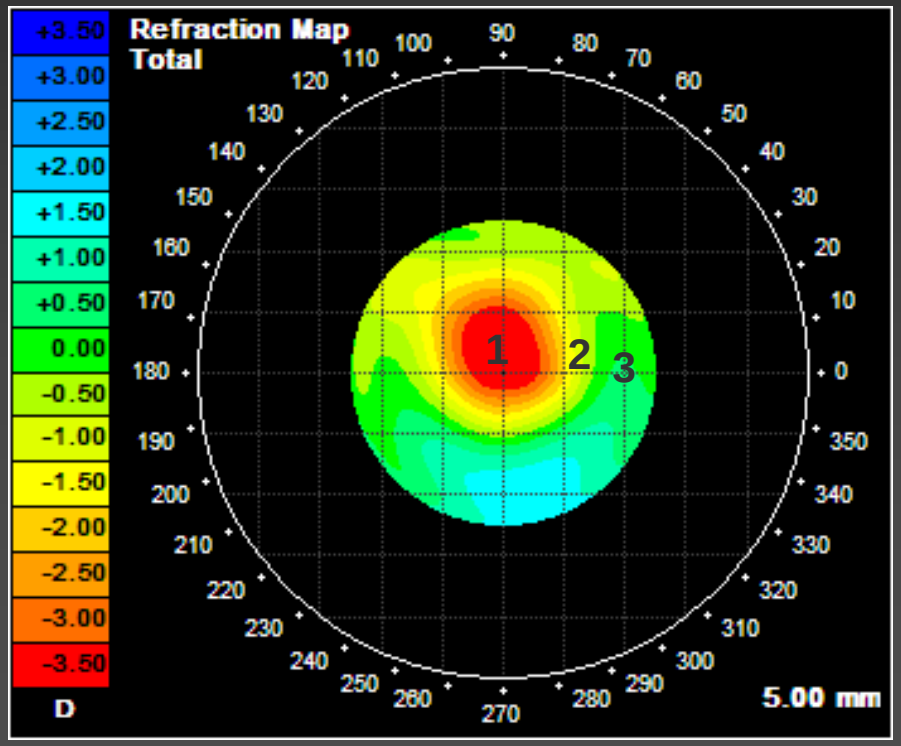
1 Near
2 Intermediate
3 Distance



Corneal Cross-section



Average diametric refraction (Tracey)



Refraction map (from Tracey wavefront data)

ReVision Optics
Design Optimization

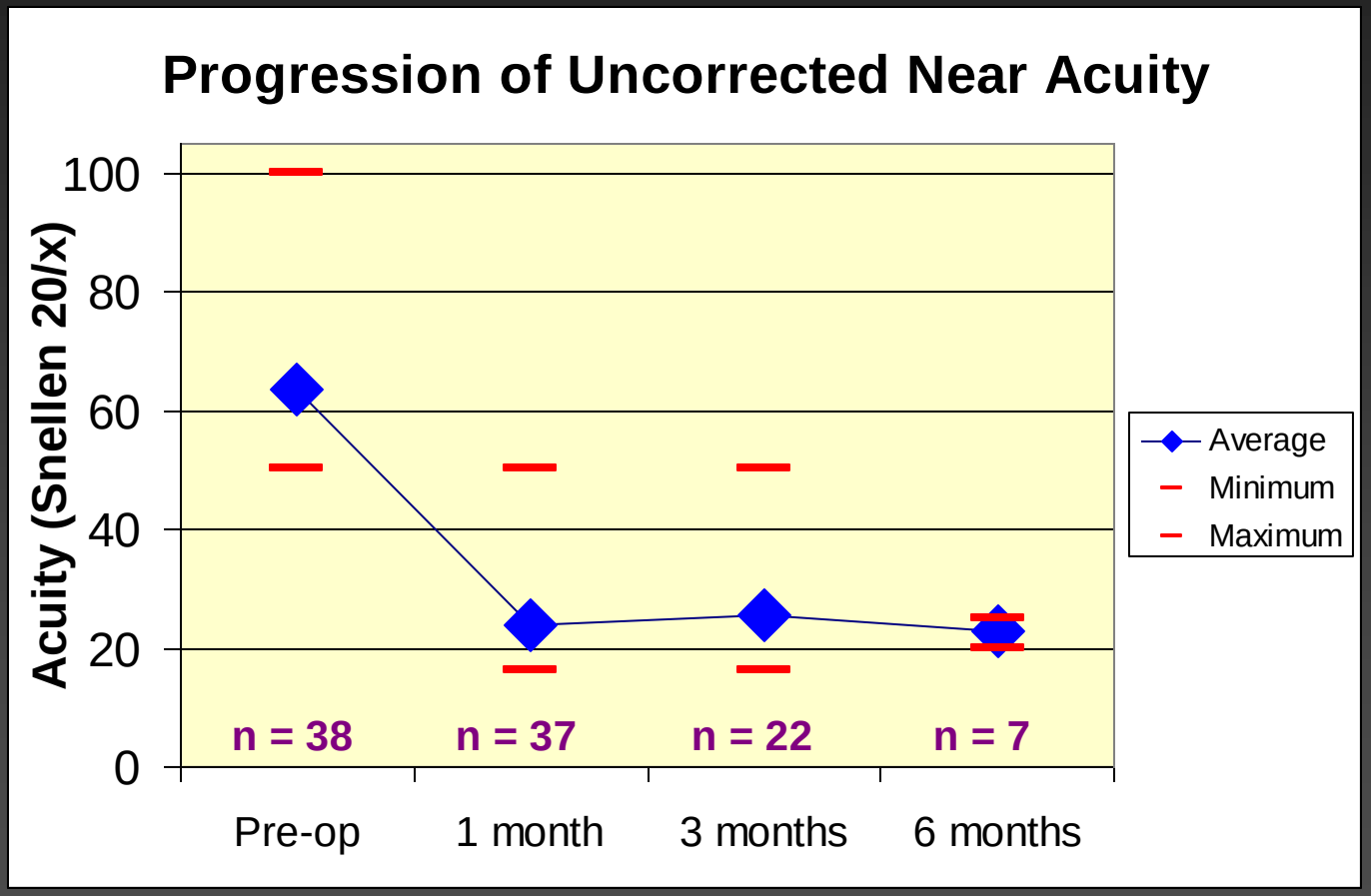
- ReVision Optics recently modified design
  - Near vision improved
  - Intermediate vision improved
  - Distance has no compromise relative to old design
- The new design is 2 mm in diameter

Demographics

2 mm Inlay **Non-Dominante Eye Implanted** **Microkeratome Flap**

(n)	38 Subjects
Sex	20 M, 18 F
Age range	45 to 56
Age average	49.4
Refractive Error	
▪ Sphere range	-0.25 to +1.00 D
▪ Sphere average	0.38 D
▪ Cylinder range	0.00 to -0.75 D
▪ Cylinder average	-0.38 D
▪ Near Add Power range	1.50 to 2.50 D
▪ Near Add Power average	1.82 D

Uncorrected Near Acuity

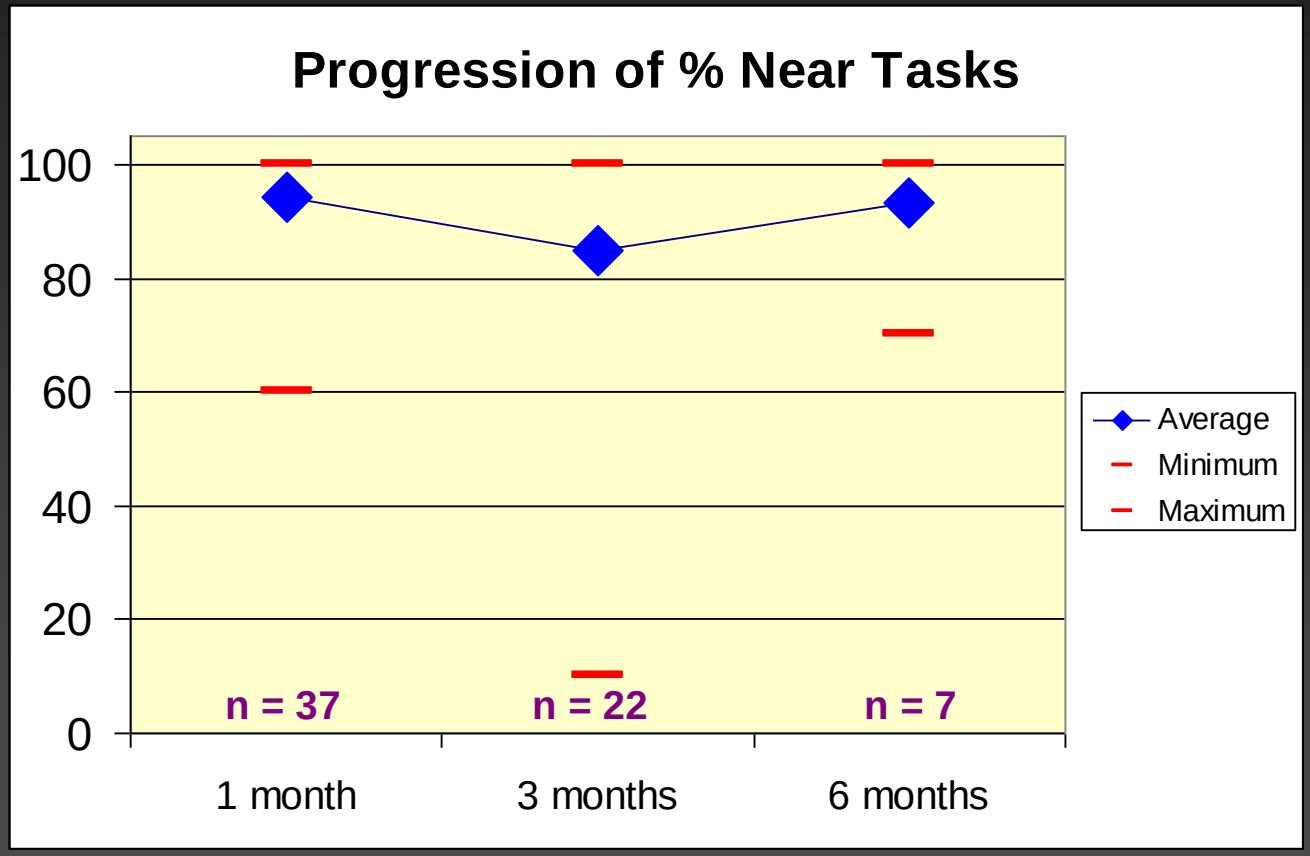


Mean uncorrected near acuity is 20/25 at all post-op visits (~ 4 lines gain)

Functional Near Vision

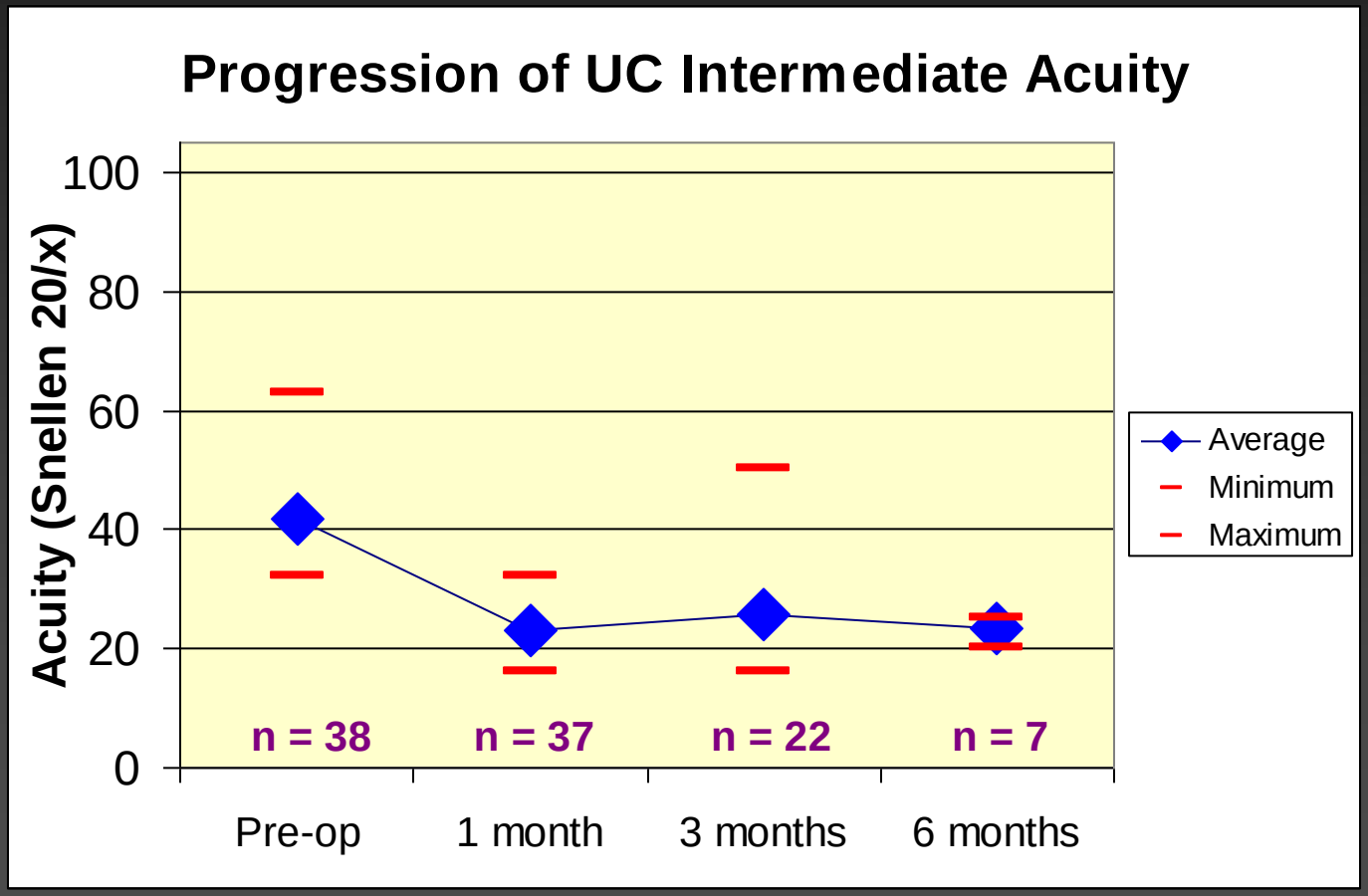
Asked patients if they can do the following tasks without glasses…

- Read medicine instructions
- Read newspaper articles
- Examine their fingernails
- Dial cell phones
- Read magazines



Majority of subjects can perform the majority of near tasks without glasses

Uncorrected Intermediate Acuity

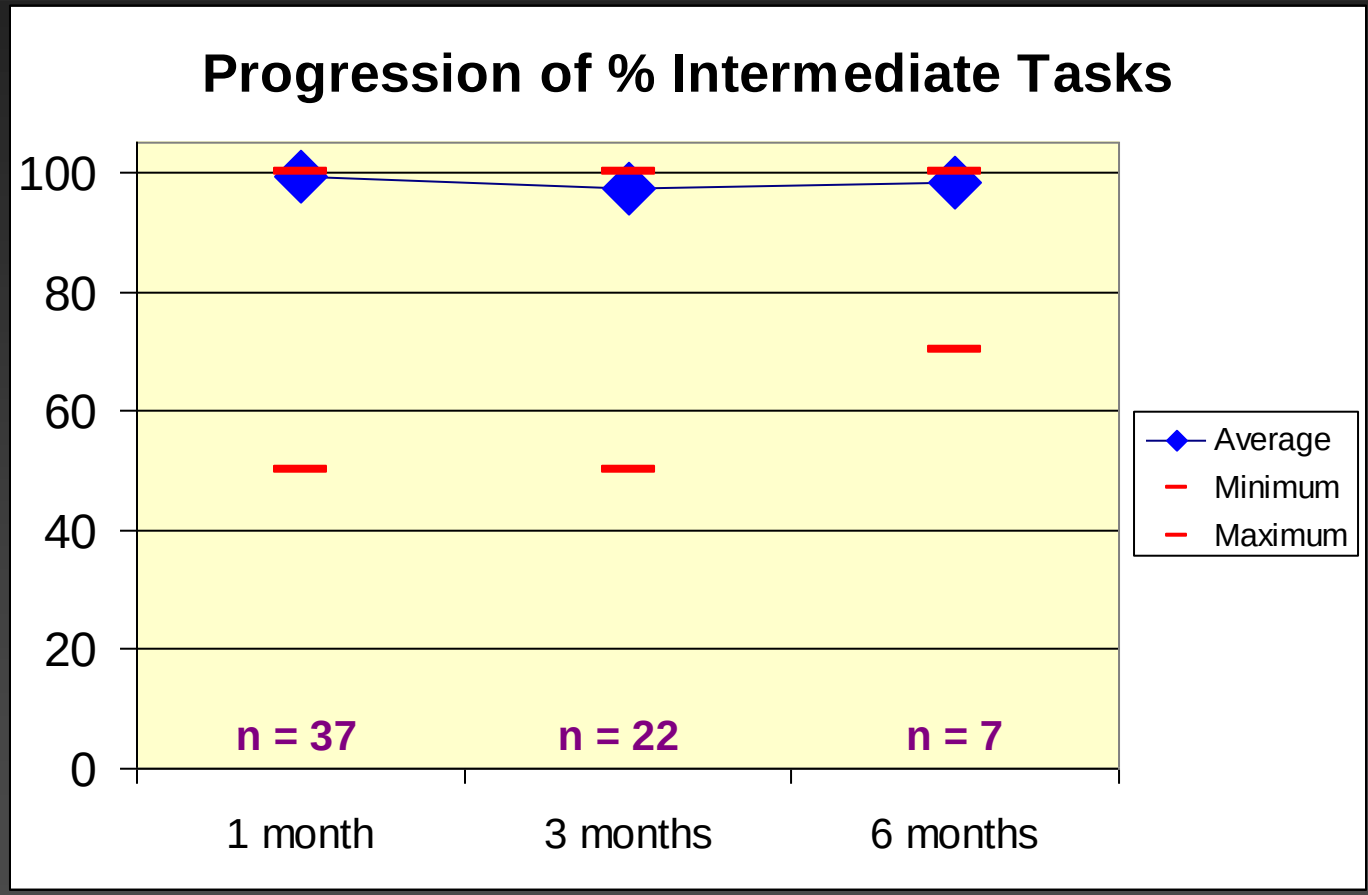


Mean UC intermediate acuity is 20/25 at all post-op visits (~ 2 lines gain)

Functional Intermediate Vision

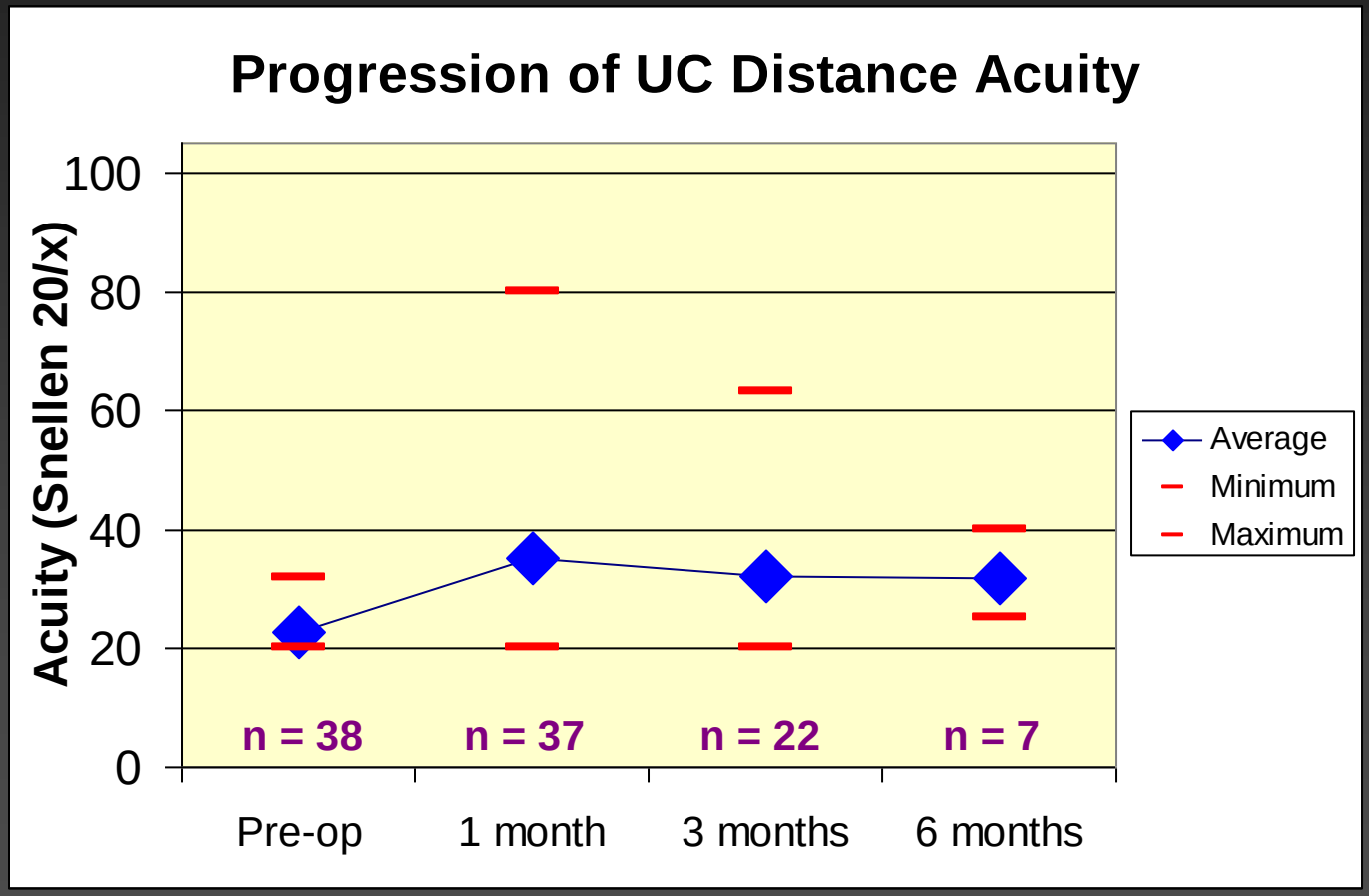
Asked patients if they can do the following tasks without glasses…

- Find items on kitchen shelf
- Read computer screens
- Use a bathroom mirror
- Use a wall calander
- Recognize photo portraits



Majority of subjects can perform a majority of intermediate tasks without glasses

Uncorrected Distance Acuity



Mean uncorrected distance acuity is 20/32 at all post-op visits (< 2 lines loss)

Summary of Outcomes

- Excellent near and intermediate visual acuity
- All patients see 20/25 or better binocularly at distance
- Strong patient satisfaction with distance vision
- No loss of two or more lines of best corrected acuity at distance or near at any visit
- Only one adverse event
  - Inlay repositioned on day one
  - Resulting vision good
- **100 % of patients stated that they would have the procedure again**