

The effect of a visual aid on the understanding of informed consent for cataract surgery in a rural, indigent South Indian population

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Disclosure

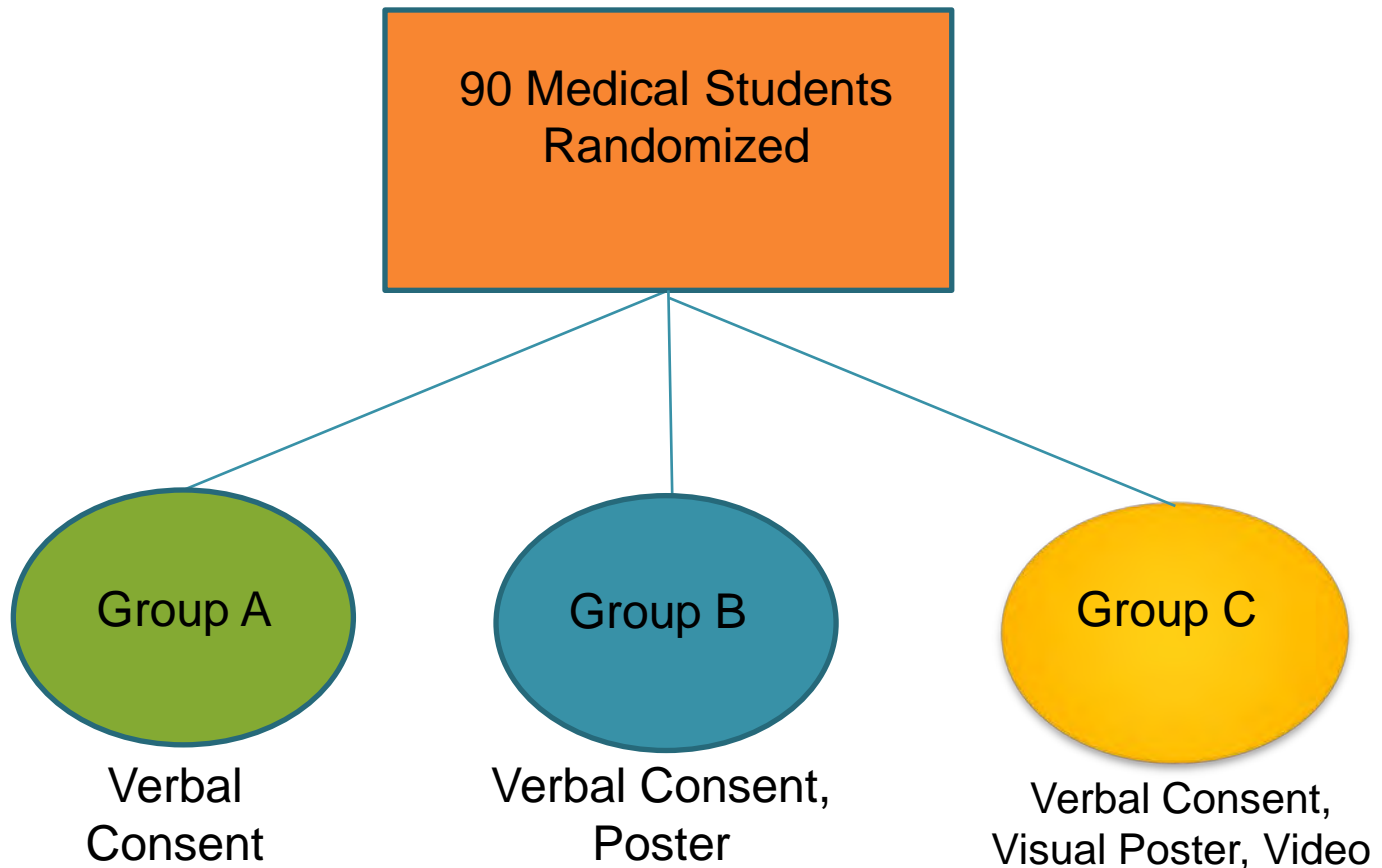
- Approval was granted by:
 - Yale University Human Subjects Committee
 - The Vision Foundation- Chennai, India
- No authors have any financial conflicts

Background

- Cataract surgery involves
 - An incision
 - Removal of the native lens
 - Placement of artificial lens
 - Risks and side effects
 - Benefits

Effects of presentation method on the understanding of informed consent.

- Moseley et al. Br J Ophthalmol 2006; 90:990–3.



Informed consent in vulnerable populations

- Barriers to informed consent include:
 - Illiteracy
 - Poor comprehension/education
 - Unfamiliarity with basic scientific and medical principles
 - Physical barriers- blindness, hearing impairment, organic brain disease...
- Physicians
 - Yousuf RM, et al. Awareness, knowledge and attitude toward informed consent among doctors in two different cultures in Asia: a cross-sectional comparative study in Malaysia and Kashmir, India. Singapore Med J. Jun 2007;48:559-65.



Overview



Villages → Uma Eye Clinic → Hande Surgical Hospital

60 Patients
Randomized

Group A
30

Group B
30

Quiz

Day of surgery

Quiz

Verbal Consent

Verbal and Poster

Quiz

Quiz

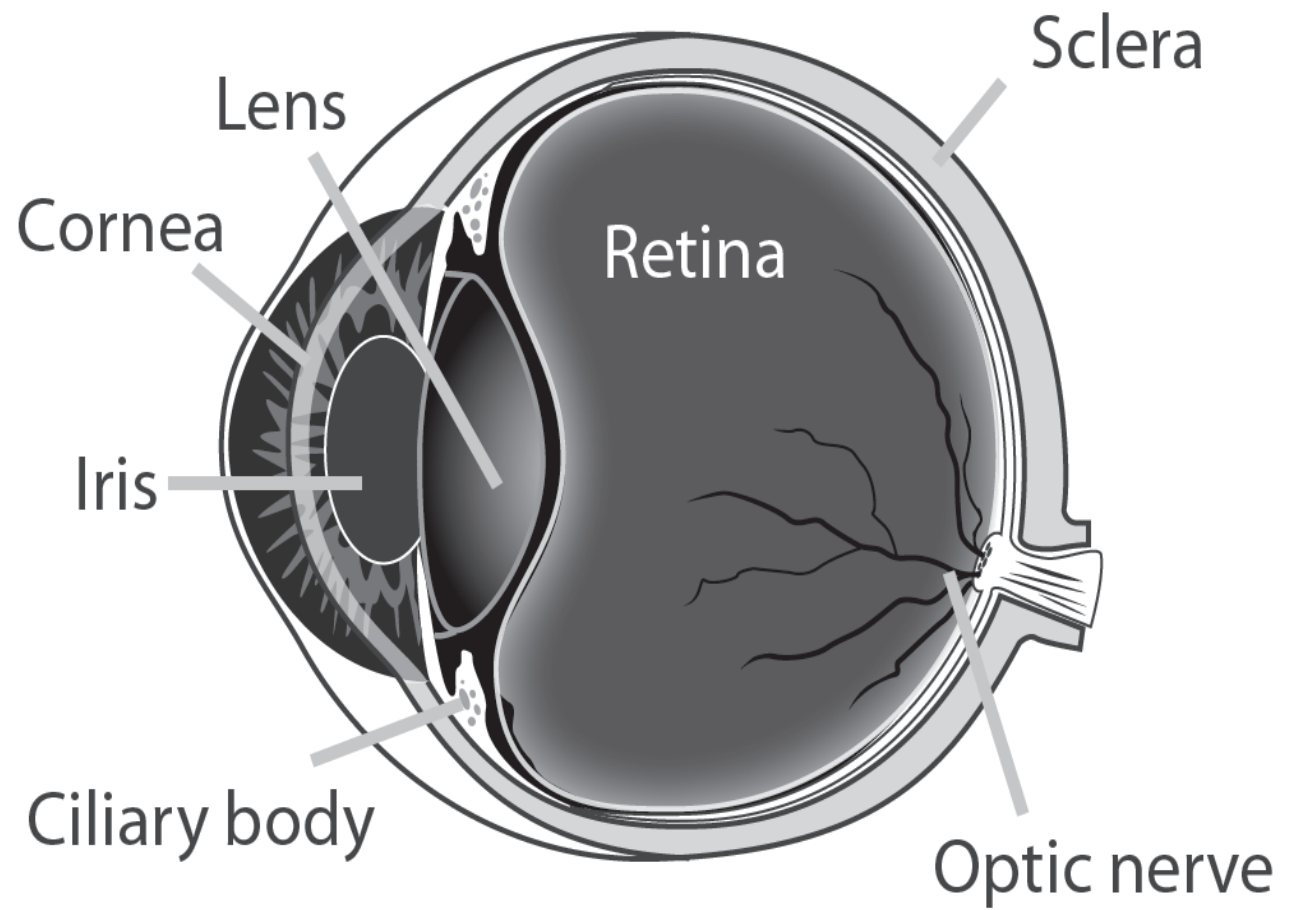
Surgery

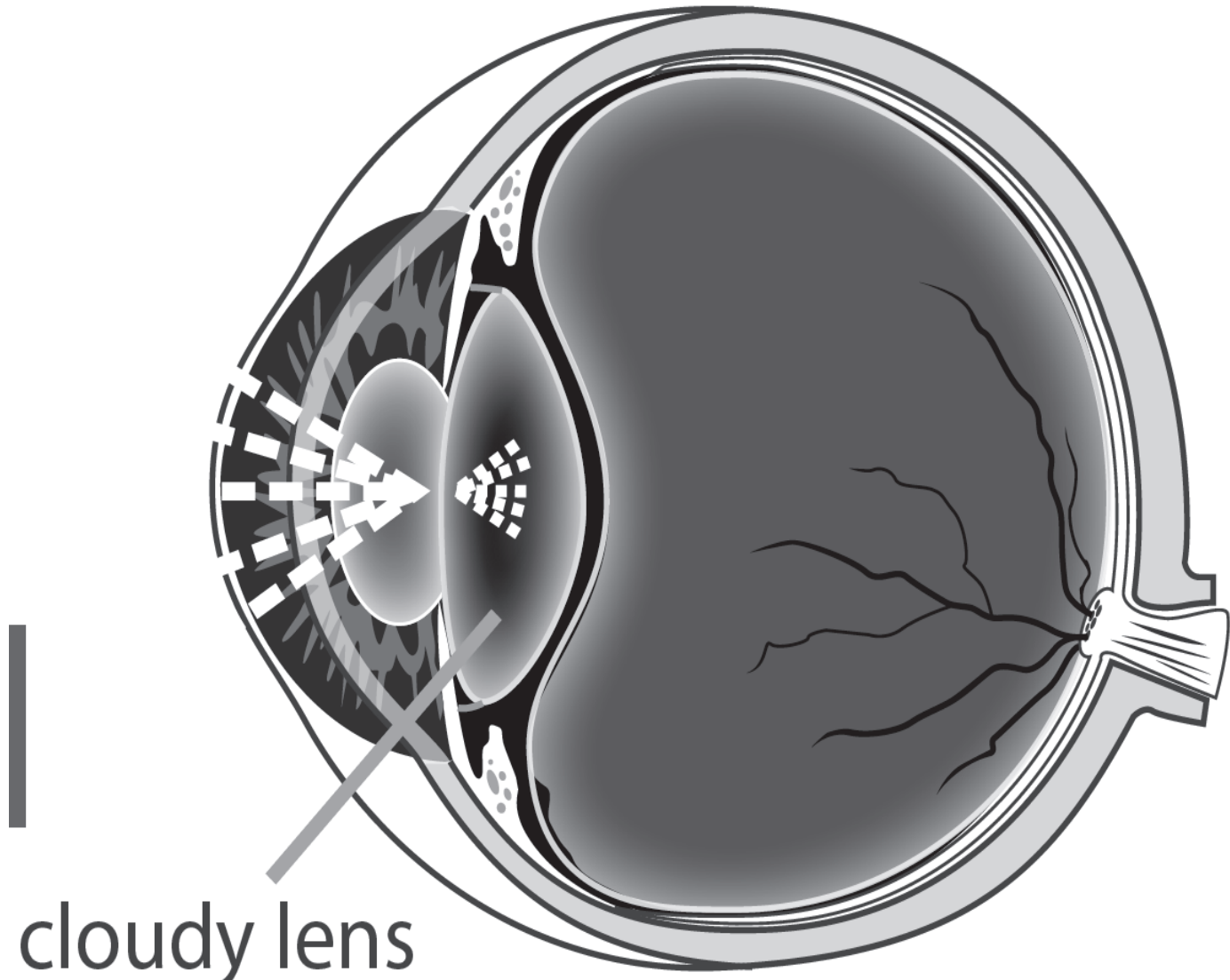
Surgery

Quiz

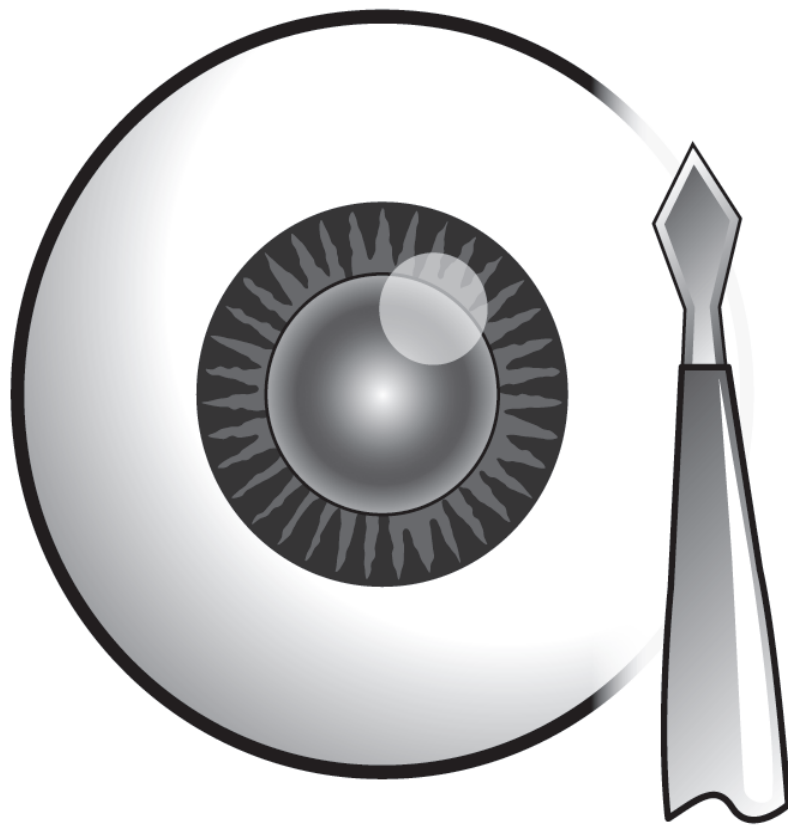
One day after
surgery

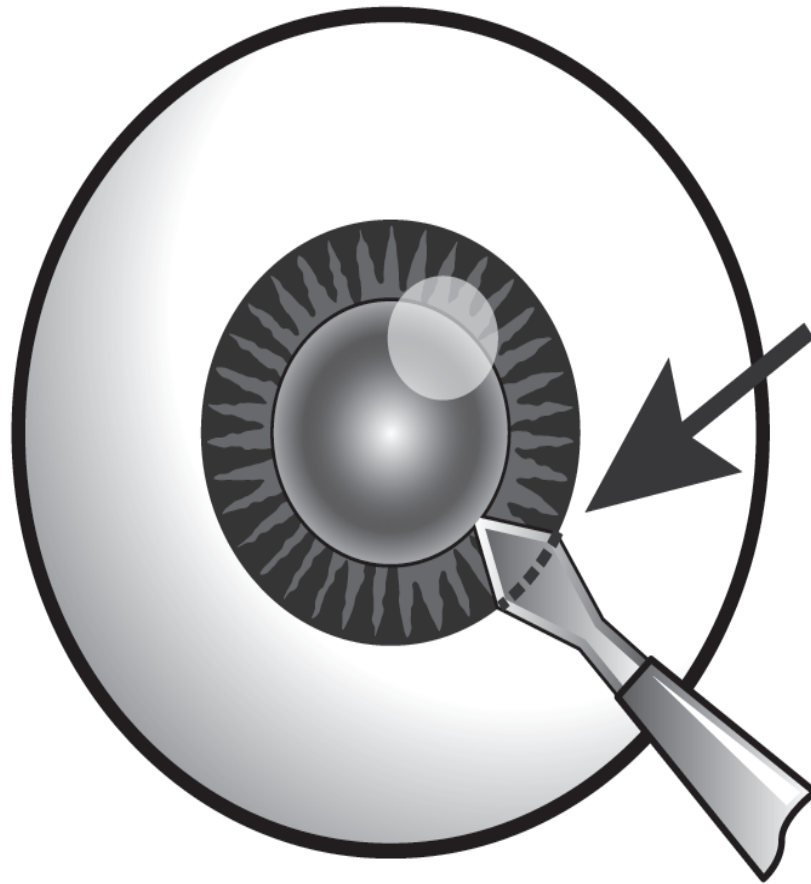
Quiz



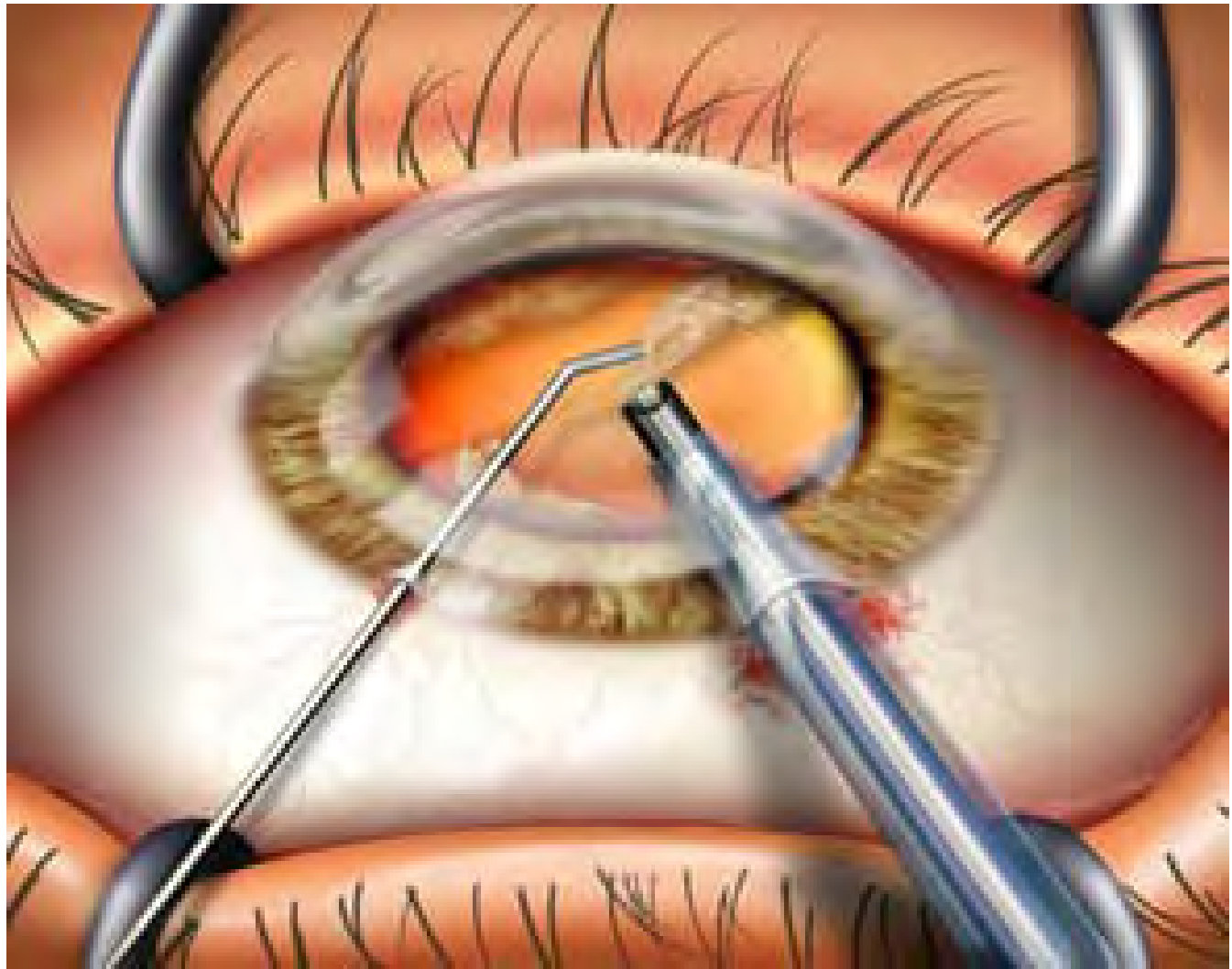


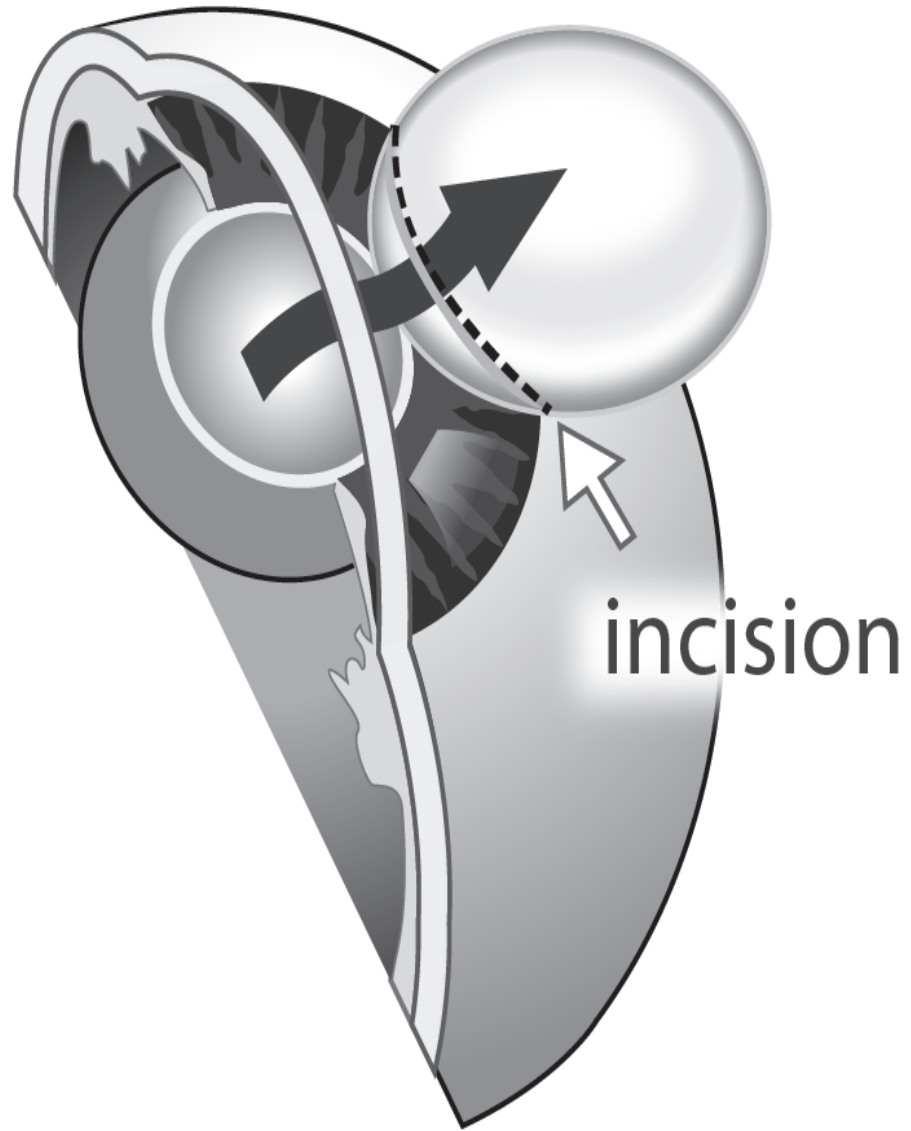
cloudy lens

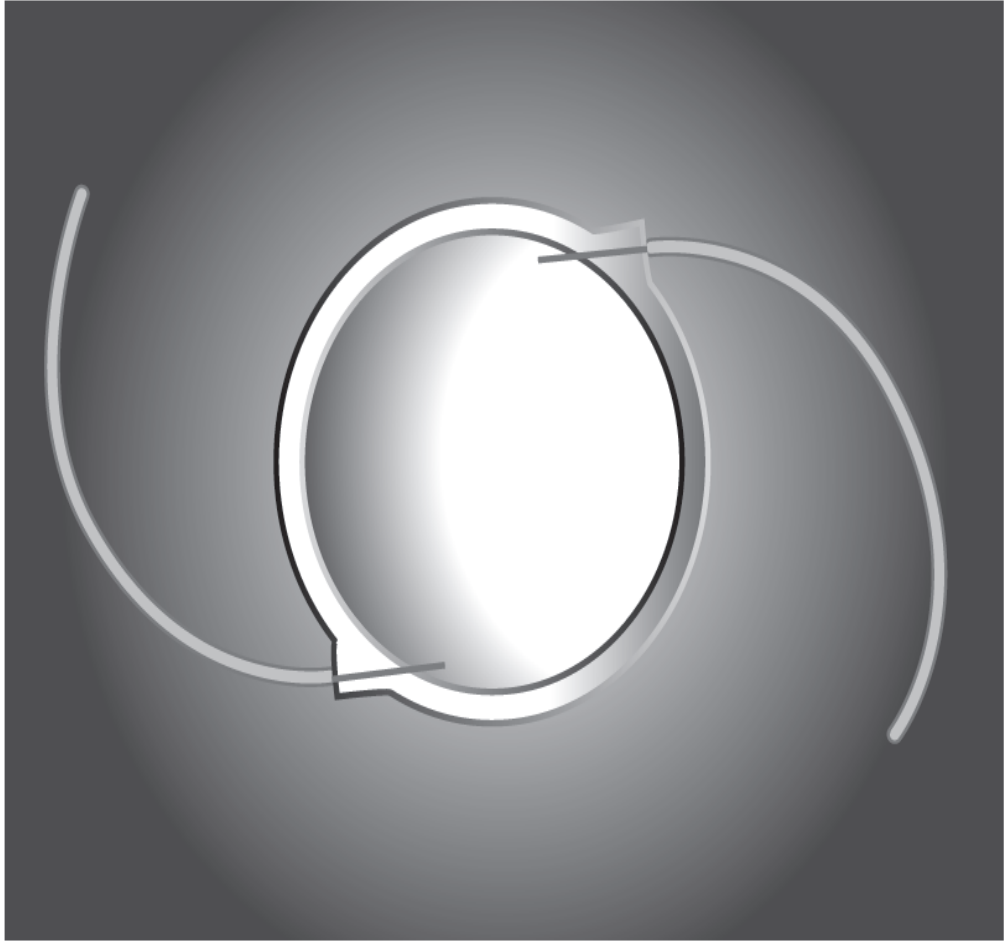


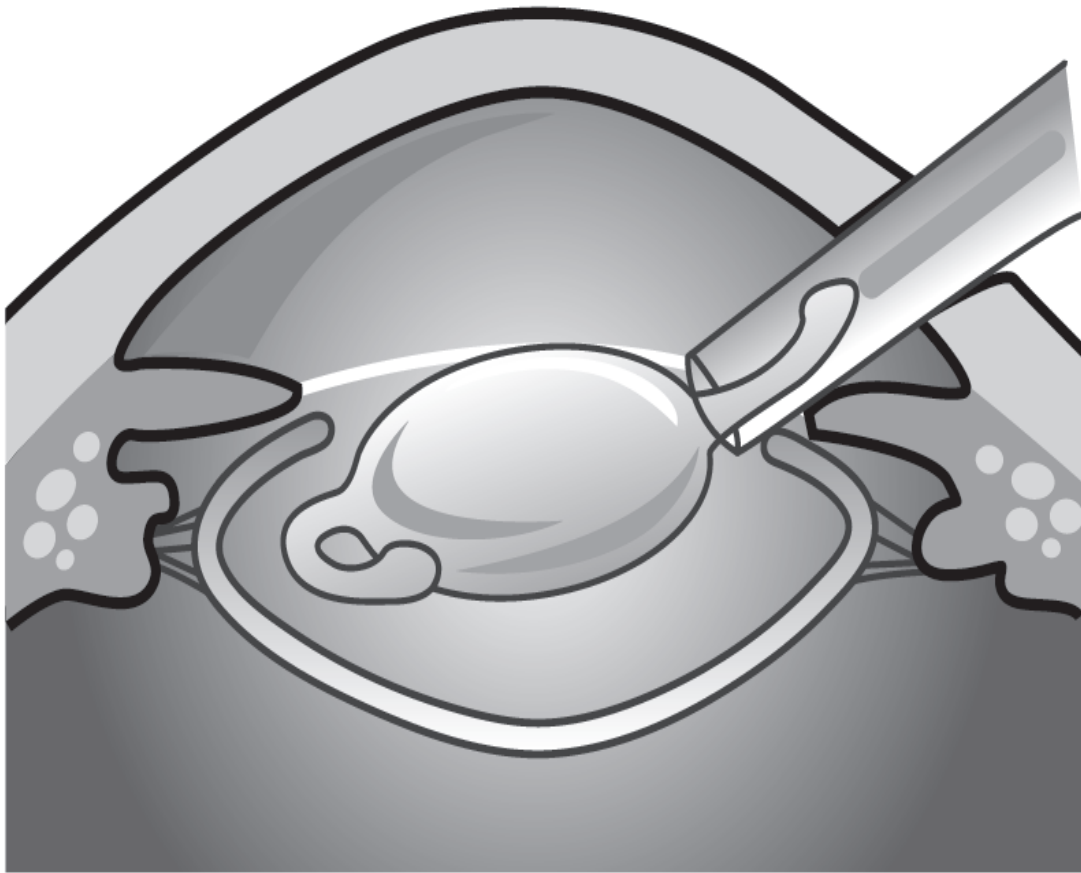


incision



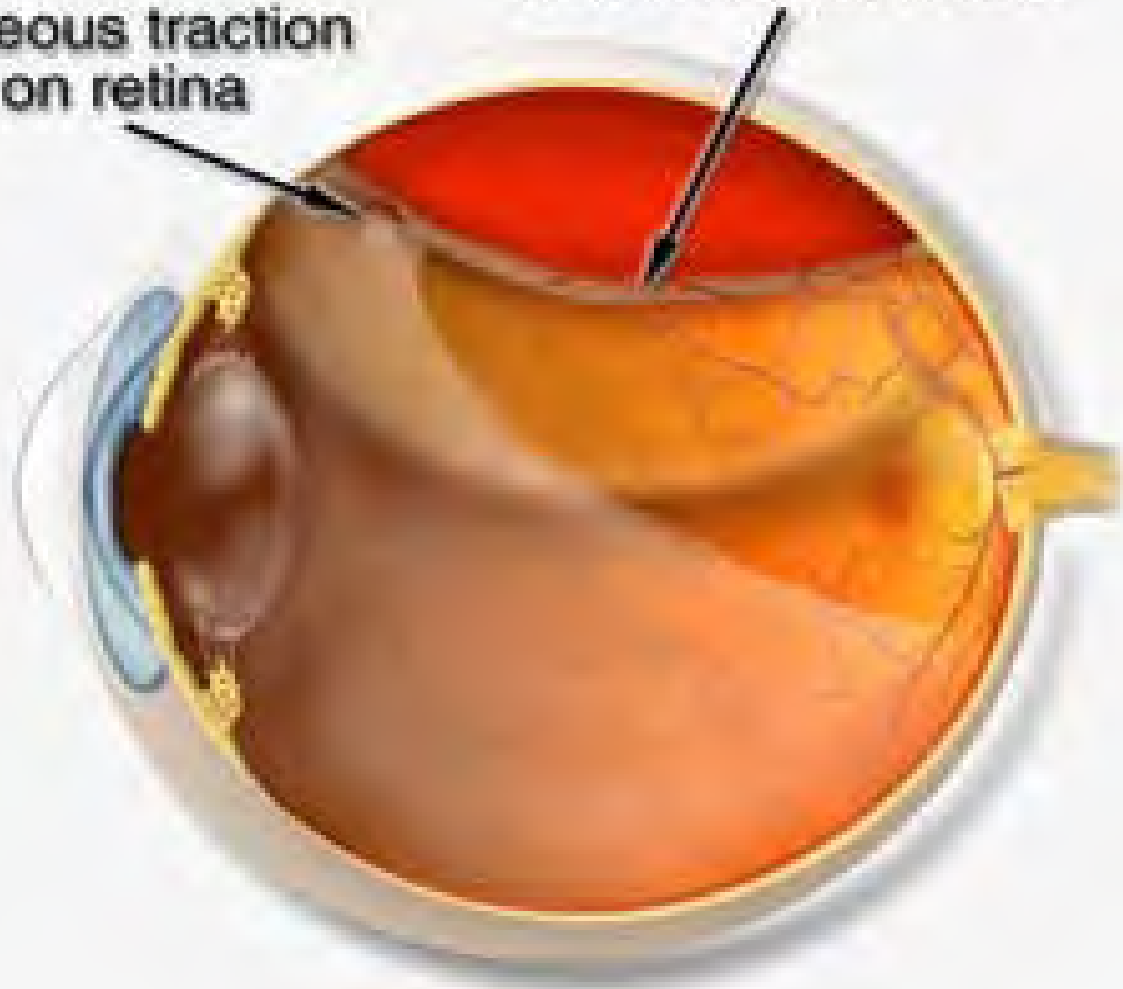






**Vitreous traction
on retina**

Retinal detachment



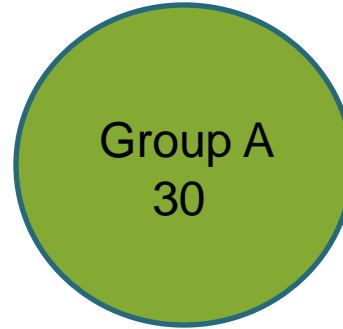
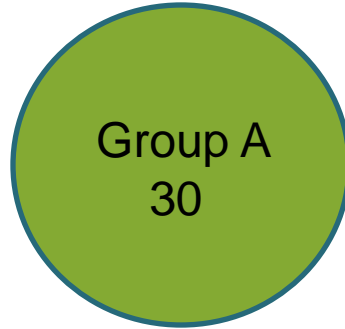


Before Informed
Consent

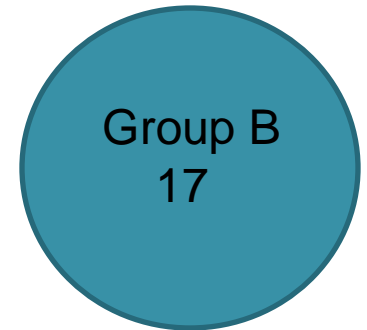
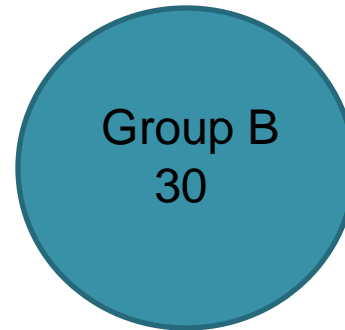
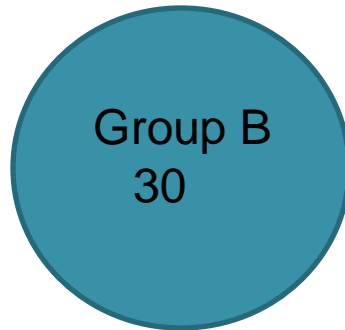
After Informed
Consent

1 Day Post-op

Verbal
Consent



Verbal
Consent
and Poster



Verbal Quiz

- Most patients were unable to read, due to education or visual impairment, so the quiz was administered verbally
- Pilot testing with Multiple Choice & Open Ended Format
 - Too difficult for patients to remember answer options
 - Patients not familiar with this testing format
- Protocol switched to an 11 Question Verbal Quiz
 - True
 - False
 - I don't know

Verbal Quiz

1. A cataract is the clouding of the lens.
2. Lack of certain vitamins, exposure to sunlight, and old age can all cause cataracts.
3. Wearing strong glasses can remove a cataract.
4. If you do not remove a mature cataract, you will suffer irreversible blindness.
5. During cataract surgery, the surgeon makes an incision in the eye with a special blade.
6. The way the surgeon removes the cataract is by breaking apart and removing the lens and placing a new, artificial lens in the eye.
7. Everyone will have improved vision after cataract surgery.
8. There are no risks involved with cataract surgery.
9. Benefits of cataract surgery include never needing glasses again.
10. The normal post-operative course is typically that vision will be perfect the next day.
11. Post-operative drops are used to prevent infection and inflammation.

Results

Average Correct Responses (out of 11)

Group	Before Informed Consent Mean (SD)		
Without poster	5.867 (2.161)		
With Poster	4.767 (1.455)		
p-value for difference between groups	0.02483		

Results

Average Correct Responses (out of 11)

Group	Before Informed Consent Mean (SD)	After Informed Consent Mean (SD)	
Without poster	5.867 (2.161)	7.900 (1.493)	
With poster	4.767 (1.455)	7.467 (2.515)	
p-value for difference between groups	0.02483	0.4212	

Results

Average Correct Responses (out of 11)

Group	Before Informed Consent Mean (SD)	After Informed Consent Mean (SD)	1 Day Post-op Mean (SD)
Without poster	5.867 (2.161)	7.900 (1.493)	7.391 (1.305)
With poster	4.767 (1.455)	7.467 (2.515)	8.706 (1.404)
p-value for difference between groups	0.02483	0.4212	0.0049

Mean Scores

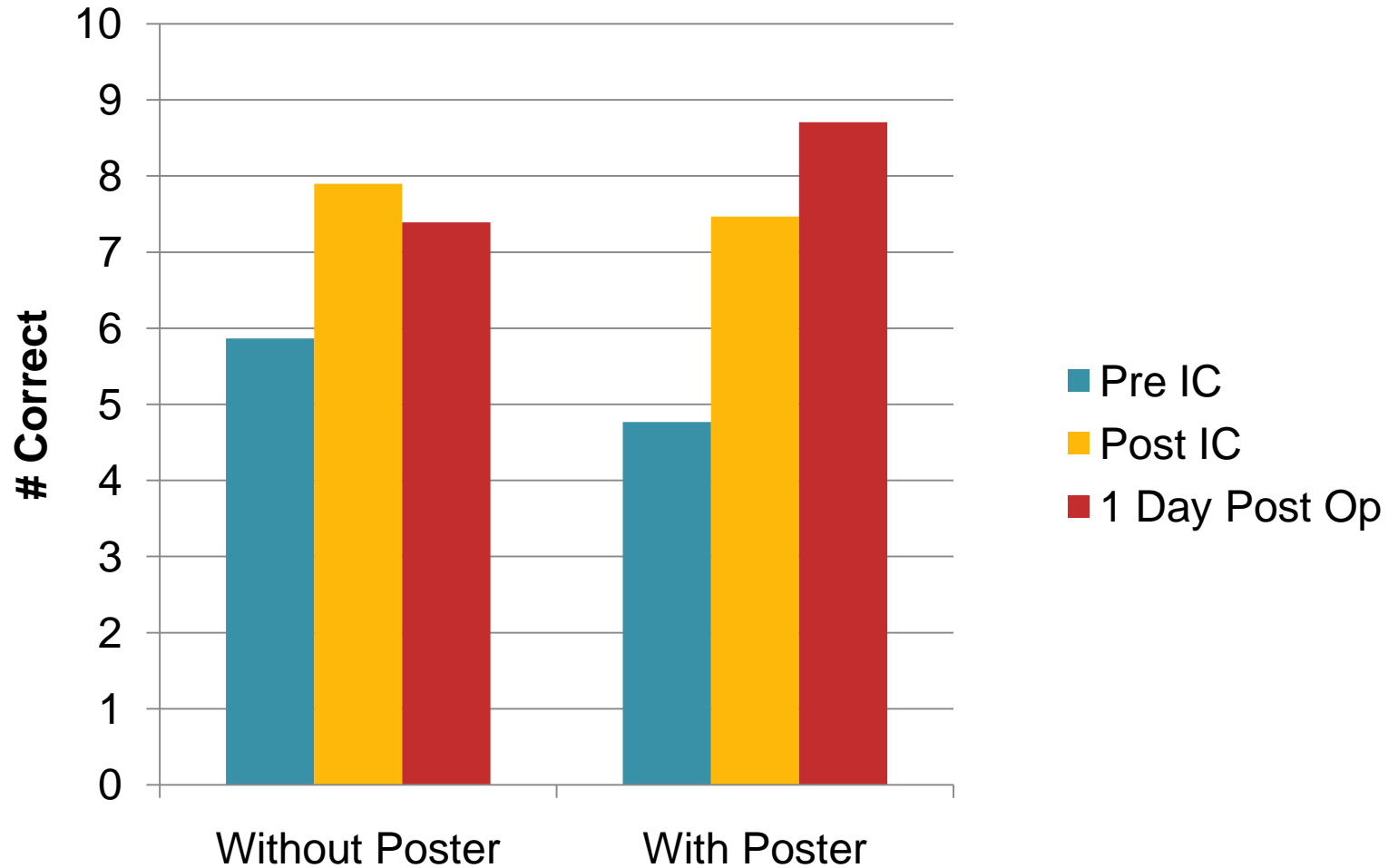


Table 2: Change in Number of Correct Responses

Group	Before Consent to After Consent <i>Mean (SD)</i>		
Without poster	2.033 (2.385)		
With poster	2.700 (2.793)		
p-value for difference between groups	0.3244		

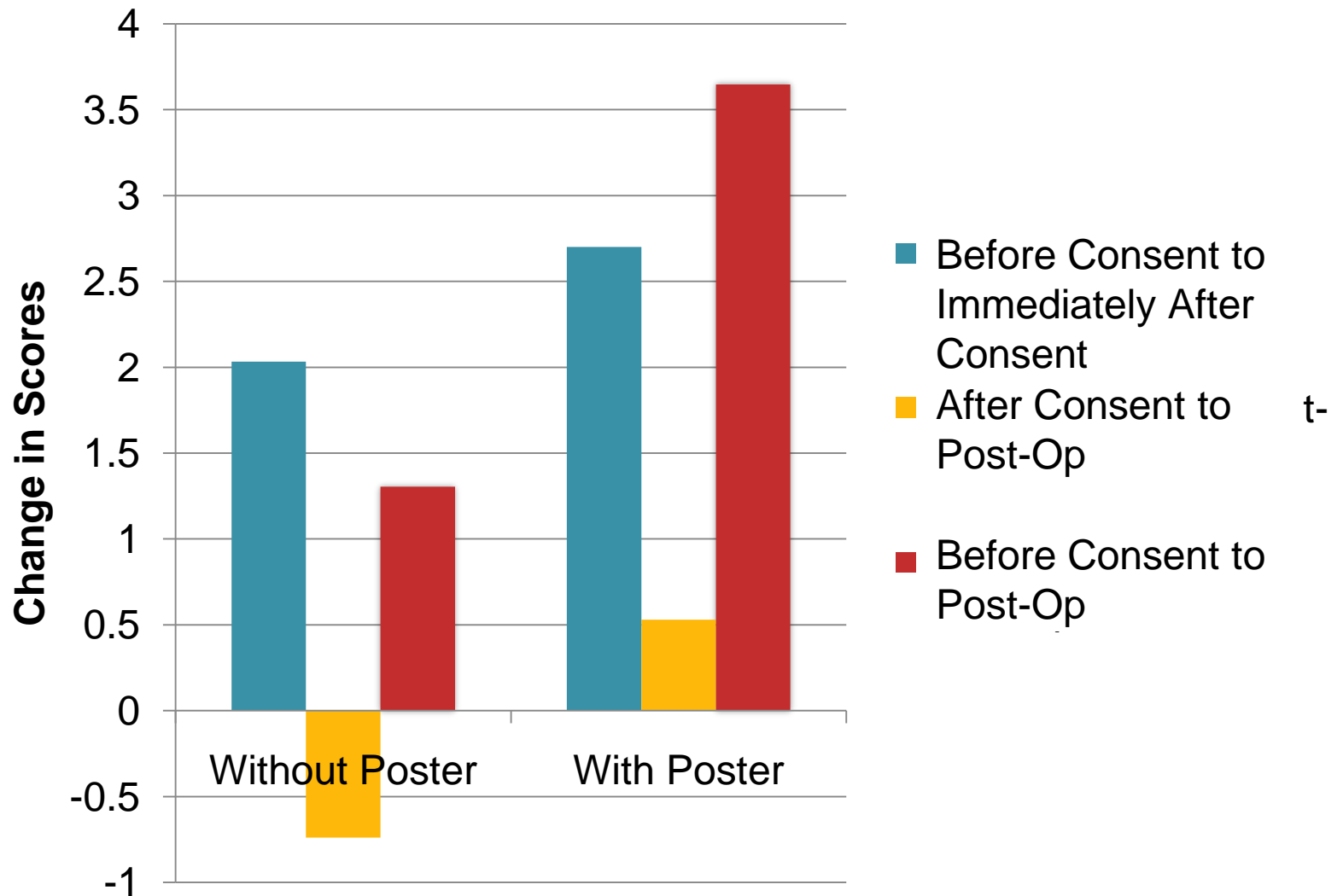
Table 2: Change in Number of Correct Responses

Group	Pre-Informed Consent to Post-Informed Consent <i>Mean (SD)</i>	Post-Informed Consent to Post-Operative <i>Mean (SD)</i>	
Without poster	2.033 (2.385)	-0.7391 (2.261)	
With poster	2.700 (2.793)	0.5294 (1.546)	
p-value for difference between groups	0.3244	0.04188	

Table 2: Change in Number of Correct Responses

Group	Pre-Informed Consent to Post-Informed Consent <i>Mean (SD)</i>	Post-Informed Consent to Post-Operative <i>Mean (SD)</i>	Pre-Informed Consent to Post-Operative <i>Mean (SD)</i>
Without poster	2.033 (2.385)	-0.7391 (2.261)	1.304 (2.636)
With poster	2.700 (2.793)	0.5294 (1.546)	3.647 (1.801)
p-value for difference between groups	0.3244	0.04188	0.001909

Change in Scores between Testing Sessions



Influence of Covariates

Was the change in scores dependent on any of the following?

Linear regression models → change in scores the dependent variable

- Group membership
- Age
- Gender
- Highest education level
- Literacy
- Previous eye surgery
- Prior knowledge of the surgery
- Visual acuity (best of the two eyes)

Only Pre-IC to Post-Op showed Group Membership to override other factors

Limitations of the study

- Difficulty in standardization due to a verbally administered quiz with translator
- Patient comprehension
- Small sample size
- Limited number of questions

- The experimental variable was based on a visual stimulus
 - Note: Analysis of covariates did not show visual acuity to be linked with any significant change in scores

Conclusions

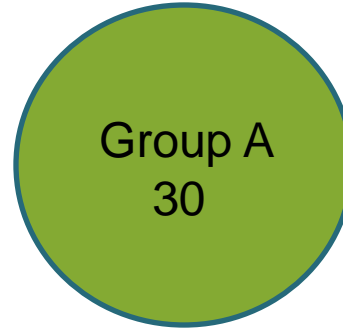
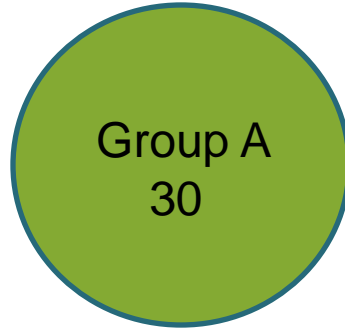
- Informed consent improves patient comprehension of the cataract surgery
- A visual aid improves comprehension and retention of information better than a verbal consent alone for rural, indigent South Indian cataract patients.
- A visual aid during informed consent makes patients not want to take a quiz on post-op day one.

Before Informed
Consent

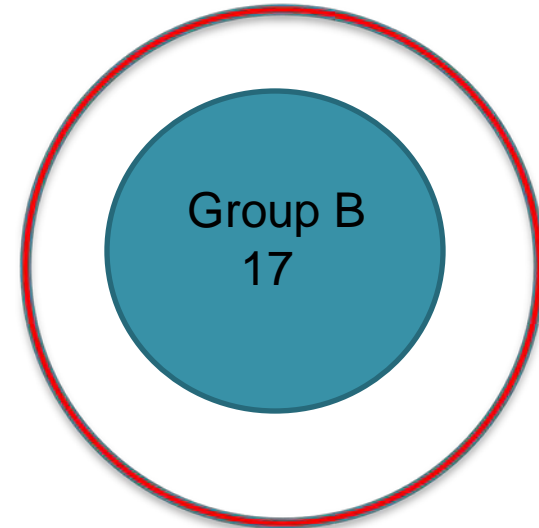
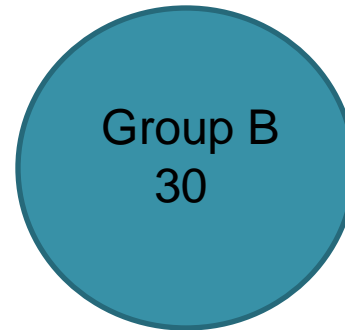
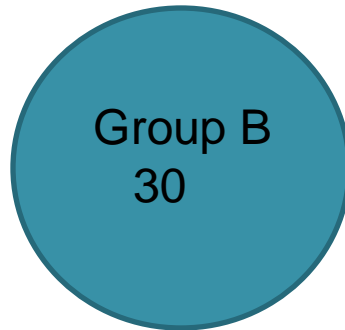
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Verbal
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Impact

- The poster has been adapted in several Unite for Sight locations as part of patient education prior to surgery

A sincere thank you to our patients and to the staff and faculty at the Uma Eye Clinic and Hande Hospital, especially to Dr. Tamarasan Senthil and Dr. Arulmozhi Varman, as well as Sasi, Thanraj, and Kumar

