Impact of a Novel Extended Depth of Focus Intraocular Lens on Lifestyle Enhancement

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Financial Disclosures

- Alanna Nattis DO, FAAO: Alcon (consultant, research), Glaukos (research), Novartis (consultant) Ocular Therapeutix (research), Sight Sciences (consultant), Tarsus (consultant)
- Eric Rosenberg DO, MSE: Alcon (consultant, research), Ocular Therapeutix (consultant) Sight Sciences (consultant), Zeiss (consultant, research), Tarsus (consultant), Eyevance (consultant), Omeros (consultant)
- Richard Nattis: none

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Purpose

• This study evaluated the ability of the Vivity (Alcon, Fort Worth TX) extended vision intraocular lens (IOL) to provide a significant impact on patient lifestyle (*independence from spectacles with a low rate of visual disturbances*) in a 'real-world' setting

Methods/Study Design

- Prospective, nonrandomized study
- Assessed the impact of pre-and-perioperative factors, (IOL formulae used, use of femtosecond laser, intraoperative aberrometry, pupillary expansion devices) on surgical success in patients undergoing bilateral sequential cataract surgery with spherical and/or toric Vivity IOL implantation across a diverse group of surgeons.
- Improvement visual acuity, as well as degree of spectacle independence, visual disturbance and visual quality was assessed at 3 months postoperative, as compared to baseline.
- Post-myopic and hyperopic LASIK/PRK patients were not excluded

Perioperative Overview

15 patients (30 eyes) underwent successful cataract extraction with Vivity IOL implantation across 4 surgeons

| | Value(s) |
|---|--|
| Sex (%M v F) | 4M (26%), 11F (73%) |
| Mean Age | 62.45 SD 11.59 (Range 34-85) |
| Mean Baseline BCVA | 20/50 (range 20/25 – 20/80) |
| % Toric IOL used | 14% (n=4) |
| % LRI Used | 86% (n=24) |
| % Femto Used | 100% |
| % ORA Used | 17% (n=5) |
| | |
| Difference between predicted refraction | 0.36 <u>+</u> 0.18 (range 0.07 - 0.61) |
| and ORA refraction | |
| % IOL changed based on ORA | 17% (n=5) |
| | |

Results: Visual Acuity at Each Time Point

| | Distance VA (Snellen) | Intermediate VA (Snellen) | Near VA (Snellen) |
|-----------|------------------------|------------------------------|------------------------|
| POD1 UCVA | 20/30 (20/20 to 20/80) | 20/25 (20/20 to 20/60) | 20/25 (20/20 to 20/60) |
| POD1 BCVA | 20/25 (20/20 to 20/80) | 20/25 (20/20 to 20/60) | 20/25 (20/20 to 20/60) |
| POW1 UCVA | 20/25 (20/20 to 20/40) | 20/25 (20/15 to 20/40) | 20/25 (20/20 to 20/50) |
| POW1 BCVA | 20/25 (20/20 to 20/30) | 20/25 (20/15 to 20/30) | 20/25 (20/20 to 20/50) |
| POM1 UCVA | 20/25 (20/20 to 20/40) | 20/25 (20/15 to 20/30) | 20/25 (20/20 to 20/30) |
| POM1 BCVA | 20/25 (20/20 to 20/30) | 20/25 (20/20 to 20/30) | 20/25 (20/20 to 20/30) |
| POM3 UCVA | 20/25 (20/20 to 20/40) | 20/25 (20/15 to 20/30) | 20/25 (20/20 to 20/30) |
| POM3 BCVA | 20/25 (20/20 to 20/30) | 20/25 (20/15 to 20/30) | 20/25 (20/20 to 20/30) |

- At POM3, there was no loss of UCVA or BCVA across patients and techniques
- No surgical complications or adverse events were recorded
- No significant difference in visual outcomes between post-LASIK and surgery-naïve eyes (t-test, distance UCVA (p=0.643), distance BCVA (p=0.926)
- No significant difference in visual outcomes between toric and non-toric eyes

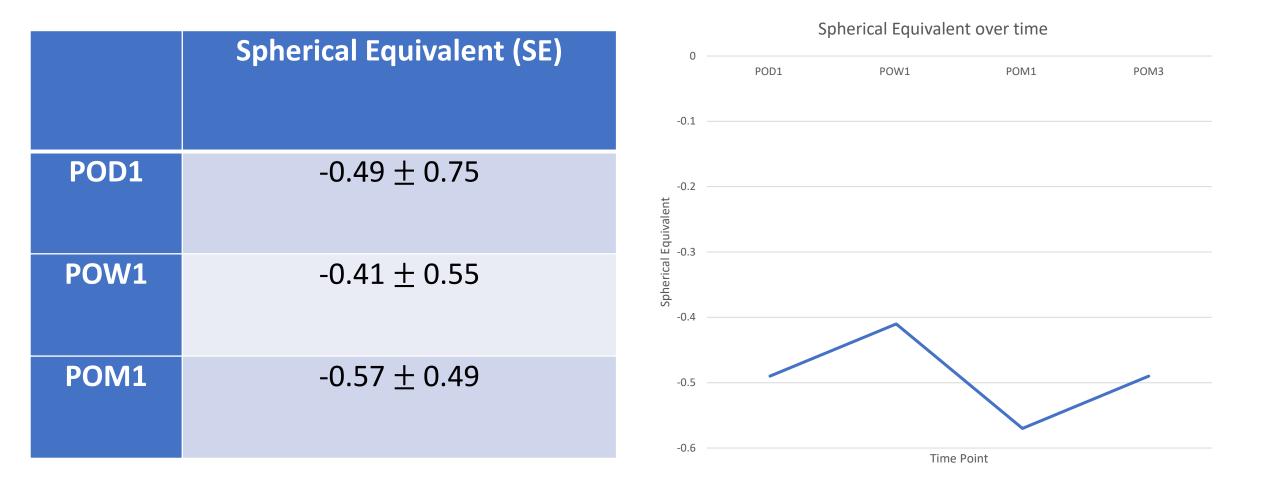
VA = visual acuity, UCVA = uncorrected visual acuity, BCVA = best corrected visual acuity, POD1 = Postoperative day 1, POW1 = postoperative week 1, POM1 = postoperative month 1, POM3 = postoperative month 3 (numbers in parentheses represent range of visual acuity)

Results: Visual Improvement Over Time

| | POD1 %20/40 or better | POD1 %20/25 or better | POW1 %20/40 or better | POW1 %20/25 or better | POM1 %20/40 or better | POM1 %20/25 or better | POM3 %20/40 or better | POM3 %20/25 or better |
|----------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Distance UCVA | 80 | 43 | 100 | 79 | 96 | 69 | 100 | 60 |
| Distance BCVA | 93 | 52 | 100 | 83 | 100 | 81 | 100 | 70 |
| Intermediate UCVA | 96 | 45 | 97 | 69 | 100 | 73 | 100 | 70 |
| Intermediate BCVA | 93 | 55 | 97 | 72 | 100 | 76 | 100 | 90 |
| Near UCVA | 93 | 48 | 97 | 76 | 96 | 62 | 100 | 80 |
| Near BCVA | 93 | 58 | 97 | 86 | 100 | 65 | 100 | 80 |

VA = visual acuity, UCVA = uncorrected visual acuity, BCVA = best corrected visual acuity, POD1 = Postoperative day 1, POW1 = postoperative week 1, POM1 = postoperative month 1, POM3 = postoperative month 3 (numbers in parentheses represent range of visual acuity)

Results: Trend in MRSE



MRSE = manifest refraction spherical equivalent, POD1 = Postoperative day 1, POW1 = postoperative week 1, POM1 = postoperative month 1, POM3 = postoperative month 3

Results: Visual Quality Questionnaire Protocol Level

Visual Quality Questionnaire

Patient ID(coded ID): Date: Surgeon: Date of Surgery: OD //OS

| 1. | Do you have difficulty seeing steps, stairs or curbs due to your vision? (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 100% never |
|-----|---|---------------------------|
| | Do you have difficulty taking part in sports (e.g. bowling, handball, tennis, golf) due to your vision? | 📫 100% never |
| | (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 100% never |
| 3. | Do you have difficulty working on a computer? a. (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 100% never |
| 4. | Do your eyes feel strained while working on a computer? (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 33% never, 33% sometimes, |
| 5. | Do you have difficulty writing checks or filling out forms? (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 33% rarely 100% never |
| 6. | Do you have difficulty playing games, such as card games, bingo, dominos? (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 100% never |
| 7. | Do you accomplish less than you would like because of your vision? (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 100% never |
| | Do you rely more on others (e.g. giving instructions, identifying objects in front of you) due to your vision? (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | ➡ 100% never |
| 9. | If you currently drive, do you find you are driving less <i>during the day</i> due to your vision? (0) N/A (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 100% never |
| 10. | If you currently drive, do you find you are driving less <i>at night</i> due to your vision? (0) N/A (1) Never (2) Rarely (3) Sometimes (4) Most of the time (5) All the time | 100% never |

Sep 21, 2020

Results: Spectacle Independence

| 1. Overall, in the past 7 days, how often did you need to wear eyeglasses to see? | | | | |
|---|---------------------------------|-------------------|---|----------------------|
| 0 | 1 | 2 | 3 | 4 |
| | | | | |
| Never → | Rarely | Sometimes | Most of the time | All the time |
| MOVE TO | - | | | |
| SECTION 2 (Page 4) 0.3 | 2 1 0 17 | | | |
| (Page 4) 0.3 | 5 _ 0.47 | | | |
| D In the next | | | | 40.000 // |
| | example, read | | o wear eyeglasses | s to see " up |
| 0 | 1 | 2 | 3 | 4 |
| | | | | |
| Never | Rarely | Sometimes | Most of the | All the time |
| 0.33 ± | 0.47 | | time | |
| | | | | |
| 3. In the past 7 arm's-leng | | | o wear eyeglasses or seeing the dasl | |
| Car)? | | | | 4 |
| 0 | | 2 | 3 | 4 |
| | | | | |
| Never | Rarely | Sometimes | Most of the time | All the time |
| | | | | |
| 4. In the past 7 lays, how often did you need to wear eyeglasses to see "far | | | | |
| 4. In the past 7 | lays, how ofte | n did you need to | o wear eyeglasse: | s to see "far |
| | Iays, how ofte ample, seeing | | o wear eyeglasses | s to see "far |
| | | | o wear eyeglasses | s to see "far 4 |
| away" (for | | | | |
| away" (for | | | 3 | |

>85% of patients stating they had 'no need for spectacle correction' for most activities in dim and bright lighting conditions

| 21. Overall, in | ····· | | | |
|---------------------------|-------------------|---|----------------|---------------------|
| 0 | 1 | 2 | 3 | 4 |
| □ Very dissatisfied | □ Dissatisfied | □ Neither satisfied nor dissatisfied | □ Satisfied | □ Very Satisfied |

| 22. Given your vision today, if you had to do it all ov lenses implanted again? | er, would you have | the same |
|---|--------------------|----------|
| 0 | 1 | |
| □ No | □ Yes | |
| Why or Why not? (Please explain): | | |

23. Given your vision today, would you recommend the lenses you had implanted to your family or friends?

Why or Why not? (Please explain): _____

0

No

"you're able to see the beauty of the world again, very clear, very safe surgery!"

Yes

Results: Visual Disturbance Profile



Halos



IF YES, answer the following questions (mark one box per row):

| 1.1 In the past 7 days, how often did you experience starbursts? | | | | | | |
|--|--|---|---|---|--|--|
| 0 | 1 | 2 | 3 | 4 | | |
| | | | | | | |
| Never | Never Rarely Sometimes Most of the time Always | | | | | |

1.2 Using the pictures below, rate how severe your <u>worst experience</u> was with **starbursts** in the past 7 days. These pictures may not look exactly like what you see, but are a guide to help you choose your answer.

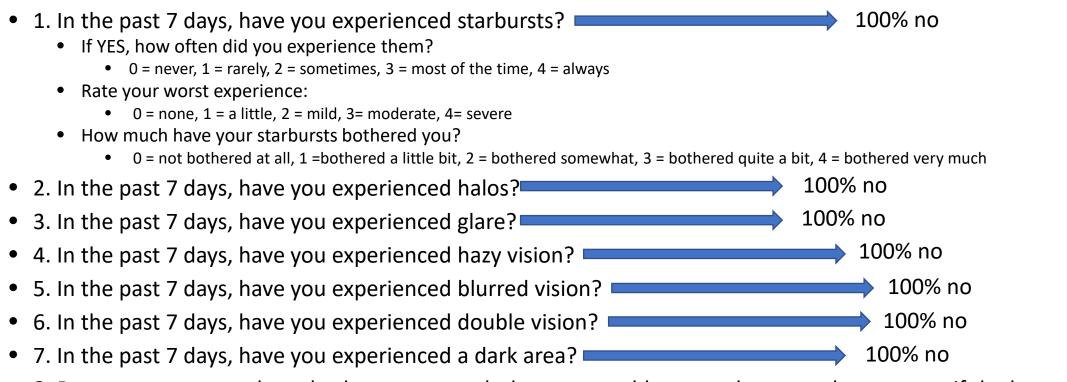
| 0 | 1 | 2 | 3 | 4 |
|------|----------|------|----------|--------|
| | | | | |
| None | A little | Mild | Moderate | Severe |
| | | ** | XX | |

| 1.3 In the past 7 days, how much have your starbursts bothered you? | | | | |
|--|-------------------------------|---------------------------|------------------------------|----------------------------|
| 0 | 1 | 2 | 3 | 4 |
| □ Not bothered at all | □ Bothered a little bit | □ Bothered somewhat | □ Bothered quite a bit | □ Bothered very much |

No Starbursts and No Halos



Results: Visual Disturbance Profile



- 8. Do your symptoms above bother you enough that you would want to have another surgery, if the lens was the cause?
 - 0 = no, 1 = yes, 3= n/a 100% n/a

Rate of visual disturbance, namely glare, haloes and starbursts VERY low!

Discussion

- Our data demonstrated significant postoperative visual success of bilateral cataract surgery with Vivity IOL implantation across multiple surgeons, techniques and pre-and-perioperative variables
 - Significant visual improvement at distance, intermediate and near
 - Significant improvement in visual quality
 - Low rate of visual aberrations
 - Significant degree of **spectacle independence**
- Results reinforce that this non-diffractive extended vision IOL is an excellent option for cataract surgery patients, including those post-LASIK

Thank you!

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