

A PARADIGM SHIFT IN CATARACT SURGERY

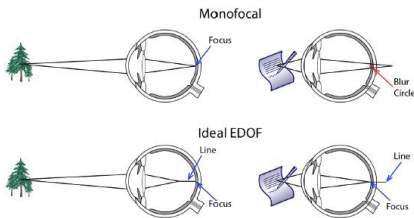
Paul H. Ernest, M.D.

1

VIVITY

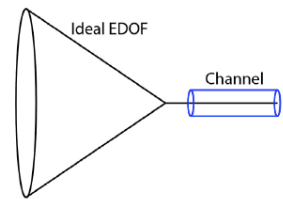
2

Extended Depth of Focus



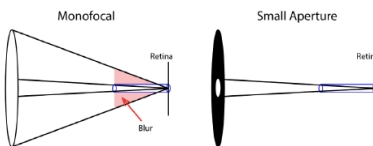
3

Ideal EDOF



4

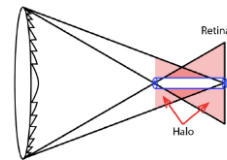
Small Aperture IOLs



May be problematic under low lighting conditions.

5

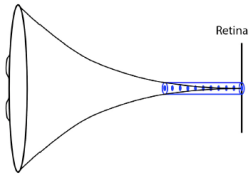
Diffraction IOLs – Multifocal IOLs



Diffractive lenses split the light into two or more foci. Here, a bifocal diffractive lens creates two distinct foci within in channel. While these rays again come to focus within the EDOF channel, away from these points, the rays lay outside of the channel leading to halo.

6

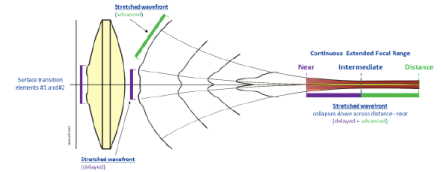
Wavefront Shaping



Wavefront shaping in the lens leads to light that is mainly confined to the EDOF channel with a halo profile similar to that of a monofocal lens.

7

X-Wave Technology (Vivity IOL)



- Surface transition element #1 alters the wavefront, stretching it
- Surface transition element #2 shifts the wavefront
- The simultaneous actions deliver a naturally occurring continuous extended focal range
- **Femtosecond laser used to ensure centration of 2.2mm central zone of Vivity.**

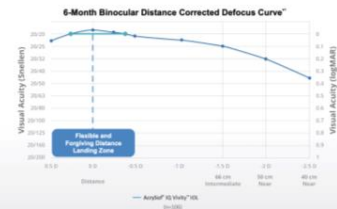
8

Vivity

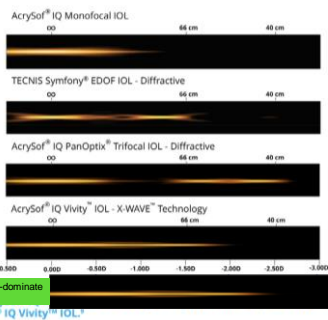


9

OUTSTANDING OVERALL PERFORMANCE: DESIGNED TO PROVIDE A CONTINUOUS EXTENDED RANGE OF VISION



10



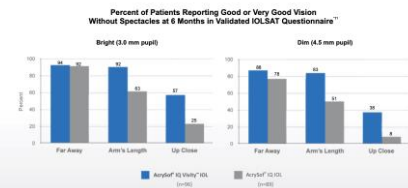
PL Dominate Eye

Target: -0.50 in Non-dominate Eye

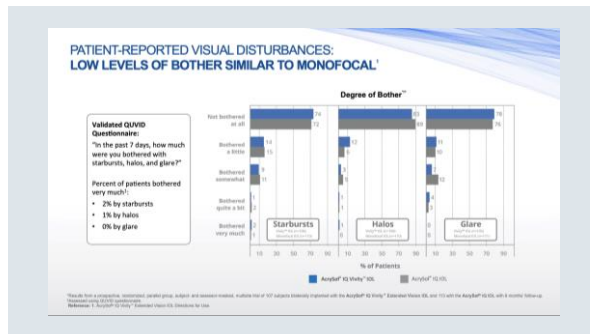
IOL and AcrySof® IQ Vivity® IOL

11

VISUAL QUALITY WITHOUT SPECTACLES: ENHANCED PERFORMANCE IN BRIGHT AND DIM LIGHT



12



13

"Originally, I felt the Vivity Lens would not be successful due to lack of near vision" – I was mistaken.

- Vivity Lens accounts for 60% - 70% of all my surgeries, it outpaces multifocal lenses at least 25 to 1.
- It outpaces monofocal lenses 3 to 1

14

Vivity Lens

- Natural EDOF of a 45-year-old with no side effects (no halos or dysphotopsia)
- 100% light energy to distance which is then "stretched" to give up to -1.50D depth of focus
- Patient can function without glasses from 20 inches to distance (no promise of 20/20)
- Patient will require low power readers (+1.25 or +1.50) for material smaller than newspaper print inside 20 inches

15

Patient Selection

- Vivity is a monofocal lens with an EDOF
- Anywhere you would use a monofocal IOL you could use Vivity
- Exceptions are patients with poor visual prognosis with diplopia requiring prism in glasses

16

Vivity = Superior Monofocal Lens

- Vivity should be thought of a superior monofocal lens and not grouped with multifocal lenses.

Incorrect Thinking

Monofocal vs. Vivity / Multifocal Lenses

Correct Thinking

Monofocal / Vivity vs. Multifocal Lenses

17

Patients that are Good Candidates

- Moderate dry eyes
- Fuchs corneal endothelial dystrophy
- ERM
- Previous LASIK
- Previous RK with reasonable topography
- Minimal VF defects
- Recent macular hole that is scheduled for surgical repair and favorable prognosis
- Stable ARMD / Macular Drusen
- OCD Patients that are obsessed with minimal imperfections in their vision
- Patient with glare complaints that have minimal cataract changes

18

MONOVISION

19

Previous Attempts to Treat Monovision

Monovision

- Historically for decades
 - One eye distance vision (plano)
 - Other eye near vision (-2.00D)
- Neither eye has middle bucket vision



Past Attempts to give patients "middle bucket" vision

- Multifocal lenses
 - Proved unsuccessful in several patients.
 - If a multifocal was used in the distance eye patients were disappointed with the quality of their distance vision and did not appreciate what they gained in middle bucket vision.
 - If used in near eye and targeted -1.00D, patients were disappointed in their quality of near vision and in certain cases (Symphony lens) they would develop a spiderweb dysphotopsia.

20

Better Approach to Monovision

- Plan:** Use a Vivity lens in distance eye
 - Patient has same quality of distance vision as with a monofocal lens
 - Patient has depth of focus of 1.5D giving them middle bucket vision
- The beauty of using Vivity in the distance eye for monovision patients, you are not taking anything away from the distance vision to give them middle vision.
- You're giving the patients something **EXTRA** they didn't have with traditional monovision.

21

Better Approach to Monovision

- Near Eye**
 - Prefer Vivity (Target -1.50 D)
 - Gives a nice depth-of-focus to -3.00D
 - When combined with distance eye (Vivity) get great range of vision
 - If patient can not afford two Vivity lenses, use a monofocal lens for near eye (target -2.00D)

22

Case Study - Monovision

- Dr. Thomas Cunningham 64 y.o. optometrist wears SCLs in monovision fashion
 - OD Distance, OS Near (-2.00D)
- Pre-Op**
 - OD -7.50 + 2.50 x 21 20/40
 - OS -7.50 + 1.25 x 17 20/30
- Surgery**
 - O.D. 1/22/2021 – Vivity Toric Lens with Femto target plano
 - O.S. 1/28/2021 – Vivity Lens with Femto target -2.00 D
- Results**
 - Refraction date 2/09/2021
 - O.D. PI -0.375x135 20/15
 - O.S. -2.00 sph 20/15
- With No Glasses**
 - O.D. has VA 20/20 from distance to 21 inches (53 cm)
 - O.S. has near vision of 20/20 from 18 inches -> 9 inches (23 cm)

23

“ I am ecstatic and will restrain myself and not hug Dr. Ernest next time I see him. I would describe myself as very Type A about my vision and I have to work at many different ranges. I wore mono vision correction in the exam room and never achieved this quality of vision.

-Thomas Cunningham, O.D.

24

Thomas Cunningham, O.D.



• <https://www.youtube.com/watch?v=wK8DFGx-H6Q>

25

VIVITY IN REVERSE

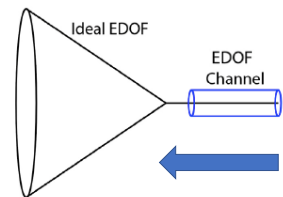
26

Vivity Lens “In Reverse”

- Great for low to moderate myopic patients who like to go without glasses most of their day except for distance activities
- Instead of setting Vivity Lens for:
 - Distance -> Middle -> Functional Near at 20"
- Reverse Process to:
 - Near -> Middle -> Functional Distance
 - Great for patients who spend vast majority of their day in middle and near vision

27

Vivity in Reverse



28

Case Study – Vivity Lens “In Reverse”

- 67 yo female, myopic, 90% of her day is middle to near activities, only small part of her day she spends walking her dog, watching tv and a little bit of driving.
- Pre-Op Refraction Pre-Op K's

• OD -4.25 - 2.50 x 105	OD 45.25 x 44.75
• OS -5.50 - 1.25 x 95	OS 45.50 x 45.50
- Plan:
 - Use Vivity in each eye. Target -1.00D OU
 - Result will be range of vision from -1.00D -> -2.50D
 - Patient will be able to do all her middle -> near activities without glasses
 - Patient will be able to do many distance activities without glasses (tv, walking her dog)
 - Patient will need driving glasses only (no bifocals or trifocals)
 - Patient had surgery – met her target and goals
 - Patient thrilled with her outcome

29

Case Study – Vivity Lens “In Reverse”

- 38 yo OD -7.00D with 4 +NS, OS -3.00D with no cataract
- Vivity in OD, target -2.00D – 2.50D
- The two eyes will be relatively the same for reading.
- The depth-of-focus of his OD will be similar to his natural accommodation of his OS eye.
- He will need glasses for distance vision.

30

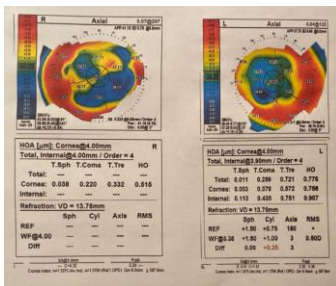
THE OTHER USES OF THE VIVITY LENS

31

Case Study

- 61 yo female
- 4 RK OU
- Pre-Op Refractive Error
 - OD +1.75 + 1.50 x 22 k's 39.25 x 41.00 x 49
 - OS +3.75 + 1.25 x 156 k's 37.25 x 38.25 x 138

32



33

Cast Study Cont.

- Plan**
- OD Vivity toric 22.5 T4
 - OS Vivity 25.0
- Post-Op Refraction**
- OD -0.25 + 0.50 x 164
 - OS Plano + 0.75 x 129

34

“The Hassle Factor”

- Surgeon and optometrists are preferring Vivity to Multifocal lenses due to lack of complaints from patients about their vision.
- No halos or glare from Vivity Lens
- Expectations are also predictable, patients aware of need for low power readers post-op for print smaller than that of a newspaper or inside 20 inches.

35

Pseudo Accommodating Myopic Shift

- Patients end up with a MR more Myopic than all calculations would indicate
- Example:
 - 66yo female
 - IOL calculation for emmetropia is 17.00 D
 - Used 16.50 D target plano -> +0.50 D
 - 1 week post op -0.25D sphere
 - 2-3 weeks post-op -0.75D sphere
- Need to push a “plus” when doing manifest refraction

36

What About Multifocal Lenses

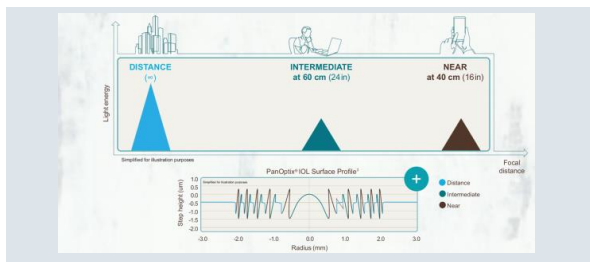
- Two current popular multifocal lenses
 - PanOptix
 - Synergy

PANOPTIX

37

38

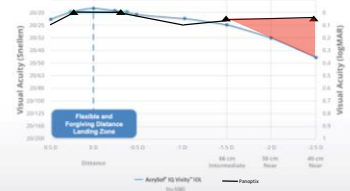
PanOptix



39

OUTSTANDING OVERALL PERFORMANCE:
DESIGNED TO PROVIDE A CONTINUOUS EXTENDED RANGE OF VISION

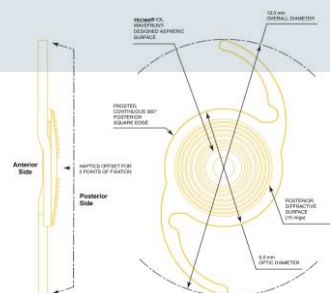
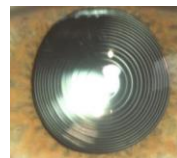
6-Month Binocular Distance Corrected Defocus Curve*



40

SYNERGY

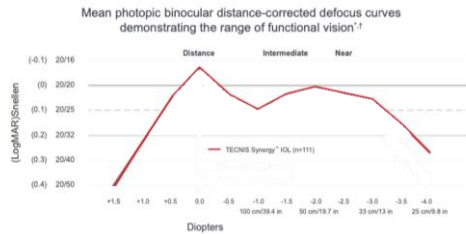
Synergy



41

42

Synergy



43

Multifocal Lenses

Panoptix

- Low myopia hyperopia
- Strong desire for spectacle independence
- Aware and accept halos
- Less halos
- Near 16"
- Middle 24"
- Need more light for near vision

Synergy

- Higher myopia -3.0 and greater
- Strong desire for spectacle independence
- Aware and accept halos
- More Halos
- Near 13"
- Better depth-of-focus due to Symfony component of the lens
- Can read in low light

44

Patient Selection Pre-op Discussion



- Using the bucket analogy, I determine relative hours spent in each bucket (distance, middle, and near)
- Get an idea of what activities your patient is most passionate about
- Ask the patient: Where is it most important for you to be spectacle free (near, distance)?
- Determine what is more important to the patient
 - Quantity of vision (spectacle independence)
 - Quality of vision (natural depth-of-focus) without side effects

45

Mix and Match One Eye Vivify / Other Eye Multifocal Lens

- First two cases were optometrists
 - Both myopic
 - Both wanted the near vision that multifocal lenses gives in one eye (dominant eye)
 - Both wanted the natural depth of focus from Vivify in second eye (non dominant) without halos
- Plan
 - Do non-dominant eye first – Vivify Lens
 - If patient not satisfied with lack of near vision, do multifocal lens in dominant eye
 - 5 patients with this combination

46

Two Factors that are Important in Successful Use of the Vivify and Multifocal Lenses

- Astigmatism control
- Reduction of higher order aberration (HOA) – Internal COMA

47

Astigmatism Control

- Reduction of pre-existing corneal astigmatism
 - Femtosecond laser
 - Works best for WTR corneal astigmatism up to 1.50D with axis of astigmatism 70° - 110°
 - Toric lens
 - Works best for oblique and ATR astigmatism
 - Recommended for WTR astigmatism greater than 1.50D

48

Astigmatism Control

- Wound construction
 - Prevention of change of axis of corneal astigmatism
 - If a toric lens is off axis by 10 degree – there is a 30% reduction in astigmatic treatment
 - Same is true if the axis of astigmatism shifts by 10 degrees
 - The more anterior the cataract incision – the more the shift in astigmatism axis
 - A posterior limbal incision that has a square configuration will not change the pre-existing axis of corneal astigmatism
 - That allows for a more accurate treatment of pre-existing corneal astigmatism

49

Case Example

- Patient had cat sx – toric lens
- Targeted 80-degree axis based on pre-op measurements
- Lens rotated to 70-degree axis 1-day post-op
- Using the “astigmatism fix formula” Berdahl and Hardten
 - New axis is at 90 degrees
- So not only did IOL rotate 10 degrees clockwise, but the axis of astigmatism shifted 10 degrees counterclockwise.
- If toric IOL did not rotate, treatment for astigmatism would be less effective due to axis shift from 80 degrees to 90 degrees

50

Reduction of HOA - COMA

- Coma is due to asymmetrical overlay of anterior capsule on optic of IOL
- When capsule contracts – get uneven forces on optic causing a “micro tilt” of lens
 - Not recognized on slit lamp exam
- Coma can be measured using Marco OPD Wavescan III
- Coma causes “flare” and reduction of contrast sensitivity
- Coma does not cause reduction of Snellen visual acuity
 - Reason why COMA problem is overlooked

51

STUDY: HIGHER ORDER ABERRATIONS FEMTOSECOND LASER-ASSISTED CATARACT SURGERY COMPARED TO MANUAL CATARACT SURGERY

Paul H. Ernest, M.D.

• Co-Authors: Marko Popovich; Matthew B. Schlenker, MD, FRCS;
• Lindsay Klumpp, O.D.; Ike Ahmed, M.D.

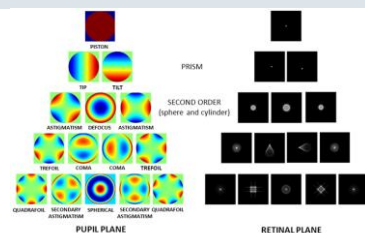
52

Recent publications¹ have shown no statistical difference regarding refractive error or uncorrected vision between FLACS and MCS

1. Popovic M, Campos-Moller X, Schlenker MB, Ahmed IK. Efficacy and safety of femtosecond laser-assisted cataract surgery compared with manual cataract surgery: a meta-analysis of 14567 eyes. Ophthalmology 2016;123(10):2113-26.

53

HOA



54

Study Parameters

- Evaluate patients with Symphony- and ReSTOR 2.5 lenses into two groups:
 - With femtosecond laser / without femtosecond laser
 - Data collected 2-14 months post-op using the Marco OPD-Scan III
- Excellent quality of surgery for each group
- Evaluate centration of lens with regards to visual axis (angle alpha, angle kappa)
- Evaluate internal coma of both study groups
- Evaluate refractive error and visual acuity
- Standardized patient satisfaction questionnaire for each patient
- Statistical analysis of results

55

Study Findings

No difference between femtosecond and non-femtosecond group

- Angle Alpha and Angle Kappa
- UCVA and BCVA
- Post-op refractive error

56

Statistical Analysis

	Symphony Femto n=32	ReSTOR 2.5 Femto n=25	Symphony Non-Femto n=50
Internal Coma μm	Range 0.019-0.296 AVG 0.109	Range 0.029 - 0.728 AVG 0.141	Range 0.029 - 2.052 AVG 0.275

	FLACS n=57	MCS n=50	p value
Internal Coma	0.12 ± 0.12	0.28 ± 0.41	p<0.05

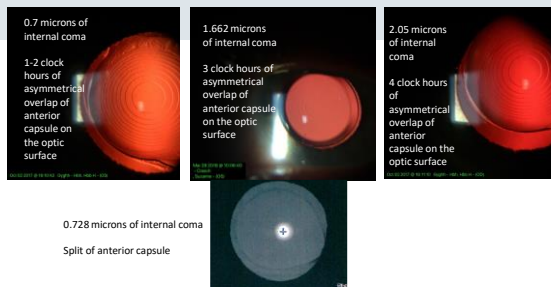
57

Outliers Internal coma ≥ 0.400 microns

Femtosecond Outliers	Non-Femtosecond Outliers
1/57	7/50

58

Study Findings Internal Coma – Outliers



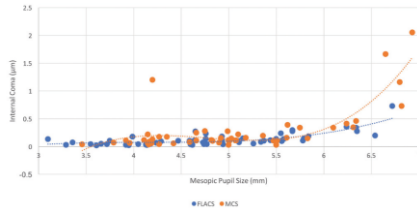
59

Study Findings Internal Coma



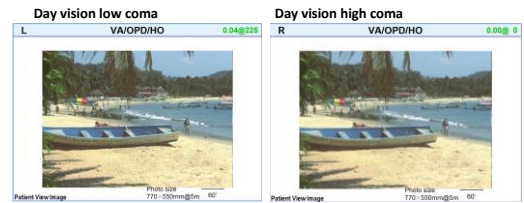
60

Scatterplot of the Relation between Mesopic Pupil Size and Internal Coma



61

Compare Patient with Low Internal Coma with Patient with High Internal Coma



62

Compare Patient with Low Internal Coma with Patient with High Internal Coma



63

Does the increase in internal coma impact patient satisfaction?

64

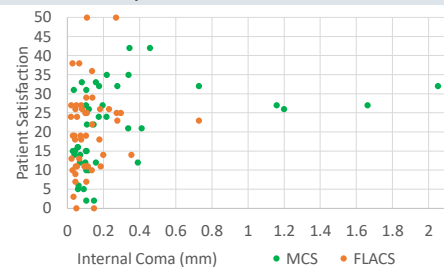
Study Findings Patient Satisfaction Survey Scores

- Patients were asked 30 questions from 10 categories with responses ranging from 0-3
 - 0 Not a problem
 - 1 Mild
 - 2 Moderate
 - 3 Severe
- 10 Categories Include
 - Glare
 - Halos
 - Starburst
 - Hazy Vision
 - Blurred Vision
 - Distortion
 - Multiple Images
 - Fluctuation in vision
 - Focusing difficulties
 - Depth perception

Coleman, J. D. et al. (2013). "The Development of an Instrument to Measure Quality of Vision: The Quality of Vision (QoV) Questionnaire." JAMA, November 2013, Vol. 310, No. 20.

65

Scatterplot of Relation between Internal Coma and Patient-Reported Satisfaction Scores



66

Comparison of satisfaction score and internal coma less than 0.20 microns

Satisfaction Score	% of People with Internal Coma of 0.20 μ or less
0-10 (n=15)	100%
11-20 (n=29)	93.1%
21-30 (n=30)	60%
>30 (n=15)	46.7%

($p < 0.001$)

67

HOA Study Summary

- There is a direct correlation between the overlap of the anterior capsule on the optic and higher order aberrations (internal coma)
- The more symmetrical the overlap of the anterior capsule on the optic, the lower the internal coma
- The Femtosecond laser gives a more symmetrical overlap of the anterior capsule on the optic ($p < 0.05$)
- Internal coma affects the quality of patients' vision under mesopic conditions especially with multifocal lenses (satisfaction survey)

68

Key Reasons for Success of Vivity

- **NO SIDE EFFECTS!!!!**
 - No Halos
 - No Glare
- Natural Depth of Focus to 20"
 - Not segmented vision as in MFL
- Versatility of the Vivity lens
- **Any patient** that is **eligible for a monofocal lens can have a Vivity Lens** providing
 - Reasonable vision potential
 - No diplopia

69

Summary

- Vivity has revolutionized cataract surgery
- **Important to use Femtosecond laser for precise centration**
- Multifocals still have a place in cataract surgery but to a lesser extent

70



QUESTIONS

71