



Evaluation of visual acuity with multifocal catenary curve-based contact lens design in different degrees of astigmatism

Gonzalo Carracedo, PhD

Professor Faculty of Optics and Optometry

University Complutense of Madrid



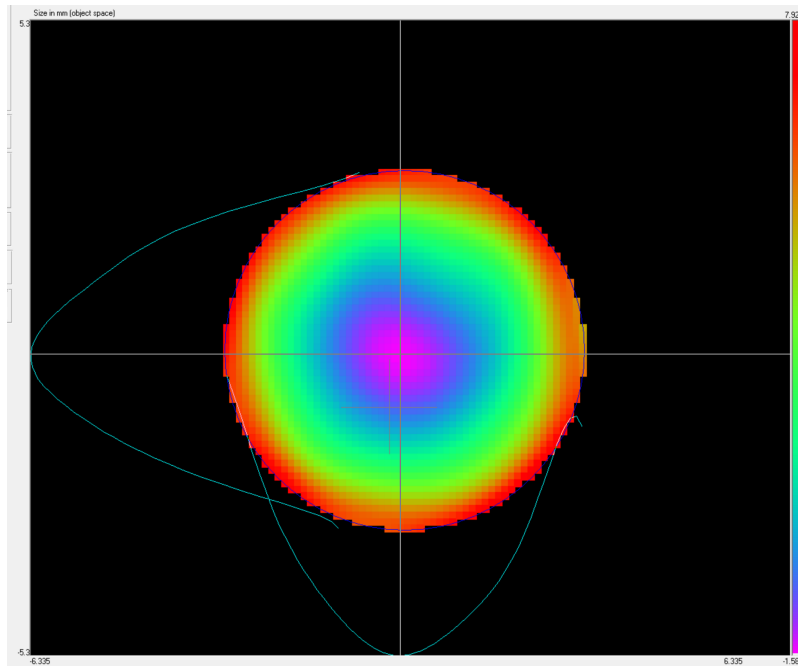
It's Getting Personal:
Customized Contact
Lens Care

January
15-18, 2025

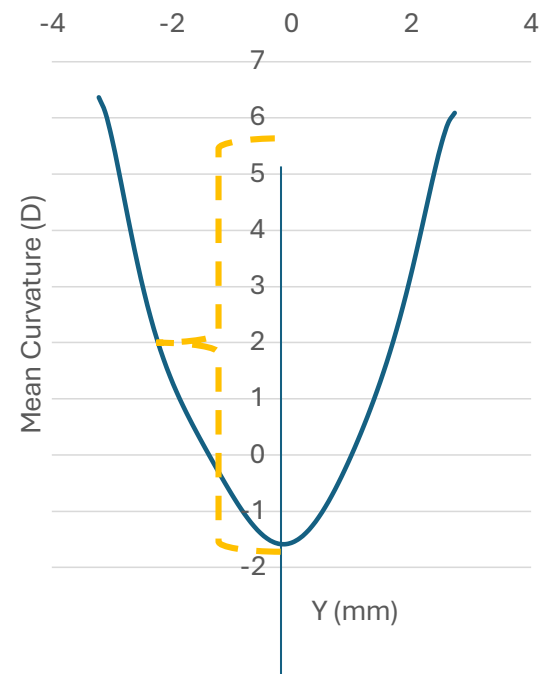
Horseshoe
Las Vegas

Catenary Power Profile

+8.00 D at 6mm diameter

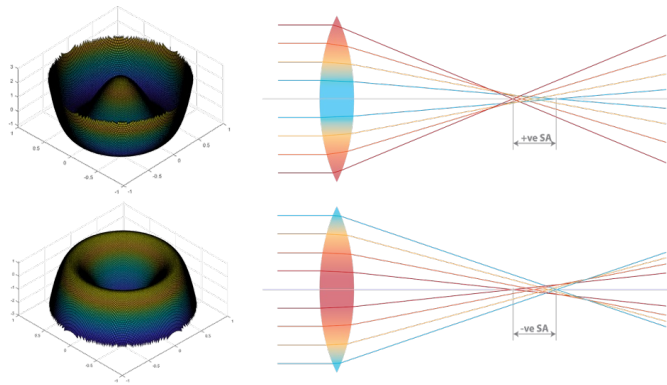


Hartmann-Shack Aberrometer

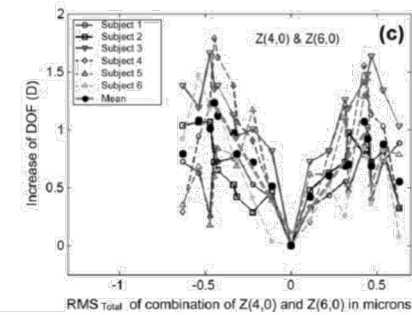
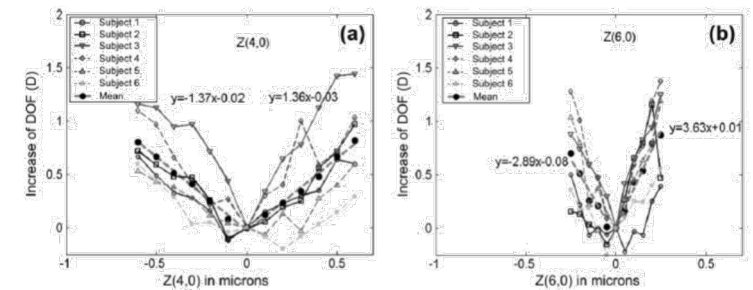


Depth of focus and astigmatism correction

Spherical Aberrations with Different Signs provide better efficiency to increase the Depth of focus

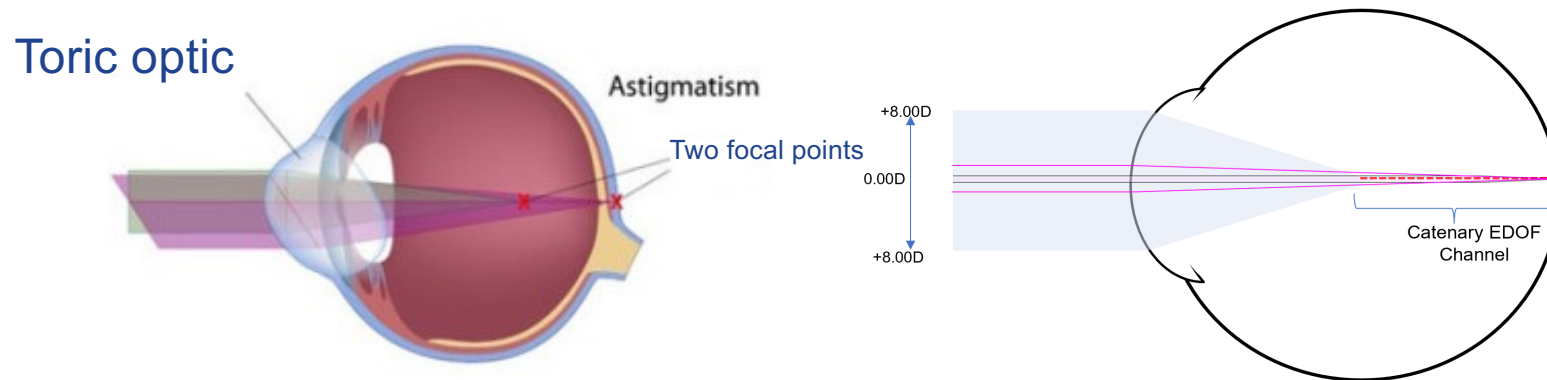


Creating spherical aberration, it is possible to obtain multifocality



Vision Research
 Depth of focus and visual acuity with primary and secondary spherical aberration
 Fan Yi^{1,2}, D. Robert Iskander^{1*}, Michael Collins¹
 *Corresponding author: d.iskander@ucl.ac.uk
¹Department of Ophthalmology and Visual Science, University College London, London, UK
²Department of Optometry, University of Northumbria, Newcastle, UK
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Depth of focus and astigmatism correction



- The astigmatic eye has two focal points
- EDOF channel can correct astigmatism (both meridians can be in focus at the same time) [The same way it corrects presbyopia]
- Approved for up to 2.00 DC



Clinical Study Report

2024 NaturalVue Multifocal Astigmatism Trial

**Principal investigator
Gonzalo Carracedo, PhD**

Study Code:	OC-VTI-0224-ECI
Report Date:	November, 2024
Sponsor Company:	Visioneering Technologies, Inc.
Document Type:	Report
Study Category:	Clinical Trial
Start Date:	10 th September 2024
Finish Date:	31 st October 2024
Clinical Site:	Ocupharm Diagnostics S.L., Faculty of Optics and Optometry; Universidad Complutense de Madrid



**Researcher
Ana Privado, PhD**



Main Objective

**Generate Scientific evidence and
Clinical data to support
the NaturalVue Multifocal
indication of astigmatism
correction up to 2.00 DC**



Study design

1. GROUPS

Divided in:

LA: Low Astigmatism

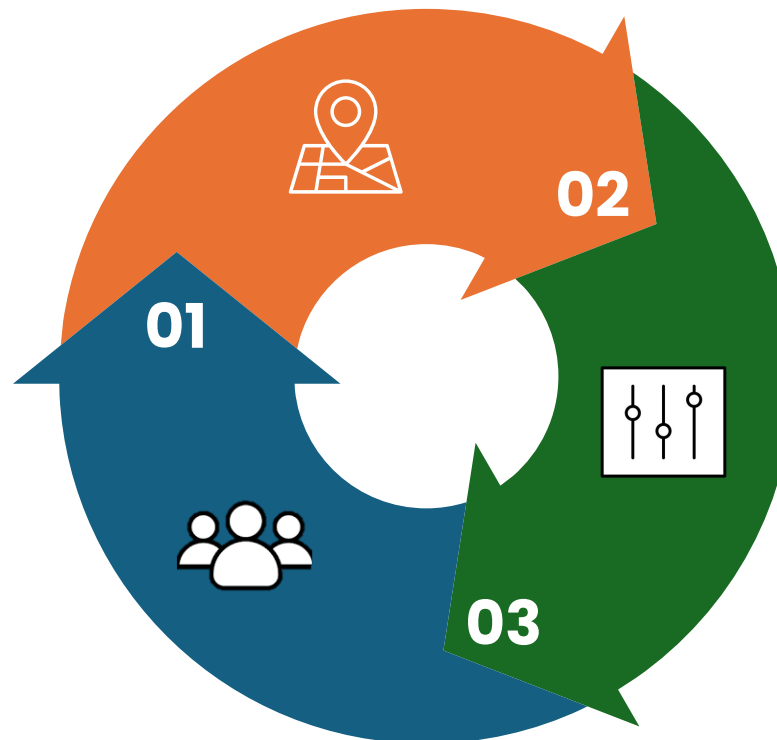
Between -0.75 and -1.25D

MA: Medium Astigmatism

From -1.50 to -2.00D

HA: High Astigmatism

Between 2.25 and -3.00D



2. VISITS

V1: enrollment; screening; order.

V2: Lens fitting and dispense.

V3: 1d follow up.

V4: 1w follow up; study exit.

3. PARAMETERS

High contrast distance binocular visual acuity (HCDBVA).

Stereopsis.

Subjective vision quality.

Subjective overall comfort.

Patients

	LOW ASTIGMATISM	MEDIUM ASTIGMATISM	HIGH ASTIGMATISM
Male / Female (n)	0 / 12	2 / 10	2 / 4
Age Mean \pm SD (min-max)	22.33 \pm 4.75 (19-33)	25.67 \pm 7.25 (19-39)	21.40 \pm 2.07 (20-25)
Sphere (D) Mean \pm SD (min to max)	-2.19 \pm 1.89 (-5 to +0.75)	-2.13 \pm 2.63 (-6.25 to +2.00)	-2.29 \pm 2.49 (-5.00 to +2.25)
Cylinder (D) Mean \pm SD (min to max)	-0.9 \pm 0.19 (-1.25 to -0.50)	-1.68 \pm 0.31 (-2.00 to -1.25)	-2.58 \pm 0.37 (-3.00 to -2.00)
K flat (D) Mean \pm SD (min to max)	43.71 \pm 0.75 (42.08 - 45.06)	42.90 \pm 2.06 (40.02 - 46.66)	42.75 \pm 1.26 (40.95 - 44.97)
K steep (D) Mean \pm SD (min-max)	44.99 \pm 1.02 (42.87 - 46.41)	44.87 \pm 2.16 (41.88 - 48.38)	45.53 \pm 1.56 (42.8 - 47.65)
HVID Mean \pm SD (min-max)	11.47 \pm 0.28 (11.0 - 12.1)	11.67 \pm 0.33 (11.1 - 12.5)	11.94 \pm 0.45 (11.3 - 12.6)
Photopic pupil size (mm) Mean \pm SD (min-max)	3.54 \pm 0.74 (2.5 - 4.8)	3.47 \pm 0.44 (2.7 - 4.3)	3.54 \pm 0.54 (2.9 - 4.4)

Lens parameters

Manufacturer	Visioneering Technologies, Inc.
Material	etafilcon A
FDA Class	Group 4
WC %	58%
Refractive Index	1.402
Base Curve (mm)	8.3
Lens Diameter (mm)	14.5
Sphere Power (D) Available	73
Wearing Schedule	Daily Disposable Wear
Oxygen Permeability (Dk)	19.73



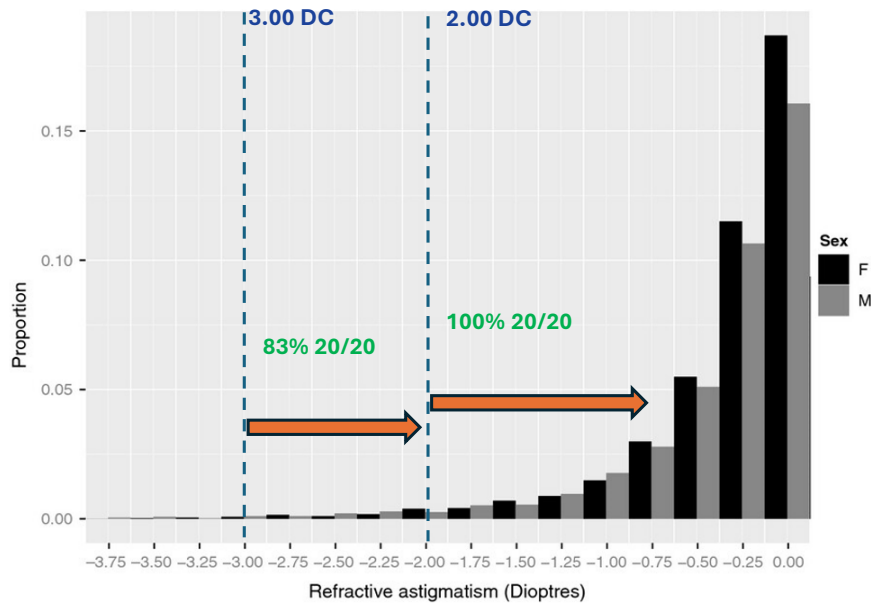
Binocular Distance Visual Acuity

	NaturalVue Multifocal VA 1-day follow-up	NaturalVue Multifocal VA 1-week follow-up	P value
LOW ASTIGMATISM	-0.15 ± 0.08	-0.16 ± 0.06	0.639
MEDIUM ASTIGMATISM	-0.13 ± 0.09	-0.09 ± 0.08	0.280
HIGH ASTIGMATISM	-0.06 ± 0.09	-0.02 ± 0.06	0.526

P-value > 0.05, Student's t-test for related samples.

W1 Binoc VA	(logMAR)	Avg±SD
-0.75 to -1.00 DC	n = 12	-0.16 ± 0.06
20/20 or better	100%	
20/15 or better	100%	
-1.25 to -2.00 DC	n = 12	-0.09 ± 0.08
20/20 or better	100%	
20/15 or better	67%	
-2.25 to -3.00 DC	n = 6	-0.02 ± 0.06
20/20 or better	83%	
20/15 or better	33%	

Binocular Distance Visual Acuity



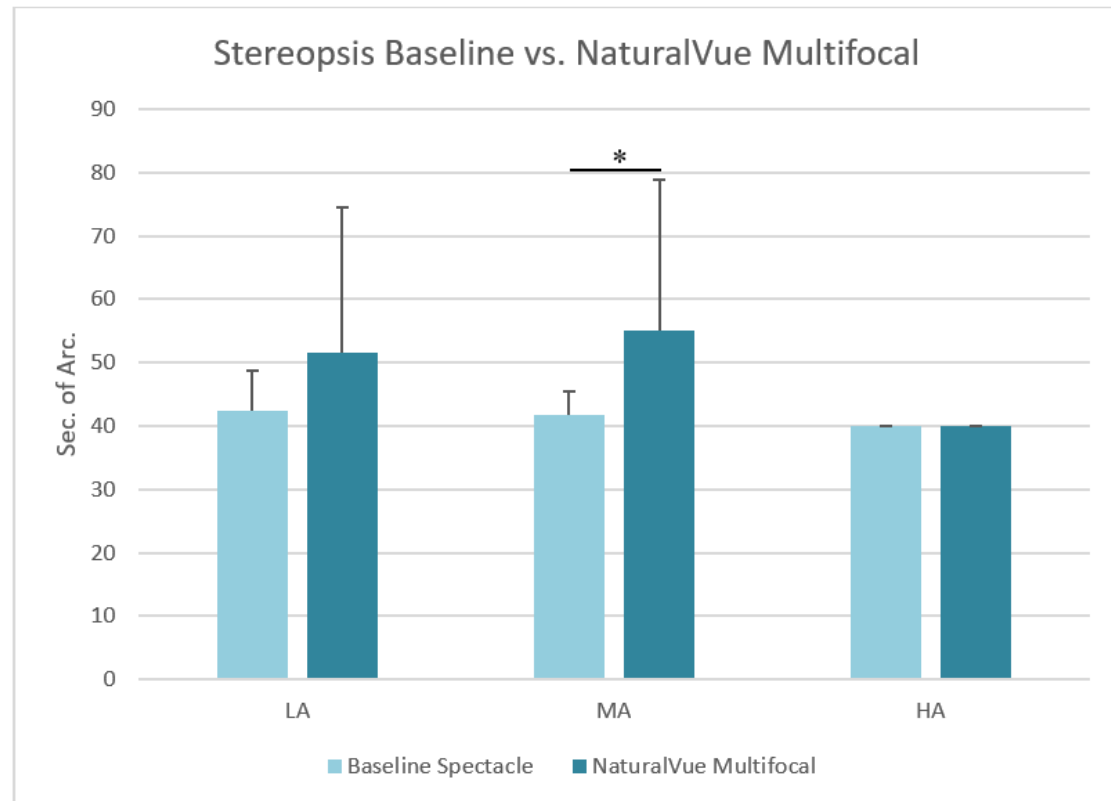
Acta Ophthalmologica, Volume: 93, Issue: 5, Pages: e377-e385, First published: 13 January 2015, DOI: (10.1111/aos.12644)

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Stereopsis

**Differences non-clinical
relevant.**

Stereopsis preserved.



Visual Analogue Scale

1. How would you rate your overall visual quality with these contact lenses, both far and near vision? The value of 0 represents very poor vision, while a value of 100 indicates perfect vision.
2. How is your overall comfort and overall satisfaction with these contact lenses? A value of 0 represents a very poor sense of comfort and overall satisfaction, while a value of 100 indicates a very good sense of comfort and overall satisfaction.

Up to 49

Unsatisfactory

Between 50 and 79

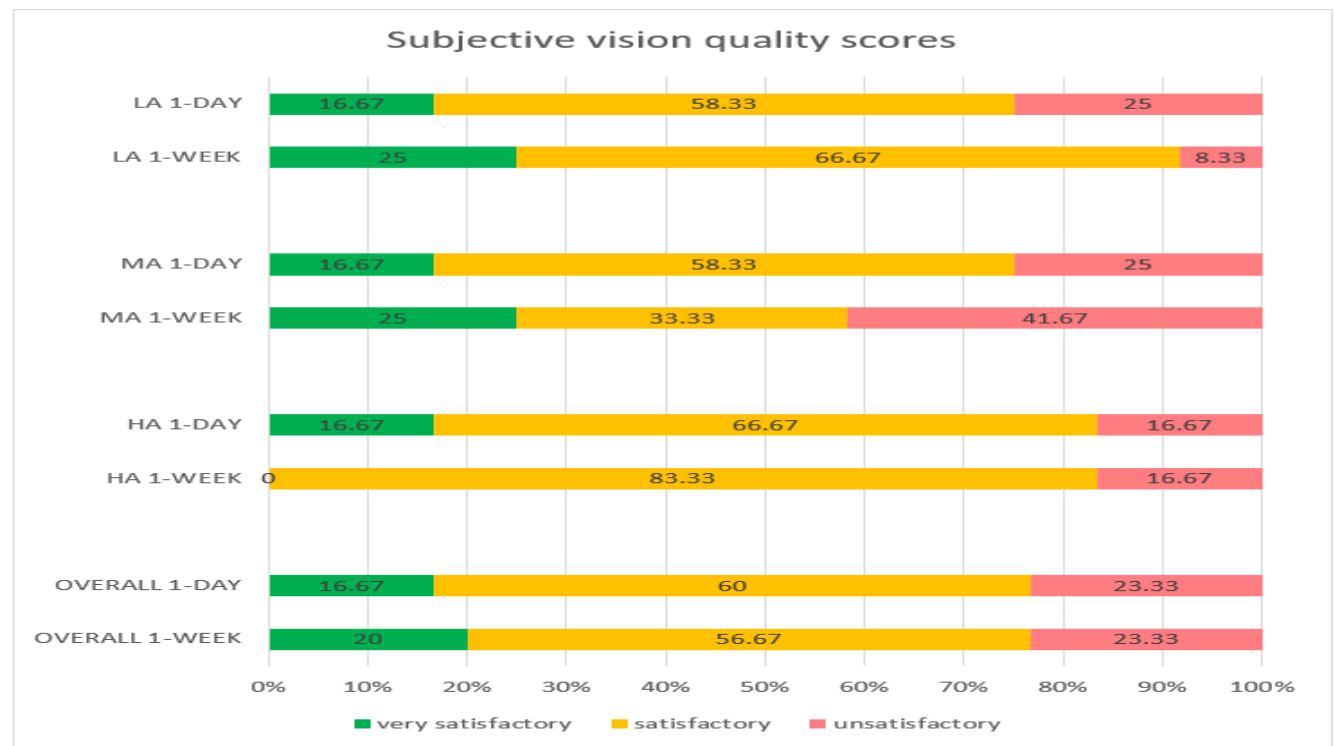
Satisfactory

More than 80

Very satisfactory

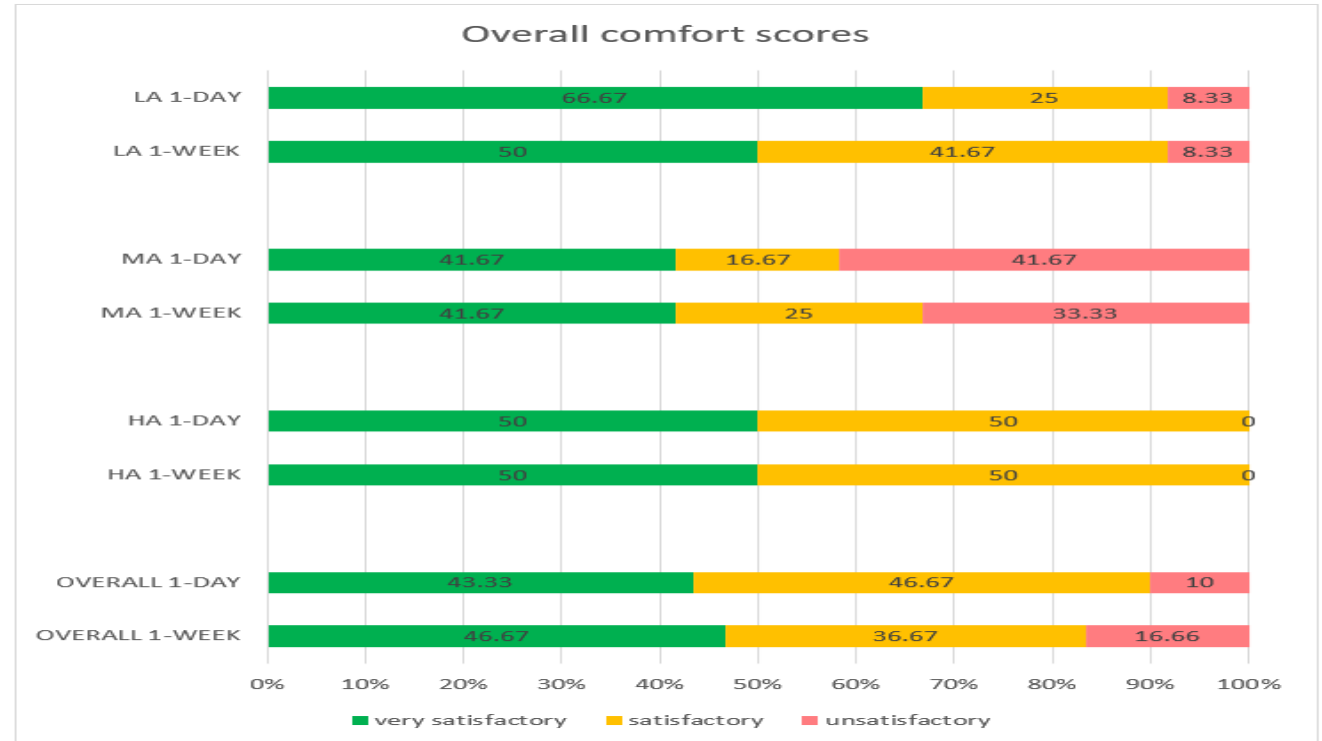
Subjective Vision Quality

**High Vision
Quality
in the 3 groups
studied**



Subjective Overall Comfort

**High Overall
comfort
in the 3 groups
studied**

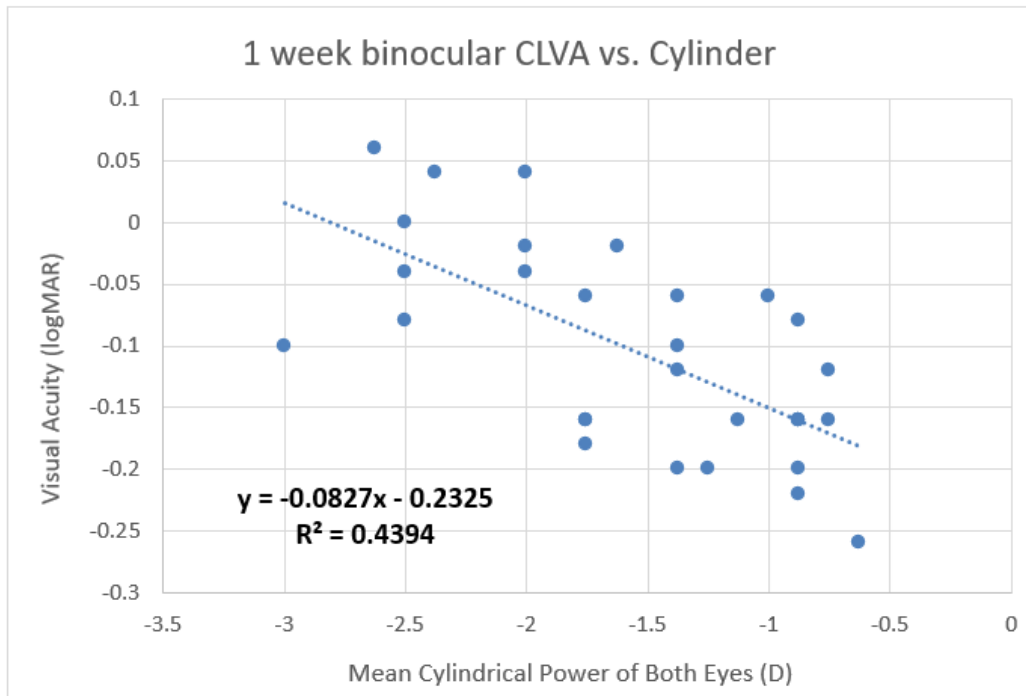


Adverse Events

	Baseline	NaturalVue Multifocal VA	P value
Conjunctival redness	0.27 ± 0.07 (0 – 2)	0.23 ± 0.08 (0 – 2)	0.593
Corneal staining	0.30 ± 0.08 (0 – 2)	0.29 ± 0.09 (0 – 2)	0.782
Conjunctival staining	0.23 ± 0.09 (0 – 3)	0.07 ± 0.03 (0 – 1)	0.071
Other finds	0.00 ± 0.00 (0 – 0)	0.00 ± 0.00 (0 – 0)	1.000

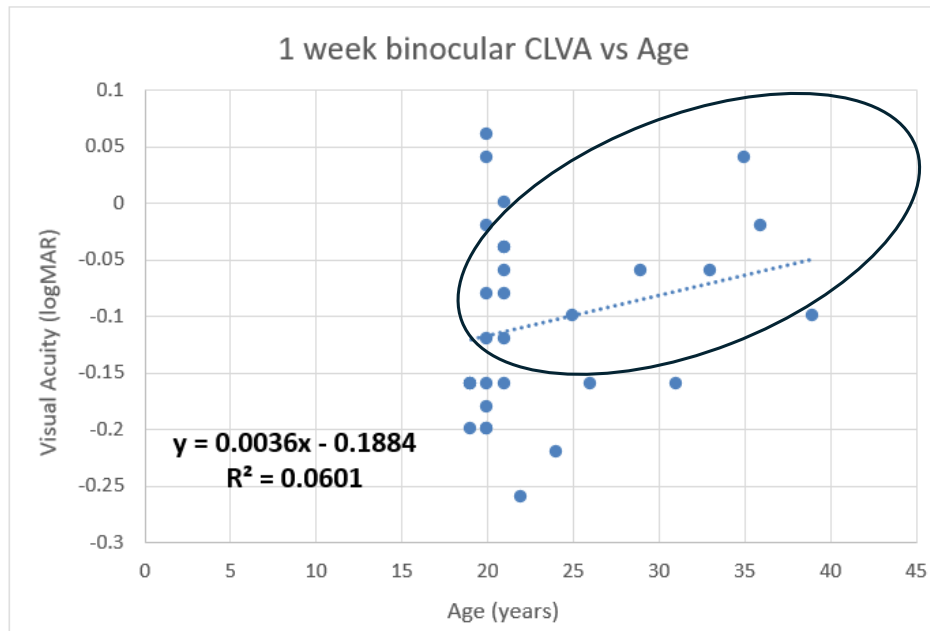
No adverse events found.

Predictors of Visual Acuity

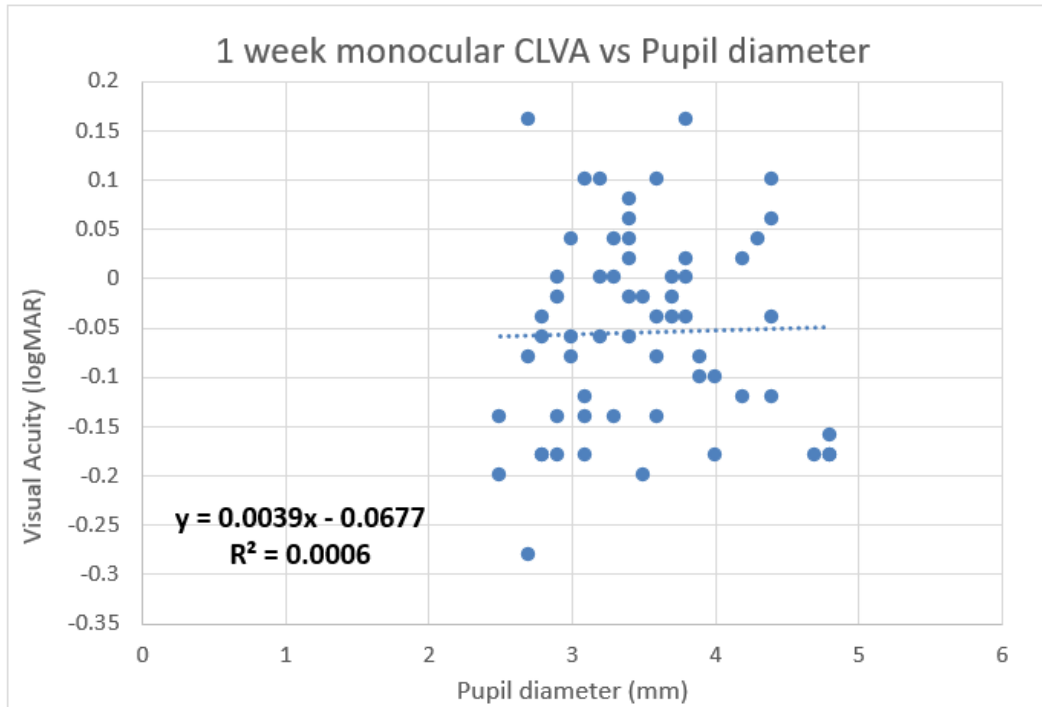


Among the range of vision,
mild association with
Magnitude of cylinder

Predictors of Visual Acuity



Predictors of Visual Acuity



Summary

- The study demonstrated that NaturalVue® Enhanced Multifocal lenses effectively corrected (with 20/20 or better vision)
- 77% rated their Overall Visual Quality as satisfactory or very satisfactory
- 83% rated their Overall Comfort as satisfactory or very satisfactory
- Stereopsis preserved
- Works well with all pupil sizes

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Conclusions

- The study found that, unlike traditional toric optics, NaturalVue Multifocal corrects an extensive range of astigmatism by enabling both meridians to focus simultaneously.
- This clinical trial validated the NaturalVue Multifocal lens's astigmatism correction indication. Multifocal catenary curve-based contact lenses are a viable option for patients with astigmatism, and can potentially reduce additional chair time needed for toric soft contact lens fitting.
- The lenses provided good visual performance and satisfaction patient feedback in vision and comfort, with no reported adverse events.



UNIVERSIDAD
COMPLUTENSE
MADRID

OCUPHARM
Research Group 


OCUPHARM
DIAGNOSTICS

 REDEFINING
VISION

Thank you

jgcarrac@ucm.es

 GLOBAL
SPECIALTY LENS
SYMPOSIUM

It's Getting Personal:
Customized Contact
Lens Care

January
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 Horseshoe
Las Vegas