# Initial clinical outcomes of a new presbyopia-correcting extended depth of focus intraocular lens

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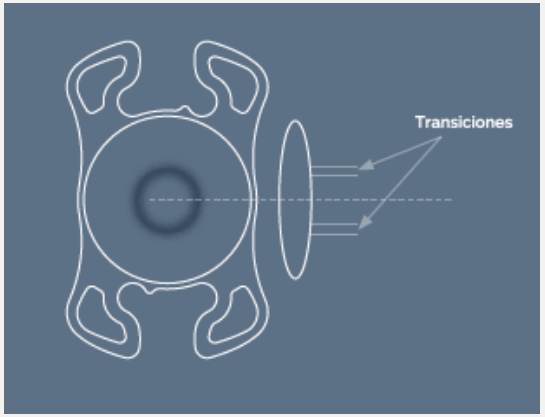
# Aim of the study

To evaluate the **initial outcomes** of the new **Synthesis® plus** extended depth of focus (**EDOF**) intraocular lens (IOL) in terms of **vision** (distance and near visual acuities), **efficacy** (subjective refraction), and **safety** (endothelial cell count and complications)



# Materials & Methods

- Single-center, prospective, interventional study
- **37 eyes** (21 right:16 left) of 37 patients (15 ♂:22 ♀)
- Nov 2019 – Sep 2020 at Centro de Oftalmología Barraquer
- Single surgeon (EB) – target refraction: emmetropia
- **Synthesis® plus EDOF IOL**
- **2-mm** micro-incision on the corneal steep axis
- Stellaris® PC platform (Bausch & Lomb, Inc., USA)
- IOL Master 700 (Carl Zeiss Meditec, Jena, Germany), **Barrett Universal II** formula

# Materials & Methods

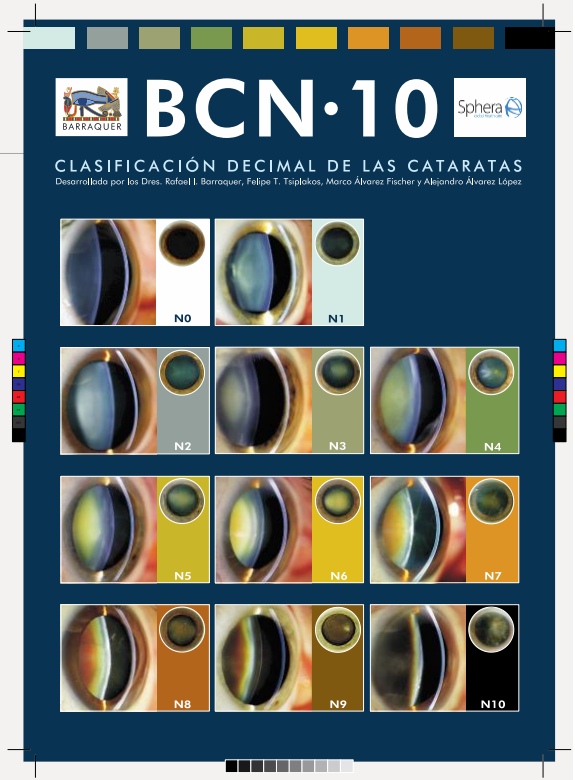
Primary outcomes:

- Uncorrected (UC) and best-corrected (BC) distance (DVA), intermediate (IVA), and near (NVA) **visual acuity**, and **endothelial cell count** (ECD)

Secondary outcomes:

- Subjective refraction (sphere, cylinder, SE)
- Nucleus grading (BCN 10*)
- IOL power
- US metrics  (power %, total time, real time)
- IOP and complications

Timepoints: preoperatively, 1 week and 1 month

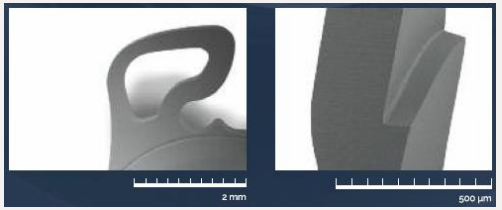



*Barraquer RI et al. Ophthalmic Res. 2017;57(4):247-251

# Synthesis plus® IOL

## Technical features

- Single-piece, preloaded, hydrophilic acrylic
- 6-mm aspheric optic with square double C-edge design
- 4 haptics with 0° angulation
- Power range: +0.0D to +32.0D
- It can be injected through a 1.6-mm
- Diameter: 10.5-11 mm (based on power)
- A-constant: 118.0
- Refractive index: 1.459 at 35°C



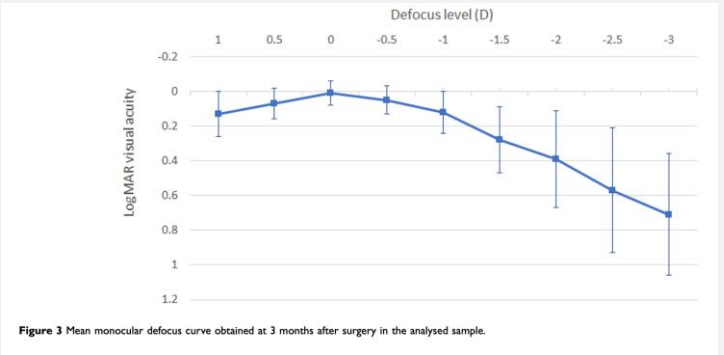




**Figure 3** Mean monocular defocus curve obtained at 3 months after surgery in the analysed sample.

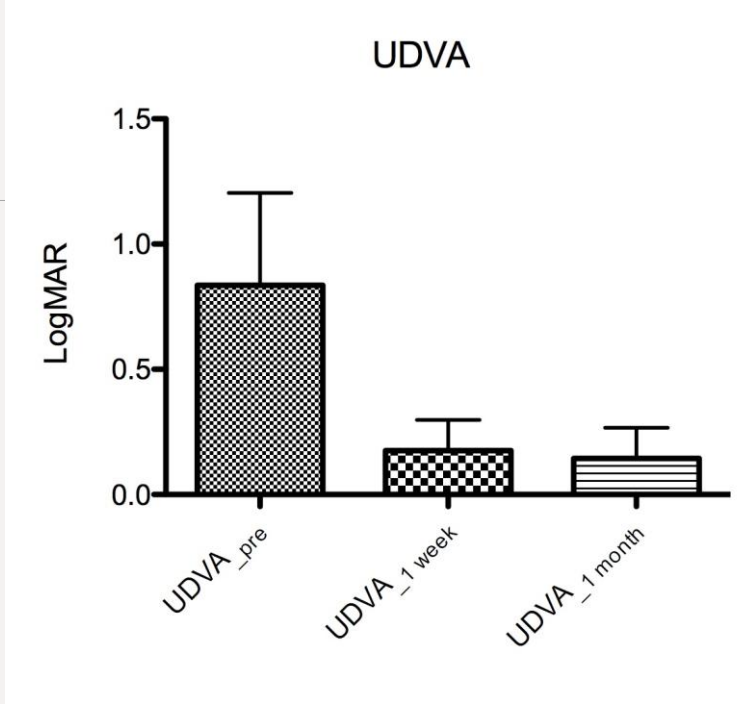
Iradier et al. Clinical Ophthalmology 2021:15 1215–1221

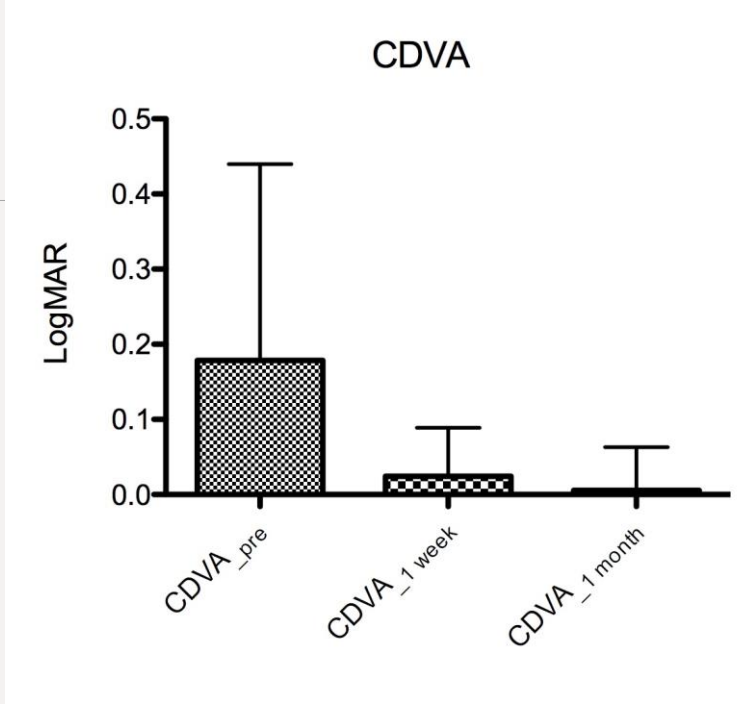
# Results

- Age: 65.9±8.7 years (range 45-80)
- Degree of cataract (BCN-10): 2.6±1.7 (range 0-5)
- IOL power: 21.6±5.4 D
- US metrics:
  - Power: 9.8±5.4%
  - Total time: 15.4±13.4 seconds
  - Actual time: 2.1±1.9 seconds

| Mean (SD)<br>Median (range) | Preoperative | 1 week | 1 month | p-value<br>(preop-1 month) |
|---|---|---|---|---|
| LogMAR UCDVA | **0.8** (0.4)<br>1.0 (0.2 to 1.5) | 0.2 (0.1)<br>0.2 (0.0 to 0.5) | **0.1** (0.1)<br>0.2 (-0.04 to 0.5) | **<0.0001 *** |
| LogMAR BCDVA | **0.2** (0.3)<br>0.1 (-0.1 to 1) | 0.02 (0.1)<br>0.0 (-0.1 to 0.2) | **0.01** (0.1)<br>0.0 (-0.1 to 0.1) | **0.0002 *** |
| LogMAR UCIVA | -<br>- | 0.2 (0.1)<br>0.2 (0.0 to 0.5) | **0.2** (0.1)<br>0.2 (0.0 to 0.4) | 0.9049 ‡ |
| LogMAR BCIVA | -<br>- | 0.2 (0.1)<br>0.2 (0.1 to 0.3) | 0.2 (0.3)<br>0.1 (-0.1 to 1.1) | 0.6613 ‡ |
| LogMAR UCNVA | -<br>- | 0.2 (0.1)<br>0.2 (0.1 to 0.5) | **0.2** (0.1)<br>0.2 (0.1 to 0.4) | 0.9352 ‡ |
| LogMAR BCNVA | **0.2** (0.3)<br>0.1 (-0.1 to 1.1) | 0.1 (0.1)<br>0.1 (-0.1 to 0.2) | **0.1** (0.1)<br>0.1 (-0.1 to 0.2) | **0.0012 *** |
| Sphere (D) | 0.25 (4.3)<br>0.75 (-14.0 to 8.0) | -0.2 (0.5)<br>0.0 (-1.75 to 1.25) | -0.2 (0.5)<br>0.0 (-1.75 to 1.25) | 0.3341 |
| Cylinder (D) | -0.6 (0.6)<br>-0.5 (-2.5 to 0.0) | -0.7 (0.5)<br>-0.75 (-2.0 to 0.0) | -0.7 (0.5)<br>-0.75 (-1.75 to 0.0) | 0.5288 |
| SE (D) | -0.1 (4.3)<br>0.13 (-14.4 to 7.6) | -0.6 (0.6)<br>-0.5 (-2.8 to 0.9) | -0.5 (0.6)<br>-0.5 (-2.6 to 0.9) | 0.3380 |

UCVA: uncorrected visual acuity; BCVA: best-corrected visual acuity; DV: distance vision; IV: intermediate vision; NV: near vision; SE: spherical equivalent; D: diopters; SD: standard deviation; preop: preoperative; * statistically significant; ‡ 1 week-1 month




At 1 month, **all** the eyes achieved a **BCDVA** of **0.1** or better, 15 eyes (**40.5%**) achieved **UCIVA** of **0.1**, 24 eyes (**64.9%**) **0.2**, and 30 eyes (**81.1%**) **0.4** or better. Finally, 8 eyes (**21.6%**) achieved **UCNVA** of **0.1**, 19 eyes (**51.4%**) **0.2**, and 32 eyes (**86.5%**) **0.3** or better.

# Conclusions

Both **c-ACXL** and **p-ACXL** seem to be equally **safe** and **effective** ACXL protocols in **stabilizing progression** of keratoconus and can be considered as alternatives to the conventional Dresden protocol.

Nonetheless, more clinical trials on **long-term** efficacy and safety with more patients may be required in the future.

# THANK YOU FOR YOUR ATTENTION!

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