Clinical outcomes of a new micro incision IOL INCISE®
## INCISE® IOL Characteristics

<table>
<thead>
<tr>
<th>Design</th>
<th>One-piece, posterior chamber IOL</th>
</tr>
</thead>
</table>
| Power range             | + 0.0 D to +10.0 D in 1.0 D increments  
     +10.0 D to +30.0 D in 0.50 D increments |
| Material                | Enhanced hydrophilic acrylic     
     22% water content 
     RI: 1.47 at 35°C  
     10% cut-off at 371nm (20D) |
| Optic:                  | Optic diameter: 6.0 mm @ 20D     
     Aberration-free aspheric |
| Overall Length          | 11.0 mm                          |
| Haptics                 | Optimized angulated haptics with 
     fenestration holes and orientation features |
| Edge Design             | 360° sharp posterior optic edge  
     Less than 5 microns radius |
| Optical biometry        | Suggested A constant: 119.1      |
|                         | New single – use Viscoject 1.5 BIO injector (Ref LP604361). |
Objective: evaluate the visual and refractive outcomes, the centration and the PCO incidence after INCISE® implantation. Prospective, Ethics Committee approved Study

100 patients

4 post-operative visits at 1-2 Days (V1); 7-15 Days (V2); 1-2 Months (V3) and 4 – 6 Months (V4) after surgery.

5 European sites: France, Germany, Italy, Spain and Sweden

Study endpoints:

• Incision size for implantation
• Uncorrected (UDVA) and Best corrected (CDVA) distance visual acuity
• Manifest Refraction
• Accuracy to target for MRSE
• IOL Centration; EPCO evaluation
Interim analysis
50 eyes at V3 (1-2M)

Gender: 20 males / 30 females
Eye: 27 OD / 23 OS
Age (mean ± SD): 71.3 ± 7.3 Range: 48 – 86 Years
Cataract:
- nuclear (38%), cortical (16%), sub capsular (8%), combination (38%)
- slight (20%), moderate (34%), dense (46%)

Biometry - A constant 119.1 – SRK/T formula
Axial Length (mean ± SD): 23.31 ± 0.8 mm Range: 21.41 – 25.15
Mean Keratometry (mean ± SD): 43.71 ± 1.4 D Range: 40.67– 46.88
Corneal Cylinder (mean ± SD): 0.76 ± 0.3 D Range: 0.27– 1.38
Power Range: 16.0 D to 27.0 D
All surgeries were performed with the Stellaris® Vision Enhancement System, using:
- the micro Coaxial (C-MICS) procedure in 25 eyes
- the Bi-axial (B-MICS) procedure in 25 eyes

The INCISE® IOL was injected using the Medicel VISCOJECT 1.5 single-use injector (Ref LP604360).

After 1.8mm C-MICS surgery, without enlargement of the incision, the lens was implanted in the bag (standard injection technique).

After B-MICS surgery the surgeon enlarged the incision to approximately 1.4 mm before implanting the lens using the wound assisted technique (WAT).
Incision size for implantation

Incision size was measured using gauges from 1.0 to 2.5mm by 0.1mm step (Asico Gauges - Ref AE-1574T) before and after INCISE® IOL injection, anterior chamber filled with viscoelastic.

Incise size after injection (Mean± SD)

In the bag technique
1.9 ± 0.1 mm with a mean stretch of 0.06 ± 0.08 mm

Wound assisted technique
1.6 ± 0.1 mm with a mean stretch of 0.17 ± 0.13 mm
Distance Visual Acuity

**Distance Visual Acuity 1-2 Months**

<table>
<thead>
<tr>
<th>20/20</th>
<th>20/25</th>
<th>20/32</th>
<th>20/40</th>
</tr>
</thead>
<tbody>
<tr>
<td>46.0%</td>
<td>68.0%</td>
<td>82.0%</td>
<td>88.0%</td>
</tr>
</tbody>
</table>

**V3 (1-2M)**

<table>
<thead>
<tr>
<th>In logMAR</th>
<th>UDVA N=50</th>
<th>CDVA N=50</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean ± SD</td>
<td>0.12 ± 0.16</td>
<td>-0.04 ± 0.07</td>
</tr>
<tr>
<td>Snellen</td>
<td>20/25</td>
<td>20/20</td>
</tr>
</tbody>
</table>

**Snellen**

- **20/25**
- **20/20**
Target Refraction (mean ± SD): 
\(-0.28 \pm 0.16\) D

MRSE (mean ± SD): 
\(-0.23 \pm 0.64\) D

88% of eyes achieved a MRSE within 1.00D of the target.
The IOL was imaged using digital slit lamp biomicroscopy. To determine IOL centration, the distance between the centers of the IOL optic edge and the pupil margin was calculated*. Centration measurements were in the form of x (horizontal distance) and y (vertical distance) co-ordinates. Total distance h was calculated using Pythagoras equation (\( h^2 = x^2 + y^2 \)).

**Absolute total centration (mean ±SD)**

V3 (n=45): 0.29 ± 0.15 mm

consistent with conventional one- or three-piece IOLs (0.20 to 0.60 mm on average)**

---

* WOLFFSOHN JS., BUCKHURST PJ: Objective analysis of toric intraocular lens rotation and centration JCRS, 2010; 36:778–782
All adverse events and complications reported during the 1-2 months follow-up of these 50 eyes were expected events after any cataract surgery with IOL implantation.

There were no unique reports associated with INCISE®.
In conclusion

Both 1.4mm wound assist and 1.8mm in the bag implantation of the INCISE® micro incision IOL were safe and effective sub-2 MICS procedures in this study.

IOL performance during implantation and placement in the capsule was controlled and predictable.

The INCISE® IOL exhibited good visual and refractive outcomes at 1-2 Months: mean UDVA of 20/25 and mean CDVA of 20/20. 88% of the eyes ± 1.0D of the target refraction. Better outcomes may be achieved with greater experience, personalizing the A constant.

The INCISE® IOL demonstrated predictable and stable centration 1-2 months post implantation. 6M follow-up should confirm this good IOL behavior.

Long-term results will be evaluated to assess the posterior capsule opacification.

®/™ are trademarks of Bausch & Lomb Incorporated or its affiliates. All other brand/product names are trademarks of their respective owners. © Bausch & Lomb Incorporated.