The aim of this retrospective study was to evaluate the medium-term results of Visian ICL (ICH V3) to correct moderate and high hyperopia (> + 4 D). Endpoints were: efficacy, predictability, stability, safety, intraocular pressure (IOP), vault, endothelial cell count over time, and adverse events. A self-administered questionnaire concerning overall subjective satisfaction with surgery outcomes and post-operative vision was issued at the last follow-up visit. 28 eyes of 15 patients were enrolled in the study, mean follow-up was 3.6 years (range 3 to 6 years), mild to moderate degrees of amblyopia were observed in 15 eyes (54% of eyes).

Results: Primary Endpoints

Efficacy  See fig. 1

- One year postoperatively, UDVA was 20/40 or better in 83% of eyes and 20/20 or better in 50% of eyes.

Predictability & Stability  See fig. 2

- At the 3 year follow-up visit, 86% of eyes were within ±1.00D manifest refraction spherical equivalent (MRSE) and 52% were within ±0.50D.

Results: Secondary Endpoints

<table>
<thead>
<tr>
<th></th>
<th>Pre-operative (n=28)</th>
<th>1 month (n=28)</th>
<th>1 year (n=24)</th>
<th>3 Years (n=21)</th>
<th>Last follow-up visit (n=28)</th>
<th>P†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraocular Pressure (mmHg)</td>
<td>15±3.2 (9 to 21)</td>
<td>13.8±2.3 (10 to 19 )</td>
<td>14±2.6 (9 to 24)</td>
<td>14.2±2.8 (10 to 21)</td>
<td>14.5±2.7 (10 to 21)</td>
<td>.3552</td>
</tr>
<tr>
<td>Vault (µm)iii</td>
<td>N/A</td>
<td>367.1±253.6 (70.0 to 1190.0)</td>
<td>317.5±240.3 (90.0 to 1010.0)</td>
<td>N/A</td>
<td>283.6±210.0 (75.0 to 915.0)</td>
<td>.0049*</td>
</tr>
<tr>
<td>Anterior chamber depth (mm)</td>
<td>2.96±0.27 (2.60 to 3.81)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>2.89±0.23 (2.48 to 3.33)</td>
<td>.0366</td>
</tr>
<tr>
<td>Anterior chamber angle width (degrees)</td>
<td>35.6±7.35 (20.10 to 52.20)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>27.68±5.65 (14.70 to 41.00)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Endothelial cell density (cells/mm²)</td>
<td>2735±350 (2288 to 3303)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>2601±357 (1754 to 3290)</td>
<td>.0885</td>
</tr>
</tbody>
</table>

i. Results of the last follow-up visit include data related to eyes after secondary refractive procedure (photorefractive keratectomy and LASIK)

ii. P values between the preoperative and last follow-up visit

iii. Data on vault at the 1-month, 1-year, and last follow-up visit were obtained for all 28 eyes

iv. Comparison of the 1-month and last follow-up visit

For further information, please contact: clinical@staarag.ch

Results: Secondary Endpoints continued

Patient Satisfaction Survey

- Nine (60%) patients were completely satisfied with their vision after the surgery and 4 (27%) patients were rather satisfied. Two (13%) patients were rather dissatisfied. No patient was dissatisfied. Having their experience with the surgery now, 14 (93%) patients would have definitely undergone this procedure again and 1 (7%) patient responded “probably yes.” Fourteen (93%) patients would recommend the surgery to a friend.

Complications

- Very fine anterior subcapsular opacities were observed in 2 eyes of 1 patient (final vault of 395 and 385µm) and cortical cataract was present in 2 eyes of 1 patient (final vault of 140 and 145µm). The opacities appeared 2 months after surgery without affecting visual acuity and remained stable and asymptomatic during a 5-year follow-up period.

Key Observations

- Most eyes improved or maintained their CDVA and no eye lost two or more lines of CDVA.
- 86% of eyes were within ±1.00 D of postoperative MRSE with good stability over the entire follow-up.
- The loss of one line of best corrected visual acuity in some eyes occurred more in amblyopic eyes (40% vs 23%) and can be explained by the elimination of the spectacle-induced magnification of the image.
- The mean loss of 4.91% of endothelial cell density between the preoperative period and last follow-up visit in the study (more than 3 years postoperatively) is similar to values reported in other studies on hyperopic ICL implantation.
- The visual recovery was fast and only took 1 day in most eyes.
- Most of the patients were satisfied with their vision and are spectacle independent.

Author’s conclusion

The authors found that implantation of Visian ICL is a safe, effective, predictable, and stable method for the correction of moderate and high hyperopia in highly selected patients. This method showed good clinical outcomes throughout a 3– to 6 year follow-up period.

STAAR’s Take-home message

- According to this retrospective study up to 6 years, the Visian ICL for Hyperopia (V3) appeared to provide good refractive and visual outcomes, with no serious complication and high patient satisfaction.
- Other previous studies demonstrate the good performance of Visian ICL for the correction of hyperopia.1–5