Refractive Surgery on Trial (Course #27-406)

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Handouts:

- Select pages from the Visian ICL™ Product Information.  

- Select pages from Informed Consent for Phakic Implant Surgery: Visian ICL.  

Warnings

- The long-term effects on the corneal endothelium have not been established. Patients should be advised about potential risk of corneal edema, possibly requiring corneal transplantation.

- The long-term rate of cataract formation secondary to implantation, removal and/or replacement of the STAAR Visian ICL is unknown.

- The potential of the lens to alter intraocular pressure (IOP) and the long-term risks of glaucoma, peripheral anterior synechiae and pigment dispersion are unknown.

- Two basal iridotomies must be performed 90° apart using a YAG laser at least 2 weeks before implantation of the Visian ICL, with confirmation of the patency of the iridotomies prior to implantation. The patients should not be taking topical steroid medication at the time of Visian ICL implantation.

- Do not attempt to re-sterilize or repackage this lens.

- Do not autoclave the Visian ICL. Do not freeze; do not expose to temperature greater than 40 degrees Celsius.

Precautions

Prior to surgery, the surgeon must provide prospective patients with a copy of the patient information brochure for this product and inform these patients of the possible benefits and complications associated with the use of this device.

1. Patients with higher degrees of myopia experience lower efficacy and higher rates of adverse events and complications.
2. The effect of pupil size on visual symptoms is not known.

3. Inadequate flushing of the viscoelastic from the eye may lead to intraocular pressure (IOP) spikes. IOP should be checked 24 hours postoperatively.

4. The effectiveness of ultraviolet absorbing lenses in reducing the incidence of retinal disorders has not been established.

5. The relationship between the STAAR Visian ICL and future lens opacities and retinal detachment is undetermined.

6. The accuracy of measurement of axial length in an eye with a Visian ICL is unknown.

The safety and effectiveness of the STAAR Visian ICL for the correction of moderate to high myopia has NOT been established in patients with:

a) greater than 20D of myopia:

b) greater than 2.5D of astigmatism

c) unstable or worsening myopia

d) a diagnosis of ocular hypertension or glaucoma

e) pseudoexfoliation

f) pigment dispersion

g) history or clinical signs of iritis/uveitis
h) insulin-dependent diabetes or diabetic retinopathy

i) history of previous ocular surgery

j) progressive sight-threatening disease other than myopia

k) serious (life-threatening) non-ophthalmic disease

Adverse Events and Complications A total of 526 eyes of 294 subjects were evaluated in the clinical trial to determine the safety of the Visian ICL.

Anterior subcapsular opacities, not all clinically significant, were observed postop in 14 eyes (2.7%). Increase in postop cylinder (>2 D) at 3 years (0.4%). Loss of BSCVA > 2 lines occurred in 4 eyes (0.8%); =2 line loss in 6 eyes (1.2%).

The adverse events/complications experienced during the clinical study of the Visian ICL (between 1 and 36 months) all occurring in ≤ 1% of cases (cumulative) and included 3 retinal detachments (0.6%), 2 cases of glaucoma (0.4%), clinically significant cataract 1 anterior (0.4%); 5 nuclear (1%). 1 case of elevated IOP > 25 mmHg / > 10 mmHg change from baseline at last visit (0.2%). 1 macular hemorrhage (0.2%) and 1 subretinal hemorrhage (0.2%). Corneal edema and iritis were not reported after the 1 week visit. No cases of macular edema, endophthalmitis, corneal ulcer, corneal haze/edema (after 1 week), hypopyon, hyphema or persistent corneal edema were reported during the study.
Incidence of adverse events/complications (compared with the FDA Grid for cataract extraction and posterior chamber IOL implantation) and incidence of surgical reinterventions are shown in the following table:

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Cumulative % (n/N)</th>
<th>FDA Grid %</th>
<th>Persistent (3 Years) % (n/N)</th>
<th>FDA Grid %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endophthalmitis</td>
<td>0% (0/526)</td>
<td>0.1%</td>
<td>0% (0/526)</td>
<td>---</td>
</tr>
<tr>
<td>Hyphema</td>
<td>0% (0/526)</td>
<td>2.2%</td>
<td>0% (0/526)</td>
<td>---</td>
</tr>
<tr>
<td>Hypopyon</td>
<td>0% (0/526)</td>
<td>0.3%</td>
<td>0% (0/526)</td>
<td>---</td>
</tr>
<tr>
<td>IOL Dislocation</td>
<td>0% (0/526)</td>
<td>0.1%</td>
<td>0% (0/526)</td>
<td>---</td>
</tr>
<tr>
<td>Cystoid Macular Edema</td>
<td>0% (0/526)</td>
<td>3.0%</td>
<td>0% (0/526)</td>
<td>0.5%</td>
</tr>
<tr>
<td>Pupillary Block</td>
<td>0% (0/526)</td>
<td>0.1%</td>
<td>0% (0/526)</td>
<td>---</td>
</tr>
<tr>
<td>Retinal Detachment</td>
<td>0.6% (3/526)</td>
<td>0.3%</td>
<td>0% (0/526)</td>
<td>---</td>
</tr>
<tr>
<td>Surgical Reintervention</td>
<td>3.1% (16/526)</td>
<td>0.8%</td>
<td>0% (0/526)</td>
<td>---</td>
</tr>
<tr>
<td>Corneal Edema (after 1 week)</td>
<td>0% (0/526)</td>
<td>---</td>
<td>0% (0/526)</td>
<td>0.3%</td>
</tr>
<tr>
<td>Iritis* (after 1 week)</td>
<td>0% (0/526)</td>
<td>---</td>
<td>0% (0/526)</td>
<td>0.3%</td>
</tr>
<tr>
<td>Raised IOP Requiring Intervention</td>
<td>3.8% (20/526)</td>
<td>---</td>
<td>0.4% (2/526)</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

SURGICAL TREATMENTS NOT MONITORED IN FDA GRID

| Refractive Procedures             | 20/526 (3.9%)      | ---        | ---                          | ---        |
| Iris Prolapse Repair              | 0.2% (1/526)       | ---        | 0% (0/526)                   | ---        |

1. There is no FDA Grid Rate for cumulative iritis.
Comparison should be made to literature for retinal detachment rates for high myopia.
Retinal detachment rates increase with increasing myopia. The risk of retinal detachment within one year of implantation of this device is 0.2%. The risk of retinal detachment for high myopes following implantation is more than 10 times the risk without surgery, i.e., greater than 10 fold the background rate of retinal detachment for high myopes (greater than minus 3 diopters). 5.0% in myopes > -6 D and 0.8% to 7.5% in pseudophakic eyes with high axial myopia.

Refractive procedures include: AK and LASIK
Surgical reinterventions (see table below) were not shown to have an impact on safety or efficacy. Surgical reinterventions occurred in 3.1% of cases.

<table>
<thead>
<tr>
<th>Visian ICL Related Additional Surgery</th>
<th>n</th>
<th>%*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visian ICL Repositioning</td>
<td>4</td>
<td>0.8%</td>
</tr>
<tr>
<td>Visian ICL Replacement, then Removal</td>
<td>1</td>
<td>0.2%</td>
</tr>
<tr>
<td>Visian ICL Replacement</td>
<td>8</td>
<td>1.5%</td>
</tr>
<tr>
<td>Visian ICL Removal</td>
<td>3</td>
<td>0.6%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>16</td>
<td>3.1%</td>
</tr>
</tbody>
</table>

*Total Study Cohort (n = 526)

Other Complications:
Postoperatively IOP > 25 mmHg during follow-up or an increase of > 10 mmHg over preoperative took place in 5 cases through 3 years (only 1 persisted at last visit); 1.4% of the Myopic Visian ICL PMA Cohort. Only 2 cases (0.4%) in the entire cohort were diagnosed with ocular hypertension and started on pressure lowering medication. No cases (0.0%) in this study exhibited optic nerve or visual field changes characteristic of glaucoma.

Clinical Results

The Visian ICL was evaluated in a prospective nonrandomized study of 526 eyes of 294 subjects, 470 of which were followed for 1 year and 369 followed for 3 years. Study Cohort demographics are as follows:

<table>
<thead>
<tr>
<th>Demographics: 526 Eyes of 294 Subjects</th>
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</thead>
<tbody>
<tr>
<td>Age Range: 22 to 45 years</td>
</tr>
<tr>
<td>Average: 36.55 ± 5.8 years</td>
</tr>
<tr>
<td>Race</td>
</tr>
<tr>
<td>Black 2.0%</td>
</tr>
<tr>
<td>Caucasian 84.7%</td>
</tr>
<tr>
<td>Hispanic 7.8%</td>
</tr>
<tr>
<td>Other 5.4%</td>
</tr>
</tbody>
</table>
4. With increasing age, patients are likely to develop cataracts. If the cataracts are significant enough to cause visual problems, the phakic implant may need to be removed so that the eye can undergo cataract removal with or without implantation of an artificial intraocular lens.

PATIENT RESPONSIBILITY FOR COSTS
Health insurance generally does not pay for elective phakic implant surgery for the purpose of correcting natural vision. Therefore, the patient is responsible for the cost of the surgery, including the surgeon’s fee, anesthesiologist’s fee, (if any), and the surgical center’s or hospital’s fee. In the event of a complication, it may be possible that other surgery, eye drops, or even hospitalization may be required. Some or even all of these costs may be covered by health insurance. The patient is responsible for the costs of any uncovered surgery-related injuries.

PATIENT CONSENT
I give my ophthalmologist permission to perform either a YAG-laser iridotomy or a surgical iridotomy AND phakic implant surgery, and acknowledge that I understand the following: the foreseeable risks of phakic implant surgery are not fully known. I have received no guarantee as to the success of my particular case and I understand that I may still need glasses, contact lenses, or a laser procedure such as LASIK for further improvement of my vision. I understand that during the surgical procedure, the doctor may decide not to implant the lens even though I have given permission to do so. Furthermore, I understand that the following risks are associated with the procedure:

Complications of Iridotomy
Potential complications of either a YAG-laser iridotomy or a surgical iridotomy are very rare but include damage to the natural lens; inflammation inside the eye; temporary increases in the pressure in the front part of the eye; cataract formation; bleeding (usually a small amount but can be a large amount); scar formation between the iris and phakic IOL (synechia) that prevents the pupil from moving correctly; corneal damage; and vision disturbances such as double vision (diplopia), glare, or halos.

Vision-Threatening Complications
1. In most cases, the surgery will be accomplished with numbing drops, but in some cases the eye surgeon may elect to use an injection around the eye for anesthesia. Very rare complications from injections include damage to the eye muscles, perforation of the eye, and damage to the retina or optic nerve leading to loss of vision.
2. I understand that mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation, blindness, or even loss of the eye.
3. I understand that I could experience damage to the iris (the colored portion of the eye) or develop a rise in the pressure in the front of my eye (secondary glaucoma). I may require another iridotomy or eye drops to control the pressure if this occurs.
4. I understand that I could develop a retinal detachment, a separation of the retina from the inside wall of the eye, which usually results from a tear in the retina and could lead to vision loss. Patients with moderate to high levels of nearsightedness have a higher risk of retinal
After-Hours Telephone Screening of Ophthalmic Problems: Sample Contact Forms and Screening Guideline

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OMIC Risk Manager

DISCLAIMER
These guidelines were adapted in part from information provided in The Physician's Guide to Eye Care and Ophthalmic Medical Assisting: An Independent Study Course, both published by the American Academy of Ophthalmology. OMIC consultant ophthalmologists also provided input during the development of these guidelines. The ultimate judgment regarding the propriety of any specific procedure or treatment must be made by the ophthalmic in light of the individual circumstances presented by the patient. These guidelines should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. This information is intended solely to provide risk management recommendations. It is not intended to constitute legal advice and should not be relied upon as a source for legal advice. If legal advice is desired or needed, an attorney should be consulted. This information is not intended to be a modification of the terms and conditions of your OMIC policy of insurance. Please refer to your OMIC policy for these terms and conditions.


Each day, countless patients call their ophthalmologist to report problems and seek advice. During the day, physicians rely upon their office staff to screen these calls and schedule appointments. After-hours, ophthalmologists themselves field many calls while providing coverage for their own and other physicians’ practices, as well as for the Emergency Departments of hospitals.

The patient safety and liability risks of telephone screening and treatment
During these telephone conversations, the health care team does not have access to the wealth of information obtained from face-to-face communication and a physical examination of the patient. Moreover, the patient may be a poor historian who does not know how to communicate what the problem is, or may not want to inconvenience the physician or appear to be whining or complaining. This situation is even more problematic after-hours, when the patient may be unknown to the ophthalmologist, and medical records may not be available at the time of the telephone encounter.

Making medical decisions on the basis of the limited information obtained over the telephone is, therefore, a risky—albeit necessary—aspect of ophthalmic practice. Indeed, OMIC claims experience confirms that inadequate telephone screening, improper decision-making, and lack of documentation all play a significant role in ophthalmic malpractice claims. Negligent telephone screening and treatment of postoperative patients is especially likely to result in malpractice claims.
Treat telephone calls as the equivalent of an office visit
What can ophthalmologists do to promote patient safety and reduce the professional liability risks associated with telephone screening and treatment?

First and foremost, exercise the same care when treating a patient over the telephone as you would during an office visit. To promote both the continuity and defensibility of care: 1) gather the information necessary to assess the situation and determine the treatment plan, 2) communicate the assessment and plan to the patient, and 3) document the encounter and your decision-making process in the medical record.

Screening and documentation of after-hours calls
OMIC claims experience includes multiple cases where the ophthalmologist’s only involvement in a patient’s care was an undocumented after-hours contact or prescription refill. A sample after-hours form is included that prompts you to ask about recent procedures or surgeries, and whether the patient has contacted other healthcare providers about the same or related problems. Compact “Patient Care Phone Call Records” can also be purchased from OMIC: these call record pads can be kept in your car, purse, briefcase or locker.

Once you return to the office, place or tape the contact form in your patient’s medical record. If you are providing on-call coverage for a physician in another practice, tell the physician when you go off-call and fax a copy of the contact form and other records; retain the original in a file designated “On-call coverage contacts.”

OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC’s confidential Risk Management Hotline at (800) 562-6642, extension 641.
After-hours/On-call Telephone Contact

Patient name: ____________________________ Date/time of call: ____________

Primary M.D.: ________________________________

Chief complaint: ________________________________

Progression (circle one) Improving Stable Worsening

Vision (circle one) Stable Decreased

Pain (circle one) None Mild (0-3/10) Moderate (4-7) Severe (8-10)

Related symptoms: ________________________________

Recent tests/procedures/surgery: ________________________________

Previous phone calls or visits to other healthcare professionals about this or related complaints:

______________________________________________

Allergies: ________________________________

Current medications: ________________________________

Other significant ocular/medical history: ________________________________

Advice or instructions given/treatment or medication ordered ________________________________

______________________________________________

Follow-up plan: ________________________________

Above information provided to primary M.D. (M.D. who is being covered):
M.D. name: ________________________________
Date/time information communicated: ________________________________

On-call M.D. signature/initials: ________________________________