Clinical Experience of Hydrogel Soft Intraocular Lenses

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Twenty-six soft intraocular lenses were implanted in twenty-six senile cataract patients from July 16, 1987, to April 15, 1988 at Kangnam St. Mary's Hospital, Seoul, Korea. The average age of the patients was seventy-six with a range from fifty-five to eight nine years old. Of the twenty-six patients at the 12 months follow up 87.5% have achieved visual acuity of 20/40 or better. The average central corneal endothelial cell loss at postoperative 7 days and 3 months were 9.8% and 12.3% respectively. Complications were observed in six patients. Two patients had pre-existing retinal and optic diseases and one had a fibrinous membrane. Three patients had transient pigmentary precipitates on IOL surface.

Key words: soft lens, cataract surgery, visual acuity, endothelial cell count, complication, fibrinous membrane.

INTRODUCTION

Cataract is one of the leading cause of blindness in the world. The surgical implantation of intraocular lenses to restore vision after cataract extraction has steadily increased in recent years. Polymethylmethacrylate has proven to be safe material for IOLs and remains the most widely used material for their manufacture. However complications from IOL implantation still occur. The hydrophobic surface of a PMMA lens is responsible for the adherence of cells to the surface of and implant on contact with the endothelium. The hard materials may also produce, mechanical irritation of sensitive uveal tissue with resulting inflammation.

Hydrogels are a class of materials that were designed for biomedical use. When hydrated they swell and become soft, flexible and hydrophilic. The IOGEL lens, poly 2-hydroxy ethyl methacrylate contains 38% water.

A hydrogel lens has been designed for posterior chamber placement. The lens is of single piece construction with a central optic of 6 mm supported by two flexible flanges. The optic is an asymmetric biconvex design with a steeper convex curve placed anteriorly (Fig. 1).

![Fig. 1. (Barrett) Design of the hydrogel lens, showing front and side views.](image)

The flanges are soft and flexible and will accommodate the expected variation in ocular size. They taper from a maximum diameter of 6.5 mm in the optic zone to 2.0 mm at the extremities to allow insertion through a small pupil. The for-
ward angulation and curvature of the flanges hold the lens away from the iris.

This paper reports the first 26 cases in Korea which were performed between July 1987 and April 1988 and have been followed for a minimum of five months.

**MATERIALS AND METHODS**

Patient selection was based on certain criteria. Patients had to be over fifty-five years or older and patients with significant pre-existing ocular disease were to be excluded. Lens implantation would be restricted to patients with a functional contralateral eye. The operation was to be done under the two surgeons and all patients received posterior chamber IOGEL lens as a primary implant.

The type of cataract extraction was (N=20) planned extracapsular and (N=6) endocapsular extraction with viscoelastic material used. The IOGEL lens should be implanted symmetrically into the capsular bag. The lower flange of the IOGEL lens is then grasped with the non-toothed forceps (McPherson) and inserted between the leaves of the anterior and posterior capsule. The upper flange is grasped with forceps at the top edge and the tip of the flange rotated posteriorly and placed beneath the iris into the capsular bag.

After finishing the lens insertion, corneoscleral suturing was done with 10-0 Nylon intercutally five to six bites. The remaining viscoelastic material was removed with an I & A machine.

**RESULTS**

The implanted group included seven males and nineteen females ranging in age from fifty-five to eighty-nine years old. The mean age was seventy-six, and most of them were in their seventies. The preoperative visual acuity ranged from light perception to 20/50. The vast majority of cataracts were senile with a relatively high incidence of mature cataract (Table 1, 2, 3). Surgeons estimated at the time of surgery the position of the IOGEL lens to be in the capsular bag in 88.5% of cases, in the sulcus in 3.9%, and one flange in and the other out in the remaining 7.7%. Decentering was not noted during the follow-up period.

Only three cases presented difficulty due to a vitreous bulge (Table 4). The mean postoperative intraocular pressure and corneal thickness were not

<table>
<thead>
<tr>
<th>Table 1. Age and sex distributions</th>
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<tbody>
<tr>
<td>Age (year)</td>
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<tr>
<td>50 - 59</td>
</tr>
<tr>
<td>60 - 69</td>
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<tr>
<td>70 - 79</td>
</tr>
<tr>
<td>80 - 89</td>
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<tr>
<td>Total</td>
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<td>Mean Age (year)</td>
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<tr>
<th>Table 2. Preoperative visual acuity</th>
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<tbody>
<tr>
<td>Visual Acuity</td>
</tr>
<tr>
<td>L.P.</td>
</tr>
<tr>
<td>H.M. - F.C.</td>
</tr>
<tr>
<td>0.1 - 0.15</td>
</tr>
<tr>
<td>0.2 - 0.4</td>
</tr>
<tr>
<td>Over 0.5</td>
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<tr>
<td>Total</td>
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*LP: light perception, H.M: hand movement, FC: finger count*

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<tr>
<th>Table 3. Type of cataract</th>
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<tr>
<td>Type</td>
</tr>
<tr>
<td>Immature</td>
</tr>
<tr>
<td>Mature</td>
</tr>
<tr>
<td>Hypermature</td>
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<tr>
<td>Posterior subcapsular</td>
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<tr>
<td>Total</td>
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<th>Table 4. Position of lens*</th>
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<tr>
<td>Eyes (%)</td>
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<tr>
<td>In the bag</td>
</tr>
<tr>
<td>In ciliary sulcus</td>
</tr>
<tr>
<td>In and out</td>
</tr>
<tr>
<td>Total</td>
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*Decentering was not noted during the follow-up period (4-12 months)*

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<tr>
<th>Table 5. Complications during surgery</th>
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<tbody>
<tr>
<td>Items</td>
</tr>
<tr>
<td>Posterior capsule rupture</td>
</tr>
<tr>
<td>Detached Descemet’s membrane</td>
</tr>
<tr>
<td>Significant anterior chamber bleeding</td>
</tr>
<tr>
<td>Iris damage</td>
</tr>
<tr>
<td>Vitreous bulge</td>
</tr>
<tr>
<td>Vitreous loss</td>
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</tbody>
</table>
Table 6. The endothelial cell density according to the duration

<table>
<thead>
<tr>
<th>Cell density (cells/mm²)</th>
<th>Preoperative</th>
<th>Postoperative days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>2384±78</td>
<td>2149±36</td>
</tr>
<tr>
<td>Percentile decrease (%)</td>
<td>9.8</td>
<td>11.2</td>
</tr>
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</table>

Table 7. Best corrected visual acuity of all patients, number of eyes

<table>
<thead>
<tr>
<th>Visual Acuity</th>
<th>Postoperative weeks (%)</th>
<th>1 week (N=26)</th>
<th>4 weeks (N=26)</th>
<th>3 months (N=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 1.0</td>
<td></td>
<td>2 ( 7.7)</td>
<td>2 ( 7.7)</td>
<td>5 (20.8)</td>
</tr>
<tr>
<td>0.9 - 0.8</td>
<td></td>
<td>3 (11.5)</td>
<td>2 ( 7.7)</td>
<td>6 (25.0)</td>
</tr>
<tr>
<td>0.7 - 0.6</td>
<td></td>
<td>8 (30.8)</td>
<td>12 (46.2)</td>
<td>7 (29.2)</td>
</tr>
<tr>
<td>0.5 - 0.4</td>
<td></td>
<td>9 (34.6)</td>
<td>7 (26.9)</td>
<td>3 (12.5)</td>
</tr>
<tr>
<td>Under 0.3</td>
<td></td>
<td>4 (15.4)</td>
<td>3 (11.5)</td>
<td>3 (12.5)</td>
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</table>

*If excluded the preexisting underlying diseases, 87.5% achieved 20/40 or better.

Table 8. Postoperative complications among 26 eyes

<table>
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<tr>
<th>Complication</th>
<th>Number of eyes</th>
<th>Incidence (%)</th>
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<tbody>
<tr>
<td>Optic nerve atrophy (pre-existing)</td>
<td>1</td>
<td>4.1</td>
</tr>
<tr>
<td>Senile macular degeneration (pre-existing)</td>
<td>1</td>
<td>4.1</td>
</tr>
<tr>
<td>After-cataract</td>
<td>1</td>
<td>4.1</td>
</tr>
<tr>
<td>Iris touch optic or haptic</td>
<td>2</td>
<td>8.2</td>
</tr>
<tr>
<td>Non pigment precipitate</td>
<td>3</td>
<td>12.3</td>
</tr>
<tr>
<td>Fibrinous membrane</td>
<td>1</td>
<td>4.1</td>
</tr>
</tbody>
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significantly different from the preoperative values. All patients returned to baseline values.

The most frequent surgical problems were vitreous buldge in 15.2% and iris damage in 7.7%. The high vitreous buldge made the inserting procedure difficult and with more manipulation the iris was likely damage. There was one case of posterior capsule rupture but the rupture was minor (Table 5).

The average central corneal endothelial cell loss was 9.8% and 12.3% at postoperative 7 days and 90 days respectively. There was no significant difference in cell loss in the other intraocular lens implanted group (Table 6).

Of the 26 patients who have reached 3-12 months, 75% have achieved visual acuity of 0.5% or better. Three patients had pre-existing retinal and optic nerve disease, and were not related to the IOGEL implantation. Actually the best visual acuity of 0.5 or better was observed in 87.5% of the patients. The visual acuity outcome 20/40 or better was evidenced in less than younger patients (Table 7).

Complications were observed in six patients. Two patients had pre-existing retinal and optic disease and one patients has a fibrinous membrane at postoperative five days and treated with steroid, the membrane had disappeared at ten days (Table 8).

**DISCUSSION**

Intraocular lenses composed of soft flexible materials were independently explored by Epstein\(^1\) (silicone and hydrogel posterior chamber implants), Mehta\(^2\) (hydrogel iris supported implants) and Parker (personal communication, September 1983) in the late 1970s. More recently, these materials have been investigated by Barrett\(^3,4\) (hydrogel implant), Mazzocco\(^5\) (silicone
SOFT IOL

implant) and Blumenthal6 (hydrogel implant) as biocompatible posterior chamber implants for insertion through a small incision following phaco emulsification.

Since the average age of patients at the time of implantation was 76 years, we performed the planned extracapsular cataract extraction and did not insert the lenses in a folded condition.

We found that both capsular bag and ciliary sulcus fixation is possible with this lens design, although the 12 mm lens is preferred for capsular bag fixation. The mechanism of fixation appears to differ from conventional implants with flexible loop haptics. Implantation with one flange in the bag and the other in the sulcus should be avoided.6

In our patients, all implants except one were implanted symmetrically in the ciliary sulcus or capsular bag.7 The surgical complications were few and most of them were unrelated to the lens implant. Two cases were preexisting with ocular conditions (optic neuritis & senile macular degeneration) and opacification of the posterior capsule was noted in one case.

One of the lens design concepts was to allow close apposition of the lens surface with the posterior capsule to provide a barrier effect and retard posterior capsule opacification.7 The incidence of cellular or other pseudophakic precipitates on the lens surface is less than that which occurs with PMMA lenses.8 Three cases with small pigmentary precipitates of indeterminate origin that do not appear to be cellular in origin have been noted. The precipitates are clearing with time. Fibrinous membrane was noted in one case in the first week postoperatively and also disappeared at ten days.

The visual acuity outcome is similar to that reported in the literature for PMMA lenses in the same age group.10,11 Patients in this study achieved 20/40 or better in 75% cases and in 97.5% of cases excluding pathologies unrelated to the lens at postoperative 3 months. The patients in the multinational trial achieved 20/40 or better in 86% of cases and in 96% of cases excluding unrelated pathologies.12

The average central corneal endothelial cell loss was 9.8% and 12.3% at postoperative 7 days and 90 days respectively. There is no significant difference in cell loss in the PMMA group.13 In general, cell loss is limited to the surgical event with most implants but some IOL designs have been associated with continuing cell loss greater than that attributable to aging. Therefore additional studies by other investigators and longer follow up are needed to confirm the safety of soft lens implants.

CONCLUSION

Our experience with a hydrogel IOL manufactured form 38% poly HEMA has been encouraging. There has been no observable degradation of the lens material. It has been relatively easy to insert, stable, well tolerated, and patients have achieved good postoperative visual acuity. Further studies by other investigators to evaluate hydrogel lens implantation are warranted.

REFERENCES


