TITLE: Sharp and Round Optic Edges of Intraocular Lenses: A Review of the Clinical and Cost-Effectiveness

DATE: 13 March 2009

CONTEXT AND POLICY ISSUES:

Cataract, an opacity of the eye lens, is the leading cause of blindness worldwide. Vision can be restored by implantation of an intraocular lenses (IOL) following removal of the cataract. Cataracts can be removed by extracapsular cataract extraction or phacoemulsification.

Posterior capsule opacification (PCO) is a common complication following cataract extraction and is treated with a neodymium:YAG (Nd:YAG) laser capsulotomy. PCO causes decreased visual acuity (VA), damaged contrast sensitivity, and glare disability. There are various interventions for the prevention of PCO, including surgical modifications, using additional implants before IOL implantation (i.e.: capsular tension rings can be implanted prior to IOL implantation), using pharmacological interventions, or by modifying the IOL design.

A reduction of PCO was seen with different IOLs, and it was initially suggested that the IOL material [e.g.: silicone, acrylic, polymethylmethacrylate (PMMA)] was responsible for this effect. However, it has been suggested that it may be IOL edge design that affects the rates of PCO.

It will be important to determine which IOL is most effective for policy development in the health care system. This report will review the clinical and cost-effectiveness of evidence on the effect of sharp edge IOLs versus round edge IOLs on rates of PCO.

RESEARCH QUESTIONS:

1. What is the clinical evidence on intraocular lens edge design affecting posterior capsule opacification rate?

2. What is the cost-effectiveness of sharp optic edges versus round optic edges on intraocular lenses?
METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, Medline, Embase, Biosis, the Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2004 and February 2009 and are limited to English language publications only. Filters were applied to limit the retrieval to health technology assessments (HTAs), systematic reviews, meta-analyses, randomized controlled trials (RCTs), controlled clinical trials, observational studies, and economic studies. Internet links are provided, where available.

SUMMARY OF FINDINGS:

HTAs, SRs, and meta-analyses, and economic evaluations were included in this report. In addition, RCTs that were published after the search dates of the systematic reviews were also included. Therefore, RCTs published after January 2007 were included.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, HTA reports, systematic reviews and meta-analyses are presented first. These are followed by RCTs and economic evaluations.

No HTAs or economic studies were identified on sharp versus round optic edges of IOLs. Three systematic reviews and three RCTs were identified.

Health technology assessments
No literature identified

Systematic reviews and meta-analyses

Three systematic reviews were identified that compared sharp and round optic edges. Two of the systematic reviews were from the same authors and appeared to report on the same data; therefore, only the Cochrane systematic review was summarized. Findl et al. (2008) reviewed various interventions for the prevention of PCO and included studies that compared edge design of intraocular lenses. RCTs in patients with age-related cataracts with a follow up of at least one year were included. There were 53 original RCTs included. Table 1 reports the summary of pooled outcome measures for PMMA, acrylic, silicone, and any type of IOL material. Outcomes measured were VA, PCO rate, and Nd:YAG capsulotomy rate. No information was provided about how VA was measured. PCO was measured by various scoring methods, including automated quantification of after-cataract (AQUA), posterior capsule opacification (POCO), Evaluation of PCO (EPCO), and Scheimpflug. Results were pooled using a random-effects model for meta-analyses containing three or more trials or a fixed-effects model for less than three trials.
Table 1: Pooled outcome measures of studies comparing sharp and round optic edges\textsuperscript{2}

<table>
<thead>
<tr>
<th>IOL material</th>
<th>Outcome</th>
<th>N (# eyes)</th>
<th>Pooled outcome measure (95% CI)</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMMA*</td>
<td>VA</td>
<td>1 (64)</td>
<td>MD -0.05 (-0.18 to 0.08)</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>PCO</td>
<td>1 (64)</td>
<td>MD -28.3 (-40.95 to -15.65)</td>
<td>Favours sharp edge</td>
</tr>
<tr>
<td></td>
<td>YAG</td>
<td>1 (64)</td>
<td>OR 0.24 (0.07 to 0.85)</td>
<td>Favours sharp edge</td>
</tr>
<tr>
<td>acrylic</td>
<td>VA</td>
<td>2 (200)</td>
<td>MD 0.06 (0.01 to 0.12)</td>
<td>Inconclusive due to heterogeneity</td>
</tr>
<tr>
<td></td>
<td>PCO</td>
<td>3 (334)</td>
<td>MOE -10.47 (17.23 to -3.72)</td>
<td>Inconclusive due to heterogeneity</td>
</tr>
<tr>
<td></td>
<td>YAG</td>
<td>2 (200)</td>
<td>OR 0.07 (0.02 to 0.32)</td>
<td>Favours sharp edge</td>
</tr>
<tr>
<td>silicone</td>
<td>VA</td>
<td>2 (196)</td>
<td>MD 0.06 (0.00 to 0.12)</td>
<td>Inconclusive due to heterogeneity</td>
</tr>
<tr>
<td></td>
<td>PCO</td>
<td>5 (462)</td>
<td>MOE -8.24 (-14.04 to -2.44)</td>
<td>Inconclusive due to heterogeneity</td>
</tr>
<tr>
<td></td>
<td>YAG</td>
<td>4 (390)</td>
<td>MOE 0.18 (0.04 to 0.72)</td>
<td>Favours sharp edge</td>
</tr>
<tr>
<td>any</td>
<td>VA</td>
<td>7 (692)</td>
<td>MD 0.09 (0.02 to 0.15)</td>
<td>Inconclusive due to heterogeneity</td>
</tr>
<tr>
<td></td>
<td>PCO</td>
<td>11 (1451)</td>
<td>MOE -8.65 (-10.72 to -6.59)</td>
<td>Inconclusive due to heterogeneity</td>
</tr>
<tr>
<td></td>
<td>YAG</td>
<td>11 (1078)</td>
<td>MOE 0.19 (0.11 to 0.35)</td>
<td>Favours sharp edge</td>
</tr>
</tbody>
</table>

CI = confidence interval; MD = mean difference; MOE = mean overall effect; N=number of RCTs; OR = odds ratio;
PMMA= polymethylmethacrylate; PCO = posterior capsule opacification; VA = visual acuity; YAG = Nd:YAG laser capsulotomy rate

* no meta-analysis was conducted for the PMMA group since only one study was included.

Only one study reported results of PMMA IOLs so no meta-analysis was conducted. Sharp and round optic edges of PMMA IOLs were compared in the one study which found no significant difference in VA between the groups, but significantly higher PCO scores and capsulotomy rates in the round edge group compared to the sharp edge group.

For all of the comparisons of the different materials, the pooled results for VA and PCO scores were inconclusive due to heterogeneity. In acrylic IOLs, one study found VA in the sharp edge group to be significantly higher and another study found VA to be non-significantly higher in the sharp edge group compared to the round edge group. The sharp edge acrylic IOLs had lower PCO scores in three studies and lower capsulotomy rates in two studies compared to the round edge group.

In silicone IOLs, no difference in VA was found in one study, whereas the other study found a significant increase with sharp edges versus round edges. PCO scores were lower in the sharp group compared to the round group in five studies. The capsulotomy rate was higher in the round edge group compared to the sharp edge group in four studies.

This systematic review also assessed the information from the RCTs without taking into consideration the type of optic material. VA was assessed in seven studies; five studies reported better VA in the sharp edge group while the other two studies did not see a difference. PCO scores were reported in 15 studies, and 14 reported lower PCO scores in the sharp edge group and one study favoured the round edge group. Only 11 of these studies were pooled due to missing data for the other four studies. Ten studies reported a lower capsulotomy rate in the sharp edge group and one reported a lower rate in the round edge group.

Quality of the RCTs was assessed and some (30/53) of the RCTs included in this systematic review did not describe the randomization process and these studies were of lower quality than the studies adequately reporting randomization.

Overall, the authors of this systematic review concluded that there was clear evidence that the development of PCO was significantly less with sharp edge IOLs compared to round edge IOLs.
made of the same material. Without considering the optic material, PCO scores, YAG rates, and VA were better with sharp edge IOLs compared to round edge IOLs.

A systematic review by Cheng et al. (2007) analyzed the effect of optic edge design on PCO. RCTs in patients with age-related cataracts were included and 23 RCTs were identified. Quality of the included studies was assessed and all received a score of fair to good quality. Seven of those studies compared optic edge design and two compared optic materials and optic edge design.

One trial compared sharp and round edges of PMMA IOLs and found a reduced Nd:YAG capsulotomy rate in the sharp edge group compared to the round edge group [risk difference (RD) -47%; 95% confidence interval (CI) -77% to -17%] with a number needed to treat (NNT) of 2.1 (range: 1.2 to 5.9).

Acrylic IOLs with sharp and round edges were compared in two studies and no statistical difference was found in the Nd:YAG capsulotomy rate (risk difference -22%; 95% CI -47% to 2%). PCO rates were found to be lower in the acrylic sharp edge group than the acrylic round edge group in one trial (RD -28%; 95% CI -50% to -7%; NNT 3.6; range: 2.0 – 14.3).

Silicone lenses were compared in five trials and the Nd:YAG capsulotomy rate was significantly better in the sharp edge group compared to the round edge group (pooled RD -9%; 95% CI – 17% to 0%). The sharp edge was significantly better than the round edge in four trials that measured PCO rates (pooled RD -37%; 95% CI -46% to -27%; NNT 2.7, range: 2.2 to 2.7).

Overall, this systematic review found Nd:YAG capsulotomy rates were reduced with the sharp edge PMMA IOLs and silicone IOLs compared to the round edge IOLs, but there was no difference between the sharp and round edges with acrylic IOLs. PCO prevention was significantly better in the silicone and acrylic sharp edge IOLs compared to the round edge IOLs. This systematic review was limited by the fact that different follow-up periods were used in the trials and various assessment criteria for PCO and Nd:YAG capsulotomy rates were used. The authors concluded that optic edge design, and not just the materials, was important for prevention of PCO.

Randomized controlled trials

A cross-over RCT published in 2007 was conducted to compare the effect of Clariflex silicone IOLs with a sharp posterior edge to SI40 silicone IOL with a round edge. The edge profile is the only difference between the lenses. Patients were included who had bilateral age-related cataracts. Patients were randomized (n=52; median age 77 years) to receive one of the types of lenses first, followed one to eight weeks later by surgery in the other eye using the other type of IOL. Follow up was one week, one month, six months, one year, two years, and three years following surgery. PCO, VA, and need for Nd:YAG laser capsulotomy was measured at follow up. There were 40 patients available for one year follow up, and 34 patients available for the two and three year follow up. The PCO scores were 0.31 in the sharp edge group and 1.28 in the round edge group at one year; 0.23 and 1.44 at two years, respectively; and 0.35 and 1.67 at three years, respectively. Before the two year follow-up, one patient had Nd:YAG capsulotomy in both eyes, and three patients had capsulotomy in their SI40 eye. Five patients had capsulotomy after three years in the SI40 eye, and one patient in the Clariflex eye (p < 0.05). VA was not different between the two groups at any time point. The authors concluded that there is a reduction in PCO with sharp edge IOLs compared to round edge IOLs.
A 2007 cross-over RCT examined the effect of square (sharp) edge and round edge PMMA IOLs on PCO. Patients with bilateral age-related cataracts were randomized to receive one type of IOL in one eye, and in a second surgery within one month, received the other type of IOL in the contralateral eye. There were 118 patients (mean age 57.8 years) included; 115 were available at one year follow up and 107 were available at two years follow up. At one year, PCO scores were the same in both eyes (i.e., both sharp and round edge IOLs) of 23 patients, were lower in the eye with the square edge IOL in 69 patients, and were lower in the eye with the round edge IOL of 23 patients. There was significantly less PCO in the eye with the square edge IOL compared to the round edge IOL (p < 0.001). After two years, there was significantly less PCO in the eyes with the square edge IOLs compared to the eyes with the round edge IOLs (p = 0.006). Fifteen patients had the same score in both eyes, 59 had a lower score in the eye with the square edge IOL, and 33 patients had a lower score in the eye with the round edge IOL. Three patients had capsulotomy in both eyes, 7 patients in the eye with the round edge IOL and 6 patients in the eye with the square edge IOL. VA was the same in both groups at one year and two years of follow up. Overall, this RCT found a modest, significant decrease in PCO with square edge IOLs compared to round edge IOLs and the authors concluded that IOLs with a square edge are beneficial.

A multi-centre RCT published in 2008 examined optic edge design in 288 patients (mean age, 73.9 years) undergoing cataract surgery. A silicone sharp edge IOL was implanted in one eye, and the other eye received either an acrylic sharp edge IOL or a silicone round edge IOL. Follow up was conducted from one day to 37 months following surgery. There were 108 patients who received the silicone round edge in one eye and the silicone sharp edge in the other eye. One hundred thirty-nine patients received the silicone sharp edge IOL in one eye and the acrylic sharp edge IOL in the other eye; 41 patients were excluded from the study. Nd:YAG capsulotomy was conducted in both eyes of three patients, two patients in the eye with the sharp edge IOL , and 12 patients in the eye with the round edge IOL . The difference in Nd:YAG capsulotomy rates between the two edges was not statistically significant ( -11.4%; 90% CI -18.1% to -4.7%). PCO scores were lower in the sharp edge group (0.00) compared to the round edge group (0.07). Overall, the authors found lower Nd:YAG capsulotomy rates in both sharp edge groups (silicone and acrylic) compared to the round edge group and concluded that PCO is less for patients who receive sharp edge IOLs.

Economic evaluations
No economic evaluations comparing sharp edge IOLs to round edge IOLs were identified.

Limitations
There was heterogeneity in the studies that were used for the meta-analysis of the Cochrane review and therefore, the majority of the results were inconclusive. Different follow-up periods and PCO scoring techniques contributed to the heterogeneity. The second systematic review only included studies published in the English language, and therefore, studies published in other languages may have been excluded. In addition, follow-up periods and assessment criteria of PCO varied in the included trials which may have affected analysis of PCO rates.

One of the RCTs did not describe the method of randomization. This RCT also had a small sample size and the same surgeon did not perform all surgeries, although both eyes for each patient were operated on by the same surgeon. Another RCT had the same surgeon perform all surgeries. The third RCT was a multi-centre RCT, and for each center, the same surgeon performed all surgeries. It is unclear whether having different surgeons performing the cataract surgery would affect rates of PCO.
There were differences across the RCTs in the setting and methods. One RCT was a multi-centre study conducted in ophthalmology centres,\(^7\) one was conducted in a small rural hospital,\(^6\) and one was conducted in a general hospital.\(^4\) It is unclear whether different health care settings would affect outcomes. Different methods to evaluate PCO were used in the RCTs; EPCO\(^7\), POCO,\(^6\) and AQUA\(^4\) were all used. In addition, the average age of participants varied. One study included a younger study population (mean age of 57.8 years)\(^6\) compared to the other two studies (mean age > 70 years).\(^4,7\) It is unclear if the results of the outcomes were influenced by these study differences.

No economic analyses about the sharp versus round optic edges of IOLs were identified and therefore, the cost-effectiveness cannot be assessed.

**CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:**

The majority of the studies directly compared IOLs made of the same material (silicone, PMMA, or acrylic) and found the sharp edge IOLs to be superior. This is based upon the systematic reviews and RCTs reporting lower PCO rates and Nd:YAG capsulotomy rates with the sharp edge IOLs compared to round edge IOLs. In addition, one systematic review also analyzed the data irrespective of IOL material, and also found that sharp edge IOLs had better PCO, VA, and Nd:YAG rates.

One RCT suggested that although optic edge significantly affected PCO rates, optic material may still have an effect.\(^4\) The authors compared their results with the silicone IOLs to results of their previous study in acrylic IOLs; the silicone sharp and round edged IOL had lower rates of PCO compared to the sharp and round edge acrylic IOLs so they deduced that silicone may be better than acrylic for prevention of IOL.\(^4\) However, this conclusion is based on indirect comparisons and thus, future research is required before this conclusion can be supported.

One systematic review stated that most round edge IOLs have been removed from the market.\(^5\) The availability of round edge IOLs, the lack of economic information, as well as the possible contributing factor of IOL material should be considered when deciding whether sharp or round edge IOLs are best for implantation following cataract extraction.

**PREPARED BY:**
Lesley Dunfield, PhD, Interim Manager  
Rhonda Boudreau, BEd, MA, Research Officer  
Emmanuel Nkansah, BEng, MLS, MA, Information Specialist  
Health Technology Inquiry Service  
Email: htis@cadth.ca  
Tel: 1-866-898-8439
REFERENCES:


