

# Initial experience with the AMO PC-28LB (Phacofit®) small-incision implant: A preliminary report

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## ABSTRACT

The methods and initial clinical results obtained using the AMO PC-28LB (Phacofit®) small-incision implant are presented.

**Key Words:** polymethylmethacrylate intraocular lens, posterior chamber implant, reduced astigmatism, small-incision implant

Recent advances in implant design, as well as developments in polymer chemistry,<sup>1-7</sup> have led to a new generation of intraocular lens (IOL) implant styles which can be inserted into the eye through smaller incisions. These small-incision implants should reduce suture-induced astigmatism,<sup>8,9</sup> reduce the time necessary to perform the surgery, and accelerate visual recovery of the patient postoperatively. This report details the initial experience of the clinical monitor (I.H.F.) of the limited core study for the AMO PC-28LB or Phacofit® lens.

## MATERIALS AND METHODS

The limited core study involved 100 patients in whom the Phacofit lens was implanted. Appropriate informed consent documents were signed by all patients. Nine surgeons participated, eight of the surgeons implanting ten lenses each. The clinical monitor implanted 20 lenses.

The implant design is shown in Figure 1. It features an optical zone 3 mm by 6 mm wide which is staked to a polymethylmethacrylate (PMMA) bridge superiorly; the sides are expanded into opacified wings. As seen in Figure 2, the wings can be flexed posterior to the clear, central portion of the optic, allowing the lens to be inserted through an incision only slightly larger than

*cases,  
instruments  
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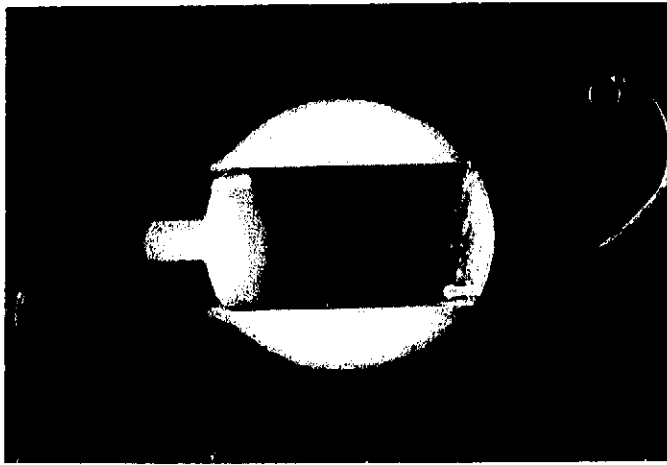


Fig. 1. (Fine) AMO PC-28LB lens.

3 mm. Because PMMA has such an excellent memory, as soon as the lens is inside the eye the opacified wings spring open, returning to the configuration seen in Figure 1. The haptics are made of blue polypropylene and are a variation of the common modified J-loop design. Figure 3 shows the pertinent dimensions of the various elements.

#### Surgical Technique

We used peribulbar anesthesia consisting of equal volumes of 4% lidocaine hydrochloride (Xylocaine®) (with hyaluronidase [Wydase®] and epinephrine) and .75% bupivacaine (Marcaine®). The Cook speculum and vertical bridle sutures were placed, and a small fornix-based flap was prepared superiorly. With a Super

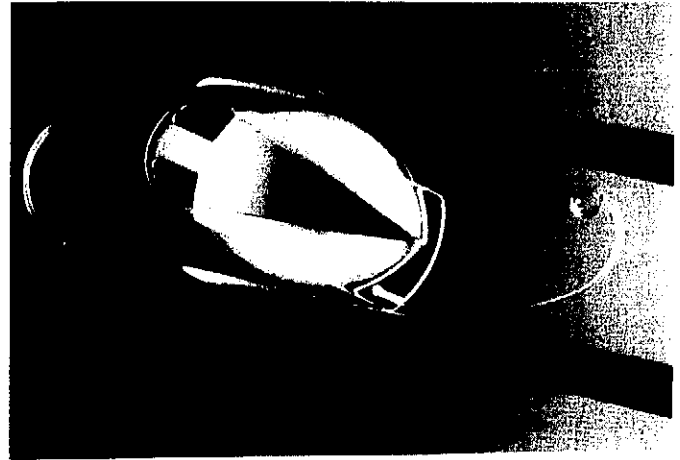


Fig. 2. (Fine) AMO PC-28LB lens with opacified wings compressed behind the clear portion of the optic.

Blade an entry into the anterior chamber was made at the limbus without dissecting a scleral tunnel. A small paracentesis was also made at the edge of clear cornea to the left. Using a bent 23 gauge needle, an anterior capsulotomy was performed with a viscoelastic substance in the anterior chamber. The limbal incision was widened with a 3 mm keratome and phacoemulsification was performed in the posterior chamber and the plane of the pupil. Irrigation/aspiration (I/A) was used for removing the residual cortex and vacuuming the posterior capsule. The capsular bag was inflated with sodium hyaluronate (Healon®). Using the Super Blade, the incision was widened to 3.5 mm through which the implant was inserted into the eye.

#### Insertion Technique

The trailing edge of the optic's clear portion was held with a lens holder or forceps as the leading haptic and bridge were introduced into the incision. The purchase of the optic's clear trailing portion was at the tip of the optic so the movement of the opacified wings would not be impeded as they flexed behind the optic. A forceps held in the nondominant hand was then used to flex the wings gently, one at a time, behind the clear rectangular portion of the optic. The implant was advanced across the anterior chamber and the leading haptic was placed in the inferior capsular fornix. The superior haptic was either dialed into the bag or compressed and placed in the bag using a Lester hook in the control tip or a forceps. The lens was centered within the capsular bag with the Lester hook. In most cases the 6 mm by 3 mm clear optic was already centered horizontally, but no particular effort was taken to ensure that orientation. The Healon was removed with the I/A handpiece and the incision was closed with two 10-0 nylon sutures. One-half cubic centimeter betamethasone sodium phosphate (Celestone® Soluspan®) was injected under the inferior conjunctiva. Timolol maleate

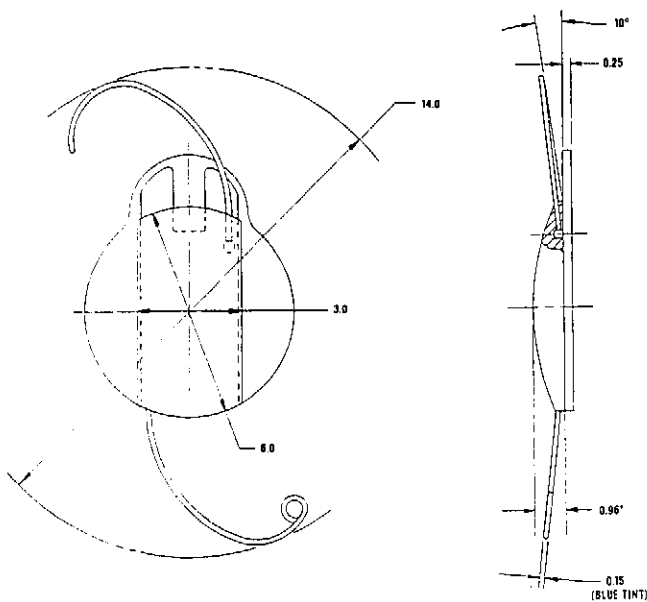


Fig. 3. (Fine) Dimensions in millimeters of the AMO PC-28LB lens.

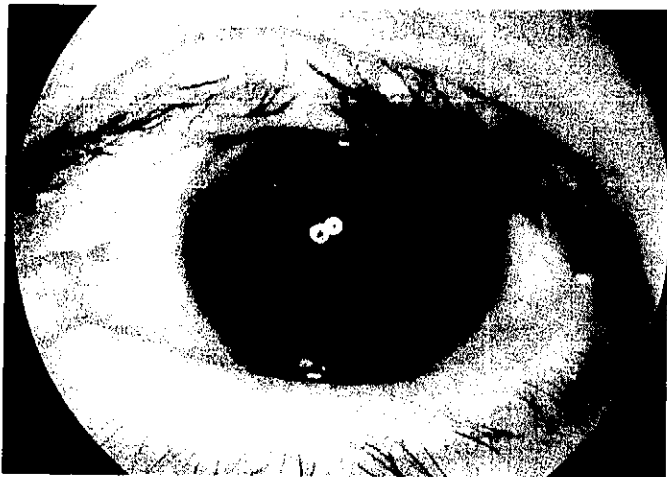


Fig. 4. (Fine) Patient with AMO PC-2SLB implanted—pupil undilated.

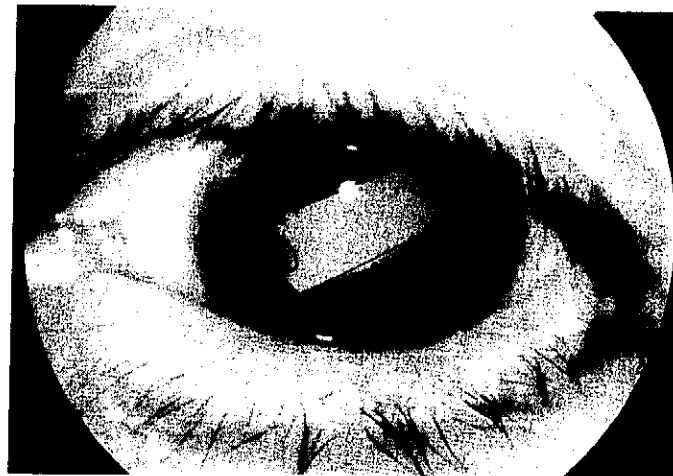


Fig. 5. (Fine) Patient in Figure 4 with pupil dilated.

(Timoptic®), dexamethasone (Maxitrol®), and pilocarpine drops were instilled, after which a patch and a Fox shield were placed.

Fourteen of the 20 patients were evaluated postoperatively by a vitreoretinal specialist (J.E.R., Jr.). All patients were offered this additional examination but six found it too inconvenient or did not wish to undergo extensive peripheral scleral depression. There were no clinical reasons for suspecting that the view of the fundus periphery in those patients not examined would be qualitatively different from the view of the fundus periphery in those patients who were examined.

### RESULTS

Figures 4, 5, 6, and 7 show two patients with the PhacoFit lens in place. With an undilated pupil there may be a small portion of the opacified edge visible within the pupillary zone (Figures 4 and 6); however,

this does not cause problems, nor is it noticed by the patients. In the same patients with dilated pupils the lenses are very well centered (Figures 5 and 7).

The postoperative data presented in Figures 8 to 11 are for 18 of the 20 patients. One patient left the area and did not return for follow-up care. A second patient, in whom posterior capsule rupture occurred, had a final visual acuity of 20/30, but required vitrectomy during the postoperative period because of retained cortex. For this patient, the parameters measured were not taken at the intervals coincident with the remainder of the study.

Figure 8 shows the visual acuity for each patient at the eighth postoperative week. Four patients had 20/15 acuity, ten had 20/20 acuity, three 20/25, and one 20/30. Figure 9 shows the distribution of refractive errors in spherical equivalents preoperatively. At eight weeks postoperatively (Figure 10) the refractive errors tend

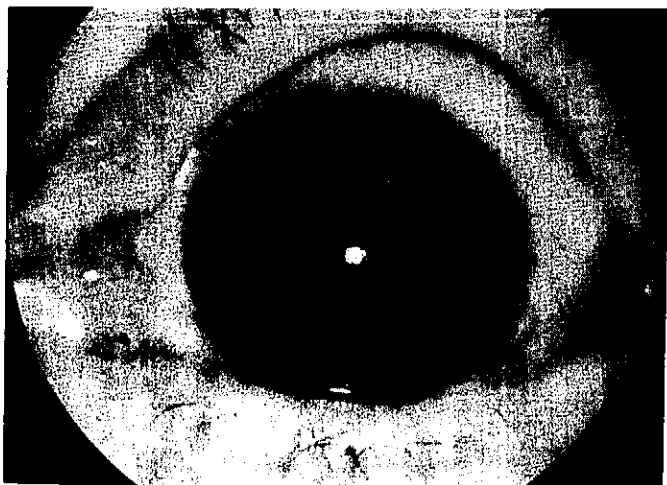


Fig. 6. (Fine) Patient with AMO PC-2SLB implanted—pupil undilated.

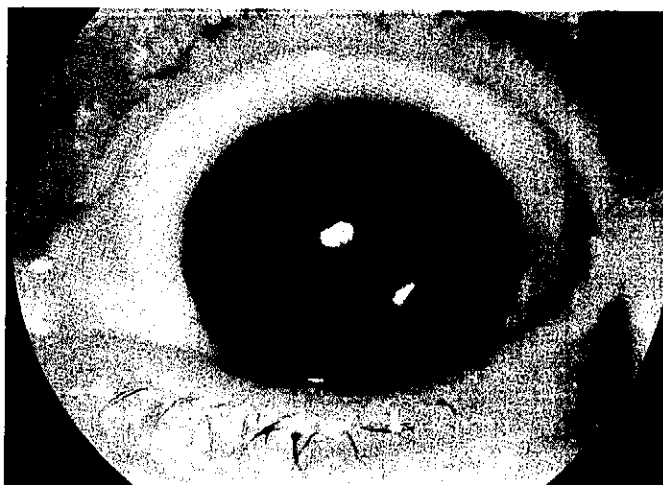


Fig. 7. (Fine) Patient in Figure 6 with pupil dilated.

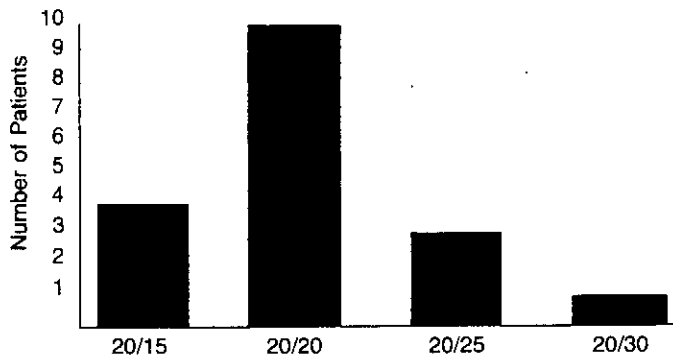


Fig. 8. (Fine) Corrected visual acuities of patients with AMO PC-28LB lens at the eighth postoperative week.

toward plano. One patient had a spherical equivalent of +0.87 at eight weeks after surgery, another a spherical equivalent of -0.75, and the remainder were within 0.50 diopter (D) of plano. One patient in whom the fellow eye was hyperopic and in whom a postoperative desired refraction of +2.00 was achieved was included in the above data as plano. At eight weeks postoperatively the average astigmatic error was 0.75 D of cylinder (Figure 11).

Endothelial cell counts were obtained both preoperatively (2,890/mm<sup>2</sup>) and postoperatively (2,794/mm<sup>2</sup>). These data show an average endothelial cell loss of only 3%.

Miller/Nadler glare testing was done preoperatively and postoperatively. The preoperative glare averaged 60% disability, and was in all cases believed to be due to cataract. The average glare disability at eight weeks postoperatively was 6.8% measured by the same instrument.

There were no patients in this study in whom the

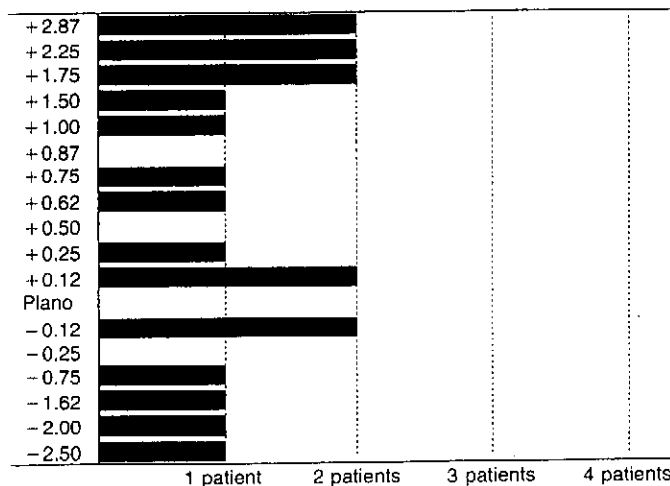


Fig. 9. (Fine) Preoperative distribution of refractive errors (spherical equivalents) of AMO PC-28LB patients.

optic was decentered postoperatively. In all patients examined the ora serrata was successfully visualized for 360 degrees. It is interesting and of probable clinical significance that the retina could be visualized more easily in the quadrants peripheral to the long axis of the lens; e.g., if the lens was oriented with the long axis in a vertical direction, the retina between 10:30 and 1:30 o'clock and between 4:30 and 7:30 o'clock was observed more easily than the retina between 1:30 and 4:30 o'clock and between 7:30 and 10:30 o'clock.

The macula in these patients was also examined by slitlamp. Both a hand-held 90+ diopter lens and a Hruby lens were used. An excellent view of the posterior pole was obtained with either technique.

### DISCUSSION

The design of the Phacofit lens addresses two potential problems related to the small size of the clear portion of the optic: glare and optic decentration. The wings of this implant have been opacified to avoid edge effects and other potential glare sources. The postoperative glare data (average disability 6.8% eight weeks postoperatively) compares favorably with Nadler's previously reported data (22%) for posterior chamber pseudophakes between nine and 17 months postoperatively.<sup>10</sup> The loops are staked to the optic in such a way that decentration based on asymmetric (sulcus/bag) implantation or asymmetric contracture of the capsular bag will occur along the long axis of the clear 3 mm by 6 mm optical zone. One would therefore expect this lens to have no optical disadvantage over a standard lens with a 6 mm optic.

Some observers have expressed concern that the contracture of the lens capsule might result in optic capture and a compression of the opacified wings

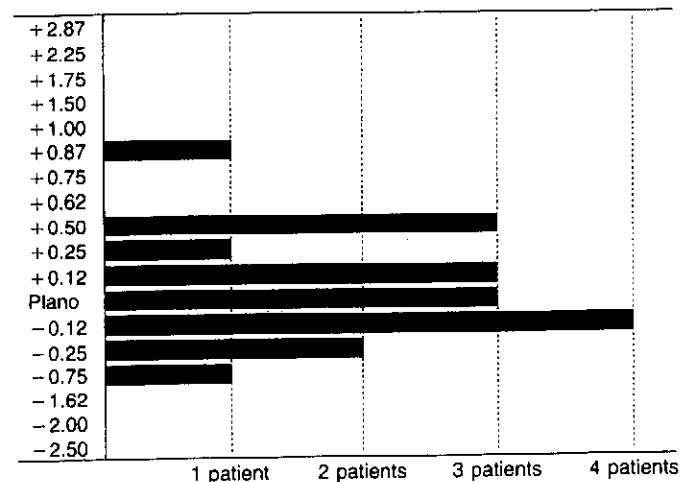


Fig. 10. (Fine) Postoperative distribution of refractive errors (spherical equivalents) of AMO PC-28LB patients eight weeks after surgery.

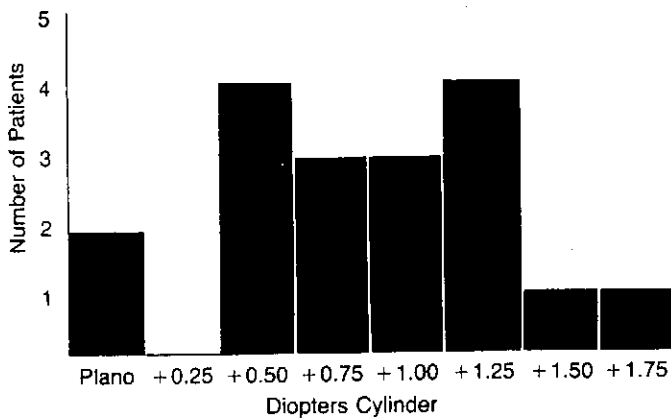


Fig. 11. (Fine) Astigmatism (diopeters of cylinder) of patients with AMO PC-2SLB lens at the eighth postoperative week.

behind the clear portion of the optic. Figure 12 demonstrates that as long as the anterior capsulotomy is slightly larger than 6 mm, soon after surgery the anterior capsular flap will become adherent to the posterior capsule, peripheral to the optic, thus precluding any possibility of optic capture and wing compression.

An additional concern regards the adequacy of the view of the fundus periphery through the rectangularly shaped optic. No clinically significant difficulties were encountered while examining the retina in these patients. Both the posterior pole and periphery were adequately visualized. The peripheral examination in these patients is technically more difficult than such an exam in the aphakic individual. However, such increased difficulty, common to all IOLs, is not an insurmountable obstacle to adequate retinal evaluation

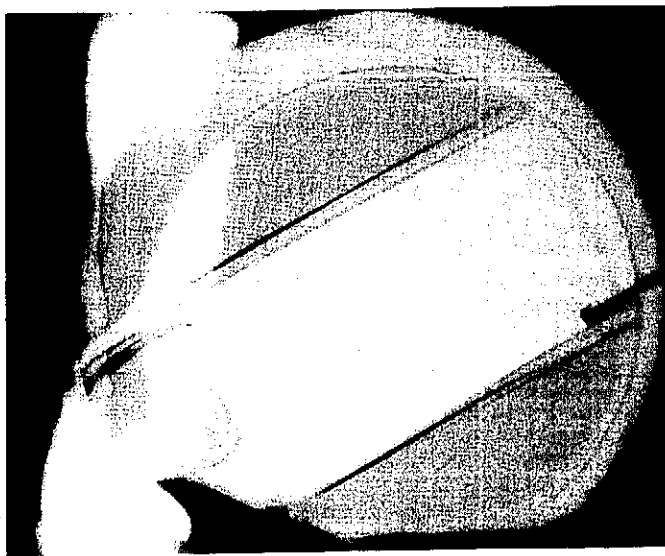


Fig. 12. (Fine) The anterior capsular flap adhering to the posterior capsule, peripheral to the optic.

by the experienced observer. It is the opinion of the vitreoretinal surgeon who performed these retinal examinations that it is the status of the posterior capsule and not the shape of the optic that will ultimately define the limits of the retinal evaluation. As long as the view through the optic remains unobstructed, no major problems are anticipated during retinal follow-up on patients with the PhacoFit lens.

Our intent was to make the patients approximately 2.50 D astigmatic with the rule at surgery so that by approximately two months after surgery astigmatic error would be under 1.00 D with the rule. These data document the ability to achieve that result with this particular implant, using a smaller incision and fewer sutures.

In our experience, the PhacoFit lens appears safe, is easily implanted in the eye, reduces surgical time, and promotes rapid visual rehabilitation of the eye because of the reduction in astigmatism. There has been a high level of satisfaction among the patients who participated in this limited core study.

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