PRELIMINARY RESULTS WITH A NEW HYDROGEL INTRAOCULAR LENS

S. P. B. PERCIVAL and A. J. JAFREE
Scarborough

SUMMARY

The merits of hydrogel as an intraocular lens material are that it is soft, foldable, hydrophilic, autoclavable and more biocompatible than polymethylmethacrylate (PMMA). Twenty eyes were implanted with a new hydrogel design after phacoemulsification. Fifty per cent achieved a corrected acuity of 6/5 and all achieved 6/9 with correction. Results confirmed an excellent biocompatibility of the material but two cases of asymptomatic decentration indicated the occasional instability within the capsular sac. For best results the hydrogel requires an intact capsulorrhexis with a diameter between 4.5 and 5.0 mm.

With the advent of small-incision cataract surgery there is a search to find an intraocular lens material which is truly suited to this approach and yet is able to retain a standard optic size of 6 mm. Hydrogel, a soft hydrophilic polymer of poly 2-hydroxyethylmethacrylate, is one such biomaterial which now has a long history of use as an intraocular lens.[1–4] The potential advantages of hydrogel over polymethylmethacrylate (PMMA) are:

1. It has a water content of approximately 38% by weight, so is soft, flexible and more closely mimicks the properties of living tissue.[5]
2. It is hydrophilic, so potentially can do less harm to the corneal endothelium.[6,7]
3. It is autoclavable, so potentially less expensive to manufacture.
4. It is foldable, so is suitable for small-incision surgery without the consequent side-effects of unwanted optical images that may be produced by PMMA lenses with narrower optics.[8,9]
5. It is more compatible with use of the neodymium:YAG laser.[3,5,7]
6. There is less evidence of lens-induced inflammation or cellular precipitation.[3,4,10–12]
7. There is less propensity for fibrous metaplasia of lens epithelial cells in contact with the lens and, although this has not been established as part of a clinical trial, it is likely that hydrogel is associated with less capsular fibrosis[12] and less chance for development of capsular contraction syndrome.[13]

Correspondence to: Mr S. P. B. Percival, Department of Ophthalmology, Scarborough Hospital, Scarborough YO12 6QL, UK.

The potential advantages of hydrogel over the commonly used three-piece silicone lenses are:

1. It is hydrophilic, so potentially can do less harm to the corneal endothelium.
2. It is autoclavable, so potentially less expensive to manufacture.
3. There is less evidence of associated inflammation and cellular precipitation.[11]
4. There have been no reports of lens discoloration[14] occurring with the passage of time.[2,3]
5. It is single piece, so there are no irregularities at the haptic/optic junctions.

The chief drawbacks to previous designs of hydrogel lenses were:

1. Reports of dislocation through lack of any adhesive property to the capsular sac.[3,15]
2. Reports of decentration[5] and 'C' deformity[3] that resulted from a design with plate haptics 12 mm in length. Hydrogel lenses are less able to resist the forces of capsular contraction than looped PMMA lenses, and if the lens itself is too long for the space into which it is intended to fit, a 'C' deformity can result.

In addition the hydrogel is not regarded as a universal lens: it is unsuitable when surgery is complicated by rupture of the lens zonule or posterior capsule, so that a back-up lens is necessary at surgery.

However, the newer design recommended by Barrett[2], has been reported to demonstrate early, reliable fixation in the capsular sac without being disadvantaged by the forces of capsular contraction. It is the purpose of this paper to provide an independent assessment of the results of this new lens.

MATERIALS AND METHODS

A prospective trial of 20 consecutive implantations was

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planned for the Iogel lens model 2000S Iogel Laboratories, Perth, Western Australia. This lens has a 6.0 mm optic that merges via a crescentic flange into a terminal loop of overall diameter 12.0 mm (Fig. 1). The haptic design allows compression in the plane of the optic without posterior vaulting on capsular contraction. The arcuate space between the haptic and optic provides an area for fusion between the anterior and posterior capsule in order to enhance capsular fixation. The lens was manufactured by a computer-controlled lathe and milling machine and was tumble-polished and autoclaved. It was presented wet in a hydrated state in a small vial of balanced salt solution.

Protocol was established whereby eyes with coexisting corneal disease, glaucoma, uveitis and retinal disease were excluded from the trial. Surgical contraindications to implantation included zonular disinsertion, incomplete anterior capsulorrhexis and posterior capsule rupture. Approval was obtained from the local Research and Ethics Committee. Before surgery each patient was able to sign a special form of informed consent.

All cases underwent a continuous tear capsulorrhexis followed by phacoemulsification. The intention was for the capsulorrhexis diameter to be around 5 mm. The lens was inserted through a 5 mm clear corneal incision without the use of folding forceps. Following placement into the capsular sac under sodium hyaluronate the wound was closed with a single X suture. Post-operatively visual acuities, refraction and slit lamp examinations were made at 1 day, 5 days, 1 month and 6 months. The 6 month examination included full mydriasis under phenylephrine and tropicamide. Particular care was taken to note any evidence of decentration, absence of capsular fusion, capsular fibrosis, precipitates on the lens surface and the size of the capsular rim.

RESULTS

Twenty patients (20 eyes) were entered into the study, with a mean age was 71.5 years (range 56–83 years). Thirteen patients were women and 7 were men.

Visual Acuity

By 5 days after surgery 19 eyes were seeing 6/12 unaided (95%) and 13 were seeing 6/9 or better unaided. At 6 months 19 were seeing 6/12 or better unaided and all were seeing 6/9 or better with correction (Table I). Fifty per cent of eyes achieved 6/5 with correction and 85% achieved 6/6.

Decentration

Estimation of centration of the 6 mm optic against a 7 mm pupil diameter was made 6 months after surgery under mydriasis. Eighteen lenses were found to be centred exactly (Fig. 2). Two lenses were decentred upwards by 1.5 and 1.0 mm, respectively. In 1 case a single radial tear had developed in the anterior capsule during surgery resulting in asymmetric contraction of the capsule post-operatively (Fig. 3). This patient noted symptoms of haloes at night when driving. There were no symptoms of unwanted optical images in any of the other patients. The other decentred lens was in association with a 5.5 mm capsulorrhexis at surgery (Fig. 4). In this case there was failure of post-operative fusion of the anterior and posterior capsular flaps inferiorly.

Inflammation

One eye developed a moderate uveitis during the first week which quickly responded to topical steroids. There were no cases of uveitis reported at 1 month or at 6 months. There were no cases of cystoid macular oedema. Apart from mild pigment dusting on the anterior surface of the lens to a variable extent, the lens surface remained clear. No macrophage precipitates were noted and there were no posterior synechiae. Three eyes (15%) were noted at 6 months to have small white dots on the posterior capsule/optic interface (Fig. 5).

Capsular Fibrosis

The posterior capsule remained clear during the period of follow-up in all cases. No evidence of fold formation or fibrosis could be detected. The anterior capsule where in contact with the hydrogel also remained clear apart from the white fibrotic rim that developed at the edge of the capsulotomy. The size of the capsulorrhexis was measured post-operatively. The mean diameter was 5.1 mm (range 4.6–6.0 mm). There was no evidence of centripetal contracture at the capsular rim during the period of follow-up. Two eyes had developed an anterior radial tear during the course of surgery leading to post-operative widening of the rim and one of these was associated with decentration.

DISCUSSION

The Iogel 2000S was designed to avoid the limitations of conventional PMMA lenses,[2,8–12] existing silicone lenses[2,11] and previous plate haptic designs of either hydrogel or silicone lenses. The superior biocompatibility compared with PMMA, the lower incidence of cellular precipitates and the relative resistance to damage by the neodymium:YAG laser have already been noted. Apple *et al.*[16] have shown how conventional loop haptics, whether of polypropylene or extruded PMMA, may deform the capsular sac, and Barrett[2] has shown an advantage of the new hydrogel design in that it does not lead to such deformation.

The present study confirms that excellent visual results may be obtained from the Iogel 2000S, which may in part be related to the absence of posterior capsular fibrosis or folding. Although some fibrosis takes place at the edge of the capsulorrhexis there appears to be less fibrosis of the adjacent capsule where it is in contact with the hydrogel optic or haptic as compared with that expected after

Table I. Visual acuities of 20 eyes at 6 months after surgery

	6/5	6/6	6/9	6/12	6/18 or worse
Unaided	1	5	6	7	1
Best corrected	10	7	3	0	0

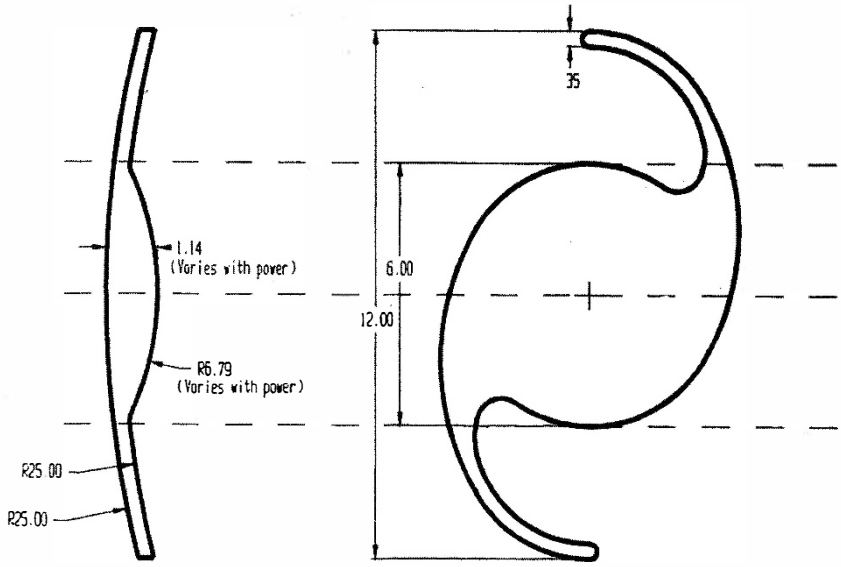

Fig. 1. *Diagram of Iogel lens style 2000S. The optic diameter is 6.0 mm, the overall length is 12.0 mm.*

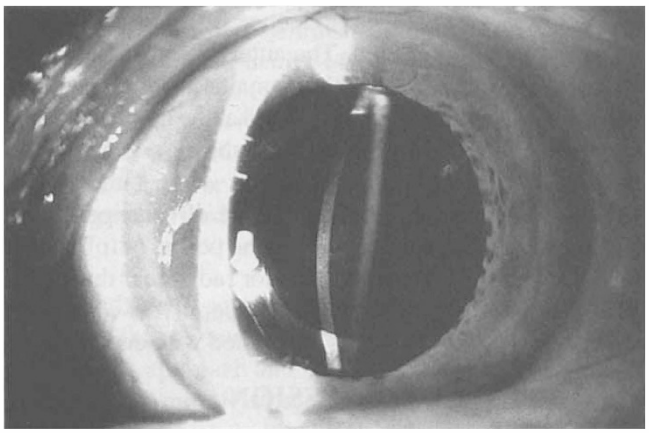

Fig. 2. *Perfectly centred Iogel 2000S photographed 7 months after surgery. The capsulorrhexis measures 5.5 mm. The anterior and posterior capsule remain clear except at the edge of the capsulorrhexis.*

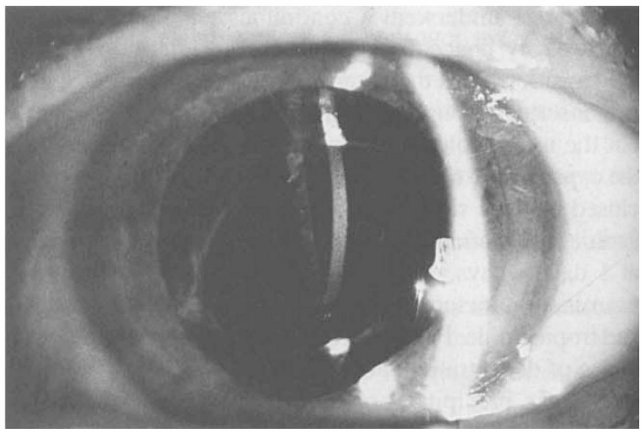

Fig. 3. *Upward decentration of 1.5 mm of an Iogel 2000S photographed 1 year after surgery. The 5.0 mm capsulorrhexis had extended in the 4 o'clock meridian because of an anterior capsular tear at surgery. Fusion of the capsular flaps is seen below the optic. Capsular fibrosis was found to be minimal except at the rim of the capsulorrhexis.*

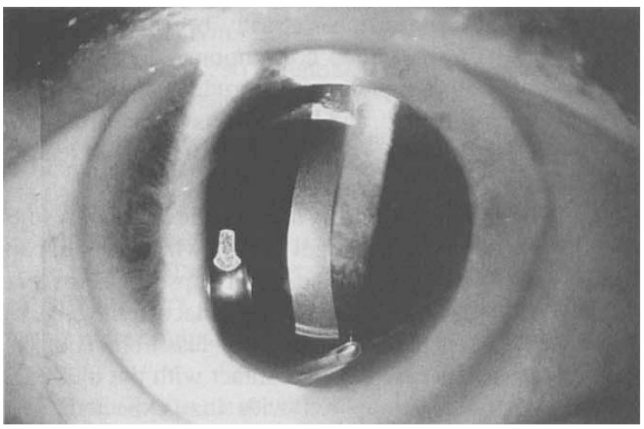

Fig. 4. *Upward decentration of 1.0 mm of an Iogel 2000S photographed 6 months after surgery. The fibrotic rim of the 5.4 mm capsulorrhexis can be seen in the path of the slit beam. A clear space exists below the inferior rim between the anterior and posterior leaves of capsule signifying that fusion had not yet occurred. In addition the tip of the inferior haptic can be seen flexed towards the optic.*

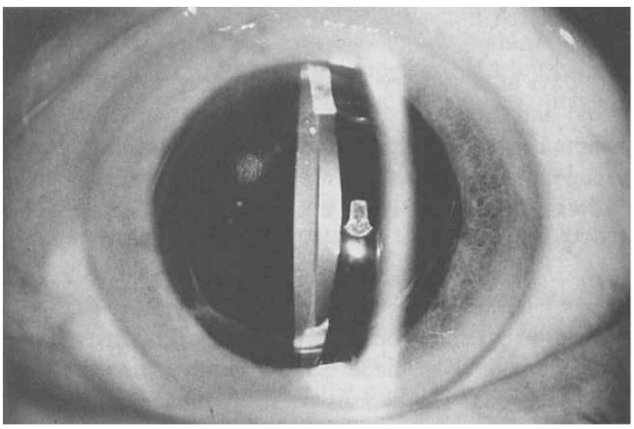

Fig. 5. *Perfectly centred Iogel 2000S photographed 6 months after surgery with a 5.5 mm capsulorrhexis. A few white spots are seen at the posterior capsule/optic interface superiorly in the path of the slit beam.*

implantation of PMMA or silicone. There was no evidence of development of the anterior capsule contraction syndrome. Ninety per cent of lenses maintained a perfect centration in the follow-up period with no evidence of loop or capsular sac deformity. Two lenses (10%) became decentred by 1.5 and 1.0 mm, respectively, in relation to asymmetric capsular contraction. The presence of an anterior radial tear has already been shown to be correlated with decentration of PMMA lenses.[17] In one case there had been an anterior radial tear in the capsule. In the other it was noted that there had been incomplete fusion between the anterior and posterior leaves of capsule. The latter finding tends to negate the suggestion by Barrett[2] that capsular fusion will prevent decentration, at least in some cases.

Small circular white dots, as noted also by Menapace *et al.*[4] at the lens/posterior capsule interface, were observed in 3 eyes without interfering with visual acuity. The significance of these small opacities is uncertain.

More than 2400 hydrogel implants have now been implanted world wide since 1984,[2] and although the lens designs have been altered, the material may be said to have withstood the test of time and to offer superior biocompatibility compared with PMMA. For best results the Iogel does, however, require faultless surgery and an intact capsular rim the diameter of which should be between 4.5 and 5.0 mm.

Key words: Biocompatibility, Capsular fibrosis, Decentration, Hydrogel, Lens design.

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