Hydrogel Intracorneal Lenses in Aphakic Eyes

Roger F. Steinert, MD; Blake Storie; Pamela Smith, MPH; Marguerite B. McDonald, MD; Gabriel van Rij, MD; Leo D. Bores, MD; Joseph P. Colin, MD; Daniel S. Durrie, MD; Curtin Kelley, MD; Francis Price, Jr, MD; Chad Rostron, MD; George O. Waring III, MD; Lee T. Nordan, MD

Background: The theoretical benefits of synthetic keratophakia over conventional corneal lamellar procedures are the elimination of donor concerns and superior refractive predictability. Additionally, synthetic material can be inspected for optical quality and power, and it can be sterilized. Furthermore, visual recovery should be more rapid since epithelium is not removed from the central part of the cornea and the need for keratocyte repopulation is eliminated.

Objective: To present results on patients who received an intracorneal implant (Kerato-Gel, Allergan Medical Optics, Irvine, Calif) that was made from lidofilcon A, a glucose-permeable hydrogel with an equilibrium water content of 68%.

Methods: The intracorneal implants were implanted in 35 adult patients for correction of aphakia. Inclusion criteria excluded patients with aphakia who were candidates for intraocular lenses.

Results: A total of 19 patients were followed up through 2 years postoperatively. For 16 patients with 2-year postoperative refractive data, the average spherical equivalent was −0.63±2.07 diopters (D). At 2 years, 88% of patients were within ±3.00 D of plano and 50% were within ±1.00 D. The mean change in Snellen's line for corrected visual acuity was −3.25 lines at 2 years for all patients and −2.0 lines for a subgroup of five patients who were free of vision-limiting preoperative disease.

Conclusions: Results suggest that this intracorneal implant is well tolerated by the cornea and can provide predictable refractive results in patients with high-risk aphakia. Limitations of the procedure are uneven microkeratome resections, loss of best-corrected visual acuity, and irregular astigmatism in some patients. Although these data show good evidence of biocompatibility of the implant material, technical surgical progress is needed to advance this procedure into clinical therapeutic practice.

(Arch Ophthalmol. 1996;114:135-141)

From the Center for Eye Research and the Department of Ophthalmology, Harvard Medical School, Boston, Mass (Dr Steinert); Allergan Medical Optics, Irvine, Calif (Mr Storie and Ms Smith); LSU Eye Center, Louisiana State University Medical Center School of Medicine, New Orleans (Dr McDonald); the Department of Ophthalmology, Groningen (the Netherlands) University (Dr van Rij); the Department of Ophthalmology, Brest (France) University Hospital (Dr Colin); Ohio State University, Columbus (Dr Kelley); Cornea Consultants, Indianapolis, Ind (Dr Price); the Department of Ophthalmology, St George's Hospital Medical School, London, England (Dr Rostron); and the Department of Ophthalmology, Emory University Eye Center, Atlanta, Ga (Dr Waring). Drs Bores, Durrie, and Nordan are in private practice in Scottsdale, Ariz; Kansas City, Mo; and La Jolla, Calif, respectively. Dr Steinert is a consultant for Allergan Medical Optics.

SEVERAL METHODS have been developed to alter the corneal curvature surgically in patients with aphakia who are contact lens–intolerant and are not candidates for intraocular lenses (IOLs). Keratophakia is a form of lamellar keratoplasty that was developed by Barraquer.[1] This equipment-intensive technique requires surgeons to cryolathe donor corneal lenticules to precise dimensions during the surgical procedure and to implant the lenticules within the recipient cornea that has been split with a microkeratome. Epikeratoplasty involves placement of a donor lenticule, prepared before surgery, on top of the recipient corneal Bowman's layer.[2] Epikeratoplasty is a more straightforward surgical method, is less invasive than keratophakia, and is reversible. With either technique, however, donor tissue must be procured, refractive results are variable, and postoperative recovery of visual acuity is often slow. Therefore, few surgeons now use these techniques.

Synthetic keratophakia offers several potential advantages over these two refractive procedures. It eliminates human donor problems, including limitation of supply, control of dimensions, and sterility. Refractive predictability of synthetic lenticules should be superior to that of tissue, because synthetic material can be inspected for optical quality and power. Visual recovery should be more rapid than epikeratoplasty since corneal epithelium is not removed and the need for keratocyte repopulation is eliminated. Synthetic corneal lenses have been used to correct aphakia in several animal models.[3-6] Most experience with synthetic materials has been associated with lenses made of either hydrogels or the high-refractive index polymer polysulfone. The

See Materials and Methods on next page

MATERIALS AND METHODS

The intracorneal lenses used in this study were made of lidofilcon A, a copolymer of *N*-vinyl-2-pyrrolidone and methyl methacrylate. This material is glucose-permeable with a water content of 68% when fully hydrated. All lenses were 5.5 mm in diameter with the exception of one: a 6.5-mm lens that was implanted in the first eye. The center thicknesses ranged from 0.24 to 0.37 mm. Lens powers that were used ranged from +8.00 diopters (D) to +17.50 D, and the lens power was the same as the preoperative manifest refraction, corrected to the corneal plane.

Inclusion criteria required eyes to be ineligible for IOL implantation, intolerant of spectacle and contact lens wear, and to have a preoperative refraction between +5.00 and +20.00 D. Since this was the first US clinical trial evaluating synthetic intracorneal lenses, the investigation was conducted by using a small population that had no other acceptable alternative for visual rehabilitation, gradual entry, and extensive follow-up. Before patient enrollment, institutional review board approval was obtained at each site. Each patient who was selected for inclusion in the study was required to review and sign an informed consent. Eleven investigators participated in this study, enrolling a total of 35 eyes of 35 patients.

The study protocol required the surgeons to use a manually advanced microkeratome to perform a dissection of the cornea, thereby producing a plano corneal disc of 0.25 mm in thickness and typically 8.2 to 8.8 mm in diameter. Twenty-five procedures were performed with the Barraquer microkeratome (Steinway Instruments Inc, San Diego, Calif), eight with the BKS-1000 microkeratome (Allergan Medical Optics), and one with the SCMD Keratome Unit (SCMD, Fountain Hills, Ariz). In one eye, inadequate suction that was caused by a filtering bleb prevented the use of a microkeratome. In this case, a hand lamellar dissection was performed by using a Hessburg-Barron trephine (JEDMED Instruments Co, St Louis, Mo) and Martinez spatula (Storz Instruments, St Louis, Mo). In all patients, the implant was placed between the corneal disc and the stroma, and the disc was sutured into position by using either running or interrupted 10-0 nylon sutures. Double running sutures were used in 59% of the procedures, interrupted sutures were used in 38%, and a combination of double running and interrupted sutures were used in 3%. Suture tension was adjusted to minimize astigmatism and allow the disc to drape over the hydrogel implant with increased anterior corneal curvature. Eyes were treated with prophylactic antibiotics and low-dose corticosteroid drops (eg, prednisolone acetate, 1/8% twice daily) until suture removal. Sutures were removed before the 3-month postoperative examination in all but four eyes.

Patients were examined preoperatively and postoperatively at a minimum of 1 day (30 eyes), 1 week to 2 weeks (33 eyes), 1 month (32 eyes), 3 months (28 eyes), 6 months (24 eyes), 1 year (23 eyes), and 2 years (19 eyes). Preoperative and postoperative examinations included uncorrected and spectacle-corrected distance visual acuity by using standard Snellen's charts, manifest refraction, and slit-lamp microscopy. Videokeratography was performed in a small number of eyes. Postoperative results were reported for all eyes with available data.

Table 1. Preoperative Diseases and Surgical Procedures*

Diseases or Procedures	No. (%) of Patients
Most frequent diseases reported	
Macular	11 (31)
Retinal, other	12 (34)
Corneal	7 (20)
Glaucoma	6 (17)
Most frequent prior surgical procedures other than cataract extraction	
IOL removal	8 (23)
Retinal	7 (20)
Glaucoma	2 (6)
Corneal/refractive	2 (6)

**IOL indicates intraocular.*

use of polysulfone lenses has been limited by its nonpermeable characteristics, leading to corneal degeneration.[7] High-water content and nutrient-permeable hydrogels have been shown to be well tolerated in nonhuman primates for up to 8 years.[8,9] Yet, few studies have been reported on the use of synthetic intracorneal lenses in humans.[10,11]

This study was initiated in March 1987 to evaluate the safety and effectiveness of hydrogel intracorneal lens implants to correct aphakic refractive error. Preclinical evaluations of this implant have been reported previously.[12,13] This article describes the clinical results of an intracorneal implant (Kerato-Gel, Allergan Medical Optics, Irvine, Calif) that was implanted in 35 eyes by 11 surgeons.

RESULTS

The average age of the patients was 64 years; 63% (22/35) of the patients were female, and 37% (13/35) were male. The mean preoperative spherical equivalent was +11.60 D, ranging from +6.00 to +14.38 D. As seen in **Table 1**, most eyes had preoperative disease (eg, glaucoma, low corneal endothelial cell counts, and macular degeneration). In addition to cataract surgery, many patients had undergone prior surgical procedures for retinal detachment, glaucoma, and IOL removal. For eyes with endothelial cell count data (n=21), the average preoperative density was 1290 cells per square millimeter, with eight (38%) eyes having a cell density of 900 cells per square millimeter or less. Preoperative demographic parameters are included in **Table 2**.

Several patients did not undergo full testing at every postoperative visit. Therefore, data on some outcome measurements may show a smaller number of patients than were actually seen at a particular visit. At the final 2-year visit, 19 patients were available for follow-up. Data were not available for 16 patients at the final 2-year follow-up owing to (1) lens removal (six pa-

Table 2. Preoperative Demographic Parameters*

Preoperative Parameter	Mean (±SD)	Range
Age, y	64 (±12)	38-81
Endothelial cell density, cells/mm² (n=21)	1290 (±642)	250-2895
Preoperative spherical equivalent refraction, D		
Refractive error	+11.6 (±1.97)	+6.00-+14.38
Refractive cylinder	1.30 (±1.01)	0-4.25

D indicates diopter.

tients), (2) death (two patients), and (3) unable to locate the patients (eight patients).

Figure 1 shows the mean spherical equivalent of the manifest refraction over time for reported follow-up on all eyes. At 3 months, the mean spherical (±SD) equivalent refraction was −0.93 D (±2.34 D [n=27]); this remained stable during the 2-year follow-up period, and it was −0.63 D (±2.07 D [n=16]) at 2 years. **Figure 2** illustrates the refractive predictability for 16 eyes with 2-year postoperative refractive data. The proportion of patients with a residual refractive error of ±3.00 D was 88%; for patients with refractive errors of ±2.00 and ±1.00 D, it was 75% and 50%, respectively. At 2 years, the mean refractive cylinder (absolute value) was 2.42 D (±1.15 D).

Figure 3 shows spectacle-corrected visual acuity results preoperatively and at 3 months and 2 years postoperatively. Before surgery, the visual acuity in 65% of the eyes was 20/40 or better. At 3 months, the visual acuity was 20/40 or better in 33% of the eyes. Of the five eyes with 20/200 or worse visual acuity at 2 years, four of five eyes had macular degeneration, cystoid macular edema, or a retinal disease preoperatively. The fifth eye had a retinal detachment postoperatively.

The rate of recovery of best spectacle-corrected visual acuity over time is illustrated in **Figure 4**. Visual acuity improved significantly during the first 3 months, and it was generally stable from 3 months to 2 years. The time course recovery of best corrected visual acuity was similar through 1 year, when considering patients without significant preoperative disease ("best case"). However, these patients did not experience as much vision loss at 2 years. The average loss in Snellen's lines at 2 years for the best-case patient group was −2.0 lines (±1.58 [n=5]) compared with −3.25 lines (±3.26 [n=16]) for all patients. Seventeen patients had 2-year visual acuity data; however, one patient did not have a valid preoperative visual acuity, and it was not included in this analysis. Evaluation of 16 eyes with 2-year and preoperative visual acuity data indicated that five eyes (31%) were within 1 line of their preoperative level, and 11 eyes (69%) had a 2-line or greater loss compared with preoperative levels (**Table 3**). The loss of visual acuity in this group can be attributed to progression of their vision-compromising ocular disease and/or postoperative irregular astigmatism.

Of the 16 eyes with uncorrected visual acuity data at 2 years, 14 (88%) achieved an improvement in their vision compared with preoperative visual acuity. Two eyes

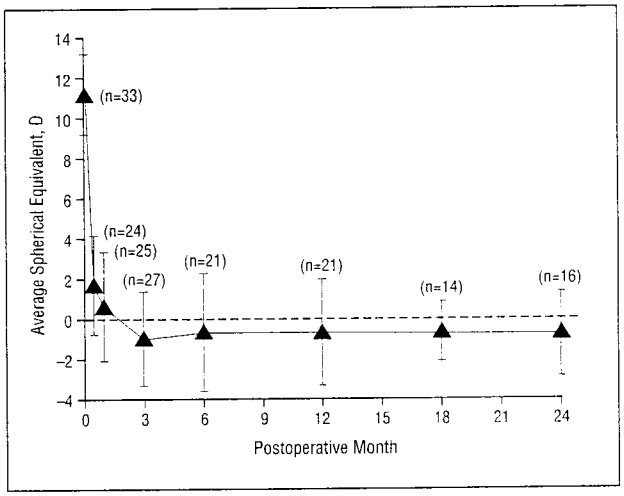

Figure 1. *Spherical equivalent refraction (mean± SD) over time for all eyes with available data. D indicates diopters.*

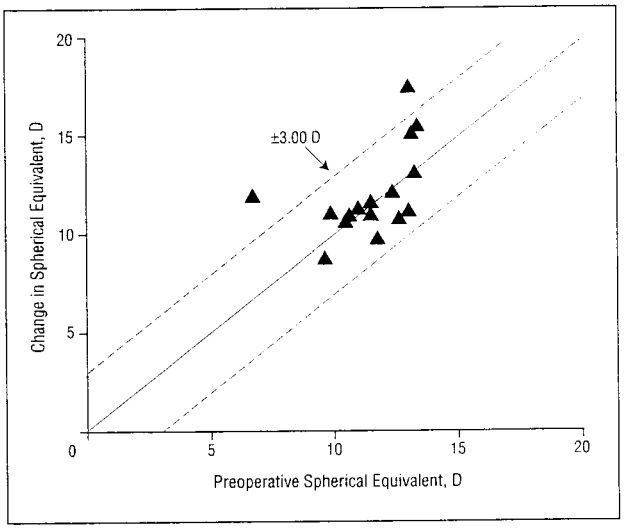

Figure 2. *Change in spherical equivalent refraction compared with preoperative refractive error for 17 eyes at 2 years. Dashed lines represent ±3 diopters (D) from plano.*

did not improve (**Table 4**). The preoperative disease of these eyes contributed to the 2-line or greater loss in spectacle-corrected visual acuity and to the lack of improvement in their postoperative uncorrected visual acuity. For the entire population (16 eyes), the average change in uncorrected visual acuity at 2 years compared with the preoperative visual acuity was +4.00 lines (±3.03).

The intracorneal lens implant was well tolerated in the human cornea (**Figure 5** and **Figure 6**). In most eyes, the cornea was clear at 1 day postoperatively. The most common postoperative complications included intracorneal deposits (13 patients), irregular astigmatism (nine patients), corneal haze (five patients), implant migration (four patients), corneal edema (three patients), slight interface haze (three patients), and lens implant removal (four patients). In two other patients, the implant was repositioned in one after it migrated, and the other patient underwent removal of epithelium from the intracorneal interface.

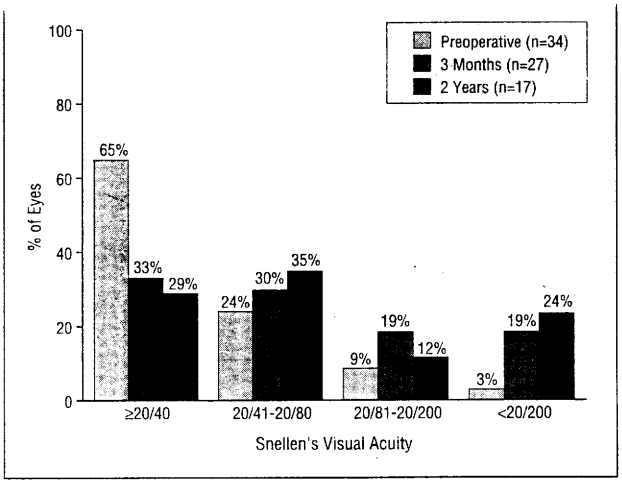

Figure 3. *Spectacle-corrected visual acuity. (Numbers do not add up owing to rounding off.)*

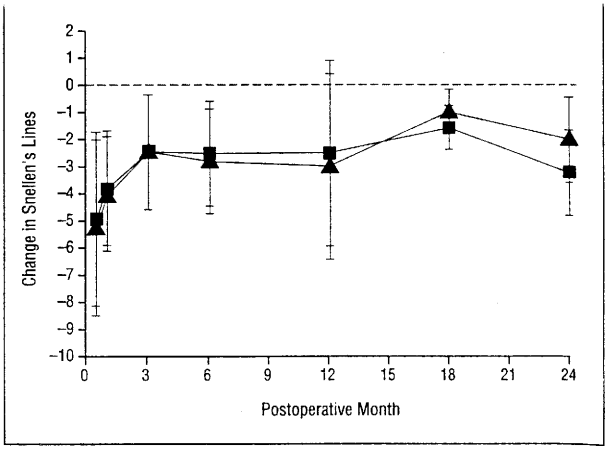

Figure 4. *Recovery of spectacle-corrected visual acuity. Change in spectacle-corrected visual acuity (Snellen's lines) from preoperative to postoperative (mean± SD) for all eyes and best-case eyes. Squares indicate all patients (n=23 [1 week], n=26 [1 month], n=26 [3 months], n=22 [6 months], n=20 [1 year], n=15 [1.4 years], and n=16 [2 years]); triangles, patients with best-corrected visual acuity (n=8 [1 week], n=10 [1 month], n=10 [3 months], n=5 [6 months], n=6 [1 year], n=4 [1.4 years] and n=5 [2 years]).*

Lenses were removed in six of the 35 eyes. In two of these patients, implants were replaced with another intracorneal lens. Patient 2414 initially had a preoperative corrected visual acuity of 20/80 with refraction and 20/30 with a hard contact lens; this patient also had a history of retinal surgery. At 7 months postoperatively, this patient achieved a corrected visual acuity of 20/80 with refraction (spherical equivalent of −6.13 D). However, intracorneal deposits in the visual axis and irregular astigmatism prompted implant removal. Two months following implant removal, this patient achieved a corrected visual acuity of 20/25 with a hard contact lens and had no further complications.

Patient 2388 initially had a preoperative corrected visual acuity of 20/25 and significant preoperative disease (eg, low endothelial cell count, corneal edema, pain, and photophobia). At intracorneal implantation, this patient had an incomplete keratectomy owing to a loss of suction of the ring. At 3 months postoperatively, the patient achieved a corrected visual acuity of 20/200 with an equivalent refraction of +0.75 D. Postoperative problems included irregular astigmatism, corneal edema, and corneal haze. The implant was removed at 4 months because of progressive severe corneal decompensation and corneal haze, and a penetrating keratoplasty was performed.

Patient 2408 had a preoperative corrected visual acuity of 20/30 with +4.25 D of cylinder and an endothelial cell count of 986 cells per square millimeter. At 6 months postoperatively, the patient's corrected visual acuity was 20/200 with a spherical equivalent of +0.75 D. The implant was subsequently removed because of irregular astigmatism. Three months later, the surgeon elected to place an iris-sutured posterior chamber IOL. Seven months later, the patient had a corrected visual acuity of 20/60.

Patient 2406 had a preoperative corrected visual acuity of 20/25 with +2.25 D of cylinder. During intracorneal implantation, the patient experienced surgical complications owing to a loss of suction. In addition, a small cut occurred in the stroma. At 3 months postoperatively, the patient's tissue cap was replaced with a donor cap because of irregular astigmatism that was attributed to a thin microkeratome cut at the time of implantation. Eight months after this procedure, the patient had a corrected visual acuity of 20/200, severe corneal scarring, and irregular astigmatism. Two months later, the pa-

Table 3. Patients With a Loss of 2 or More Snellen's Lines in VA*

Patient	VA		No. of Lines Lost	Preop Pathology or Prior Surgery in Operated-on Eye
	Preop	Postop		
2378	20/60	20/200	−4	Macular degeneration, cystoid macular edema
2381	20/30	20/60	−3	None
2383	20/25	20/50	−3	Glaucoma, corneal pathology, vitreous fills anterior chamber
2384	20/30	20/100	−6	Macular degeneration, drusen, irregular epithelial pigmentation
2385	20/200	Finger counting	−3	Glaucoma, senile macular degeneration, irregular epithelial pigmentation, diabetes, glaucoma surgery, cataract surgery and vitrectomy
2386	20/20	20/40	−3	Retinal detachment, refractive surgery, cataract surgery
2390	20/40	20/80	−4	Cystoid macular edema, cataract surgery, IOL removal
2397	20/20	20/30	−2	Cataract surgery
2401	20/20	20/50	−4	Cataract surgery
2405	20/25	Finger counting	−11	Glaucoma, cataract surgery, iridodialysis
2412	20/30	20/400	−9	Cystoid macular edema, cataract surgery, IOL removal

**VA indicates visual acuity; Preop, preoperative; Postop, postoperative; and IOL, intraocular. Two-year Postop vs Preop values are given. Irregular astigmatism, which occurred in patients 2378, 2401, and 2405, was reported at any time Postop.*

Table 4. Patients Whose Uncorrected VA (Snellen's Lines) Did Not Improve*

Patient	Uncorrected VA		SE		Preop Pathology
	Preop	Postop	Preop	Postop	
2385	Finger counting	Finger counting	11.50	−0.25	Glaucoma, senile macular degeneration, irregular epithelial pigmentation, diabetes, glaucoma surgery, cataract surgery and vitrectomy
2405	20/400	Finger counting	11.00	−4.50	Glaucoma, cataract surgery, iridodialysis

VA indicates visual acuity; Preop, preoperative; Postop, postoperative; and SE, spherical equivalent. Two-year Postop vs Preop values are given.

tient underwent removal of the intracorneal implant in conjunction with a penetrating keratoplasty and implantation of an anterior chamber IOL. Four months later, the patient had a corrected visual acuity of 20/40 with no complications.

Patient 2400 initially had a preoperative corrected visual acuity of 20/80 (+4.00 D of cylinder), an endothelial cell count of 850 cells per square millimeter, and prior macula-off retinal detachment. The intracorneal implant was removed after 1 month because of extrusion of the implant through the wound. One month following implant removal, the patient had a corrected visual acuity of 20/80 with no additional complications. The patient then underwent implantation of a second intracorneal implant. At 2 years postoperatively, the patient had a corrected visual acuity of 20/200 with a spherical equivalent of −3.38 D and a cylinder of −4.25 D.

Patient 2380 had a preoperative corrected visual acuity of 20/20 and a history of iritis. At 1 month postoperatively, this patient had a corrected visual acuity of 20/40 with a spherical equivalent of −0.50 D. At 6 months, the corrected acuity was 20/60, and the implant was removed because of intracorneal epithelial deposits that affected vision. Three months later, the patient had a corrected visual acuity of 20/30 with no complications. The patient then underwent implantation of a second intracorneal implant; at 1 year postoperatively, the patient had a corrected visual acuity of 20/30 with a spherical equivalent of +0.13 D and cylinder of +1.25 D.

Videokeratography analysis (**Figure 7** and **Figure 8**) was performed in several patients. Surface topography varied among patients. Figure 7 illustrates an eye with a +10.50-D lens that had a largely spherical optic zone. Figure 8 illustrates an eye that was implanted with a +12.50-D lens and had more surface irregularity.

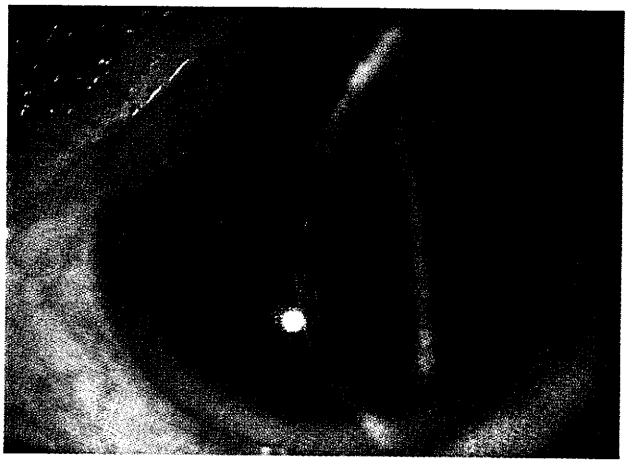

Figure 5. *Slit-lamp photomicrograph appearance at 2 years after aphakic hydrogel keratophakia in a 65-year-old man who had previously undergone explantation of an anterior chamber intraocular lens because of chronic cystoid macular edema. Spectacle-corrected visual acuity recovered to 20/50. To avoid further intraocular surgery that might stimulate further cystoid macular edema, the patient underwent intracorneal implantation of the lens (Kerato-Gel) used in this study. Power was +15.0 diopters with a 5.5-mm diameter.*

COMMENT

This study was performed to assess the safety and effectiveness of hydrogel intracorneal implants for correction of aphakia. The study population comprised patients with severe preoperative disease and poor prognoses for significant improvement of visual function by other modalities. The results of this study were compared with those for epikeratophakia since epikeratophakia was the most likely alterative treatment available to these patients. When this study was designed in the mid-1980s, the principal choice for secondary IOLs was limited to anterior chamber IOLs. At that time, iris- or scleral-sutured IOLs were not considered as viable or available alternatives. The intention of this procedure was to offer an alternative to invasive surgery for patients, who at the time, were considered ineligible for secondary IOLs because of low endothelial cell counts or other serious preoperative disease.

The emphasis in this study was to assess refractive predictability and stability, verify biocompatibility, and identify any operative or postoperative complications. Refractive correction generally stabilized within the first 3 months and remained unchanged throughout the follow-up period. Refractive predictability was reasonable, with 88% of eyes within ±3.00 D of plano at 2 years (n=16); this finding compares favorably with results for epikeratophakia in which 75% of the eyes were within ±3.00 D of emmetropia, with a mean follow-up time of 6 months.[14] Results from several keratophakia studies have reported a similar accuracy, with an average of 75% of the eyes within ±3.00 D of intended correction.[15] Implantation of hydrogel intracorneal implants in monkey eyes provided similar refractive results.[12]

Although data through 2 years postoperatively were not available for 16 patients, six of these patients had undergone lens removals, and two had died. This study has been closed, and patients were no longer being followed up formally as part of this study protocol; thus, not all

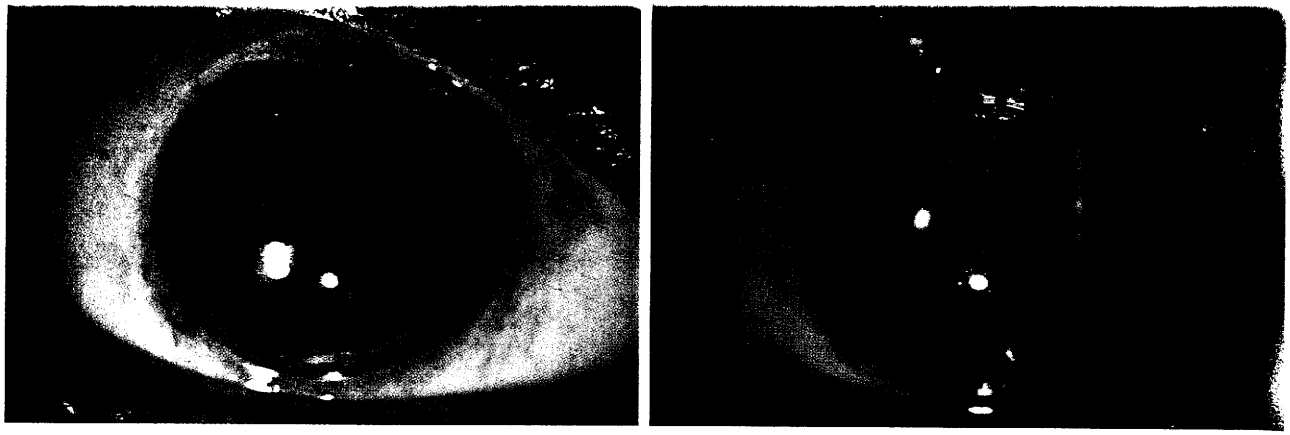

Figure 6. *Slit-lamp photomicrographic appearance at 1 year postoperatively in a 65-year-old woman who had previously undergone removal of an anterior chamber intraocular lens for cystoid macular edema. She was unable to tolerate an aphakic contact lens. Preoperative spectacle-corrected visual acuity was 20/50-2. She underwent implantation of an intracorneal lens (Kerato-Gel) with a power of +15.5 diopters and a 5.5-mm diameter. The patient had a spectacle-corrected visual acuity of 20/70 with a refraction of +2.50 −1.00×140.*

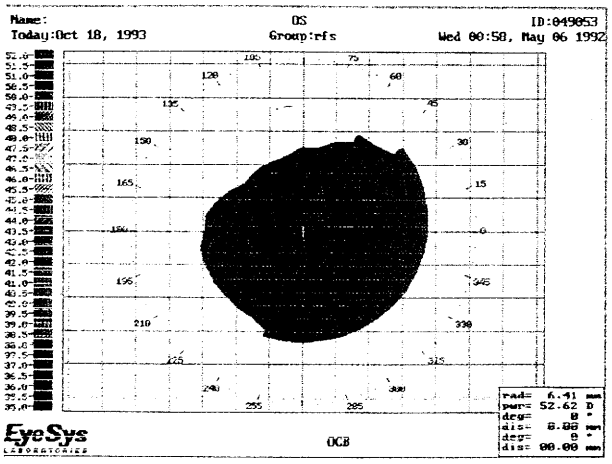

Figure 7. *Videokeratograph of an eye with a +10.5-diopter hydrogel intracorneal lens that had a largely spherical optic zone. Peripheral corneal irregularity over the microkeratome wound prevent topographic analysis outside the disc.*

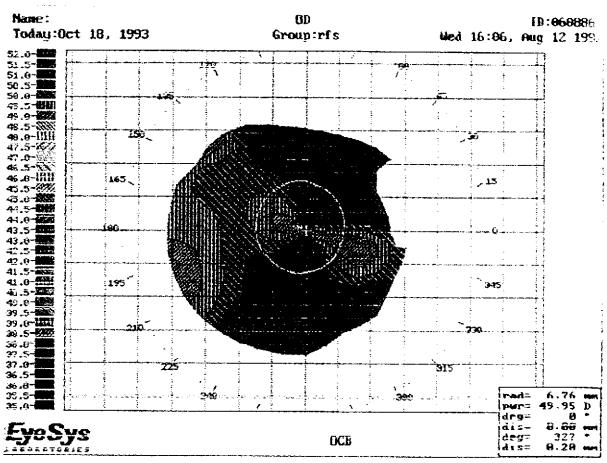

Figure 8. *Videokeratograph of an eye implanted with a +12.5-diopter hydrogel intracorneal lens with irregular astigmatism.*

patients were available to the original investigators who performed the implantations for follow-up. Nevertheless, none of the investigators has seen or been notified of any cases of subsequent corneal degeneration, decompensation, or other evidence of intolerance of the implanted material.

While some eyes maintained their level of spectacle-corrected preoperative visual acuity, 69% lost greater than 1 Snellen's line at 2 years. In the nationwide epikeratophakia study, 31% lost greater than 1 line of spectacle-corrected visual acuity.[14] Loss of spectacle-corrected visual acuity in our study population appeared to have several causes, with irregular astigmatism and intracorneal deposits the most frequently reported factors. The ultimate measure of irregular astigmatism would be an assessment of the difference in best-corrected visual acuity by using hard contact lenses vs best spectacle-corrected visual acuity. However, the measurement of best-corrected visual acuity via hard contact lenses was not performed in this study. It is reasonable to attribute some loss of corrected acuity to irregular astigmatism in those patients with clear corneas and no sign of intracorneal deposits, as some degree of irregular astigmatism may be inherent in this technique, particularly when sutures stabilize the corneal disc. In some patients, complications were associated with technical difficulties during the microkeratome procedure, whereas in other patients, the cause was unknown. In addition, some of the loss in spectacle-corrected visual acuity could be attributed to worsening preoperative ocular disease.

A benefit that was experienced by most patients was the improvement in uncorrected visual acuity. Because these patients were not contact lens or IOL candidates, the hydrogel implant was one of the few available alternatives to restore visual function. Uncorrected visual acuity of eyes in this study improved by an average of 4 Snellen's lines at 2 years postoperatively (44% with ≥4 lines of improvement). In the nationwide epikeratophakia study, the uncorrected visual acuity improved by 4 Snellen's lines in 53% of the patients.[14]

Of the six eyes that required removal of the intracorneal lens impant, four removals were related to the surgical aspects of this procedure: an irregular microkeratome resection, interface epithelial ingrowth, or lens migration. In this study, lens removal and exchange were shown to be possible in two eyes. Once satisfactorily implanted, the intracorneal lens implant was well tolerated in human corneas, with 19 lenses in place for more than 2 years. This finding corroborates the results from an earlier animal study.[13] The long-term tolerance of hydrogel intracorneal lenses has been reported previously in monkey eyes.[8,9,13]

The clinical experience from this study has demonstrated the feasibility of using hydrogel intracorneal lenses to achieve good refractive predictability, stability, and biocompatibility in adult patients with aphakia. However, limitations to this procedure have also been demonstrated. The microkeratomes employed were difficult to use and could produce irregular tissue resections. Furthermore, postoperative lens migration, interface deposits, and irregular astigmatism necessitated lens removal, repositioning, or replacement of the corneal disc with a donor cornea in many patients. Although these lenses provided predictable and stable refractive results, many eyes experienced a loss in spectacle-corrected visual acuity. Meanwhile, the surgical techniques for alternative secondary IOLs have improved. Substantial advances in microkeratome instruments and surgical techniques could potentially lead to improved results by using hydrogel intracorneal lenses. Specifically, recent advances in microkeratome instrumentation plus applications (eg, the flap keratomileusis technique and sutureless caps) conceivably may yield less irregular astigmatism. Until these other tools are refined, however, further work to continue development and evaluation of this hydrogel intracorneal implant will not be pursued.

Accepted for publication July 13, 1995.

This study was supported in part by Allergan Medical Optics, Irvine, Calif.

Interim results of this study have been presented in part at the meetings of the Contact Lens Association of Ophthalmologists, New Orleans, La, 1989; the American Society of Cataract and Refractive Surgery, Los Angeles, Calif, 1990; the Welsh Congress, Galveston, Tex, 1990; the European Intraocular Implantlens Council, Dublin, Ireland, 1990; the European Society of Cataract and Refractive Surgery, Valencia, Spain, 1991; and the American Academy of Ophthalmology, Anaheim, Calif, 1991.

Reprint requests to 50 Staniford St, Boston, MA 02114 (Dr Steinert).

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