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UPDATE ON POLYSULFONE CORNEAL INLAYS

(INTRACORNEAL LENSES)

by

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SUMMARY

54 polysulfone corneal inlays (intracorneal lenses) have been inserted into human corneae since early 1981.

Provided they were placed close to an intact Descemet's membrane, no serious complications have been observed. The 6 mm and 5 mm diameter inlays are providing useful vision up to 66 months later with an average follow-up of 33 months. Insufficient data exists to make a judgement on their use in cataract/aphakia. The best results are in high myopia.

Animal work in the USA directed by Lindstrom confirms Choyce's clinical finding that the best results are obtained by placing thin (myopic) inlays close to Descemet's membrane.

Over-correction, due to a false assumption in calculating the optics of the inlays, has been put right. Fluctuating vision remains a problem in some cases.

It has been demonstrated in some of Lindstrom's cats and a patient of Mr Starr's, that the inlays can be removed with restoration of the cornea to its pre-operative state. In another case of Choyce's, over-correction was successfully dealt with by replacing the inlay.

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Keratorefractive surgical techniques have been under investigation as an alternative to spectacle or contact lens correction of refractive errors for several decades. Sato and Fyodorov popularized radial keratotomy, but this technique is only suitable for relatively small degrees of myopia. José Barraquer has pioneered the development of keratophakia and keratomileusis. Although effective, these techniques have proven to be technically complex and require sophisticated instrumentation. Based upon Barraquer's work Werblin and Kaufman developed epikeratophakia, which although technically simpler, is not yet fully predictable and may require months for full visual rehabilitation.

Verzella[1] has recently revived, using modern microsurgical techniques, the concept of clear lens extraction in the treatment of high miopia, which he has recently combined with the placement of posterior chamber lenses when this is necessary to get close to emmetropia. However this aggressive approach sometimes results in complications such as retinal detachment, cystoid macular oedema, endophthalmitis and corneal endothelial trauma, inseparable from opening the chambers of the eye. Nevertheless, Verzella's opinion is that the risks justify the benefits brought to the high myope.

In an attempt to overcome some of these problems attention has turned to the use of alloplastic materials to be used as intrastromal lenses. So far as I am aware I was the first to explore the potential of polysulfone in this role[2],[3],[4].

Dr. Richard L. Lindstrom of the University of Minnesota, Minneapolis, became interested in this work and visited me in Westcliff-on-Sea, in June 1984. He and his team made numerous observations on a number of my patients. In his opinion what he had seen and the data he had collected showed sufficient promise to justify a full-scale investigation. He recruited several co-investigators who shared the animal work between them. Dr. Lindstrom's team operated on cats, Drs. Waring and McCarey on monkeys in Atlanta and Dr. Perry Binder on baboons in San Diego*. Lindstrom and his associates have recently reported[5],[6] on the animal work and also concerning those of my patients his team examined in June 1984, in the following terms:

FOOTNOTE:

The polysulfone corneal inlays (= intracorneal lenses) used in the American animal studies were supplied by SURGIDEV CORPORATION of Minneapolis.

Of the seven myopes, 2/7 complained of glare and 1/7 of fluctuating vision. None of the 3 aphakics had any complaints and all 10 patients said they were happy with their operative results. The complications noted were incisional scars (all cases) and refractive particles (all inlays); interface nebular opacity in 5 7 myopes and 2/3 aphakics which were not however visually significant.

Irregular astigmatism was noted in 3/7 in the myopic group and 1/3 in the aphakic group, and induced regular astigmatism in 2/7 in the myopic group and in 0/3 in the aphakic group. 1/7 of the myopic group had a Bowman's layer nebular opacity, none had this finding in the aphakic group. This opacity was not visually significant. 1/7 of the myopic patients had significant intralamellar debris while none had this in the aphakic group. 1/7 myopic patients noted a decrease of greater than one line in best corrected vision while none had this complication in the aphakic group. Best corrected vision increased more than one line in 4/7 myopic patients and in none of the aphakic patients.

NUMBER OF INLAYS INSERTED

The total of inlays inserted, 1981-1986, is now 54 including 1 inserted by Mr Starr. Table I lists the latest 14. The previous 40 (inserted February 1981 - March 1984) are listed in Table I, Ref. 4.

SURGICAL TECHNIQUE

This remains essentially the same: a superior incision, 7.0 mm long, just on the corneal side of the limbus, at an angle of 45 degrees. Ultrasonic pachymetry is a great help; if this shows a thickness of for example 0.7 mm. I suggest a setting of 0.6 mm on the micrometer screw-gauge on the diamond knife, which is the same as a vertical incision 0.42mm in depth. Dissecting the pocket is the most difficult part of the procedure. My experience with Healon (see below) was counter productive. Instead of Healon, balanced salt solution (BSS) should be used liberally throughout the dissection of the corneal pocket. The best results are obtained if the inlay is placed as close as possible to Descemet itself. It is actually easier to do this than make a pocket somewhere in the corneal lamellae. I am still using interrupted 8/0 virgin silk sutures to close the incision. Perhaps 9/0 Nylon would be better. Improved instruments are available, made from titanium steel, to aid the pocket dissection and the introduction of the inlay.

EFFECT OF THE INLAYS ON THE CORNEA

Up to five and a half years there is not much to report. Happily there have been no infections, no cases of anterior stromal necrosis exposing the inlay, no

erosions of Descemet depositing the inlay in the anterior chamber, no migrations out of place, no corneal decompensation.

Four of the last 12 (33%) show very small discrete white dots on the interfaces, more anterior than posterior. In some cases a few white dots are visible outside the circumference of the inlay but none outside the area of pocket dissection.

Three of the last 12 (15%) show 1-3 leashes of fine blood-vessels descending from the original incision in the track of the dissection of the pocket. When the blood vessels reach the inlay they spread round the top of it, presumably in the (nearly) dead space where the thick edge of the inlay is located. Whitish material accompanies the blood vessels.

TABLE I
Polysulfone Corneal Inlays
Inserted into human eyes
Since July 1984

Case	Age	Preoperative Refraction	VA	Postoperative Refraction	VA	Follow-up Months	Comments
1	74	—12/ 2	6/60	0 0	6/24	20	White spots & BV's
2	4	—16	HM	0/0	4/60	20	White spots
3	23	8.5	6/6	+2.5	6 6	18	Diurnal variation
4	59	for PPBK**	HM	***	3/60	13	Comfortable
5	75	for PPBK**	HM	***	3/60	13	Comfortable
6	17	—7/—6	HM	0/—2	6/60	12	
7	45	—7	6/6	+2.5	6/6	10	Diurnal variation
8	62	—26	6/36	+6.5	6/18	9	Inlay exchanged for overcorrection
9	46*	—26/+4	6/18+	+7.5	6/18	3	Inlay removed for over correction
10	37	—21 1	4/60	—2	6/60	3	
11	36	—10.5/—1.5	6 9	2/—1	6/9	3	Diurnal variation
12	23	—7.50/—3.5	6/60	—3	6/36	2	
13	38	13/ 4	6/36	2.5	6/24	2	
14	62	+6.5	6 18	2	6/18	1	Exchange of inlay in case 8

*. Mr. Starr's Case

**. Pseudophakic bullous keratopathy

*** Retinoscopy blurred: no subjective improvement with lenses.

Two of the myopes and two of the aphakes show a faint nebula over the centre of the inlays in the region of Bowman's membrane, resembling early band degeneration. One aphake developed a painful plaque over the apex of the inlay which was removed and the discomfort subsided. The plaque was inspissated fibrin and epithelial cells. Healon may have contributed to these changes.

Looking at the artists paintings as a group, they are interesting because they show that although the inlays are designed to carry the power variation on the anterior surface, it seems as though the posterior surface is the one which is changing the posterior curve of the cornea, and not the anterior corneal curve which is being changed by the anterior curve of the inlay. Photographs do not bring out the features described above with the same clarity as the artists paintings.

There has been a slight loss of acuity (about one line) due to the faint nebulae, otherwise the changes have not adversely affected the vision.

HISTOPATHOLOGICAL CHANGES

Steele has reported[7] on two of my cases which underwent penetrating keratoplasty at Moorfields in June 1984. It is of interest to follow their subsequent progress.

In Steele's Case 1 (originally a bilateral case of myopia right and left preoperative refraction = — 12DS/—4DC the graft remains clear. The contralateral inlay-containing eye, originally over-corrected by + 4.5 DS will now only accept +1.5DS, possibly due to nuclear sclerosis. This over-correction which is not worn because the unaided vision is 6/18+, the same as the best corrected pre-inlay acuity.The refractive particles surrounding the inlay have diminished and the associated fine blood vessels coming down from the section are now ghost vessels. It is possible the refractive particles were due to the use of HEALON. Beekhuis and van Rij[8] dissected corneal pockets of monkeys in Atlanta, using HEALON to aid the dissection (without inserting an inlay). Although they washed the HEALON out of the pockets mid-stromal crystalline deposits resulted very similar to those seen in Case 1. Based on the improvement in appearance and visual performance of the "control" eye over the past two and a half years I consider that Steele should have treated the other eye expectantly; it is my opinion that improvement would have occurred and that this graft was unnecessary. The patient would then have been spared the 18D of anisometropia with which she has been afflicted since the graft.

In Steele's Case 2, a principal feature of the pathology was a defect in Descemet's membrane. The hospital records show that this was caused during the dissection of the pocket prior to the insertion of the inlay. Thus, the histopathological findings do not tell us much about the effect of a polysulfone corneal inlay inserted into a pocket with intact Descemet. Unfortunately this graft has been subject to rejection episodes, presumably not attributable to the polysulfone. In their paper Steele et al, raised the question of possible degradation of polysulfone on exposure to UV light. Accelerated UV exposure tests have been carried out in Lindstrom's laboratory on polysulfone discs without any evidence of this ocürring.

EFFECT OT THE INLAYS ON THE VISUAL PERFORMANCE

a) *The amblyopic eyes.* At the start of this investigation five and a half years ago it seemed prudent to offer this procedure to patients with one eye considerably less effective than its fellow, or at least to commence with the non-dominante eye. Of the first 20 eyes only 5 had the potential to see 6/9 corrected of better with correction[3]. Following up these patients indicates that 12 of the first 20 eyes are now seeing 6/9 or better. Neutralising the minification inseparable from high myopia is one reason but there has been a tendency for the vision of several of these amblyopic eyes to improve with the passage of time, in keeping with the observations of others e. g. Cameron[9] who reported on 7 amblyopic eyes whose acuity improved signficantly when the good eyes lost vision.

b) *Eyes with the potential to see 6/12 or better.* There are 11 of these and they all see 6/12 or better. Four more have improved from less than 6/12 to 6/12 or better.

c) *Astigmatism.* Many eyes had a considerable cylindrical error, up to 6D. The inlays being more rigid than the cornea, there is a tendency to neutralise the astigmatism which was reduced in all, eliminated in some, and increased in none (See[3], Table III and Table I this paper).

d) *Over-correction.* Six eyes out of 54 have been over-corrected: two by +2.5D, 2 by +4.5D and 2 by +7.5D.

e) *Fluctuating vision.* Additionally, three cases show marked diurnal variation, in that as the day wears on they become more hypermetropic - the opposite of what happens following radial keratotomy. One case (Case 7, Table I), has a refraction of +1.5D at 9.00 a. m. and +5D at 9.00 p. m., and another (case 11 table I) has a refraction of —3D at 9.00 a.m., —1.5D at 1.00 p. m. and 0 at 5 p. m. (Appendix I).

APPENDIX I
Case 11 (Table I)

Preoperative refraction

6 6 with −10.25/−1.50 × 180
K Readings 7.55 × 90
7.18 × 180

Power of inlay inserted

−11.23 to leave −3D residual correcion

3 months post-operatively:

9.00 a. m. 6/60 unaided. 6/18 with −3.0 −1.0/155
Slight stromal oedema noted.
K readings 7.67 × 155
7.43 × 15

1.00 p. m. 6/24 unaided, 6/9 part with −1.5/−0.75 × 155
K readings 7.95 × 155
7.80 × 65

5.00 p. m. 6/6 unaided. No overcorrection
K readings 8.14/8.11

DISCUSSION

I Have shown that polysulfone intracorneal lenses are capable of correcting large refractive errors in humans. Many of my patients have maintained clear corneas with no complications and have remained stable for up to six years.

Although it is a serious matter to insert a polysulfone lens into a pocket in a healthy cornea, these results justify continuing research.

To date, polysulfone intracorneal lenses have been used exclusively to correct high myopia or aphakia. However, other applications could prove beneficial; for example high degrees of compound hypermetropic astgmatism, possibly early keratoconus. Polysulfone can be made in any colour and tinted polysulfone lenses could aid patients with aniridia or albinism as was earlier demonstrated using annular PMMA corneal inlays[10]. In addition, some cases of aphakia that are not suitable for contact lenses or secondary intraocular lenses because of proliferative diabetic retinopathy, peripheral anterior synechiae, pupillary irregularities, or angle abnormalities may benefit from intracorneal polysulfone intracorneal lenses. Lastly, polysulfone intracorneal lenses could be utilized to

correct infantile aphakia following congenital cataract extraction. The potential for preventing amblyopia may prove even more successful than intraocular lens or contact lens use.

After five and a half years there are three main problems:

A. The refractive particles, interface changes and occasional leashes of blood vessels. They are not seen in every case, which raises the possiblity that they are connected in some way with the operative procedure itself.

If not due to a toxic effect of the polysulfone on the keratocytes, collagen, etc., what do they represent? They could be:

1. Polishing compound left on the inlay;

2. Debris from the container in which the inlay is autoclaved;

3. Healon used to aid the dissection of the pocket;

4. Epithelial and other debris carried in with the inlay.

Do the deposits matter? They tend slowly to diminish over the years and the blood vessels regress. They only interfere with vision if they coincide with the visual axis. It should be possible to eliminate 1, 2, 3 and greatly reduce 4.

B. Overcorrection. Mr Jalie has addressed himself to this problem and has modified his original method of calculating the curves and edge thicknesses of the inlays. My 5 most recent cases (Cases 10, 11, 12, 13 and 14 Table I) have received inlays made to the new specifications and their final refractions are between —2D and —3D, the target aimed at.

C. Fluctuating vision. This is an unexpected and disturbing occurrence. Because polysulfone is not completely permeable the most likely hypothesis is that during the day the corneal stroma become dehydrated and shrinks causing slight induced flattening of the cornea. Further very precise measurements of corneal thickeness and K. readings during the day are clearly necessary to elucidate this problem. The findings in case 11 (Table I) are given below (Appendix I).

However, it is not a universal finding in my patients. Why not? Perhaps naturally moist eyes are less prone to this happening.

From the practical stand point myopes should be left approximately – 3D. thus should they have this tendency to increasing hypermetropia as evening approaches, they will not be seriously inconvenienced thereby.

Over 20 years ago I endeavoured to increase the tolerance of the cornea to PMMA inlays by perforating their periphery. So did Moss[11]. Perhaps the next generation of inlays should be provided with an outer 1 mm. of microperforations during manufacture.

As Linsdstrom and his co-workers have said[4,5], human studies are essential to answer these functional questions.

REVERSIBILITY

One of the most serious criticisms of other forms of refractive surgery (except some of the epi-procedures) is that they are NOT REVERSIBLE. Several of Lindstrom's cats have had their inlays removed 12 months later and the corneae are perfectly clear.

In 1981/82 I had to remove 4 inlays within a month of insertion because of:

a) Injury to Bowman's membrane due to too superficial a dissection of the corneal pocket resulting in a sterile exudate between the inlay and Bowman's membrane, or.

b) Because I had gone too deep and had torn Descemet so that the inlays had started to slide into the anterior chamber. I referred to these cases in my earlier paper to the Oxford Congress[3].

Since then no removals have been indicated until we come to Mr Starr's case (No. 9 in Table 1). The over-correction (+7.5D) caused the patient considerable distress. Mr Starr therefore removed the inlay through his original incision. No great technical difficulty was ecountered and the end result is a perfectly clear cornea except for a faint greyish ring 5 mm in diameter marking the circumference of the in-dwelling inlay. The refraction has returned to its pre-inlay level (6/12 + with —22D). It is reassuring to know that a PCI can be removed, without undue difficulty, in case of need, leaving the eye almost in its original state.

EXCHANGE OF INLAY

Another case (Cases 8 and 12, Table 1) was over-corrected by +6.5D. I exchanged this inlay for one made to Jalie's revised formula, designed to leave a refraction of —3D. This has been achieved.

Re-opening the corneal pocket from above and effecting this exchange was not as technically difficult as I had expected. Clearly it is desirable not to have to exchange an inlay and it is hoped that in future this will not be necessary.

CONCLUSIONS

1) A significant percentaje of mm and 5 mm diameter polysulfone corneal inlays (intracorneal lenses) inserted into human eyes have not produced serious complications and are providing useful vision up to 66 months later with anaverage follow-up of 33 months.

2) insufficient data exists to make a judgement on their use in cataract, aphakia.

3) The most grateful patients are the high myopes.

4) Animal work in the USA directed by Lindstrom has led to a more refined surgical technique and shed considerable light on the histo-pathological changes induced by the inlays. The American experience confirms my finding that the best results are obtained when thin (myopic) inlays are placed close to Descemet's membrane.

5) Some refractive problems (over-correction, and diurnal variation) have come to light. Over-correction has not been a problem with the last 5 cases, with inlays made to Jalie's new especifications. Diurnal variation remains a problem in some cases.

6) Of the various substances used as intracorneal lenses polysulfone appears to be the most promising.

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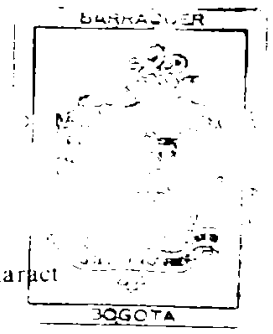

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