

Radial Keratotomy: 500 Consecutive Cases

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Summary

A report on 500 consecutive eyes having radial keratotomy for myopia and myopic astigmatism is presented. Surgery was on an out-patient basis under local anaesthetic, with a follow-up of 99.2% of cases, 91.8% of the 294 patients elected to have radial keratotomy on the fellow eye. The surgical protocol was designed to minimise side effects and complications rather than maximise the reduction in myopia. 6/12 unaided vision or better was achieved by 99% of cases in the low myopia group, 91% in the middle and 41% in the high myopia group. Persistent hypermetropia of +1.00D or greater occurred in only 0.4% of cases and secondary astigmatism of 1.00D or greater in 1% of cases. Corneal perforations were minimised by single-pass incisions, but this was at the cost of lesser myopic corrections in the higher myopic group. Centering on the visual axis rather than the centre of the pupil minimised glare sensitivity. No patient developed potentially blinding complications.

Selection of Patients

Patients were selected on the following criteria:

- (1) Lower age limit was 18 years, there was no upper limit for the surgery.
- (2) The refraction was stable.
- (3) There was no active external ocular disease.
- (4) Physiological myopia was present without the ophthalmoscopic signs of progressive pathological myopia.
- (5) Candidates were either intolerant of contact lenses or required reduction or abolition of their refractive error for occupational reasons or because of sporting activities.
- (6) Amblyopic eyes were accepted.
- (7) Patients were informed of the advantages and disadvantages of radial keratotomy.
- (8) Patients were counselled on the possible side effects and complications of radial keratotomy.
- (9) Patients were given an estimate of the

likely visual and dioptric results of the surgery.

(10) Although many patients were seen direct, they were encouraged to visit their general practitioner before attending the centre. Consultation reports were sent to general practitioners before treatment together with an account of radial keratotomy, and an operation report on the day of surgery. A final report was sent on completion of treatment.

Technique of radial keratotomy

- (1) All surgeries were done on an out-patient basis in a sterile operating theatre and using sterile surgical techniques.
- (2) Surgery was done using an operating microscope.
- (3) Pre-medication of 10 mg valium was given orally.
- (4) Surgery was done on the non-dominant eye first followed by the fellow eye approximately six weeks later.

- (5) The amount of surgery was planned by nomogram based on patient's age and refractive error.
- (6) Ultrasonic pachymetry to determine corneal thickness was performed immediately preoperatively.
- (7) The eye was anaesthetised with Guttae Amethocaine 1%.
- (8) The eye was kept minimally moist with sterile normal saline during the surgical procedure.
- (9) Great care was taken to mark the intersection of the visual axis on the cornea.
- (10) Dull marking trephines with cross hairs and 3.00, 3.25, 3.50, 3.75, 4.00, 4.50, 5.00 and 6.00 mm diameters were used.
- (11) Radial incisions were done with a single-edged 45° angle diamond blade set at 115% of the average para-central corneal depth measured by ultra-sonic pachymetry, aiming to achieve between 90% and 95% depth at the commencement of the radial incisions. Incisions were centrifugal, *i.e.* from optical zone to periphery. The ultrasonic probe was placed exactly on the optical (clear) zone mark in the position of the radial incisions.
- (12) Transverse incisions were done with a double-edged diamond blade.
- (13) Diamond blades were set in micrometer handles and calibrated with a blade gauge.
- (14) Both eyes of the same patient were done with the same blade.
- (15) Incisions were thoroughly irrigated with normal saline at the conclusion of the surgery.
- (16) Guttae Gentamycin and Guttae Cyclogyl 1% were instilled in the operated eyes.
- (17) The eye was lightly patched for three hours only.
- (18) Post-operative pain was controlled with tablets DF118 for 12 to 18 hours only.
- (19) Guttae Maxitrol was instilled post-operatively twice a day for two weeks.
- (20) Follow-up was at two weeks and again at the two weeks after the second operation and requested at six months and one year. No patients have been discharged from care.

The standard interval between eyes having surgery was six weeks, and between primary and secondary surgery on the same eye was between three and six months.

Study Population

Five hundred consecutive eyes had radial or

radial and transverse keratotomy. Secondary surgery was performed on 54 eyes or 10.8% of the total (PERK 9%). The total number of patients treated was 294, of which: 194 (66%) were males (PERK 52%) and 100 (34%) females (PERK 48%). Follow up was possible in 496 out of the 500 cases (99.2%). Maximum follow-up was two years. Out of 294 patients, 270 (91.8%) elected to have radial keratotomy on the fellow eye. (Some of these cases are not included in the 500 consecutive keratomies described here). Seven patients had planned uniocular surgery. At baseline the spherical equivalent refraction was (i) $-1.00D$ to $-3.00D$ in 127 eyes (plus two not followed up and therefore excluded). Eighty nine of these had radial keratotomy and 38 had radial and transverse keratotomy. (ii) $-3.25D$ to $-6.00D$ in 211 eyes with 153 patients having radial keratotomy and 58 having radial and transverse keratotomy. (iii) $-6.25D$ to $-9.00D$ in 117 eyes (plus two eyes not followed up and therefore excluded). One hundred and one cases had radial keratotomy and 16 had radial and transverse keratotomy. (iv) over $-9.00D$ in 45 eyes.

Some of the reasons given for wanting keratotomy surgery included: (i) intolerance of contact lenses.

(ii) Fear of losing glasses or contact lenses in an emergency.

(iii) Thickness and weight of glasses.

(iv) Inability to participate in outdoor activities particularly swimming but also other sports *i.e.* mountaineering and skiing.

(v) Improvement of unaided visual acuity to meet occupational requirements.

(vi) No surgery was done for cosmetic reasons only.

Visual results

The visual results are expressed as a percentage of 6/12 uncorrected visual acuity since it is considered that this is the most meaningful statistic to present to the patient considering radial keratotomy surgery. Average predicted result or average dioptric result gives a less meaningful forecast to the patient. The percentage of patients achieving emmetropia is not used, since for reasons described later, it is not always desirable to aim for this. Success of the surgery as defined by the International

Society of Refractive Keratoplasty is 6/12 (20/40) unaided vision.²

In the low myopia group of $-1.00D$ to $-3.00D$, 125 eyes out of 127 achieved 6/12 unaided vision or better. Of the remaining two cases, one had 4 cylinder pre-operatively and one case was amblyopic.

In the group of moderate myopia of $-3.25D$ to $-6.00D$, 211 eyes had surgery. One hundred and eighty-six out of the 211 eyes achieved 6/12 vision unaided or better.

In the high myopia group of $-6.25D$ to $-9.00D$, 117 eyes had surgery, forty-five of these achieved 6/12 vision or better unaided following surgery.

In the very high myopia group of greater than $-9.00D$ 45 eyes had surgery. Every eye achieved a significant and major reduction in the myopic spherical equivalent.

Most refractions were stable at between one and two months and 5% of cases continued to decay up to the sixth month gate and three eyes to the one year gate.

The surgical plan was slightly conservative in the surgery on the first eye and used the experience of the response of that eye in planning the operation on the second eye. Thus most of the secondary surgery was done on the first eye. It was found that the response of the second eye could be predicted accurately from the response of the first eye.

Table I lists the results of post-operative unaided visual acuity and where there has been decay of effect up to 12 months the results are corrected accordingly. There was no decay of effect after the 12th month gate.

Table II lists the results of this study with other comparable ones.^{1,3,4,5,6} However it should be noted that only the United States studies used independent examiners for the measurement of visual acuity and refraction. The studies are comparable although there is some difference in the parameters of the groups of myopes. To assist in the comparison, amblyopic eyes in this study have been excluded in the visual results as they were in other studies.

Complications

Post-operative complications are divided into three groups as in the PERK Report.

(1) Transient signs and symptoms.

(2) Persistent signs and symptoms that did not reduce best corrected visual acuity.

(3) Complications that actually or potentially reduced visual acuity.

(1) Transient Signs and Symptoms

Ocular pain often described as similar to toothache in the eye was common but was usually controlled by oral analgesics such as DF118. Pain was nearly always better by the following day and was eased on the day of surgery by removal of the eye patch. Many patients described a slightly scratched feeling in the eye for two weeks post surgery after which it gradually subsided. Pain was usually more severe when an increased number of incisions had been made or where the corneal epithelium had tended to strip off during the incision. Very little conjunctival injection was caused by this surgery.

Fluctuation of vision more properly described as variation of refraction, was reported by many patients especially during the first month but this decreased steadily. (Table III) The eye became more myopic during the day but only one patient has required two pairs of glasses (for day and evening wear). Variation of refraction probably occurs in all cases but is often not apparent to the patient. It is caused by the increased flexibility of the cornea during the healing period and is therefore more marked in the older patient with slower healing, particularly in the higher myopic group. The variation occurs as a response to diurnal changes in intraocular pressure and upper lid pressure during sleep.⁷

(2) *Persistent signs and symptoms that did not reduce corrected visual acuity.* (Table IV).

Initial hypermetropia of $+1.00D$ or greater occurred in five eyes out of 500 (1%). If this persisted at one month Guttæ Timolol Maleate 1% was administered twice a day to the hypermetropic eye. This resulted in the abolition of the hypermetropia in three of the eyes presumably by lowering the intraocular pressure, although it is possible that there was a decay in the surgical effect. Persistent hypermetropia occurred in two out of 500 eyes (0.4%). The PERK Report recorded secon-

Table I Post-operative unaided visual acuity

Myopia group and surgery	6/6	6/9	6/12	6/18	6/24	6/36	6/60	6/60+
1. Low								
-1.00 to -3.00 (total 127 eyes)								
i. Radial K. (89 eyes)	64 (71.9%)	19 (21.5%)	4 (4.5%)	1 (1.0%)	1 (1.0%)			
ii. Radial and Transverse K. (38 eyes)	13 (34.2%)	15 (39.5%)	8 (21.0%)	1 (2.6%)	1 (2.6%)			
2. Middle								
-3.25 to -6.00D (total 211 eyes)								
i. Radial K. (154 eyes)	58 (38%)	54 (34.6%)	25 (17.6%)	7 (4.6%)	3 (2.0%)	2 (1.3%)	4 (2.6%)	
ii. Radial and Transverse K. (57 years)	19 (33.3%)	15 (26.3%)	15 (26.3%)	2 (3.5%)	6 (10.5%)			
3. High								
-6.25 to -9.00 (total 117 eyes)								
i. Radial K. (101 eyes)	6 (6.0%)	9 (8.9%)	22 (21.8%)	10 (9.9%)	10 (9.9%)	13 (12.8%)	17 (16.8%)	14 (13.9%)
ii. Radial and Transverse K. (16 eyes)	3 (18.8%)	1 (6.2%)	4 (25.0%)	1 (6.2%)	4 (25%)			3 (18.8%)

Total: 455 eyes (15 amblyopic eyes at less than 6/12 included, 45 eyes at greater than -9.00 excluded)

dary hypermetropia of 11% in the lower myopic group, 12% in the middle myopic group and 6% in the higher myopic group.

Five eyes in the study of 500 eyes (1%) developed secondary astigmatism of 1.00D or greater. This compares with 9.5% in the PERK Report and Percival³ reporting 5% secondary astigmatism. Secondary astigmatism can be caused by uneven spacing of the incisions and variations in depth achieved and is probably aggravated by re-incising the primary incisions.

Epithelial 'pearls' or inclusion cysts and other debris in the scars occurred in only two incisions in the series. These were probably due to inadequate irrigation of the wounds with normal saline at the conclusion of the

surgery. Such inclusions can cause delay in wound healing⁸ and may become a site for late keratitis.⁹ They can be dissected out under local anaesthetic post-operatively.

Epithelial iron lines were common¹⁰ but often very difficult to see and tended to occur at one year post-operatively or later. Iron lines may be related to changes in corneal curvature. They are more frequent in high myopic corrections and are possibly due to the deposition of iron from tear pooling¹¹ but they do not affect visual acuity.

(3) Complications that actually or potentially reduced visual acuity (Table V)

A decrease in the best visual acuity of more than one line occurred in nine patients

Table II Comparison studies of post-operative unaided visual acuity (amblyopic eyes excluded)

	Jory	Perk ¹	Percival ³	Ark I ⁴	Ark 2 ⁵	Neuman ⁶
Low group -1.00 to -3.00D (126 eyes)	99%	92%	100%	97%	94%	93%
Middle group -3.25 to -6.00D (206 eyes)	91%	81%	85%	87%	96%	90%
High group -6.25 to -9.00D (108 eyes)	41%	63% (-8.00D)	55% (-10.00D)	70% (-10.00D)	87% (-10.00D)	81% (-8.00D)

Table III *Disabling variation of refraction (fluctuation)*

At	2 Weeks	30	=	6.0%
	1 Month	24	=	4.8%
	2 Months	20	=	4.0%
	3 Months	14	=	2.8%
	4 Months	8		
	6 Months	4		
	1 Year	2		

(1.8%), PERK reporting 13% and Percival 3% having such a reduction. On the other hand, 15 eyes (3%) had an increase in best visual acuity. There were no macular changes noted which would have been caused by the microscope light during surgery¹² and these variations may be due to mild irregular astigmatism.

Macro-perforations cause wound gape, loss of anterior chamber and require suturing, however there were none in this series. Micro-perforations occurred in seven cases (1.4%) but none of these required suturing, all anterior chambers were maintained and surgery was completed in every case. PERK reported 2.9% micro-perforations, Arrow-smith 35% and Deitz⁴ 36% micro-perforations in their first studies, later reducing to 7%⁵ in their second studies. Of the seven cases of micro-perforation in this series, three were due to incorrect calibration of a new knife and blade, three occurred in inferior transverse keratotomy incisions and one occurred in a radial incision probably as a result of crossing an uncharted posterior corneal dimple.

Epithelial basement changes¹³ and erosions such as map fingerprint occurred in the epithelial basement membrane in two cases but these resolved at two months. There were no cases of corneal epithelial erosions. Such corneal erosions can occur where incisions cross on the cornea.

Post-operative Trauma. There were four cases of trauma occurring in the first month post-operatively. One patient experienced a continued and violent sneezing episode between one and two hours post-operatively. The intraocular pressure in such episodes has been calculated to increase considerably.¹⁴ The patient had had 16 radial keratotomy incisions and returned on the next day with a flat anterior chamber which eventually

resulted in suturing of three of the wounds. This induced some corneal scarring and was one of the five cases of secondary astigmatism. The patient's other eye with similar surgery six weeks previously remained intact. This episode demonstrates the increase in wound strength at six weeks. Two patients were forcibly poked in the eye on the day of surgery causing intense pain and the fourth patient travelling on his motorbike at 80 mph on the M1 motorway somersaulted several times after being thrown off. The accident occurred one month post-operatively. All four cases have a corrected visual acuity of 6/6 and the last three cases maintained the integrity of their radial keratotomy incisions.

Glare sensitivity is subjective and it is very difficult to evaluate although some investigators have used glare testers.¹⁵ It can be said to be common in the first two weeks, uncommon at three months and occasional at one year. All patients were asked to report this at post-operative examination but few complained about glare after two weeks and only two patients reported reducing their night driving. Persistent glare can be minimised by ensuring that the visual zone is centred on the visual axis rather than on the centre of the pupil.¹⁶ The radial incisions must be perpendicular to the cornea and not slanted, particularly at the visual zone margin, they should not be deepened by a second pass of the knife and must be thoroughly irrigated.

Flare is common with the patient seeing the central ends of the incisions which pick up light at night against a dark background. However few patients complain of this after first noting it and it is gradually ignored.

Specular microscopy had previously documented endothelial cell loss of between 5% and 8%.^{17,18} This is in line with other studies^{19,20} and its measurement had been discontinued prior to this series.

Potentially blinding complications. No

Table IV *Persistent refractive complications*

	Jory	Perk	Percival
2° Hypermetropia + 1.00D or more	0.4%	10.0%	N.R.
2° Astigmatism + 1.00D or more	1.0%	9.5%	3.0%

Table V Complications that actually or potentially reduced visual acuity

	<i>Jory</i>	<i>Perk</i>	<i>Percival</i>	<i>Art 1</i>	<i>Art 2</i>
% Reduced V.A.	1.8%	13%	3%	NR	0.3%
Microperforations	1.4%	2.9%	NR	35%	7%
Corneal erosions	0%	1%	NR	0%	0%
Delayed bacterial keratitis	0%	2%	NR	NR	1%
Other potentially blinding	0%	0%	0%	0%	0%

patient developed keratitis, uveitis, cataract or endophthalmitis. One patient developed steroid-induced glaucoma which subsided on the cessation of the Guttae Maxitrol being used post-operatively. It was interesting to note the enhanced effect of the surgery with the raised intraocular pressure which then diminished when the glaucoma was brought under control. No maculopathy was observed from the use of the operating microscope and its bright illumination. The rule was observed to make the incisions slowly and perform the operation quickly, both to guard against such maculopathy and also corneal thinning which would negate the accuracy of the ultra-sonic pachymetry.

Discussion

All patients obtained a significant and worthwhile reduction in their myopia. The best results occurred in the lower and middle myopia groups with over 99% and 91% success rate respectively, but provided patients were advised of the likely outcome of their surgery those in the high myopia groups were just as pleased with the substantial reduction in the myopia as those who had had their myopia abolished. Although there was a better than 99% follow-up post-operatively the percentage of long term follow-up at six months and one year was less than the other studies quoted. This reflects the much wider geographic origin of patients in this study. Nevertheless, the visual results in the lower two myopia groups compare well with the other studies published^{1,3,4,5,6} but it is significant that the reduction in myopia in the higher groups was not as great. This was almost certainly due to the policy of not re-incising primary incisions to avoid increasing the incidence of micro-perforations. Glare was minimised by single pass incisions and the care was taken to centre all surgery upon the visual axis and not

on the centre of the pupil. The presence of a large angle alpha becomes particularly important when operating on a visual zone of only 3.00 mm. It must be emphasised that total predictability of results^{21,22} still eludes the surgeon who is doing radial keratotomy surgery although results are improving.²³ This almost certainly relates to variable healing response due to individual biological variation²⁴ with some patients under responding and others over responding to surgery. This is a problem with all invasive surgical procedures for the correction of refractive error whether by blade or by laser.

No cases of infection occurred during this series. There have been isolated reports in the literature of delayed bacterial keratitis and these are thought to be due to epithelial inclusions in the wounds. Such inclusions are minimised by meticulous irrigation of the wounds at the completion of surgery. Prolonged firm patching post-operatively can cause epithelial downgrowth into the wounds and should be avoided. The low frequency of infection reported in all studies of radial keratotomy compares very favourably with the relatively high incidence of severe corneal infection from the use of soft²⁵ and extended wear contact lenses.^{26,27,28,29}

There is no evidence that radial keratotomy permanently weakens the eye. Nevertheless, all surgical wounds take time to gain strength particularly in the vascular cornea.³⁰ Only isolated cases of traumatic radial keratotomy wound dehiscence have been reported,^{31,32} whilst other reports have demonstrated wound integrity even when scleral rupture has occurred.³³ Larsen³⁴ reported 33% optic nerve evulsions in his control group and only 2% in his radial keratotomy group. The corneal incisions appear to act in some protective way against more serious injury. This is probably due to increased flexibility of the radial

keratotomy cornea caused by the surgical interruption of the long collagen fibrils embedded in the corneal matrix which control corneal flexing as do carbon fibre rods in a fibreglass yacht hull.

Conclusions

Radial keratotomy achieves a worthwhile visual improvement in virtually all myopic patients.³⁵ Side effects such as glare and variation of refraction can be reduced by careful surgery.³⁶ Severe complications are very rare.³⁷ The visual benefits must be balanced against the refractive side effects of possible secondary astigmatism, secondary hypermetropia from over correction and the effects of the onset of presbyopia.^{38,39,40,41} Ten years ago, radial keratotomy was considered an experimental procedure. It has now been proved effective in reducing myopia in both clinical and laboratory studies and its potential implications have been well delineated. Therefore the International Society of Radial Keratoplasty no longer considers it either experimental or investigative² and it is now widely practiced by eye surgeons around the world.

Radial keratotomy is a stepping stone on the pathway of refractive surgery.^{42,43,44,45,46} Other surgical procedures include epikeratophakia which unfortunately has a tendency towards regression of effect,^{47,48} polysulfone corneal inlays^{49,50,51} and hydrogel implants⁵² and the use of the Excimer laser for sculpting the cornea.^{53,54,55} All of these methods are in their early stages of development and testing and will not be available for regular clinical use for several years. It is important to keep an open mind on all these procedures rather than championing one against the others; the sum of our corneal knowledge is increased by them all. It may well be that we will progress to synthetic epikeratophakia⁵⁶ as an additive procedure and corneal sculpting with the Excimer Laser as a subtractive one.⁵⁷ All surgical procedures involve wound healing to some degree and total predictability will still be a problem in these more sophisticated operations.⁵⁸ Experiments so far with wound healing modifiers have been disappointing.^{59,60}

Radial keratotomy is currently the most tested⁶¹ and widely-used procedure in our progress to a world without glasses.

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