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Frank A. Ukockis

Pacific University
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REVIEW OF RADIAL KERATOTOMY IN LITERATURE

Thesis project by:
Frank A. Uckockis

Thesis Advisor:
Dr. R. Dirks

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Abstract

Radial keratotomy is a recent surgical technique designed to reduce and/or eliminate myopic refractive error by altering the corneal curvature. Since being introduced to the United States in the late seventies, this procedure has received much attention in the medical literature where there is considerable debate concerning the long and short term efficacy, predictability, and safety. Some of this literature is reviewed in this paper. The aspects that are investigated are the history, surgical technique, results, and postsurgical complications.
History

The first report of this procedure was by Tutomo Sato of Japan in 1953. Sato's procedure was different from present day anterior radial keratotomy in that Sato made radial, partial thickness incisions from the endothelial side as well as from the epithelial side of the cornea. In the report, Sato claimed that the procedure would cure or adequately alleviate 95% of the cases of myopia in Japan without complications. Although Sato may have had minimal short term complications, long term effects caused by the surgery proved to be disastrous. Yamaguchi re-examined 80 of 281 eyes that had undergone Sato's surgery ten to twenty years later. Sixty of the 80 eyes had developed bullous keratopathy. Regardless of the patient's age at the time of surgery, the onset of the keratopathy occurred when the patient was around 40 years of age. Most authors seemed to agree that the corneal edema and subsequent bullous keratopathy developed as a result of damage to the endothelium done by the posterior incisions at the time of surgery. But at least one author has questioned whether the endothelial incisions were in fact the only factor in causing the keratopathy years after the operation.

Fyodorov and Durnev of the USSR described the first anterior radial keratotomy procedure to the western world in a published report in 1979. Fyodorov and Durnev performed their work in the mid-seventies on 60 patients with myopia ranging from 0.75D to 3.0D. Fyodorov used 16 radially oriented incisions extending from 1.5 mm off the optical center to or across the corneoscleral
limbus. Fyodorov believed that the corneal optical power was changed by the anterior radial incisions dissecting the corneal circular ligament. Because of the dissection of these collagen fibers, the mechanical stability of the peripheral cornea was weakened causing the intraocular pressure to bulge the periphery outward. Concurrently, the central portion of the corneal flattened in a compensatory fashion resulting in reduction of the optical power.

In his addendum to the article3, Fyodorov stated that of the 565 patients done since his initial report, 87% attained an unaided visual acuity of 20/50 or better and were able to perform normal everyday functions without the need for spectacles. More importantly, Fyodorov reported that of the 60 patients on whom the surgery was initially performed, none had complications leading to reduced ocular functioning.

Leo Bores7 is generally credited with duplicating Fyodorov's procedure with patients in the United States in 1980. Bores performed the surgery from 1978 to 1979 on 400 eyes and noted mild side effects and substantial reduction of myopia immediately after surgery, with stabilization occurring at three months following the operation.5

Buoyed by the apparent good success of Fyodorov and Bores, great interest in radial keratotomy has been shown in the United States by surgeons and lay people alike. This has been reflected by the multitude of published reports seen in the literature.
Surgical Technique

There are many surgeon-specific variations to this procedure which has prompted at least one author to advocate precision standardization for the purpose of obtaining meaningful comparative data among surgeons. Allowing for these variations, the surgical technique for radial keratotomy will be described.

The patient is placed in a supine position, the adnexa is prepared for surgery with alcohol and iodine, then draped. A local topical anesthetic of 0.5% tetracaine hydrochloride or 0.5% proparacaine is applied to the operative eye and a lid speculum is inserted. The patient is instructed to fixate on the central aspect of the operating microscope light filament (Zeiss Opmi 6S microscope) while a 25 or 26 gauge needle is utilized to mark the center of the corneal reflex and location of the visual axis. Since the corneal light reflex is assumed to be .3 to .5 mm superior to the patient's visual axis, the appropriate correction is noted in the marking. A marking trephine (Hoffer) of necessary diameter is used to circumscribe the visual axis optical zone and a second trephine of larger diameter (11 mm) is used to demarcate the peripheral extent of the incisions. Prepackaged 76A Beaver microblades held in a modified Katen blade breaker handle seemed to be the instrument of choice for the actual incisions. The depth of the incisions is related to preoperative pachometry measurements. A corneal incision depth of 85% to 95% is generally used. The number of incisions ranges from eight to twenty four although most surgeons in later studies prefer eight.
After the incisions are completed and verified for depth and uniformity, they are irrigated with a balanced salt solution (BSS) to remove any blood or foreign material.

At the end of the procedure 5% homatropine or 1% atropine and gentamycin sulfate (20 mg) or betamethasone (0.5 ml) are topically instilled. The operative eye is doublepatched for one to five days. Postsurgical medication regimen usually includes dexamethasone (Maxitrol), polymycin B sulfate, neomycin sulfate, Neodecadron, and Cyclogyl.

Results

Published reports on the efficacy of this technique have varied widely. Results range from highly effective in reducing and/or eliminating most degrees of myopia with excellent predictability3-5,9,12, to only marginally effective in cases of mild to moderate amounts of myopia with much unpredictability10,11.

It is extremely difficult to compare each author's work side-by-side because the many variables involved with this procedure: length, depth, spacing, number of incisions and the diameter of the optical zone, seem to be influential. All authors agree that radial keratotomy does reduce myopic refractive error in patients to some degree. The one report in the literature of a patient whose myopia actually increased followed circular keratotomy rather than radial13.

Fyodorov3 divided his patients into 2 categories. Group A consisted of 130 patients and had myopia ranging from 0.75D to
3.0D. After the initial stabilization period of 3 months, 101 patients obtained emmetropia; 13 had mild hypermetropia (0.25D-0.75D); and 16 had mild myopia (0.25D-0.75D). All obtained an unaided visual acuity of 20/50 or better and 85% reached acuities of 20/25 to 20/20. Fyodorov's second group of 546 patients had myopia of 3.25D to 6.0D. After the stabilization period, 114 became emmetropic and the remaining 408 had residual myopia, the majority of whom (366) had mild to low myopic refractive errors. Fyodorov reported that 83.7% of all patients attained uncorrected visual acuities of 20/50 or better.

Bores also had 2 groups of patients. Group 1 consisted of patients who had surgery between April and October of 1979. Group 2 were patients that had undergone the procedure from November of 1979 through December of 1980. In Bores second group, 65% attained uncorrected visual acuities of 20/20 to 20/40 as opposed to only 29% that attained those acuities in the first group. Bores attributed this discrepancy to using a modified surgical technique with the second group. Bores concluded from his data that patients with myopia from 2D to 6D have the best prognosis for vision without spectacles or contact lenses.

Cowden, in a retrospective study at the Kresge Eye Institute, found that the mean preoperative unaided visual acuity of 20/400 had reduced to a mean of 20/60 postoperatively after 6 months. Cowden concluded that the possibility of getting rid of spectacle correction was not likely except for patients with less than 3 to 4 diopters of myopia.
Grady \textsuperscript{14} reported a final uncorrected visual acuity of 20/20 to 20/40 in 96\% of operated eyes followed 5 to 16 months. Most of the patients in this study (88\%) had refractive errors from \textbf{1.50D to 5D of myopia} which could explain the high success rate.

Arrowsmith \textsuperscript{15} divided his patients into four groups designated by the amount of preoperative refractive error. Group 1 had myopia of 3.0D or less; group 2 had 3.0D to 6.0D of myopia; group 3 had 6.0D to 9.0D; and group 4 had more than 9.0D of myopia. At six months, 92\% had unaided visual acuities of 20/40 or better in group 1. In group 2, 80\% obtained that acuity level. In group 3, it was 63\% and, in the last group, it was 33\%. As with the other studies, Arrowsmith obtained the best visual results in the groups with mild to low myopic refractive errors. Higher preoperative refractive errors had the lowest percentage of eyes achieving at least 20/40 unaided visual acuities.

Kremer \textsuperscript{12} categorized his four groups the same way as Arrowsmith. In Kremer's first group (preoperative myopia of 3D or less), 93\% achieved uncorrected visual acuities of 20/15 to 20/50 one year following surgery; 82\% in group 2 (3D-6D of myopia) attained 20/50 or better; 45\% in group 3 (6D-9D) had 20/50 or better; and 0\% in group 4 (over 9D of myopia) recorded 20/50 or better.

Rowsey \textsuperscript{10}, in his study, re-examined his patients after one year. In his first group, the mean preoperative spherical equivalent of the patients was 6.50D of myopia. One year post-operatively, it was 2.40D of myopia. In the second group, the
mean spherical equivalent changed from 6.58D to 1.48D of myopia. Overall, of the patients with greater than 4.0D of myopia before surgery, only 46% were able to attain uncorrected visual acuities of 20/40 or better. Of the patients with preoperative myopia under 4.0D, 88% achieved 20/40 or better acuities.

A major 5-year study started in 1980 is the National Eye Institute's study called the Prospective Evaluation of Radial Keratotomy (PERK). Initial results on 413 patients performed at nine medical clinics, nationwide have shown that 78% of the patients achieved postoperative unaided visual acuities of 20/40 or better. Thirty percent of the patients, though, required further refractive correction (spectacles or contact lenses); 10% were overcorrected and another 10% developed astigmatism from 1.0 to 2.25D. In patients whose initial myopic refractive errors were 2.0 to 3.12D, 84% were corrected to ±1.00 of emmetropic; of those patients with preoperative myopia ranging from 3.25 to 4.37D, 62% were corrected to ±1.00D of emmetropic; and of those patients with 4.50 to 8.0D of myopia, 38% were corrected to ±1.00D.

Post-surgical Complications

There has been extensive coverage in the literature concerning the safety of radial keratotomy. As with the results, there is considerable debate and controversy over the severity, frequency, and magnitude of postoperative complications. The reports range from mild and unimportant postsurgical side effects
to extensive primary complications and possible severe morphological and histological changes in the corneal epithelium and endothelium. At this time two sight threatening complications have been reported. The first case involved an intumescent cataract that developed 16 weeks after radial keratotomy secondary to a small anterior chamber perforation that occurred during surgery. The second case involved a S. epidermidis endophthalmitis that developed nine days after surgery following another anterior chamber perforation. Systemic antibiotic therapy with a pars plana vitrectomy was required and the patient obtained a recovered visual acuity of 20/30 three months later.

While much seems to be known concerning the short term postsurgical complications and side effects, little is known about the long term effects of radial keratotomy.

Rowsey reported 18 primary complications of radial keratotomy which included: missing the visual axis while marking the central cornea, regression of myopic flattening, epithelial defects, recurrent erosions, stromal overgrowth, Cogan's map-dot fingerprint corneal dystrophy with Moncreiff iron lines, blood in the incisions, vascular ingrowth, perforation of the anterior chamber, induction of astigmatic errors, epithelial ingrowth, glare complaints and decreased night vision, pain, fluctuating vision from morning to evening, overcorrection and unpredictable results, contact lens refitting difficulties, endothelial cell loss, and corneal scarring. Other complications being noted in
the literature are persistent iritis\textsuperscript{11}, superficial punctate keratitis and stromal keratitis\textsuperscript{5,11,12}, photophobia\textsuperscript{5,12}, subconjunctival hemorrhage\textsuperscript{5}, and paraincisional edema\textsuperscript{3,5,12}.

Most authors agreed that glare and fluctuating vision are experienced by a majority of patients at some postsurgical period during the first few months. Glare is thought to occur because the semitransparent incision scars scatter the light rays. It is especially bothersome at night because of pupil dilation. Also, irregular cuts in the periphery which are associated with oblique incisions appear to contribute to the glare problem. Daily fluctuations in visual acuity occur as a result of the patient's cornea steepening throughout the day and subsequently becoming more myopic as the day progresses.

There is a disagreement, however, on the frequency of these two complaints after the stabilization period of three months. Rowsey\textsuperscript{16} reported glare complaints in 50\% of his patients at three months while 36\% to 79\% of patients had problems with fluctuating vision at that same time period. Cowden\textsuperscript{11} reported glare and/or fluctuating vision in over one third of the patients 6 months after surgery. According to Arrowsmith\textsuperscript{15}, 20\% had mild to moderate glare sensation after 6 months. Bores\textsuperscript{5} recorded just 4\% of his patients with glare difficulties after three months and 10\% with vision fluctuations.

One possible explanation for this discrepancy can be attributed to these studies measuring glare sensitivity in patients using subjective terms. A clinical glare tester recently developed by Miller\textsuperscript{27} has the capability to measure glare in objective
terms using a glare sensitivity index. Glare difficulty does seem to decrease after time but whether it is due to a decrease in scar density or to patient adaptation may be determined by the glare tester.

Frank perforations of the anterior chamber and microperforations can pose serious postsurgical complications ranging from infection to induced corneal astigmatism. The incidence rate of perforation was initially significant; 35% microperforation rate, to 10% frank perforation. Perforation usually occurs in the inferior portion of the cornea, caused mainly by blade plowing from backhand incisions and recutting with pressure. Perforations still occurs but at a decreased rate due to improved technique and instrumentation.

Complications in contact lens fitting and wear has not been well documented thus far. Katz, in an animal study with rabbits, found that corneal neovascularization occurred earlier and progressed further in eyes fitted with cellulose acetate butyrate (CAB) contact lenses on an extended wear basis that had had radial keratotomy. Rowsey described fitting difficulties due to inadequate tear flow between the contact lens and cornea. This appears to occur because of the steep knee in the periphery of the cornea that develops after surgery. This knee is a result of a sharp change in the corneal curvature at the mid periphery.

The most common epithelial changes observed after radial keratotomy were Moncreiff iron lines associated with corneal scarring. Kremer reported an incidence rate of 33% in his
patients but stated that the lines tended to be present at the inferior aspect of the central optical zone and thus were not associated with any visual symptoms. Other changes seen and noted were epithelial ingrowth, stromal overgrowth, recurrent erosions, and epithelial inclusion cysts.10,11,16,24

Change in the endothelium is regarded as the most potentially serious long term complication of radial keratotomy. These changes take the form of polygonal changes in the endothelial cells and endothelial cell density loss. Since endothelial cells are incapable of division or reproduction, any cell loss after surgery is not replaced. Surgical cell loss along with normal cell loss associated with aging raises the possibility of total corneal decompensation at a later time. In studies central endothelial cell density loss has ranged from 4% to 10%.26 Salz17 reported a 24% endothelial cell loss from a patient who had undergone four additional reoperations. Jester23 reported a 14% to 15% endothelial cell loss in primates.

Histologic examination of human and animal eyes after radial keratotomy has documented posterior folds in Descemet's membrane. Binder18 postulated that the severe folding in Descemet's membrane ruptured the underlying plasma membranes of the endothelial cells. He also concluded that these longitudinal folds were not artifacts. Yamaguchi20 found in a histologic and electron microscopic study of radial keratotomy monkey eyes, edema, degeneration, endothelial cell loss, and inflammatory cells in the endothelial layer. Yamaguchi believed that cuts in Bowman's membrane and in the stromal tissue may cause corneal
stretching, resulting in continued injury to the endothelial cell layer.

Conclusion

Based upon the evidence and results presented in this paper, it appears that radial keratotomy will remain a controversial procedure. The conclusions that can be made concerning radial keratotomy are that it does seem to reduce myopia to some degree in most patients and that this procedure appears to be most effective with patients having mild to moderate amounts of myopia. The most pressing questions yet to be answered involve the predictability, reliability, and, more importantly, the long term safety and efficacy of this surgery.
References


