KERATOMILEUSIS FOR MYOPIA: INITIAL EXPERIENCE IN SAUDI ARABIA

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ABSTRACT

Autoplastic Myopic Keratomileusis (MKM) was performed on one hundred patients (147 eyes in total), in the period between August 1985 to November 1986, to correct moderate to high degrees of myopia (range -4.25 to -22.25) Diopters. Of the 147 eyes who underwent MKM, 130 (representing 88.43%) were followed up for a minimun period of 6 months and a maximum period of 21 months following surgery (mean 9.25). Clinical and refractive results obtained during that period are depicted as follows.

The average pre-operative degree of myopia was found to lie at -9.525Diopters, whilst the average degree of post-operative myopia was found to lie at -1.295 Diopters. This signifies an average correction of 86.40% with a correlation coeficient of 0.815 (p < 0.0001). 70% of patients who underwent MKM had a visual acuity --CORRECTED--- of 20/40 or better in the pre-operative period. Whilst 51.53% could reach a visual acuity ---UNCORRECTED--- of 20/40 or better in the post-operative phase.

The predictability of accurate correction in this series was considered to be satisfactory in the majority of patients showing a minimal rate of significant complications that were temporary in nature.

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INTRODUCTION

The principle of Keratomileusis for the correction of myopia was introduced by Dr. Jose Barraquer in 1961. Keratomileusis studies have been limited since then¹, ², ³, ⁴, ⁵, ⁶, ⁷, ⁸, ⁹, ¹⁰, but have established the efficacy, and safety of the procedure. Since then the use of computers, and other sophisticated apparatus have contributed more towards the increased predictability and accuracy of such a procedure, thus establishing the surgical possibility of correcting myopia as a plausible alternative to be considered in a variety of patients.

Since the introduction of Keratomileusis more that twenty five years ago, recently but modified techniques to Barraquer's principle have evolved, such as 'Epikeratophakia'¹¹ and 'Non freeze Keratomileusis'¹² developed by Werbling and Krumeich respectively. But the continous overall improvement in Keratomileusis evidenced by published results, together with the increased accuracy it has now attained, has helped in increasing to a great extent the predictable accuracy of correction in such a procedure. Basically this presently represents a clear advantage for Keratomileusis when considering the surgical alternative of correcting moderate to high degress of myopia.

In Saudi Arabia geographic and climatic conditions are but some of the reasons rendering a large number of myopic patients intolerant to wearing contact lenses. Kerato-refractive surgery has thus found an appropriate place for its application and development in a wide spectrum of the population.

On the other hand, the wide variety of corneal pathology, characteristic to this part of the world, was a limiting factor for its wide application.

The following report represents the results of 130 cases operated on and followed up in the Kingdom of Saudi Arabia by the author.

SUBJECTS AND METHODS

The age of patients selected for surgery was above 17 years, and all of the patients shared a refractive error of at least 4.25 Diopters of myopia as considered by spherical equivalent. The majority of the patients were considered to be contact lens failures, and were dissatisfied with their spectacles.

Patients with corneal, ocular or sistemic disease which could interfere with post-operative healing were excluded in this study. Patients suffering from trachoma — which is endemic in the Middle East— and found to have middle or peripheral corneal scarring, or extensive pannus were also excluded.

The pre-operative evaluation of these patients included refraction without cycloplegia, uncorrected near visual acuity revealed more information as to the real degree of amblyopia. Keratometry readings, slit lamp biomicroscopy, pachymetry, axial length, and keratography-which is considered to be very useful for locating the visual axis, being mandatory for a good keratectomy. Keratoscan was particularly helpful to analyse the corneal topography in the pre and post-operative phases, which topic will be considered in further studies.

Both, pre and post-operative measurements of visual acuity and refraction were performed under standard condition as follows: the patient was seated four meters from a high contrast projected Snellen chart which consisted of ten different lines, 20/400, 20/250, 20/160, 20/100, 20/70, 20/50, 20/40, 20/30, 20/25 and 20/20. To avoid the possibility of patients memorizing the letters, three different charts were used. The first chart was an alphabet, the second a digital —both had four symbols per line—, and the third was an 'E' chart-three symbols per line. The Snellen Acuity was determined when the patient could identify correctly either three of four, or two of three symbols. The Snellen fraction was converted into a decimal value, to allow for easier statistical computation¹⁰.

For the sake of reaching a higher degree of accuracy as to post-operative refraction, Keratography was used in conjuction with routine refractive examination methods.

Surgery was conducted under general anaesthesia in all of the cases. The surgical procedure was adopted as to Barraquer's original technique. Since the Keratomileusis procedure has been described in detail previously by different authors¹³, such a matter will not be considered in this paper, except where minor modifications have been involved. The required average diameter of the disc was 7.33 mm +/- 0.216. For cases of myopia higher than 15 Diopters discs of smaller diameter were used down to a minimum value of 6.5 mm.

The microkeratome plate used in the majority of cases was #35, which yielded a corneal disc of average thickness 0.29 + / - 0.03. A computer program (KMMIOPICA 24-VI-84) developed by Barraquer was used for the operative calculations, which basically allows for a minimum thickness of the lenticule after lathing of 0.14 mm (except in five cases in which the computer operator modified this instruction to allow a thickness of 0.109), a fixed increment of 1.0908 which compensates the factor of expansion of water and a fixed contraction factor of 1.09.

Table (1) shows some pre-operative and operative parameters expressed as average values +/- standard error of deviation and ranges. Post-operative

Table 1

Pre-Operative	<u>Average</u>	<u>S.D.</u>	<u>Minimum/</u> <u>Maximum values</u>
Age	26	+/. 6.397	16-44 years
Pachymetry	0.57	+/.0.026	0.52-0.62 mm
Axial Length	26.415	+/_ 1.752	23.64-31.07 mm
Operative			
Initial Radius	7.65	+/_0.215	7.25-8.30 mm
Diameter of the disc	7.325	+/_0.216	6.50-8.00 mm
Thickness of the disc	0.290	+/_0.03	0.19-0.39 mm
Preserved disc	0.289	+/_0.029	0.19-0.38 mm
Thickness after Lathing	0.165	+/_0.36	0.109-0.268
Freezing Time	131.96	+/_26.868	90-300 seconds

Pre-Operative and Operative Parameters

follow up visits were two days, fifteen days (removal of sutures), one month, three months, six months and twelve months. Topical steroids (prednisolone acetate 1%), and anhydrous glycerine were prescribed three times a day for the period of two weeks.

Four patients required Secondary Homoplastic MKM because of various operative and post-operative complications (three of them performed by a second more experienced surgeon). Whilst a fifth patient required an additional keratomileusis to correct a high degree of residual myopia. Astigmatic keratotomy was also performed on nine patients, and radial keratotomy on six others.

Gas permeable contact lenses were fitted on seven patients because of persistent irregular astigmatism up to six months after the initial surgery. Refraction data and clinical examination were gathered prospectively and the surgeon's findings were used. The data was edited using dBase III, whilst for analysis, tables and graphics the Microsoft Excel program was used. The statistical methods used in the analyses depended on the variables being studied.

RESULTS

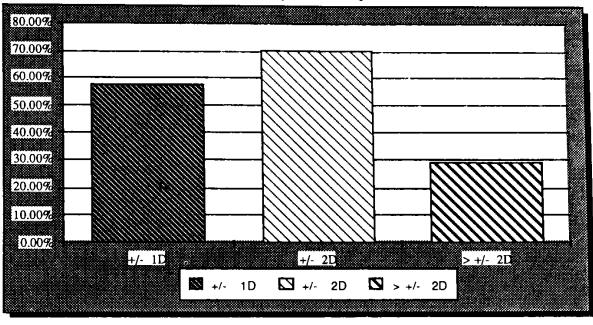
The following refractive results expressed as average values were derived from post-operative follow up of 130 patients (Table 2).

Table 2

	Refractive Results of Myopic	Keratomileusis
	Pre-Operative	Post-Operative
VA sc	20/600 (0.03 +/_ 0.013)	20/41 (0.487 +/_0.293)
Sph	-9.013 +/_ 4.167	-0.61 +/_ 2.5
Cyl	-1.03 +/_ 0.9	-1.37 +/_ 1.17
S.E.	-9.525 +/. 4.28	-1.295 +/.2.54
VA cc	20/30 (0.659 +/_ 0.304)	20/30 (0.66 +/_ 0.264)

Table 3 summarizes the pre-operative and post-operative refractive results for the 130 patients. It is worthwhile to note that 57.69% of the patients had a post-operative spherical equivalent between +/-1 D, whilst 70.76% had a post-operative spherical equivalent greater than +/-2 D. (Fig. 1).

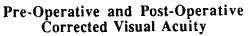
Figures 2 and 3 illustrate the pre and post-operative "best corrected" visual acuity. Of the 130 patients 44.61% maintained the same "best corrected" visual acuity, 31.53% had an increase of visual acuity of a minimum of one line and a maximum of three lines of the Snellen chart. Whilst 23.84% lost vision between a minimum of one line and a maximum of four lines (only one case lost vision down to four lines).



Post-Operative Spherical Equivalent



The majority of the patients were between +|-2 Diopters in the post-operative when considered by spherical equivalent.



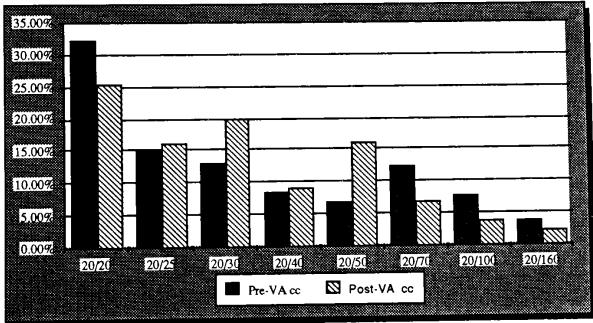
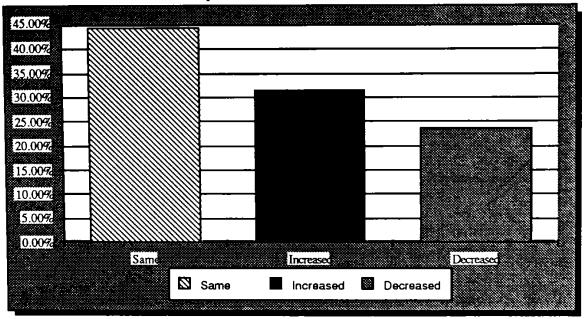


FIGURE 2

The percent of patients with pre-operative corrected vision of 20/20, decreased slightly post-operative.



Comparative Pre-VA ec and Post-VA cc

FIGURE 3

The corrected acuity increased or maintained in 76.16% of the eyes, while in 23.84% was decreased.

As noted in Table 2, the average astigmatism was not increased significantly when determined by subjetive refraction, however referring to Table 3 we could find induced astigmatism greater than three diopters in twenty four of the patients representing 18.46% of the patients. Nine of these patients had to undergo astigmatic keratotomy, and yielded satisfactory results.

Figure 4 illustrates the incidence of astigmatism relative to the location of the flat meridian, observing an increase in the incidence of "against the rule and oblique" astigmatism, whilst there was a reduction in "with the rule" astigmatism in the post-operative.

Table 4 shows a comparative study —Pearson Correlation test— between 'Diopters Requested' and 'Diopters Obtained'. Fig. 5 illustrates a comparative Scattergram between the same.

Tables 5 and 6 show major operative and post-operative complications. Major complications were found to be regarding the keratectomy. Three patients required secondary homoplastic keratomileusis because of irregular keratectomy which resulted in severe irregular astigmatism in one case,

Table. 3

										GIT WOLLOG	
	Pre-01	Pre-Operative Re	Refraction	Post-Op Sphere	perative Rel Cylinder	<u>Refraction</u> er Axis	Pre-Op VACC	Post-Up VACC	VASC	TIME	COMMENTS
	3 JUICE C			-0.75	-0.50	30	20/20	20/25	20/30	12 M	
	4 C 8	2007 1	0	±1.25	-1.75	75	20/70	20/50	20/70	13 M	
	ы. В. б.	3.8	8 <	Diano	000	0	20/20	20/20	20/20	12 M	
	(7.1-	0.0	001	Diano Diano	-1.00	40	20/25	20/20	20/25	12 M	RK
	00.8-	00.0-	100		-1.50	100	20/30	20/50	20/70	13 M	
	00.21-	00.1-	180	001-	400	45	20/30	20/50	20/50	13 M	
	-12.00	00.1-	190	20 7 7	-2.00	120	20/50	20/50	20/100	13 M	HOMO-MIKM
	-10.00	05.1	20 C	-5 00	-3.50	01	20/70	20/50	20/160	13 M	
	0.01-	001-	25	-0.75	-1.25	70	20/40	20/30	20/40	6 M	
	00.61-	9 -	145	-100	0.00	0	20/25	20/30	20/40	6 M	
		200-74-		Plano	-1.25	06	20/25	20/25	20/25	12 M	AK
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	88	-0.50	64	Plano	00.0	0	20/20	20/20	20/20	6 M	
	4.50	-0.75	6	Plano	-0.75	110	20/25	20/20	20/20	6 M	
	-7.50	-0.75	50	+1.75	-4.50	175	20/25	20/20	20/100	13 M	
	-8.25	-0.50	165	-1.25	-1.00	125	20/20	20/20	20/70	13 M	
•	-16.00	-2.25	180	-10.00	0.00	0	20/50	20/50	20/160	12 M	
•	-15.00	-2.00	180	-7.00	-1.50	20	20/40	20/50	20/160	12 M	
	-7.50	-1.00	120	+1.00	-1.25	80	20/25	20/20	20/25		
	-8.00	-1.25	4	Plano	0.00	0	20/25	20/20	20/20	12 M	
	4.50	0.00	0	Plano	-1.75	65	20/20	20/20	20/25	12 M	
	4.75	-0.50	80	Plano	-0.50	175	20/20	20/20	20/20	12 M	
	4.75	-0.50	95	-2.75	0.00	0	20/20	20/20	20/70	12 M	
•	-12.75	-2.00	180	-1.00	0.00	0	20/40	20/40	20/70	12 M	
•	-13.00	-1.00	120	-3.50	-1.00	80	20/70	20/40	20/100	12 M	
·	-17.00	00.0	0	4 8	0.00	0	20/70	20/50	20/100		
•	-14.00	-1.00	30	+0.50	-2.00	160	20/70	20/50	20/50	12 M	
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	COMMENTS			A L	AN								AK	RK [.]												ECT A CI A										
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	Post-Op VACC	20/40		30.02	C2/07	20/30	20/20	20/20	20/50	20/30	20/25	20/25	20/30	20/30	20/20	20/20	20/02	20/20	20/30	2020	2005			0//07	20/30	20/30	20/50	20/10	20/100	20/30	20/25	20/40	20/40	0202		REFRACTIVE RESULTS OF KERATOMILEUSIS IN 130 PATIENTS (Page 3)
	Pre-Op VACC	UV/UC	20.40	C7/07	20/20	20/20	20/25	20/20	20/100	20/30	20/20	20/20	20/40	20/50	20/20	20/20	0000	2020	02/02	0000		05/07	20//07	20/100	20/30	20/25	20/30	20/70	20/160	20/20	20/30	20/40	01/06		001/07	eusis in 13
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.50 80 Plano 0.00 0 20/20 20/20		-2.00	80	-1.50	0.00	0	20/50	20/40	20/50	6 M	
			80	Plano	0.00	0	20/20	20/20	20/20	6 M	

Table. 3

	dil'M	E COMMENTS											-	
	Post-On FOLLOW-IIP	TIME	6 M	N 9	W 9	W 2		ΜO	6 M	6 M	M 20 0	EAT C7.6		~
	1		20/20	20/50	20/160	20150		M1/07	20/25	20/30	1 487	20/41		TS (Page 5
	Post-On	VACC	20/20	20/40	20/30	02/02	05/06	00/07	20/20	20/20	0 660	20/30		30 PATIEN
	Pre-Op	VACĊ	20/20	20/100	20/100	0000	2020	07/07	20/20	20/20	0 650	20/30		KEFKACIIVE RESULIS OF KEKATOMILEUSIS IN 130 PATIENTS (Page 5)
Table. 3	efraction	Axis	105	120	85	40	140		ŝ	105				KATOMIL
	Post-Operative Refraction	Cylinder	-0.75	-1.25	-1.00	-1.50	-250		-1.50	-1.00	-1.373	1.17		LIS OF KE
	Post-Op	Sphere	Plano	+0.25	+3.00	+1.50	±4.50		00.04	-0.50	-0.610	2.50		IIVE RESU
	raction	Axis	110	8	4 5	55	0	, <u>c</u>	2	120				VEFRAC
	Pre-Operative Refraction	Cylinder	-0.50	-1.75	-1.50	-0.50	0.00	20.05	C7.0-	-0.25	-1.027	06.0		-
	Pre-0	Sphere	-5.50	-9.50	-14.00	-10.75	-10.00	3C V	3 i	4.7	-9.013	4.17		
	Pt.	20. 2	124	125	126	127	128	170	271 271	130	Aver.	XTDEV		

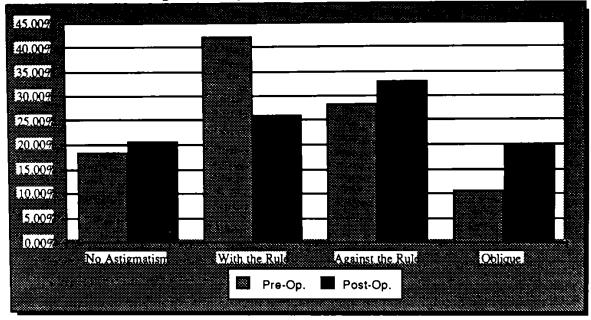
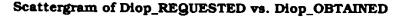


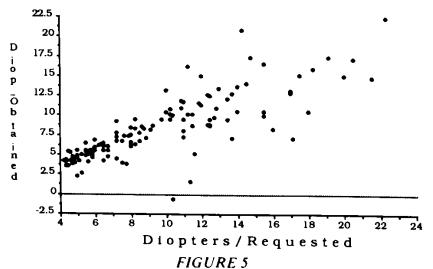
Fig.4 Pre-Operative and Post-Operative Astigmatism

FIGURE 4

"With the Rule" astigmatism was prevalent pre-operative, while "against the Rule" astigmatism was prevalent post-operative.

Table 4Diopters Requested vs. Diopters Obtained
Correlation Coefficient: .8156
(P < 0.0001)</td>





Scattergram: Diopters of correction obtained plotted against diopters of correction requested, based on subjective refraction.

	Fable 5
OPERATIVE	COMPLICATIONS

-

Microkeratome	Number
Irregular keratectomy Thin keratectomy Bigger disc than required Smaller disc than required Deep keratectomy Oval disc Descentered resection Perforation of anterior chamber	8 4 1 2 2 1
Crvolathe and Computer Wrong calibration Double freezing Delayed freezing (>3 min) Error in computer Perforation at lathing	0 1 2 1 1 0

Table 6POST-OPERATIVECOMPLICATIONS

Central opacity	8 (relative to Trachoma)
Significant epithelial inclusions	3
Corneal ectasia	1
Infections	0
Vascularization	0
Loss of lenticule	0
Retinal detachment	0

epithelial inclusion compromising the visual axis in another one, and corneal melting in a third case.

In another patient a deep keratectomy resulted in further and progressive ectasia of the posterior leyers of the cornea with total loss of correction. A gas permeable lens was fitted and was well tolerated by the patient. No significant complications were atributed to the cryolathe use.

Eight patients developed unusual and progressive central and/or paracentral opacities of the lenticule three to six months following surgery. Careful examination at this stage revealed that these patients were suffering from trachoma which was affecting the tarsus, but leaving the cornea clear of any changes; and could thus explain why the diagnosis was fissed pre-operatively. One of the these patients suffered from significantly decreased visual acuity due to these opacities, and a secondary homoplastic keratomileusis was then indicated. The corneal lenticule was removed, and is presently under investigation but will be the subject of a further publication (Fig. 6). Another association found in these patients who developed opacities and had trachoma changes was the high correction requested in all cases but except one.

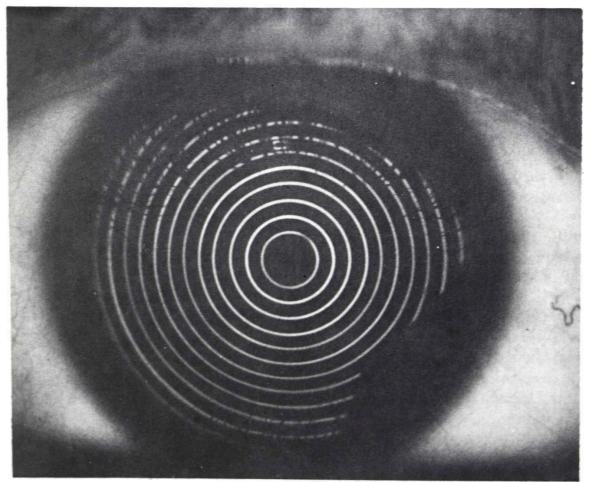


FIGURE 6 Pre-operative keratography of a patient with refraction: -5.75 --0.50 X 80.

CONCLUSIONS

The above results provide some useful information. The relatively short span of time (fiften months) it took to perform one hundred and forty seven keratomileusis procedures in Saudi Arabia, in patients who basically were dissatisfied with conventional methods of correcting their disability signifies the surprisingly increasing demand of high myopic patients resorting to a surgical solution for the correction of their optical error.

The refractive results from this study are encouraging. Amblyopic patients showeds an improvement in their best corrected visual acuity, although some of the patients with good initial visual acuity went slightly down. The highest correction in this series was 22.25 Diopters, although it is intersting to observe from the above results that patients with myopia greater than 14 D were not consistently fully corrected. The predictability of correction was satisfactory when considering keratomileusis in patients with myopia below 6 Diopters. Several anatomical and surgical factors support these observations. From a clinical and surgical point of view the fact is that patients with moderate degrees of myopia do not develop the extreme deformities in axial length and corneal curvature seen in patients with high degrees of myopia, representing technical difficulties in performing the keratectomy. The diameter of the resected corneal disc in the group of moderate myopes is reasonably large. The optic carving performed in a relatively larger diameter will lead to removal of minimal corneal tissue being removed by the lathing thus resulting in a lenticule with a fair residual thickness, which in turn allows for better stability of the cornea and easier re-adaptation; as the flattening obtained will not exceed the physiological limits. The keratography sequences documented in different follow up phases showed a minimal rate of irregular astigmatism in this group of patients, and when present disappeared relatively fast (Figs. 6 and 7).

Post-operative complications characterized by opacification of the lenticule late after surgery was found to be closely linked to the presence of Trachoma in those patients. Chlamydia Trachomatis is an intra-epithelial microorganism that does not invade tissues, but is able to release its antigen into the superficial stroma leading to an inflamatory response with subsequent scarring (personal communication, Khalid Tabbara, MD 1987), which could be enhanced by the inflammatory response following the freezing process¹⁴, ¹⁵. Although strict criteria were instituted for the selection of surgical patients, still a few of them affected by trachoma were missed, especially those who presented with no corneal affecting but instead had tarsal involvement. I would thus strongly recommend that stringent and meticulous examination be followed for detecting

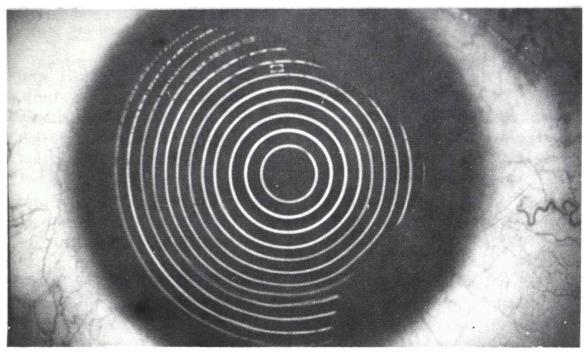
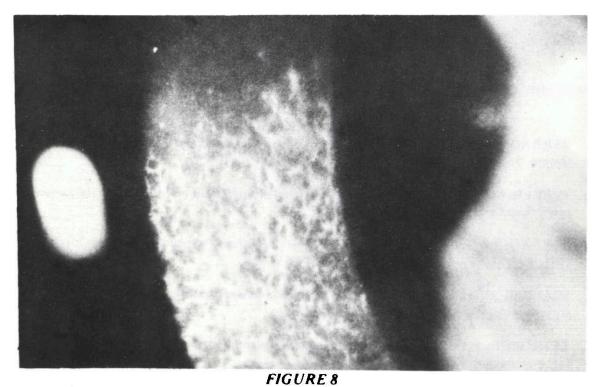


FIGURE 7

Six months post-operative keratography of the same patient with a refraction: Plano. Notice perfect regularity of the central and mid peripheral rings.



Corneal opacities in a patient affected of Trachoma. His bes corrected acuity went down two lines.

trachoma when selecting suitable patients for keratomileusis since the disease is no more limited to certain parts of the world.

Finally, additional techniques such as "Non-freeze Keratomileusis" and "Myopic Epikeratophakia" are now the subjects of intensive study. Theoretically the Planar Lamellar Refractive Keratoplasty has a primary advantage over the classical Barraquer approach which lies in the fact that freezing is eliminated, but we vet have to await the publication of results in that matter¹². On the other hand, the principle of Epikeratophakia relies on the fact that it is a reversible operation but preliminary reports do not indicate significant predictability for its resulte, characteristic of homoplastic procedures¹⁶, ¹⁷.

Keratomileusis is considered, by the majority of ophthalmic surgeons to be a difficult technique which requires sophisticated and expensive equipment, however with proper training like any surgical procedure would become yet another important pathway for correcting moderate and high degrees of myopia in properly selected patients. It is also considered to be the lamellar refractive keratoplasty with the longest period regarding clinical observation, and is regarded to be safe, effective for the surgical correction of myopia.

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