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REFRACTIVE KERATOPLASTY USING PRE-LATHED PRESERVED CORNEAL MATERIAL

MILES H. FRIEDLANDER, M. D.

THEODORE P. WERBLIN, M. D., PH. D.

HERBERT E. KAUFMAN, M. D.

NICOLE S. GRANET, B. A.

New Orleáns, Louisiana, USA

ABSTRACT

Worldwide interest in refractive keratoplasty is evident from the steadily increasing number of cases being performed and from the rapidly growing number of applicants for instructional courses. Even greater utilization of this surgical technique will occur when pre-lathed and preserved corneal material is made available. Evaluation of methods of preservation in animal and clinical studies has shown no deleterious effects resulting from prolonged storage of the lenticules before surgical insertion. A randomized, prospective study of keratomileusis hyperopia homoplastica and epikeratophakia is currently underway to evaluate the relative efficacy and safety of these two forms of refractive keratoplasty.

Refractive keratoplasty, developed by Dr. Jose Barraquer, is an efficacious and precise extraocular method of correcting moderate to high degrees of myopia and hyperopia. Analysis of Dr. Barraquer's cases [1, 2] as well as of those cases performed by surgeons in the United States [3, 4] confirms that the Barraquer techniques of refractive keratoplasty yield excellent and predictable visual results.

International instructional courses were initiated in Bogota by Dr. Barraquer in july, 1977, and continue to be offered periodically. Because

of the overwhelming number of applicants, additional instructional sites have been designated in the United States.

Many surgeons in the United States performing the procedures are enthusiastic, but general acceptance by the ophthalmic community will very likely be delayed because of the limited number of instructional courses available, the problems associated with the delivery and ongoing modification of cryo equipment and other hardware, and the problems associated with persuading ophthalmologists to master techniques foreign to their surgical training.

At least some of these problems may be eliminated if preserved, precarved and custom lathed donor tissue can be made available. This will allow the anterior segment surgeon to order lenticules much like ordering a contact lens; refractive keratoplasty then can be accomplished by the ophthalmic surgeon using familiar corneal surgical techniques.

In the 1950's, Rycroft and Eascott [5, 6] demonstrated that using lamellar corneal sections stored at -75ºC yielded a high percentage of clear corneal grafts. King [7] showed similar results with corneal tissue preservation in glycerine and silica gel at room temperature. Barraquer [8] demonstrated that freezing destroys the keratocytes in the stroma of stored corneal tissue. These data were confirmed and expanded upon in recent studies by Rich, et al. [9]. Using vital staining and current techniques of cryolathing and preservation, it was shown that, although the donor stromal keratocytes are killed in the lathing process, repopulation of the non-living stromal matrix by keratocytes from the host cornea begins within ten days.

Based on the above experiments, we theorized that preservation and continued storage of the cryolathed lenticule would not affect its ultimate transparency. In animal studies using cats as the experimental model, we compared resulting graft clarity using freshly lathed and preserved lenticules [4]. Lenticules of similar dimensions were cryolathed using the computer program for keratophakia. The lenticules were divided into three groups: 1) lenticules implanted immediately after lathing; 2) lenticules stored in liquid nitrogen for at least one week before surgical implantation; and 3) lenticules stored in glycerine for at least one week before surgical implantation.

Three months after surgery, there was virtually no difference among the three groups in graft clarity, in increased corneal thickness, and in the anticipated increase in dioptric power of the cornea.

Fifteen keratophakia patients are being followed in the clinical trial of cryopreserved and fresh keratophakia lenticules [4]. Six received freshly carved lenticules and nine received liquid nitrogen preserved (cryopreserved) lenticules. A total of seven patients had keratophakia and intracapsular cataract extraction combined; eight patients had keratophakia alone (Table).

Selection was based on 20/40 or better vision in the fellow eye, contact lens failure or refusal to wear a contact lens, and desire for refractive keratoplasty instead of intraocular lens implantation. With one exception, all patients showed excellent corneal clarity postoperatively. There were no infections, no graft rejections, and no eyes lost. The one exception, patient Nº 2, had persistent edema of the cornea secondary to inadvertent entrance of the anterior chamber with the microkeratome.

Within six months, all patients had functional visual acuity, with three exceptions. Of the patients having keratophakia as a secondary procedure, one (Nº 2 as above) had accidental perforation of the anterior chamber (surgery related), one had cystoid macular edema (not thought to be related to the refractive keratoplasty procedure), and a third patient had a retinal detachment four months postoperatively (not thought to be related to the refractive keratoplasty procedure). The remaining 12 patients had visual acuities equal to or within one line of their preoperative best corrected visual acuities.

The excellent corneal clarity and visual acuity obtained in this study led to the conclusion that pre-lathed, liquid nitrogen preserved corneal tissue could be successfully used in refractive keratoplasty.

In the treatment of hyperopia, hypermetropic keratomileusis has to some extent replaced keratophakia. It appears that the recovery of final visual acuity is achieved more rapidly with hypermetropic keratomileusis, possibly because the healing process involves only one interface, in contrast to the two interfaces that must heal after the keratophakia procedure [10]. Dr. Barraquer's technique of keratomileusis involves the lathing of a lamellar section of the patient's own cornea. In the event of an accident rendering the patient's own corneal tissue unusable, a separate computer program for keratomileusis hyperopia homoplastica (KMHH) provides for lathing donor tissue as a substitute. We propose that KMHH be employed as a primary procedure, using the pre-lathed and preserved corneal tissue techniques that we developed in the keratophakia study [4].

In an attempt to further simplify the techniques of refractive keratoplasty in the correction of aphakia, Dr. Theodore P. Werblin suggested suturing a pre-lathed, donor corneal cap over the patient's de-epithelialized, but otherwise intact, cornea [11]. Dr Werblin, Dr. Herbert E. Kaufman and Dr. Miles H. Friedlander have development this idea into a practical surgical procedure called epikeratophakia and clinical trials are currently underway.

To evaluate the respective merits of keratomileusis hyperopia homoplastica and epikeratophakia, and to compare liquid nitrogen and glycerine preserved, pre-lathed corneal tissue, a long term, prospective study has been initiated at the LSU Eye Center in New Orleáns, Louisiana by drs. Kaufman, Werblin and Friedlander. This double blind, randomized study will follow at least 40 patients for two to five years. Selection criteria for this study will be aphakia in the operated eye and functional visual acuity in the fellow eye.

Patients will be randomized into four groups. Group I will have keratomileusis hyperopia homoplastica, using cryopreserved donor corneal tissue lathed according to the calculations of Dr. Barraquer. Group II will be similar to Group I, but will receive grafts stored in glycerine at room temperature. Groups III and IV will undergo epikeratophakia, using the programs and calculations of Dr. Werblin. Group II will receive grafts that have been stored in liquid nitrogen (cryopreserved); Group IV will reveive grafts stored in glycerine at room temperature.

Preoperative evaluation will include a complete ophthalmic examination, including the following specialized tests: ultrasound, keratometry, endothelial cell counts, Shirmer (severe dry eyes excluded), corneal sensitivity, pachometry, visual fields, and corneal photographs.

Techniques of suturing, suture material, and postoperative medications will be standardized. Periodic postoperative examinations with special emphasis on visual acuity, time of recovery of visual acuity, pachometry, and keratometry with mire quality will be conducted. Evaluation of visual results will be performed by an examiner other than a member of the surgical team who will have no knowledge of patient selection or surgical technique. In this way, we hope to eventually accumulate sufficient data to successfully evaluate the relative efficacy and safety of these two techniques.

TABLE: Comparison of Liquid Nitrogen Preserved and Fresh Lenticules in Patients (adapted from Friedlander, et. al.[4]).

	Followup to Date	Graft Clariti	Diopters to Correct [1]	Diopters Uncorrected [2]	Preop Visual Acuity	Postop Visual Acuity
LENTICULES USED INMEDIATELY AFTER LATHING						
1—Keratophakia	2 yr	0.5	+ 18.25	— 2.75	20/30	20/30 [5]
2—Keratophakia	2 yr	4 [3]	+ 18.25	+ 2.00	20/50	20/200 [5]
3—Keratcphaquia	2 yr	0.5	+ 13.25	+ 2.75	20/50	20/50
4—Intracapsular cataract extraction Keratophakia	21 mo	0	+ 17.00	+ 3.75	20/200	20/40
5—Intracapsular cataract extraction Keratophakia	18 mo	0	+ 18.00	+ 1.25	20/400	20/25
6—Intracapsular cataract extraction Keratophakia	18 mo	0	+ 14.00	+ 1.50	Count Fingers	20/25
LENTICULES STORED IN LIQUID NITROGEN						
7—Intracapsular cataract extraction Keratophakia	1 yr	0	+ 12.50	— 3 00	Hand Motions	20/30
8—Keratophakia	4 mo [4]	0	+ 13.00	+ 3.00	20/25	20/50 [4]
9—Keratophakia	9 mo	0	+ 12.00	+ 1.00	20/40	20/50
10—Intracapsular cataract extraction Keratophakia	9 mo	0	+ 15.00	+ 2.50	20/100	20/40
11—Keratophakia	6 mo	0	+ 11.00	+ 2.50	20/30	20/40 [6]
12—Intracapsular cataract extraction Keratophakia	6 mo	0	+ 16.00	+ 2.00	Hand Motions	20/40 [6]
13—Keratophakia	9 mo	0	+ 12.00	+ 0.50	20/40	20/50
14—Keratophakia	6 mo	0	+ 11.75	+ 1.75	20/25	20/30
15—Intracapsular cataract extraction Keratophakia	6 mo	0	+ 12.00	+ 1 50	Count Fingers	20/40 [6]

[1] Calculated dioptric correction for emmetropia; [2] Residual correction - spherical equivalent; [3] Anterior chamber inadvertently entered, residual corneal edema; [4] Retinal detachment ocurred 4 mos. postoperatively; [5] Developed cystoid macula edema documented by fluorescein angiography 4 months postoperatively; [6] Corrected to 20/25 or 20/30 with bandage plano T lens and over-refraction.

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