Thermokeratoplasty for the treatment of hyperopia: A clinical follow-up

Termoceratoplastia para a correção de hipermetropia: Um estudo clínico

Luciene Souza [1]
Walton Nosé [1]
Mauro Campos [1]
Peter J. McDonnell [2]

SUMMARY

Corneal curvature can be altered by shrinking stromal collagen with a retractable cautery probe tip that produces controlled thermal burns in a procedure termed hyperopic thermokeratoplasty (HTK). This procedure induces steepening of the central cornea. We performed HTK in 12 sighted eyes from eight patients placing a radial pattern of spots on the peripheral cornea, using the Fyodorov thermal unit. The number of spots and the shape of the optical zone (rounded or ovoid) was determined by a computer software provided by the manufacturer. Follow-up ranged from 24 to 54 weeks (mean of 31.50 weeks). Spherical equivalent changed from a preoperative mean of 4.10±1.12 diopters to -0.85±0.86 (P=0.001), 0.74±1.26 (P=0.001), 1.05±1.34 (P=0.001) and 3.84±1.13 diopters (P=0.16), respectively at 4, 12 and 24 weeks after the surgery and at the last Follow-up. The induced keratometric steepening at 4 weeks postoperatively (4.50±1.31, P=0.001), reduced to 1.04±0.43 diopters of corneal steepening at the last Follow-up (P=0.25). Uncorrected visual acuity improved at least two lines in nine eyes (75.0%), remained unchanged in one eye (8.3%) and decreased in two eyes (16.7%). Eight eyes (66.6%) had uncorrected visual acuity equal to or better than 20/40 at the last visit. None of the patients had recurrent erosions, stromal necrosis or vascularization. Endothelial cell counts performed six months after surgery in two patients that underwent unilateral surgery indicated no quantitative or qualitative effects from HTK. These data support previous studies indicating that central corneal topography can be modified by heating corneal stroma in a controlled fashion. Regression of effect and induction of astigmatism limited the success of our series.

Surgical correction of hyperopia includes hyperopic keratomileusis, hyperopic epikeratophakia, hexagonal keratotomy, thermokeratoplasty and more recently photorefractive keratectomy. [1-5] Thermokeratoplasty, a surgical procedure that involves heating of the corneal tissues, was initially attempted in patients with keratoconus. [6] Initial reports of success [6] were followed by reports of profound initial flattening but with subsequent return to preoperative topography,[7] and complications such as delayed epithelial healing, recurrent epithelial erosions, aseptic stromal necrosis and melting and vascularization [8]. The Los Alamos probe, an instrument designed to heat the stromal collagen using radio frequency waves, was reported to procedure short-lived topographic changes. [9, 10] Alternative methods of heating the corneal stroma to steepen the central cornea or using a hot copper wire, such as the one introduced by Fyodorov, or others using different types of thermalasers, have been reported. [4, 11-16]

Clinical experience reported in the literature with heating of the corneal tissues to produce topographic changes is limited. We report here our results in a prospective study using the Fyodorov thermal unit to treat hyperopia and hyperopia associated with astigmatism in sighted eyes.

Key Words: Hyperopia; Thermokeratoplasty; Cornea, Stromal shrinkage

(1) From the Department of Ophthalmology, Paulista School of Medicine, São Paulo, Brazil
(2) Doheny Eye Institute and the Department of Ophthalmology, University of Southern California School of Medicine, Los Angeles.

None of the authors have any financial or proprietary interest in the instruments or techniques mentioned in this manuscript.

Endereço para correspondência: Dr Mauro Campos - R. Botucatu, 824 - São Paulo, SP.

http://dx.doi.org/10.5935/0004-2749.19970075

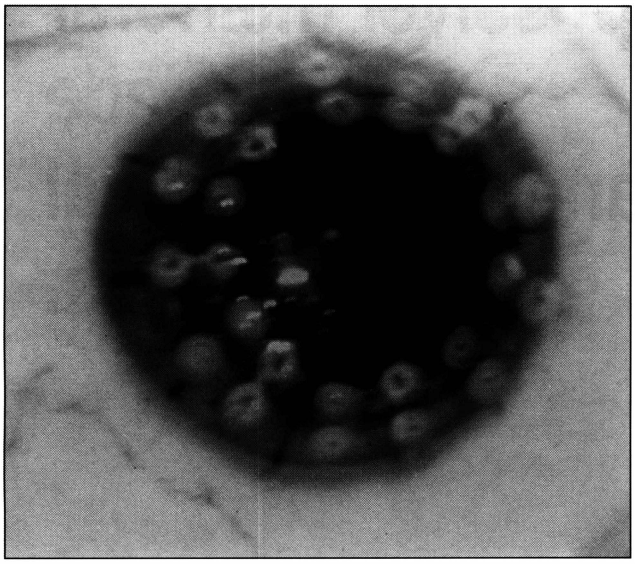

Fig.1 - Slit-lamp photograph of a patient one day after laser thermokeratoplasty for treatment of hyperopia alone or associated with astigmatism. Localized areas of stromal cloudiness are observed at the treatment sites.

PATIENTS AND METHODS

Twelve sighted eyes from eight patients were enrolled in this study. The nature, risks and alternatives to thermokeratoplasty as treatment of hyperopia was fully explained and discussed with all the patients. All patients were glasses or contact lenses intolerant. This study was carry out under a protocol approved by the Paulista School of Medicine committee of clinical studies. Preoperative examination included visual acuity, cycloplegic refraction, biomicroscopy, keratometry, ultrasonic pachymetry, corneal diameter, applanation tonometry, axial lenght and fundoscopy. Patients with external diseases or other pathologic conditions, besides refractive errors, were excluded from the study. Postoperative measurements were performed 4, 12, 24 and 54 weeks after surgery and included visual acuity, cycloplegic refraction, biomicroscopy, applanation tonometry and keratometry. Endothelial cell counts (Bio-Optics, Arlington, MA) were performed 24 weeks after the surgery in two patients that underwent unilateral thermokeratoplasty. The unoperated contralateral eye was used as a control for the endothelial cells counts. All measurements were performed by an experienced observer. A paired two-tailed Student-t-test was used to compare preoperative and postoperative measurements. Data were computed as mean ± standard deviation.

SURGICAL PROCEDURES

The surgical device used for treatment was the Fyodorov thermal unit. The surgical algorithm was determined according to a software supplied by the manufacturer (infraredkeratoplasty software v.3.0, Intersectoral Research and Technology Complex Eye Microsurgery, Moscow, USSR.) The software calculates the amount of surgery (number of spots and radials and the shape and size of the optical zone) based on preoperative measurements of age, visual acuity, refraction, corneal thickness and diameter, keratometry and axial length. According to the software, a 5.0 mm clear zone diameter with 8 rays of radial spots and 90% depth of coagulation induces 2 to 7 diopters of refractive change towards myopia depending on the patient preoperative measurements.

All patients received topical proparacaine and were operated under a surgical microscope. The retractable probe tip was calibrated using a block type gauge and adjusted to 90% of the central corneal thickness. After marking the visual axis, optical zone and radials, the tip was heated by the thermal unit to a temperature of 600°C and inserted in the cornea for 0.3 seconds. Three to four

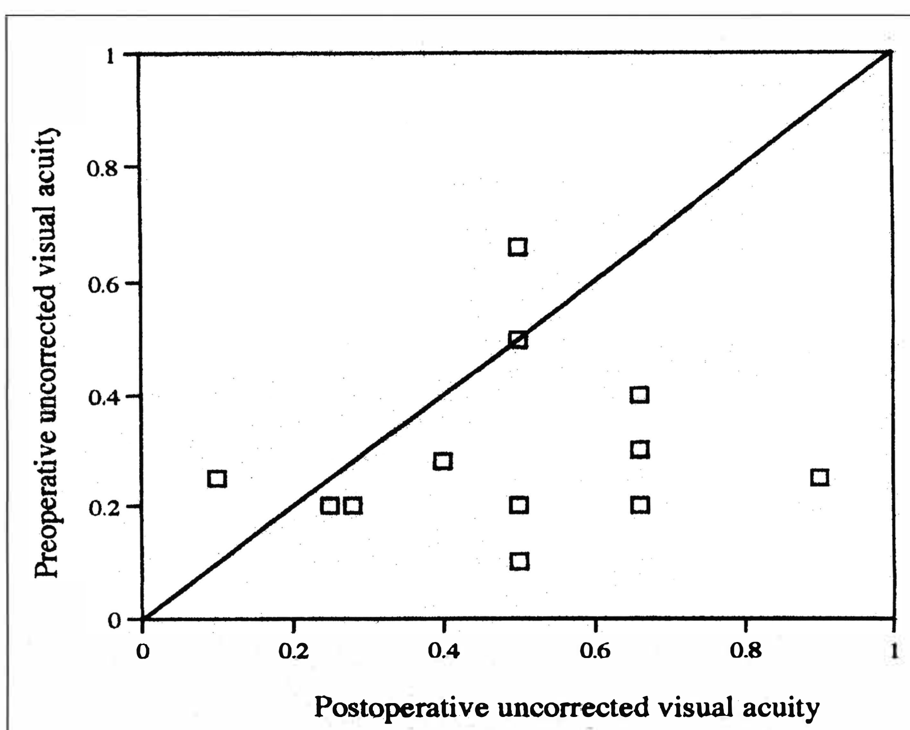

Fig.2 - Graph of preoperative uncorrected visual acuity plotted against postoperative uncorrected visual acuity of twelve eyes from eight patients 24 weeks after thermokeratoplasty for correction of hyperopic refractive errors.

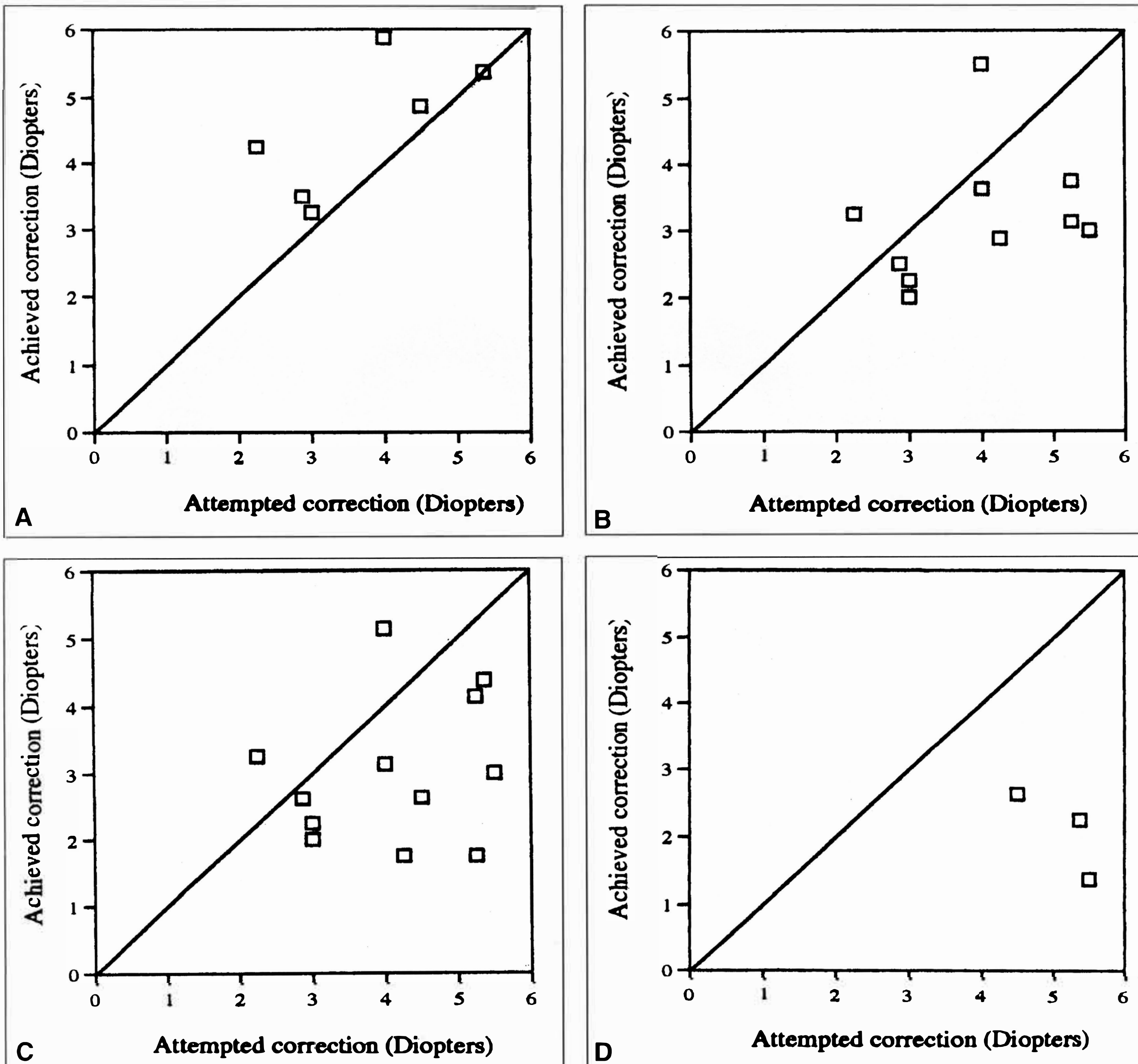

Fig.3 - Graph of attempted correction plotted against achieved correction obtained in twelve eyes from eight patients that underwent thermokeratoplasty for correction of hyperopic refractive errors. (A - 4 weeks, B - 12 weeks, C - 24 weeks and D - 54 weeks).

spots were placed on each of the radials depending on the amount of hyperopia. An elliptical zone was used in the cases with associated astigmatism, with the narrowest dimension of the ellipse oriented in the flattest preoperative meridian. After the surgery, the eyes were patched for 24 hours. No epithelial defects were observed after 24 hours. Patients were treated postoperatively with a combination of 0.1% dexamethasone sodium phosphate and 0.3% tobramycin sulfate solution four times daily for ten days.

RESULTS

The characteristics of the patients that underwent thermokeratoplasty for correction of hyperopia and hyperopic astigmatism are presented in the Table.

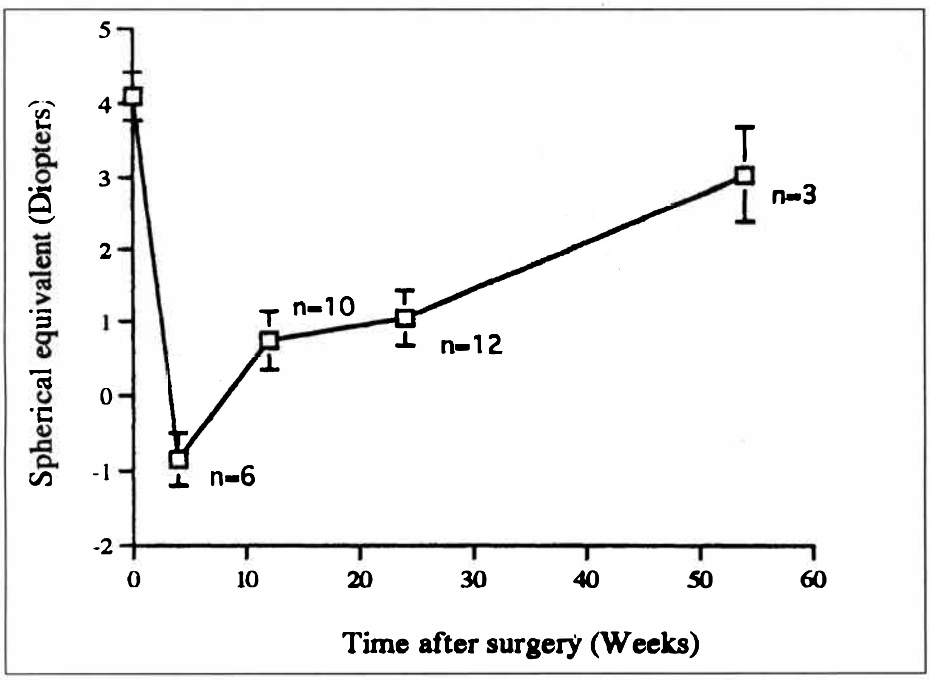

Fig.4 - Graph of the spherical equivalent observed in twelve eyes from eight patients that underwent thermokeratoplasty for correction of hyperopic refractive errors. Values represent mean ± SE.

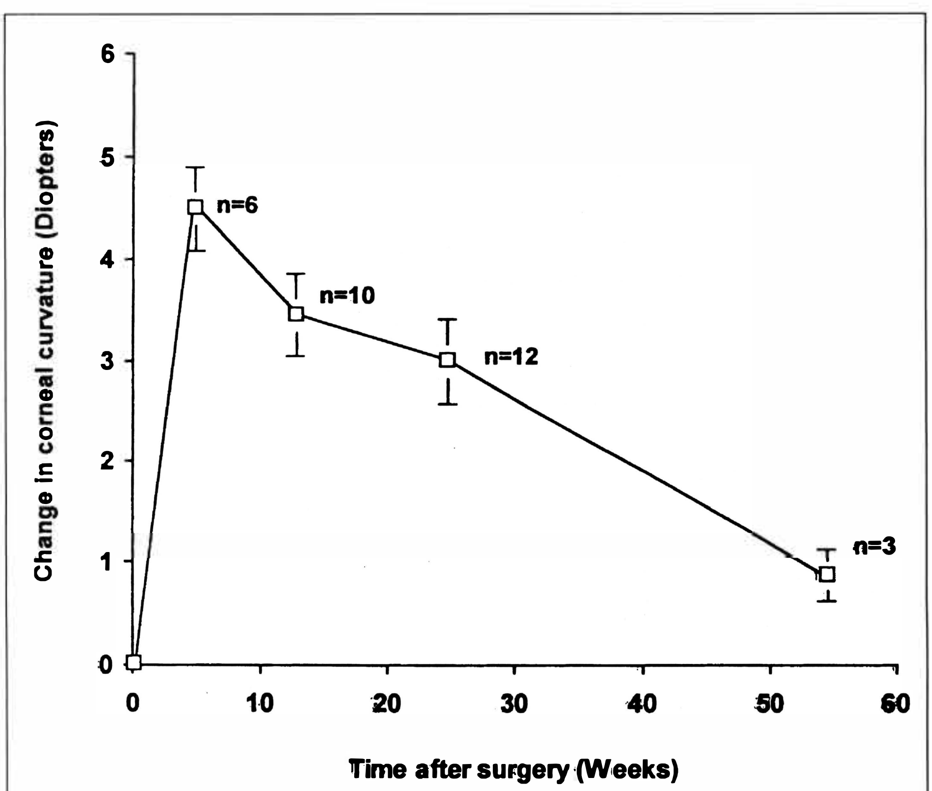

Fig.5 - Graph of induced corneal steepening observed in twelve eyes from eight patients that underwent thermokeratoplasty for correction of hyperopic refractive errors. Values represent mean ± SE.

Patients were followed for a mean of 31.5 weeks (range from 24 to 54 weeks).

Biomicroscopy

Immediately after surgery, the eyes had slight uptake of fluorescein over one or more of the treatment sites. The focal area of application was white. Stress lines of variable directions were seen between the radials. The underlying stroma was mildly opacified (Fig.1). This area of stromal cloudiness remained localized to the irradiation site. The spots tended to reduce in size with time during follow-up, resolving from posterior to anterior stroma. Six months after surgery, the scar is located in the anterior stroma, close to Bowman's membrane. No epithelial irregularities or corneal erosions occured during the entire follow-up.

No aqueous flare, iris abnormalities, lens opacities, corneal neovascularization or elevated IOP were noted during the follow-up.

Visual acuity

At the most recent visit, uncorrected visual acuity improved by at least one Snellen line in nine eyes (66.6%), remained unchanged in one eye (8.3%) and decreased one and two Snellen lines in two eyes (16.7%) due to induced astigmatism (Fig.2). The visual acuity corrected with spectacles improved in three eyes (25%), remained unchanged in seven eyes (58.3%) and reduced in two eyes (16.6%) (Table). One eye decreased spectacles corrected visual acuity from 20/20 to 20/25, while a second eye had reduction from 20/20 to 20/30. The cause of visual loss was believed to irregular astigmatism. Both patients were correctable to 20/20 with rigid contact lenses.

Spherical equivalent

Hyperopic thermokeratoplasty was performed according to the algorithm generated by the predictive software. The objective of the treatment was to correct the patients' refractive errors to near plano. Figures 3 (a-d) show the attempted correction plotted against the achieved correction respectively at 4, 12, 24 and at the last follow-up (R^2 = 0.48, 0.09, 0.05 and 0.05 respectively).

The mean preoperative spherical equivalent was 4.10 ± 1.12 diopters. The mean change in the spherical equivalent was determined (Fig.4).

Preoperative spherical equivalent was 4.10 ± 1.12 diopters. Postoperative measurements at 4, 12 and 24 weeks and the last follow-up disclosed - 0.85 ± 0.86 (P=0.001), 0.74 ± 1.26 (P=0.001), 1.05 ± 1.34 (P=0.001) and 3.84 ± 1.13 diopters (P=0.16), respectively. All patients showed regression on the initial (4 weeks) reduction of the spherical equivalent.

Keratometric changes

Corneal steepening was induced in all patients that underwent thermokeratoplasty for correction of hyperopic refractive errors. Four weeks following surgery, the induced corneal steepening was maximal (4.50 ± 1.31 diopters). Figure 5 shows a pattern of regression on the initial surgical effect. At the last follow-up, the induced corneal steepening had reduced to 1.04 ± 0.43 diopters (P=0.002).

Refractive cylinder

Patients nº 1, 3(OS), 5, 9(OD) and 9(OS) with preoperative astigmatism ranging from 0.50 to 2.75 diopters had surgery with elliptical clear zones designed to reduce the astigmatism. In these eyes, mean preoperative astigmatism was 0.60 ± 1.72 diopters and this was changed to 1.45 ± 1.44, 1.00 ± 0.57, 0.70 ± 0.21 and 1.38 ± 0.71 diopters, respectively at 4, 12, 24 weeks and at the last Follow-up. Induced astigmatism of more than 0.5 diopters was observed in four eyes at the last visit, including one eye with - 2.25 diopters of induced astigmatism (Table).

Endothelial cells studies

Endothelial cell counts was performed on two patients that underwent unilateral thermokeratoplasty. The other two unilateral operated patients refused to undergo especular microscopy. Both operated and unoperated eyes of the studied patients had estimated endothelial cell counts of 2500 cells. None of the studied eyes (patients 4 and 6) presented pathological morphologic changes in the operated or unoperated eyes.

DISCUSSION

The results obtained in the present study support those of other investigators who have reported that substantial corneal topographic changes can be achieved with stromal heating. [15] The success reported on initial studies was followed by reports of regression of the initial refractive effect and complications such as delayed epithelial healing, recurrent epithelial erosions, aseptic stromal necrosis and melting and vascularization. [4, 6, 7, 9] Despite a history of failing to achieve permanent corneal topographic changes as a result of heating the stroma, stable curvature changes with laser thermokeratoplasty have been reported. Seiler et al [13] used a pulsed Holmium: YAG laser with wavelength of 2.06 microns to steepen corneas of blind eyes; they described hyperopic changes of up to five diopters that remained stable. Horn et al [14] used a Co: MgF_2 laser that was tunable to a wavelength of 1.65

Table. Patient Data

Patient nº, Sex Age	Preoperative Cycloplegic Refraction	Preoperative Uncorrected Visual Acuity	Preoperative Best corrected Visual Acuity	Postoperative Cycloplegic Refraction	Postoperative Uncorrected Visual Acuity	Postoperative Best corrected Visual Acuity	Follow-up (Weeks)
1, F, 35	+4.50 - 0.50 x 160°	20/100	20/70	+2.50	20/70	20/40	24
2, F, 50 (OD)	+5.25	20/100	20/20	+3.50	20/80	20/20	24
2, F, 50 (OS)	+5.25	20/100	20/30	+1.50 - 0.75 x 80°	20/40	20/20	24
3, F, 48 (OD)	+3.00	20/50	20/30	+1.00	20/30	20/20	24
3, F, 48 (OS)	+2.50 - 0.50 x 110°	20/40	20/20	-1.00	20/40	20/20	24
4, F, 35	+ 4.00	20/200	20/20	+2.00 - 2.25 x 75°	20/40	20/20	24
5, M, 42	+3.50 +200 x 81°	20/70	20/20	+2.50 - 1.25 x 5°	20/30	20/20	24
6, M, 29	+4.00	20/30	20/20	-0.50 - 1.25 x 150°	20/40	20/30	24
7, F, 52 (OD)	+3.00 - 0.25 x 90°	20/80	20/25	+0.75 - 1.00 x 90°	20/25	20/25	24
8, F, 52 (OS)	+3.00	20/100	20/25	+0.75	20/30	20/25	54
9, F, 34 (OD)	+7.00 - 2.75 x 5°	20/80	20/30	+5.25 -2.15 x 15°	20/200	20/30	54
9, F, 34 (OS)	+6.00 - 1.25 x 170°	20/70	20/20	+3.50 - 0.75 x 170°	20/50	20/25	54

microns to 2.25 microns and described curvature changes in rabbits of as much as eight diopters that were stable for at least one year. These studies indicate that lasting topographic changes can be achieved if stromal heating of appropriate magnitude and depth is accomplished.

However the results observed in the present study, using the Fyodorov thermal unit to produce surgical correction of hyperopia showed a substantial loss of effect with longer follow-up. The initial corneal steepening (observed at four weeks postoperatively) induced in all of our patients remained stable in only one patient (Patient nº 3-OS). Although the uncorrected visual acuity improved considerably in nine eyes (75%), two eyes (16.6%) experienced worsening of their preoperative uncorrected visual acuity. At the last follow-up, the improvement in the spherical equivalent was no more statistically significant. Feldman et al., performed HTK on four patients and reported that only 18% of the desired effect remained at one year postoperatively that is comparable to our results. [17] Both our results and those of Feldman et al. disagree with previous study of retrospective chart review reported an overall refractive stability of the initial refractive effect over one year period. [16] The regression of the initial achieved refractive result was troublesome for at least half of our patients, whose uncorrected visual acuity dropped bellow 20/40.

Previous work has demonstrated that corneal stromal collagen shrinks to about one-third of its original length when heated to a temperature in the range of 60 to 65ºC. [18, 19] At higher temperatures, substantial additional shrinkage does not occur, but thermal injury and necrosis result. Using a thermokeratophore, Mainster [20] showed that peak temperature in thermokeratoplasty is achieved at the corneal surface, not in the stroma where collagen shrinkage is desired, and thus accounts for unwanted injury to the basement membrane-Bowman's membrane complex. We did not observe any epithelial damage in our patients during the study period. The initial uptake of fluorescein disappeared by 24 hours after surgery. We evaluated the endothelial cell counts in our two unilateral operated patients using the contralateral unoperated eye as a control for the endothelial studies. We observed no differences between operated and unoperated eyes, agreeing with previous results in human and animal eyes. [15, 17]

Based on these results, we believe that further technical improvements are needed before thermokeratoplasty is likely to be a successful refractive procedure.

RESUMO

A curvatura corneana pode ser alterada através da concentração das fibras colágenas com a utilização de um cautério sob a forma de sonda, em um procedimento denominado termoceratoplastia para hipermetropia. Este processo induz aumento da curvatura corneana e acentuação de seu poder dióptrico. Doze olhos hipermétropes de oito pacientes foram tratados por esta técnica aplicando-se a unidade térmica de Fyodorov de forma radial. A programação cirúrgica foi determinada pelo "software" que acompanha a unidade. O acompanhamento variou de 24 a 54 semanas (média de 31,5). O equivalente esférico variou de 4,10±1,12 dioptrias para -0,85±0,86 (P=0,001), 0,74±1,26 (P=0,001), 1,05±1,34 (P=0,001) e 3,84±1,13 dioptrias (P=0,16), respectivamente aos 4, 12 e 24 semanas após a cirurgia e na última consulta. O aumento induzido de curvatura corneana regrediu significantemente entre 4 semanas e a última avaliação. Setenta e cinco por cento dos pacientes apresentaram melhora na acuidade visual não corrigida de pelo menos duas linhas. Em nenhum dos pacientes avaliados observou-se erosões recorrentes, neovascularização ou necroses estromais. Em dois pacientes onde foi realizada microscopia especular seis meses após a cirurgia não se detectaram alterações endoteliais. Este estudo confirma o efeito limitado e temporário da termoceratoplastia na correção da hipermetropia.

Palavras-chave: *Hipermetropia; Termoceratoplastia; Córnea*

REFERENCES

1. VILLASENOR, R. A. - Keratophakia: Long term results. *Ophthalmology*, **90**: 673-75, 1983.
2. MCDONNELL, P. J.; DIETZE, T.; DURRIE, D. S.; SCHANZLIN, D. J. - Surgical correction of aphakia: Intraocular lens implantation and epikeratophakia. *J Ref Surg*, **3**: 209-14, 1987.
3. NEUMAN, A. C.; MCCARTY, G. R. - Hexagonal keratotomy for correction of low hyperopia: Preliminary results of a prospective study. *J Cat Ref Surg*, **14**: 265-69, 1988.
4. NEUMANN, A. C.; SANDERS, D. R.; SALZ, J. J. - Radial thermokeratoplaasty for hyperopia. Encouraging results from early laboratory and human trials. *Refractive Corneal Surg*, **5**: 50-4, 1989.
5. DAUSCH, J.; KLEIN, R.; SCHROEDER, E. - Excimer laser photorefractive keratectomy for hyperopia. *Refractive Corneal Surg*, in press.
6. GASSET, A. R.; KAUFMAN, H. E. - Thermokeratoplasty in the treatment of keratoconus. *Am J Ophthalmol*, **79**: 226-32, 1975.
7. KEATES, R. H.; DINGLE, J. - Thermokeratoplasty for keratoconus. *Ophthalmic Surg*, **6**(3): 89-92, 1975.
8. AQUAVELLA, J. V.; SMITH, R. S.; SHAW, E. L. - Alterations in corneal morphology following thermokeratoplasty. Arch Ophthalmol **94**: 2082-5, 1976.
9. ROWSEY, J. J.; GAYLOR, R.; DAHISTROM, R.; DOSS, V. D. - Los Alamos keratoplasty techniques. *Contact Intraocular Lens Med J*, **6**: 1-12, 1980.
10. MCDONNELL, P. J.; GARBUS, J.; ROMERO, J. L. et al. - Electrosurgical keratoplasty. Clinicopathologic correlation. *Arch Ophthalmol*, **106**: 235-8, 1988.
11. BECKMAN, H.; FULLER, T. A.; BOYMAN, R. et al. - Carbon dioxide laser surgery of the eye and adnexa. *Ophthalmology*, **87**: 990-1000, 1980.
12. PEYMAN, G. A.; LARSON, B.; RAICHAND, M.; ANDREWS, A. H. - Modification of rabbit corneal curvature with use of carbon dioxide laser burns. *Ophthalmic Surg*, **11**: 325-9, 1980.
13. SEILER, T.; MATALLANA, M.; BENDE, T. - Laser thermokeratoplasty by means of a pulsed holmium: YAG laser for hyperopic correction. *Refractive and Corneal Surgery*, **6**: 335-9, 1990.

14. HORN, G.; SPEARS, K. G; LOPEZ, O. et al. - New refractive method for laser thermal keratoplasty with the Co: MgF_2 laser. *J Cataract Refract Surg*, **16**: 611-6, 1990.
15. MOREIRA, H.; CAMPOS, M.; SAWUSCH, M. R.; MCDONNELL, J. M.; SAND, B.; MCDONNEL, P. J. - Holmium thermokeratoplasty. *Ophthalmology*, **100**: 752-61, 1993.
16. NEUMANN, A. C.; FYODOROV, S.; SANDERS, D. R. - Radial thermokeratoplasty for the correction of hyperopia. *Ref Corneal Surg*, **6**: 404-12, 1990.
17. FELDMAN, S. T.; ELLIS, W.; FRUCHT-PERY, J.; CHAYET, A.; BROWN, S. I. - Regression of effiect following radial thermokeratoplasty in humans. *Ref Corneal Surg*, **5**: 288-91, 1989.
18. MAPSTONE, R. - Measurement of corneal temperature. *Exp Eye Res*, **7**: 237-49, 1968.
19. SHAW, E. L.; GASSET, A. R. - Thermokeratoplasty (TKP) temperature profile. *Invest Ophthalmol*, **13**: 181-6, 1974.
20. MAINSTER, M. A. - Ophthalmic applications of infrared lasers-thermal considerations. *Invest Ophthalmol Vis Sci*, **18**: 414-20, 1979.