

Outcomes of radiofrequency in advanced keratoconus

João Marcelo Lyra, MD, PhD, Fernando Cançado Trindade, MD, PhD, Daniela Lyra, MD, Antônio Bezerra, MD, PhD

PURPOSE: To evaluate the use of radiofrequency energy to correct advanced keratoconus.

SETTING: Universidade Federal de Minas Gerais, Belo Horizonte, and Universidade de Ciências da Saúde de Alagoas, Maceió, Brazil.

METHODS: In this prospective comparative study, radiofrequency was applied to 25 eyes of 21 consecutive patients. One group comprised patients with a K-reading between 54.0 diopters (D) and 58.0 D; 8 thermal spots were placed at the 4.0 mm optical zone. The other group comprised patients with a K-reading greater than 58.0 D; 16 spots were applied at the 4.0 mm and 5.0 mm optical zones. The minimum follow-up was 18 months in all patients. Differences between preoperative and postoperative uncorrected visual acuity, best spectacle-corrected visual acuity (BSCVA), manifest refraction, and K-readings were clinically and statistically evaluated.

RESULTS: At end of the 18-month follow-up, the mean BSCVA in the 8-spot group improved from 20/100 (0.71 ± 0.25 logMAR) preoperatively to 20/40 (0.32 ± 0.11 logMAR) and in the 16-spot group, from 20/200 (1.03 ± 0.30 logMAR) to 20/60 (0.62 ± 0.22 logMAR). The mean manifest refractive spherical equivalent (MRSE) improved from $-7.70 \text{ D} \pm 5.20$ (SD) preoperatively to -6.82 ± 4.41 D after 18 months in the 8-spot group and from -11.33 ± 6.70 to -8.38 ± 5.12 D, respectively, in the 16-spot group. The mean best contact lens-corrected visual acuity was 20/30 (0.18 ± 0.24 logMAR) in the 8-spot group and 20/40 (0.31 ± 0.19 logMAR) in the 16-spot group. A dense corneal scar was seen in 1 patient in the 16-spot group at the 6-month follow-up.

CONCLUSIONS: Radiofrequency appeared safe for the treatment of advanced keratoconus. Contact lens fitting was stable in all cases.

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Surgical correction of keratoconus using thermal energy has long been a challenge for ophthalmologists.^{1–4} Several researchers have attempted to treat keratoconus by applying heat to its apex, thus flattening it and creating firm scar tissue and leukoma.^{5–7}

Applying hot cautery causes massive collagen destruction and corneal tissue melting. Thermokeratoplasty for keratoconus was abandoned because of complications and poor predictability.^{8,9} In the mid-1970s, thermokeratoplasty was modified and reintroduced by Gasset and Kaufman.⁷ Their technique consisted of the insertion of a 115°C probe at the apex of the cone. However, other authors report considerably lower success rates and a high incidence of morbidity after thermokeratoplasty.^{8,9}

Radiofrequency was recently reintroduced to correct hyperopia.¹⁰ It consists of the delivery of radiofrequency energy through the corneal stroma using a probe tip. Corneal tissue resistance to the passage of radiofrequency energy heats the collagen, causing it to shrink. Temperatures ranging from 65°C to 75°C denature corneal tissue in a controlled and stable way.^{10–12} The tip is inserted deep into the corneal stroma (80%) to create a uniform cylinder. To correct

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From the Universidade de Ciências da Saúde de Alagoas (J.M. Lyra, D. Lyra, Bezerra), Maceió, and Universidade Federal de Minas Gerais (Trindade), Belo Horizonte, Brazil.

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Corresponding author: João Marcelo Lyra, MD, Departamento de Oftalmologia, Universidade de Ciências da Saúde de Alagoas, Rua Des. Tenório 80, Farol, Maceió - AL 57050050, Brazil. E-mail: joaomlyra@hotmail.com.

hyperopia, the spots are placed in the circumference of the mid cornea and midperipheral cornea (6.0, 7.0, and 8.0 mm optical zones). The resulting collagen shrinkage has a "belt-tightening" effect, increasing the curvature of the central cornea. This approach does not rely on the heated tip used by Fyodorov and others in their thermokeratoplasty techniques.

This study presents a surgical technique using radiofrequency and application of position-modified thermal spots. The goal is to achieve corneal modeling and better regularization in patients with advanced keratoconus.

PATIENTS AND METHODS

This study was performed at the Universidade Federal de Minas Gerais and at the Universidade de Ciências da Saúde in Brazil. Twenty-five keratoconic eyes (21 patients) were included in the prospective comparative consecutive study.

All patients in the study had advanced central keratoconus, and contact lens fitting was not possible because of intolerance or mechanical instability caused by the irregularity of the corneal surface. Corneal topography examination was performed with the EyeSys corneal topographer (Vista). The patients had preoperative corneal topographic steepening extending at least 1.0 mm above and below the 180-degree meridian of the cornea (central cone). Cases of advanced keratoconus with central leukoma or a history of hydroids were excluded from the study.

The patients were divided into 2 groups based on the results of the preoperative corneal topographic examination. One group comprised patients with stage III keratoconus and a K-reading between 54.0 diopters (D) and 58.0 D; 8 thermal spots were placed at the 4.0 mm optical zone. The other group comprised patients with stage IV keratoconus and a K-reading greater than 58.0 D; 16 spots were applied at the 4.0 mm and 5.0 mm optical zones.

Preoperative Evaluation

The preoperative evaluation included uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest and cycloplegic refractions, slitlamp biomicroscopy, ophthalmic examination, corneal topography (EyeSys), Goldmann tonometry, and ultrasound pachymetry (Sonomed). Visual acuity was measured using the Snellen chart and converted to logMAR for further statistical analysis.

Radiofrequency Equipment

The Wavetronic Genius (Loktal) is a high-frequency device used in ocular surgery. It has been tested according to required legal protocol. Adjustable output power is available for cutting, bipolar waveform, microcoagulation, and radiofrequency. The radiofrequency generator emits macropulses up to 1 second long. Each macropulse consists of micropulses, which are 350 kHz sinusoidal waveforms. The electrical return path afforded by the generator passes through the optical zone marker. The current is directly delivered into the corneal stroma by a single-use, stainless-steel tip 90 μ m in diameter and 350 μ m in length. There is an insulated stopper at the most distal portion of the tip to ensure correct corneal penetration.

Surgical Technique

All procedures were performed by the same surgeon (J.M.L.). First, topical anesthesia comprising proparacaine (Anestalcon) was applied 3 times at 10-minute intervals. A marker (Oduos) was placed to identify the 4.0 mm and 5.0 mm optical zones concentric to the corneal limbus.

The 350 μ m tip was placed perpendicular to the cornea at the treatment points. Slight pressure was then applied until the tip penetrated the corneal stroma to its insulator stopper. Energy was then applied by depressing the foot pedal. All eyes were treated at the default setting of 350 KHz, 60% power for 0.6 seconds.

The number of thermal spots and their locations were determined by the degree of corneal curvature, determined from the preoperative videokeratography (Figure 1, A and B).

A single drop of tobramycin (Tobrex) was instilled 4 times a day for 5 days as part of the postoperative treatment. Postoperative follow-up visits were conducted at 24 hours and 1, 3, 6, 12, and 18 months. The minimum follow-up period for all patients was 18 months.

Statistical Analysis

Statistical evaluation of the results was conducted using Epi-Info software for Windows (WHO). Statistically significant differences between sample means were determined using a parametric analysis of variance (ANOVA) or

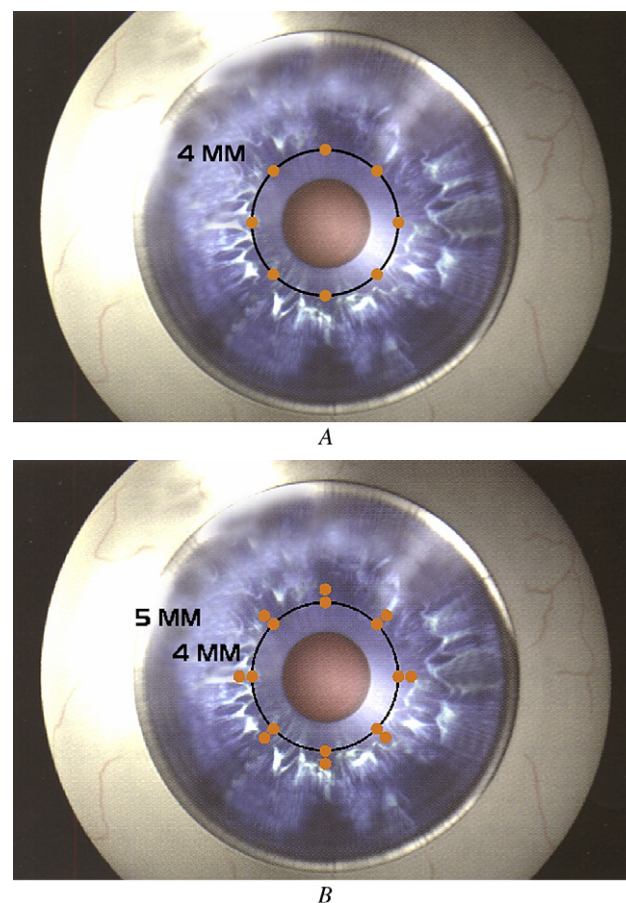


Figure 1. A: Eight-spot treatment, 4.0 mm optical zone. B: Sixteen-spot treatment, 4.0 mm and 5.0 mm optical zones.

Table 1. Preoperative patient data in both groups.

Parameter	Mean \pm SD	
	8-Spot Group	16-Spot Group
Age (y)	26.58 \pm 10.04	30.87 \pm 12.67
UCVA (logMAR)	1.28 \pm 0.41	1.54 \pm 0.34
BSCVA (logMAR)	0.71 \pm 0.25	1.03 \pm 0.30
Sphere (D)	-7.70 \pm 5.69	-12.33 \pm 6.70
Cylinder (D)	-3.78 \pm 2.35	1.88 \pm 1.90
SE (D)	-7.70 \pm 5.20	-11.33 \pm 6.70
US pachymetry, central cornea) (μ m)	432 \pm 28.77	385 \pm 18.03
K1	49.75 \pm 2.57	54.62 \pm 5.37
K2	55.14 \pm 2.17	62.02 \pm 6.34

BSCVA = best spectacle-corrected visual acuity; K1 = minimum keratometric reading; K2 = maximum keratometric reading; SE = spherical equivalent; UCVA = uncorrected visual acuity; US = ultrasound

nonparametric Mann-Whitney test. *P* values less than 0.05 were considered significant. Statistical analysis of visual acuity data was done using logMAR notation.

RESULTS

The study included 12 women and 9 men. Their preoperative data are shown in Table 1 and their postoperative data, in Tables 2 and 3 (8 spot group and 16-spot group, respectively). The 8-spot group included 16 eyes of 13 patients and the 16-spot group, 9 eyes of 8 patients.

Eight-Spot Group

Visual Acuity Preoperatively, the mean UCVA was 1.28 logMAR \pm 0.41 (SD) (range 0.6 to 1.6 logMAR) and the mean BSCVA was 0.71 \pm 0.25 logMAR (range 0.48 to 1.3 logMAR). At the end of 18 months, the means had improved to 1.03 \pm 0.33 logMAR and 0.32 \pm 0.11 logMAR, respectively (*P* < .0009) (Table 2).

Table 2. Postoperative data in 8-spot group.

Parameter	Mean \pm SD				
	1 Month	3 Months	6 Months	12 Months	18 Months
UCVA (logMAR)	1.10 \pm 0.39	1.08 \pm 0.39	1.08 \pm 0.38	1.06 \pm 0.36	1.03 \pm 0.33
BSCVA (logMAR)	0.39 \pm 0.27	0.37 \pm 0.22	0.36 \pm 0.21	0.36 \pm 0.16	0.32 \pm 0.11
Cylinder (D)	-3.59 \pm 2.31	-3.55 \pm 2.36	-3.56 \pm 2.36	-3.56 \pm 2.16	-3.42 \pm 2.01
SE (D)	-7.54 \pm 4.56	-7.12 \pm 4.52	-6.95 \pm 4.48	-6.90 \pm 4.50	-6.82 \pm 4.41
K1	49.52 \pm 3.15	50.54 \pm 3.11	50.63 \pm 3.17	50.64 \pm 3.16	49.38 \pm 2.97
K2	55.23 \pm 2.46	55.12 \pm 2.20	55.32 \pm 2.43	55.16 \pm 2.32	54.31 \pm 2.21

BSCVA = best spectacle-corrected visual acuity; K1 = minimum keratometric reading; K2 = maximum keratometric reading; SE = spherical equivalent; UCVA = uncorrected visual acuity

Safety After the 18-month follow-up, 3 eyes (18.4%) had a 5-line improvement in BSCVA; 2 (12.5%), a 4-line improvement; 5 (31.2%), a 3-line improvement; 3 (18.4%), a 2-line improvement; and 1 (6.2%), 1-line improvement. The correlation coefficient was 0.84. Figure 2 shows the plotting of the BSCVA results.

Spherical Equivalent The mean manifest refractive spherical equivalent (MRSE) decreased from -7.70 \pm 5.20 D to -6.82 \pm 4.41 D (*P* < .12).

Keratometry Eighteen months after the surgery, the mean minimum and maximum keratometric readings remained nearly the same in 12 eyes (75.0%). Preoperatively, the mean minimum K-reading was 49.75 \pm 2.57 D and the mean maximum, 55.14 \pm 2.17 D. At 18 months, the means were 49.38 \pm 2.97 D and 54.31 \pm 2.21 D (*P* = .11), respectively. Four eyes (25/5%) had a slight increase in central curvature, probably a result of centralization of the cone toward the optical axis.

Sixteen-Spot Group

Visual Acuity Preoperatively, the mean UCVA was 1.54 \pm 0.34 logMAR (range 1.0 to 2.0 logMAR) and the mean BSCVA was 1.03 \pm 0.30 (range 0.48 to 1.30 logMAR). At the end of 18 months, the UCVA and BSCVA values had improved to 1.22 \pm 0.32 (*P* < .002) and 0.62 \pm 0.22, respectively (*P* < .0009) (Table 3).

Safety After 18 months, 1 eye (11.1%) had a 6-line improvement in BSCVA; 2 (22.2%), a 5-line improvement; 1 (11.1%), a 4-line improvement; 2 (22.2%), a 3-line improvement; 1 (11.1%), a 2-line improvement; and 2 (22.2%), a 1-line improvement. The correlation coefficient was 0.70. No surgical complications occurred. Figure 3 shows the plotting of the BSCVA results.

Spherical Equivalent The MRSE decreased from -11.33 \pm 6.70 D to -8.38 \pm 5.12 D (*P* < .014).

Keratometry Eighteen months after surgery, the mean minimum and maximum keratometric readings were

Table 3. Postoperative data in 16-spot group.

Parameter	Mean ± SD				
	1 Month	3 Months	6 Months	12 Months	18 Months
UCVA (logMAR)	1.31 ± 0.39	1.33 ± 0.39	1.25 ± 0.38	1.25 ± 0.40	1.22 ± 0.32
BSCVA (logMAR)	0.69 ± 0.27	0.67 ± 0.22	0.64 ± 0.21	0.64 ± 0.23	0.62 ± 0.22
Cylinder (D)	-1.42 ± 1.71	-1.37 ± 1.69	-1.33 ± 1.64	-1.33 ± 1.65	-1.31 ± 1.57
SE (D)	-9.02 ± 4.81	-8.71 ± 4.90	-8.50 ± 4.93	-8.45 ± 5.03	-8.38 ± 5.12
K1	54.50 ± 3.71	53.10 ± 3.41	52.68 ± 3.38	52.58 ± 3.32	51.02 ± 3.11
K2	61.88 ± 5.00	60.27 ± 4.75	59.31 ± 4.74	59.23 ± 4.67	58.01 ± 4.69

BSCVA = best spectacle-corrected visual acuity; K1 = minimum keratometric reading; K2 = maximum keratometric reading; SE = spherical equivalent; UCVA = uncorrected visual acuity

reduced in 6 eyes (66.7%) (Figure 4, A and B). Preoperatively, the mean minimum K-reading was 54.62 ± 5.37 D and the mean maximum, 62.02 ± 6.34 D. The differences between the preoperative and 18-month minimum and maximum readings separately were not statistically significant. Three eyes (33.4%) had a decrease in central curvature, probably a result of centralization of the cone toward the optical axis.

Complications

Intraoperative complications such as decentration and corneal perforation did not occur in any eye in the study. Postoperative complications such as infection, hydrops, and corneal neovascularization were not observed at the end of the 18-month follow-up period.

A dense corneal scar was seen in 1 eye in the 16-spot group at the 6-month follow-up examination (Figure 5). This case had the most advanced keratoconus, a K-reading of 77.0 D, and corneal thickness of 370 µm. Contact lens fitting was possible and resulted in a final visual acuity of 0.60 logMAR (20/80).

Contact Lens Fitting

Visual acuity improved in all cases. Contact lens fitting became easier because of improved cone centralization (Figure 6). The mean best contact lens-corrected visual acuity was 0.18 ± 0.12 logMAR (20/30) in the 8-spot group and 0.31 ± 0.19 logMAR (20/40) in the 16-spot group (Figure 7).

DISCUSSION

New contact lens models and materials have been developed in the past 2 decades; however, surgical intervention is still necessary in cases of advanced keratoconus when contact lens fitting is not possible.¹³ Corneal transplantation usually yields good results in such cases,¹⁴ notwithstanding complications such as rejection, graft failure, irregular astigmatism, secondary cataract, glaucoma, and infection.¹⁵⁻¹⁷

New surgical techniques to correct advanced keratoconus have been limited by current technology. Procedures such as epikeratophakia and laser in situ keratomileusis have led to disappointing results and

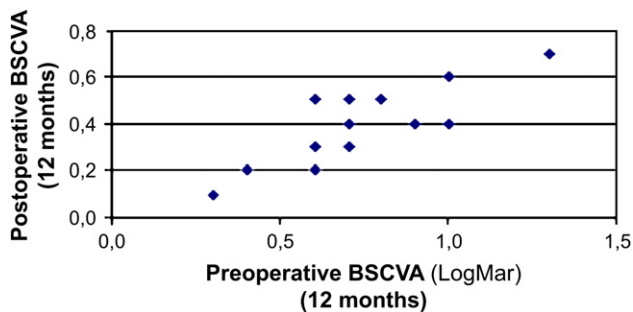


Figure 2. Correlation between preoperative BSCVA and postoperative BSCVA in the 8-spot group (logMAR) (BSCVA = best spectacle-corrected visual acuity).

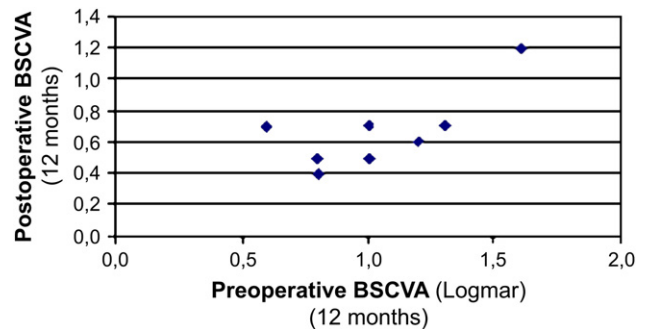
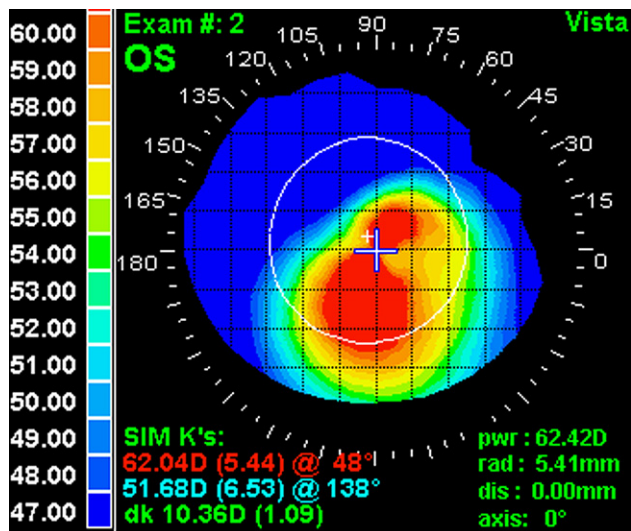
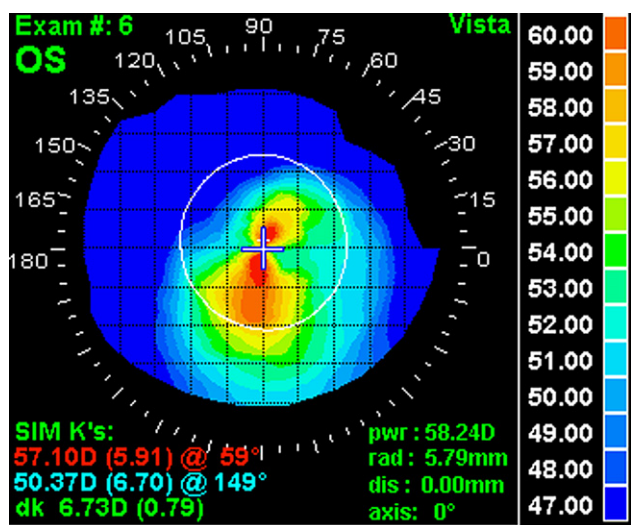


Figure 3. Correlation between preoperative BSCVA and postoperative BSCVA in the 16-spot group (logMAR) (BSCVA = best spectacle-corrected visual acuity).



A



B

Figure 4. A: Preoperative topography of keratoconus. B: Eighteen-month postoperative topography of keratoconus shows centralization and decrease in K-reading.

are not recommended in these cases.¹⁸⁻²⁰ Correction of the myopic component can be achieved by using phakic intraocular lenses (IOLs) or clear lens extraction with IOL implantation, although these are not very effective in improving visual acuity in cases of irregular astigmatism.²¹ Recently, the use of intrastromal corneal ring segments has produced good results in cases of mild to moderate keratoconus.

The insertion of intrastromal corneal ring segments when the preoperative thickness is greater than 420 μm is sometimes advised.²²⁻²⁶ However, their use in advanced cases is limited by low corneal thickness. Intrastromal segments should not be implanted when corneal thickness is less than 410 μm , which could lead to complications such as corneal perforation,

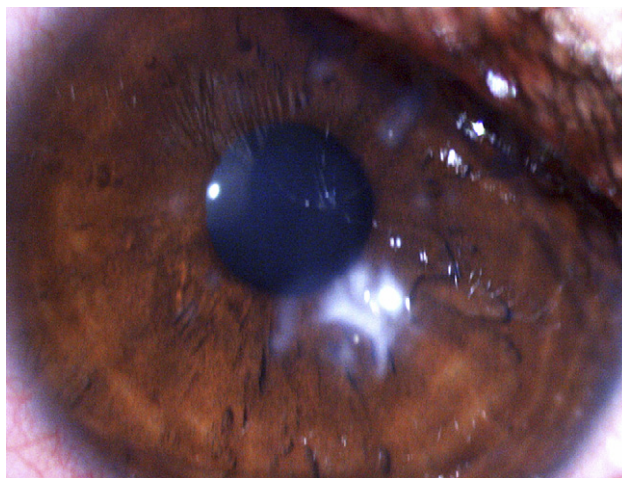


Figure 5. Dense corneal scar 6 months postoperatively.

segment migration, and extrusion.^{27,28} Other reported complications are haze, infection, and corneal neovascularization, which render graft rejection more likely in a future corneal transplantation.²⁷ The patients in the current study had advanced keratoconus (mean corneal thickness: 8-spot group, 432 μm ; 16-spot group, 385 μm); thus, intrastromal segments would not be advisable for most of them (65%) because of a corneal thickness of less than 410 μm .

This study shows the efficacy of radiofrequency in centering and making the cornea more regular in cases of advanced keratoconus. Collagen contraction caused by thermal spots in the midperipheral corneal stroma (6.0, 7.0, and 8.0 mm) increases the radius of corneal curvature, resulting in the correction of hyperopia and presbyopia.¹⁰⁻¹² Studies suggest that radiofrequency might be effective in providing stability when correcting mild to moderate cases of hyperopia in patients older than 40 years.

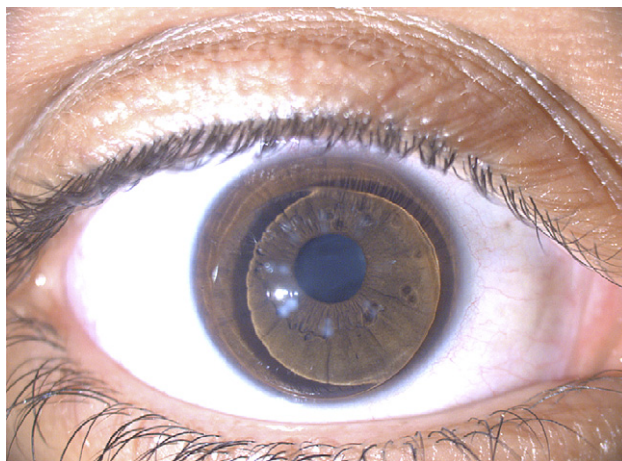


Figure 6. Contact lens centralization.

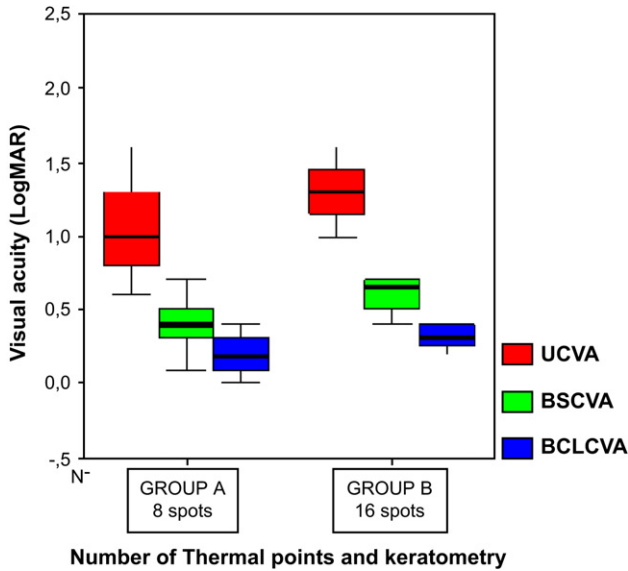


Figure 7. Comparative analysis of visual acuity (logMAR) and number of thermal points 18 months postoperatively (UCVA = uncorrected visual acuity; BSCVA = best spectacle-corrected visual acuity; BCLCVA = best contact lens-corrected visual acuity).

Pallikaris et al.²⁹ and Alió et al.³⁰ found radiofrequency to be efficient in correcting some cases of irregular hyperopic astigmatism and keratoconus. In these 2 studies, thermal spots were positioned at the 6.0 and 7.0 mm optical zones in the flattest area of the cornea. By steepening the curvature in these areas, they would pare down irregular astigmatism at the optical axis. Using a similar technique, Hycl et al.³¹ found similar results after diode laser thermokeratoplasty in 4 keratoconic eyes.

Trembly et al.³² applied microwave energy to elevate the temperature of the paracentral stroma (3.2 mm) in porcine corneas. The mean flattening within the 3.0 mm optical zone was 6.60 ± 6.00 D, showing that the effect on the central cornea when thermal spots are placed closer to the optical axis is contrary to that seen in the treatment of hyperopia.

The results obtained by Trembly et al.³² led us to attempt a similar approach in the treatment of keratoconus. The technique places spots at the 4.0 mm optical zone, 5.0 mm optical zone, or both. The equidistant distribution of these focal points causes collagen to retract, making the central cornea more regular and flatter. The short distance from the visual axis might explain why the curvature is reduced in the most severe cases.

Centralization of the keratoconus was another important modification, reducing irregular astigmatism in the visual axis. The central cornea (4.0 mm and 5.0 mm optical zones) is thin in keratoconus. The mean corneal thickness was 432 ± 28.77 μ m in the 8-spot

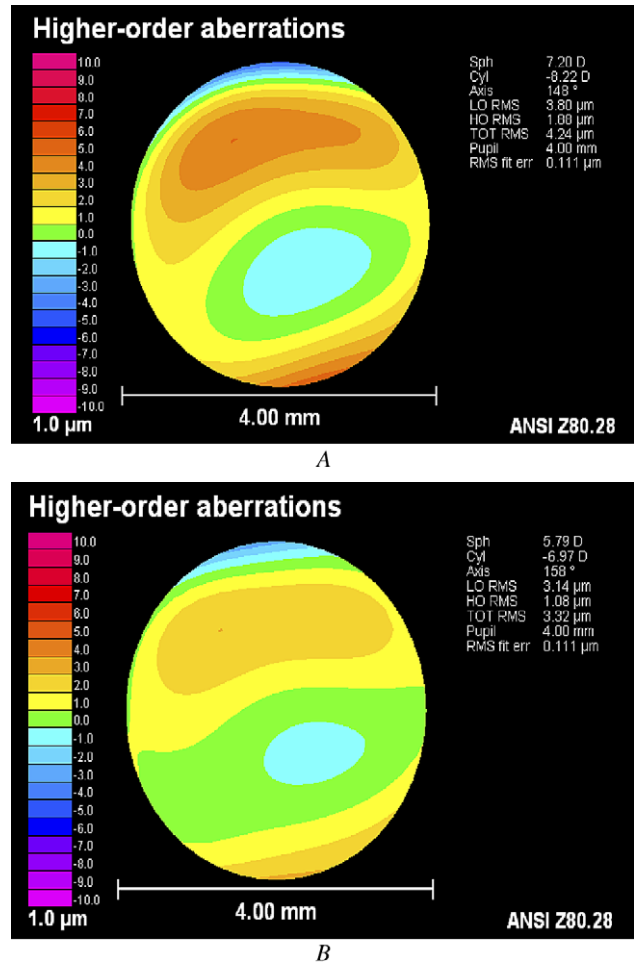


Figure 8. A: Preoperative wavefront aberrometry. B: Eighteen-month postoperative wavefront aberrometry.

group and 385 ± 18.03 μ m in the 16-spot group. The tip of the radiofrequency device had to be made shorter, from 450 to 350 μ m, to avoid corneal perforation.

This technique was first reported by Trindade, who used it to treat 3 cases of advanced keratoconus (F.C. Trindade, MD, PhD, "Radiofrequency: Expanding Applications," video presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, San Francisco, California, USA, April 2003).

Alió et al.³³ evaluated 25 eyes of 21 patients who had implantation of intrastromal segments (Intacs, Addition Technology) to correct keratoconus. The 20 eyes in group A gained 3 lines or more of BSCVA, while the 5 eyes in the 16-spot group lost 1 line of BSCVA. The group A had a mean K-reading of 53.0 D or less. In the 16-spot group, 4 eyes (80.0%) had a mean K-reading of 55.0 D or more. One arrives at the conclusion that poor results can be anticipated when using segments in advanced keratoconus (K-reading ≥ 55 D).³³ In the current study, no eye lost lines of acuity

when radiofrequency was used for a K-reading higher than 55.0 D (19 of 25 eyes). Despite the advanced keratoconus, all 25 eyes had been treated with radiofrequency statistically significant improvements in UCVA and BSCVA after the 18-month follow-up.

The videokeratography images that show keratoconus centralization and a more regular central cornea partly explain the improvement in visual acuity, even in cases with no decrease in the K-reading. The use of maps that make wavefront aberrometry assessment feasible is revealing, as can be observed in Figure 8, A and B.

A corneal scar was observed in 1 eye in the 16-spot group. This patient had the most advanced case of keratoconus in the study, with a K-reading of 77.0 D. Scar tissue formation is probably more intense in eyes with thinner corneas as a result of an inflammatory reaction.

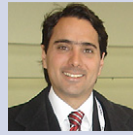
Corneal transplantation is still the treatment of choice in these advanced cases. However, one should add long waiting lists for transplantations in some regions of Brazil to the inherent risks involved in such a procedure.

In this study, radiofrequency was shown to be safe for the treatment of advanced central keratoconus. It reduced irregular astigmatism near the visual axis and led to swift improvement in visual acuity in all cases. Contact lens fitting was easier and postoperative rehabilitation proved faster (3 months) than with corneal transplantation.

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First author:

João Marcelo Lyra, MD, PhD

*Universidade de Ciências da Saúde de
Alagoas, Maceió, Brazil*