Visual rehabilitation using mini-scleral contact lenses after penetrating keratoplasty

Reabilitação visual após transplante penetrante de córnea com lentes de contato mini-esclerais

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ABSTRACT

Purpose: To report the visual rehabilitation outcomes and complications of patients fitted with mini-scleral rigid gas-permeable (RGP) contact lenses (mini-SCLs) after penetrating keratoplasty.

Methods: We retrospectively reviewed 27 eyes (21 patients) that were fitted with mini-SCLs between October 2013 and December 2014. We analyzed demographic data, previous corneal disorders, visual outcomes, interval from keratoplasty to contact lens fitting, topographic and specular microscope data, fitted contact lens parameters, and complications. The patients were divided into two groups according to the elapsed time since surgery: Group A, grafts with <10 years (n=14 eyes); and Group B, grafts with ≥10 years (n=13 eyes).

Results: Lens use was discontinued in four eyes, and microbial keratitis developed in one eye during follow-up. No corneal graft rejection was observed. The mean interval between grafting and initial contact lens fitting was 10.6 ± 7.3 years (range: 1-29 years). The most frequent reason for keratoplasty was keratoconus (22 eyes, 81.4%). The mean contact lens-corrected visual acuity (CLCVA) was 0.09 ± 0.12 logMar (range: 0.50-0.00 logMar). The average topographic astigmatism, mean steepest keratometry (K_{max}), and average cellularity on specular microscopy were 6.19 ± 3.49 diopters (D), 58.4 ± 7.8 D, and 1,231 ± 723 cells/mm^2, respectively.

Conclusions: Mini-SCL use allowed successful visual rehabilitation after corneal keratoplasty, particularly in patients who required corrective lenses for low visual acuity and were unable to wear RGP contact lenses. Our results indicate that mini-scleral lenses may be an option for the treatment of corneal irregularities, such as those associated with keratoplasty.

Keywords: Corneal transplantation; Keratoplasty, penetrating; Contact lenses; Keratoconus; Astigmatism; Corneal diseases/rehabilitation

RESUMO

Objetivos: *Avaliar a reabilitação visual e complicações com o uso de lentes de contato rígidas gás-permeáveis mini-esclerais em pacientes submetidos ao transplante penetrante de córnea.*

Métodos: *Estudo retrospectivo de 27 olhos (21 pacientes) adaptados com lentes de contato mini-esclerais entre outubro de 2013 e dezembro de 2014. Informações demográficas, doença corneana prévia, acuidade visual, tempo decorrido entre transplante e adaptação da lente, dados topográficos e de microscopia especular, parâmetros da lente de contato adaptada e complicações foram analisadas. Os pacientes foram divididos em dois grupos, levando em consideração o tempo decorrido do transplante de córnea: menos de 10 anos (Grupo A, n=14 olhos) e mais de 10 anos (Grupo B, n=13 olhos).*

Resultados: *Quatro olhos desistiram do uso da lente de contato e 1 paciente apresentou quadro de ceratite infecciosa durante o período de acompanhamento. Não ocorreu episódio de rejeição de botão corneano transplantado durante o período avaliado. O tempo médio entre o transplante e a adaptação da lente de contato foi de 10,6 ± 7,3 anos (variação de 1 a 29 anos) e a causa mais frequente de ceratoplastia foi ceratocone (22 olhos, 81,4%). A acuidade visual média corrigida com lente de contato foi de 0,09 ± 0,12 logMar (variação de 0,50 a 0.00 logMar). O astigmatismo topográfico médio foi de 6,19 ± 3,49 dioptrias (D), a ceratometria média mais curva (K_{max}) foi 58,4 ± 7,8 D e a celularidade média na microscopia especular foi 1.231 ± 723 células/mm^2.*

Conclusões: *Este estudo retrospectivo mostra o sucesso da adaptação de lentes de contato mini-esclerais na reabilitação visual após o transplante de córnea, especialmente em pacientes com baixa acuidade visual com óculos e intolerância ao uso de lentes de contato rígidas gás-permeáveis. Nossos resultados demonstram que as lentes de contato mini-esclerais são um opção para córneas com irregularidades corneanas, assim como aquelas após o transplante de córnea.*

Descritores: *Transplante de córnea; Ceratoplastia penetrante; Lentes de contato; Ceratocone; Astigmatismo; Doenças da córnea/reabilitação*

INTRODUCTION

Keratoplasty remains one of the best options, and in some cases, it is the only available option for visual rehabilitation in patients with various corneal pathologies. However, this procedure remains associated with poor postoperative visual outcomes, such as postoperative astigmatism, irregularity, and anisometropia[1-3]. Studies of keratoplasty outcomes have demonstrated that acceptable postoperative astigmatisms of <3.00 diopters (D) and 5.00 D were achieved in 27-34%[3-5] and 18-23%[6,7] of treated patients, respectively, although these rates depended on the surgical indication.

Currently, some surgical and nonsurgical procedures are available to manage unsatisfactory results and to achieve visual improvement as well as binocularity. Approximately 10% of patients who undergo keratoplasty require another surgical intervention[8], and of these procedures, elective suture removal is the easiest and often the first option during the first year of follow-up[9]. Other surgical procedures may be performed three months after the removal of all sutures, depending on evidence of stability[10]. Well-tolerated surgical approaches for the correction of postoperative residual ametropy include the relaxation of incisions on steeper axes and compressive sutures on flatter axes[8,11], *excimer* laser correction[12,13], intra-corneal ring segment (ICRS) implantation[14,15], and intraocular lenses[16]. Nonsurgical strategies include spectacles and contact lenses-although, as spectacles tend to offer insufficient correction of strong or irregular astigmatism, as well as anisometropia, contact lenses remain a better option for visual improvement and achievement of binocularity. However, contact

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lens fitting may be challenging after keratoplasty because of the grafted corneal profile, which is usually centrally flat and peripherally steep as a result of the scar between the graft and the host cornea or the tension of the sutures applied[8-10,12].

Rigid gas-permeable (RGP) contact lenses are currently considered the best option for patients with irregular corneas[17,18]. However, the wide variations in curvature and corneal asymmetry usually lead to decentration and intolerance. The use of hydrogel lenses is limited because of the inability of these lenses to correct irregular or highly astigmatic corneas[1,18,19]. In addition, hydrogel lenses may promote reduced gas transmission, with consequent corneal ischemia and a higher risk of graft rejection[20]. In recent years, scleral contact lenses (SCLs) have been used in patients with keratoconus or other corneal irregularities[6,21-25] and to treat or protect corneal integrity in eyes with surface diseases[22,26]. Although SCLs were used after keratoplasty in the early 1960s[27], the lens material (PMMA) used at that time induced high rates of corneal hypoxia, thus reducing the utility of this treatment. The subsequent development of gas-permeable materials, which were first described by Ezekiel[28], have led to reductions in corneal hypoxia. As a result, SCL use has returned to daily practice.

Contact lenses diameters and bearings vary widely[29], and encompass the following categories: (1) corneal lenses, with diameters of 8.0-12.5 mm and all lens bearing on the cornea; (2) corneo-scleral lenses, with diameters of 12.5-15.0 mm and shared lens bearing on the cornea and sclera; (3) mini-scleral contact lenses (mini-SCLs), with diameters of 15.0-18.0 mm; and (4) large-scleral lenses, with diameters of 18.0-25.0 mm. In the latter two types, all lens bearing is on the sclera; these lenses differ in terms of tear reservoir capacity, which is somewhat limited with mini-SCLs and unlimited with large-scleral lenses. The present study aimed to determine the visual rehabilitation outcomes and complications after corneal grafting in patients fitted with mini-SCLs.

METHODS

The Institutional Review Board approved this study, which was conducted according to the tenets of the Declaration of Helsinki. The retrospective data evaluation conducted in the present study included all patients with a history of penetrating keratoplasty who were fitted with ESCLERA™ contact lenses (Mediphacos, Buritis, MG, Brazil) at the Cornea and Contact Lenses Department of Hospital Oftalmológico de Brasília (HOB; Brasilia, DF, Brazil) between October 2013 and December 2014.

Data extracted from medical records included age, previous corneal disorders, interval from keratoplasty to contact lens fitting, postoperative uncorrected visual acuity (UVA), postoperative spectacle-corrected visual acuity (SCVA), refraction in terms of the spherical equivalent (SE) and manifest cylinder (Cyl), endothelium density (CellChek XL™ specular microscope; Konan, Irvine, CA, USA), corneal mean steepest keratometry (K_{max}) and astigmatism (ΔK) (Pentacam™; OCULUS Optikgeräte GmbH, Wetzlar, Germany), fitted contact lens base curve, diameter, sagittal height, and contact lens-corrected visual acuity (CLCVA).

Because corneal grafts tend to manifest recurrent ectasia and increasing astigmatism[6], we conducted an additional analysis of our studied cohort after we divided patients into two groups according to the time elapsed after surgery: Group A, grafts with <10 years (n=14 eyes); and Group B, grafts with ≥10 years (n=13 eyes).

MINI-SCLERAL LENS FEATURES

ESCLERA™ is a rigid, gas-permeable mini-SCL composed of Boston XO_2™ material, with a permeability (DK) value of 141 x 10^{-11} (cm^2 ml O_2)/(s ml mmHg) (International Organization for Standardization [ISO] - Fatt) when using surface plasma treatment. ESCLERA™ lenses are available in the following ranges in parameters: 16.0-18.7 mm in diameter; 6.37-8.44 mm in base curve; 9.0-11.5 mm in optical zone; and 4.12-6.82 mm in sagittal height.

FITTING PROCEDURE

A single ophthalmologist evaluated the fitting of all lenses (G.A.N.R.). Every fitting process began with two simple steps: (1) lateral visualization of the corneal shape for sagittal height prediction and (2) white-towhite compass measurement for diameter determination. Additional aspects intended to improve fitting were subsequently evaluated to ensure the following criteria were met: the lens diameter should exceed the limbus by ≥2.0 mm; the ideal sagittal height should be approximately 100 µm; and the peripheral edge profile should not be excessively raised or, more importantly, impinge into the conjunctiva. Maintenance of a minimal sagittal height, which reduces the accumulation of tear debris, ensures a safe oxygen transmissibility index and good visual acuity.

The presence of corneal irregularity may present challenges to achieving a homogeneous sagittal height. In many cases, the eyelids compress lenses and can promote corneal contact; therefore, it is important to perform a dynamic evaluation of the cornea and contact lens. Once the best preliminary lens was chosen, approximately 40 minutes elapsed before the next sagittal height evaluation. Subsequently, after selecting the correct lens, the refractive power was determined through dynamic refraction.

RESULTS

Twenty-seven eyes of 21 patients (12 females) were evaluated: 15 patients were fitted for lenses in one eye, and six patients, in both eyes. All patients had been prescribed mini-SCLs because their visual acuity was insufficiently corrected with spectacles, and they were unable to tolerate or achieve better results with other contact lens models. The mean patient age ± standard deviation (SD) was 42.3 ± 13.1 years (range: 18-75 years). The most frequent reason for keratoplasty was keratoconus (22 eyes, 81.4%), and the mean interval between grafting and SCL fitting was 10.6 ± 7.3 years (range: 1-29 years) (Table 1).

Eleven eyes (40.7%) were classified as having irregular astigmatism, and 10 eyes (37%) were classified as having regular astigmatism with a refractive cylinder of ≥5 D. The remaining six eyes (22.3%) had regular astigmatism with a refractive cylinder of <5 D. The overall mean SCVA and CLCVA were 0.39 ± 0.34 logMar (range: 1.8-0.0) and 0.09 ± 0.12 logMar (range: 0.50-0.00), respectively; and the CLCVA did not differ significantly between the groups (Group A: 0.10 ± 0.14 logMar versus Group B: 0.07 ± 0.09 logMar, p=0.50). However, the overall CLCVA improved relative to the SCVA (p=0.00002, paired *t* test) (Figure 1). Improvements in visual acuity, defined as a gain of ≥2 decimal acuity lines, were achieved in 21 eyes (77%). Fourteen (51.8%) achieved a visual acuity of 0.00 logMar and 26 eyes (96.3%), ≥0.30 logMar. There were no statistically significant differences in endothelium density, manifest cylinder, corneal K_{max}, and astigmatism between the groups (Table 2).

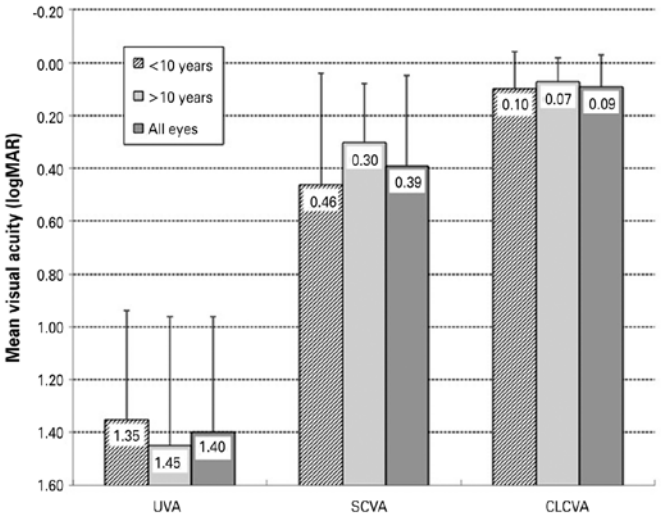
Sixteen variations of parameters were used to fit lenses to the 27 eyes. Ten eyes (37%) were fitted with 16.0 mm diameter lens; five eyes (18.6%), with 16.5 mm; 10 eyes (37%), with 17.5 mm; and two eyes (7.4%) with 18.2 mm. The most frequently fitted contact lens, which was used in five eyes (18.6%), had a 6.75-mm base curve, 16.0-mm diameter, and 4.63-mm sagittal height.

The follow-up duration for 20 eyes (74%) was greater or equal to six months. Among these eyes, six (30%) developed complications during lens use. In one patient (#10) who had undergone penetrating keratoplasty more than nine years earlier and had a bilateral corneal endothelium cell density of <1000 cells/mm^3, both eyes developed corneal edema that led to patient discontinuation of lens use. In another patient (#6) who had undergone surgery 25 years before lens

Table 1. Demographic data of patients fitted with mini-scleral contact lenses after penetrating keratoplasty

Patient	Age (years)	Sex	Eye	Time for SCL use after PK (years)	Indications for keratoplasty
1	48	F	OD	6	Keratoconus
2	32	F	OD	10	Keratoconus
3	62	F	OD	29	Keratoconus
4	43	F	OS	6	Keratoconus
5	36	M	OD	12	Keratoconus
6	44	M	OS	25	Keratoconus
7	46	M	OD	10	Post-trauma
8	39	F	OD	22	Keratoconus
			OS	18	Keratoconus
9	37	M	OD	12	Keratoconus
			OS	15	Keratoconus
10	48	F	OD	9	Keratoconus
			OS	22	Keratoconus
11	39	M	OS	12	Keratoconus
12	52	F	OS	2	Post-LASIK ectasia
13	75	M	OD	8	Fuchs dystrophy
			OS	8	Fuchs dystrophy
14	33	F	OD	6	Keratoconus
15	37	M	OD	2	Keratoconus
			OS	2	Keratoconus
16	50	F	OS	1	Post-RK
17	18	M	OS	5	Keratoconus
18	49	F	OD	8	Keratoconus
19	29	M	OS	4	Keratoconus
20	31	F	OD	7	Keratoconus
21	29	F	OD	14	Keratoconus
			OS	12	Keratoconus

CL= contact lens.



UVA= uncorrected visual acuity; SCVA= spectacle-corrected visual acuity; CLCVA= contact lens-corrected visual acuity

Figure 1. Visual acuity of eyes fitted with mini-scleral contact lenses after penetrating keratoplasty according to elapsed time after surgery. Error bars represent standard deviations.

fitting and had an endothelial cell density of <700 cells/mm^3, mini-SCL use was limited (4-6 hours per day) because of discomfort. Two other patients (#3 and #4) developed intolerance. The first decided to undergo a repeat keratoplasty, and the second selected surgical correction of the astigmatism. One patient (#9) developed microbial keratitis in the left eye during follow-up. During a slit-lamp examination, this condition presented as a small paracentral 2-mm diameter stromal infiltrate associated with bulbar hyperemia. Contact lens wear was suspended, and an appropriate topical broad-spectrum antimicrobial agent (gatifloxacin 0.5%) was administered. He exhibited a good evolution during treatment and was able to resume lens use after two weeks; no other complication or signs of infection have occurred in the six months since this episode. Complications were not observed in the remaining seven eyes (26%) that were subjected to less than six months of follow-up. No corneal graft rejection occurred during our follow-up period.

DISCUSSION

Currently, astigmatism is most frequent cause of decreased visual acuity after keratoplasty[1-3], and this condition usually remains even after suture removal. Many patients that have undergone penetrating keratoplasty depend on spectacles or contact lenses to achieve the desired visual rehabilitation. Smiddy et al. reported that more than 50% of patients would need to wear contact lenses after successful penetrating keratoplasty[30]. In our series, the mean UVA after corneal transplantation was 1.4 ± 0.44 logMar, which improved to a mean SCVA with spectacles of 0.39 ± 0.34 logMar. This low level of visual rehabilitation without correction, and even with spectacles, motivated us to suggest mini-SCL fitting although we consider it important to mention that all patients initially tried other types of lenses.

Because of the profile characteristics of the grafted cornea, the best contact lenses options may include hybrid lenses, small-diameter RGP lenses, scleral lenses, reverse geometry hydrogels, and large-diameter inverse geometry RGP lenses[3,6,17,19]. However, corneal grafts increase the ocular demand for oxygen[5], thus limiting the use of hydrogels and hybrid lenses because of the increased lens thickness required to neutralize irregular or high astigmatism[19]. Currently, RGP lenses are usually considered gold standard for visual rehabilitation in patients with irregular corneas[6]. However, patient adaptation may not always be possible because of decentration, epithelial abrasions, keratitis, and discomfort, and we note that all patients in our study had a previous inability to tolerate RGP lenses after keratoplasty.

Our results from this study are similar to those reported by others. For example, 26 eyes (96.3%) in our study achieved a visual acuity of ≥0.30 logMar, and 21 eyes (77%) achieved an improvement of ≥2 visual acuity lines relative to the best SCVA. In comparison, Severinsky et al. reported that among 36 eyes fitted with SCLs, 31 eyes (94%) achieved an improvement in BCVA of ≥2 visual acuity lines, and 23 patients (82%) achieved an improvement of ≥0.5 Snellen[6]. That study also found no differences in refraction, topographic parameters, or visual acuity when the time of grafting was considered. Pullum and Buckley reported a visual acuity of 20/60 or better in 77% of 530 patients referred for SCL fitting[21]. Vreugdenhil reported an improvement in decimal visual acuity from a previous mean SCVA of 0.59 to a CLCVA of 0.75 with semi-scleral lenses[22]. Segal et al. reported a CLCVA of 20/40 or better in 81.8% of eyes that underwent keratoplasty[23], and Tan et al. reported an improvement to 20/40 or better in 72% of 118 fitted eyes[24]. Alipour et al. additionally described mini-SCL fitting in 56 eyes of post-keratoplasty patients and observed a visual improvement from 1.05 logMar (UCVA) to 0.17 logMar (CLCVA)[25].

In our series, six eyes (22%) developed complications during mini-SCL wear. Three patients (four eyes, 14.8%) failed to wear mini-SCLs. One discontinued mini-SCL use after several hours because of bilateral corneal edema, and two discontinued use because of intolerance to the lenses. Another patient developed microbial keratitis

Table 2. Refractive and corneal data of eyes fitted with mini-scleral contact lenses after penetrating keratoplasty

Time after surgery	n	SE ± SD	CYL ± SD	ΔK ± SD	K_{max} ± SD	SM ± SD
<10 years	14	-5.74 ± 4.66	-3.98 ± 3.15	5.16 ± 3.02	59.09 ± 5.90	1383.6 ± 803.3
>10 years	13	-5.59 ± 4.72	-4.79 ± 2.16	7.30 ± 3.73	59.72 ± 13.02	1049.8 ± 612.8
p	-	0.93	0.45	0.11	0.87	0.24
All eyes	27	-5.67 ± 4.60	-4.37 ± 2.70	6.19 ± 3.49	58.40 ± 7.80	1222.9 ± 724.5

SE= spherical equivalent (diopters; D); SD= standard deviation (D); Cyl= manifest refraction; astigmatism (D); ΔK= topographic astigmatism (D); K_{max}= mean steepest keratometry (D); SM= average endothelium cell density on specular microscopy (cells/mm^2).

in left eye, but continued to use the lens after receiving treatment. In comparison, the complication and failure rates vary somewhat. Severinsky et al. reported usage failure in 19.4% of cases, with 10 eyes (30%) experiencing at least one episode of graft rejection and two eyes developing microbial keratitis[6]. Tan et al. reported a usage failure rate of 8% after an average follow-up of 15.3 months[24], whereas Pullum and Buckley described a 22% of failure[21] and Segal et al., a 7.5% rate[23]. In contrast, Alipour et al. reported a success rate of only 25% (i.e., failure rate of 75%)[25]. Among 58 tested eyes (45 patients), lenses were ordered for only 23 eyes (19 patients), and of these, lens usage was continued in only 14 eyes of 11 patients. Four eyes were lost after follow-up, and five others discontinued use because of contact lens intolerance in two eyes, handling difficulties in one eye, and economic reasons in one eye. In that study, the only reported complaints were conjunctival hyperemia and contact lens intolerance after three hours of use in both eyes of a single patient, and no graft related complications such as rejection or decompensation occurred.

In conclusion, this retrospective study demonstrates the successful visual rehabilitation facilitated by mini-SCL use after corneal keratoplasty, especially in patients with low SCVA and an inability to wear RGP contact lenses. Our results indicate that mini-SCLs may be a valid option for eyes with corneal irregularities, such as those associated with keratoplasty.

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