Use of a Mini-Scleral Lens for Vision Correction

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Abstract

Purpose: To evaluate the initial results with fitting of a mini-scleral lenses (MAXIM®, AccuLens Inc. Denver, CO) for various corneal refractive problems and irregular astigmatism.

Methods: Charts of patients fit with a mini-scleral lens on the cornea service at University of Colorado Denver over a period of 18 months were retrospectively reviewed. Outcome measures included diagnosis, best corrected vision pre and post fit, the success rate of fitting, and complications. Lens parameters were analyzed and included the lens diameter, SAG value and number of refits needed to achieve a successful fit.

Results: The charts of 63 patients (104 eyes) were reviewed. Patient's included 40 male and 23 female patients between the ages of 28-73 years of age. 16 patients had 1 eye and 46 patients had both eyes fit. The average follow up period was 7.65 months with range of follow up from 3 days to 24 months. Two patients (3 eyes) were lost to follow up after initial consultation for contact lens fitting. The primary indication for fitting was RGP intolerance for 47 out 63 patients (74.6 %). Ocular diagnoses were as follows: Keratoconus (15 patients), pellucid marginal degeneration(6 patients), post=penetrating keratoplasty (17 patients), post-LASIK corneal ectasia (8 patients), post-RK related irregular astigmatism(4 patients), corneal dystrophy/degeneration(4 patients), corneal scarring after chemical burn or trauma(3 patients), post-epikeratophakia(1 patient), irregular astigmatism (1 patient), high myopia (1 patient), pterygium(1 patient), nystagmus(1 patient), myopia/presbyopia for monovision(1 patient).

Average lens wear achieved was 13 hours per day. Level of comfort (on a scale of 1-10 ten being best) ranged from 3 to 10 with an average of 8.

Minor complications occurred in about one-third of the eyes.

Failures occurred in 13 out of 101 eyes (8 patients).

Conclusions: A mini-scleral contact lens represents a promising alternative in contact lens treatment for corneal problems considered to be difficult to fit with more traditional lenses.

Introduction

Contact lens fitting remains a viable alternative for visual rehabilitation in patients with compromised vision due to a variety of corneal disorders or irregular astigmatism. Historically, rigid gas permeable (RGP) lenses have been the main method used for visual correction when spectacles fail to provide adequate vision. Other alternatives include a piggyback method with an RGP lens fit over a soft lens carrier, hard lenses with a soft skirt such as the Softperm ®, Saturn II ® and SynerGIZE® lenses, and scleral lenses such as the Boston® scleral lens. Each lens has advantages and disadvantages. The Saturn II and Softperm® lenses for instance, have fallen out of favor because of associated peripheral corneal neovascluarization and a tendency to fit too tightly[1]. The SynerGIZE lens has avoided some of these problems by increasing the overall DK value of the lens and skirt The dk of the gp has increased 130 dk as has the water content of the soft skirt. However the soft skirt is still very low 32 %. Tight fitting lenses with a low skirt can cause corneal issues; however, the skirt has been subject to tearing and patients may be more likely to develop giant papillary conjunctivitis than with standard RGP lenses [2]. The Boston Scleral lens has proven to work well for patients with severe ocular surface compromise caused by Steven-Johnson syndrome and stem cell deficiency[3]. Drawbacks, include expense, difficulty of insertion and removal, and the fact that only a few centers around the country are currently fitting this lens.

The Maxim® mini-scleral lens represents a new alternative for contact lens wear that addresses some of these issues. It is made of a high DK material (Boston

XO-2®, 141 DK), has no soft skirt, is relatively easy to fit, and is smaller than traditional scleral lenses. We describe its use for vision correction in a variety of difficult corneal problems not amenable to standard RGP lens wear or spectacle correction.

Materials and Methods

Charts of patients fit with MAXIM® mini-scleral lenses (manufactured by AccuLens Inc. Denver, CO) on our cornea service at the University of Colorado Denver during a period of 18 months (January 11, 2008 to September 30, 2009) were retrospectively reviewed.

The patient data collected included sex, age, ocular diagnosis and indications for contact lens fitting. The patient's entering visual acuity and previous method of correction (glasses or contact lens type) was noted. Corneal topographies were reviewed if available in patients with keratoconus, pellucid marginal degeneration, post PK, or irregular astigmatism.

Fitting data included the lens diameter, SAG value, and number of refits of the lens in order to achieve the optimal result during the follow up period. Final lens selection was based on clinical performance.

Outcome measures included best corrected visual acuity, range of wear of the mini-scleral lens (days to months), duration of wear (hours per day), level of comfort, complications, and reasons for discontinuation of scleral lens wear. Level of subjective comfort was ascertained based on a scale of 1-10 with 1 representing severe discomfort and 10 representing no discomfort whatsoever on

a follow-up visit after the initial fitting. Objective complications and reasons for discontinuing lens wear were reviewed and recorded.

Results

The charts of 63 patients (104 eyes) were reviewed. The cohort included 40 male patients and 23 female patients between the ages of 28-73 years of age. Sixteen patients had 1 eye fit and forty six patients had both eyes. The average follow up period was 7.65 months with range of follow up from 3 days to 24 months. Two patients (3 eyes) were lost to follow up after initial consultation for contact lens fitting.

Ocular diagnosis were as follows: keratoconus(15 patients), pellucid marginal degeneration (6 patients), post penetrating keratoplasty (17 patients), post LASIK corneal ectasia (8 patients), post RK irregular astigmatism (4 patients), corneal dystrophy or degeneration (4 patients), corneal scarring after chemical burn or trauma (3 patients), post epikeratophakia (1 patient), irregular astigmatism (1 patient), high myopia (1 patient), pterygium (1 patient), nystagmus (1 patient), myopia and presbyopia for monovision (1 patient). Patient diagnosis is summarized in Table 1.

Most patients had failed other types of contact lenses prior to fitting the MAXIM® mini-scleral contact lens. RGP intolerance was noted in 47 patients, intolerance and poor vision with piggyback lenses (RGP over a soft contact lens) in 5 patients, poor vision with regular soft contact lenses (4 patients), poor vision with spectacle correction (4 patients), and 3 patients who were not wearing any forms

of correction prior to fitting. There were 20 patients (31.7%) who had tried and failed more than one type of lens or combination of lenses, including RGP, soft contact, and a piggyback RGP over a soft lens without achieving successful contact lens wear.

Corneal topography measurements were reviewed if available in patients with keratoconus, pellucid marginal degeneration, post PK, or irregular astigmatism. However, corneal curvature readings were not essential in fitting a mini-scleral lens.

Lens parameters were analyzed and included the lens diameter, SAG value and number of refits needed to achieve a successful fit. Although the lens diameter is available in two sizes (16.0 and 17.5 mm), the lens diameters used for all patients in this study was 16.0 mm. The SAG values used ranged from 4.12 to 5.37 (mean SAG of 4.462). SAG values for patients with keratoconus or pellucid marginal degeneration ranged from 4.12 to 5.09 (mean SAG of 4.495). 42 eyes did not require refitting at all while 57 eyes required refitting. Out of 57 eyes that required refitting, 31 eyes were refitted once, 21 eyes were refitted twice, and 5 eyes required greater than 2 refits. The most common reason for refitting was presence of apical touch. The second most common reason for refitting was adjustment of the lens power.

Visual acuities overall were improved with the use of the mini-scleral lens. Appropriate power by over-refraction was determined once the lens was fit successfully. Visual acuity of 20/20 to 20/25 was achieved in 49 out of 101 eyes (48.5%), 20/30 to 20/40 in 39 out of 101 eyes (38.6%), while ten eyes had vision

between 20/50 and 20/100. There were no eyes with visual acuity less than 20/100. One patient who had visual acuity of 20/100 in the right eye and 20/80 in the left eye had underwent bilateral epikeratophakia associated with significant interface opacity. Overall, visual acuity with the lens improved by 1.7 lines (Snellen chart) when compared to previous forms of correction in 70 out of 101 eyes (70%). Visual acuity stayed the same in 20 out of 101 eyes (20%). In eleven eyes (10.8%) visual acuity decreased by 2 lines; however none of these above patients discontinued wear of the lens since they had a subjective improvement in comfort.

Patient's responses were collected on duration of wear of the contact lens in hours per day and on the level of comfort. Level of comfort was graded subjectively on a scale from 1 to 10 where level 1 corresponded to severe discomfort and level 10 corresponded to maximal comfort of lens wear. Forty-five patients out of sixty-three responded to the questionnaire. Lens wear ranged from zero hours to 16 hours per day (two patients that discontinued wear due to discomfort responded zero hours on the questionnaire). Average lens wear was 13 hours per day. Level of comfort ranged from 3 to 10 with an average of 8. The most common patient complaint was mild to moderate discomfort and redness; this complaint was usually associated with a tight fit (35 out of 101 eyes, 34.6%). Other complaints included blurry vision (25 out of 101 eyes, 24.7%), difficulty inserting and removing the lens (3 out of 101 eyes, 2%), and photophobia (1 out of 101 eyes, <1%). Most of these issues resolved after refitting the lens by changing the SAG value or changing the power of the lens.

Complications were minor and non-sight threatening: they occurred in about one-third of the eyes. These included presumed lens or solution allergy (irritation/redness 18 out of 101 eyes), dry eye syndrome (7 out of 101 eyes), superficial punctuate keratitis (5 out of 101 eyes), debris under the lens (4 out of 101 eyes), corneal epithelial defects/abrasions (2 out of 101 eyes), corneal edema (3 out of 101 eyes), and corneal pannus with neovascularization (2 out of 104 eyes). This information is also summarized in Table 1. No eyes developed a corneal ulceration during the study period. Of the above patients with initial complications, only 5 patients (7 eyes) stopped contact lens wear for that reason. Overall, failures occurred in 13 out of 101 eyes (8 patients). Three patients did not provide any specific reason for discontinuation of lens wear. Two patients stopped wear secondary to difficulty with insertion of the lens. Three patients stopped using them secondary to severe discomfort. One of these three patients resumed using standard RGP lenses. The other two patients are awaiting a corneal transplant.

Discussion

Scleral lenses for vision correction have been used for more than a century and were first introduced by Fick in 1888[4]. The failure rate of early lenses was high due to problems with material, design and manufacturing. In 1938, polymethylmethacrylate (PMMA) was introduced as a material for use in scleral lenses. Hypoxia and corneal edema remained a problem. In 1948, corneal contact lenses were introduced and rapidly became the lens of choice for most

providers[3]. It was not until 1983 that gas permeable scleral lenses were developed[6]. They have proven useful in managing a variety of difficult cornea refractive problems.

Like other scleral lenses, the Maxim® mini-scleral lens differs from standard RGP corneal contact lenses in that the primary bearing surface is the sclera instead of the cornea. Fitting is relatively simple but does require a trial fitting set and the ability to either measure or estimate central clearance of the lens. The lens is fit in four steps. First, the diameter of the lens is determined. Currently, there are two available diameters; 16 and 17.5mm. We have found the 16mm lens to be adequate for most patients. Next, the appropriate vault and SAG value is determined by using a trial lens set. The goal is to find the minimum SAG value that succeeds in vaulting the central cornea with no apical touch. A simple formula helps adjust the SAG value; for every 1.0 mm of apical touch noted on a trial lens, the SAG value is increased by 0.1mm. Corneal curvature does not need to be accurately measured or estimated to obtain a good fit; this is especially helpful in corneas that may be too irregular to measure with standard placido based topography or keratometers. The third step is to evaluate the lens periphery and determine the ideal edge necessary to prevent impingement of the conjunctiva and a tight fit. Finally, the lens power is determined by overrefraction. Although smaller than the Boston® Scleral lens, it can be challenging to insert and remove, especially in patients with small orbital fissures, tight lids, or a compromised fornix and therefore requires special instruction on use, even in previous contact lens wearers. Unlike soft lenses or RGP lenses

fused with a soft skirt such as the SynerGIZE ® lens, GPC is rare and in fact, only one patient in this series developed GPC. Comfort is generally excellent with a good fit, and may be attributed to the fact that the lens does not move very much with blinking.

A variety of different complications have been reported for various contact lens designs. For instance, one of the most common complications for the SoftPerm® hybrid lens reported by Chung et al, was breakage of the lens at the RGP/hydrogel junction (48.5%)[6]. In a study by Abdalla and co-authors on SynergEyes® hybrid lenses, breakage decreased significantly (3.2%)[2]. In our study none of the patients reported a torn/or broken contact lens. This is most likely due to very different design of the two lenses. The second most common complication of hybrid lenses in these two studies was giant papillary conjunctivitis (27.3% and 11.5% respectively). As noted, there was only one patient (1.0%) that developed significant giant papillary conjunctivitis in our study. This is much lower rate than that reported for soft contact lens wear (32%), piggyback lens wearers (18%), and RGP wear (below 10%), based on a recent study[7].

The third most common complication that occurred with SoftPerm® hybrid lenses was a surpisingly high rate of pannus formation and corneal neovascularization (27.3%) reported by Chung et al. The underlying mechanism of corneal neovascularizton in SoftPerm® lenses was attributed to chronic hypoxia secondary to low oxygen permeability of both the rigid center and the soft skirt of the lens. This can be especially problematic in a patient population

(keratoconus) that may need future corneal tranplantation. The study on SynergEyes® hybrid lenses revealed almost no corneal neovascularization and was attribuited to the high oxygen permeability of the lens. In this study, similar results were observed with only 2 out of 101 eyes (1.9%) showed significant corneal pannus and neovascularization formation. In 2 eyes that developed corneal neovascularization, at least three refits were required to raise the SAG value enough to stop any further corneal damage. Neither of these patients stopped using the lens and the final outcome was successful with the attainment of good comfort and visual acuity

Most of the patients in this series had failed traditional RGP or soft contact lens wear because of poor comfort or poor vision. Although some patients do not successfully convert to scleral lens wear as in our series, our results are encouraging since the patients who were successfully fit were able to avoid surgery such as a corneal transplant with its attendant risks. As noted, most patients also showed an improvement in vision over their previous spectacle or contact lens use.

In summary, the Maxim® mini-scleral lens represents a viable treatment alternative for vision correction for patients with difficult corneal refractive problems such as keratoconus, pellucid marginal degeneration, and patients who have experienced complications of previous refractive surgery and should be considered when more traditional lens designs fail.

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TABLE 1. Ocular diagnosis and follow up data on initial fitting results with MAXIM semi-scleral lens

Ocular Diagnosis	Number of Patients/Eyes	Average follow up in months (range)	Average wear hours/day (range)	Level of Comfort (range)	Average BCVA prior to fitting with MAXIM	Average BCVA post fitting with MAXIM
Keratoconus	**15/25 eyes**	**7.2 (1-18)**	**12.4 (5-16)**	**9.0 (8-10)**	**20/40**	**20/30**
PMD	**5/9 eyes**	**5.5 (1-10)**	**11.5 (4-15)**	**6.0 (3-9)**	**20/30**	**20/25**
Post PKP	**16/27 eyes**	**8.5 (1-24)**	**13.4 (6-16)**	**8.0 (3-10)**	**20/56**	**20/30**
Post LASIK ectasia	**9/16 eyes**	**5 (1-18)**	**12.5 (8-16)**	**9.5 (9-10)**	**20/40**	**20/30**
Post RK ectasia	**5/9 eyes**	**5.7 (1-18)**	**14 (10-16)**	**7.2 (4-9)**	**20/35**	**20/28**
Pterygium	**1/1 eye**	**1**	**12**	**10**	**20/40**	**20/20**
Corneal dystrophy/degeneration	**3/4 eyes**	**6.5 (3-10)**	**10 (8-12)**	**9**	**20/40**	**20/40**
Post epikeratophakia	**1/2 eyes**	**18**	**15**	**N/A**	**20/130**	**20/60**
Corneal scarring	**3/4 eyes**	**6 (1-15)**	**8 (5-14)**	**8.5 (8-9)**	**20/90**	**20/40**
High Myopia	**1/1 eye**	**15**	**16**	**9**	**20/20**	**20/20**
Irregular astigmatism	**1/2 eyes**	**Lost to follow up**	**Lost to follow up**	**7 (original)**		
Nystagmus	**1/2 eyes**	**Days**	**5**	**9**	**20/80**	**20/50**
Myopia/presbyopia for monovision	**1/1 eye**	**10**	**14**	**9**	**20/25**	**20/25**

TABLE 2. Objective complaints and outcomes in patients fitted with MAXIM semi-scleral lenses

Complaints	Number of Eyes (percentage %) and Outcomes
Discomfort/redness	35/101 (34.6)
Resolved after refitting	30/101 (29.7)
Stopped contact lens use	5 eyes
Blurry vision	25/101 (24.7)
Resolved after refitting and power adjustment	25/101 (24.7)
Stopped contact lens use	0 eyes
Difficulty inserting/removing lens	3/101 (2)
Resolved	1/101 (<1)
Stopped contact lens use	2 eyes
Photophobia	1/101 (<1)
Resolved after refitting	1/101 (<1)
Stopped contact lens use	0 eyes

TABLE 3. Complications in patients fitted with MAXIM® semi-scleral lenses

Complications	**Number of Eyes (percentage %)**
Tight lens syndrome (redness and discomfort after few hours)	18/101 (17.8)
Dry Eye Syndrome	7/101 (7.9)
Superficial punctuate keratopathy (SPK)	5/101 (4.9)
Metabolic debris under the lens	4/101 (3.9)
Corneal epithelial defects/abrasions	2/101 (1.9)
Corneal edema	3/101 (2.9)
Corneal pannus/neovascularization	2/101 (1.9)
GPC	0/101 (0.0)