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Mini Review

Excimer Laser Corneal Multiple-Light-Redirection (Excimer-MLR): Rapid and Sustained Refractive Neuroadaptive Vision Restoration in Retinal Macular Disorders, Including Macular Degeneration and Geographic Atrophy

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ABSTRACT

Macular disease often causes irreversible vision loss and central scotomas from continued use of the damaged Preferred Retinal Locus (PRL). Magnifying devices and implants improve only a narrow monocular field without PRL disruption. Excimer laser Multiple-Light-Redirection (Excimer-MLR) is a rapid corneal procedure using unmodified lasers shallowly ablating through four small non-central openings in a silicone hydrogel corneal shield. Modified corneal curvature, defocusing at the PRL and focusing at multiple non-PRL areas provide rapid and multiyear statistically significant vision (mean gains >25 Early Treatment Diabetic Retinopathy (ETDRS) letters; 86% eyes>15 letters) and quality of life restoration in eyes with 20/70-20/1000 preoperatively. Immediate fixation shifts and brain integration of healthier photoreceptor signals produce scotoma disappearance with visual acuity, contrast sensitivity and retinal sensitivity gains increasing for 12 months-18 months, even as topography reverts towards baseline. Excimer-MLR for macular degeneration, geographic atrophy and other disorders provides benefits with minimal treatment burden and risk, is multiple repeatable if necessary, and can be synergistically combined with retinal treatments.

Keywords: Excimer-MLR; Corneal laser; Multiple-light-redirection; Macular degeneration; Geographic atrophy; Retinal treatment

INTRODUCTION

There have been many advances in pharmacological and surgical treatments of retinal macular disorders. Nonetheless, many patients have irreversible retinal damage and central visual loss with a profound detrimental effect on quality of life. These patients have scored poorly on the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) due to impaired visual, mental, and social functioning, and loss of independence. Functionally meaningful vision restoration for many daily activities remains an unmet need for patients with central visual loss from macular disorders [1].

The retinal location used by an eye to fixate on a visual target is the Preferred Retinal Locus of fixation (PRL). The PRL is in a fixed location within the foveolar region in a normally functioning visual system [2]. The visual system is accustomed to relying upon the PRL, but continued fixation using this very small retinal region when photoreceptors are damaged and no longer functional in the PRL area produces central light scotomas. These blank spaces may be perceived as missing words during reading, not recognizing faces or blurred vision. The visual system sometimes spontaneously and slowly maladapts. These neuroadaptations often do not integrate input from the most functional retinal areas and produce additional visual distortions, such as metamorphopsia and dark scotomas. The visual system also sometimes spontaneously adapts by developing an eccentric PRL location either within or outside of the fovea. The eccentric PRL is never located at a retinal location with the best retinal sensitivity [3]. Therefore, fixation at this eccentric PRL or increasing fixation stability at the eccentric PRL by visual

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training does not make use of integration of visual signals from better functioning photoreceptors in multiple other areas. Microperimetry does not measure many factors contributing to functional vision [4]. Therefore, restricting fixation by biofeedback to a retinal location chosen by microperimetry has not effectively produced sustained visual improvement [5].

Wearable or surgically implanted devices monocularly magnifying a field of view or projecting camera-derived highly magnified images with increased contrast and brightness have been used in patients with central visual loss with or without simultaneous cataract extraction. Extensive visual training is usually required to teach the patient to use only one eye at a time. These intraocular lenses and wearables just magnify at the PRL and do not disrupt the eye's dysfunctional PRL pathway. Some wearables project magnified images to other parts of the retina without disrupting the PRL pathway. Magnifying devices only offer improved monocular non-ambulatory viewing of a very narrow visual field [6].

LITERATURE REVIEW

A new corneal laser refractive neuroadaptive procedure, Excimer Laser Multiple-Light-Redirection (Excimer-MLR), has been introduced to provide rapid and sustained vision improvement without intraocular surgery or magnification in eyes with central visual loss from retinal macular disorders [7,8]. Excimer-MLR was proposed by Serdarevic to direct environmental light away from the PRL and defocus environmental light at the PRL while simultaneously increasing relative focusing at multiple retinal areas that are not the PRL [9]. These defocusing and focusing effects have been confirmed by aberration and refractive map analyses [7,8]. The light redirection in multiple directions away from the PRL has been documented by ray tracing analyses [7,8]. Excimer-MLR redirects enough light away from the PRL to disrupt the dysfunctional PRL pathway to immediately increase visual search, fixational eye movements and retinal photoreceptor stimulation in multiple retinal areas that are not the PRL. Fixation points are immediately shifted with the centroid shifted by 0.2 degrees up to several degrees. The shifts are smaller in eyes with very localized retinal pathology like macular holes than in eyes with very extensive retinal pathology [8]. Excimer-MLR spontaneously allows viewing of central objects by additional functional photoreceptors in multiple areas without any pre-treatment localization or customization. Visual psychophysical studies have demonstrated that the brain uses a remapping system with fine spatial selectivity for object identification and integrates object features that are not in proximity on the retina because of eye movements. Natural integration of new and more correct signals about previously missing visual information enables the brain to receive enough fragments of objects in the field of view to invoke memory representations. This produces sharper and more accurate perception of central and peripheral visual fields and ongoing beneficial neuroadaptation [9,10].

Excimer-MLR is a rapid, superficial, noncentral and multifocal corneal laser procedure performed either unilaterally or bilaterally using unmodified commercially available corneal excimer lasers and standard PRK (Photorefractive Keratectomy) or LASIK (Laser-Assisted *in Situ* Keratomileusis) software. A single use, non-customized and fenestrated silicone hydrogel MLR corneal shield is placed on the cornea during treatment to protect the central optical zone and most of the corneal epithelium from desiccation and laser light. These safety benefits and the ability to use unmodified already-approved PRK or LASIK software outweigh performing non-Food and Drug Administration (FDA)-approved transepithelial laser ablation without the shield. The shield has four small openings with their centers 90 degrees apart and 3mm from the center of the shield. Prior to laser ablation, circular 1.5-mm–wide areas of the epithelium are removed with a 0.5 mm burr through the 2.0 mm-wide openings. Laser ablation is centered on the PRL by asking the patient to look up at the laser's fixation light while the surgeon centers on the Purkinje images. The shield is positioned to center the holes over the 1:30, 4:30, 7:30 and 10:30 clock hours, the most isotropic portions of the cornea where fibril dispersion is greatest [11]. Bowman's layer is the most rigid part of the cornea and has a mean midperipheral thickness of 17.7 ± 1.6 μm [12]. Gradated ablation of Bowman's layer in the central section of each corneal quadrant facilitates effective localized deformation and efficient modification of anterior corneal Radii of Curvature (ROC) throughout each corneal quadrant by the least ablation [9]. The dioptric correction chosen depends on the optical zone and ablation profile of the specific laser and software. Ablation depth varies from 0 μm at 3.75 mm from the optical center to 20 μm at 2.25 mm from the optical center [7]. The shallow gradated laser ablation within the very small paracentral holes facilitates rapid epithelial healing without any need for a postoperative bandage lens.

Removal of wide areas of Bowman's membrane has been safely performed during refractive and therapeutic excimer laser procedures for 40 years since therapeutic and wide area corneal ablations were first performed by Serdarevic, et al. [13]. Excimer-MLR is even safer than PRK or LASIK. Excimer-MLR does not ablate any tissue in the central optical zone and ablates very small areas of Bowman's layer. The minimal ablation of four very small paracentral areas re-epithelializes within about a day. Excimer-MLR has not caused any adverse events to date. Unlike PRK or LASIK, very precise and permanent topographic and refractive changes are not intended effects of Excimer-MLR. The intended rapid disruption of the PRL pathway occurs because immediate modifications of anterior corneal Radii of Curvature (ROC) cause defocusing at the PRL and increased focusing at retinal areas that are not the PRL. Despite variations in preoperative topographies and refractions in different eyes and small variations in ablation profiles of different lasers producing varying ROC modifications, non-customized Excimer-MLR immediately increases defocusing at the PRL and focusing at multiple retinal areas peripheral to the PRL in all eyes. Unlike conventional laser vision correction procedures, Excimer-MLR minimally ablates only one very small paracentral corneal area in each quadrant resulting in topographies, aberrations and refractions reverting to preoperative levels starting at a few days postoperatively. Nonetheless, visual functions continue to improve up to 12-18 months after Excimer-MLR because of ongoing neuroadaptation. It is well documented that refractive

errors at retinal areas at up to several degrees around the PRL normally vary by up to two diopters in all eyes [14]. Therefore, even when initial ROC modifications change over time with epithelial and stromal healing, the visual system continues to search and integrate better signals from better functioning photoreceptors at more focused retinal areas. Eyes with retinal pathology throughout the macular area continue to search with fixational eye movements over larger areas than eyes with healthier photoreceptors much closer to the PRL. Most eyes require only one treatment to maintain improved vision over several years. In eyes with very progressive photoreceptor loss in large retinal areas, repeat Excimer-MLR has been successfully performed [8]. Excimer-MLR could even be multiply repeated if necessary. Excimer-MLR's very superficial photoablative treatment does not produce corneal stromal scarring that would preclude multiple retreatments with other lasers, such as thermal lasers. Very importantly, Excimer-MLR does not preclude subsequent treatment with any other current or future neuroregenerative, genetic, optogenetic, cell, or prosthetic therapies, if adequate visual function is not achieved or if visual gains are lost over time.

Not all eyes with central visual loss from macular disorders can gain vision from Excimer-MLR because of insufficient functional photoreceptors for beneficial integration. Therefore, it is very convenient that patients can be screened for potential visual improvement after Excimer-MLR using an inexpensive hand-held Gonzalez-Markowitz (GM) eye chart. Potential visual acuity testing with GM charts has been shown to be a better predictor of visual improvement after Excimer-MLR than microperimetry [8]. Studies using adaptive optics documented survival of cone photoreceptors with highly variable density even in regions with atrophy where photoreceptors are not visible by OCT [15]. Therefore, vision restorative treatments bypassing photoreceptors should not be used unless and until treatments exploiting remaining photoreceptors fail to restore and maintain adequate functional vision.

Corneal laser ROC modification has produced multiyear vision restoration in eyes with visual acuities between 20/70 and 20/1000 and macular disorders, including intermediate and late adult-onset macular degeneration with drusen, atrophy or fibrosis; myopic macular degeneration; macular cysts; inherited retinal macular dystrophies; chronic medically unresponsive macular edema; and surgically treated macular holes. Preoperative central light and dark scotomas rapidly disappeared or became smaller and peripheral after Excimer-MLR [7,8]. Amsler grids were normal in 86% of eyes at more than 18 months postoperatively with increased retinal sensitivity in a small clinical study of eyes with large preoperative dark central scotomas [8]. Excimer-MLR produced statistically significant rapid and sustained mean gains of 25 to 29 ETDRS letters in Best-Corrected Distance Visual Acuity (BCDVA) and Best-Corrected Near Visual Acuity (BCNVA) without magnification or postoperative change in refractive correction [8]. No treated eyes lost any letters from baseline during follow-up and 86% of eyes gained ≥ 15 ETDRS letters at 18-24 months [8]. Corneal laser ROC modification also produced statistically significant increases in short- and long-term total NEI VFQ-25 scores and contrast sensitivity [8].

Excimer-MLR is an off-label procedure. Corneal shields are classified by the FDA as Class 1 devices. Corneal excimer lasers are widely available with about 5000 lasers installed globally. Corneal shield Class 1 accessory device classification by the FDA of an Excimer-MLR corneal shield manufactured by a silicone hydrogel contact lens company could allow marketing for use in patients with low vision from retinal macular disorders with PRK or LASIK software approved for reducing refractive errors. This would provide rapid patient access for this great unmet need. Photobiomodulation has been FDA-approved for treatment in eyes with early and intermediate dry AMD with visual acuity no worse than 20/70 [16]. Optogenetics is intended to restore visual function after photoreceptors have been lost and has been tested in eyes with retinitis pigmentosa with visual acuity no better than 20/1600 (mean pre-treatment visual acuity 20/3170) [17].

CONCLUSION

Excimer-MLR has the potential to provide ambulatory and binocular-viewing vision restoration in patients with retinal macular disorders with visual acuities between 20/70 and 20/1000. Staged treatment adding Excimer-MLR to currently available retinal pharmacologic and surgical treatments of macular degeneration, geographic atrophy and other macular disorders could offer rapid and lasting visual and quality of life benefits with minimal additional treatment burden and risk.

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