MYOCONTROL: A FREE-FORM DESIGN FOR MYOPIA CONTROL

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ABSTRACT

In recent years, thanks to a deeper understanding of the human emmetropization process, many optical and pharmacological strategies aimed at slowing myopic progression have gained popularity. Our engineering team, skilled in freeform ophthalmic surfaces design, developed a myopia control freeform design called Myocontrol, featuring a symmetrical and concentric positive defocus. In this short paper, after an overview of the topic, a case study is presented: a well-known freeform laboratory in Italy shares product reorder data at 6 months, observing no significantly update of prescription in 6 months.

INTRODUCTION

Myopia is the leading cause of distance vision impairment globally. Brien A. Holden et al. (2016) [1] published a widely known meta-analysis on the global prevalence of myopia, analysing 145 studies from 1995, covering 2.1 million participants. The results were alerting, as from the year 2000 to 2050 myopic people will increase from 22% of the world population to 48.9% [95% C.I.]. High myopia (≥5,00D) prevalence estimates are also concerning, increasing from 2.7% to 9.8% of the world population (2000-2050).

In addition to the social impact of this myopia epidemic, the larger problem is the well-documented correlation between myopia and risk of eye disease. Myopia is strongly linked to higher risk of cataract, retinal detachment and myopic maculopathy, posterior staphyloma, glaucoma [2], [3]. Moreover, pathological risk is higher as myopia increases, and every diopter matters: while the overall risk of myopic maculopathy is higher in a −6-diopter myope than in a −3-diopter myope, slowing their myopic progression by 1 diopter during childhood should lower the risk by 40% in both [4].

In this short paper, we will rapidly overview the evolution of myopia control theories and we will present our freeform design engineered for such purpose: Myocontrol.

Furthermore, an effectiveness estimation of this design is presented by a concrete case study conducted at DAI Optical ophthalmic laboratory.

RELATED WORKS

The idea of slowing myopic progression did not arise recently. As early as the 1950s, numerous strategies to slow myopia progression have been proposed and tested over the last decades.

The first theory of myopia development was based on eye accommodation. It has been postulated that the increased amounts of accommodation and convergence that occur at near are linked to the development of myopia [5]. Further to this, myopia is suggested as an adaptation to a mismatch of the accommodative and vergence systems on the near visual plane [5].

Although these mechanisms were not fully understood, the correlation between near work and myopia development seemed clear [6]–[10].

Therefore, strategies used in the past to control myopia includes PALs and prismatic bifocals, probably in the attempt to relax the accommodation/convergence during near tasks and / or compensate for LAG of accommodation. However, progressive addition lenses (PALs) have shown non-consistent efficacy in slowing myopic progression, as efficacy depended mainly on the choice of patient sample (esophoria, accommodative lag) [11], [12]. Prismatic bifocal lenses, indeed, have been found to have an efficacy of about 50 percent in slowing myopic progression [11],[13], but it is a drastic and unesthetic solution.

Moreover, it was discovered that orthokeratology could influence the progression of myopia as well. Although the exact reason for this finding was unknown at the time, numerous clinical trials have been conducted in this regard. As a result, orthokeratology has shown to be effective in slowing myopic progression [12], [14], later tested even in combination with low concentration atropine [15]. In the wake of these findings, soft contact lenses have also been developed to control myopic progression [16] and all these devices leverage the principle of positive peripheral defocus.

The New York International Myopia Institute (IMI), based on these findings and reviewing decades of animal experimental studies, proposed a heuristic model of human emmetropization in 2019 [17]. Since ocular development is a complex problem involving many variables, this is currently the most widely accepted model of emmetropization process, and it also explain the effectiveness of myopia control strategies (*Fig* 1). In summary, the model considers the optical defocus signal on the peripheral retina to be one of the main stimuli for controlling ocular growth. In fact, although emmetropization is a complex multifactorial process (including genetic, environmental factors), imposing hyperopic or myopic defocus in animal models results in compensatory changes in eye growth that reduces the imposed refractive error.

Furthermore, visual signals guiding eye growth are processed locally within the retina. This optical signal processing leads probably to a biochemical signal

cascade (*Fig.* 2), resulting in altered scleral remodelling and growth (thanks to modified gene expression). Consequently, introducing a myopic defocus on the peripheral retina could lead to myopia progression control.

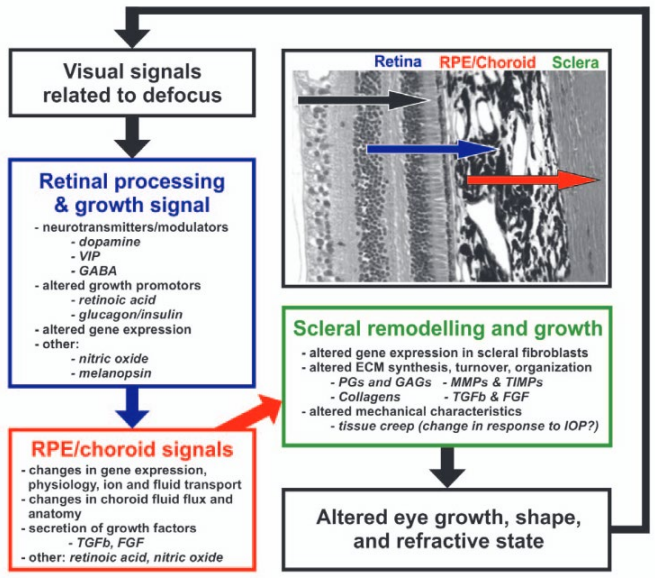

Figure 2: Biochemical retinal signal(s) in response to myopic or hyperopic defocus conditions, may initiate a signal pathway cascade from retina to RPE, the choroid, and eventually sclera, controlling the remodelling and synthesis of scleral extracellular matrix and eye growth directly or in response to IOP effects. [17]

THE MYOCONTROL DESIGN

In this section, we introduce Myocontrol design, a novel ophthalmic lens-based approach for myopia progression control.

The goal of Myocontrol Design is to compensate for hypermetropic defocus on the peripheral retina or, in the best refractive cases, to introduce myopic defocus on the peripheral retina. Thus,

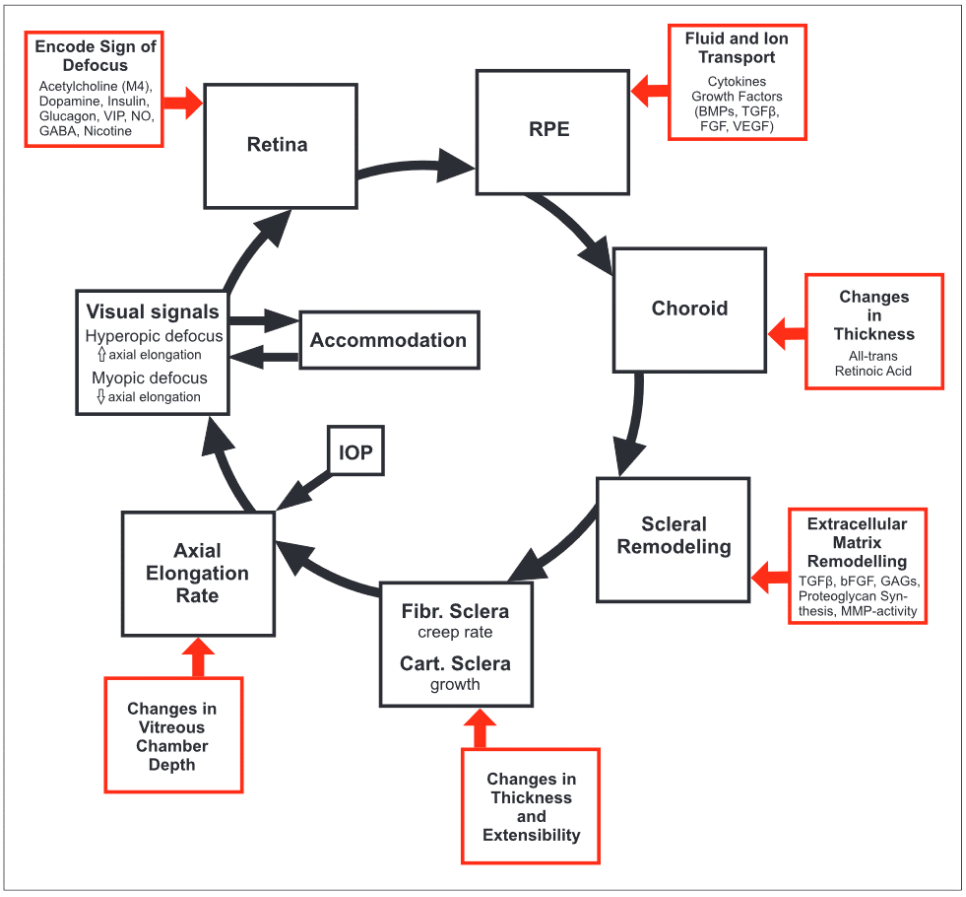

Figure 1: A heuristic model of the visually regulated control of eye growth and refractive state. [17]

following the emmetropization model described above, in comparison with classic single vision lenses, this design could control the progression of myopia. In fact, SV lenses don't compensate for hyperopic peripheral defocus [18]. Myocontrol design introduces a positive defocus of 2.00-3.00 dioptres (based on myopia entity) following a symmetrical power law, equal on all lens meridians.

Moreover, the power law is optimized to maintain the induced cylinder at minimum values, and it is the best compromise between defocus amount and lens adaptation: from our internal data, 90% of wearers adapt within the first 3 days, and we have not recorded any cases of complete lens rejection.

Considering the power law curve (Fig. 3), observed on one of the meridians, three optical zones can be schematized:

i. **Myopia Correction Zone:** this zone starts from the optical centre and extends for 4.5 mm radius, resulting in a 9mm diameter circle. It is designed with the wearer prescription and is intended to ensure sharp distance vision.

ii. **Defocus Transition Zone**: in this lens area, extending from 4.5 mm to 17.5 mm radius, the defocus increases and reaches its maximum value.

iii. **Constant Defocus Zone**: in this zone the defocus is constant and corresponds to the maximum value, to not over-interfere with peripheral vision.

CASE STUDY

In this section, we introduce a case study regarding the implementation of Myocontrol Design in D.A.I. Optical Industries (DAI Optical).

DAI Optical is a well-known mid-size ophthalmic laboratory based in Italy and a long-time ProCrea partner. It both manufactures and distributes ophthalmic lenses. Since 2020 it has

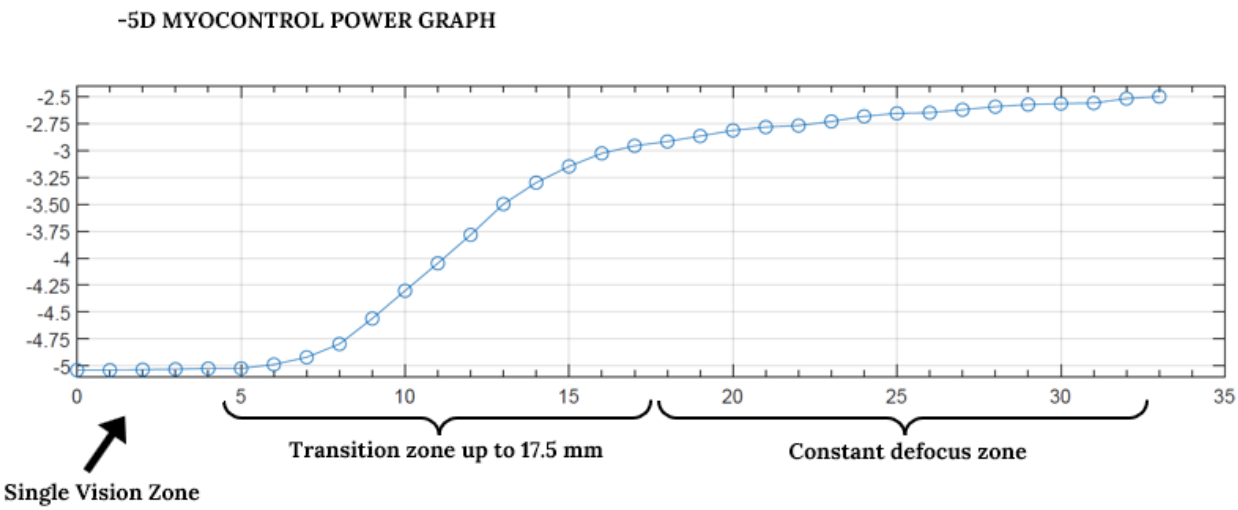

Figure 3: -5 diopter Myocontrol power map starting from the lens centre in 0 mm: single vision zone, defocus transition zone and constant defocus zone are highlighted.

been selling Myocontrol design under the brand "MYOGA".

Myoga has been highly appreciated by opticians thanks to its flexibility as it can be realized on any semi-finished of any refractive index.

In order to estimate the lens effectiveness on myopia progression, we partnered with DAI to carry out a marketing campaign whose conditions are described as follows: if myopia increases during the first year from the purchase date, one lens is free of charge for the second order.

The analysis of Myoga (Myocontrol design) orders presented in this section covers the period from August 1-2020 to September 30-2021, for a total of 425 days. In this period, 1680 Myoga orders were placed, for a total of 3360 eyes involved in this analysis. The average spherical refractive error of these 3360 eyes is -3,29 ± 2,04 Dp and the frequency for each dioptric value (-0,5D step) is plotted in Figure 4.

Among of all the orders, only 19 people took advantage of the promotion, reporting a myopia increase in the first year of use. Thus, DAI Optical received 19 reorders out of 1680 orders, that result in 1.13% of total Myocontrol orders in 425 days.

Considering the reorders sample, the mean spherical refractive error is -4,09±3,27 Dp, and the frequency map is represented in figure 5.

Although the above statistic does not consider dropout customers who chose not to reorder the lens (despite the clear economic advantage), it is worth noting

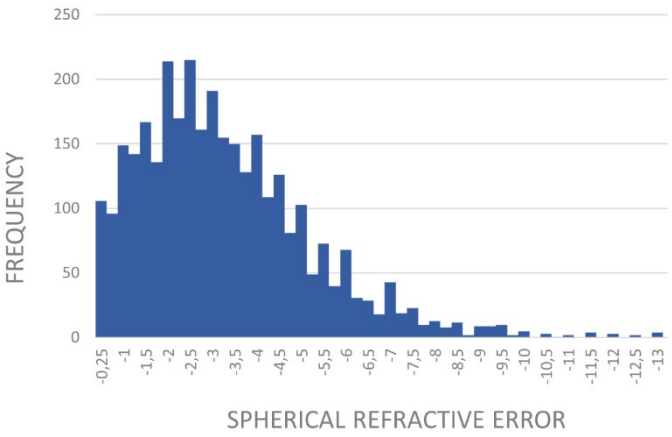

Figure 4: number of myopic eyes of the entire sample for each spherical dioptric value, in steps of -0.50.

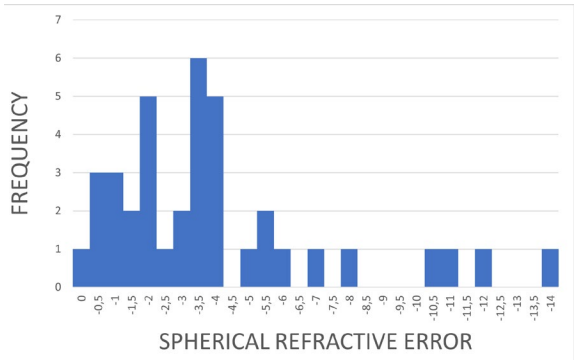

Figure 5: number of myopic eyes of the reorder sample for each spherical dioptric value, in steps of -0.50.

that the percentage of reorders is extremely low and almost negligible.

This is symptomatic that there were very few cases that experienced myopia progression in the first year, otherwise this percentage would have been higher.

Furthermore, the average myopia progression for a European Caucasian child aged 6 to 12 years is 0,55±16,5 Dp/year[19].

Therefore, considering the expected myopia progression at 1 year, the economic advantage that encourages re-ordering and considering the relevant size of the statistical sample

(3360 eyes), it can be suggested that Myocontrol helped to control myopia progression in this population, as the reordered lenses rate after 1 year is negligible.

CONCLUSION

In this short paper we presented Myocontrol, a novel freeform design engineered by ProCrea Tech to control myopia progression.

The latest human emmetropization model, which guided us in the product design phase, was unfolded, as well as some earlier theories. This provides a full understanding of the lens function.

In addition, we shared the data analysis arising from our collaboration with DAI Optical. Through a marketing campaign, it was possible to observe that in a period of 425 days only 1.13% (19 reorders) out of 1680 Myocontrol orders needed to update their eye prescription by taking advantage of the promotion.

Although this statistic does not account for people who decided not to reorder the product (despite the economic advantage), considering the relevant sample size (3360 eyes) and the expected myopia progression of 0,55±16,5 Dp/year, it can be suggested that Myocontrol helped to control myopia progression in this population, as the reordered lenses rate at 1 year is negligible.

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