IMPROVING MYOPIA AND AXIAL LENGTH MANAGEMENT WITH THE USE OF A CUSTOMIZED- PROPRIETARY OK DESIGN (3MOD)

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INTRODUCTION

Over the last 10 years. authors had been working to develop a clinical algorithm to manage myopia and axial length. This method, known as myopia Management with Orthokeratology Design (3MOD) is based on the following 3 pillars:

1. Control of the environmental conditions
   — Outdoor. lightning. working distance. computer use.
2. Control of the binocular vision function
   — Phoria at far, accommodative, etc…
   — Vision therapy as needed
3. Control of the central and peripheral optical blur
   — maximize peripheral myopic defocus: put the + in the pupil
   — add high enough not to be used to fix BV issues

Intervention is dictated by the predicted outcome

1. Threshold for refractive error < 6 D @ 18 years old
2. Threshold for axial elongation < 26 mm @ 18 years old

Authors found that customization of the contact lens parameters is an important element to enhance better control. Instead of using regular OK lenses, RGP Designer software was used to design lenses since 2017.

OBJECTIVES

- To evaluate the efficacy of customized OK lens design on a population of myopic patients
  — 1st outcome: axial length elongation over time
  — 2nd outcome: myopia progression over time
- To analyze induced corneal shape modifications using differential tangential maps

CUSTOMIZATION PARAMETERS

1. Treatment zone parameters was determined based on corneal curvatures, eccentricity and pupil area.
2. Overall diameter and alignment curves toricity are designed to promote perfect centration of the lens

METHODS

- Retrospective analysis. Charts of patients newly fitted using 3MOD design (RGP Designer software), between May 2017-July 2019. (N=246)
- IRB #17-135-CERES-D from Université de Montreal Ethic Committee
- Control group: chart of every young (< 20 y.o.) myopic (>-0.50D at baseline) patient fitted with commercial OK and soft MF designs, between 2012 and 2017, and followed for at least 5 months.. (N=489)
- In both groups, lenses were worn for 7 days a week. at least 8 h00 overnight

Exclusion criteria :

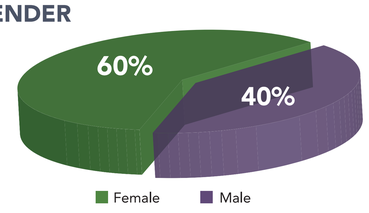
- previous optical myopia control strategy

STUDY POPULATION (n=246)

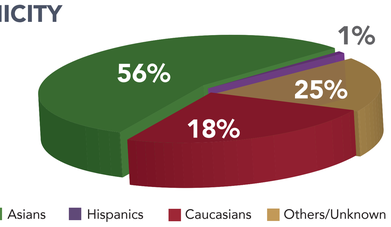
— Age: 11.7 + 2.4 years old

— 54% - at least 1 parent myopic yopic

GENDER



ETHNICITY

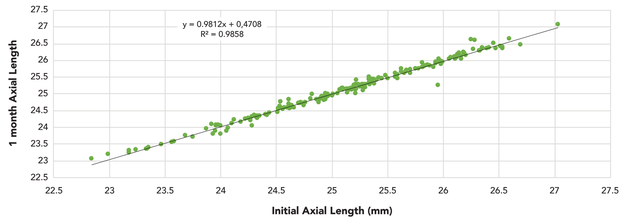


RESULTS

Ocular Parameters at Baseline

	OD		OS	
Axial Length (mm)	25.058	±0.824	25.048	±0.876
Spherical Equivalent (D)	-3.61	±1.31	-3.61	±1.38
Sim K Flat (D)	42.97	±1.39	42.95	±1.38
Sim K Steep (D)	44.19	±1.50	44.24	±1.58
Eccentricity Flat	0.63	±0.10	0.63	±0.11
Eccentricity Steep	0.47	±0.16	0.47	±0.15

Initial Axial Lenght compare to 1 month axial lenght post-treatment with Lenstar



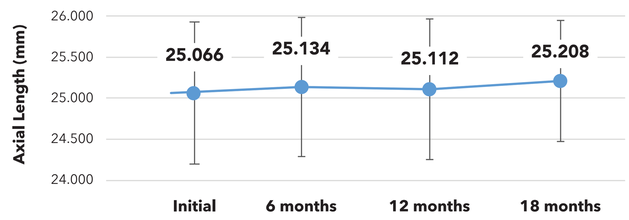
Comparative Axial Length

N=190	Average (mm)	Standard Deviation (mm)
Initial Axial Length (t=0)	25.092	±0.837
1 month Axial Length (t=1)	25.091	±0.827
Difference: 1 month-0	-0.002	±0.100

1 Month Axial Length by group

Group P < 0.000	Average (mm)	Standard Deviation (mm)
Reduction	-0,068	0,488
Elongation	0,059	0,269

AL (mm) 18 months period



Absolute progression (mm) compare to baseline

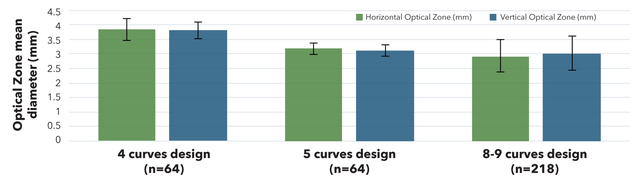
	6 months	12 months	18 months
AL Progression (mm)	0.056±0.267	0.085±0.312	0.123±0.223
Fast progressors (>0.20 mm in 6 months)	9.7%	8.9%	5.8%

Axial Length (mm) by group age at baseline

At 12 months	< 10 years old	10-14 years old	14 years old
	Average (mm)		
Customized OrthoK (3MOD)	0.139±0.197	-0.030±0.233	-0.056±0.101
Regular OrthoK Control	0.222±0.200	0.126±0.209	0.002±0.109
Soft Multifocal Control	0.262±0.132	0.094±0.138	0.100±0.101
ANOVA (3MOD vs Control -OK)	p=0.251	p<0.000	p=0.244
ANOVA (3MOD vs Control- soft MF)	p=0.075	p=0.025	p=0.000

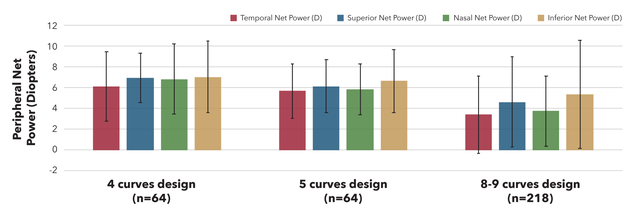
TOPOGRAPHY ANALYSIS

Corneal modification vs OK designs



Design	Horizontal Optical Zone (mm)	Vertical Optical Zone (mm)
4 curves	3.84 ± 0.38*	3.81±0.32*
5 curves	3.18 ± 0.20*	3.11±0.21
8-9 curves	2.94±0.56*	3.02±0.59*
ANOVA Analysis	* P < 0.001	* P < 0.001

Quadrant Specific Peripheral Net Power (Diopter) vs OK design



Design	Temporal Net Power (D)	Superior Net Power (D)	Nasal Net Power (D)	Inferior Net Power (D)
4 curves	6.1±3.33*	6.94±2.36*	6.81±3.38*	7.02±3.46*
5 curves	5.67±2.6*	6.19±2.53ϕ	5.82±2.43*	6.64±3.02ϕ
8-9 curves	3.39±3.74*	4.61± 4.33*ϕ	3.74±3.36*	5.33±5.18*ϕ
ANOVA Analysis	* P < 0.001	* P < 0.001 ϕ P < 0.014	* P < 0.001	* P < 0.001 ϕ P < 0.014

DISCUSSION

- 3MOD generates +8 D power, within the pupil, in average
- This customized OK design improves myopia and axial length management over 18 months (vs control)
- A few outliers exist for AL evolution (younger patients)
- Fast progressors define as > 0.20 mm of progression in 6 months is below 10 % and tends to reduce over time
- Higher standard deviation of the topographical analysis data translates the fact that lens design was fully customized
- Next step will be to compare 1 month axial length change to long term axial length control

CONCLUSION

- Customizing Orthokeratology design seems to be more effective compared to commercial regular design, at least on a short and mid term basis (18 months follow-up)
- Age at baseline seems to influence the rate of progression
- Increased treatment (higher +, smaller central zone, combined low dose atropine) is needed for fast progressors

Conflicts of interest and source of funding

- All 3 authors: Co-owner USPTO 62/590,388
- Medical device for axial length and myopia management
- Langis Michaud: Honorarium received as a speaker, consultant
- Research grants: Blanchard Labs; Bausch & Lomb; Cooper Vision; Contamac
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