

# Myopia Progression Before and After Fitting with the NaturalVue Multifocal Contact Lens: A Case Series Analysis (#4770 - B0271)

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## Purpose

Myopia progression control has been demonstrated in several studies with distance center multifocal contact lenses.<sup>1-5,7</sup> Regulatory bodies and many practitioners and parents may prefer to utilize a daily disposable modality in a pediatric population.<sup>8</sup> Until recently, there were no daily disposable distance center multifocal lenses on the market in the US. One published pilot study has reported myopia progression control with a novel distance center, extended depth of focus design multifocal in a daily disposable modality in Etafilcon A material (Visioneering Technologies, Inc, Alpharetta GA).<sup>6</sup> That pilot study pooled data from multiple private practices and did not include axial length measurements. Reported here is a retrospective, observational clinical trial of the rates of myopic progression in a series of young patients in the author's office before and after switching to this novel design.

## Methods

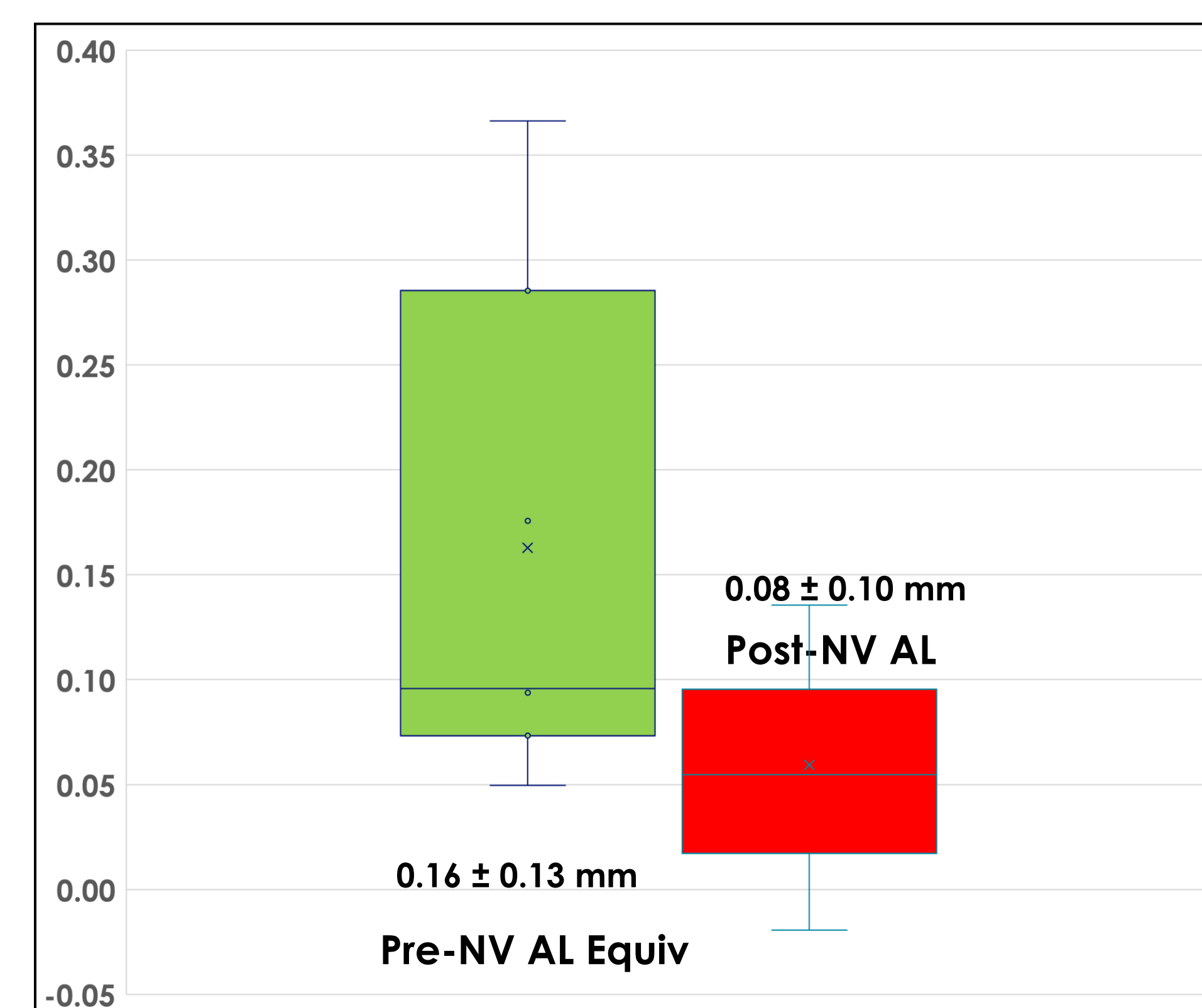
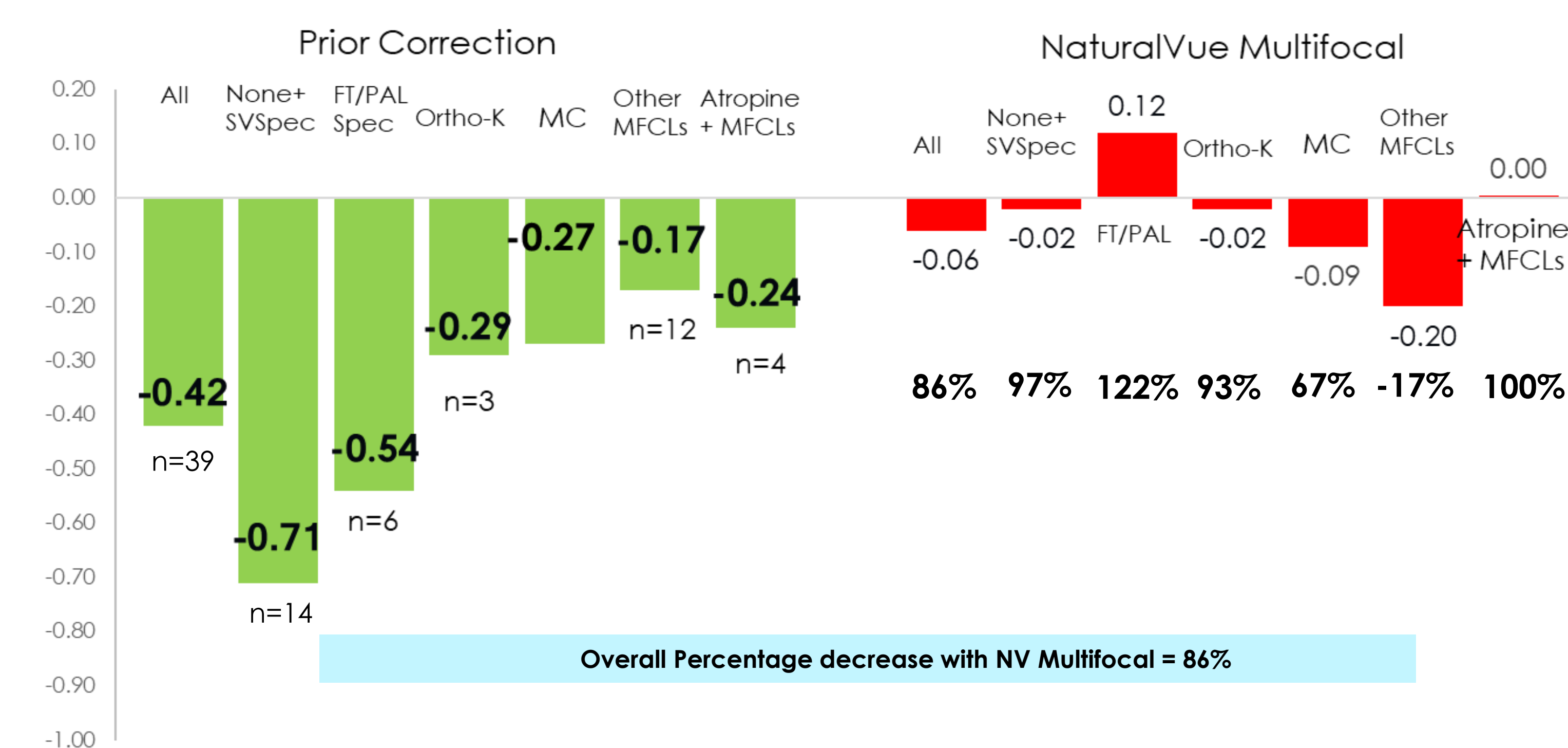
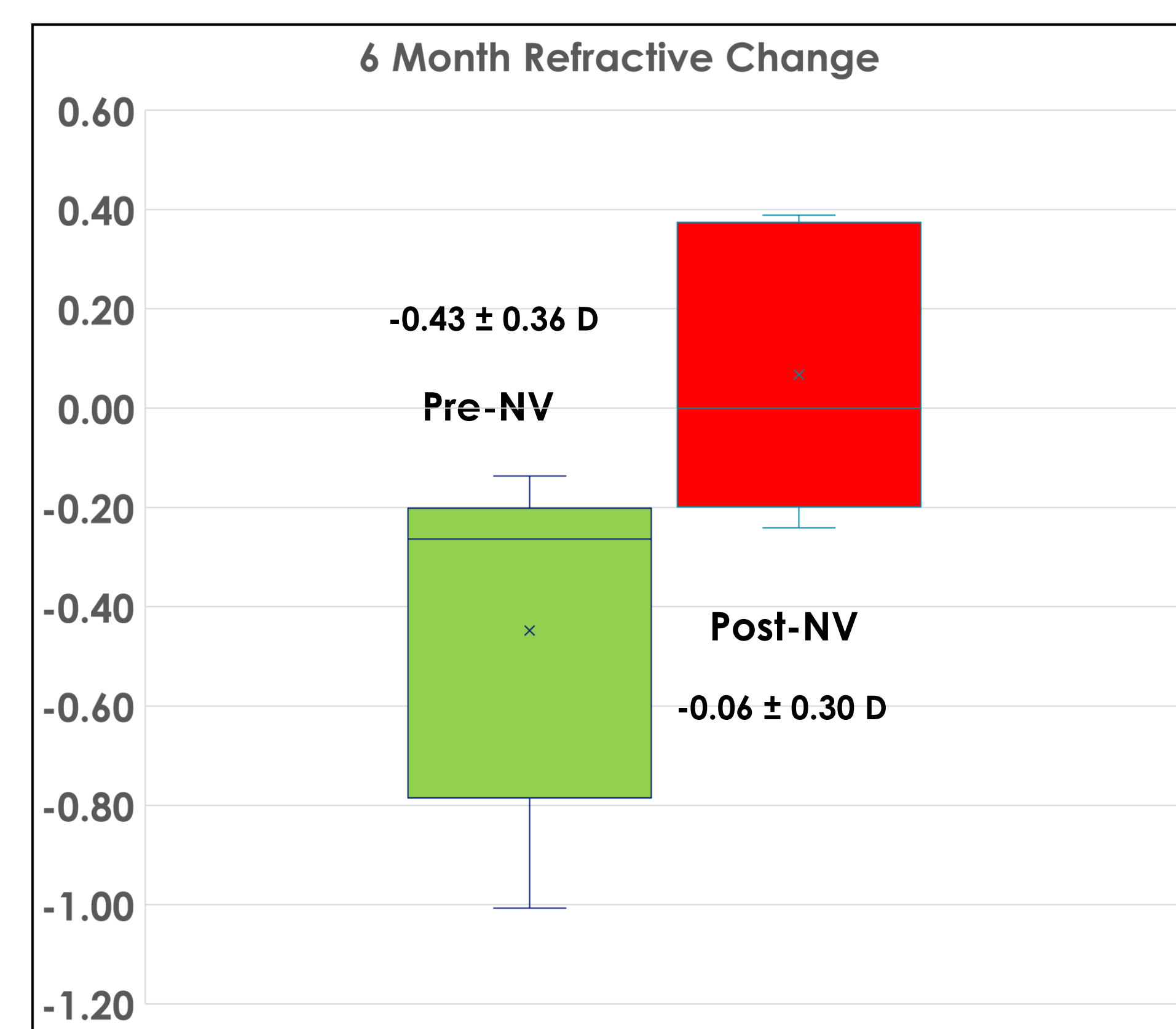
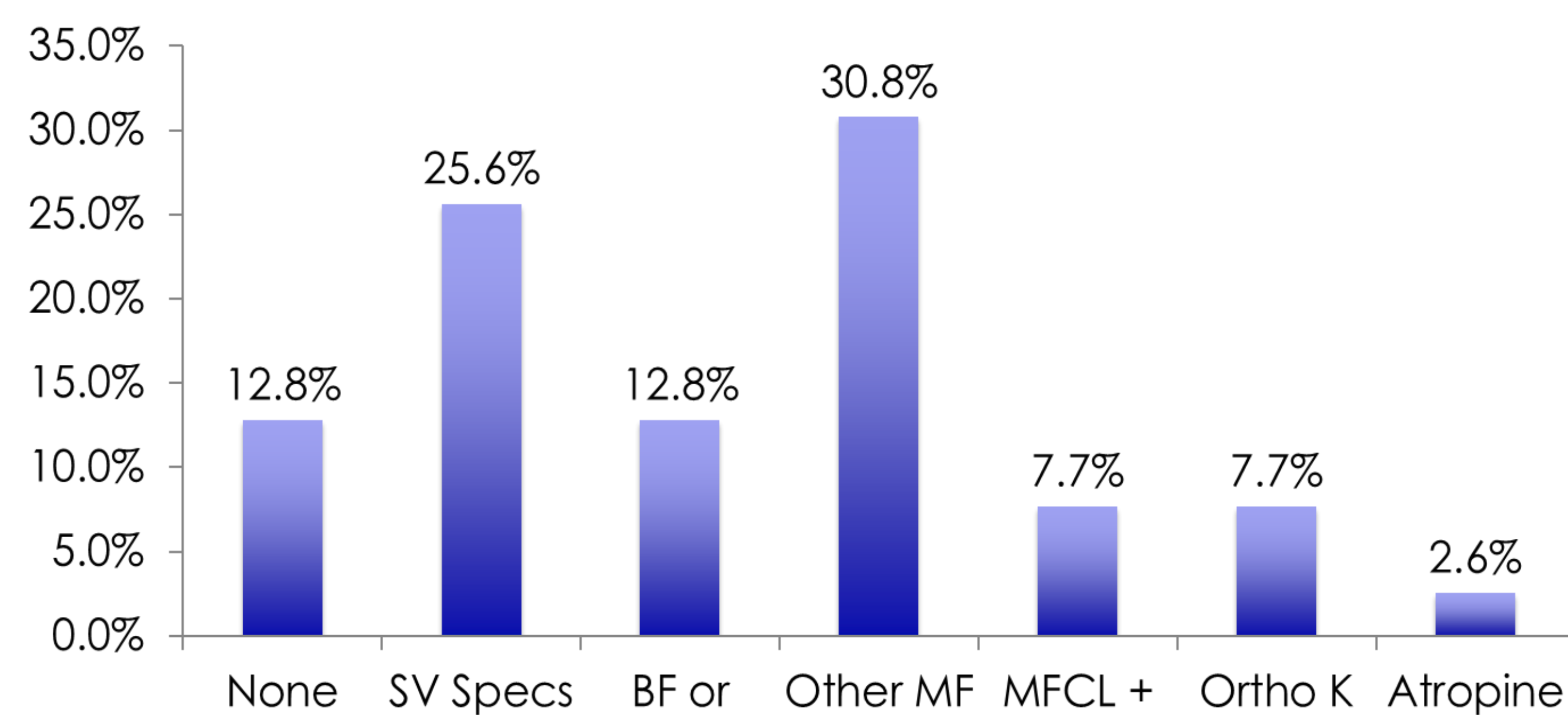
All consecutive patients presenting with a change in their spherical equivalent refraction in either eye equal to or exceeding -0.12D in the prior year during the data collection phase of this study who chose to be fitted with the novel multifocal and have completed their six-month post-fit visit (n=39) were included in this analysis. Refractive data are reported as the binocular average of the spherical equivalent subjective refraction. Axial lengths and corneal curvatures are binocular averages as measured by the Zeiss IOLMaster. For each eye, both the pre- and post-fit myopic progression were adjusted to six-month rates. A subset of patients who have completed their 12-month visits (n=16) are also reported.

## Results

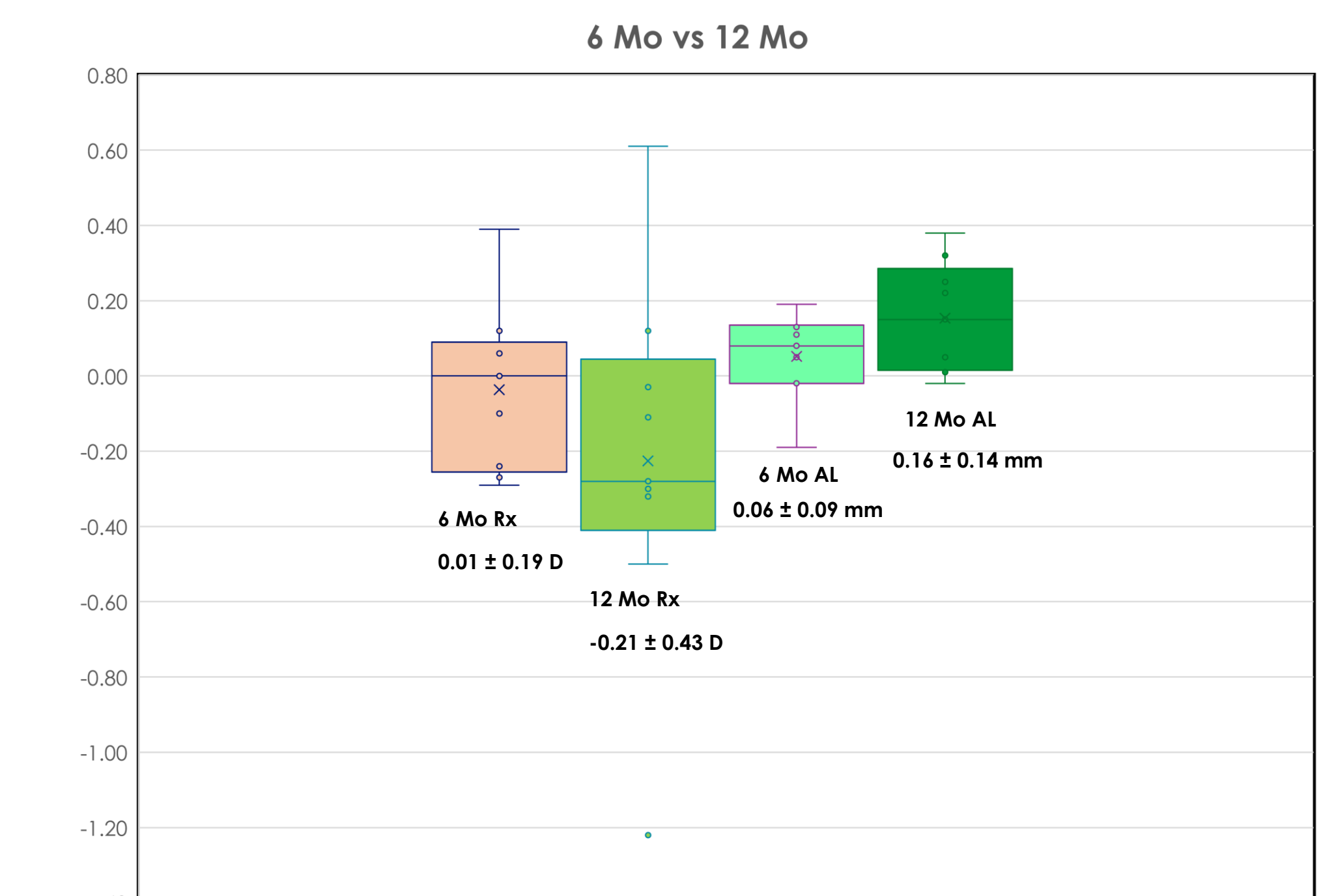
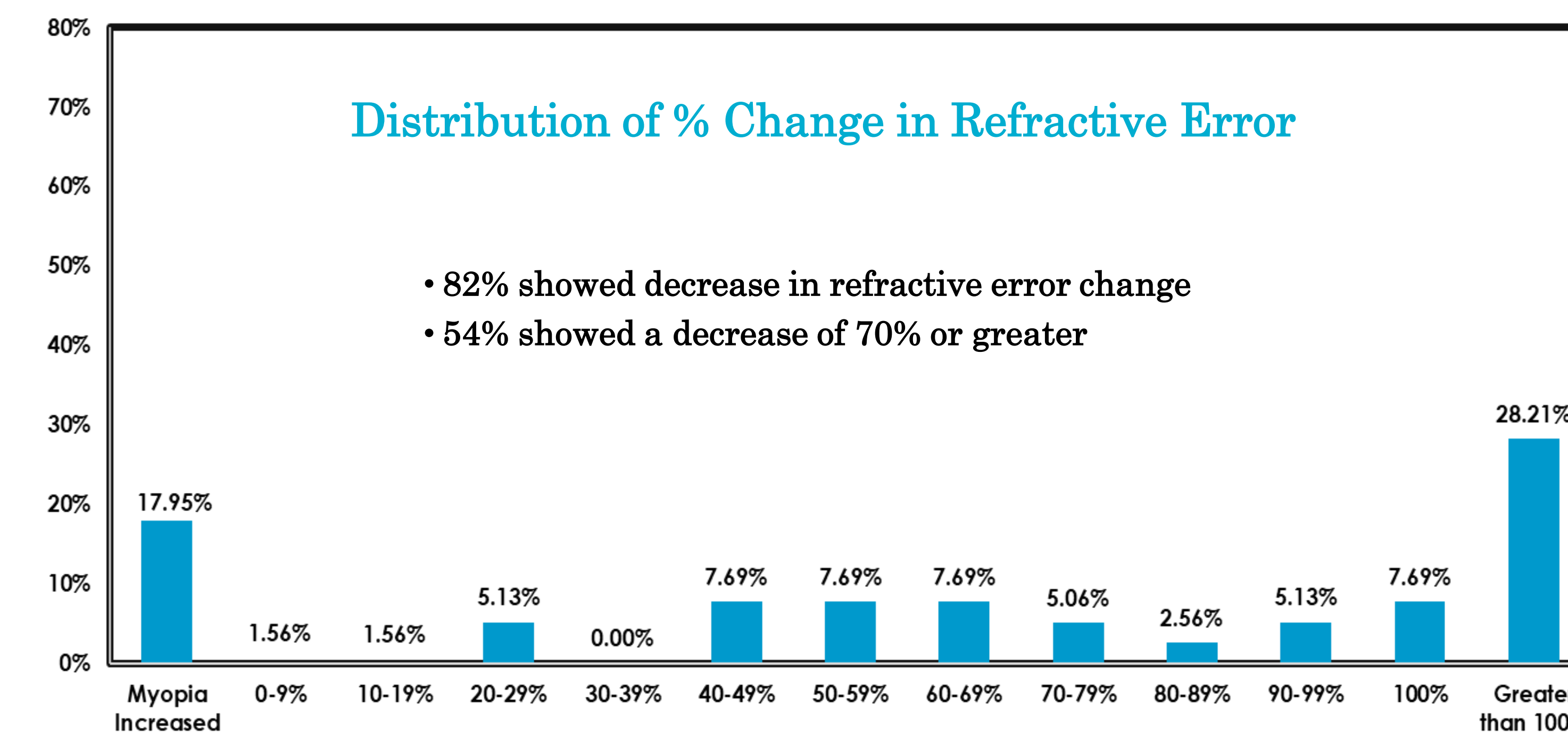
| Age                | Sex                                | Ethnicity  |
|--------------------|------------------------------------|--|
| 12.08 ± 3.62 Years | Female: 24 (62%)<br>Male: 15 (38%) | Caucasian: 6 (15%)<br>Asian: 14 (36%)<br>Mixed Asian: 9 (23%)<br>Indian: 7 (18%)<br>Hispanic: 3 (8%) |

| Refractive and Biometric Data | Baseline        | 6 Month         |
|-------------------------------|-----------------|-----------------|
| Average Spherical Equivalent  | -4.22 ± 2.53 D  | -4.32 ± 2.53 D  |
| Average Axial Length          | 24.95 ± 1.32 mm | 25.06 ± 1.34 mm |
| Average Keratometry           | 43.86 ± 1.29 D  | 43.84 ± 1.33 D  |

### What children were wearing prior to NaturalVue Multifocal



## Results (Continued)



## Conclusions

In this case series of 39 young patients progressing in myopia with a variety of myopia treatments, a clinically significant reduction in myopia progression and axial elongation was observed when switching patients to the NaturalVue Multifocal, offering further evidence that these extended depth of focus, distance center multifocal contact lenses may be an effective treatment for myopia progression.

This pilot study, however, suffers from a number of flaws which will prevent any strong conclusions. Each patient served as his own control, and though it largely matches the design of several recent studies,<sup>6,7</sup> this is a poor substitute for a randomly selected control group. Another fatal flaw is the reliance on manifest subjective refractive data, though this is a clinical case series using conventional methods of refraction and prescribing strategies based on manifest refractions. The only saving grace in this series is the use of the IOLMaster to measure axial lengths, though only a small percentage of the patients had axial lengths available prior to refitting with this novel multifocal lens.

Another limitation in this case series which might make it difficult to reliably predict outcomes in general practices, is that the majority of patients participating in this study were already being maximally treated with myopia control treatments. 64% of these patients were wearing either large segment bifocal glasses, progressive addition lenses, various bifocal or multifocal soft lenses and some were using low dose atropine either alone or in combination with multifocal soft lenses. A very high percentage of patients being treated in the author's practice are being treated for myopia progression, so most of the patients available to enroll in this study with either conventional single vision spectacles or single vision contact lenses or with no previous treatment, are patients new to the practice without any axial length measurements available for comparison. Another possible quirk in this patient population is that patients with previous myopia control treatments, and particularly those wearing multifocal contact lenses are unable to enroll if they have no progression and may be less likely to enroll if they have a minimal amount of progression. Thus, there may be a self-selected population of patients who are relatively unsuccessful with optical treatments prior to being refit with NV multifocals.

Despite all of these shortcomings, this pilot study still offers intriguing results which should encourage practitioners to try this type of multifocal lens for their progressing myopes who prefer a daily disposable lens. While this study is projected to compile three years of post NV multifocal lens wear data, only a long-term, multi-site, randomized, prospective, double-masked clinical trial can offer scientific evidence of the effects of this novel lens on the myopic progression in children and adolescents.

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