

SUBJECTIVE WEARING EXPERIENCE OF A NOVEL SPECTACLE LENS FOR MYOPIA MANAGEMENT BASED ON PERIPHERAL ASYMMETRIC MYOPIC DEFOCUS.

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INTRODUCTION

Myopia is a prevalent eye condition which is increasing worldwide (1-2) linked to severe ocular risks, particularly with the progression to high myopia (-6.00 D and more). High myopia increases the risk of developing retinal detachment, myopic macular degeneration, glaucoma, and, in certain instances, can result in blindness (3). Recent studies predicted that by 2050 nearly half of the population will be myopic, with 10% of high myopia (4). This awareness makes necessary to search for effective strategies to control myopia progression, especially in early childhood. In this regard, recent studies have shown that myopic defocus is a key mechanism for myopia control, which can be achieved through orthokeratology, contact lenses, and ophthalmic lenses (5-6).

These myopia control strategies are based on provide central correction for distance vision and induce peripheral myopic retinal defocus, simultaneously. Although these methods have been shown to be effective in reducing the progression of myopia, several studies have shown a positive effect between treatment efficacy and wearing time, with effectiveness increasing with longer lens wearing time (7-8). For this reason, a key factor for an effective myopia control treatment is that the child wears the spectacles comfortably for extended periods. Therefore, this study examines the subjective experience and comfort of wearing a newly developed spectacle lens which utilizes peripheral asymmetric myopic defocus to slow the progression of myopia.

PURPOSE

To determine the subjective wearing experience of a novel spectacle lens designed to slow myopia progression based on peripheral asymmetric myopic defocus after 6 months of use.

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MATERIALS & METHODS

Study type: A prospective, double-blind, randomized study was carried out to evaluate subjective wearing experience with a novel lens spectacle (MyoLess, IOT, Spain) and a control single-vision lens. The study adhered to the Declaration of Helsinki's principles. Full approval for the study was obtained from the Hospital Clínico San Carlos Ethics committee (Madrid, Spain). Before beginning the study, participant's parents signed written informed consent.

Participants: 83 children aged between 5 to 12 years old who met the following inclusion criteria: 1) Cycloplegic spherical equivalent less than -0.50 D; 2) Astigmatism less than 1.50 D; 3) Anisometropia less than 1.50 D, and 4) visual acuity 20/20 or better. Children who had previously undergone myopia control treatment, had any eye conditions, were using medications affecting pupil size, or had systemic diseases impacting vision were excluded from the study.

Procedure: To ensure that all participants satisfied the inclusion criteria, they were all given a thorough ophthalmology examination. After researchers confirmed that the children met the inclusion criteria, fitting parameters (pupillary distance and pupil height) with a frame previously selected were measured, and lenses were ordered. Participants were randomized to receive MyoLess (n=41) or single-vision (n=42) spectacle lenses. At an additional visit, the study spectacles were provided, and the researchers verified the fitting of the spectacles. Participants were asked to wear them full-time for 6 months, and a wearability questionnaire was provided to be filled out after 6 months of use in a 1-10 scale.

Ophthalmic lenses: MyoLess (IOT, Spain) lens design included a central blur-free area shaped ovoidal, with a horizontal size of 7mm. The peripheral treatment area is characterized by an asymmetrical horizontal myopic defocus with an addition power of +1.50 D at 25 mm towards the nasal side and +1.80 D at 25 mm towards the temporal side. Furthermore, the lens had an inferior myopic defocus with an addition power of +2.00 D. Figure 1 shows the technical characteristics of the lens used in this work. Lenses were manufactured in index 1.6 material with anti-reflective coating using free-form technology, they were calculated using an optical software (Free-Form designer, IOT, Spain) considering prescription, pupillary distance, and pupil height.

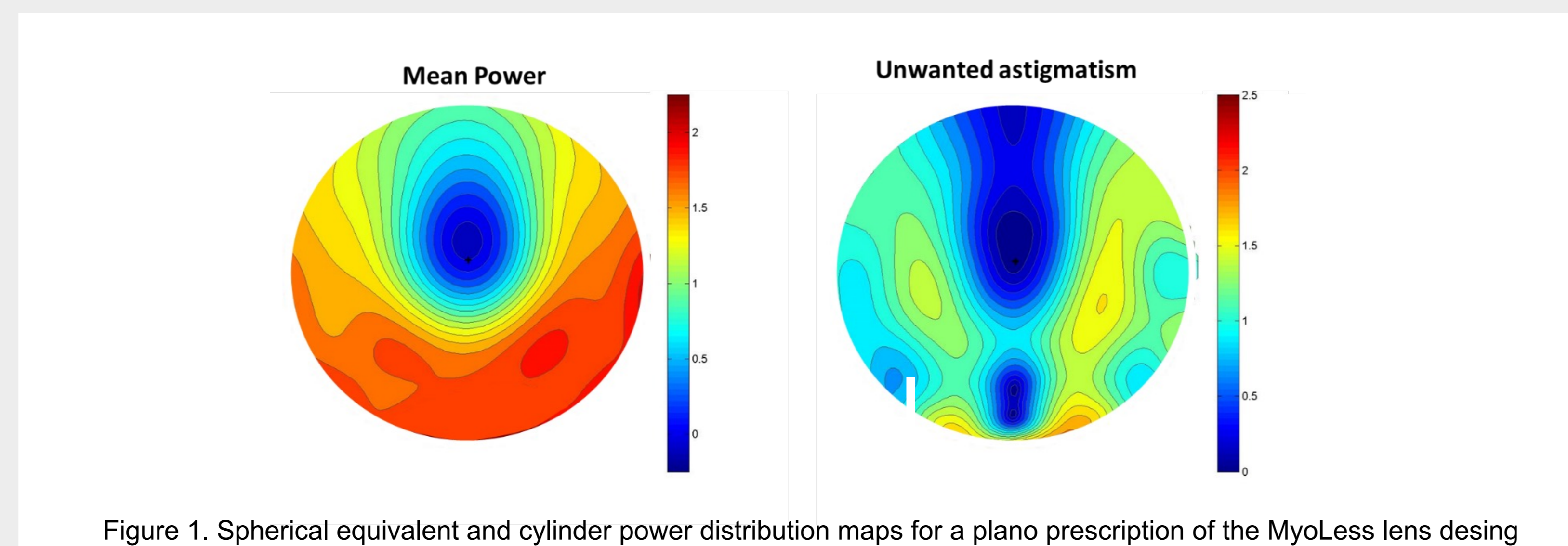


Figure 1. Spherical equivalent and cylinder power distribution maps for a plano prescription of the MyoLess lens desing

Statistical analysis: Unpaired t-test was applied to compare wearing experience after 6 months of use between lenses. Analysis was done by Statgraphics Centurion XVI.II. Significance p<0.05*.

RESULTS

Satisfaction rates: After 6 months using single-vision and MyoLess lenses, children reported high mean satisfaction rates for all questions for both lenses. Satisfaction rates for comfort were 8.5±1.6 for single-vision lenses and 9.2±1.1 for MyoLess lens. Sharpness rates were 9.1±1.3 and 9.1±1.3 for single-vision lenses and MyoLess lens respectively. Vision for sports was rated 8.5±1.3 for single-vision and 8.8±1.5 for MyoLess lens (Figure 2).

The subjective wearing experience did not show statistically significant differences between the two lens groups (p>0.05)

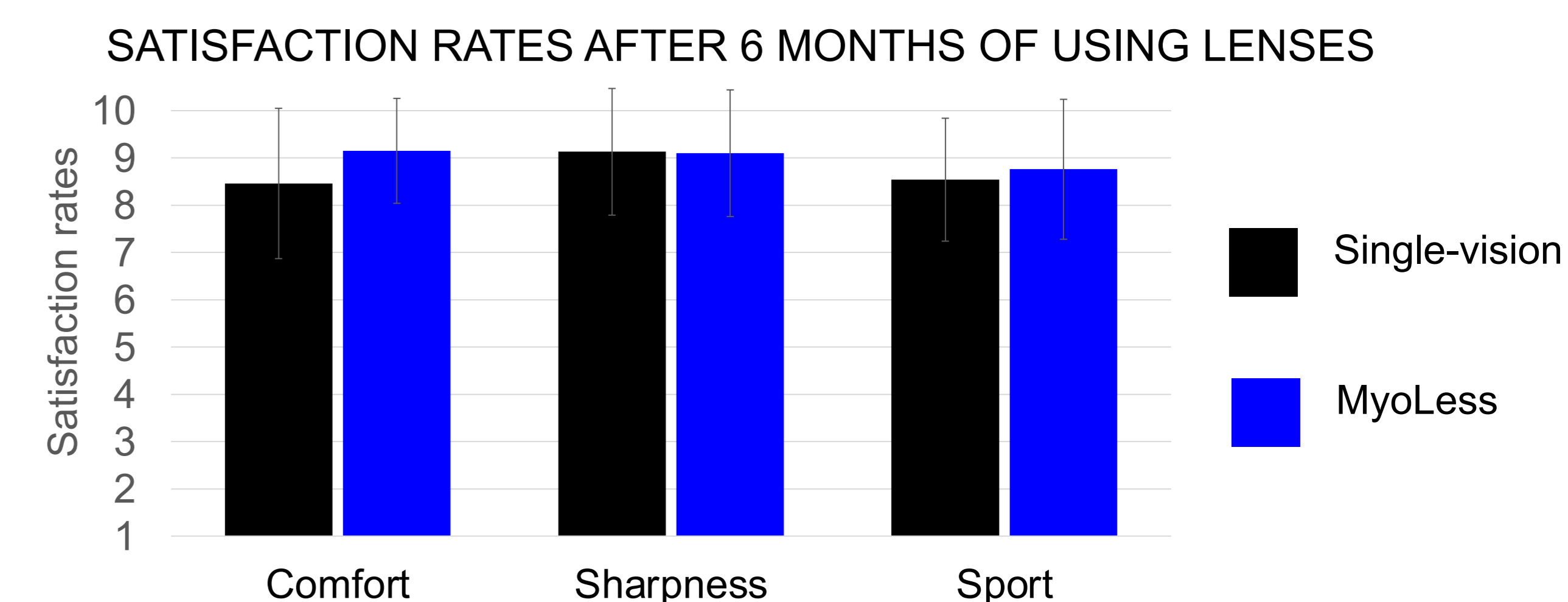


Figure 2. Mean and standard deviation of satisfaction rates for comfort, sharpness, and sports after 6 months of using a single-vision lens (in black) and MyoLess lens (in blue).

Lens performance: After 6 months wearing MyoLess and single-vision lenses, 95 % of children wearing MyoLess lenses reported excellent performance for comfort, 90% for sharpness, and 92% for vision for sports (Figure 3). While 72% of children wearing single-vision lenses reported excellent performance for comfort, 90% for sharpness, and 86% for vision for sports.

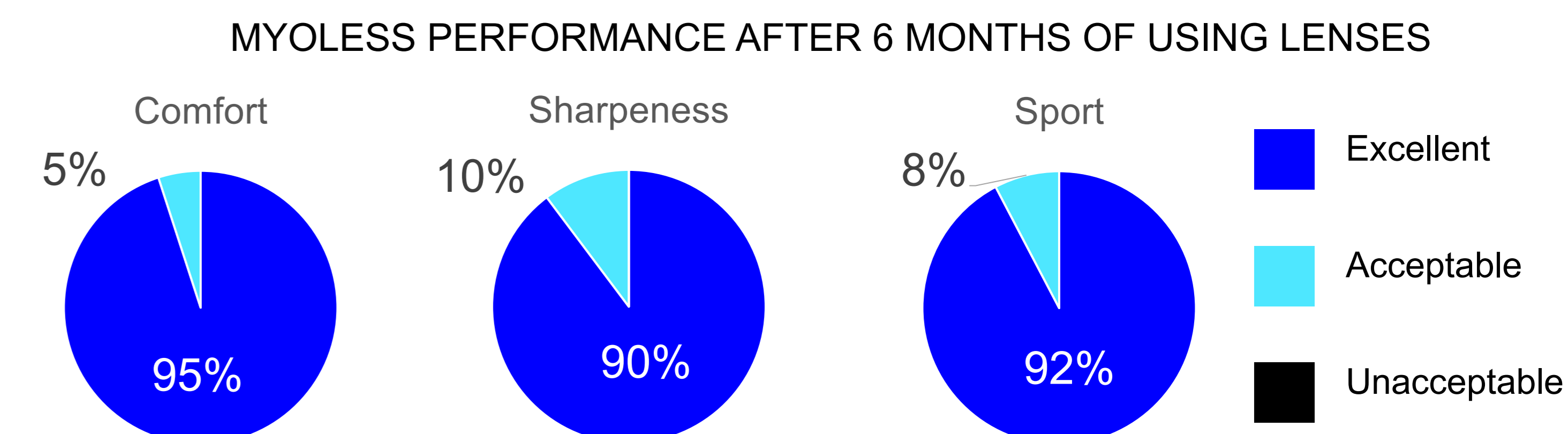


Figure 3. MyoLess performance after 6 months of use for comfort, sharpness, and sports. Performance ratings between 8 and 10 were considered excellent, ratings between 5 and 7 were deemed acceptable, and ratings below 5 were considered unacceptable.

CONCLUSION

The new lens with peripheral asymmetric myopic defocus provides after 6 months of use similar subjective wearing experience than standard single-vision lenses.