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## Authors' Response: Visual Performance of Center-Distance Multifocal Contact Lenses Fit Using a Myopia Control Paradigm

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We welcome the opportunity to respond to Dr. Benoit's concerns. Our study team unequivocally stands by our published paper<sup>1</sup> and disagrees with the suggestion that the study was biased against the NaturalVue Multifocal. The study results indicate that the visual performance of the NaturalVue Multifocal is consistent with that of the other multifocal lens in the study and other multifocal lenses in the published literature. We make the following observations and provide support from the peer-reviewed literature to support our conclusions.

First, the assertion that we introduced bias by failing to follow the published fitting guide regarding selection of the initial lens power is inaccurate. Dr. Benoit states that after obtaining a refraction to 20/15, a binocular duochrome test is required to put the patient "one step into the green" to make the initial lens selection. He notes that we pushed maximum plus and that they "do not advise over-refraction to enhance vision." These statements unfortunately do not align with the fitting app available at the time this study was conducted or the current NaturalVue Multifocal Professional Fitting and Information Guide.<sup>2</sup> Per the fitting guide, the initial lens selection is based on a current refraction. The guide then provides two "Best Success Tips" for initial lens selection. Tip 1 is to "ensure the refraction is the most plus/least minus spherocylindrical distance power that provides optimal vision." As noted in our paper, we used maximum plus power to maximum distance visual acuity (optimal vision) when determining each participant's manifest refraction. Tip 2 involves procedures to "double check that the patient is not overminused", which the guide notes "is somewhat common in presbyopes." The guide states that introducing +0.25 diopters over the

distance refraction should not blur the 20/20 line, +0.50 diopters should result in the patient just beginning to note that the 20/20 line is “not quite as clear,” and that +0.75 diopters over the distance refraction should cause the 20/20 line to be “noticeably blurry.” This recommendation is at odds with the fitting guide’s previous statement of using the “most plus/least minus...power that provides optimal vision.” The “success tip” also suggests the use of the binocular duochrome test “to double check that the patient is not overminused,” yet recommends that all patients should be “one click into the green,” which in the case of a patient who noted equality of the red and green fields of the chart, would then overminus them by  $-0.25$  diopter.<sup>3</sup> Standard clinical texts note multiple factors that can result in an inaccurate duochrome test endpoint, specifically in myopic eyes and in non-presbyopes with active accommodation that can lead to overminusing.<sup>3</sup>

Because the goal of our study was to fit lenses as they would be for a non-presbyopic myopia control patient, we ensured that we maximized distance vision without overminusing. On average, distance and near high-contrast visual acuity in our study was better than 20/15 at both distance and near with the NaturalVue Multifocal, confirming that participants were not under minused/over plused. The NaturalVue Multifocal fitting application version available at the time of our study also did not mention the duochrome test and instructed the user to enter the “Best Corrected Spectacle Refraction,” which was done as reported in the manuscript. We note that since the study was conducted, the fitting application has been updated to instruct the user to enter “Spectacle Refraction – 1 Click into the GREEN.”

Second, Dr. Benoit asserts that they “do not advise over-refraction to enhance vision, but rather a change of on-eye lens power, based on subjective patient preferences” and that “the overrefraction adjusted maximum plus power to maximum distance visual acuity technique used in the study would therefore be erroneous.” Dr. Benoit’s statement is contrary to the company’s professional fitting and information guide which states, “Over-refract with handheld trial lenses or flippers ( $+0.25D/-0.25D$ ) to ensure that the initial lenses are at the most plus/least minus power that provides the most optimal distance and near vision.”<sup>2</sup> It is also important to note that the fitting guide is presumably written for fitting presbyopic patients, whereas the study fitted non-presbyopic myopic participants.

Regarding visual performance of the NaturalVue Multifocal, Dr. Benoit’s statement that “our premarket evaluations showed that visual acuity with NaturalVue Multifocal was within two letters of best corrected spectacle acuity under all illumination and contrast conditions” included no citations to these results in the peer-reviewed literature for evaluation and no such publication of a robust clinical trial seems to exist. Hence critical details are not evident including the subject demographics, the methodology used to test acuity, the contrast levels tested, statistical analyses, or results. In the absence of these important details, we are not able to evaluate his statement and contrast it with published peer-reviewed methods and results. His assertion that “NaturalVue Multifocal was within two letters of best corrected spectacle acuity under all illumination and contrast conditions” is not aligned with numerous studies in the peer-reviewed literature that report reductions in low-contrast acuity with multifocal and dual focus optics. For photopic, high-contrast acuity, the NaturalVue Multifocal was better than  $-0.1$  logMAR at distance and near, which is

consistent with reports that multifocal contact lenses have little to no effect on acuity under these conditions.<sup>4–11</sup> When considering photopic, low-contrast acuity, our finding of modest reductions in vision with both multifocal designs tested were similar to other reports in the literature testing multifocal and dual focus contact lens designs.<sup>6, 8, 11</sup> Likewise, our low-contrast, low-illumination data with both multifocal designs tested showed reductions in visual acuity that were again consistent with the performance of other multifocal and dual focus contact lens designs in the peer-reviewed literature.<sup>7</sup> We presume the uncited data to which Dr. Benoit refers pertains to presbyopic patients; again it is important to note that we fit these lenses on non-presbyopic participants as would be done for a myopia control strategy. Age and pupil size are established in the literature to have clinically meaningful influences on image quality<sup>12</sup>, but we were unable to compare these important factors between our study and the study mentioned by Dr. Benoit without a citation.

Our data support the statement that the NaturalVue Multifocal performed in a manner consistent with the other multifocal lens tested in our study, in line with the results of other studies of multifocal contact lenses in the peer-reviewed literature. Dr. Benoit claims that failure to follow the fitting guide introduced bias, and further suggests that our paper should be withdrawn. Given the contradictions between the statements made in his letter and the current fitting guide along with differences in the fitting guide application available when these data were collected, we disagree. We strongly stand by our data and their ability to provide practitioners using all lenses tested in our study with evidence-based results describing their visual performance when fitted on non-presbyopic patients.

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