Tsubo Lab

イノベーションで、世界をごきげんに、健康にする

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Major milestone in exploratory clinical trial for a medical device:

Confirmation of the suppressive effect of violet light on myopia progression

Tsubota Laboratory, Inc. is engaged in research and development to decrease the global myopic population by innovative and revolutionary technology development and application to medical devices.

In order to evaluate the safety and efficacy of a medical device for suppressing myopia progression using our proprietary violet light technology based on joint research with Department of Ophthalmology, Keio University School of Medicine, we started an exploratory clinical trial for elementary school children in April 2019, titled "A Pseudo Placebo-controlled Parallel Group Comparative Exploratory Clinical Trial to Evaluate the Safety and Efficacy of TLG-001 (*1) on Schoolchildren with Myopia in a Randomized Double-Blind Study."

In this exploratory clinical trial, we have confirmed the primary endpoint, short-term safety of this medical device which was reported on December 22, 2020. (Link: https://tsubota-lab.com/wp/wp-content/uploads/2020/12/pdf newsrelease j 201223.pdf)

This time we further evaluated the secondary endpoint, efficacy, and are pleased to report that statistically significant differences were observed in the subgroup analysis for the children 8 to 10 years of age in the following parameters: changes in axial length and cycloplegic objective/subjective refractions.

The efficacy was analyzed for the subgroup of 8-10 year olds. Myopia-related factors such as the amount of time spent for near work, the amount of time spent outdoors, and the amount of exposure to violet light from the outdoors, were used as fixed effects in the analysis. As shown in Fig. 1, the change in the ocular axial length for the test device group was significantly ($p<0.001$) less than that for the control device group. The suppression rate was 40%. As the axial length elongation is an indicator related to myopia progression, this result

reflects the suppressive effect of myopia progression.

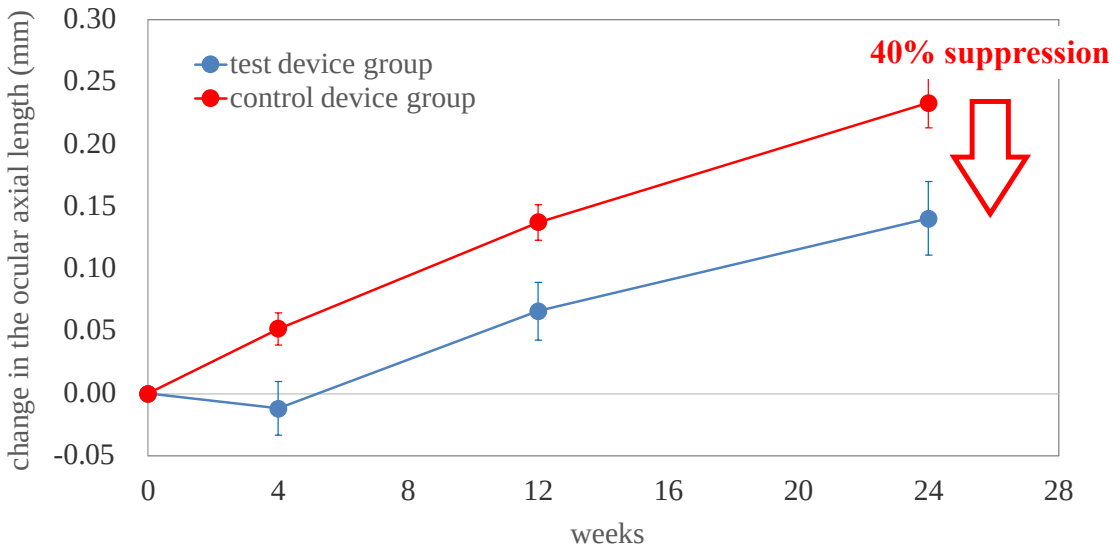

Figure 1. Change in the ocular axial length

Furthermore, the myopia progression in the cycloplegic subjective and objective refraction values for the test device group was significantly ($p<0.001$, $p=0.003$) smaller than those for the control device group at 24 weeks. These are shown in Fig. 2 and 3, and the suppression rates were 73% and 80%, respectively.

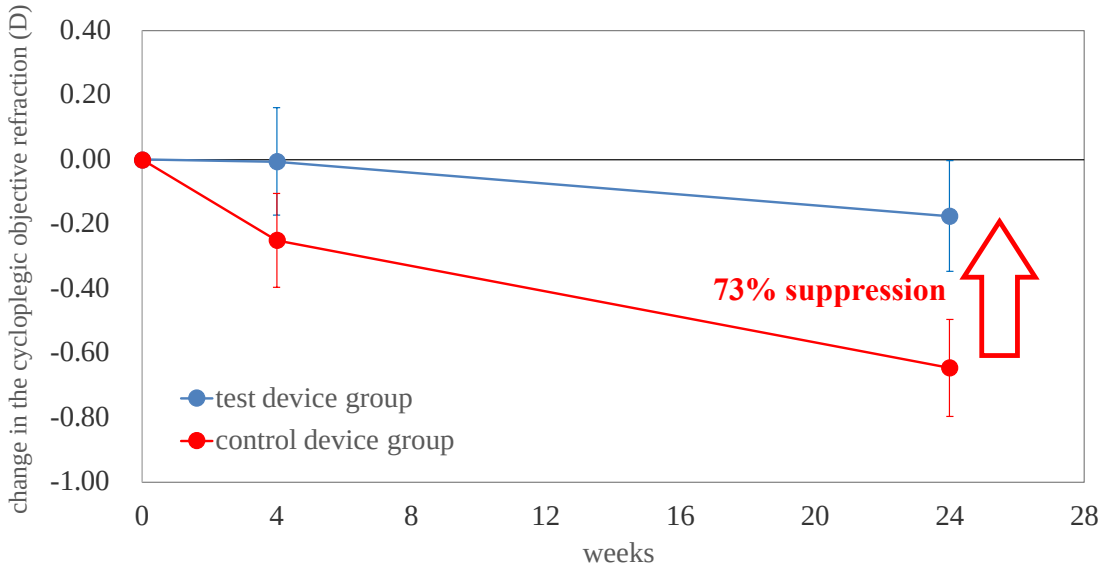

Figure 2. Change in the cycloplegic objective refraction

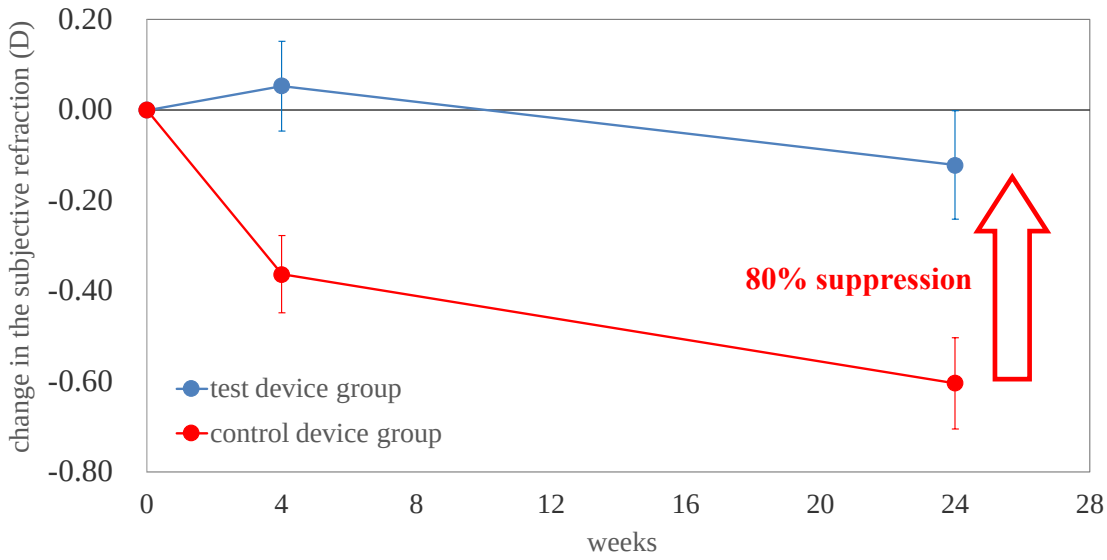

Figure 3. Change in the subjective refraction

Based on the results of this study, we have been consulting with the Pharmaceuticals and Medical Devices Agency (PMDA) for the final, confirmatory, clinical trial, aiming at an approval for the manufacture and sale of the medical device. The main endpoint of this clinical trial is to confirm the efficacy of the device. With the increased enrolment of 150, we plan to start the trial at a few clinics by the end of 2021.

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Our CEO Kazuo Tsubota said, ”The fact that we confirmed the significant efficacy in myopia-related indices such as the ocular axial length and refractions in this exploratory trial is an extremely important milestone in our goal of developing medical devices to reduce myopia. We will continue to make further progress toward solving the growing social problem of myopia in children.”

*1
TLG-001：Name of the device being developed by Tsubota Lab as a medical device to suppress the progression of myopia

Company profile

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