

SUNY

State College of Optometry
New York, New York

To Whom It May Concern:

RE: Clinical Significance of TOZAL Supplementation

I had the opportunity to review the major results of the multi-center TOZAL study recently and herein furnish my professional assessment of the study and my opinions.

The TOZAL study incorporated taurine, omega-3 fatty acids, zinc, antioxidants and lutein. With the exception of taurine, this formulation is very similar to the AREDS II formulation that is in the first year of a six-year trial. The TOZAL Study Design had as a primary objective the measurement of change of Visual Acuity (VA) as measured with the ETDRS charts in subjects with intermediate dry, Age Related Macular Degeneration (AMD) who were treated with either this novel nutritional supplement and Micro Current Stimulation (MCS) or the same novel nutritional supplement and Sham MCS. The range of best-corrected VA at baseline was 20/32-20/125, the same range of VA used in the MIRA-1 study that I have also reviewed in detail previously. The MIRA-1 study was used as a “distant” control group. The study contrasted VA (and other parameters) at baseline to VA measured under the same conditions at 6 months. Based upon other studies, it is well acknowledged that VA in a group of subjects with intermediate AMD decreases over a 6-month period and the decrease has been demonstrated to be about 1.5 lines.

Remarkably, the results of both arms of the TOZAL study revealed that more than half (57%) of the subjects in both treated groups (nutritional supplement with MCS and nutritional supplement with sham MCS) improved at 6 months. In contrast to the well known natural course of AMD that demonstrates deterioration, nearly 77% treated with the nutritional supplement improved or stayed the same and only about 23% worsened (but no worse than placebo). Based upon statistical analysis, MCS did not provide additional improvement over the nutritional supplement group with sham MCS. Hence, the TOZAL supplement formula alone in this study has altered the natural course of the progression of intermediate AMD. It is well known that the original AREDS study demonstrated that nutritional supplements reduced the progression in the treated group when compared to the placebo group by about 25% but the subjects still demonstrated progression of the disease process and lost visual acuity. The AREDS II is now underway but the results will not be available for approximately 5 years. Since the TOZAL formulation is very similar (but not identical) to the AREDS II formulation, the TOZAL results predict the eventual positive AREDS II results. Conservative clinicians may choose to wait another 5 or so years for the AREDS II results to be announced before recommending the AREDS II or similar nutritional supplements.

Alternatively, many less conservative clinicians may choose to treat their patients with intermediate AMD at the present time in order to provide the additional 5 or so years of protection and perhaps even result in VA improvement in as little as 6 months.

In summary, the TOZAL study has demonstrated the clinical significance of VA improvement and/or stability for subjects with intermediate AMD who were treated with the TOZAL formulation of taurine, omega-3 fatty acids, zinc, antioxidants and lutein. These findings predict that the results of the much larger AREDS II study, to be available in approximately 5 years, will yield similar positive effects.

Respectfully,

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