Abstract
Investigational Study
3:1 rTG Omega-3
(1680mgEPA/560mgDHA)

Background:

Investigational Study (Smith et al.)

Purpose: To investigate the potential effect of the oral supplementation of rTG omega-3 fatty acids on lipid composition of meibum, Tear Break up Time, Tear Osmolarity and Corneal Staining in patients with symptoms of Dry Eye.

Methods: In a pilot study, patients with dry eye received a daily dose of rTG Omega-3s containing 1680 mg of eicosapentaenoic acid, 560 mg of docosahexaenoic acid, and 1000mg of Vitamin D3 (Dry Eye Omega Benefits, Physician Recommended Nutriceuticals, Plymouth Meeting, PA) for 60 days. There were 3 patient visits: baseline, 4 and 8 weeks. At baseline, 4 and 8 week visit, patients completed the ocular surface disease index to score subjective symptoms, given slit-lamp examinations, and tested for tear breakup time, corneal staining and tear osmolarity (TearLab). At baseline and 8 weeks compliance was monitored measuring EPA and DHA RBC (red blood cells) saturation using an omega-3 index (OmegaQuant). Collection of meibomian gland secretion samples for lipid composition were collected using the Mastrota paddle and measured at baseline and 8 weeks. The meibum samples were examined by Microbial ID, INC and analyzed using fatty acid profiling by gas chromatography for the Sherlock MIS system.

Results: A total of 20 patients completed the study. At the end of the study, all patients reported a reduction of their primary complaint and 14 of the 20 (70%) patients became completely asymptomatic. The improvement in Tear Breakup Time was statistically significant ($p < .00027$). Patients with hyperosmolarity (>308mOsm/L) at baseline, improved 25% after 4 weeks and 17% after 8 weeks. 9 of 20 patients did not present with Corneal staining at baseline, but the 11 patients that did all had significant improvement. Note: When flourescein with anesthetic is placed, this creates huge variability with these patients. The initial samples of meibum were collected without the use of the Mastrota Paddle and only 7 samples were readable due to the amount collected. None of the pretreatment samples contained Omega-3s. Bacterial Fatty Acids composed 10 to 15% of the sample, linoleic acid (Omega-6), ranged from 34 to 60%. Of the 20 patients that completed the study, 3 had meibum samples that were not recognizable. 14 of the remaining 17 had DHA present in the meibum after 8 weeks of treatment. As measured by the Omega-3 Index, patients EPA levels increased significantly ($p<.00000$) in the RBCs from baseline and 8 weeks, .8% and 3.2% respectfully. DHA increased ($p<.00349$) in the RBCs from baseline and 8 weeks, 3.3% and 4.1% respectfully. Arachidonic Acid, direct precursor to pro-inflammatory eicosanoid derivatives, decreased significantly ($p<.00004$) from 12.2% at baseline to 10.3% at 8 weeks. The overall Omega-3 index increased significantly ($p<.00000$) in the RBCs from baseline and 8 weeks, 4.6% and 7.8% respectfully.