Neurolenses Proven to Reduce Headache Symptoms

Neurolens Clinical Team

A few years ago, neurologist Dr. Carol Nelson conducted a clinical study in South Dakota with 179 subjects suffering from chronic headaches[1]. The subjects had tried several pharmacological interventions over the years, but none had any impact on their headaches or on their quality of life. In collaboration with an optometrist, Dr. Jeff Krall, these patients were provided with Neurolenses, and the subjects' headache symptoms were reevaluated after 90 days. Over 80% of the subjects enrolled reported an improvement in their symptoms after wearing Neurolenses for 90 days. Most importantly, 54% individuals reported that their symptoms were basically gone or reduced substantially after wearing Neurolenses for 90 days. It was a very impactful result given that 1 in 2 individuals with long-standing headaches reported a substantial improvement in their headaches. It was a pilot study and, although powerful, was not a controlled clinical trial. Following a logical evolution in clinical testing, Neurolens launched a first-of a-kind, double-masked, randomized, cross-over clinical study[2].

Clinical Study Data

The study was a 4-visit-long double-masked design where neither the subject nor the investigator knew what lens (placebo or treatment) was offered to the patient at each visit[2]. It was a cross-over study where each subject who was enrolled and randomized had to wear both the control lens and the treatment lens for 20-40 days each. The subjects were randomized to either wear a control lens without prism (Shamir Autograph II single vision or progressive-addition lenses (PALs) with Crizal rock) or treatment lens (NL single vision or PAL with premium antireflection coating). The coating provided on both the lenses was kept similar to ensure that the lenses looked similar and did not induce any bias. The validated Headache Impact Test (HIT-6) questionnaire was used to quantify the symptom change after they wore the treatment/control lens. A total of 300 subjects were enrolled across 10 optometry practices in the United States between October and December 2021, with all visits completed by May 2022. The only two major inclusion criteria for enrollment included good stereoacuity and being symptomatic based on the HIT-6 responses. The mean Neurolens value (prism prescription) that was provided in the study was 1.29 base-in prism diopters. As shown in Figure 1, an average of a 5-point reduction was noted with Neurolenses relative to the baseline visit as opposed to a 3-point reduction with the control lens. The 5-point reduction with Neurolenses was a clinically significant reduction in symptoms.*

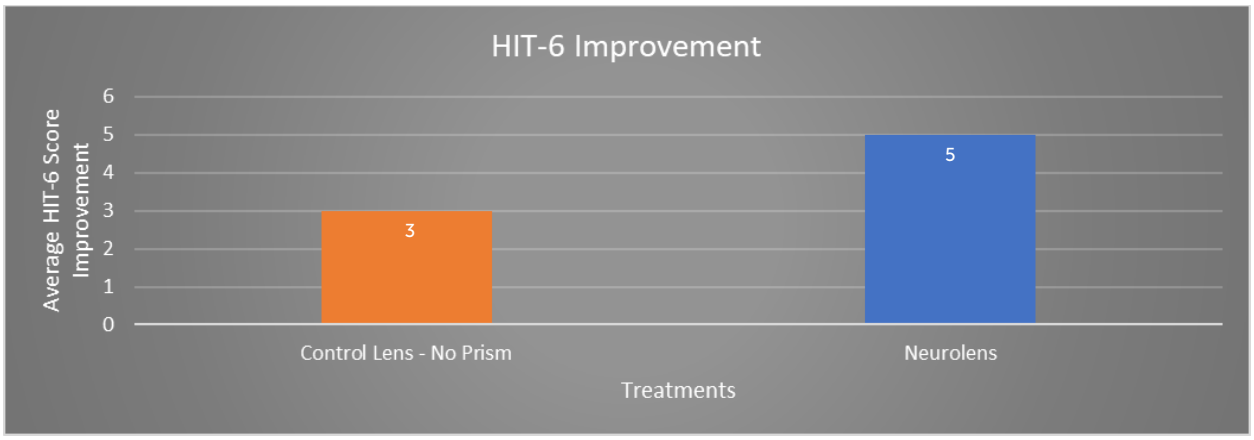

Figure 1: Average change in the HIT-6 score was plotted as a function of different interventions. A larger value on the y-axis would indicate more relief in headache symptoms relative to the baseline visit.

When evaluating the difference in symptom relief between Neurolenses and the control, a statistically significant difference (p = 0.01) was observed. The proportion of individuals that had a clinically significant reduction in the symptoms (>2.5-point reduction) was higher with Neurolenses compared to the control lens (p = 0.01). One in every two individuals reported a clinically significant reduction in their symptoms post wearing Neurolenses for 20-40 days. Neurolens outperformed the control lens every time, which is not by chance (p = 0.01)

Headaches and other digital eyestrain-related symptoms are very common in this modern-digital era. A recent Vision Council report[3] suggested that 80% of the patients who walk into an optometry office experience some level of digital eyestrain on a day-to-day basis. It is, therefore, very critical to accurately detect and treat these problems. Based on this clinical trial, it is clear that the Neurolens process provides an effective way to detect, diagnose and treat patients with vision-related headaches. The study also suggested that it is important to evaluate and treat vision-related disorders in patients significantly impacted by headaches who won't fit the current diagnostic criterion for binocular vision disorders.

Literature Review

A review of the published literature on the interventions that were tested to treat/relieve headache/migraine symptoms was conducted. All these studies used HIT-6 questionnaire as one of the outcome parameters. A comparison of the data from the current Neurolens study with published data on different pharmacological[4,5] interventions was performed and the data is shown in the table below.

1st Author (year)	Treatment type	Study Population	Study Design	Treatment Duration in Weeks	Treatment	Sample Size	Mean Age (SD)	Mean Reduction in HIT-6 Score
Labhishetty (2024)	Contoured Prism	Adults with HIT-6 score ≥56; stereopsis (≤50 arc sec)	Randomized Double-Mask Crossover	4	Neurolens, Control	195	37.34 (10.85)	Neurolens: 5 Control: 3
Blumenfeld (2020)	Pharmacological	Adults with Chronic Migraine	Randomized Parallel group	6, 18, 30	OnabotulinumtoxinA (BOTOX®)	110	40.2 (11.7)	Week 6: 4 Week 18: 5.1 Week 30: 5.6
					Topiramate (Topamax®)	115	39.4 (12.6)	Week 6: 2.2 Week 18: 1.6 Week 30: 1.3
Lipton (2019)	Pharmacological	Adults with Chronic Migraine	Randomized Double-Blind	12	Erenumab (Aimovig) 70 mg	188	41.4 (11.3)	5.6
					Erenumab (Aimovig) 140 mg	187	42.9 (11.1)	5.6
					Placebo	281	42.1 (11.3)	3.1

Table 1: Study characteristics of included articles.

Both the Blumenfeld and Lipton studies evaluated subjects with chronic migraine; whereas the Neurolens study evaluated subjects with a self-reported level of headache symptoms based on the HIT-6 score. Blumenfeld, et al., found a greater reduction in HIT-6 scores for subjects treated with Botox than Topamax over the course of the study. Of note, the initial effect of Botox at week 6 in the study was an average improvement of 4 points which trended towards an eventual improvement of 5.6 points at week 30; the initial improvement with Topamax was 2.2 points, which dropped to an average improvement of only 1.3 points at week 30. Lipton, et al., evaluated 2 dosing levels of Aimovig (70 mg vs 140 mg) and found that both levels resulted in a mean reduction in the HIT-6 score of 5.6 points at 3 months. The authors provide a graph showing the improvement in HIT-6 score is nearer to 4 to 4.5 points at 1 month and near 5 at 2 months; however, no specific values are provided in the paper.

When comparing the Neurolens and control lens data reported in the current study to pharmacological interventions like Aimovig, Botox and Topamax, symptom relief based on the HIT-6 questionnaire with Neurolenses is on par with what was reported with other pharmacological interventions. We realize that the population subgroups and study designs are different between the studies. However, the purpose of this comparison was to highlight the effectiveness

Conclusions

The current report highlights the data from the recently published double-masked, randomized Headache Study[2]. Based on the clinical study data, Neurolenses provide a statistically significant improvement in headache symptoms. A quick literature review suggests that the improvement noted in the current study is on par with several commercially available pharmacological solutions. The Neurolens process provides a simple and effective way to detect, diagnose and treat patients with digital eyestrain and headaches.

* Efficacy & adverse events have been fully evaluated and discussed in the peer-reviewed publication.

References

1. *Krall J, Nelson C. Visually Induced Trigeminal Dysphoria: A Potential Leading Source of Headaches, Eyestrain and Dry Eye Sensation. Supplement to Modern Optometry, 2019.*

2. *Labhishetty V, Cortes J, vande Pol C, Maanpaa V, Plumley A, Amin N, Hurley J, Barton T, White T, Szeliga R, Dixon JM, Grosswald D, Knutson J, Maier H. Impact of Neurolens use on the quality of life in individuals with headaches: A randomized double-masked,cross-over clinical trial. Transl Vis Sci Technol. 2024;0(0):6170, https://doi.org/10.1167/tvst.0.0.6170*

3. *The 2022 Vision Council Report (https://thevisioncouncil.org/product/focused-insights-2022-digital-habits-report).*

4. *Blumenfeld AM, Patel AT, Turner IM, Mullin KB, Manack Adams A, Rothrock JF. Patient-Reported Outcomes from a 1-Year, Real-World, Head-to-Head Comparison of OnabotulinumtoxinA and Topiramate for Headache Prevention in Adults With Chronic Migraine. Journal of Primary Care & Community Health. 2020;11. doi:10.1177/2150132720959936*

5. *Lipton, R. B., Tepper, S. J., Reuter, U., Silberstein, S., Stewart, W. F., Nilsen, J., ... & Lenz, R. (2019). Erenumab in chronic migraine: patient-reported outcomes in a randomized double-blind study. Neurology, 92(19), e2250-e2260.*