Healio OCULAR SURGERY NEWS

Short course of steroids may improve outcomes for dry eye patients

A clinician evaluated whether adding a steroid or an NSAID at the start of dry eye therapy made a difference.

Ocular Surgery News U.S. Edition, October 25, 2015
Cynthia Matossian, MD, FACS

Dry eye is estimated to affect between 20 million and 25 million Americans, with women more affected than men. In my practice in the suburban Philadelphia area, I can personally attest to that: Almost 30% of my practice is devoted to treating symptomatic dry eye patients. Most of these patients have already tried artificial tears, usually more than one brand, without substantial relief.

Once we have confirmed a diagnosis of dry eye, we typically begin patients on a course of re-esterified oral omega-3 supplements and Restasis (topical cyclosporine 0.05%, Allergan). Some patients are content supplementing with artificial tears until this combination approach starts to work; others, often those with more advanced disease, complain about instillation pain and stinging. This latter group of patients may remain frustrated, leading to the discontinuation of their prescribed cyclosporine regimen.

As clinicians, we want to decrease the discomfort our patients experience and improve their condition as soon as possible. With that goal in mind, I have been prescribing a short course of steroids and/or NSAIDs along with Restasis to help alleviate the initial complaints and to "jump start" the anti-inflammatory therapy.

Study design

Cynthia Matossian

In my investigator-initiated study, I wanted to determine whether adding either a steroid or an NSAID would result in better patient compliance in those prescribed Restasis compared with patients who were prescribed Restasis alone.

We enrolled 50 patients into this study: Restasis alone (group 1, 18 patients), Restasis plus Lotemax gel drops (loteprednol, Bausch + Lomb; group 2, 13 patients) and Restasis plus Bromday/Prolensa (bromfenac, Bausch + Lomb; group 3, 19 patients). All patients were

instructed to instill Restasis twice daily; group 2 instilled the steroid drops 15 minutes before each Restasis instillation for the first 2 weeks and then discontinued steroid use. Group 3 instilled the NSAID 15 minutes before each Restasis drop for 2 weeks and then discontinued its use.

Subjects underwent four study visits (initial visit and at months 1, 3 and 6 after the initial visit date), and all subjects underwent tear osmolarity testing and lissamine green staining at each visit. In addition, we used the OPD-Scan III (Marco) to take Placido disc images and asked patients to complete the Ocular Surface Disease Index (OSDI) questionnaire at baseline and again at the last visit.

Study outcomes

There were no statistical differences in any of the parameters tested, but there were distinct clinical differences and improvements. As might be expected, all groups improved in the objective signs of dry eye; adding a steroid or NSAID did not substantially alter those findings.

The two surprising outcomes were in tear osmolarity and the OSDI scores.

At baseline, the average tear osmolarity was 315.31 mOsmol/L in the right eye and 313.84 mOsmol/L in the left eye. At the final visit, tear osmolarity had improved in all groups to an average of 308.43 mOsmol/L in the right eye and 308.57 mOsmol/L in the left eye (Table 1).

Table 1. Average tear osmolarity in all groups

	Baseline		6 months	
	Right eye	Left eye	Right eye	Left eye
Average tear osmolarity, mOsmol/L	315.31	313.84	308.43	308.57

Source: Matossian C

Table 2. Interocular differences in tear osmolarity per group

	Mean change in tear osmolarity from baseline to final visit	
	Right eye	Left eye
Group 1 (n = 18)	5.44 mOsmol/L	0.19 mOsmol/L
Group 2 (n = 13)	1.25 mOsmol/L	–2.75 mOsmol/L
Group 3 (n = 19)	–6.35 mOsmol/L	2.65 mOsmol/L

Source: Matossian C

What interested me the most were the different osmolarity scores between treatment groups (Table 2). When evaluating the right eye, in group 1 the mean improvement in tear osmolarity was 5.44 mOsmol/L compared with an improvement of 1.25 mOsmol/L in group 2 and a decrease of –6.35 mOsmol/L in group 3. Yet the same test in the left eye resulted in vastly different mean improvements/decreases: Group 1 showed a 0.19 mOsmol/L improvement, group 2 a –2.75 mOsmol/L decrease and group 3 a 2.65 mOsmol/L improvement. The interocular difference can be a reflection of the unstable and unhealthy tear film, which can show swings between eyes and from visit to visit. It is important to note that even after 6 months, only one patient's results improved to a normal level, reiterating the chronicity and severity of this disease. It is the overall trend that I evaluate with tear osmolarity results.

If patients were compliant with therapy, we should see an improvement in OSDI scores across all groups. However, group 1 had a decrease in OSDI scores from baseline to final visit of 4.07, meaning those patients did not believe their symptoms were better at final visit than at baseline. It is possible

that the difficulty with instillation and/or discomfort associated with instillation negatively affected patient-perceived symptoms as measured on the OSDI. Yet group 2 had the greatest improvement in scores (–7.08), and group 3 also had an improvement in OSDI scores (–4.77) at final visit compared with the baseline evaluation. This suggests that adding either a steroid or an NSAID to Restasis improves patient-perceived symptoms and/or the level of discomfort associated with the drop instillation, which likely translates into increased overall ocular comfort and, hopefully, better treatment compliance.

When a short course of steroids was added to Restasis, patients reported better outcomes than if an NSAID or nothing was added. The addition of a short course of loteprednol etabonate gel drop formulation steroid as concomitant therapy at the time of Restasis initiation may benefit patients during the cyclosporine dose-loading period.

For more information:

Cynthia Matossian, MD, FACS, is the founder of Matossian Eye Associates, with offices in Doylestown, Pa., Hopewell, N.J., and Hamilton, N.J. She can be reached at cmatossian@matossianeye.com.

Disclosure: Matossian reports she is an investor in and serves on the board of directors of Physician Recommended Nutriceuticals (PRN), now owned by Alphaeon. She reports she is an investor in Strathspey Crown, which owns Alphaeon, and a consultant and speaker for PRN, TearLab and Allergan.