



Clive Peckar

# Sodium hyaluronate-based products

Cheryl Guttman  
in Berlin

TWO different commercially available drops containing sodium hyaluronate are useful choices in the management of post-LASIK dry eye and other dry eye problems.

Colin S Tan MD, and colleagues from the National Healthcare Group Eye Institute, Tan Tock Seng Hospital, Singapore, conducted a prospective, randomised, controlled study evaluating Blink Contacts (Advanced Medical Optics), a multi-dose product formulated with 0.15 per cent sodium hyaluronate and a proprietary, short-term, low toxicity preservative (Ocupure) that decomposes into sodium chloride and oxygen when exposed to light. The comparator group used Tears Naturale Free (Alcon), a single-dose, preservative-free artificial tear preparation containing hydroxypropyl methylcellulose.

Eighty patients undergoing bilateral LASIK were randomised to use one of the two products four times a day for three weeks. Dry eye symptoms were assessed at baseline and at the end of the study using the Ocular Surface Disease Index (OSDI). The results showed significant improvements occurred with both products, and there were no differences in final symptom severity between the two groups.

**“The results of our study show that at least one preservative-containing ocular lubricant, Blink Contacts, is well-tolerated and as effective as a commonly used preservative-free preparation for treating dry eye symptoms after LASIK”**

Colin S Tan MD

“Dry eye after LASIK is a cause of patient discomfort and can also contribute to vision fluctuations, delayed healing, exacerbation of astigmatism, and poor vision quality. Refractive surgeons usually prescribe preservative-free lubricants to manage post-LASIK dry eye, but multi-dose products containing a preservative are more convenient and less expensive.

The results of our study show that at least one preservative-containing ocular lubricant, Blink Contacts, is well-tolerated and as effective as a commonly used preservative-free preparation for treating dry eye symptoms after LASIK,” said Dr Tan at the XXVI Congress of the ESCRS.

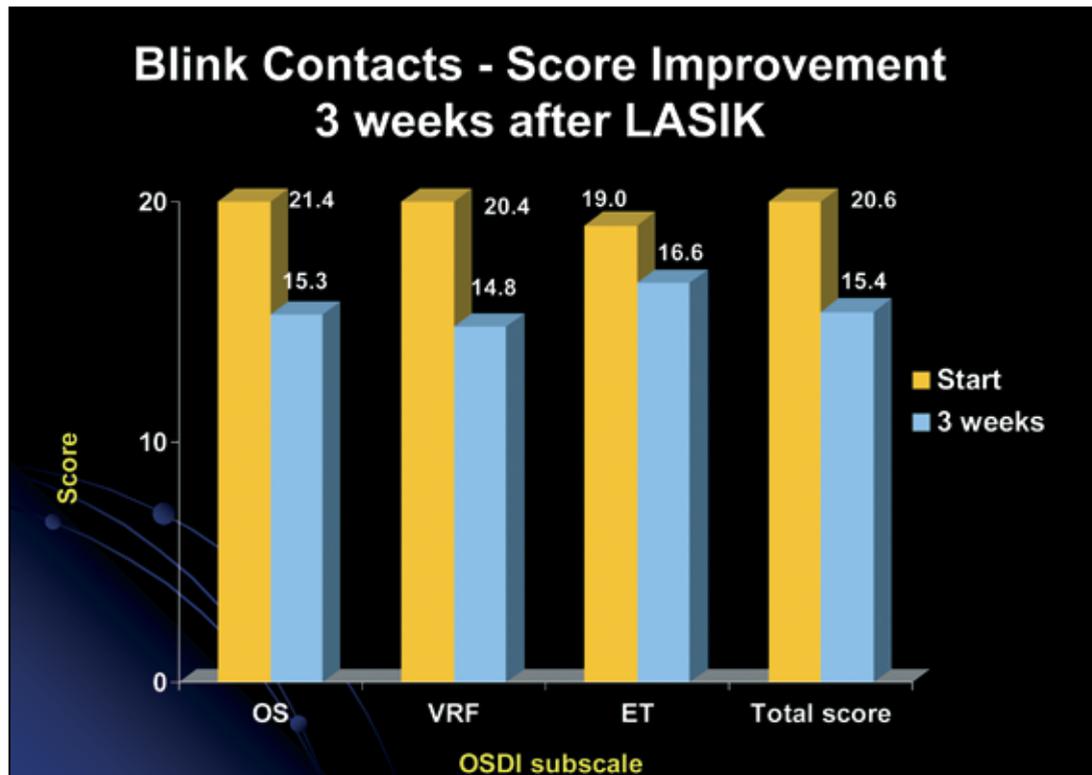
He added that sodium hyaluronate has several properties that make it useful for treating dry eye. In particular it has water retentive properties that minimise tear film evaporation, and it is also mucomimetic, so that it helps to stabilise the tear film and may promote ocular surface healing.

Dr Tan explained that the OSDI was chosen to assess dry eye severity in this study because it is a well-designed and validated questionnaire. The main outcome measures were the total OSDI score along with subscale scores for ocular symptoms, vision related function, and environmental triggers.

“Clinical assessment of objective signs of dry eye is important, and was performed in our study as well. However, the clinical signs may not correlate with the severity of symptoms experienced by patients, which is why the OSDI results were used for the primary determination of efficacy,” Dr Tan said.

Patients were excluded from the study if they had severe dry eye symptoms, punctal plugs, or concurrent ocular pathology. The enrolled patients had a mean age of about 32 years, and were similar in the two groups with respect to demographic features and mean OSDI scores prior to LASIK and after the surgery. As expected, the three subscale scores and the total OSDI score worsened after LASIK in both groups.

Both groups showed improvements in all



subscale and total OSDI scores after three weeks of treatment with their assigned artificial tears. The improvements were statistically significant in the Tears Naturale Free group for all of the OSDI scores and for the ocular symptom subscale and total OSDI score in the Blink Contacts group. The improvements in the vision related function and environmental triggers subscale scores in the Blink Contacts

group approached statistical significance.

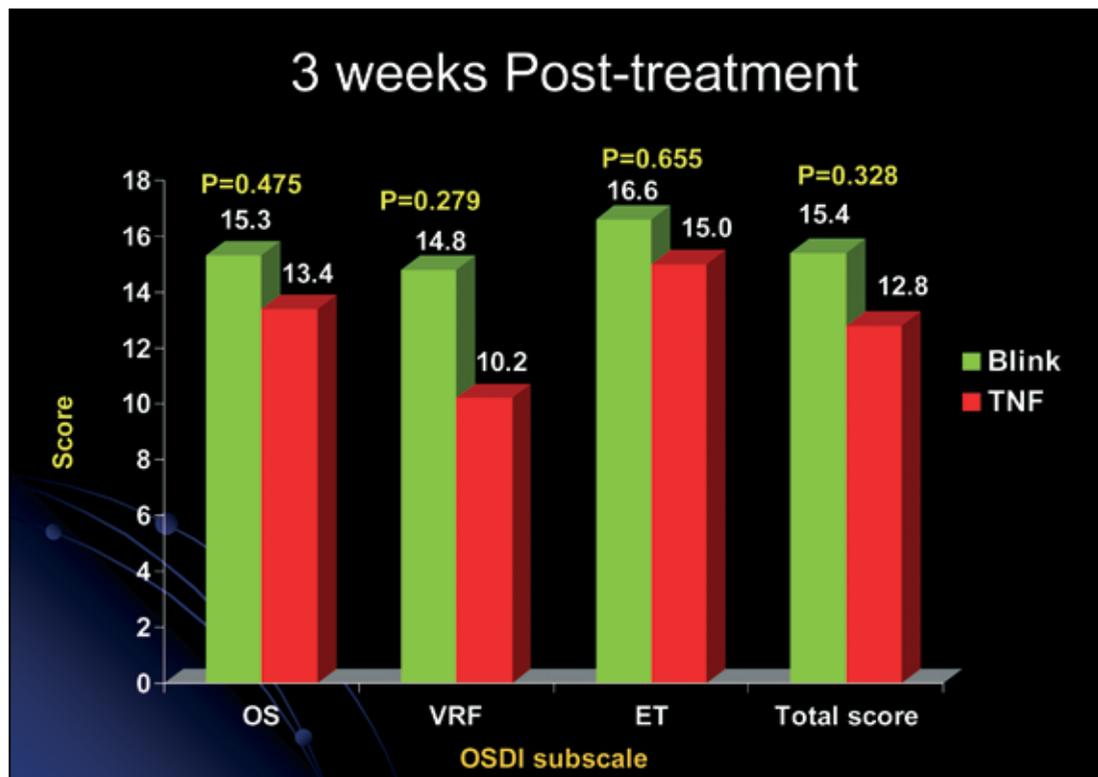
“Although the magnitude of change in scores was consistently greater in the Tears Naturale Free group and numerically, all mean scores at study completion were better in the Tears Naturale Free group as well, the final means for all of the OSDI scores were not significantly different between the two groups,” noted Dr Tan.

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# effective choice for managing dry eye



Courtesy of Colin S Tan MD

Ophthalmologists from Chulalongkorn University, Thailand, reported the results of a prospective, randomised, investigator-masked study comparing six months of treatment with a preservative-free 0.18 per cent sodium hyaluronate product (Vislube, TRB Chemedica) versus saline 0.9 per cent in 53 patients who had undergone LASIK.

A variety of objective and subjective

endpoints were evaluated, and the results showed consistent improvements in both groups, but with some benefits for the sodium hyaluronate product.

“Overall, the findings from our study showed this hypotonic sodium hyaluronate product was effective, safe, and well-tolerated when used after LASIK. Although differences between groups did not achieve statistical significance for

several of our outcome measures, perhaps our relatively small patient population limited our ability to detect a difference in favour of the sodium hyaluronate group,” said Usanee Reinprayoon, MD.

The patients included in the study had no history of dry eye prior to LASIK. All of the refractive procedures were performed using the Nidek EC-5000 laser. Patients were instructed to use their assigned treatment every two hours during the first 28 days after their surgery. For the last five months of the study, the frequency of administration was decreased to one drop four times a day.

Tear film stability at six months, assessed by measurement of tear film break-up time

(TBUT), was significantly longer in the patients using the sodium hyaluronate-containing product compared with the saline-treated controls, 7.98 vs. 7.0 seconds. Treatment with the sodium hyaluronate solution was also associated with a faster improvement in the impact of dry eye symptoms on activities of daily life, such as screen work, TV watching,

reading, and driving, and in measurement of tear production using the phenol red thread test.

“The phenol red thread test showed a faster recovery after surgery and a greater increase in tear volume in the sodium hyaluronate group compared with controls (19.5 vs. 14.24 mm/15 s).

In both treatment groups, the Schirmer I test (without anaesthesia) returned to normal by day 28 and there were no significant differences between groups in the result at any visit.

There were also no significant differences between groups in results of visual analogue

scale ratings of symptom severity or in fluorescein corneal staining.

## Option for severe dry eye

To manage patients with moderate-to-severe dry eye, Clive Peckar, MD, consultant ophthalmic surgeon, Warrington Hospital and Spire Cheshire Hospital, Warrington, UK, favours inferior canalicular occlusion as a strategy to increase the availability of natural tears on the ocular surface. He uses the reversible thermodynamic hydrophobic acrylic implant (SmartPlug, Medennium) and ocular lubricants, including 0.18 per cent sodium hyaluronate drops, as an adjunct as needed. In patients who remain symptomatic despite this combination approach, changing the ocular lubricant to 0.3 per cent sodium hyaluronate gel appears to be beneficial, according to Dr Peckar.

Since May, 2004, he has used this strategy in 20 patients with severe dry eye representing a variety of underlying diagnoses. A review of the experience showed that all 20 patients achieved considerable improvement in ocular comfort and precorneal tear film stability after changing from 0.18 per cent sodium hyaluronate drops to the more concentrated gel preparation. One patient with bullous keratopathy and corneal decompensation required a bandage contact lens to maintain comfort and was switched back to the 0.18 per cent sodium hyaluronate drops.

Dr Peckar attributes the increased therapeutic effect to the higher viscosity of the gel formulation and increased water retention afforded by the higher concentration of sodium hyaluronate.

“Sodium hyaluronate has several properties that make it useful for treating dry eye. It has an amphiphilic structure that allows it to trap and retain large volumes of water. In addition, it is muco-adhesive so it stabilises the tear film and promotes epithelial healing, and it has dynamic viscoelastic characteristics so that it provides a lubricating, protective film over the ocular surface but responds to shearing forces for ongoing comfort during blinking. Importantly, the 0.3 per cent gel is also a preservative free product. Therefore, issues relating to preservative-induced epithelial toxicity are not a concern,” said Dr Peckar.

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