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Treatment and benefits of Sorgyva® artificial tears in patients affected by alterations and dysfunctions of the cornea and lacrimal apparatus

David Ciacci[1], Francesca Jonsson[2]

[1] *Head of Ophthalmology, Chiros Srl, Turin, Italy; Director of Ophthalmology Service, Cidimu Group SpA, Turin, Italy; IRR Rehabilitations Institute, Turin, Italy*

[2] *Orthoptist and Ophthalmic Assistant, Chiros Srl, Turin, Italy; Ophthalmology Service, Cidimu Group SpA, Turin, Italy; IRR Rehabilitations Institute, Turin, Italy*

Contents

Treatment and benefits of Sorgyva® artificial tears in patients affected by alterations and dysfunctions of the cornea and lacrimal apparatus

Abstract

The objective of this 30 ± 5 day study was to evaluate the effectiveness of a tear substitute based on 0.2% hyaluronic acid and amino acids (Sorgyva®) in alleviating and improving the subjective discomfort experienced by patients with lacrimal dysfunction or corneal disorders.

A sample of 20 patients with severe subjective qualitative disorders of lacrimation, dry eye, corneal disorders or alterations, such as corneal dystrophies, keratopathies, epitheliopathies and/or outcomes of corneal transplants, was selected. The patients used the tear substitute over a period of 30 ± 5 days and were assessed for objective and subjective improvements by means of ophthalmological examination, specific tests, and questionnaires administered at baseline and after 30 ± 5 days of treatment tear film break-up time test, and Ocular Surface Disease Index questionnaire. All assessments were carried out at baseline and after 30 ± 5 days of treatment, and the results were compared. At the end of the study all patients completed a questionnaire investigating their satisfaction with the use of the eye drops.

The response and tolerance to the eye drops was reported to be good by most patients, with a significant improvement in the subjective discomfort caused by dysfunction of the lacrimal apparatus.

Keywords: corneal disorder, dry eye, lacrimal disfunction, tear substitute

Abbreviations: OSDI (Ocular Surface Disease Index), TFBUT (tear film break-up time)

Introduction

Dry eye syndrome is an ocular disorder caused by reduced tear production (hypolacrimia), excessive tear evaporation or altered tear quality and composition (dyslacrimia)[1,2].

Only in Italy, dry eye affects 25% of the population, most of whom women older than 45 years and with higher rates among postmenopausal women. In fact, dry eye syndrome is divided into primary and secondary, and the latter is a consequence of systemic diseases, such as those affecting the immune system (lupus, rheumatoid arthritis, Sjögren syndrome, etc.), or a consequence of hormonal changes (menopause, pregnancy, etc.). In addition, pollution and the prolonged exposure to computer screens typical of today's working conditions can lead to dry eyes, which can evolve to dry eye syndrome in predisposed patients.

Excessive evaporation of the tear film is also caused by a variety of factors, such as inflammation of the ocular adnexa, conjunctivitis, blepharitis, incorrect or excessive use of contact lenses, chronic intake of local therapy (e.g., hypotonizing agents in glaucoma) or systemic therapy (hormones, immunosuppressants, antihistamines, antidepressants, etc.), outcomes of surgical interventions (photorefractive keratectomy, phacorefractive surgery, cataract surgery, etc.)[2-4]. Lastly, advancing age also contributes to the onset of dry eye.

The main symptoms reported by the patients are ocular pain, foreign body sensation, redness, burning, blurred vision, increased blinking, and photophobia. Paranasal disorders may also commonly be associated, as occurs in seasonal allergies.

Ophthalmological assessment involves taking a careful ophthalmological history, eliciting the patient's symptoms, carrying out a complete eye examination to detect the objective signs of dry eye using slit-lamp biomicroscopy and, finally, performing diagnostic tests, such as the tear film break-up time (TFBUT) test, the Schirmer test, meibography, and a tear osmolarity test, to determine the extent of dry eye and the severity of the patient-reported disorders[2,5].

Aim

The objective of this study was to evaluate whether treatment with a new tear substitute could improve the patients' subjective disorders and thus visual well-being and if this result corresponded to an objective improvement of the ocular parameters measurable through diagnostic tests and/or eye examination.

Materials and methods

The study was conducted on a sample of 20 patients suffering from congenital or acquired disorders of the cornea (cornea guttata, keratopathies, epitheliopathies, corneal dystrophies) and lacrimal alterations with severe subjective disorders. The sample was selected from a larger population of patients who were assessed and interviewed in order to exclude those affected by pathological conditions that could reduce sample homogeneity or cases that could interfere with the study objectives and results[6,7].

The subjective and objective effectiveness of the treatment with artificial tears was evaluated based on the following parameters assessed at baseline and after 30 ± 5 days of treatment: complete ophthalmological examination, TFBUT test results, and Ocular Surface Disease Index (OSDI) score; in addition, at the end of the 30 ± 5 day treatment period, patients were administered an individual questionnaire investigating patient satisfaction with the use of the artificial tears.

The study lasted a total of 30 ± 5 days and was divided into two main phases:

- 1st visit (time 0) in which patients underwent a complete eye examination, TFBUT testing, and OSDI evaluation;
- 2nd visit (time 0 + 30 ± 5 days) in which patients underwent an eye examination to check treatment adherence and tolerance, an interview to verify correct use of the eye drops, TFBUT testing, OSDI evaluation, and an additional questionnaire investigating patient satisfaction with the use of the eye drops. A final global evaluation by the ophthalmologist was also carried out.

The TFBUT test, which measures the time it takes the tear film to break up on the corneal surface, was performed using the SIRIUS instrument without the use of fluorescein and instructing the patients to blink twice and then to keep the eyes open as long as possible. The OSDI questionnaire was used to investigate the effect of symptoms on the patients' daily life.

The new Sorgyva® product is a preservative-free multidose eye drop solution with 0.2% sodium hyaluronate, L-leucine and L-lysine hydrochloride. Sodium hyaluronate, combined with amino acids, is able to form a protective film on the ocular surface that provides protection and hydration to the eye. The amino acids contained in the formulation help to improve the distribution and adhesion of sodium hyaluronate on the corneal surface, favoring its hydration and protective effect and, as precursors of the mediators of cellular protein synthesis, they promote re-epithelialization and reduction of damage to the ocular surface. Patients were instructed to instill the Sorgyva® eye drops 3 times a day in combination with other ongoing therapies for corneal alteration and lacrimal dysfunction.

Particular attention was paid to the method of instillation, the number of instillations and the consistency of treatment over the 30 ± 5 day study period. The eye drops were provided by our office to all patients.

All patients were highly selected and particularly motivated and willing to use the eye drops owing to their clinical situation, and they attended all of the scheduled visits, allowing for accurate assessment of the results.

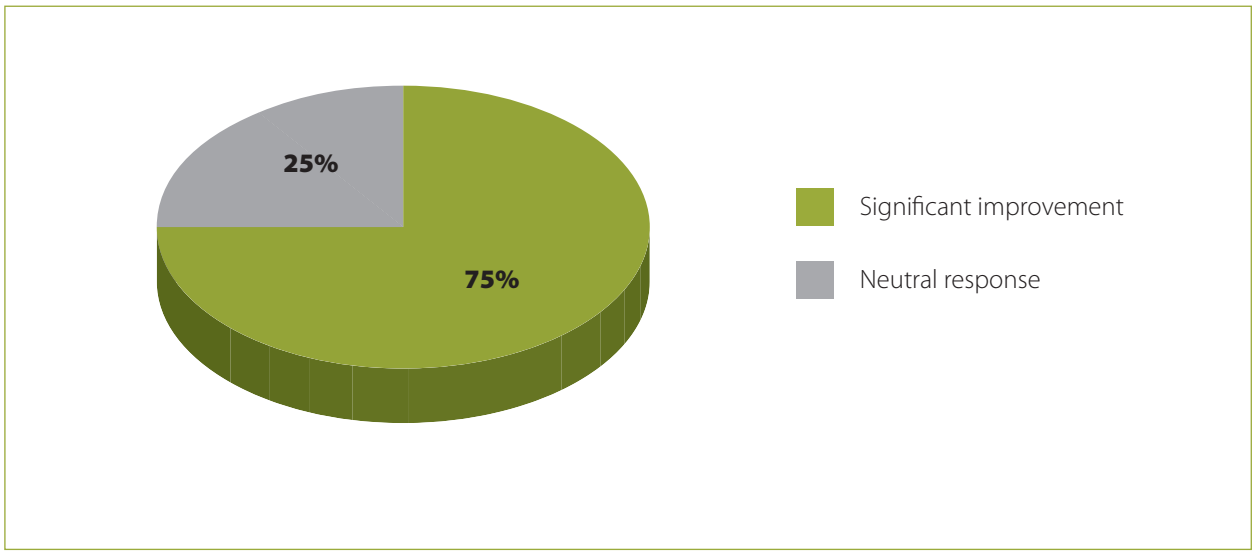
Results

A total of 20 patients were studied over 30 ± 5 days, and all patients completed the study. Considering the subjective results based on the patient-satisfaction questionnaire, a general subjective improvement was reported by all patients who used the eye drops with good tolerance and good compliance with the tear substitute. Patients reported a subjective improvement in disorders and quality of life, expressing their intention to continue using the eye drops, and in many cases asking for additional samples. In particular, out of 20 patients, 15 reported a significant improvement in symptoms and ocular disorders and 5 patients had a neutral response (i.e. no improvement) to the use of the eye drops (**Figure 1**).

From an instrumental and diagnostic point of view, the TFBUT test did not show any particular changes or improvement, as the study was carried out in a limited time frame of only 30 ± 5 days, which is considered insufficient to highlight any appreciable change in this parameter. A slight improvement occurred in only 4 patients but this was not clinically significant. The average TFBUT values measured at the beginning of the study varied from 2 to 6 and no appreciable variations were detected after 30 ± 5 days of treatment with the tear substitute.

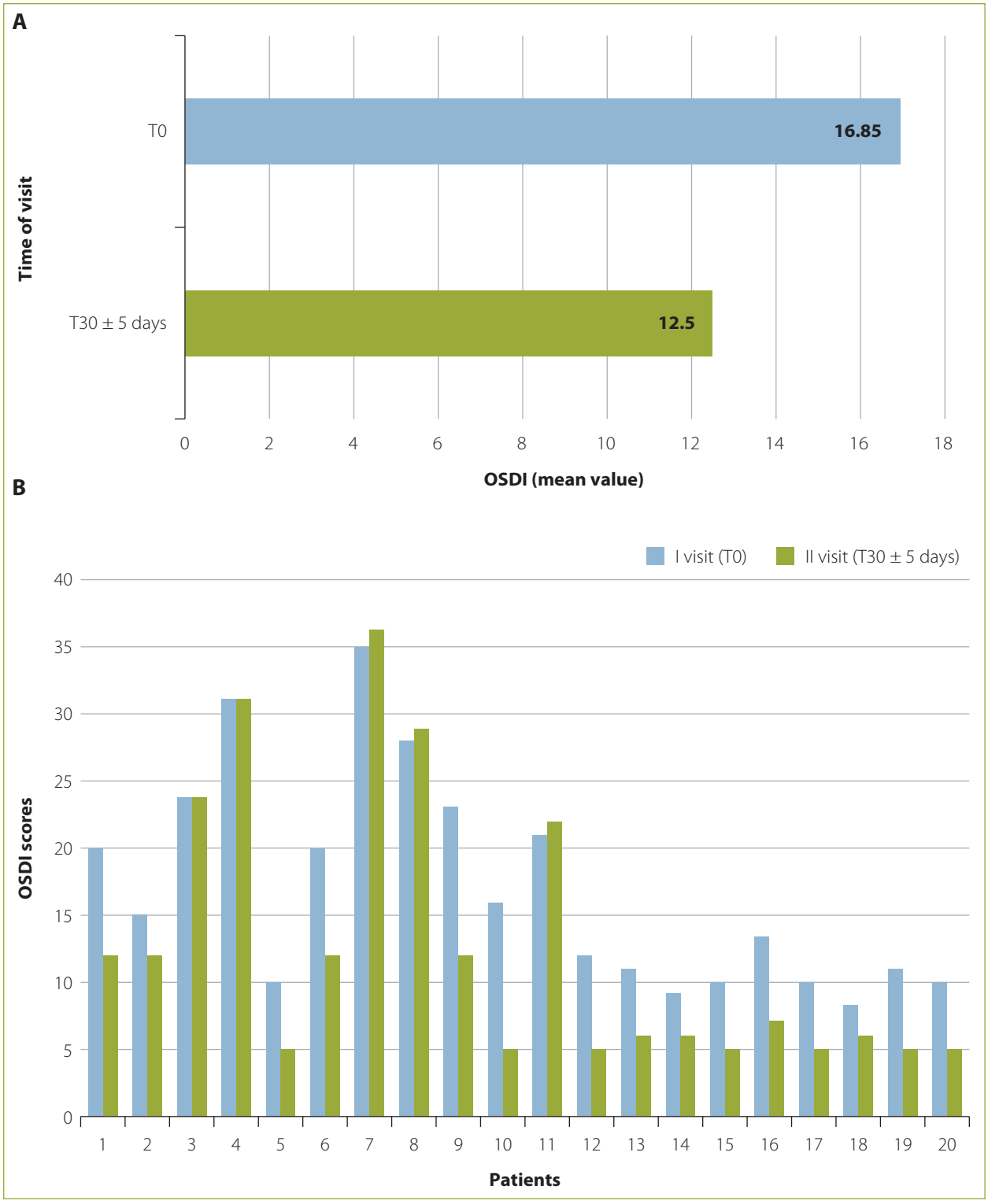
A particular improvement was instead high-

Figure 1. Improvement in symptoms evaluated as the percentage of patients with significant improvement or neutral response measured by means of the patient-satisfaction questionnaire at 30 ± 5 days. Total number of patients: 20.



lighted by the scores of the OSDI questionnaire administered to patients at the beginning and at the end of the study (**Figure 2**, **A** and **B**), reflecting a reduction of ophthalmological discomfort in the patients' daily life; likewise, the final questionnaire investigat-

Figure 2. OSDI measured at baseline (T0) and at the end of the study (T30 ± 5 days), showing the reduction in scores. **A**, mean OSDI scores at T0 and T30 ± 5 days; **B**, OSDI scores for each patient at T0 and T30 ± 5 days. Total number of patients: 20.



ing patient satisfaction with the Sorgyva® eye drops was of great significance, and allowed evaluation of the tolerance (**Figure 3**) and benefits (see **Figure 1**) of the tear substitute. **Figure 4** shows the final evaluation of improvement by the ophthalmologist.

Figure 3. Tolerance evaluated with the patient-satisfaction questionnaire at T30 ± 5 days, as the percentage of patients with good/excellent or poor tolerance of the tear substitute. Total number of patients: 20.

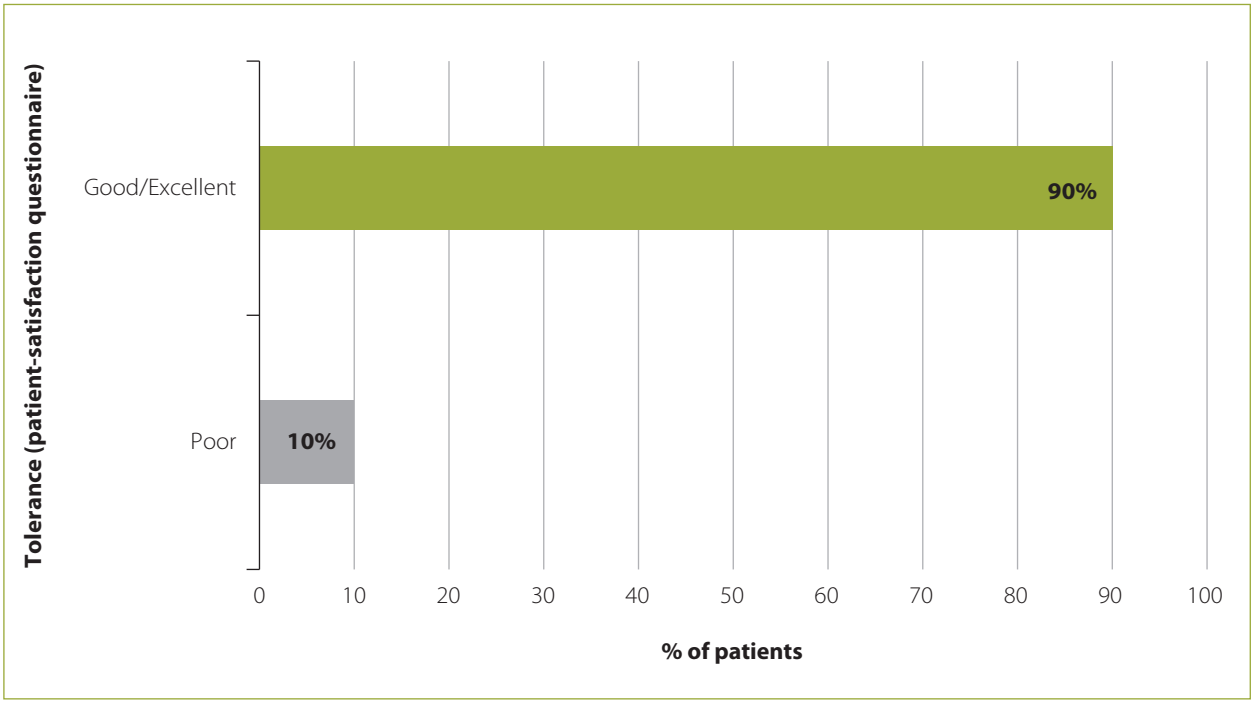
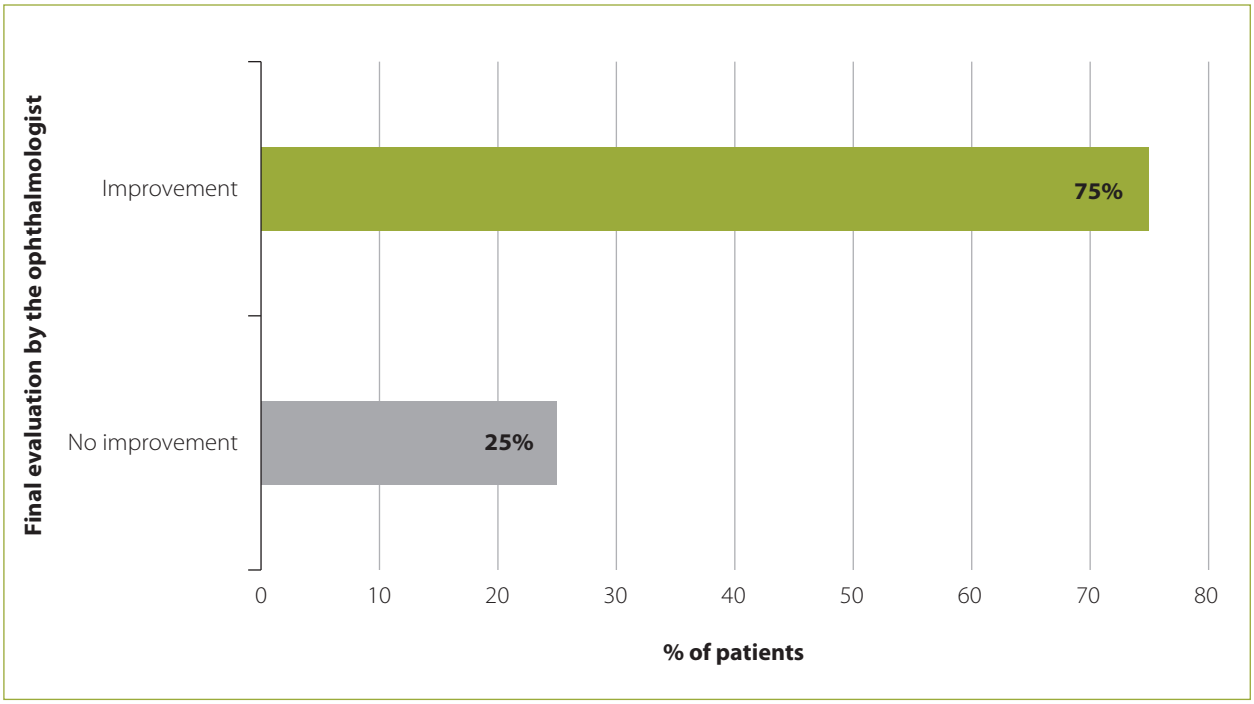


Figure 4. Final evaluation by the ophthalmologist at T30 ± 5 days: percentage of patients with improvement or no improvement after the treatment with the tear substitute. Total number of patients: 20.



Conclusions

Sorgyva® eye drops were used over a period of about 30 ± 5 days by a sample of 20 patients who presented with lacrimation disorders and corneal alterations.

The patients' subjective response and tolerance were excellent, with reports of benefits appearing immediately after the first instillation and persisting for up to 5-6 hours thereafter. The eye drops were very well tolerated by all patients, who showed good compliance with the product over the days and weeks following first use.

Ophthalmologically, the use of Sorgyva® eye drops allowed a reduction of the patients' self-reported complaints and symptoms, and ophthalmological examinations at 1 month showed a reduction in inflammatory phenomena or previously noted epitheliopathy, with a reduction in conjunctival hyperemia.

Importantly, almost all patients reported a qualitative improvement in vision and subjective discomfort, with only a small percentage reporting no improvement or a neutral response to the use of the eye drops.

In summary, the use of Sorgyva®, which may be combined with pharmacological therapy, seems to lead to a qualitative improvement in the patients' vision with lessening of all subjective symptoms related to lacrimal disorders, keratopathy or corneal dystrophy, and is therefore associated with a better subjective quality of life for the patients.

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