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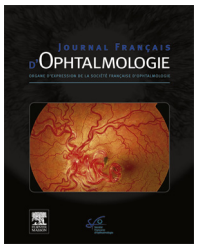

ARTICLE ORIGINAL

Comparison of objective optical quality measured by double-pass aberrometry in patients with moderate dry eye: Normal saline vs. artificial tears: A pilot study

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Summary Dry eye is defined by a tear film instability resulting in variable but systematic fluctuations in quality of vision. Variability in optical quality can be demonstrated using a double pass aberrometer such as the Optical Quality Analyzing System, Visiometrics (OQAS). The goal of this work is to compare fluctuations in objective quality of vision measured by OQAS between treatment with normal saline eye drops and treatment with carmellose 0.5% and hyaluronic acid 0.1% (Optive Fusion [OF], Allergan) in patients with moderate dry eye syndrome. Optical quality was measured by evaluating the variations in the Optical Scattering Index (OSI) over 20 seconds using the OQAS. Inclusion criteria were dry eye syndrome with an ocular surface disease index (OSDI) score > 23 treated only with artificial tears. The patients were their own controls: OF in one eye and normal saline in the fellow eye. The choice of the subject eye and control eye was determined in a randomized fashion. OSI variations were measured in each eye before instillation, 5 minutes and 2 hours after instillation. The primary endpoint was OSI fluctuation over 20 seconds of measurement. Secondary endpoints were the number of blinks and patient preference (preferred eye). Preliminary results were obtained on 19 patients. Average OSDI score was 36.8. Visual acuity was 10/10 with no significant difference between the two eyes. Prior to instillation, there was no significant difference between ''normal saline'' and ''OF'' eyes in terms of OSI, OSI variability or number of blinks. In the normal saline eye, there were no significant variations in mean OSI, OSI variability, OSI slope, or number of blinks. However, in

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the ''OF'' eye, there was a significant variation between initial and 2-hour OSI variability (0.363 versus 0.204, $P < 0.05$), the average slope of OSI (0.04 versus 0.01, $P < 0.05$) and the number of blinks (4.2 versus 2.8, $P < 0.05$). Among the patients, 65% preferred the OF eye, 24% did not have a preference, and 11% preferred the normal saline eye. Objective quality of vision measured by OQAS is an interesting parameter for evaluating the effectiveness of a lacrimal substitute. The purpose of artificial tears is, among other things, to provide comfort and a reduction of dry eye symptoms such as poor quality of vision. This study demonstrates that 0.5% carmellose and 0.1% hyaluronic acid allowed better stabilization of the tear film and thus a significant improvement in the quality of vision compared to normal saline.

Dry eye syndrome is a multifactorial disease of the tears and the ocular surface, causing symptoms of ocular discomfort, visual difficulties and instability of the tear film, which may be associated with ocular surface lesions [1]. This chronic pathology, the high prevalence of which increases with age, reaches almost 15 to 20% of patients over 65 years of age [2]. The management of patients with dry eye syndrome is sometimes confusing for the practitioner due to a significant mismatch between functional symptoms described by the patient and clinical signs. In addition to discomfort or pain, a number of patients report blurred, fluctuating or poor quality vision, while the clinical examination seems relatively normal to the clinician. In fact, in addition to the mechanical, antibacterial and metabolic functions of the tear film, it performs an essential optical role, since it insures the regularity of the anterior surface of the cornea [3,4]. Thus, with a mean thickness of 30 to 40 μm, the tear film is the primary refractive surface of the eye (almost 60% of the total refractive power) due to the air-tear film interface and the corneal curvature. Tear instability in dry eye syndrome thus causes a direct visual effect; variable but systematic. This alteration in the quality of vision is directly related to increased optical higher order aberrations (HOA) and increased light diffusion phenomena induced by irregularity of the tear film. A direct link has thus been demonstrated between severity of the dry eye and the level of HOA [5,6] and between the intensity of the dry eye syndrome and diffusion of light [7]. In this manner, Hartmann-Shack or double-pass aberrometers, which evaluate fluctuations in measurements during continuous recording, allow for an appreciation of the functional effects of dry eye, notably in mild to moderate cases.

Tear substitutes are the foundation of dry eye treatment. Well beyond simple wetting agents, the specific pharmacologic properties of modern forms of these substitutes allow for at least partial stabilization of the tear film. From this comes a beneficial improvement for patients in the optical quality of the tear film. Several studies have thus found functional improvement in terms of visual acuity [8], HOA [9,10], contrast sensitivity [11—13] or optical diffusion of light [14] after instillation of tear subsitutes.

The purpose of this study is to compare, in patients with moderate dry eye syndrome, the fluctuations in objective quality of vision measured by Optical Quality Analyzing System, Visiometrics (OQAS) double-pass aberrometry, between treatment with normal saline and with 0.5% carmellose and 0.1% hyaluronic acid (Optive Fusion®, Allergan laboratories).

Materials and methods

We performed a single-center (Tours university research medical center), prospective, comparative study of normal saline vs. 0.5% carmellose and 0.1% hyaluronic acid (Optive Fusion® or OF, Allergan) using a single-blind design: with the patient as his/her own control (one ''control'' eye: normal saline and one ''test'' eye: OF). The choice of test eye and control eye was determined in a randomized fashion. The study was performed in accordance with preferred practice patterns and with the Helsinki declaration.

Patients over 18 years with bilateral moderate dry eye who met the following inclusion criteria were included between August and October 2016:

- symptoms suggestive of bilateral dry eye with an OSDI score ≥ 22 consistent with moderate dry eye;
- use of tear substitutes for at least 3 months and at least 3 times per day;
- global corneal staining score ≥ 4 and ≤ 9 on the Oxford scale and at least one of the following objective signs:
  - unanesthetized Schirmer's test ≥ 3 mm and ≤ 9 mm/5 minutes;
  - or 3 consecutive measurements of tear break-up time (BUT) ≤ 10 seconds.

The exclusion criteria were:

- difference in visual acuity between the two eyes > 2 lines or best corrected visual acuity < 5/10 in at least one eye;
- use of eye drops other than artificial tears (glaucoma drops) or contact lenses;
- severe dry eye with one of the following problems: lid abnormalities, severe blepharitis, corneal opacities, ocular surface metaplasia, filamentary keratopathy, corneal neovascularization;
- history within the prior 3 months of ocular trauma, infection or inflammation;

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