



Effects of Sodium Hyaluronate plus Hydrocortisone Sodium Phosphate Eye drops on Signs and Symptoms of Patients with Dry Eye Disease

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Purpose

To examine the changes of ocular surface parameters in patients with dry eye disease (DED) instilling hyaluronate/hydrocortisone 0.001% eye drops *versus* hyaluronate/trehalose 3% eye drops.

Methods

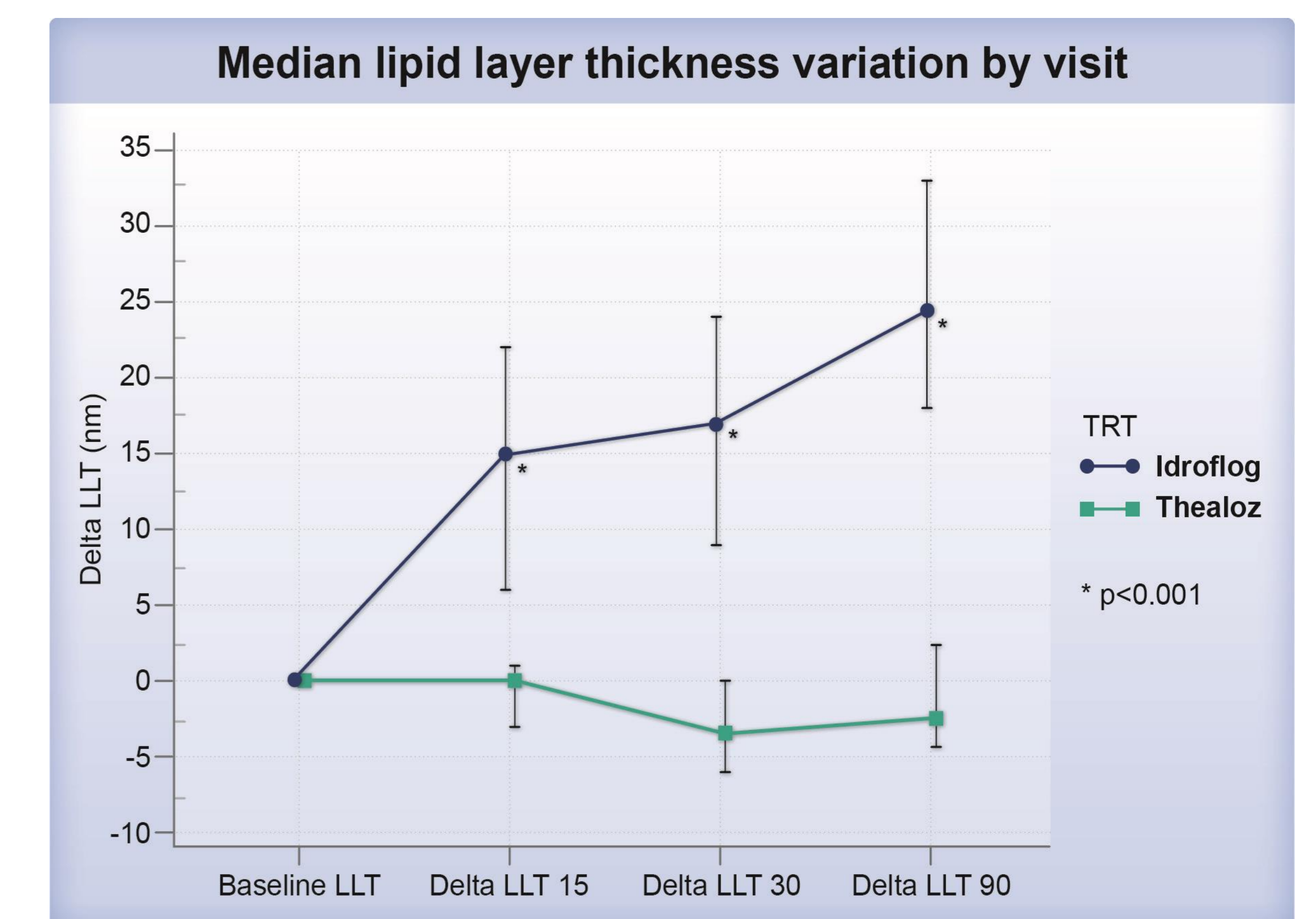
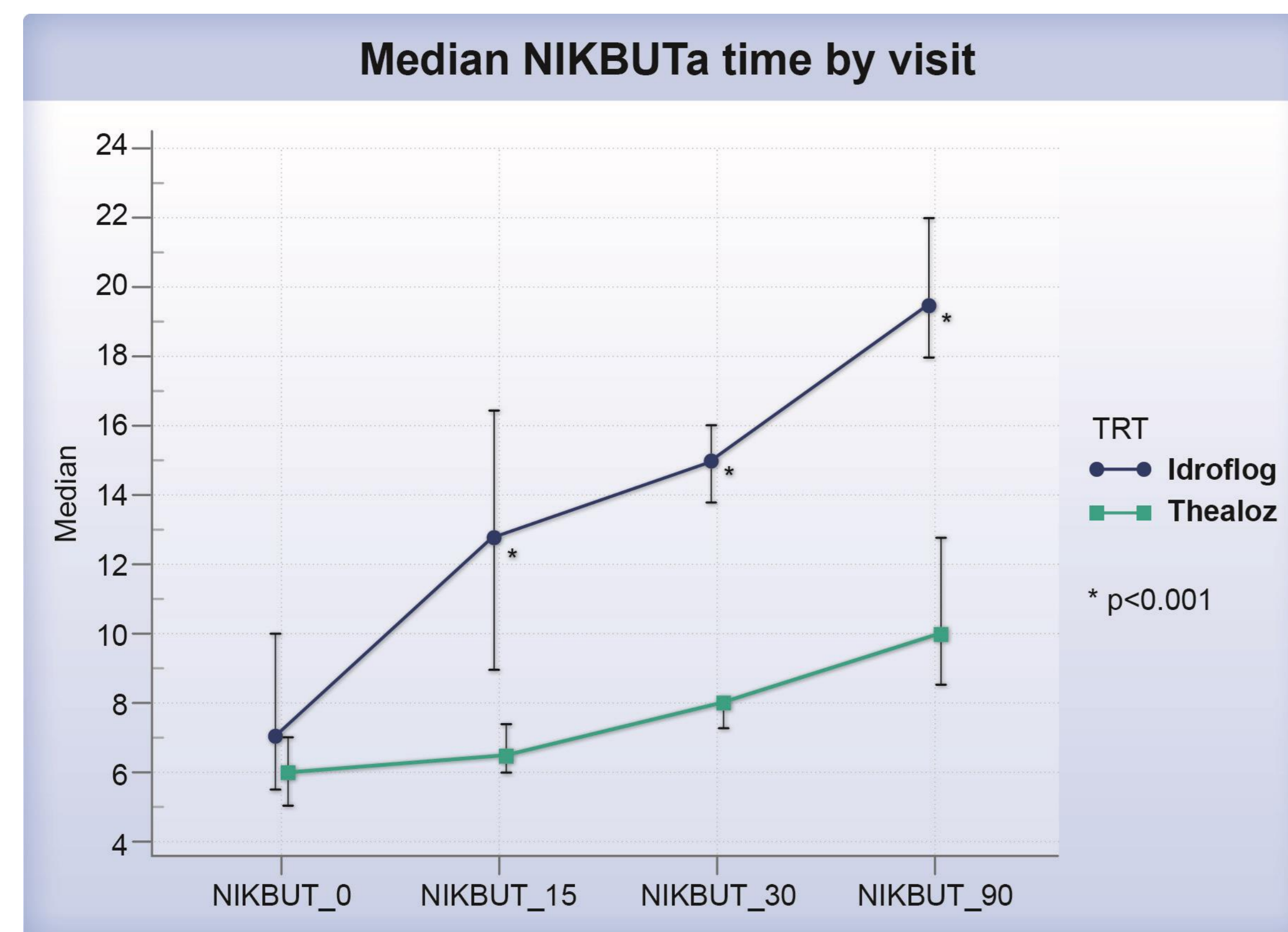
Thirty-eight patients (19 males, 19 females, mean age 51 years) affected by mild-moderate DED associated with meibomian gland dysfunction (MGD) were enrolled; inclusion criteria were non-invasive Keratograph breakup time average (NIKBU_{Ta}) <14 sec plus lipid layer thickness (LLT) <75 nm and/or ocular surface disease index (OSDI) score between 13 and 32. Of these, 19 patients were treated with **an artificial tear substitute containing sodium hyaluronate 2 mg/ml plus hydrocortisone sodium phosphate 10 mcg/ml (group 1, study group Idroflog)** whereas 19 patients were treated with **an artificial tear substitute containing sodium hyaluronate 1,5 mg/ml and trehalose 30 mg/ml (group 2, control group Thealoz)**. The posology was 1 drop 4 times/day for 3 months for both groups. Patients were examined at baseline (T₀), day 15 (T₁), day 45 (T₂) and day 90 (T₃) by means of Keratograph 5M[®] for NIKBU_{Ta} and LipiView[®] for LLT. Symptoms of ocular discomfort were scored at the same time points by means OSDI questionnaire.

Results

A statistically significant difference was found at all follow up visits between the 2 groups in terms of **NIKBU_{Ta}** (median value in group 1 vs group 2 was respectively at T₀=7.0 sec vs 6.0; p= 0.162 ; while at T₁=12.8 vs 6.5; at T₂=15.0 vs 8.0; at T₃=19.5 vs 10.0; **p<0.001**) and in terms of **variation of LLT** (Delta-LLT group 1 vs group 2 was: ΔT₁-T₀=15 vs 0 nm; ΔT₂-T₀=17 vs -3.5; ΔT₃-T₀=24.5 vs -2.5; **p<0.001**).

Only eyes belonging to group 1 showed a significant increased of the LLT at all visits vs T₀ (median T₁=78 nm; T₂=87; T₃=97 vs T₀=63; p<0.001).

Both groups showed a significant decreased of the OSDI score at all the visits (p<0.001), without significant difference between groups.



Conclusions

Both treatments determined a significant amelioration of ocular discomfort symptoms. However, hyaluronate/hydrocortisone eye drops showed a statistically significant better performance in terms of increase of NIKBU_{Ta} and LLT compared to hyaluronate/trehalose eye drops. Probably the low dose of hydrocortisone is useful to improve tear film stability in patient affected by MGD-associated DED, reducing the inflammation of meibomian glands and consequently allowing a higher production of the lipid layer.