

Semifluorinated Alkane Eye Drops for Treatment of Dry Eye Disease – A Prospective, Multicentre, Non-Interventional Study*

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Purpose: Evaporation and meibomian gland dysfunction are discussed as core reasons for dry eye disease (DED). Recently the novel substance perfluorohexyloctane, a semifluorinated alkane, has been introduced as a non-blurring, preservative-free wetting agent that reduces shearing forces between surfaces. After successful preclinical testing perfluorohexyloctane has been approved as a medical device (EvoTears®). A non-interventional study was undertaken in patients with mild to moderate DED.

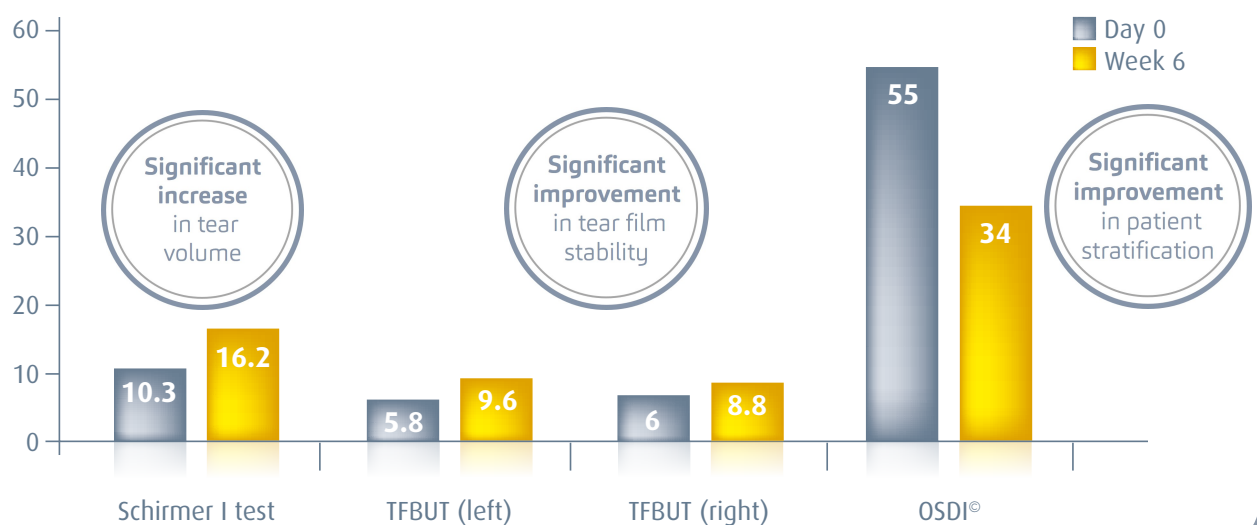
Methods: 30 Patients with evaporative DED were included in an open, prospective, uncontrolled post-market clinical follow-up study after providing their informed consent. The patients applied perfluorohexyloctane 4 times daily in both eyes for 6 weeks. Clinical examinations included visual acuity, intraocular pressure (IOP), Schirmer I test, tear film break-up time (TFBUT), corneal fluorescein staining and meibum secretion. In addition each patient completed a questionnaire similar to the Ocular surface disease index (OSDI®: questionnaire for the identification and quantification of common dry eye symptoms).

Results: Visual acuity and IOP did not change with time, Schirmer I test increased significantly ($p = 0.0011$) from 10.3 to 16.2 (mean of both eyes). TFBUT also increased significantly from 6.0 to 8.8 ($p = 0.0026$) and from 5.8 to 9.6 ($p = 0.0006$) in the right and left eye, respectively. Ocular surface staining decreased significantly

in the right ($p = 0.0013$) and left eye ($p = 0.0041$) and the OSDI® decreased highly significantly ($p < 0.0001$) from 55 to 34 (mean of both eyes). Symptoms such as redness, itching etc. improved whereas meibum quality only improved in some patients. A total of five adverse events were reported of which two were unrelated to the substance tested, two were likely to be unrelated and one was related. The latter showed itself as a mild hypersensitivity which resolved immediately following discontinuation of treatment.

Conclusions: This first prospective non-interventional study of perfluorohexyloctane shows beneficial effects in patients suffering from evaporative DED. In particular, tear film stability and tear production increased, while corneal staining and OSDI® score decreased significantly. Perfluorohexyloctane was well tolerated and the low number of adverse events proved the safe application of this new type of preservative-free artificial tear in evaporative DED.

Non-Interventional Study in Evaporative Dry Eye Patients*



* Steven, P. et al. J Ocul Pharmacol Ther, 2015. 31(8): 498-503.