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Objective. The Italian Register of Patients affected by Tear Dysfunction was born on 2008.

Tear Dysfunction (a term which can replace the more familiar but less correct term of "dry eye") affects people of any age, with particular frequency in adults over 40 years old.

This definition indicates a multifactorial disease of tears and ocular surface, associated with symptoms of ocular discomfort, visual disturbances, tear film instability and epithelial damage, connected to hyper-osmolality and ocular surface inflammation (1-9).

According to the Women's Health Study (WHS) and the Physicians' Health Study (PHS) about 4.91 million over fifty-year-old Americans, suffer from Tear Dysfunction (TD). Furthermore, the use of contact lenses (CL) and the habit of spending several hours on the computer is frequently associated with TD.

TD can be considered as an emerging pathology related to the increase of the causes which determine its onset, such as **air pollution, the increasingly massive use of audiovisual media** (computers, video games, television, PDA etc.), **the spread of certain therapies and types of surgery**, directly correlated to lengthening of life expectancy (10-16).

The aim of the Register is

- taking a census of patients suffering from Tear Dysfunction;
- entering the most notable data, at a personal and a clinical level, in an **on-line Case History Chart**,

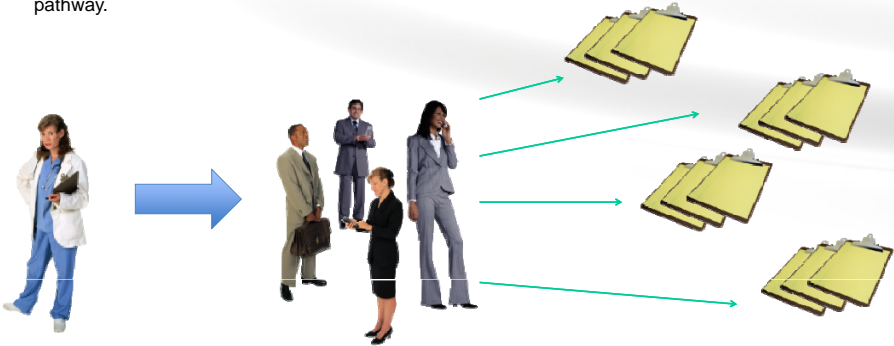
to which only authorized Ophthalmologists may gain the access.

With the web based Case History, patients with Tear Dysfunction will be diagnosed and followed according to the most updated parameters. This census will allow to start to have an idea of the spread of this disease in the Italian population and ultimately to treat it better.

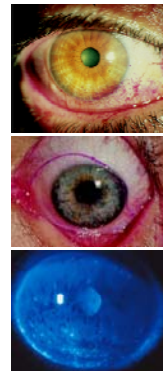
The build-up of a Register will have a social relevance more than just a clinical one: for the first time in Europe and in the World we can take a picture, follow and manage this disease.

Need of a Register of Patients with Tear Dysfunction

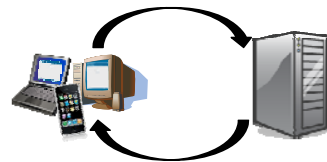
- High prevalence of the disease (16-30% of the population);
- Uncertainty about causes and build-up of the disease;
- Variability of Clinical Presentations:
 - unknown correlation between clinical features and causes of the disease;
 - unknown correlation between clinical features and symptom presentation;
 - unknown correlation between clinical features and evolution of the disease;
 - lack of validated, aimed therapies for each clinical presentation.
- Uniform data collection by all participating ophthalmologists on the basis of "evidence based" significant parameters:
 - each Eye Doctor takes part of an ongoing process of learning of up to date diagnostic techniques
 - the diagnostic process can be free and limited on the judgment of the Eye Doctor but in a standardized pathway.



1. Begley CG, Chalmers RL, Abetz L, et al. The relationship between habitual patient-reported symptoms and clinical signs among patients with dry eye of varying severity. *Invest Ophthalmol Vis Sci* 2003; 44:4753-61. 2. Adatia FA, Michaeli-Cohen A, Naor J, et al. Correlation between corneal sensitivity, subjective dry eye symptoms and corneal staining in Sjogren's Syndrome. *Can J Ophthalmol* 2004; 39:767-71. 3. Rieger G. The importance of the precorneal tear film for the quality of optical imaging. *Br J Ophthalmol* 1992; 76:157-8. 4. Rolando M, Iester M, Macri A, Calabria G. Low spatial-contrast sensitivity in dry eyes. *Cornea*. 1998 Jul;17(4):376-9. 5. Goto E, Nagi Y, Matsumoto Y, Tsubota K. Impaired functional visual acuity of dry eye patients. *Am J Ophthalmol* 2002; 133:181-6. 6. Holly F, Lemp MA. Formation and rupture of the tear film. *Exp Eye Res* 1973; 15:515-25. 7. Farris RL, Stuchell RN, Mandel ID. Tear osmolality variation in the dry eye. *Trans Am Ophthalmology Soc* 1986; 84:250-68. 8. Plugfelder SC, Jones D, Ji Z, et al. Altered cytokine balance in the tear fluid and conjunctiva of patients with Sjogren's syndrome keratoconjunctivitis sicca. *Curr Eye Res* 1999; 21:221-32. 9. Schein OD, Munoz B, Tielsch JM, et al. Prevalence of dry eye among the elderly. *Am J Ophthalmol* 1997; 124:723-8. 10. Moss SE, Klein R, Klein BE. Prevalence of and risk factors for dry eye syndrome. *Arch Ophthalmol* 2000; 118:1264-8. 11. Schaumburg DA, Sullivan DA, Buring JA, Dana MR. Prevalence of dry eye syndrome among US women. *Am J Ophthalmol* 2003; 136:318-26. 12. Miljanovic B, Dana MR, Sullivan DA, Schaumburg DA. Prevalence and risk factors for dry eye syndrome among older men in the United States. *Invest Ophthalmol Vis Sci* 2007; 13. Moss SE, Klein R, Klein BE. Long term incidence of dry eye in an older population. *Optom Vis Sci* 2008 Aug;85(8):668-74. 14. Viso E, Rodriguez-Ares MT, Gude F. Prevalence of and associated factors for dry eye in a Spanish adult population (the Salnes Eye Study). *Ophthalmol Epidemiol* 2009 Jan-Feb; 16(1):15-21. 15. Uchino M, Schaumburg DA, Dogru M, Uchino Y, Fukagawa K, Schimmura S, Satoh T, Takebayashi T, Tsubota K. Prevalence of dry eye among Japanese visual display terminal users. *Ophthalmology* 2008 Nov; 115(11):1982-8. 16. Uchino M, Dogru M, Uchino Y, Fukagawa K, Schimmura S, Satoh T, Takebayashi T, Schaumburg DA, Tsubota K. Japan Ministry of Health Study on prevalence of dry eye among Japanese high school students. *Am J Ophthalmol* 2008 Dec; 146(6): 925-9.



Method. To enter patients' data in a web based Case History Chart, the Ophthalmologists need to connect to the Lacrima® website, at the URL www.occhiosecco.it, and fill in the Registration Form in the reserved area.

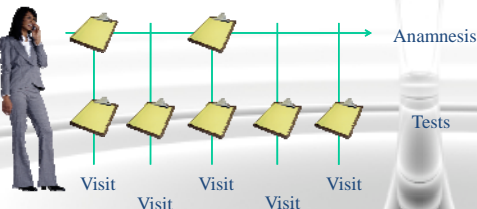
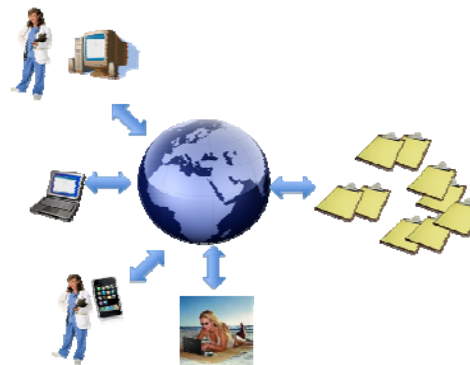


The web-based Case History Chart was aimed to manage the online patient case history, enabling the Ophthalmologists to manage their patients database using any personal computer and an internet connection everywhere and every time they need.

The Register's subscriber is provided with a Username and a Password which give the access to his own patients' case histories.



The structured Case History Chart provides a guide to step by step input of clinical as well as anamnestic information about life style environment or medical conditions, according to the latest indications of scientific knowledge. This leads to shareable homogeneous data available for consultation and statistical evaluations.



The **Identity Code**, that will preserve patients' privacy, also allows the patient to require a second opinion to another Ophthalmologist. The server, where the case history and the website are housed, is a devoted server equipped with a 128bit SSL certificate: this is the same protection of the home-banking web-site. The server-farm is provided with anti-intrusion measures, anti-flooding, generators, anti-fire, back-up systems and remote control. Moreover, the Register has been provided with useful facilities such as Informed Consent Form for data treatment, encryption of sensible data and daily back-up.

To guarantee patients' privacy, personal data are also stored into the server separately from the case history, and these are encrypted.



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Conclusion. The purpose is to create a network of centers across Italy and possibly world-wide that will operate accordingly the most up-to-date guidelines on the approach to the patient affected by Tear Dysfunction.

The identified Pool of Specialists over the years will perform further studies, meetings and seminars to improve their culture on Tear Dysfunction, to compare with colleagues and to give life to new approaches to this disease.

The data processing system will map out all users who had previously inserted/modified the case history data.

The List of Ophthalmologists afferent to the Register will be visible on the appropriate website at the URL www.occhiosecco.it: it will be constantly updated and it will bring together all those who wish to be at the cutting edge in knowledge of Tear Dysfunction, allowing patients to easily reach interested and competent ophthalmologists.



Benefits for the patient

- he or she will be able to be followed nationwide, through the ophthalmologist's Network, so that costs deriving from diagnostic or therapeutic contradictory overlappings, will be cut down
- the evaluation of the data collected will allow to:
 - improve diagnostic methods
 - evaluate of the efficacy of therapeutic approaches
 - give new therapeutic indications to treat the disease.

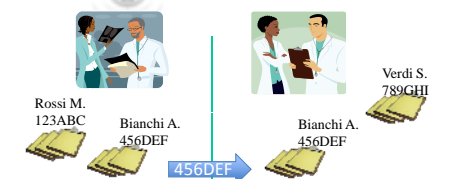
Benefits for Ophthalmologists and Researchers

- will have free access to the Web Based Case History Chart
- will be able to reach, control and update in every moment the chart of his own patients
- filling in a minimal number of charts, if he/she likes, he/she will be able to participate to studies, statistical evaluations and disease revisions including the patients he/she collected.
- will be constantly updated on the information obtained through the Register
- have hints on frequency and characteristics of the different presentations of the disease
- understand patients needs
- spread and uniform data collection according to the international guidelines
- easy data exchange between colleagues of the same or different specialties (ophthalmologists, gynecologists, rheumatologists etc.)
- produce diagnostic protocols and more efficient therapies
- warn and encourage the Competent Authorities to care about the disease
- improving social support for patients



A personal **Identity Code** will be linked to each patient: this code allows the **specialist** to require a second opinion to a colleague afferent to the Lacrima® network.

With patient permission, the data will be easily available to other ophthalmologists to obtain a second opinion from a colleague afferent to Lacrima® network.



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