

## METHOD OF EARLY DIAGNOSIS OF GLAUCOMA

### DESCRIPTION OF THE TECHNOLOGY

Glaucoma (GL) is a multifactorial neurodegenerative disease that includes a group of optic neuropathies that lead to irreversible blindness and with it, loss of quality of life. It is characterized by the progressive loss of retinal ganglion cells, responsible for transducing information from the retina to the brain. This disease affects 15 million people worldwide and 1 million people in Spain. The main risk factor for the disease is ocular hypertension (OHT), and the only treatment is hypotensive, although it does not prevent the progression of this neuropathy. Primary Open Angle Glaucoma is the most common form of glaucoma (POAG).

According to the WHO, glaucoma is one of the preventable blindnesses, since early identification of the subject with OHT, and immediate instauration of hypotensive treatment is the only way to counteract the inevitable evolution towards optic neuropathy and vision loss.

A fundamental concept in understanding the danger posed by OHT to the eyes and vision is that OAG is asymptomatic in its early stages. It is referred to as "the silent thief of vision". That is why ophthalmologists and vision science researchers have been trying for many years to find clinically usable biomarkers as a diagnostic alternative for POAG and to develop new therapies.

Researchers from the Universitat Politècnica de València, Universitat de València and the Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO) have developed an in vitro method for the early detection, diagnosis and prognosis of POAG using a tear sample. The method also allows follow-up in patients already diagnosed.

The developed method consists of a metabolomic analysis by high-field NMR spectroscopy of a biological sample.

### MARKET APPLICATION SECTORS

Clinical diagnostic companies.

### TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

The sample used, tear, is easily accessible, and is obtained by a non-invasive, painless and inexpensive procedure. It can be stored frozen until the time of metabolic analysis. It can be obtained punctually in a wide range of subjects for screening studies to detect the disease, or it can be obtained periodically in the same patient, to follow up the disease and observe the evolution with treatment.

The sample preparation is simple compared to other techniques, and a protocol has been designed that allows the study to be carried out with a reduced amount of tears, adapted to the real possibilities of sample volume obtained in the real clinical context.

Samples from glaucoma patients and control subjects without glaucoma were used in the study. The rest of the circumstances that accompany the patients or the control group have not been taken into account so that, given the results, it is a selective procedure to discriminate patients at risk of glaucoma regardless of whether they suffer from OHT, dry eye and other related pathologies.

Metabolic analysis by NMR, although performed using sophisticated and expensive equipment, can be performed in different facilities of universities and research centers that have this equipment and allow subcontracting for a reduced cost. The technique itself is highly reproducible and allows the comparison of results obtained at different times, from the same set of patients, or the addition of results from samples taken at different times from the same set of patients. set of patients or to add results from additional samples to complete a large number of samples or to give a particular result on a given patient's sample.

### CURRENT STATE OF DEVELOPMENT

A test has been performed with a sample of 30 subjects, 11 patients diagnosed with primary open-angle glaucoma and 19 healthy control subjects without ocular pathology. A statistical model was obtained with 66% of the samples and subsequently applied to the validation subset, 33% of the samples. A sensitivity of 100% and specificity of 83% was obtained for the discrimination of tears from patients with primary open-

## METHOD OF EARLY DIAGNOSIS OF GLAUCOMA

angle glaucoma versus samples from control subjects. The sensitivity and specificity data in the validation set support the robustness of the model and its great potential as a tool to support the diagnosis of glaucoma.a.

## INTELLECTUAL PROPERTY RIGHTS

Patent pending number P202131032 submitted to the OEPM (Spanish Patent Office) with priority date November 3, 2021. It has been extended internationally via PCT.

## COLLABORATION SOUGHT

A licensee company is sought for the commercialization of the product.

## RELATED IMAGES

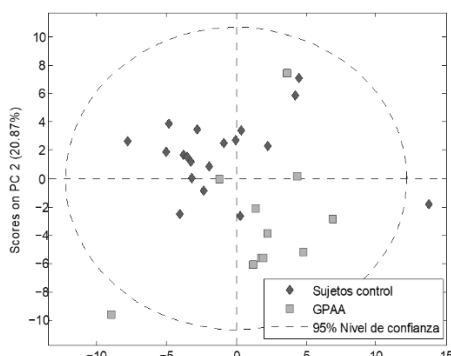


Figure 1: Principal component analysis, PCA. It is observed that there are differences between tear samples from healthy subjects and those from subjects with POAG.

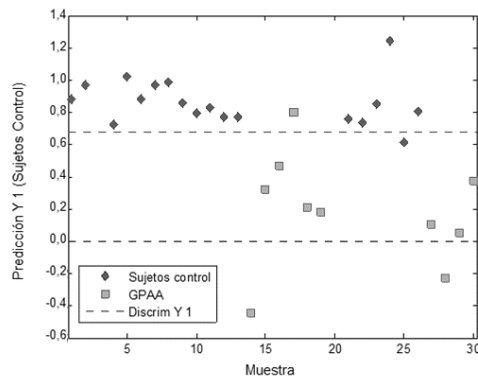


Figure 2: Partial least squares discriminant analysis, PLS-DA. It is observed that there are differences between tear samples from healthy subjects and subjects with POAG. Furthermore, in the PLS-DA study, the model has been calculated with the samples of the training set and applied to the samples of the validation set, obtaining a mostly accurate prediction of the group to which each tear belongs.

## CONTACT

Innovation Area  
FISABIO  
Avda. Catalunya, 21 46010 València (Spain)  
Tel. +34 961926351  
E-mail: [innovacion\\_fisabio@gva.es](mailto:innovacion_fisabio@gva.es)  
Web: [www.fisabio.es](http://www.fisabio.es)