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Opportunity

To accelerate the development of this innovation, through licensing or direct investment, contact

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Non-invasive biomarker for diabetic neuropathy

Tear film neuropeptide Y (NPY) as a non-invasive biomarker for early diabetic neuropathy

The Technology

- More accessible diagnostic tool that can help to improve the early-stage diagnosis and monitoring of peripheral neuropathy in people with diabetes and/or be used as a companion diagnostic.

Market Need

- Diabetic corneal disease is a significant clinical problem affecting over a half of diabetic population. However, it is not receiving proper attention from physicians and remains underdiagnosed and underestimated.

Technology Status

- The proposed technology is an easy, non-invasive biomarker test that can be potentially further developed to be used as a kit by optometrists and GPs (including in remote areas where access to optometry services can be limited).

Market Need

Diabetic corneal disease is a significant clinical problem affecting over a half of diabetic population. However, it is not receiving proper attention from physicians and remains underdiagnosed and underestimated.

Damage to small nerve fibres, including those in the cornea, occurs early in the diabetic neuropathy disease course. Nerve biopsy is currently the gold standard procedure for examining small nerve fibre integrity, but biopsy procedures are invasive and not easily repeatable; therefore, they are infrequently used in practice. Corneal nerve anatomical parameters, quantified from in vivo confocal microscopy (IVCM) images (as we have done in our clinical studies described above), are valid surrogate marker to evaluate peripheral nerve healthy. Corneal nerve density is a valid measure of small nerve fibre integrity, with a reported 85% sensitivity and 84% specificity for peripheral neuropathy diagnosis. However, IVCM devices are expensive and require highly trained operators; they have limited availability in Australia or overseas, being mainly used in clinical research settings rather than being broadly implemented in medical practice.

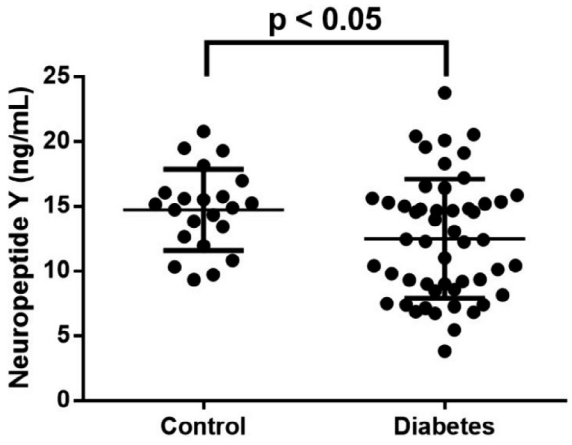

Figure 1. Comparison of tear NPY levels in individuals with diabetes vs healthy control participants without peripheral neuropathy symptoms. NPY levels were lower in the diabetes group compared with control group.

Solution

Proposed is a novel biomarker that can be measured in tears with standard immunoassay methods.

Supporting this invention are findings from a cross-sectional study, evaluating tear neuropeptide levels in people with and without diabetes, and a randomised, placebo-controlled trial, evaluating change in corneal nerve structure and tear NPY levels with oral omega-3 fatty acid supplementation in type 1 diabetes.

Making diagnostics more accessible can help to improve the early-stage diagnosis and monitoring of peripheral neuropathy in people with diabetes.

The technology can also be used as a companion diagnostic for use:

- in the selection of patients for treatment with a particular medicine or biological;
- or in the monitoring of patients who are being treated with a particular medicine or biological;
- or in both selection and monitoring of treatment with a particular medicine or biological.

Technology and IP Status

Provisional patent application has been filed including claims around a method of:

- diagnosing a presence of or pre-disposition for corneal nerve damage, or loss
- risk stratification or treatment stratification
- selecting a treatment or modifying a treatment, based on the diagnosis, evaluation, or prognosis
- monitoring treatment efficacy or disease progression of a subject having corneal nerve damage or loss

Tech name and number	2021-096 Tear film NPY as a non-invasive biomarker for early diabetic neuropathy
Researchers	Assoc. Prof. Laura Downie, Dr. Ceecee Britten-Jones
Patents	Provisional application AU2022/902982 filed on 12 October 2022
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