

# MacularNEWS

The Macula Research Group's (MRG) Clinical Research Unit is embarking on an exciting clinical trial studying a new low power Near Infrared light for the treatment of diabetic macular oedema (DMO).

## Background

Diabetic retinopathy is where the blood vessels of the retina become damaged by high blood sugar levels in people with diabetes. It is a common cause of severe loss of vision and the most common cause of blindness in individuals between the ages of 20 and 65 years in developed countries. Swelling of the central retina, or DMO, is the commonest cause of visual loss in diabetic retinopathy.

DMO has in the past been treated with thermal laser which photocoagulates (seals off by burning) leaking blood vessels in the macula. This treatment does not usually improve vision and causes some permanent damage to the area of the macula that is treated. More recently, injections into the eye of drugs such as vascular endothelial growth factor (VEGF) inhibitors (e.g. Avastin, Lucentis or Eylea) or steroids (triamcinolone, Ozurdex) have become first line treatment for DMO, however these need to be given regularly, are expensive and have some associated side effects.

Near Infrared (NIR) light is long wave-length light that is not

visible to the human eye. NIR treatment using power densities 100 times lower than conventional thermal laser has been shown in animal studies to promote the healing of injured cells, including blood vessels and neurons (nerve cells).

Studies suggest that NIR treatment enhances the metabolism of cells, enhances the function of mitochondria (the energy producing structures that are found in all cells that look like cockroaches), increases the activity of an important metabolic enzyme called "cytochrome C oxidase", stimulates antioxidant protective pathways (pathways that protect against cell damage) and promotes cell survival.

## Foundation work by the Macula Research Group's Laboratory Unit

The MRG's Laboratory Unit has contributed important findings on the role of disturbed metabolism in retinal disease. Both photoreceptors (cells that pick up light) and retinal "Müller cells" (supporting cells of the retina in which our group has a major interest) are full of mitochondria. Müller cells have high metabolic activity and photoreceptors have a high energy demand. Our lab's studies on a mouse model of retinal vascular leak, caused by selective removal of Müller cells, suggest that NIR treatment not only prevented photoreceptor degeneration but also reduced vascular leak.

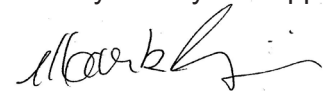


Our research relies exclusively on external grants and fundraising.

If you are in a position to support macular research, please know that we are extremely grateful and that your donation will be well used.

You may also like to consider remembering macular research in your will.

Thank you for your support.



Prof. Mark Gillies  
Macula Research Group

## Early Clinical Trials

A small scale preliminary clinical trial, completed in the United States, involved twice-daily administration of the NIR treatment with a hand held device over two months. The study found this reduced swelling by 20%. Other clinical trials are in progress, but none have used any form of laser, which we

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believe is required for optimal results.

## Macula Research Group's NIR Clinical Trial

The MRG's NIR clinical trial improves on previous clinical applications by using a purpose built NIR laser generated light source mounted on a slit lamp biomicroscope (Image 1). While previous treatments have just used lights that doctors held in their hands and pressed against the patients' eyes, our laser delivers precisely the amount of light energy to exactly the region that is required. We have designed the laser to deliver the light in a ring around the centre of the macula. This will prevent any damage to the centre of the macula if the treatment has any adverse events, which we believe are highly unlikely, given the low energy that we will use (Image 2).

The patient sits at the NIR mounted slit lamp and an ophthalmologist administers the NIR light over 90 seconds. This method ensures that the amount of treatment is delivered at an accurate predetermined dose and the dose is administered to the part of the retina where it is required.

The aim of the trial is to see whether NIR treatment is as effective as the thermal laser in reducing macular oedema. Patients will receive a total of 12 treatments over five weeks

and will then be followed up in the Macula Research Clinic for another five months. If found to be effective, NIR may become an important non-invasive treatment option for DMO. Successful results of this study will lay the foundation for testing the NIR treatment for other macular diseases by our group.

## Funding and Support

The Australian company Ellex Medical Lasers Ltd, have built the NIR laser that has been mounted on a slit lamp specifically for our NIR clinical trial in DMO. Ellex are providing the laser unit on loan for the duration of the trial. Funding to support the coordination of the trial has been granted through the Sydney Eye Hospital Foundation (SEHF). We are very grateful for the support of the SEHF and for Ellex's collaboration and loan of the NIR laser.

We are also exploring the potential application of NIR light in Macular Telangiectasia Type 2 (MacTel Type 2). MacTel Type 2 is a degenerative condition of the macula that affects both eyes. The condition may cause progressive loss of vision which is due to degeneration of photoreceptors, the cells that detect light in the retina, for which there is currently no approved treatment. As well as treating retinal blood vessels, we and others have also shown that NIR laser can repair damaged



Image 1: Near Infrared slit lamp mounted biomicroscope (source: Ellex)

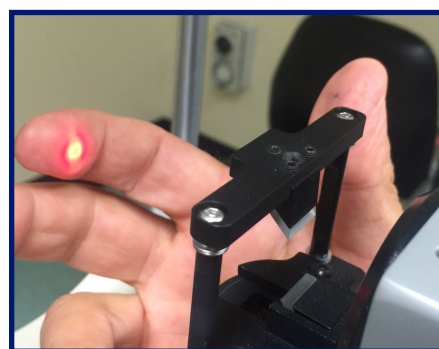


Image 2: Laser beam cannot be felt at all (aiming beam shown in image)

nerve cells, which is what photoreceptors are.

Sounds a bit like Star Trek, right? You may recall Dr McCoy shining a light in people's eyes to fix them. Maybe it is that simple, but it may not be. We need to study such things as how long the effect lasts, if there is any effect at all, and how often the laser can be repeated. The first thing is to establish proof of principle - whether NIR treatment can be effective for macular disease. This is what we are concentrating on now.

Save Sight Institute is a centre of The University of Sydney.



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