MacularNEWS

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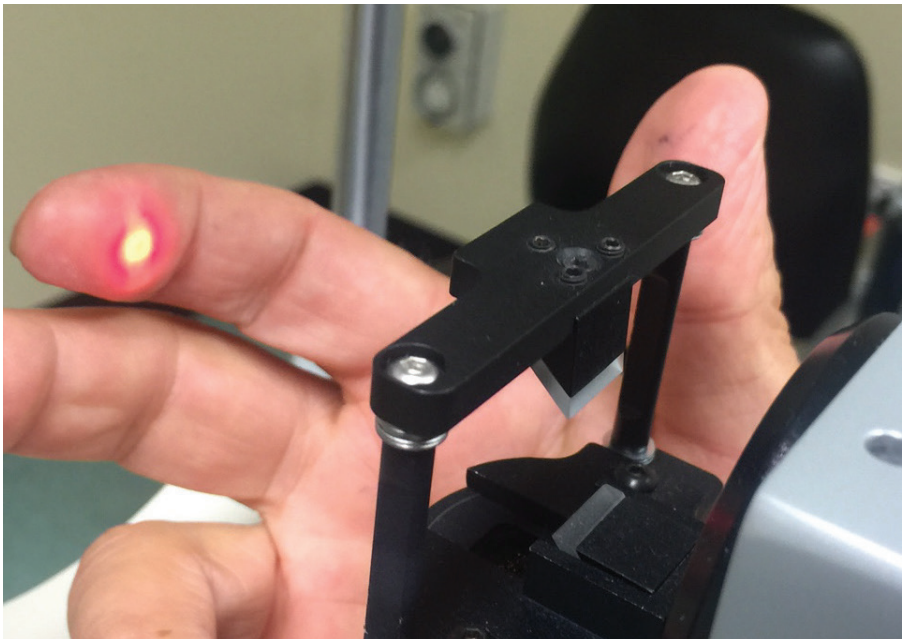

Photobiomodulation for Diabetic Macular Oedema – the NIRD Clinical Trial

Diabetic macular oedema (DMO) is the most common cause of vision loss in people with diabetes. It occurs when high blood sugar levels damage the blood vessels in the retina, causing fluid leakage and swelling of the central retina. DMO is treated with injections of vascular endothelial growth factor (VEGF) inhibitors or steroids into the eye.

Although the injections are extremely effective, some people can find them invasive, and they often must be given many times over several years before the disease stabilises. The drugs are also very expensive, meaning some people, especially in the developing world, may not be able to get them.

In the Autumn 2016 issue of MacularNEWS, we wrote about our animal studies of photobiomodulation (PBM) – a potential treatment for certain retinal diseases that exposes affected tissue to a low intensity of light.

Director's Message

To recognise our relationship to the University of Sydney, we have adopted the University's brand identity. This is still the same MacularNEWS that you are used to, just with a new look.

This issue focuses on the results of our clinical trial into a potential treatment for diabetic macular oedema. Although the injections we currently use are extremely effective, they are expensive and invasive so anything that made them last longer would be a major advance. Thank you for your support.

Professor Mark Gillies
Macula Research Group

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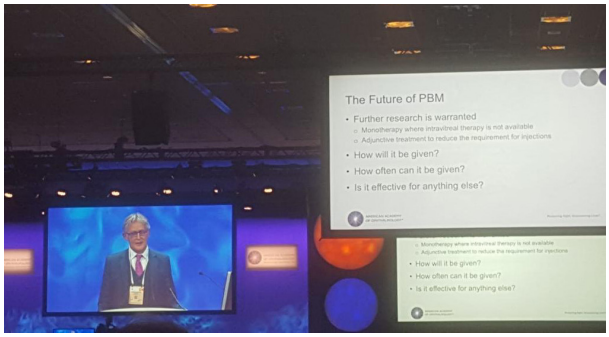
At the time, we also announced that we were about to start a clinical trial, which has since been completed, with the results published in the scientific journal, *Diabetologia*.

The **NIR** (Near Infrared light) for **D**iabetic Macula Oedema (NIRD) study included three groups of seven patients with loss of vision from DMO. It was an open-label dose escalation clinical trial, meaning everybody received the treatment (no placebo) and each group was exposed to a stronger dose of laser after the previous energy level was found to be safe. We conducted this study in collaboration with our friends at Royal Adelaide Hospital. Twelve treatments were administered over five weeks. Macular thickness – a way of assessing the severity of DMO – and vision on a visual chart were measured after two and six months. The proportion of eyes that needed to be rescued with eye injections because the NIR did not work sufficiently was also assessed.



Professor Gillies presented the results of the NIRD study at the American Academy of Ophalmology (pre-COVID).

We observed a modest but significant overall reduction in macular thickness two months after PBM treatment, which was more pronounced after six months even though they did not receive any further treatments during this period. There was a significantly greater reduction in macular thickness in the two higher energy groups at month six.

On average, the vision of all groups improved two months after treatment by approximately one line on the chart however, unlike the effect on macular thickness, this was not sustained six months after treatment.

Rescue standard of care treatment was administered in five eyes: three from Group 1 (lowest energy), two from Group 2 and none from Group 3 (highest energy). Reassuringly, there was no sign of the collateral damage that conventional laser treatment causes, and the treatment was well-tolerated by patients.

Few other clinical trials have reported the effects of PBM on DMO in humans – most studies have been in animal models of human disease. A similar reduction in macular thickness to what we observed had been reported in just four patients who received PBM treatment for DMO that was not affecting their vision.

Overall, we found at least anatomical evidence (that is, the reduction in macular thickness) of efficacy of PBM for DMO in this dose escalation study. There was an overall dose-dependent reduction in macular thickness at six months after treatment. The groups receiving higher power laser (100mW/cm2 and 200mW/cm2) had greater reduction of macular thickness, which was about the same as the reduction reported for eyes treated with conventional laser photocoagulation for DMO. Also, as no patients in Group 3, which received the highest power laser, needed rescue treatment, this suggested that the 200mW/cm2 NIR laser was the most effective of the three doses we tested.

Our study produced encouraging results, however, further studies are needed to assess the effectiveness of PBM before it can be recommended for patient care. A larger clinical trial that includes a masked placebo group is underway, and is being performed by our colleagues in the United States. It will be interesting to see whether they confirm our observation that the treatment seems to keep working for months after it was given. The clinical trial from the US will likely report in a year or so.

In the meantime, we plan to continue to explore other potential applications of PBM for macular disease. We have applied for approval to run a similar pilot study of PBM for the second most common disease affecting the retinal blood vessels after diabetic retinopathy: retinal vein occlusion. This study will be led by Dr Elisa Cornish and is planned to start enrolling later this year. People who have suffered a retinal vein occlusion can access further information on the relevant clinical trials by calling the Clinical Research Unit office: **(02) 9382 7309.**

Early Bird Gets the Treatment – A Reminder to Attend Regular Eye Examinations

Recently, Professor Mark Gillies contributed to a paper written by Dr Alice Gibson of the University of Sydney, which found that only around half of people with diabetes in Australia were having the eye checks they need to detect diabetic retinopathy before it affects their vision. People with diabetes need to have their eyes examined more frequently than the general population.

This is because they do not know when they are about to lose vision and when they do, it often happens very quickly and can usually be avoided by these routine checks. So, we encourage everyone with diabetes to attend their regular eye exams, even if they have not noticed any changes in their vision.

The research paper mentioned here, 'Adherence to eye examination guidelines among individuals with diabetes: An analysis of linked health data' was published in *Clinical and Experimental Ophthalmology*.

SSI Granted ACTA Membership

The Save Sight Institute (SSI) has been granted Associate membership of the **Australian Clinical Trials Alliance (ACTA)**. The membership will allow SSI to contribute to discussions on research and healthcare policy, and advocate for clinical research within Australia. We are delighted to be a member and look forward to further contributing to clinical trials and registries in Australia.

Save Sight Registries Team Update

Although the Save Sight Registries (SSR) team has been working remotely for most of the year, we have still managed to welcome new members.

Mila Kolmogorova
Project Manager

Satya Vedantam
Senior Software Engineer

Alison Grinyer
Project Support Officer

Dianna Raad
Research Support Officer

The SSR Team is working hard to develop new modules to track the "real world" outcomes of treatment of eye diseases, to improve the User experience and to continually expand and introduce new countries to the growing project. Currently the modules that track outcomes of treatment for retinal diseases (DMO, age-related macular degeneration, retinal vein occlusion) are used in Australia, New Zealand Singapore, Switzerland, The Netherlands, France, Spain, Italy, UK and Ireland.

If you would like to make a tax-deductible donation or discuss leaving a bequest to support macular research please visit **sydney.edu.au/save-sight-institute/support-us/donate.html**, call us on **(02) 9382 7309** or post a cheque to: Save Sight Institute, South Block, Sydney Eye Hospital, 8 Macquarie Street Sydney NSW 2000 made out to 'The University of Sydney'

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

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