Randomized controlled trial of corneal collagen cross-linking - 2011 update

Now in its fifth year, researchers at the Centre for Eye Research Australia (CERA) and the Royal Victorian Eye and Ear Hospital, are continuing their work with the world's first randomized controlled trial of a treatment for Keratoconus known as corneal collagen cross-linking (CXL). This novel treatment aims to stop the progression of keratoconus by increasing the rigidity of the cornea. A combination of topical Riboflavin (vitamin B2) and a defined dose of ultra violet light (UVA) irradiation are applied to the eye which triggers a photo-chemical reaction in the cornea and strengthens the corneal tissue.

One-hundred participants between 16 and 42 years of age (average age 26 years) have been randomly allocated to either the treatment group (50 patients) or control group (50 patients). Patients from both groups are followed according to the same schedule which includes subjective tests (i.e. vision testing) and more objective measurements such as corneal curvature and cell density.

Interim results:
Data analysis including up to 4 year findings were presented at the 6th International Congress of Collagen Cross Linking in Milan in January 2011.

At the time of the last interim analysis, nine treated patients and ten patients from the control group had completed their four year follow-up. While there are considerable individual differences in the initial post-operative period, follow-up at the 4 year mark indicates that patients who receive CXL remain stable or show a slight improvement in either vision, corneal steepness, or both.

Participants in the control group on average experienced a slight worsening of their condition. In cases where marked progression was noted, patients in the control group were offered the treatment on compassionate grounds. To date, 13 patients have received CXL for this reason.

It should be emphasized that this trial only involves patients with progressive keratoconus who are 16 years or older. While there is increasing interest in CXL for younger patients, there is currently only limited research data available to support this. Therefore any decision to treat a patient under 16 years of age with CXL would need to be carefully considered and can only be made on an individual basis.

The conference highlighted the high level of interest internationally of the Australian trial. During the congress, two major variations of the current recommended protocol were the subject of lively discussion. These were: 1) the potential to achieve effective CXL treatment without removing the corneal epithelium (outer skin of the cornea) and 2) variations in the treatment parameters intended to achieve comparable results with shorter treatment times.

While these amendments would be equally appealing to both people undergoing the treatment and clinicians performing CXL, doubts were expressed about the efficacy of the currently trialed ‘epithelium on’ options. Although the concept of a shorter treatment time might hold great future potential, the majority of Congress delegates agreed that there is a need for thorough scientific evaluation of any treatment variation and that a formally structured protocol should be developed.

Update on local Pilot studies

Two pilot studies, one involving keratoconus patients with a cornea thinner than 400µm (‘thin cornea’ study’) and one including patients who have developed Keratectasia after laser surgery (a complication with symptoms similar to those of keratoconus) are currently underway and still recruiting participants. See below for further details.

Interested in becoming a study participant?

Patients who are interested in participating in the ‘thin cornea’ pilot study, keratectasia pilot, or in being involved in future trials are advised to contact their eye care specialist or Tony Wu (Trial Coordinator) on 03 9929 8618 or tonyn@unimelb.edu.au.

Funding to continue these important trials is still required. If you would like to donate, please contact Jessica Boccamazzo (CERA Fundraising Administrator) on 03 9929 8426 or jboc@unimelb.edu.au.