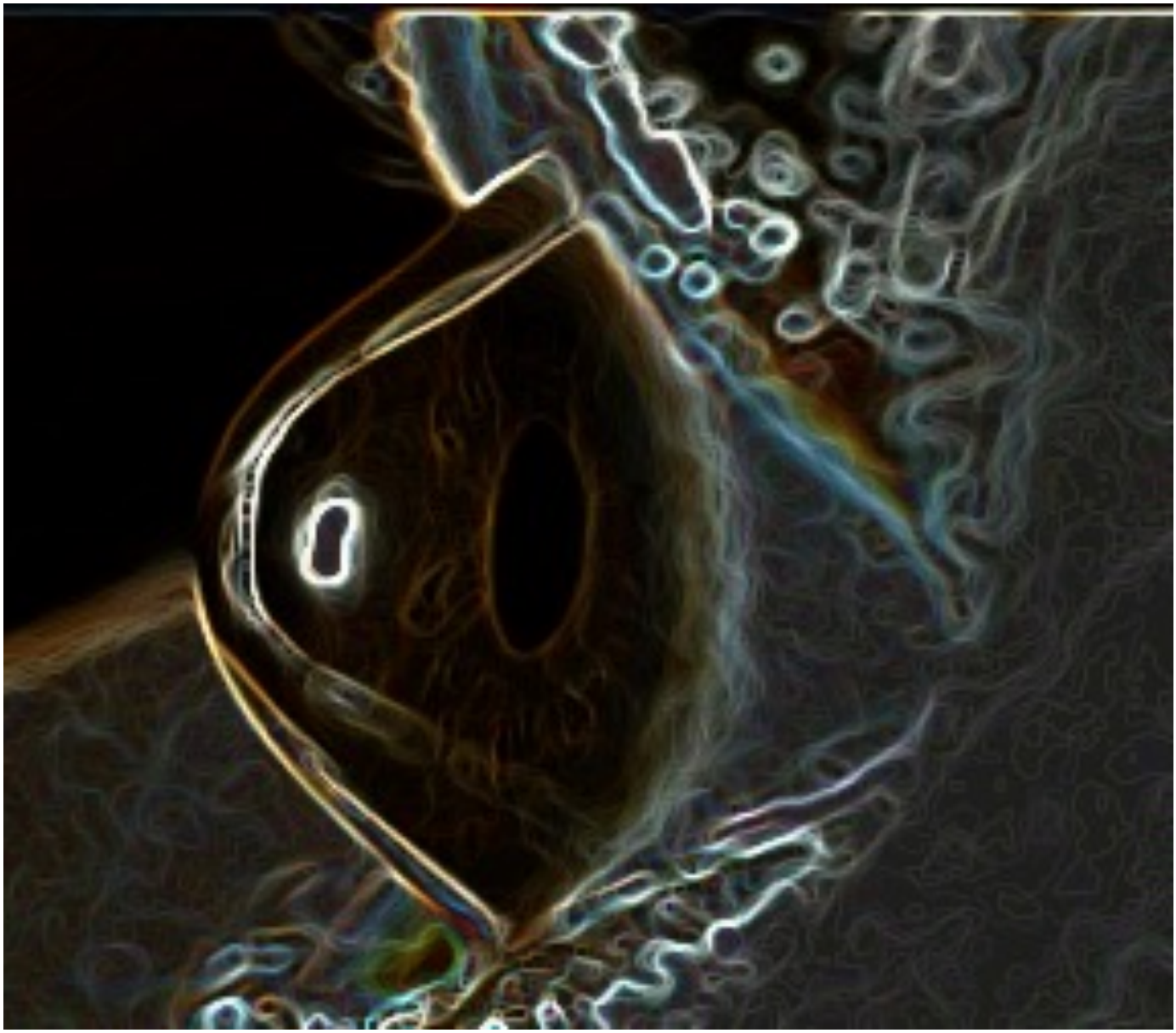
KERATOCONUS Australia



2016 ANNUAL REPORT

THE ASSOCIATION

Keratoconus Australia Inc is a not-for-profit association created to prevent and control the eye disease, keratoconus, and visual impairment caused by keratoconus. The Association was registered in April 2000 and is operated by volunteers. It is completely self-funded from donations.

A committee of management administers the Association. All committee members have keratoconus or are parents of children with keratoconus.

Full membership of the Association is open only to people with keratoconus or the parents and guardians of minors with keratoconus. Anybody can become a supporter of the Association or assist with its work.

Keratoconus Australia believes there are a number of ways to prevent and control the impact of keratoconus in the community. Our efforts are directed in particular at:
(1) raising the awareness and understanding in the medical, optometric and general community of keratoconus, its signs, symptoms and effects;

(2) promoting research into the causes, prevention and control of keratoconus; and

(3) acting as a representative body on behalf of people with keratoconus and providing, where necessary, counselling, support and referrals to the people with keratoconus and their families.

We provide support for people with keratoconus and their families through regular group meetings, help lines, individual counselling and the dissemination of information.

We are also:

- Assisting people to find optometrists and ophthalmologists / corneal surgeons experienced in treating keratoconus
- Helping to develop a network of support groups throughout Australia
- Publishing a regular electronic newsletter with information on a wide range of issues affecting people with keratoconus
- Acting as a representative group for keratoconus patients to improve health rebates for treatments (contact lens and solutions, glasses) and corneal surgery, and to obtain higher funding for local research into the condition
- Supporting the development of a national registry and database on Australian keratoconus patients designed to assist in networking individuals and groups within Australia, and to form a basis for future research work
- Supporting efforts to increase organ donations and in particular to reduce waiting times for corneal graft

KERATOCONUS AUSTRALIA INC ABN 80 683 325 208 A0039546H
PO Box 1109 Hawksburn VIC 3142 Australia
PHONE 0409 644 811 EMAIL info@keratoconus.asn.au WEB www.keratoconus.asn.au

FROM THE PRESIDENT

Keratoconus Australia is small as not-for-profits go. We are run by a handful of volunteers who all have full time jobs elsewhere – and keratoconus. We operate solely thanks to donations; we receive no external funding. Last year, we had income of $10,000 and made an operating profit of around $6,000. Maybe “tiny” is a more appropriate word to describe us.

Yet read our annual report and you will see that we are trying hard. We provide support to hundreds of people with keratoconus and their families every year. Many are young - some very young – and just entering a cycle of study, work and creating families. We hope we make a difference by assisting them to unearth specialist eye care and help them find the strength to continue striving for a better life despite having a progressive and potentially serious eye disease.

We act as an advocate for the keratoconus community, we provide information about keratoconus and hold seminars, we encourage training of eye-carers to help future generations, we try to find innovative ways of lowering the cost of treatments that can alleviate hardship stemming from vision loss. We also support research into keratoconus, treatments and cures.

A tiny group like Keratoconus Australia cannot do all these things without help from others. We have therefore formed partnerships with a range of organizations – big and small. Some provide us with pro bono services for our legal and accounting requirements or access to free meeting rooms. Others provide discounted amenities such as information booklets, printing and video facilities. Many have supported the Association since its inception 16 years ago. Finally, a small group of eye-carers have provided us with a range of advice, opinion and information about keratoconus and help answer queries from our members.

Over the past 18 months, one of the key eye-carer partnerships formed by Keratoconus Australia has been with Save Sight Institute in Sydney. As you may know, I provided seed funding to allow the launch of the Institute’s Australian Crosslinking Registry. I did so because we all believed it was critical to have better information on the outcomes of what has become standard practice in the care of keratoconus patients. As the Australian Government’s Medical Services Advisory Committee noted in its July 2016 report on an application for funding of crosslinking by Medicare, there is very little in the way of evidence from randomized trials on the safety and efficacy of crosslinking despite its use in Australia for more than a decade. Hopefully the Australian Crosslinking Registry will help fill that knowledge gap.

Professor Stephanie Watson who heads the Australian Crosslinking Registry is more than just a clinician and researcher. She is one of the breed of medical practitioners who

actually listens to the needs of patients. She has done so much more than just graciously accept funding for her research projects. She has listened to our thoughts and ideas on what else can be done to improve life for people with keratoconus and their families.

When I told her a condition of funding for the Australian Crosslinking Registry would be patient involvement in its administration, she offered three patient positions on the Registry Advisory Board. When we suggested at the first Advisory Board meeting that there needed to be involvement of optometrists to ensure long term tracking of crosslinking outcomes, she saw the wisdom of the suggestion and the Registry software is now being modified with the assistance of Optometry Australia representatives.

When we told her we thought there was a serious lack of knowledge about the dangers of eye rubbing for keratoconus patients and a public information campaign would be useful, Professor Watson launched one. Not only did she do so via SSI, she also got the Royal Australian and New Zealand College of Ophthalmologists on board. Thanks to the resources provided by SSI, we now send information on eye rubbing to all our members.

When we told her NSW desperately needed a patient support group operating locally, she listened and last October SSI and Keratoconus Australia launched a Keratoconus Club at the Sydney Eye Hospital. The club and its activities will be coordinated by Michelle Urquart, whom I met through SSI at the launch of the Registry in November 2015.

At our suggestion, Professor Watson is even trying to form a partnership with optometrists to develop a keratoconus contact lens clinic at Sydney Eye Hospital to provide access to lower cost contact lenses for patients.

We need more partnerships like the one we have today with Save Sight Institute. Ideally, we should have similar relationships with the major eye hospitals and research centres around Australia.

These partnerships are formed when patients and their eye-carers can foster connections outside of the medical practice room. More of our members need to step up and take on responsibility in their own area for the development of links with eye-carers for the mutual benefit of everyone with keratoconus.

People with keratoconus cannot expect their interests to be taken into account in research and clinical practice unless they demand a place at the decision making table and proclaim their needs loud and clear.

As presently structured, Keratoconus Australia can do only so much. Are you prepared to take on the responsibility for doing more?

Larry Kornhauser
November 2016

SUPPORT

Introduction

Keratoconus Australia is dedicated to providing support for people with keratoconus and their families.

The Association is operated by people with keratoconus; we do not have medical qualifications or training nor do we provide medical advice. What we do is talk to patients and family members about our own experiences with keratoconus. We have access to a range of specialists working in the field of keratoconus and all medical questions are directed to these eye-carers for their expert opinion. However a full examination of a patient's eye is required before even a medical practitioner will provide clear and considered advice on keratoconus treatment and management options. Which is why any advice coming via Keratoconus Australia will always be generalized, with the caveat that the patient needs to be reviewed by a keratoconus specialist.

Trends in 2015-16

Requests for support over the past twelve months followed similar patterns to previous years. The Association continues to field many requests for assistance on diagnosis of keratoconus. These come from patients and their families seeking to alleviate concerns – often serious – about the nature of the disease and its likely evolution and impact. Despite abundant information available today online, many people are ill-informed about keratoconus, its effects and the treatments available.

Finding keratoconus specialists, both contact lens fitters and corneal surgeons remains a perennial problem for many newly diagnosed patients and those experiencing progression and who require new treatments to manage their deteriorating vision.

As discussed in last year's report, the sharp increase in patients being referred to corneal surgeons for crosslinking has led to an upsurge in inquiry about other types of surgeries to improve vision. Patients are being offered what were previously considered less conventional surgery for keratoconus including intrastromal corneal ring segments and intraocular lens (IOLs) to correct their vision. As we noted last year, these surgical procedures may be relevant in certain unusual cases. But they are very expensive and often provide a short to medium term improvement in vision at best. They are not risk free and can have long term consequences for the patient's vision. Keratoconus Australia believes that for most of the keratoconus population, contact lenses offer far superior long term vision correction.

There continues to be confusion over corneal collagen crosslinking. A number of support requests in the past year have come from patients who had crosslinking done on an eye without progressive keratoconus simply because the other eye was progressing and needed the operation. In some cases, these patients have experienced negative side effects on their vision in the stable eye following crosslinking.

The Association emphasizes that crosslinking is not a benign, risk free procedure. Like many corneal surgeons, we believe that the operation should be considered only on an eye that is experiencing progressive keratoconus. Surgeons generally like to monitor a patient's corneas for at least three to six months before deciding to proceed with crosslinking. Each eye should be considered individually as keratoconus usually progresses at different rates and most patients have a "good eye" and a "bad eye."

Again we urge all patients considering crosslinking to ask the following key questions to their corneal surgeon

- Is my eye suffering from progressive keratoconus?
- If so, what type of crosslinking are you proposing. Is it the Dresden protocol (the current gold standard based on randomized clinical studies) or some other protocol?
- What evidence is there to support the use of this protocol and what results have been achieved to date?
- Are you submitting your results to the Australian Crosslinking Registry which began operating in late 2015? If not, why not?

Corneal transplantation also appears to cause confusion among patients based on inquiries received in 2015-16. It should be understood that in the past no more than 15-20% of people with keratoconus would ever progress to the point of requiring a corneal transplant. This number is falling as crosslinking is being used to slow or halt progression in many younger patients who were often the most affected by progressive keratoconus.

A corneal transplant is no longer considered as major surgery by ophthalmologists and can be performed under a local anesthetic. However, recovery times are long and it may be up to two years before the transplant stabilizes and vision can be assessed. Rejection can occur at any time and needs to be treated immediately to ensure reversal and to preserve the longevity of the grafted tissue. A graft generally lasts between 15-20 years based on statistics from the Australian Corneal Graft Registry which means that many recipients may require more than one in their lifetime. Second and subsequent grafts have a higher failure rate than the first.

Finally, and perhaps most importantly for people with keratoconus who think that a corneal transplant is a "cure" for keratoconus, a majority of graft recipients still require vision correction (glasses or contact lenses) to achieve best corrected vision outcomes.

As such, a corneal transplant is a life changing event and should be considered as a last resort once all other options – notably contact lenses - have been tried under the supervision of a specialist contact lens fitter for keratoconus. Poorly fitted lenses can cause irritation to the cornea and eventually permanent scarring which can be corrected only by a corneal transplant. Which is why it is so important to have lenses fitted correctly and not to wear lenses which are uncomfortable.

The other key concern for patients continues to be the cost of treatments. Questions about costs, health insurance and reimbursements. Crosslinking is the major focal point as the procedure, which has now become standard care for any patient diagnosed with progressive keratoconus, is still not being reimbursed by Medicare and the private health insurers. Although some eye hospitals in the eastern capital cities are providing a limited number of publicly funded crosslinking procedures, waiting lists are often long. Keratoconus Australia

notes that the cost of a crosslinking operation done privately by a corneal surgeon averages around $2,500 per eye; patients should be wary of ophthalmologists seeking to charge significantly more.

The cost of contact lenses remains a sore point with many patients and their families. Hybrid and scleral lenses are particularly expensive while private health fund rebates remain low. Keratoconus Australia receives a steady flow of complaints about the cost of this critical treatment option for keratoconus patients which is the difference between having good vision or a disabling eye condition.

We note again that some eye clinics in the capital cities offer cheap lenses for health card holders and pensioners. The University of Melbourne's Eyecare clinic also offers Keratoconus Australia members bulk billing for appointments and heavily discounted contact lenses fitted by students under the supervision of keratoconus specialists. Members continue to report satisfaction with the service at Melbourne Eyecare and we will try to improve that relationship in the coming year. The University of NSW contact lens clinic offers a similar service.

Support in figures

Keratoconus Australia data show subtle changes in the type of support sought by members and their families in 2016. Overall, support logged by Association rose slightly last year by 3% to 327 contacts. These contacts take various forms, but are mainly via email, phone calls and meetings.

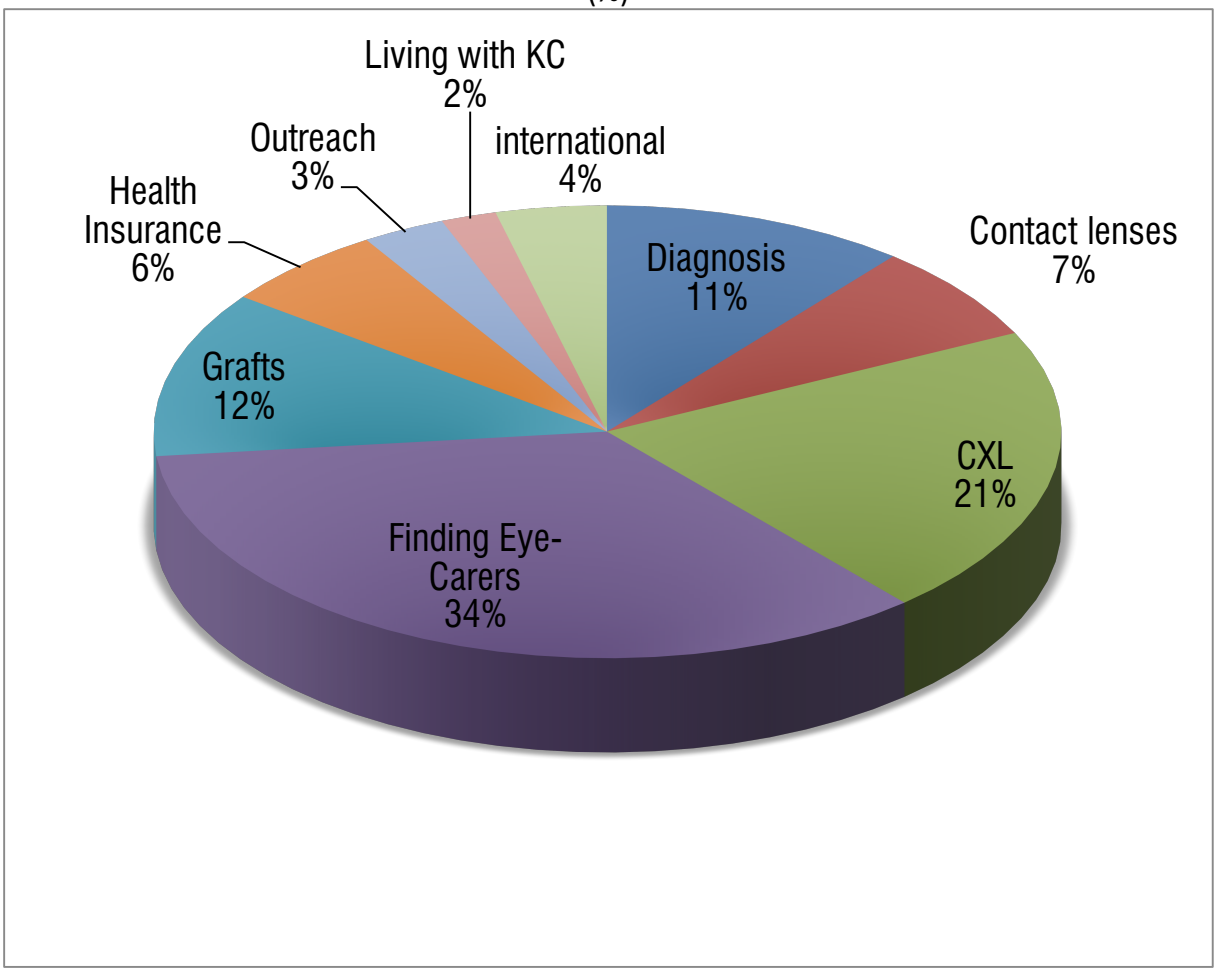
The largest increase in support requested was for help in finding eye-carers. As discussed above, people still have difficulty in identifying eye-carers in their area - corneal surgeons and particularly contact lens fitters – who specialize in keratoconus. Direct requests for assistance in locating specialists jumped by 11% in 2015-16 to 113, thereby accounting for over one-third of all support requests received by the Association. As noted in past reports, regardless of the reason someone initially contacts Keratoconus Australia, most support requests conclude with the Association assisting the person to find a keratoconus specialist. So overall, some 87% of support could be characterized as falling into this category.

Questions about crosslinking were the next largest category of support, accounting for 21% of all contacts last year, followed by requests about various types of other surgery at 12% (notably corneal transplantation), concerns after a diagnosis of keratoconus (11%) and contact lens related issues (7%).

The Association received a handful of requests for information and support from persons requiring assistance overseas. These included requests for contact lens fitters in France and South Korea and information on keratoconus for persons in Kenya and the Philippines.

Below is a percentage breakdown of support logged in 2015-16 by type

Support by Type 2015-16
(%)



RESEARCH

One of the key purposes of Keratoconus Australia is to promote research into the causes, prevention and control of keratoconus. The Association surveys its members for basic information about their keratoconus to assist researchers identify particular areas of interest. Although it does not conduct formal research itself, it does support research projects in various ways including funding, collection of information and assistance in the recruitment of participants.

Save Sight Institute, Sydney Eye Hospital

Australian Keratoconus Registry

Keratoconus Australia was pleased to be a key player in the launch of the Save Sight Institute's (SSI) Australian Crosslinking Registry (ACR) in November 2015. The Crosslinking Registry is a world first and has the potential to be the most important keratoconus research project launched in Australia since the Australian Corneal Graft Registry opened in 1985.

SSI developed the crosslinking registry as the first module for its web-based data collection system, the Fight Corneal Blindness (FCB) project. The FCB project is itself an offshoot of the Institute's Fight Retinal Blindness registry, which it developed eight years ago and which has led to world-leading outcomes for patients with retinal disease and macular degeneration.

The specially developed FCB registry module, will

- investigate and evaluate the clinical effectiveness, cost-effectiveness and safety of emerging therapies for the treatment of keratoconus.
- develop strategies to ensure the use of evidenced based guidelines in the management of keratoconus."
- for the first time, include patient-generated quality of life information relating to the post-crosslinking experience and wellbeing.

Clinical Professor Stephanie Watson

The project is being headed by Clinical Professor Stephanie Watson, of Save Sight Institute.

The Association has repeatedly expressed concern about the lack of research and evidence to support the variety of protocols being used to perform corneal collagen crosslinking in Australia. Apart from the Dresden protocol, which has been shown to be largely safe and effective in small scale randomized clinical studies, there remains a serious lack of clear, reliable information for patients about the safety and effectiveness of the other procedures being used by

ophthalmologists on Australian keratoconus patients.

Variations to the Dresden protocol include leaving the epithelium intact, swelling the cornea to crosslink thin corneas, accelerated crosslinking using higher power ultraviolet light for shorter periods etc. The long term effects of crosslinking and its durability remain unknown.

As noted previously, crosslinking is not a risk free operation. SSI acknowledges that serious complications including corneal oedema, microbial keratitis, corneal melting and perforation along with sterile corneal infiltrates have been reported following cross- linking. Data is lacking on the complication rates and side-effects of this procedure.

Early data entry into the registry has already pointed to high rates of corneal hazing following crosslinking, while 50% of patients tracked exhibited some form of complication.

From a patient perspective, the key features of the crosslinking registry are that:

1. Patients will have a direct say in the governance of the Keratoconus registry. Keratoconus Australia has been given a position on the Advisory Committee along with two keratoconus patients
2. Patients will themselves respond to a quality of life survey as part of the registry data entry process. This will provide first person information on the impact of treatments on patient wellbeing for the first time in a keratoconus registry
3. A list of doctors participating in the registry will be available to patients to enable them to choose corneal surgeons for crosslinking who will share their data with the registry, who are benchmarking their own performance against national averages and best practice and who are theoretically adopting the safest and most effective crosslinking techniques as demonstrated by the registry data.

The Role of Keratoconus Australia

The Association believes that the widespread use of crosslinking today by ophthalmologists makes it critical that patients have access to the latest information and evidence on the various protocols being used around the country and overseas. Keratoconus Australia has participated in the development of the Crosslinking Registry from the outset as part of its mission to ensure crosslinking is a safe and effective procedure and to protect patients' interests in the implementation of the registry.

Seed funding for the Crosslinking Registry was provided to SSI from the Ophthalmic Research Institute of Australia and Keratoconus Australia president Larry Kornhauser in 2014.

In June 2015, SSI sought funding from Keratoconus Australia for a patient awareness campaign (see Annexes) to publicise the Crosslinking Registry and its benefits for crosslinking patients. Keratoconus Australia agreed to provide funding for the Keratoconus Registry project once the relevant protocols were in place to guarantee patient involvement in the registry governance and operation.

At the November 2015 launch of the Crosslinking Registry, Mr Kornhauser said "One of the most important aspects of this registry is its inclusion of patient reported outcomes. It is so critical to include those with the most at stake in the process, to ask them about their lived experience and to incorporate their responses in the overall assessment of treatment approaches." (see attached articles in Annexes)

In December 2015, SSI provided Keratoconus Australia with the terms of reference for the Crosslinking Registry Advisory Committee created to "consider, discuss and make recommendations on all matters related to strategic directions, adoption of outcomes of the research and future development, to achieving the primary aims of the Project." The Association was granted one position on the committee which includes provision for two other consumer representatives.

One of these consumer positions was filled by former Keratoconus Australia secretary and Vision 2020 National Advocacy Adviser, Belinda Cerritelli. Other groups represented include the Centre for Eye Research Australia, the Optometrist Association and the Therapeutic Goods Association.

In March 2016, KA President Larry Kornhauser attended the first meeting of the Crosslinking Registry Advisory Committee held in Sydney. A report tabled by the Registry secretariat showed that release 1 of the registry software was being updated in line with international standards/regulations in terms of privacy and confidentiality as well as data transmission requirements. The Registry reported that 36 doctors at 20 sites had been recruited to the project including ophthalmologists in Switzerland and New Zealand.

At the meeting, Keratoconus Australia argued strongly in favour of including optometrists into the Registry to ensure long term reviews of crosslinking patients. Mr Kornhauser noted that optometrists are the first line of contact for most keratoconus patients. "Optometrists provide patient education on their disease and that is where the process should start. This is an important step," he told the Committee.

In discussing desired outcomes from crosslinking, Keratoconus Australia reinforced that stopping the progression of keratoconus and stabilizing the vision is the key outcome for patients. Not having any hazing/ photosensitivity is paramount; not having to wear glasses is a bonus.

The Advisory Committee agreed that future feasibility and development will include the evaluation and feasibility of achieving Optometry involvement. The committee agreed "optometrists are often the first point of call for patients as well as a follow-up source of monitoring and patient care."

In May 2016, Mr Kornhauser and optometrist representative on the Crosslinking Advisory Committee Dr Laura Downie, who also heads the University of Melbourne keratoconus and contact lens clinic, subsequently met with Jessica Chi, Victorian and National president of the Cornea & Contact Lens Society of Australia, to discuss ways of integrating optometrists in to the Crosslinking registry project. A range of initiatives arising from that meeting are now being implemented with Professor Watson and the Crosslinking Registry team to include optometric data in the registry, to promote the registry in the optometry community and to include optometrists with large keratoconus practices.

Mr Kornhauser reported to the Keratoconus Australia Committee of Management on his discussions with SSI and other participants in the Crosslinking Registry project and the measures already in place to promote patient input to the project. The Committee subsequently approved a $10,000 donation to the Crosslinking project to help fund the publicity campaign to promote patient awareness of the Registry in accordance with the SSI proposal of June 2015.

These funds have now been made available to SSI. A copy of the SSI Statement of Recognition has been included in the Annexes

Finally, in June 2016 Keratoconus Australia acted as a facilitator between the US National Keratoconus Foundation and Save Sight Institute in a move which will hopefully see US corneal surgeons join the Crosslinking Registry project in the future.

Once again the Association applauds Professor Watson and her team at SSI for launching this vital research project to evaluate crosslinking protocols and promote best practice.

The Association's participation in the development of the crosslinking registry has played an important role in ensuring the registry will be patient friendly and provide keratoconus patients with a greater say in their treatments than ever before in Australia.

Any Keratoconus Australia member with experience in medical research and who could assist in coordinating our involvement in this landmark project should contact the Association.

OTHER RESEARCH

Centre for Eye Research Australia, Melbourne

The Centre for Eye Research Australia is expanding its research into keratoconus. The Head of its corneal research Associate Professor Mark Daniell and key CERA keratoconus researchers Dr Elsie Chan and Dr Srujana Sahebjada kindly provided Keratoconus Australia with a private update briefing in June 2016.

CERA is engaged in a suite of keratoconus research ranging from the cost of keratoconus, various aspects of crosslinking and corneal transplantation, the development of a bioengineered cornea and a corneal tissue biobank.

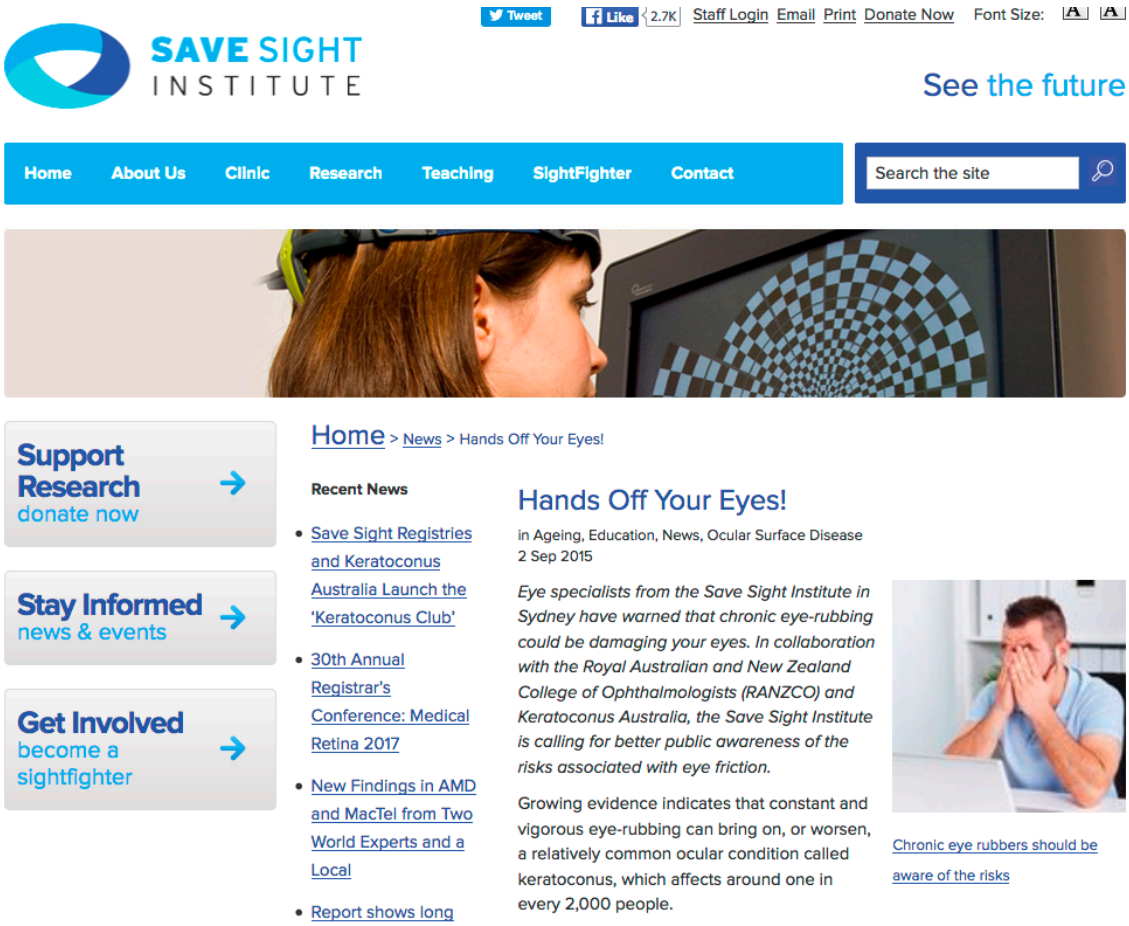
Keratoconus Australia is a long time supporter of CERA and its research. Following meetings in the second half of 2016, we hope to collaborate more closely in launching ground breaking research in 2017.

Members who would like to be involved in funding or working with the various keratoconus research projects should contact the Association.

Stop Eye Rubbing campaign

The partnership between Keratoconus Australia and Save Sight Institute of the Sydney Eye Hospital has borne more fruit than just the Australian Crosslinking Registry.

As noted in last year's Annual Report, discussions between Keratoconus Australia president Larry Kornhauser and Crosslinking Registry Director, Professor Stephanie Watson in mid-2015 resulted in the elaboration of an information campaign to warn people with keratoconus of the dangers of eye rubbing.



Vigorous eye rubbing has long been identified as a serious risk factor for either triggering keratoconus or worsening progression in existing keratoconus. However many members contacting us for support are surprised to hear about the link between eye rubbing and progression in keratoconus. Some corneal surgeons point to anecdotal evidence of progression halting once vigorous eye rubbing is stopped.

The joint SSI-KA campaign entitled *Hands Off Your Eyes* also won the support of the Royal Australian and New Zealand College of Ophthalmologists. All three organisations issued media releases in early September 2015 to alert patients and eye carers (optometrists and

ophthalmologists) of the dangers of eye rubbing, which can exacerbate other serious eye diseases including glaucoma and myopia. It also can cause infections from dirty hands and should be avoided after any eye operation such as a corneal transplant, LASIK, cataract or other surgery.

In launching the campaign, Keratoconus Australia said it believed that publicising the effects of eye rubbing could be a simple but significant step in the fight to minimize the impact of keratoconus in the community. “Eye-carers and allergists have a responsibility to inform their patients of the impact of eye rubbing and offer effective treatments for itchy eyes” Mr Kornhauser said in the media release.

The campaign received extensive coverage in the media and professional journals. Professor Watson has also appeared in several forums to promote the campaign and participated in a panel on Channel Ten to discuss aspects of eye health including the dangers of eye rubbing.

RANZCO renewed its eye rubbing message in early 2016.

The Association is now collecting information on its registration form about patients’ eye rubbing history to assist in research.

An information poster explaining the impact of eye rubbing has been included in the kit sent to all new members and is being made available to eye-carers on request. Contact the Association if you would like a copy.

The Association and SSI also prepared a guide to how patients can stop eye rubbing regardless of the cause. Adjunct Professor Charles W McMonnies of the School of Optometry and Vision Science at the University of New South Wales – a specialist in eye rubbing – has provided invaluable assistance to this campaign.

We are hoping this will be the first of many specific issue campaigns aimed at improving knowledge of keratoconus and its management within the patient, eye-carer and general communities.

Members interested in assisting with this work should contact the Association.

KERATOCONUS AUSTRALIA

MEDIA RELEASE
September 8, 2015

HANDS OFF YOUR EYES!
The hidden dangers of chronic and vigorous eye rubbing

Eye specialists from the Save Sight Institute in Sydney have warned that chronic eye-rubbing could be damaging your eyes. In collaboration with the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) and Keratoconus Australia, the Save Sight Institute is calling for better public awareness of the risks associated with eye friction.

Growing evidence indicates that constant and vigorous eye-rubbing can bring on, or worsen, a relatively common ocular condition called keratoconus, which affects around one in every 2,000 people.

Keratoconus blurs vision by thinning the cornea, the transparent front part of the eye. As the cornea thins, it begins to distort and bulge, and becomes cone-shaped rather than the usual round shape. Significant loss of vision can result as the cornea is primarily responsible for the eye's focusing power.

In its early stages, vision may be corrected with spectacles although there may be an increased sensitivity to light. As the condition advances, vision may no longer be adequately corrected due to the high irregularity of the cornea.

Both eyes are usually affected, but may respond in different ways, and 20% lead to severe visual impairment. As the condition continues to deteriorate, a corneal graft may be required.

According to Clinical Professor Stephanie Watson from the Save Sight Institute "Eye rubbing is often caused by allergies, and this can become a problematic habit. In chronic eye rubbers, more severe keratoconus often corresponds with the dominant hand."

Twenty-four year old Darren Wright is one person who found out the hard way that vigorous and prolonged eye rubbing can have unfortunate consequences. Recently diagnosed with Keratoconus, he said "I didn't know that just rubbing my eyes was so bad for, and especially that it has contributed to my deteriorating vision".

The precise cause of keratoconus is unknown. It is thought that genetic factors may contribute, and that eye rubbing can lead to eye trauma, as well as trigger the release of enzymes which weaken the cornea.

Mr Larry Kornhauser, President of Keratoconus Australia is concerned about the lack of public awareness of the risks of eye rubbing.

"The Association regularly hears from young people with progressive keratoconus who ask why their vision deteriorates so quickly," he said. "We ask them if they have itchy eyes and if they rub their eyes vigorously and most say 'yes, why?'. They get upset when told that eye rubbing is contra-indicated with keratoconus as it can trigger or accelerate the disease. They (or their parents) always say, 'why didn't anyone tell us?' "

Keratoconus Australia believes that publicising the effects of eye rubbing could be a simple but significant step in the fight to minimize the impact of keratoconus in the community. Eye-carers and allergists have a responsibility to inform their patients of the impact of eye rubbing and offer effective treatments for itchy eyes.

Researchers from the Save Sight Institute are working hard to find new and improved ways of treating this eye disorder.

In progressive cases of keratoconus, a technique known as 'corneal cross-linking' is commonly used, using UV light and a photosensitiser to strengthen chemical bonds in the cornea, ultimately with the aim of halting the progressive degeneration.

The Ocular Repair Group at Save Sight Institute, under the leadership of Professor Watson, has recently launched a sophisticated web-based software platform to collect data across a large number of real-life clinical settings.

"This allows us to analyse high volume patient outcomes from the procedure" says Prof Watson "and this important information plays a direct role in improving the way in which we care for patients affected by keratoconus, now and in the future".

The Corneal Disease Group at Save Sight Institute, under the leadership of Professor Gerard Sutton and Dr Con Petsoglou, have had considerable success in identifying an important protein which is expressed by people affected by keratoconus, and are working towards possible future treatments targeted at this protein.

To support eye research at the Save Sight Institute please visit savesightinstitute.org.au

Media Enquires:
Save Sight Institute
Professor Stephanie Watson
Ophthalmologist and Head of the Ocular Repair Research Group stephanie.watson@sydney.edu.au
0400 050 480

RANZCO
Ms Suzanne Lyon Advocacy Officer slyon@ranzco.edu (02) 9690 1001

Keratoconus Australia
Mr Larry Kornhauser President info@keratoconus.asn.au 0409 644 811

Poster being sent to all new members of Keratoconus Australia

ABNORMAL EYE RUBBING:

What Families Need to Know

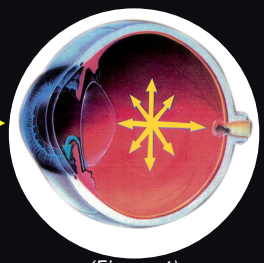
Institute for Eye Research

EYE RUBBING is abnormal when it lasts *too long*, or occurs *too frequently*, or uses *too much force*, or keeps recurring over a long period.

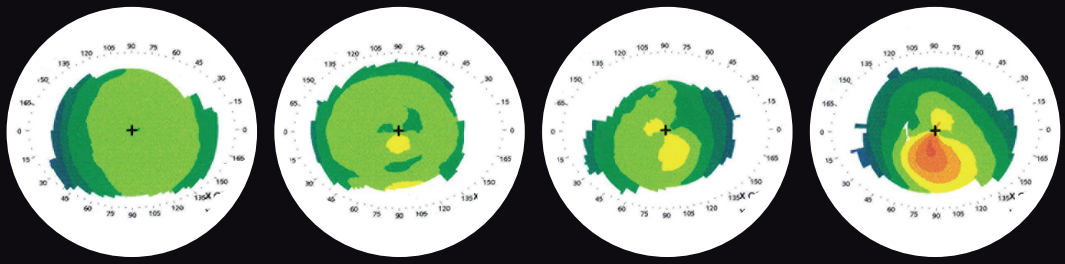
* Even gentle rubbing causes the pressure inside the eye to *more than double*. Hard rubbing results in pressure which can be *more than 10 times normal*.[1,2]

* The cornea *may become damaged* when it is squeezed between rubbing force and the high pressure inside the eye. (Figure 1).

* The damaged cornea may become weakened and *less resistant* to the pressure inside the eye. The weakened cornea can bulge forward into an *irregular conical shape* (as illustrated by the sequence of corneal shape maps: A (normal), B, C, D (Conical cornea or keratoconus).[3]



(Figure 1)



A B C D

* Eye rubbing pressure may be high enough to *cut blood flow* to the back of the eye and cause *temporary vision loss*.

* When the cornea is very thin, (e.g. in conical cornea), rubbing may cause the cornea to *rupture*, with the risk of corneal *scarring* and *loss* of vision.[4,5]

* Eye rubbing after any type of *eye operation* such as corneal graft, LASIK or cataract surgery, may *damage* the eye.[6]

* Rubbing can transfer *germs* to the eye, and increase the risk of *infection*.

* The *most harmful* time for rubbing can be on waking and after removal of contact lenses.[7]

WHAT CAN YOU DO TO AVOID EYE RUBBING?

If possible, it is better *not to rub* at all. Apart from causing soreness and redness of the eyes and lids, rubbing may actually *increase* itchiness. To reduce itch and irritation, maintain all forms of *allergy avoidance and treatment*. To reduce the temptation to rub, follow your practitioner's advice for *lash hygiene* and management of *dry eye*, as well as other conditions that cause *irritation*. Sometimes *stress management* can help.

Please enquire to: enquiry@ier.org.au

Developed by Charles McMonnies.
Figure 1: Highlights of Ophthalmology

Courtesy of Professor Charles McMonnies

University of Melbourne -

Department of Optometry and Vision Sciences (DOVS)

Keratoconus Australia continued its partnership with the University of Melbourne's Department of Optometry and Vision Sciences (DOVS) in 2015-16 to help train a new generation of specialist contact lens fitters for keratoconus.

In early 2016, the Association and its members again helped organize the keratoconus training clinics conducted for 3rd and 4th year optometry students at the University's DOVS. Four keratoconus and four post graft clinics were organized in March and April.

These clinics have been held in conjunction with the DOVS since 2006 and provide optometry students with a unique opportunity to fit contact lenses onto keratoconus and corneal transplant patients prior to graduating. They are the only specific keratoconus training clinics in Australia.

Keratoconus Australia members kindly volunteered their time and their corneas to ensure the clinics were again a success.

UoM Eyecare Keratoconus Clinic

In addition to the DOVS training keratoconus clinics discussed above, the University of Melbourne Eyecare's regular Keratoconus Clinic offers an avenue for all members to obtain contact lenses at up to a 50% discount. We continue to receive good reports from members who have used the clinic over the past year.

This Keratoconus Australia initiative provides an opportunity for optometry students to gain valuable experience in full fits of all types of contact lenses on keratoconus and post-graft patients under the supervision of keratoconus contact lens fitters.

The participation of additional qualified specialist contact lens fitters for keratoconus has enabled Eyecare to provide more appointments for patients.

We again commend the DOVS on supporting this initiative and hope it can serve as a model for similar clinics in other states.

Eye-carer relations

The Association maintains regular contact with specialists working in the field of keratoconus.

We recognise in particular the invaluable contribution of many eye-carers in the keratoconus community who answer questions from our members and hold informal discussions with committee members. These contacts are a two-way affair and enable us to provide feedback on our members' concerns. We have a range of information resources available for eye-carers and continue to provide these at a nominal cost to eye-carer practices.

We also maintain a list of these keratoconus specialists to assist members and their families in obtaining the best possible care in their area.

Other eye-carer projects

The Association has raised the possibility of launching two new projects in conjunction with keratoconus eye-carers in attempt to improve the quality of care and treatment for people with keratoconus.

One way of expanding and formalizing our links with eye-carers that has been canvassed is the creation of a scientific committee to advise Keratoconus Australia on all matters relating to keratoconus, its management and treatment and research in this field.

As discussed in last year's annual report, the original submission to the University of Melbourne that led to the creation of the keratoconus clinic at UoM's Eyecare practice also included a proposal for the creation of a post-graduate scholarship to enable an outstanding optometry graduate the opportunity to further their studies in keratoconus.

Although in abeyance since put forward, discussions are still being held to implement this part of the original proposal.

This initiative – if adopted – would involve providing an annual bursary to the candidate selected by a panel of optometrists in conjunction with Keratoconus Australia to enable him/her to travel around Australia to work in the leading keratoconus practices in each state. Funding will be an issue and hopefully co-funding with the optometry community can be negotiated.

Members interested in assisting the Association in advancing these proposals should contact us.

ADVOCACY

Corneal collagen crosslinking rebate

Corneal collagen crosslinking is now a routine procedure recommended by ophthalmologists to patients with progressive keratoconus under the age of about 50. However, at the end of the 2015-16 financial year there was still no Medicare rebate for the operation. Crosslinking generally costs about $2,500 per eye and is being offered free through only a very limited number of hospitals in Australia.

As noted in the **Support** section of this report, faced with pressure from keratoconus specialists to undergo crosslinking, many patients and their families suffer distress because of the financial burden associated with this procedure. This adds to concerns over deteriorating vision and the prospect of severe vision loss over time. Add to this the cost of contact lenses and sundry expenses on solutions and regular checkups, a keratoconus diagnosis can be the start of an expensive journey for many.

A survey done by Keratoconus Australia shows that in total, a patient could face an initial outlay of $800-$2,300 on contact lenses and backup glasses and ongoing costs thereafter of $700-$2,500 annually simply to maintain a stable condition. Costs then spiral upwards for a patient with a progressive condition.

Last year, the Association responded to a call from the Australian Government's Medical Services Advisory committee (MSAC) which sought feedback on an application from the Royal Australian and New Zealand College of Ophthalmologists for a crosslinking subsidy. We also publicized the request for public feedback on the application.

Keratoconus Australia provided a submission in support of a subsidy of around $1500 per eye. Details of the Keratoconus Australia submission were published in the 2014-15 Annual Report.

At its July 2016 meeting, MSAC deferred advice to the Federal Minister for Health "due to concerns that the revised economic model had not been adequately verified and that the riboflavin drops used in rendering this service were not registered on the Australian Register of Therapeutic Goods (ARTG)."

MSAC requested the following information to enable it to finalize its advice:

- a more detailed rationale for the proposed fee, including the range of applicable protocols to render the service, and how these range in both complexity and duration
- an assessment by its Evaluation Sub-Committee (ESC) comparing the revised modelled economic evaluation with the version initially developed, and examining the sensitivity of these models to variations in the proposed fee

- clarification from the Therapeutic Goods Administration (TGA) regarding the consequences of the varying regulatory status of the codependent ultraviolet lamp device and the various riboflavin eye drop options used in rendering the service
- MSAC noted reports that several large well-designed clinical trials due to report in 2016– 17 have discontinued their control arms. Any further assessment of this application may want to address the progress of those trials.
- Data cited in the pre-MSAC response said to be available in patients with ectasias other than keratoconus.

We have included the full interim report from MSAC's July 2016 meeting in the Annexes for members to read.

However, it would appear from MSAC's concerns that a decision on the Medicare-funded crosslinking rebate is unlikely for some time yet.

Corneal collagen crosslinking costs

While awaiting the MSAC decision, we again note that there can be wide discrepancies in the cost of corneal collagen crosslinking procedures. This is of particular concern as patients will need to meet the full cost of the operation regardless of whether they have private health insurance or not.

A survey done by Keratoconus Australia indicates that keratoconus specialists in Sydney and Melbourne are charging between $1,800-$2,600 per eye for crosslinking. These costs generally exclude an initial consultation and may vary depending on several factors – notably, how many follow-ups are included in the first 3-6 months after the operation.

The Association hopes that the crosslinking registry project will help standardize protocols for best practice crosslinking and normalize costs in the future.

In the meantime, crosslinking can be obtained free at the corneal clinics of the Royal Victorian Eye and Ear Hospital and the Alfred Hospital in Melbourne, and the Sydney Eye Hospital. Subsidized procedures are available in other states through eye hospitals.

A better deal on contact lenses

As much as we would like to report progress in this campaign for a fairer deal on contact lenses for keratoconus, sadly we cannot again in 2015-16.

In the absence of lower prices or higher rebates on contact lenses for keratoconus, Keratoconus Australia notes that members can access cheaper lenses in a number of ways.

We are pleased to report, however, that our discussions with Professor Stephanie Watson of SSI have raised interest in SSI opening a contact lenses clinic at the Sydney Eye Hospital. We have facilitated meetings between Dr Laura Downie who oversees the keratoconus clinic at the University of Melbourne's Eyecare practice and Professor Watson and we hope to see a new contact lens clinic emerge in the new future to offer another alternative for patients to access cheap contact lenses.

We have established an agreement with the University of Melbourne's Eyecare practice that offers a range of lenses for keratoconus at a 50% discount. The Eye and Ear Hospital in East

Melbourne has also opened a keratoconus clinic which is offering contact lenses and crosslinking at minimal cost to patients.

Similar services can be obtained through the Sydney Eye Hospital for crosslinking and the University of NSW eye clinic for contact lenses (although this is not a specialised service for keratoconus).

In Brisbane, patients referred to the corneal clinic at Mater Hospital with a visual acuity of less than 6/12, can receive a script for contact lenses to be fitted by one of the local keratoconus specialists and billed to Mater.

These are just some of the options available to patients experiencing financial difficulty in purchasing contact lenses (and crosslinking) for keratoconus.

Patients can also request bulk billing of optometrist services when experiencing financial hardship. It never hurts to ask. Many optometrists have told us they can provide significant discounts on contact lenses in special cases.

Vision 2020

Keratoconus Australia is currently an associate member of Vision 2020 Australia, the peak body in Australia for all eye related organizations.

We have a representative on the Vision 2020 Independence and Participation Committee. However due to work commitments, our representative rarely has time to participate in the meetings which are held during business hours.

We request that anybody who is interested in eye health policy contact the Association to participate in this committee during 2017. Teleconferencing is available for members unable to attend the Melbourne meetings.

Optometrists

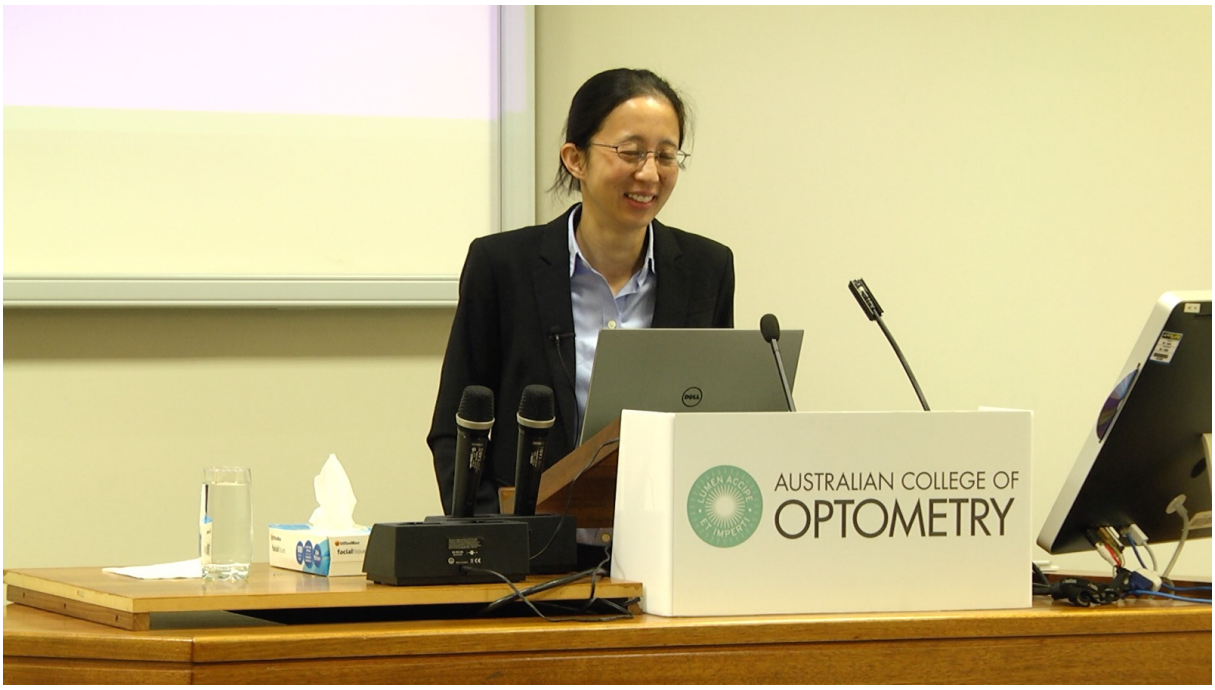
The Association has previously asked members to assist in lobbying Optometry Australia for support in its campaign over the cost of contact lenses. We urge members who have experience and time to engage in this type of advocacy to contact us immediately so that this matter can be progressed in 2016-17.

Write to your Private Health Fund!

As always, we repeat our suggestion that members put pressure on their private health funds to recognize the special nature of contact lenses for keratoconus and to provide higher rebates on claims for these specialized and indispensable lenses. With the assistance of the US Keratoconus Foundation, we have prepared a letter, which members can download, modify and print, to send along with their contact lens claims to their private health fund.

Please send this letter to your health fund EVERY TIME you submit a claim for a rebate on your new contact lenses. The letter to request a higher rebate from your health fund can be downloaded in Word format off our website at http://www.keratoconus.asn.au/Resources-F/KA_Insurance_letter.pdf.

An update on Crosslinking seminar
25 August 2015



Dr Elsie Chan, researcher at the Centre for Eye Research Australia (CERA) presented an update on the latest results from the world's longest running randomized trial of crosslinking which was conducted at CERA.

Dr Chan reviewed developments in crosslinking around the world, where a range of protocols are now being adopted to ameliorate the outcomes of crosslinking for patients while minimising side effects and discomfort.

These include the epithelium-on method, accelerated crosslinking and repeat crosslinking.

Once again, Dr Chan emphasized that crosslinking is not a risk free operation and should be considered only when a patient has progressive keratoconus. Keratoconus should be monitored for at least three to six months before deciding to proceed.

Finally Dr Chan discussed the Crosslinking Registry being developed at Sydney's Save Sight Institute in collaboration with CERA and with the support of Keratoconus Australia. She explained why this will be a critical tool in the evaluation of crosslinking in Australia, and benchmarking of patient outcomes.

Free Audio Podcasts

Free audio podcasts of recent Keratoconus Australia seminars are available on the Association's website.

Launch of SSI Australian Crosslinking Registry

20 November 2015

Keratoconus Australia supported the launch of Save Sight Institute's Australian Crosslinking Registry at the Sydney Eye Hospital in November 2015.

KA President Larry Kornhauser was one of a panel of speakers at the launch, and told the audience of the importance of patient involvement in the new registry. He noted it was "critical" to include patients in the process, to ask them about their experiences and to incorporate their responses in the overall assessment of treatment approaches.

Other speakers included the head of the Crosslinking Registry, Professor Stephanie Watson, the head of Save Sight Registries, Professor Mark Gillies and Corneal specialist Dr Con Petsoglou. Keratoconus patient, Michelle Urquart also spoke eloquently about her own experiences with keratoconus and how a series of corneal transplants had affected her life.

Keratoconus Australia promoted the event amongst its membership and we were delighted to meet a number of you at the luncheon kindly organized after the launch. We look forward to holding more events in conjunction with SSI in the near future.

For more details on the Registry project, see **Research**.

THE ASSOCIATION

Membership

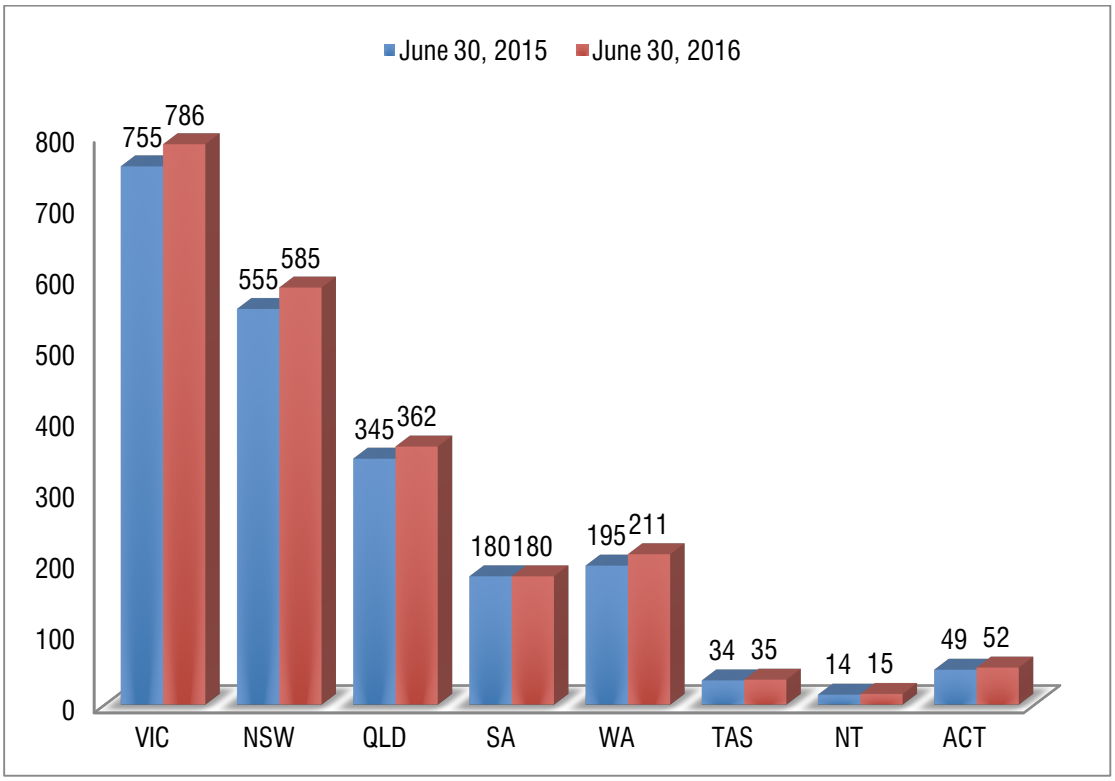
At 30 June 2016, Keratoconus Australia had 2,226 registered members. This represented an increase of 5% (adjusted) above the 2,127 members registered one year earlier.

Membership grew fastest in Western Australia reaching 211, up 8.2% compared to the same time last year (195 members). However, Victoria remained the largest state with 786 members (+4.1% compared to the previous total at 30 June 2015), followed by NSW with 585 members (+5.4%). Membership in Queensland also grew strongly last year to 362 members (+4.9%) making it the third largest in the Keratoconus Australia membership base.

At the end of the 2015-16 financial year, Victorian members accounted for 35.3% of the total, NSW 26.3% followed by Queensland at 16.3%, and WA at 9.5% slightly ahead of South Australia at 8.1%.

(Please note that constant updating of information in the KA database means that membership data is not directly comparable from one year to the next.)

Membership by state



Supporters

The Association receives benefits from a range of companies in the form of free facilities for meetings and pro bono services. We thank all of these companies for their kind assistance again in 2016, notably Deloitte Private, The Australian College of Optometry (seminar venue) and Viewgrow Capital Pty Ltd (meeting venue and administrative support services) and Herbert Smith Freehills for legal services. The US-based National Keratoconus Foundation provides the Association with patient booklets at a reduced rate.

In early 2015, Melbourne communications agency Big Red kindly agreed to assist with the redevelopment of the Association's website and social media platform. This work is almost finalised. We greatly appreciate the assistance provided to date.

As discussed previously, the University of Melbourne has strongly backed Keratoconus Australia's efforts to improve access to cheap, well-fitted contact lenses for keratoconus patients through its EyeCare clinic, which runs regular keratoconus clinics.

The Save Sight Institute is becoming a key partner of Keratoconus Australia on a number of projects and assisting with the development of material for the keratoconus community. We thank Professor Stephanie Watson for her dedication in trying to improve patient outcomes through both the development of the Crosslinking Registry and a series of patient focussed initiatives.

Review of rules

The committee initiated a review of the Association's constitution and rules to ensure they conformed with recent legislative changes relating to associations and charities. Changes were required by new provisions of either the *Associations Incorporation Reform Act 2012* (**Act**) or the *Australian Charities and Not-for-Profits Commission Act 2012* (**ACNC Act)**. In 2014, we engaged Herbert Smith Freehills, which has in the past acted on behalf of the Association on a pro bono basis. This review is now complete. The Committee has approved the new rules and they will be submitted for ratification by the membership at the 2016 Annual General Meeting.

Fundraising and Grants

We would like to thank all donors who made significant contributions during the 2015-16 financial year.

No grants were sought or received during the year.

We are now also registered as a charity on the GoFundraise platform should members wish to fundraise on behalf of Keratoconus Australia. https://www.gofundraise.com.au/

Donations

Donations to the Association can now be made by **credit card online** via the Give Now website at https://www.givenow.com.au/keratoconusaustralia.

Please give generously.

Local Groups

NSW

A NSW-based group has long been overdue. Despite a few false starts in the past, we hope now to create a sustainable group in the Sydney area. Once again, our partnership with Save Sight Institute has been invaluable. Contacts made at the Save Sight Institute launch of the

Australian Crosslinking Registry led to Michelle Urquart agreeing to act as facilitator for a NSW based keratoconus support group called the Keratoconus Club. Ms Urquart is canvassing members for ideas for the new group and we are looking forward to new activities in Sydney during 2017. We strongly urge Sydney-based members to contact us if they would like to assist Michelle in the coming 12 months.

Members on the Gold Coast, Tasmania, SA, and the ACT have expressed interest in forming local groups in the past. If you want to make a long-term commitment to organizing drinks or social events with other keratoconus patients, please contact us and we will assist in contacting other people in your area.

Website and Social Media

Big Red completed its new website for the Association in 2015-16. We are now hoping to populate the site with up-to-date contact in the next few months and launch the site in 2017. This has taken an inordinate amount of time due to time constraints of our volunteer committee.

We hope to revamp our social media strategy as part of the new site launch.

The Committee of Management

The Committee holds regular meetings to discuss the Association's plans and projects and to review its finances and procedures. In 2015-16, the committee met three times and held informal discussions on other occasions.

The committee last year comprised:

Larry Kornhauser, President
Neil McFarlane, Secretary
Ryan Kaplan
Alejandro Molano
Tamalii Laloulu

Mary Veal acts as the Association's Administrative Assistant in an unpaid capacity.

Volunteers still required urgently

Since requesting assistance 12 months ago, a number of members have kindly offered to help us. We thank those members greatly for those offers. However, in most cases, we were unable to match up the desire to do something with the Association's specific needs.

We therefore renew our request noting that the Association urgently requires *highly skilled* volunteers who are self-motivated to assist with a variety of tasks. If you want to help, please understand we need people able to initiate, follow up and complete tasks as we are unable to provide advice and supervision in these specialist areas. These include:

Strategy and Management	• Experience in developing strategy and management policies for not for profit organizations
Volunteer coordinator	• experience in managing volunteers, allocating tasks, follow-up
Website	• design, content development and maintenance
Social media	• formulate policy guidelines for Facebook and Twitter and other platforms

	• provide and monitor content and postings
Advocacy	• experience in writing submissions to government and other representative organizations
	• understanding of the Medicare system
	• representatives for the SSI Crosslinking Registry
Research	• ability to initiate, understand and evaluate research projects and ethics protocols in the health and medical field
	• coordinate with research teams
	• experience in writing submissions
Fundraising	• ability to develop and implement a fundraising strategy
	• event management
Treasurer	• ability to develop budgets and forecasts of funding requirements
	• manage research budgets
Design	• assist in the design and preparation of templates for invitations, newsletters, brochures and other printed and electronic material for distribution

The Association will be closing for the summer holiday break in early December 2016. However, you can email us over the holiday period if you would be interested in contributing in 2017 to any of the above areas.

Please contact KA Administrative Assistant Mary Veal directly on 0409 644 811 if you wish to participate.

The Committee of Management would like to thank everyone who has supported the Association over the past 12 months.

With your assistance, we can do much more in the coming year. If you believe in patients having a voice in their own care and can provide some expertise in the areas we are targeting, please join us in improving the lives of people with keratoconus and their families.

The Committee of Management
23 November 2016

FINANCIAL REPORTS

The Association reported a net operating profit in the 2015-16 financial year of $6,347. This was an increase of 42% on the previous year's net operating profit of $4,189. However the Association incurred a net loss of $3,653 after payment of a $10,000 gift to the Save Sight Institute in support of its Australian Crosslinking Registry project.

The higher operating result largely reflected a sharp increase in donations as expenses remained largely unchanged last year. In the absence of a major fundraiser, donations nonetheless jumped 63% to $8,982 compared to $6,320 previously. This largely reflected a greater influx of donations via the Give Now portal which offers donors the option of donating online and via credit card. Falling interest rates led to a slight decline interest income to $1,038 (-16%).

Overall expenses were flat at $3,828 (+2% compared to $3,760 in 2014-15). Although the Association conducts most of its correspondence online these days, it is still incurring significant postage costs ($605 in 2015-16) due to the number of members who fail to notify us of their email addresses.

The balance sheet on June 30, 2016 showed net assets of $83,674, or 9% lower than one year earlier ($87,327). End-year assets totalled $83,944 ($87,502 on June 30, 2015), held mostly in cash ($81,719). Some $75,981 of this is held in a high interest bearing deposit account at Westpac. Liabilities totalled $271 at the end of the 2015-16 financial year – these related to GST.

The accounts have been finalized and reviewed by our accountants, Deloitte Private, who prepare them for the Association on a pro bono basis.

Please direct any questions or comments about these accounts to Mary Veal.

Deloitte Private

Deloitte Private Pty Limited
ACN 120 167 455

550 Bourke Street
Melbourne, VIC, 3000
GPO Box 78
Melbourne, VIC, 3001

DX
Tel: +61 (0) 3 9671 7000
Fax: +61 (0) 3 9671 7001
www.deloitte.com.au

COMPILATION REPORT
TO KERATOCONUS AUSTRALIA INC

We have assisted in the compilation of the accompanying special purpose financial statements of Keratoconus Australia Inc for the year ended 30 June 2016.

The Responsibility of Public Officer

The public officer is solely responsible for the information contained in the special purpose financial statements.

Our Responsibility

On the basis of information provided by the public officer, we have assisted in the compilation of the accompanying special purpose financial statements in accordance with the significant accounting policies adopted as set out in APES 315: Compilation of Financial Information. The Balance Sheet and Profit and Loss Account information has been extracted from the MYOB accounting records which have been solely maintained by the public officer and management of the incorporated association.

Our procedures use accounting expertise to collect, classify and summarise the financial information, which the public officer provided, in compiling the financial statements. Our procedures do not include verification or validation procedures. In addition, these procedures do not include an assessment of the integrity of the MYOB file provided to us. No audit or review has been performed and accordingly no assurance is expressed.

The special purpose financial statements were compiled exclusively for the benefit of the public officer of Keratoconus Australia Inc. We do not accept responsibility to any other person for the contents of the special purpose financial statements.

Deloitte Private Pty Limited

Kevin Slomoi
Director

Dated: 14/11/2016

Keratoconus Australia
PO Box 1109
HAWKSBURN VIC 3142

Profit & Loss [Last Year Analysis]

July 2015 through June 2016

	This Year	Last Year
Income		
Donations	$8,980	$6,320
Seminar Entrance Fees	$79	$0
Video Sales	$9	$0
Booklet sales	$68	$23
Bank Interest	$1,038	$1,607
Total Income	$10,175	$7,949
Cost of Sales		
Gross Profit	$10,175	$7,949
Expenses		
Advertising	$390	$290
Domain Name Registration	$107	$54
Bank Charges	$1	$3
Catering	$49	$71
Stationery	$19	$205
Amortisation Expense	$670	$1,450
Dues & Subscriptions	$0	$229
Late Fees Paid	$15	$0
Vision 2020	$257	$0
Postage	$605	$653
Photocopying	$98	$131
Booklets	$172	$106
PO Box Rental	$121	$105
Video Recording	$364	$0
Website Hosting	$327	$327
Telephone and Internet	$64	$84
Travel	$415	$0
Sundry expenses	$154	$53
Total Expenses	$3,828	$3,760
Operating Profit	$6,347	$4,189
Other Expenses		
Gifts / Contributions		
Gift - Save Sight Institute	$10,000	$0
Total Other Expenses	$10,000	$0
Net Profit / (Loss)	($3,653)	$4,189

This report should be read in conjunction with the attached compilation report

Keratoconus Australia
PO Box 1109
HAWKSBURN VIC 3142

Balance Sheet [Last Year Analysis]

June 2016

	This Year	Last Year
Assets		
Current Assets		
Cash On Hand		
Westpac DGF Account	$5,738	$6,783
Westpac Max-iDirect	$75,981	$79,949
Total Cash On Hand	$81,719	$86,732
Trade Debtors	$0	$100
GiveNow Receivables	$2,225	$0
Total Current Assets	$83,944	$86,832
Intangible Assets		
Website Development - At Cost	$6,975	$6,975
Accumulated Amortisation	-$6,975	-$6,305
Total Intangible Assets	$0	$670
Total Assets	$83,944	$87,502
Liabilities		
Current Liabilities		
GST Liabilities		
GST Collected	$273	$270
GST Paid	-$2	-$95
Total GST Liabilities	$271	$175
Total Current Liabilities	$271	$175
Total Liabilities	$271	$175
Net Assets	$83,674	$87,327
Equity		
Retained Earnings	$87,327	$83,137
Current Year Earnings / (Losses)	-$3,653	$4,189
Total Equity	$83,674	$87,327

KERATOCONUS AUSTRALIA INC

NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2016

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The public officer of the incorporated association has prepared the financial statements of the incorporated association on the basis that the incorporated association is a non-reporting entity because there are no users dependent on general purpose financial statements. The financial statements are therefore special purpose financial statements that have been prepared in order to meet the requirements of the constitution and the information needs of the members.

The financial statements have been prepared in accordance with the significant accounting policies disclosed below, which the public officer has determined are appropriate to meet the purposes of preparation. Such accounting policies are consistent with the previous period unless stated otherwise.

(a) Revenue and Other Income

Revenue from direct donations is recognised on a cash receipts basis.

Revenue from GiveNow is recognised on a receivables basis and paid by GiveNow to the incorporated association in the month following receipt.

(b) Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts. Bank overdrafts are shown within short-term borrowings in current liabilities on the balance sheet.

ACKNOWLEGEMENTS

Keratoconus Australia would like to acknowledge the special contributions of the following people and organizations during 2015-16.

Associate Professor Richard Vojlay

Associate Professor Stephanie Watson

Big Red Communications

Belinda Cerritelli

Dr Laura Downie

Audio Visual Solutions

Centre for Eye Research Australia

Deloitte Private

Dr Michael Loughnan

Dr Jacqueline Beltz

Dr Elsie Chan

Dr Srujana Sahebjada

Herbert Smith Freehills

Jessica Chi

Optometry Australia

Professor Mark Daniell

Professor Charles McMonnies

Richard Lindsay

Save Sight Institute

The Australian College of Optometry

The Department of Optometry and Vision Sciences, University of Melbourne

The Eye Foundation

Viewgrow Capital Pty Ltd

Vision 2020 Australia

ANNEXES

Statement of Recognition

10 December 2015

KERATOCONUS AUSTRALIA COMMITTEE
Keratoconus Australia
PO Box 1109
Hawksburn VIC 3142

Thank you for approving Professor Stephanie Watson's proposal for $10,000 donation.
Please accept this as the Statement of Recognition requested by the committee to release these funds.

Recognition of Keratoconus Australia

- ✓ Where applicable Keratoconus Australia will be acknowledged as a financial Supporter of the Project in the following terms
  Kindly supported by Keratoconus Australia (2015) or relevant dates

- ✓ Keratoconus Australia will be invited to attend sessions relating to Patient Engagement and may be invited to provide advice or suggestions, which will be non-binding, and which will be considered in line with the Project's objectives, regulatory and ethical obligations.

- ✓ Keratoconus Australia may be invited to present on KA support at these sessions

Patient Representation at Project level

- ✓ A patient representatives from Keratoconus Australia will be invited to form part of the Keratoconus Registry's Advisory Committee.
- ✓ Keratoconus Australia will be invited to put forward a nomination for this role.
- ✓ Nominated representatives will be expect to undergo the nomination/acceptance process.

Please let me, or Professor Watson (stephanie.watson@sydney.edu.au) know if you have any queries on the above.

Sincerely,
Amparo Herrera-Bond
Manager
Save Sight Registries
Save Sight Institute | The University of Sydney
T. +61 2 9382 7304 | +61 408 123 730 F. +61 2 9382 7278
E: amparo.herrerabond@sydney.edu.au

Hands Off Your Eyes!

in Ageing, Education, News, Ocular Surface Disease
2 Sep 2015

Chronic eye rubbers should be aware of the risks

Eye specialists from the Save Sight Institute in Sydney have warned that chronic eye-rubbing could be damaging your eyes. In collaboration with the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) and Keratoconus Australia, the Save Sight Institute is calling for better public awareness of the risks associated with eye friction.

Growing evidence indicates that constant and vigorous eye-rubbing can bring on, or worsen, a relatively common ocular condition called keratoconus, which affects around one in every 2,000 people.

Keratoconus blurs vision by thinning the cornea, the transparent front part of the eye. As the cornea thins, it begins to distort and bulge, and becomes cone-shaped rather than the usual round shape. Significant loss of vision can result as the cornea is primarily responsible for the eye's focusing power.

In its early stages, vision may be corrected with spectacles although there may be an increased sensitivity to light. As the condition advances, vision may no longer be adequately corrected due to the high irregularity of the cornea.

Both eyes are usually affected, but may respond in different ways, and 20% lead to severe visual impairment. As the condition continues to deteriorate, a corneal graft may be required.

According to Clinical Professor Stephanie Watson from the Save Sight Institute, "Eye rubbing is often caused by allergies, and this can become a problematic habit. In chronic eye rubbers, more severe keratoconus often corresponds with the dominant hand."

Twenty-four year old Darren Wright is one person who found out the hard way that vigorous and prolonged eye rubbing can have unfortunate consequences. Recently diagnosed with Keratoconus, he said "I didn't know that just rubbing my eyes was so bad for, and especially that it has contributed to my deteriorating vision".

The precise cause of keratoconus is unknown. It is thought that genetic factors may contribute, and that eye rubbing can lead to eye trauma, as well as trigger the release of enzymes which weaken the cornea.

Mr Larry Kornhauser, President of Keratoconus Australia is concerned about the lack of public awareness of the risks of eye rubbing.

“The Association regularly hears from young people with progressive keratoconus who ask why their vision deteriorates so quickly,” he said. “We ask them if they have itchy eyes and if they rub their eyes vigorously and most say ‘yes, why?’. They get upset when told that eye rubbing is contra-indicated with keratoconus as it can trigger or accelerate the disease. They (or their parents) always say, ‘why didn’t anyone tell us?’ ”

Keratoconus Australia believes that publicising the effects of eye rubbing could be a simple but significant step in the fight to minimize the impact of keratoconus in the community. Eye-carers and allergists have a responsibility to inform their patients of the impact of eye rubbing and offer effective treatments for itchy eyes.

Researchers from the Save Sight Institute are working hard to find new and improved ways of treating this eye disorder.

In progressive cases of keratoconus, a technique known as ‘corneal cross-linking’ is commonly used, using UV light and a photosensitiser to strengthen chemical bonds in the cornea, ultimately with the aim of halting the progressive degeneration.

The Ocular Repair Group at Save Sight Institute, under the leadership of Prof Watson, has recently launched a sophisticated web-based software platform to collect data across a large number of real-life clinical settings.

“This allows us to analyse high volume patient outcomes from the procedure” says Prof Watson “and this important information plays a direct role in improving the way in which we care for patients affected by keratoconus, now and in the future”.

The Corneal Disease Group at Save Sight Institute, under the leadership of Professor Gerard Sutton and Dr Con Petsoglou, have had considerable success in identifying an important protein which is expressed by people affected by keratoconus, and are working towards possible future treatments targeted at this protein.

To support eye research at the Save Sight Institute please click here.

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RANZCO The Royal Australian and New Zealand College of Ophthalmologists
THE LEADERS IN COLLABORATIVE EYE CARE

(/)

Hands off your eyes!

THE HIDDEN DANGERS OF CHRONIC AND VIGOROUS EYE RUBBING.

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To support eye research at the Save Sight Institute please visit savesightinstitute.org.au (http://savesightinstitute.org.au)

For more information or to arrange an interview contact Emma Carr or Laura Safaj at RANZCO on +61 426 842 121 or 02 9690 1001 and media@ranzco.edu (mailto:media@ranzco.edu)

Collagen corneal cross-linking registry

Tuesday, January 5, 2016

Professor Stephanie Watson launching the module Image: Save Sight Institute

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By Helen Carter

Journalist

A world-first project launched in Sydney will assess real life treatment outcomes of collagen corneal cross-linking on keratoconus patients.

Save Sight Institute's Save Sight Registries online platform analyses real life treatment outcomes globally. The first two modules were for macular degeneration and diabetic retinopathy, and a third module, keratoconus, has been added to the registries framework.

The keratoconus module will collect and analyse real time clinical data and patient outcomes from current and emerging approaches to managing keratoconus. Collagen cross-linking will be the first treatment examined, making the module the world's first large-scale assessment of collagen cross-linking.

Clinical Professor Stephanie Watson, who heads the keratoconus module, said ophthalmologists were involved in recording data on the registry but optometrists had an important role in educating patients about the registry and would have a greater role in the future.

'Phase one of the registry allows ophthalmologists to enter and access data but phase two will look at how optometrists will be more actively involved,' she told *Australian Optometry*.

'I am looking forward to exploring the options and challenges for greater optometric involvement.

'Cross-linking is what we are analysing now but in the future it will be expanded for existing and emerging therapies. No-one else in the world has a system like this to collect data from all clinical settings.'

Professor Watson said collaboration was the most powerful tool in the fight against blindness and more people could be helped by working together and harnessing the huge amounts of available data.

The registries enable any clinician administering treatments and performing procedures to contribute. Ophthalmologists from Australia, New Zealand, Europe, Asia and America are participating.

The head of Save Sight Registries, Professor Mark Gillies, instigated the registries as a research tool with differences from randomised clinical trials eight years ago.

'Registries track patient outcomes in the real world,' he said at the 25 November launch. 'Clinical trials tend to exclude certain patient groups and are also conducted for a limited time frame with a limited number of patients.

'We track all patients over the long-term. It's quick and easy for clinicians to use during routine consultations, taking just 15 seconds to enter patient data.'

The registries allow doctors to audit their own patient outcomes anonymously by comparing results so that they can benchmark themselves with other clinicians. There is no charge to use the system, and patient and doctor data are anonymous.

Easily generated reports in graphical form helped clinicians anticipate how a prescribed treatment regime should work, Professor Gillies said.

Keratoconus Australia president Larry Kornhauser Image: Save Sight Institute

Keratoconus Australia president Larry Kornhauser, who provided seed funding to launch the project, said one of the most important aspects of the registry was its inclusion of patient reported outcomes.

'It is so critical to include those with the most at stake in the process, to ask them about their lived experience and to incorporate their responses in the overall assessment of treatment approaches,' he said.

Optometrist Esther Euripidou asks a question at the launch Image: Save Sight Institute

Role for optometry

Sydney optometrist Esther Euripidou, who sees keratoconic patients and comanages their treatment, attended the launch at Sydney Eye Hospital to learn more about optometrists' involvement and the latest information on case management of keratoconic patients.

'I have referred patients for collagen cross-linking. They are often lost to follow up so it's hard to be 100 per cent conclusive that they have had an optimal result,' Ms Euripidou told *Australian Optometry*.

'It will be particularly important to know if those who declined treatment declined in visual acuity and if they presented later for treatment, if it was just as effective at a later stage.

'It will give important information to younger people who are more likely to have progressing symptoms. Initiating suitable treatment at the earliest stage of progression is critical to preserving vision,' she said.

Ms Euripidou said Mr Kornhauser had addressed a problem, stating that many keratoconic patients were not happy with counselling from optometrists who were not skilled in fitting patients with keratoconus and that poorly fitting contact lenses could make keratoconus patients' problems worse.

She said she found it confronting and thought provoking listening to his personal experiences and about interactions with patients seeking support from the organisation, but she now felt more confident in her methods and approach with keratoconus patient counselling and management.

'I had questioned my initial over-testing and time spent with the patient at diagnosis but now I realise the importance of tailoring the approach to sensitive patients,' she said.

Corneal specialist Dr Con Petsoglou encouraged optometrists to refer to ophthalmologists involved in the initiative because data would be detailed in a way to allow patient follow-up and used for evidence-based approaches to future patient management.

Patients, optometrists, clinicians and industry stakeholders attended the launch and asked questions of a panel of corneal specialists including Professor Watson, Dr Petsoglou, Dr Yves Kerdraon and Dr John Males.

Keratoconus patient Michelle Urquhart Image: Save Sight Institute

Keratoconus patient Michelle Urquhart was diagnosed as a teenager and has undergone corneal grafts.

'My world has often turned fuzzy as my eyesight fluctuated. I've felt very unsure about what the future held for me. I wasn't always able to see the features of my beautiful babies,' she said.

'It's been quite a journey but I'm now benefitting from the amazing research already undertaken. This new phase is very exciting and I know that the results from this registry will benefit many more people in the future.'

Ms Euripidou said it was great to see ophthalmologists, optometrists and patients working towards the common goal of understanding the condition and supporting those affected.

See the Save Sight Registries

This entry was posted by Sandra Shaw, on Tuesday, January 5, 2016

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Medical Services Advisory Committee

Public Summary Document

Application No. 1392 – Corneal Collagen Cross Linking as early intervention in progressive keratoconus

Applicant: **Royal Australian and New Zealand College of Ophthalmologists (RANZCO)**

Date of MSAC consideration: **MSAC 67th Meeting, 28-29 July 2016**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at MSAC Website

1. Purpose of application and links to other applications

An application requesting a new Medicare Benefit Schedule (MBS) listing of Corneal Collagen Cross Linking (CCXL) as early intervention in progressive keratoconus was received by the Department of Health from RANZCO.

2. MSAC's advice to the Minister

After considering the available evidence presented in relation to safety, clinical effectiveness and cost effectiveness, MSAC deferred its advice to the Minister on public funding for CCXL in patients with corneal ectatic disorders due to concerns that the revised economic model had not been adequately verified and that the riboflavin drops used in rendering this service were not registered on the Australian Register of Therapeutic Goods (ARTG).

MSAC requested the following information to enable it to finalise its advice:

- a more detailed rationale for the proposed fee, including the range of applicable protocols to render the service, and how these range in both complexity and duration
- an assessment by its Evaluation Sub-Committee (ESC) comparing the revised modelled economic evaluation with the version initially developed, and examining the sensitivity of these models to variations in the proposed fee
- clarification from the Therapeutic Goods Administration (TGA) regarding the consequences of the varying regulatory status of the codependent ultraviolet lamp device and the various riboflavin eye drop options used in rendering the service
- MSAC noted reports that several large well-designed clinical trials due to report in 2016–17 have discontinued their control arms. Any further assessment of this application may want to address the progress of those trials.
- Data cited in the pre-MSAC response said to be available in patients with ectasias other than keratoconus.

3. Summary of consideration and rationale for MSAC's advice

CCXL is a novel treatment claimed to halt progression of corneal ectasia (bulging of the cornea that can cause significant visual impairment). Treatment involves soaking of the cornea with a solution of riboflavin 0.1% and dextran. An ultraviolet A light source is then shone onto the cornea. This increases inter molecular bonds between collagen fibres and stiffens the cornea reducing the risk of ectasia progression.

The intended use of CCXL is in patients with corneal ectatic disorders with evidence of disease progression. Keratoconus accounts for approximately 90% of these disorders, with an estimated prevalence of one in 2000, or 0.05% of the population. The onset of keratoconus can occur anywhere between the ages of 8 and 45years, with the majority of cases occurring in patients aged 16-30years of age. MSAC acknowledged the consumer feedback from the consultation process highlighting the value patients with these disorders place on reducing progression of visual impairment.

Once progression of a corneal ectatic disorder has been identified, current treatment involves attempting to improve vision firstly with glasses or soft contact lenses before progressing to hard contact lenses. If hard contact lenses cannot be fitted or are unsuitable, the patient may require corneal transplantation.

MSAC accepted that CCXL is intended as a first-line treatment once there is evidence of disease progression. The proposed treatment pathway utilises CCXL as preventive treatment (intending to halt the progression of the disease). MSAC therefore considered the early interventions in the current treatment pathway to be the appropriate comparators.

In considering the evidence for efficacy and safety of CCXL, MSAC noted that the few published randomised controlled trials (RCTs) available were small and of low quality. The evidence base presented primarily consisted of non-randomised studies which analysed CCXL results at various time points after the procedure compared to baseline. Comparisons with the current treatment pathway are therefore either not possible or difficult due to limitations in the quality of the evidence available. MSAC also noted that all evidence available was for patients with keratoconus. In the pre-MSAC response, the applicant noted that some data were available for other conditions, though these were not included with the response.

Three systematic reviews and meta-analyses (Craig JA et al 2014, Li J et al 2015 and Meiri Z et al 2016) formed the basis of the safety and efficacy effect estimates in the contracted assessment report. These were supplemented with the findings of RCTs and non-randomised studies which had been excluded from or published after these reviews. MSAC noted that the Craig JA et al 2014 review on the safety and efficacy of epithelium-off CCXL was used as the basis of approval of this intervention in the United Kingdom. MSAC was advised that approval had also been granted in the United States, Europe and New Zealand.

MSAC noted that adverse events and complications after CCXL were not well reported in the RCTs and hence there are few comparative safety data available. The contracted assessment indicated that a range of adverse events have been reported with CCXL, but these were generally minor and transient in nature. Minor corneal haze was found to be common but was noted to resolve over time. A small number of cases of serious corneal oedema, infection, repeat surgery and stromal scarring were also reported. Despite the lack of direct comparative safety data, MSAC considered that on aggregate it was reasonable to assume from the available evidence that the absolute complication rate arising from the procedure is low.

MSAC was however concerned that, while the ultraviolet lamp devices are included in the ARTG, the 0.1% riboflavin eye drops used in rendering this service are not. The riboflavin drops are accessed via the TGA's Special Access Scheme. This means that the quality, safety and efficacy of these drops has not been formally evaluated by the TGA and places responsibility for use of an unapproved product on the prescribing physician in terms of safety and efficacy. Special access requests are processed by the TGA on a per patient basis, placing an additional administrative burden on the prescriber to obtain the necessary approvals. MSAC noted that there have been no adverse events for the riboflavin solution recorded in the TGA database of adverse event notifications. MSAC requested clarification from the TGA regarding the consequences of the varying regulatory status of these two components of this service.

In considering the efficacy of CCXL, MSAC was concerned that the presented clinical data did not definitively demonstrate that CCXL delays the need for a corneal transplant. MSAC recognised that due to the extended period of time between diagnosis and transplant

(10–20years) it was unlikely that RCT data answering this question would become available. MSAC noted that two studies which reviewed registry data (Sandvik GF et al 2015, Godefrooij DA et al 2016) indicated that there was a reduction in the number of corneal transplants for patients with keratoconus in the years since the introduction of CCXL. However, MSAC was concerned that these were observational studies and hence other factors could be driving the reductions seen, for example the time between increases in CCXL and decreases in corneal transplant did not match the plausible time course of disease progression. MSAC noted that a CCXL register has recently been set up at the University of Sydney.

As comparisons with the current treatment pathway were not possible, the efficacy of CCXL per se was reviewed. MSAC accepted that the evidence available, while limited, does show that CCXL leads to improvements over baseline in corrected visual acuity, uncorrected visual acuity, Kmax and spherical equivalent refractive error. These improvements were maintained over at least 2years with one study (Raiskup F et al 2015) indicating that improvements remain evident at 10years.

MSAC noted that some additional, but very low quality, data on quality of life (QOL) was also identified, suggesting possible QOL improvements over baseline in those who have undergone CCXL compared to those with contact lenses.

Scant data pertaining to the use of CCXL in children and adolescents were evident. MSAC noted that, where the procedure has been attempted in this population, the outcomes have been similar to those for adults or all ages. However, MSAC noted that there was emerging evidence which indicated that the effect of halting disease progression in this population might not be as sustained as in adults (Godefrooij DA et al 2016, Chatzis N and Hafezi F 2012) in particular incidence of disease progression in 22% of treated eyes cited by Godefrooij DA et al 2016.

MSAC noted that research on CCXL continues with over 70 trials, primarily focusing on procedure variations, currently registered in clinicaltrials.gov. MSAC considered that it was unlikely that these trials would provide long-term efficacy data as most were to be conducted over a one-year period and involved surrogate outcomes. MSAC was concerned with reports that several large well-designed clinical trials due to report in 2016–17 have discontinued their control arms. MSAC considered that details about the reasons for the premature cessation of these trials may assist in its assessment of the current application.

MSAC noted that both ESC and the applicant had reviewed the original economic model for this application and raised a number of concerns. A revised economic model was subsequently submitted however the timing did not allow review by ESC or the applicant. MSAC noted that the revised model included inputs to address a number of the issues initially raised. However, MSAC was concerned that variations between the two models indicated the incremental cost per QALY was unstable. MSAC was also unable to determine the extent to which cost effectiveness was driven by avoidance of corneal transplant and requested that the revised economic evaluation enable a comparison with and without inclusion of corneal transplants avoided. MSAC noted that the study by Salmon H et al 2015, which was used to inform the structure and assumptions of the revised model, indicated that the effect of CCXL after 5years was a key driver of cost effectiveness, although there were no clinical data to support any assumptions made after three years. MSAC considered that the utility weights, their origin and their application in the economic model also needed adjustment. MSAC requested that ESC review the revised model and compare it with the version initially developed as MSAC was concerned that the revised economic model had not been adequately verified. MSAC also requested that ESC examine the sensitivity of these models to variations in the proposed fee.

MSAC noted that the proposed fee for this service had not yet been agreed. The Protocol Advisory Sub-Committee had suggested a value between $900 and $1300 based upon the current fees for cataract surgery and corneal transplant MBS items, respectively. However, MSAC was concerned about using these MBS items as fee-setting benchmarks, noting that the fees may be higher than appropriate for CCXL. MSAC noted that Godefrooij DA et al 2016 detailed the costs associated with CCXL in clinical practice for 43 patients (86 eyes) in the Netherlands. Costs varied depending on who was undertaking the procedure (optometrist versus ophthalmologist) and the protocol used to render the service. MSAC requested that a revised fee for CCXL be developed with the rationale for the costs and charges detailed.

MSAC noted further that as variations of the CCXL procedure exist, ranging in both complexity and duration, the revised fee should also take into account the range of applicable protocols currently available to render the service.

MSAC considered whether the proposed MBS item descriptor should be restricted to patients with keratoconus as data for the use of CCXL in other corneal ectatic disorders was not presented. MSAC foreshadowed that any MBS item descriptor would remain inclusive of other corneal ectatic disorders and requested that the applicant provide data on other ectasias referred to in their pre-MSAC response to assist in informing this decision. MSAC also foreshadowed that the item would not be restricted to one service per lifetime per eye, as not enough data was currently available on long-term disease progression to inform this restriction. MSAC noted that the department had received advice of use of CCXL in patients with post-LASIK[1] ectasia and foreshadowed that wording may be required in any descriptor to exclude use in this population for a CCXL item. MSAC also foreshadowed that it would be reasonable to require mandatory recording of services provided and their outcomes on a CCXL register.

MSAC was satisfied that, on the basis of the evidence presented, CCXL has acceptable safety and clinical effectiveness in the proposed population. However, MSAC was unable to support public funding at this time due to concerns that the revised economic model had not been adequately verified and that the riboflavin drops used were not registered in the ARTG.

[1] LASIK: Laser-Assisted *In Situ* Keratomileusis (commonly referred to as laser eye surgery)

MSAC requested the following information before it could finalise its advice:

- a more detailed rationale for the proposed fee, including across the range of applicable protocols to render the service, which range in both complexity and duration
- an assessment by ESC comparing the revised modelled economic evaluation with the version initially developed, and examining the sensitivity of these models to variations in the proposed fee
- clarification from the TGA regarding the consequences of the varying regulatory status of the ultraviolet lamp device and the various riboflavin eye drop options used in rendering the service
- MSAC noted reports that several large well-designed clinical trials due to report in 2016–17 have discontinued their control arms. Any further assessment of this application may want to address the progress of those trials.

4. Background

MSAC has not previously considered Corneal Collagen Cross Linking.

5. Prerequisites to implementation of any funding advice

The CCXL procedure requires 0.1% riboflavin eye drops, which are not currently registered on the Australian Register of Therapeutic Goods. The riboflavin drops may be accessed via the TGA's Special Access Scheme.

6. Proposal for public funding

The application proposed fee and MBS item descriptor is shown in Table 1.

Table 1 - Proposed MBS item descriptor for corneal collagen cross-linking

Category 3 – Therapeutic Procedures – Ophthalmology Services
MBS [item number] Corneal Collagen Cross Linking, for patients with corneal ectatic disorders with evidence of progression Fee: $1500 Anaes.
Explanatory Note: Evidence of progression in patients over the age of twenty five is determined by the patient history including an objective change in tomography or refraction over time. Evidence of progression in patients aged twenty five years or younger is determined by patient history including an objective change in tomography or refraction over time and/or posterior elevation data and objective documented progression at a subclinical level.

The application proposed fee is $1500. PASC suggested a fee of $900-$1300 would be appropriate (between the cost of cataract surgery and corneal transplant). During the public

consultation, consumers advised that currently, they are being charged between $2000–3000 per eye ($4000–$6000 for both eyes).

The CCXL procedure can be performed in day surgery facilities or other facilities that have adequate air handling systems and sterile conditions.

7. Summary of Public Consultation Feedback/Consumer Issues

PASC received three responses from peak bodies, two responses from organisations, 14 responses from specialists, 20 responses from consumers and 12 responses from carers.

Consultation feedback for the proposal was positive. Issues raised in the responses were:

- The proposed population should be expanded to patients with corneal ectatic disorders.
- Corrective lenses including hard lenses only address the symptoms of the medical condition. The two treatments for the medical condition are the proposed procedure and penetrating corneal grafts, therefore the procedure should be used as a first line treatment.
- Additional measures should be used to determine evidence of progression of the medical condition in patients under 25 as there is a high risk of rapid progression in this population group. These measures may include posterior elevation data and objective documented progression at a subclinical level.
- The MBS Item fee should be revised from $1500 to greater than $2000 to reflect current procedure costs.

8. Proposed intervention's place in clinical management

CCXL will be used in patients with corneal ectatic disorders (primarily keratoconus) with evidence of progression of the disease.

Keratoconus accounts for 90 per cent of patients with corneal ectatic disorders, with an estimated prevalence of one in 2000, or 0.05 per cent of the population.

The current approach to treating patients with corneal ectatic disorders involves, in the first instance, attempting to improve the patient's vision with glasses (or soft contact lenses), if possible. If the condition progresses, and the glasses/soft contact lenses no longer improve the patient's vision, hard contact lenses are fitted. If the lenses cannot be fitted, or are unsuccessful, patients undergo penetrating corneal graft. Some patients currently access corneal collagen cross-linking as an alternative to corneal grafting by self-funding the procedure.

Under the proposed clinical management algorithm, CCXL would be used as a first line treatment once there is evidence of progression, regardless of whether glasses or contact lenses have been tried. The proposed treatment pathway utilises CCXL as a preventative treatment (intending to halt the progress of the disease early). It involves glasses/soft contact lenses, then CCXL, then hard contact lenses and then penetrating corneal graft.

9. Comparator

The current treatment pathway involves attempting to improve the patient's vision with glasses or soft contact lenses, and if no improvement or deterioration then hard contact

lenses. If hard contact lenses cannot be fitted or are unsuccessful, then patients undertake penetrating corneal graft.

10. Comparative safety

Adverse events and complications after CCXL are not well reported in the randomised trials, so there are few comparative safety data. A range of adverse events were described but these are generally minor and transient. Corneal haze was common but resolves over time.

The assessment report stated that it was not possible to assess the safety of CCXL relative to the conventional management pathway without CCXL. Therefore, at best, CCXL can be assessed to be non-inferior with respect to safety.

11. Comparative effectiveness

The included studies comprised 7 randomised controlled trials, 8 systematic reviews and 50 nonrandomised studies (cohort studies and case series). Primary effectiveness outcome measures analysed were best corrected visual acuity, uncorrected visual acuity, corneal topography, and spherical equivalent refractive error.

A summary of key results for the standard CCXL procedure over 12 months or longer is shown in Table 2.

Table 2 Evidence profile: Overall clinical effects of standard CCXL as measured in key included systematic reviews and randomised trials with 12 months followup or greater

Outcomes (units)	Participants (studies)	Type of study	Quality of evidence (GRADE)[a]	Effect (summary)
Corrected visual acuity (logMAR)	Craig 2014; Meiri 2016	Meta-analysis (RCTs and NRS)	Low	–0.1 at 12&24 months: –0.09 at ≥36 months:
	Li 2015	Meta-analysis (RCTs)	Low	–0.1 (3–36 months)
	#997 Seyedian 2015 #1204,1205 Wittig-Silva 2008 and 20014	RCTs	Low	–0.1 at 12 months;
Uncorrected visual acuity (logMAR)	Craig 2014; Meiri 2016	Meta-analysis (RCTs and NRS)	Low	–0.1 to –0.2 at 12&24 months –0.1 at ≥ 36 months:
	Li 2015	Meta-analysis (RCTs)	Low	–0.18(3–36 months)
	#1204,1205 Wittig-Silva 2008 and 20014	RCTs	Low	–0.1 at 12 months
Max K (D)	Craig 2014; Meiri 2016	Meta-analysis (RCTs and NRS)	Low	Relative to baseline/preCCCXL: –1 at 12&24 months –0.4 at ≥ 36 months
	Li 2015	Meta-analysis (RCTs)	Low	Relative to controls: –2.05 D (3–36 months)
	#997 Seyedian 2015 #1204,1205 Wittig-Silva 2008 and 20014	RCTs	Low	Relative to baseline and/or controls (up to 36 months): –1 to –2 D
Spherical equivalent refractive error (D)	Craig 2014; Meiri 2016	Meta-analysis (RCTs and NRS)	Low	Relative to baseline: 0.1–0.5 at 12 months 0.7 at 24 months 0.5 at ≥36 months
	Li 2015	Meta-analysis (RCTs)	Low	Relative to controls: –0.96 (3–36 months)
	#997 Seyedian 2015 #1204,1205 Wittig-Silva 2008 and 20014	RCTs	Low	Little change to baseline and/or controls
Quality of life	NRS		Very low	Some improvements for people with CCCXL compared to those with rigid contact lenses

[a] Based on GRADE Working Group grades of evidence. However, the evidence collected for this review was all low quality and did not lend itself well to a formal GRADE analysis
High quality: We are very confident that the true effect lies close to that of the estimate of effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

On the basis of this evidence profile, the assessment report suggested that, relative to the current treatment pathway, CCXL has noninferior safety and noninferior (possibly superior) effectiveness.

Considerable further comparative data would be required to make a more definitive conclusion relative to the conventional management pathway. The assessment report stated that several large clinical trials are due to report in 2016–17.

12. Economic evaluation

The assessment report presented a cost-utility analysis over a time horizon of 50years to reflect the long-term impact of a disease for which there is a predictable number of diagnoses per year.

The overall costs and outcomes, and incremental costs and outcomes as calculated for the intervention and comparator in the model, and using the base case assumptions, are shown in the Table 2. This indicates that CCXL treatment pathway has a lower cost and higher incremental benefits compared to the current treatment pathway.

Table 2 Incremental cost effectiveness ratio, discounted

	Cost ($)	Incremental cost ($)	Effectiveness (QALYs)	Incremental effectiveness	ICER
Intervention	21 926 707		145 145		
Comparator	23 057 646	-1 130 939	144 877	268	-4 215

The assessment report noted that with respect to CCXL, the ICER is an imperfect measure of value because is results in improved outcomes at a lower cost. Although CCXL treatment pathway 'front loads' treatment costs, there is an incremental saving as it avoids corneal transplants which are significantly more expensive due to hospital and eye bank fees. The benefit attributed to CCXL is also likely understated as the utility measures do not reflect the improved quality of life from not undergoing an invasive surgical procedure, or experiencing life as a young person without deteriorating vision. Data limitations prevent allowances being made for these factors in the analysis.

A sensitivity analysis was conducted, the key findings were:

- the incremental cost of the CCXL treatment pathway is highly sensitivity to the discount rate used because, compared to the current treatment pathway, under CCXL a larger proportion of treatment costs are incurred on diagnosis.
- increasing the number of treatments for individuals previously diagnosed with corneal ectatic disorders, has a significant impact on the costs of the CCXL pathway.
- changing the costs of CCXL treatment has significant impacts on the results. Applying a range of 30 per cent either side implies costs could be between $4.1 million lower under the CCXL pathway or $7.1 million higher in present value terms (over 50years).
- Overall the project generally has incremental benefits (increase QALYs) across the range of scenarios tested.

13. Financial/budgetary impacts

An epidemiological approach was used to estimate the financial implications of the introduction of CCXL.

The expected use of CCXL treatments depends both on the stock of potential patients in Australia, new patients that are diagnosed each year, and the suitability of CCXL to their condition.

Not all people with corneal ectatic disorders in Australia need to be counted in the model as being potentially eligible for CCXL primarily because:

- some will have already had CCXL in one or two eyes.
- some will experience stabilisation of their condition rather than deterioration.
- some will be too advanced in their condition to benefit from CCXL and are likely to continue with the current treatment pathway and receive a corneal graft.

The utilisation model begins with an estimate of prevalence (1 in 2000, or 1 in 1625 people aged 15 and over). It then increases the prevalence pool estimate on an annual basis as new patients are deemed to be diagnosed, as the severity status of existing patients changes, and as patients die.

The estimated potential patient population shows around 12,000 people might receive CCXL at some point in their lives. Forecasts change in line with expected population growth and changes in the stage of the disease for each person. Those that are estimated to receive CCXL over the next 5years is estimated based on the evidence around progression of the disease following diagnosis, the distribution of disease severity in the literature previously mentioned, and suitability of alternative treatments such as corneal grafts.

Given CCXL activity to date, 1,642 treatments are estimated to occur in 2016-17 and then taper down substantially as much higher levels currently being treated are not believed to be sustainable.

The financial implications to the MBS resulting from the proposed listing of CCXL are summarised in Table 3. The estimated cost to the MBS of CCXL is $2.5 million in the first financial year, which tapers off and stabilises around $600,000 thereafter.

This is reducible by approximately $65,000 annually as a result of avoided corneal grafts and associated complications.

Table 3 Total costs to the MBS associated with CCXL

		2016-17	2017-18	2018-19	2019-20	2020-21
Preliminary consultations		$ 140 473	$38 583	$30 883	$32 338	$33 279
CCCXL procedures		$ 2 134 600	$ 586 300	$469 300	$ 491 400	$ 505 700
Follow up consultations after 1 year		$211 818	$ 58 179	$ 46 569	$ 48 762	$ 50 181
Total cost to the MBS		**$2 486 891**	**$683 062**	**$546 753**	**$572 500**	**$589 160**

14. Key issues from ESC for MSAC

ESC advised that the key issues below would be most relevant to MSAC decision-making.

CCXL offers, at best, non-inferior safety and non-inferior, possibly superior, effectiveness, relative to the current treatment pathway, based on low level clinical evidence. Considerable further comparative data would be required to make a more definitive conclusion relative to conventional management pathway. ESC added the following caveats:

- There were no true long-term follow-up data (longer than 3years) that tested the durability of the procedure or the outcomes in terms of corneal grafts avoided. There was no evidence on which to base an assessment of whether patients had an inadequate or less-than-permanent response, or the risk of eventual disease progression;
- 100% of the clinical data were collected in patients with keratoconus, which, while the most prevalent of the corneal ectatic disorders, constitutes only 90% of Australian patients with corneal ectatic disorders;
- There was an overall lack of evidence for comparative safety. Adverse events were not well reported in the clinical evidence; in particular there was a lack of data to support the safety of the CCXL procedure, the types of events observed, their frequency and grade, especially with respect to complications and also in comparison with conventional management.
- Nonetheless several large, apparently well-designed clinical trials registered in clinicaltrials.gov are due to report in 2016–17.

The economic model was uncertain in multiple respects, including the inputs, numbers, outcomes and the extent of current use and thus numbers eligible for future use. ESC queried the validity of including the costs of CCXL procedure in the current (comparator) management pathway, also, the modelling for number of diagnoses per year does not account for permanent net overseas migration;

- The application did not specify costs of other resources used in the CCXL procedure. These should be included in the inputs to the economic model;
- The 50year modelled time horizon was appropriate for the target population but was otherwise unsupported by the clinical data;
- The model lacked clinical evidence for the estimates of rates of disease progression over 5 or 10years;
- The model assumes a 0% failure rate, which was unsupported and considered unlikely. Evidence-based rates for CCXL failure and complications should be incorporated in the model;
- The ICER did not reflect patient utilities including preference to avoid corneal grafts.

The applicant's claim that CCXL had become, in effect, the standard of care for this indication (based on a reported 70% uptake rate) was not independently verified for Australian patients nor supported with dependable health outcomes data. This flowed on to uncertainty in the utilisation and financial estimates.

With respect to the age of the patients who would receive CCXL treatment:

- The applicant did not adequately specify the age group of the intended population. Nor was evidence presented for the age of disease onset of keratoconus or other types of ectatic disorders;

- ESC noted the apparently young age of diagnosis for the conditions but that relatively few clinical data were available in that patient age group;
- In general the clinical evidence represented patients with variable/heterogeneous age and disease severity;
- MSAC may wish to consider, once the above information is available, whether patient age should be specified in the MBS item descriptor.

The clinical algorithm proposed should be modified to show CCXL either at or before the trial of glasses and/or soft contact lenses, given that the procedure is proposed as first line management.

The application would benefit from including more detail to support the natural history of the conditions being treated, including rates, with evidence, of expected progression to corneal transplant; need for other interventions; and time to progression in the second eye.

With respect to an appropriate MBS item descriptor:

- Anaesthetic drops to be used during the procedure should be specified in the descriptor.
- MSAC may also wish to consider including a once per lifetime per eye treatment criterion.

A number of other interventions were likely to be co-administered with CCXL, including at least two that are not MBS items (ultrasonic pachymetry and partial coherence laser inferometry).

The proposed fee is $1500. PASC suggested $900-$1300 (a range defined by current cataract surgery and corneal transplant items). However, consumers advise the procedure currently costs $2000–3000 per eye ($4000–$6000 for both eyes) suggesting that patient out of pocket costs may be high.

The CCXL procedure requires 0.1% riboflavin eye drops, which are not currently registered on the Australian Register of Therapeutic Goods and would either need to be approved by TGA or continue to be supplied under the TGA's Special Access Scheme.

15. Other significant factors

Nil.

16. Applicant's comments on MSAC's Public Summary Document

Keratoconus is a disease primarily starting in the late teenage years or early twenties. Some cases are mild and manageable by simple measures such as glasses and contact lenses. A significant percentage however go on to need corneal transplantation. Indeed Keratoconus is the commonest single indication for corneal transplantation [Australian Corneal Graft registry]. Although transplants are relatively successful in the very long term the rate of failure increases and so a percentage of patients end up with severe disability .A treatment to prevent this sequence of events is highly desirable, and as an intervention in young people comparable to childhood immunisation and fluoridation of water.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website.