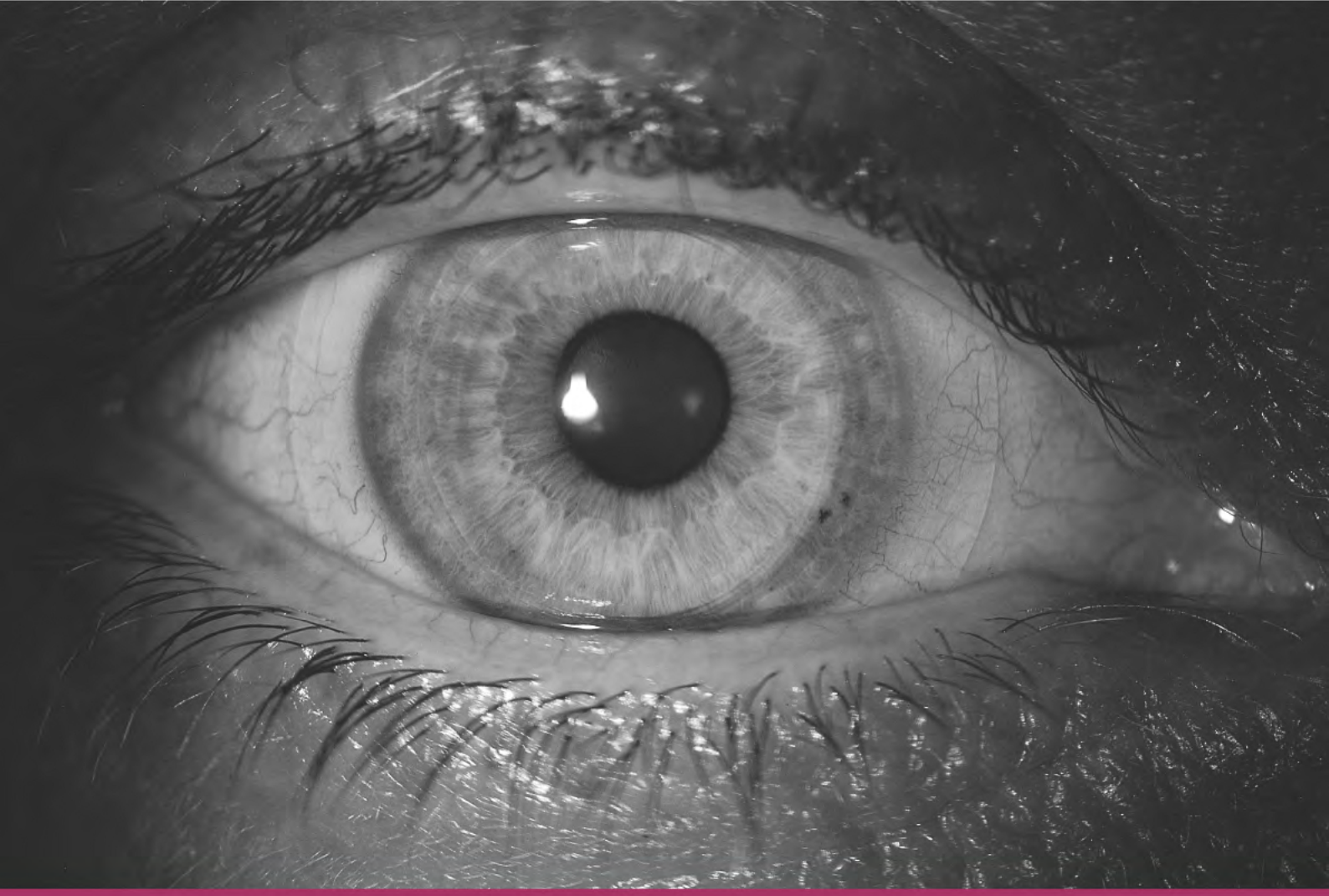


ANNUAL REPORT 2017

KERATOCONUS AUSTRALIA

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.org.au WEB www.keratoconus.org.au

FROM THE PRESIDENT

There's nothing like some complicated eye surgery to remind one how precarious life is with keratoconus.

Lying on a gurney, waiting for surgery, wondering whether your corneal surgeon had a big night out before coming in to work. Hearing the anaesthetist's comforting words before slipping towards a chemically induced near-death unconsciousness. Waking in the recovery room next to your beloved with furrowed brow. The long, one-eyed drive home, comforting words of support from family and friends. Removing the eye patch for the first time and seeing only white. Follow up visit with surgeon. Hear operation was more difficult and complex than anticipated. Outcome less certain, recovery time estimated at 3-4 months.

Days then spent lying around, unable to read or work. Sensitive to light. Struggling to wash your hair while keeping water and soap from your wounded eye. Checking the time for the next interminable round of eye drops. Then more drops and more. Taping the eye shield in place before going to bed and taking the selfie of the one eyed extra-terrestrial staring back at you in the mirror. Wondering whether to post to Instagram or… naa, hit delete. Days pass slowly. Eye stinging, becoming very red. Back to surgeon. Learn steroid drops have "burnt" an ulcer into the old graft. Change drops – fingers crossed no permanent damage. Relief – new drops working. Weeks crawl by. Start light exercise at the gym. Slow improvement, faint vision returning. Visit to contact lens fitter to discuss a return to a lens at some unspecified time. Still difficult to walk without losing balance. Driving banned for at least three months. Acquaint myself with the wonders of Uber. More visits to surgeon. Less drops. Lifting heavier weights at the gym. Teleconferencing for work instead of travelling.

Month four. Back to surgeon to have sutures removed. All healing well if slowly.

Month five, quick visit to corneal surgeon for final verification before trying a contact lens. Oops, what's that? "Oh another suture that I must have missed last time." Grr – another week lost to healing time. Off to the contact lens fitter. Finally! Try a new large contact lens. Good vision – relatively speaking but poor comfort. Slow build up causing hazing of old graft so back off and up steroid drops. Change to smaller design lens. New lens lost in post – two weeks lost. Better but still causing hazing of graft.

Months drift by. Driving again in local area- mostly one-eyed. Decide with optometrist to stop trying lenses and let graft settle for a month and restore its pristine condition before trying a new lens. Change again to an even smaller contact lens. Ahh finally progress. No haze and graft seems to be clear. Vision improved but nothing great. More reviews coming up soon.

It's now been 5 months since we started trying lenses and 11 months since the operation.

What are the lessons so far from my latest encounter with the surgeon's scalpel?

1. Eye surgery is great when unavoidable. But it's an imprecise tool for restoring sight with uncertain longevity. Contact lenses before surgery remain the best option for restoring vision lost to keratoconus. After surgery, they are generally still required and harder to fit.
2. When dealing with keratoconus, patience is a great virtue for patient and eye-carer
3. Speak up! Your eye-carers can't listen if you don't tell them what's wrong.
4. Eye-carers are precious; they set the path for your journey, can tell you what to expect and help with the hiccups along the way.
5. But it's a journey you take essentially with your family and friends. Those who are with you 24/7 and who pick you up when you fall down – in both body and soul.

Which is a reminder why Keratoconus Australia exists as a keratoconus support group and why we remain governed only by people with keratoconus or their immediate family.

We know what it's like, we know what you are going through.

It's also the reason why we need your support and assistance.

Larry Kornhauser
November 2017

PS Twelve hours after I wrote that prophetic first sentence, I was woken by a violent punch to my operated eye thrown (accidentally) by my sick toddler who was sleeping in our bed. My old, wheezy corneal graft seems okay this morning – but it gave me one hell of a fright.

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 2016-17

Support contacts logged by the Association were down by almost 20% from about 327 to 266 in 2016-17. It is difficult to know exactly what explained this decline but the proliferation of keratoconus-related information on the internet would probably be a factor.

Certainly, most of the people contacting the Association these days have some notion of what keratoconus is and what treatments are available. As with all medical conditions, the problem with using Dr Google for keratoconus is that it fails to provide information tailored to a person's unique condition and circumstances. And often the information is out of date or just plain wrong. Or is marketing material designed to bait the unsuspecting user to buy a particular treatment or product. Sadly, some ophthalmologists engage in promoting themselves and their clinics in less than scrupulous ways.

We believe that newly diagnosed patients and those facing progression in their disease and seeking information about their options can benefit from communicating directly in person or by phone or email or text or social media etc. with other people with keratoconus at Keratoconus Australia.

Support provided by the Association in 2016-17 fell into four main categories:

1. Assistance in finding specialist optometrists and corneal surgeons to provide the best treatment and management options for keratoconus (38%)
2. Support for patients and families on diagnosis of the disease (13%)
3. Information about contact lenses and especially the larger types which are becoming more popular with contact lens fitters (12%)

4. Information about corneal collagen crosslinking – the primary treatment today for patients with progressive keratoconus. (12%)

Although these reflect similar patterns to previous years, the Association detected subtle shifts in the type of support requests it received over the past twelve months.

Despite all the information available on the internet about keratoconus, the key issue facing people with keratoconus remains how to locate an optometrist or corneal surgeon specialising in keratoconus. Regardless of the initial reason for contacting the Association, most of our support contacts with patients and their families result in us providing guidance on where to find an appropriate specialist to deal with their issue.

It is critical that patients do see a specialist as too many of the problems our members raise with us are the result of poor contact lens fittings or surgery performed by eye-carers who are relatively inexperienced in managing the particular issues involved in keratoconus.

One long-time member Greg even contacted last year to ask us to remove him from our mailing list. **He recently found out he had been misdiagnosed 30 years ago… *and did not actually have keratoconus!***

While this may seem like a mildly amusing anecdote, Greg said the following:

Understandably it was stressful to me over all these years believing I had keratoconus and may one day lose my vision. I continued to have regular check-ups with local optometrists and told them about my keratoconus and they just accepted that… About a year ago I went to an Optometrist who actually took some time to investigate and run a few more Tests. He informed me that I definitely do not have keratoconus and never did. He took time to explain why and provided the evidence. I had mixed emotions, with the relief about being told I don't have keratoconus but understandably annoyed at going though almost 30 years of stress."

Not a proud moment for one of Australia's leading chain optometrists.

Corneal collagen crosslinking and **contact lenses** were again the focus of many inquiries and concerns.

There continues to be much confusion over **corneal collagen crosslinking**. Who should have it? When to have it? Who should not have it? Are there different types of crosslinking? What are success rates?

The Association tries to answer these questions as best it can. But as noted above, we are not medical practitioners and can give out only general information we have from ophthalmologists and researchers. We have tried to provide more detail about crosslinking on our new website and are preparing a brochure for patients in conjunction with Save Sight Institute that will be sent to all members soon.

The Association repeats over and over to patients and their families that crosslinking is not a benign, risk free procedure. Like many corneal surgeons (although not all), 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." Bilateral operations are generally discouraged for that reason and because of the risk of disabling a patient for a long period of time.

The Association explains to patients that the need for crosslinking and outcome of the procedure can depend to a large degree on the age of the patient. The older the patient the less the need for crosslinking and the better the results as keratoconus tends to slow and stabilize anyway when a patient reaches their 40s.

Younger patients tend to have more aggressive keratoconus. Yet sadly studies show that crosslinking is the least effective in those patients and some 25% or more continue to progress after being crosslinked. Repeat crosslinking may be required at some stage for those patients - with uncertain results.

The so–called Dresden protocol which involves removing the epithelium from the cornea, bathing the eye in riboflavin for about 30 minutes and then irradiating the cornea with ultraviolet A light for about 30 minutes, has a success rate of 70-90%. It remains the "gold standard" in crosslinking and appears safe and effective in most patients.

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?
- If the Dresden protocol is not being used, could you explain in detail what you propose to do?
- 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?

The cost of crosslinking remains a sore point for patients and their families. Crosslinking is the standard care for any patient diagnosed with progressive keratoconus but 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.

The Association has heard that a decision on the rebate application for crosslinking is imminent and may be given before end 2017. (See **Advocacy**)

Keratoconus Australia notes that the cost of a crosslinking operation done privately by a corneal surgeon averages around $2,500-$3,500 per eye; patients should be wary of ophthalmologists seeking to charge significantly more.

Contact lenses remain a hot topic in the keratoconus community for two reasons.

First, there is an increasing range of sclerals and mini sclerals available, which offer the hope of better vision and comfortable fits. These, in turn, can delay the need for corneal transplants for many patients. Patients are eager for more information about these larger lenses and how to access them from specialist contact lens fitters for keratoconus.

Our recent Sydney KeraClub 2017 meeting addressed the issue of big lenses versus small lenses and we hope to offer further information seminars on the new breed of contact lenses in other cities in the near future.

Second, the cost of contact lenses is becoming a major concern to patients. The use of larger lenses and new materials has led to a sharp increase in the price of lenses. Linked to uncapped fees for optometric services, patients have seen the cost of their lenses spiral upwards in the past three years. The Association is constantly being asked how patients can afford to pay for their lenses - some of which like hybrid lenses – need to be replaced at least every 12 months.

Last year, we raised the issue of corneal surgeons offering prospective crosslinking patients a range of 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 then, 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.

We are concerned that some patients are opting for these procedures in the belief they will enable them to avoid the often crippling, long term costs of replacing expensive contact lenses. Yet, optometrists say contact lenses or spectacles are often required anyway for best corrected vision after these surgeries and can be much harder to fit.

Contact lenses are still considered the best long term solution to vision loss from keratoconus and this critical treatment option is, for so many, the difference between having good vision or a disabling eye condition.

Meanwhile, optical rebates from private health insurers have barely moved over the same period and are generally capped at $300-$350 per annum.

Keratoconus Australia would like to conduct a full investigation into the cost of contact lenses and optometry costs in 2018 to see if anything can be done to rectify this situation. Please contact us if you would like to assist.

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.

On a brighter note, support requests for corneal transplantation and other surgery fell last year.

Corneal surgeons say that overseas studies are reflecting a decline in the number of corneal transplants performed for keratoconus. Crosslinking is probably helping to prevent many patients progressing to an advanced stage of keratoconus. New larger, complex contact lens designs are also enabling more advanced keratoconus patients to maintain useable vision longer and delaying corneal graft surgery.

Even prior to these new treatments, no more than 15-20% of people with keratoconus would ever progress to the point of requiring a corneal transplant. Hopefully this number will continue to decline as crosslinking slows or halts progression in many younger patients who were often the most affected by keratoconus.

However, there are still some corneal surgeons in Australia who consistently advise patients to have premature corneal transplants without properly exploring their options with contact lenses.

Support by example

Below we have listed some examples of the questions posed by members last year and outcomes.

- A patient was interested in finding a contact lens fitter who bulk billed. We provided some names in his area but emphasized that while cost was certainly a valid concern, obtaining properly fitted contact lenses was critical to his ability to maintain functional vision.
- A young woman with special needs was having trouble finding an optometrist who could fit her lenses properly and who would believe her feedback on how poor her vision was due to keratoconus. We directed her to Margaret Lam who has been wonderful in assisting her to learn how to use contact lenses and working with her carers.
- One member was having trouble sourcing particular contact lens products so we used our contacts to find him a suitable substitute.
- Providing advice to patients to explore all types of contact lenses before agreeing to a life changing corneal transplantation.
- Providing counselling for a patient extremely concerned about the change in her vision after crosslinking and thought her keratoconus was progressing again. We advised her to consult a new contact lens fitter and it turned out that her contact lenses were giving her blurry vision because her eyes had *improved* since being crosslinked.
- Assisted a woman whose intacs were causing her problems and needed them removed.
- Provided confirmation from our consulting optometrist on advice received by a patient that she would need to use glasses over her contact lenses to correct an unusual astigmatism.
- Referred a patient working in a dusty environment to a scleral lens specialist to see if those lenses would be better than his current RGPs which he was unable to wear for long periods.

Support in figures

The largest increase in support provided by the Association in 2016-17 was for issues with contact lenses (+40%), which accounted for 12% of the support total. Some of the reasons for this are discussed above. Direct requests for assistance in finding keratoconus specialists fell by around 12% last year compared to 2015-16 but still accounted for 40% of all support contacts with the Association. As many of those seeking assistance for contact lens related matters needed to find a new contact lens fitter, the proportion of support requests leading to us helping a patient find a new keratoconus specialist would have been considerably higher.

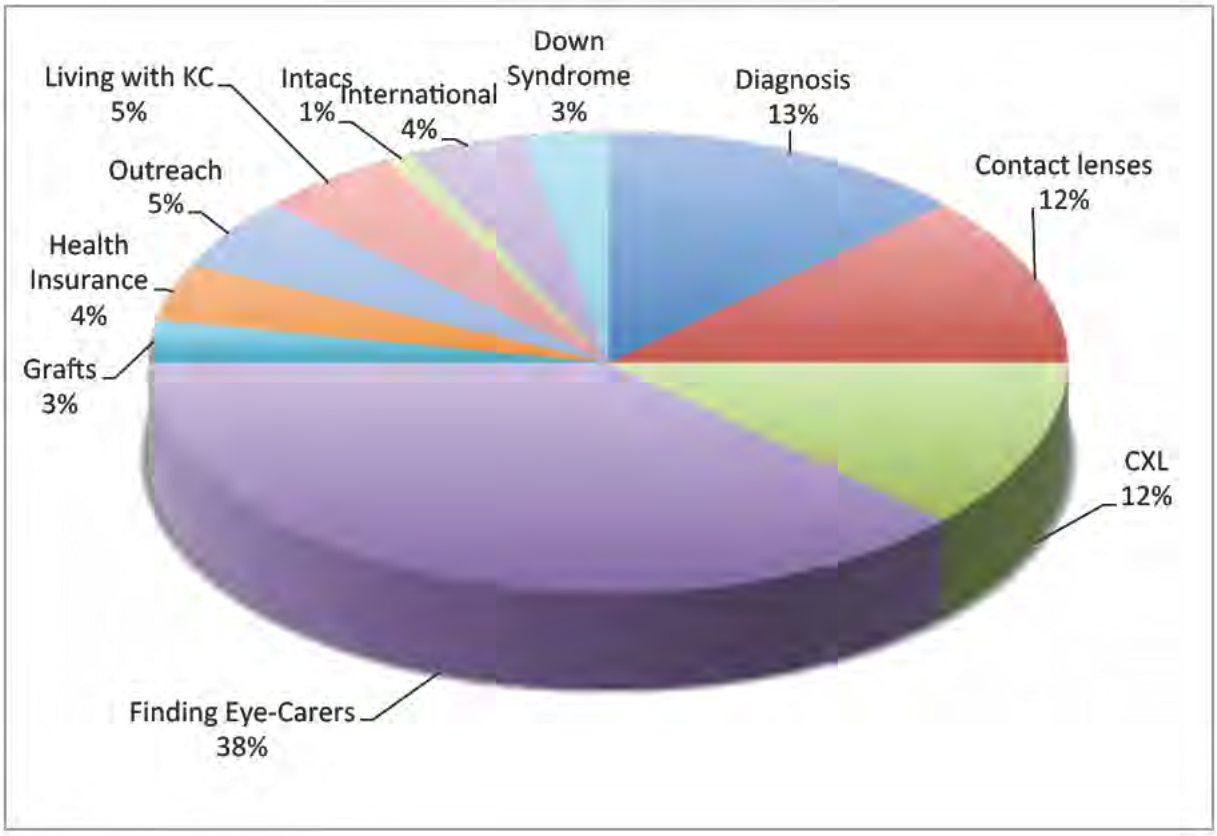
Support for patients and their families on diagnosis of keratoconus remained fairly steady and accounted for 13% of the total.

Questions about crosslinking accounted for 12% of all contacts last year. The Association also provided outreach support to a number of persons and assisted others with questions relating to study and work issues.

The Association received a handful of requests for information and support from persons requiring assistance overseas. These included requests for information on keratoconus and crosslinking for a person in India and on the career choices available for people with keratoconus from the mother of a patient in the UK.

Below is a percentage breakdown of support logged in 2016-17 by type

Support by Type 2016-17
(%)



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 at this time, 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 is proud to be a key partner in the Save Sight Institute's (SSI) Australian Keratoconus Registry (AKR), which launched its Crosslinking module in November 2015.

Professor Stephanie Watson

The Keratoconus registry is a world first whose aim is "to investigate and evaluate the clinical effectiveness; cost effectiveness and safety of current and emerging therapies" for treatment of keratoconus... In particular to determine the most effective and safest treatment regimens for Corneal Cross Linking (CXL), according to SSI. The need for the registry stems from the lack of data available to guide clinicians on best practice and clinicians are currently following different treatment protocols.

The Crosslinking Registry module is already producing some interesting results on the outcome of actual crosslinking done on patients. These were presented to patients and eye-carers by the project leader, Professor Stephanie Watson, at seminars held in Sydney in October 2016 and again in Melbourne in October 2017 and Sydney in November. A slide summary of Professor Watson's 2017 presentation can be downloaded in the Australia Keratoconus Registry section of our website at https://www.keratoconus.org.au/wp-content/uploads/2017/11/Keratoconus-Australia-talk-2017-web.pdf.

In our 2015-16 Annual Report, we described in detail the genesis of the Registry project and Keratoconus Australia's role in funding and developing the project. The Registry is governed by a 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.

At the March 2016 meeting of the Advisory Committee, KA President Larry Kornhauser argued for the inclusion of optometrists with large keratoconus practices in the collection of patient data to ensure long term reviews of crosslinking patients

Professor Watson and Optometrist Association representative, Dr Laura Downie have since been working on ways to modify the registry to include this optometric data. We hope that can be completed in 2018.

Meetings of the Advisory Committee were held in October 2016 and May 2017. Mr Kornhauser attended both of these meetings on behalf of the Association.

At the May 2017 meeting, Professor Watson reported that a total of 32 sites had registered with the Registry to provide their crosslinking data: 27 in Australia (8 in NSW, 1 in Queensland, 3 in South Australia, 13 in Victoria, 1 in Western Australia and 1 in Tasmania) and 5 sites in New Zealand. There was also interest in Switzerland and France in joining the registry project.

She said that 3,216 eyes had been entered into the registry and 558 treatments had been received for a total 6,391 visits. Patient reported outcomes questionnaires totaled 321. The data showed that of these treated eyes, 77 had suffered adverse effects, 70% of which related to significant corneal haze. Scarring, persistent epithelial defects and sterile infiltrations accounted for 10% respectively of the remaining adverse effects of crosslinking.

The meeting was also told that the patient quality of life questionnaire had been changed to *Keratoconus Outcomes Research Questionnaire (KORQ)* developed specifically for keratoconus by Flinders University researcher, Professor Konrad Pesudovs. That questionnaire was developed with the assistance of Keratoconus Australia (see below).

Professor Watson also outlined measures that had been taken to promote the registry amongst ophthalmologists which included settings up booths at conferences run by The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) in 2015-2017, The Association for Research in Vision and Ophthalmology, Inc. (ARVO) in 2017 and the Australian Society of Ophthalmologists (ASO) in 2016-2017. Professor Watson has also presented papers on the registry in Australia, the US and Singapore during the past year.

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.

We note that the Registry project requires further funding for its continuation and the Association is planning to coordinate a fundraising program with SSI in the near future.

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

Flinders University, Adelaide
Keratoconus Outcomes Research Questionnaire (KORQ)

In November 2014, a research team headed by Professor Konrad Pesudovs of Optometry and Vision Science of the School of Medicine at Flinders University, contacted Keratoconus Australia to assist with the validation of quality of life (QOL) questionnaire for keratoconus patients. The project was named the Keratoconus Outcomes Research Questionnaire (KORQ). As no Keratoconus-specific questionnaire existed, the KORQ had the potential to be the only patient-reported outcome measure suitable for any research looking at the efficacy of new treatments/interventions (including studies on cornea cross-linking) from patients' perspectives.

The Flinders team needed 100-150 keratoconus patients to complete the questionnaire to complete its validation. The Association contacted members who responded *en masse* to the call for assistance.

As reported in our 2015 Annual report, we contacted Professor Watson to tell her about this QoL which we felt could be used for the Australia Keratoconus Registry.

In January 2017, we received the following email from Dr Jyoti Khadka, a Research Associate on the KORQ project:

Dear Keratoconus Australia
It is my pleasure to share you the peer reviewed paper published on Keratoconus data we got from the KA members. This study has developed a validated questionnaire to measure self-reported quality life parameters for people with Keratoconus. Both the paper and the questionnaire are attached herein.

I would like to thank you for your kind support and all the KA members for taking their time to complete the survey questionnaire, without whom this study would not have been possible. This KORQ questionnaire is now in high demand as from researchers and clinicians around the globe are asking for it because it is the first validated questionnaire for keratoconus.

Many thanks

Dr Jyoti Khadka
Research Associate
Optometry and Vision Science | School of Health Sciences
Flinders University

The 29-question survey has since been adopted by the Australia Keratoconus Registry project for patient feedback on treatments and has become an international benchmark for assessing the quality of life of people with keratoconus. The paper referred to by Dr Khadka can be found in the Annex to this report.

We thank all members who participated in this vital research.

School of Optometry and Vision Science, University of New South Wales

A prospective, observational, cross sectional, comparative study to investigate ocular symptoms, corneal nerves and neuromarkers in keratoconus.

In August 2016, the Association was contacted by Preeji Mandathara, a PhD Candidate, who was trying to recruit keratoconus patients for a study into ocular symptoms, corneal nerves and neuromarkers in keratoconus.

Changes in corneal sensitivity, tear film constituents and corneal nerve architecture have been reported in keratoconus. But to date not much is known about their effect on patient symptoms and in the pathophysiology of keratoconus. The UNSW study was focussed on patient symptoms, corneal nerve morphology and function, tear film osmolarity and neuromediators in keratoconus and aimed to correlate these findings with the severity of the disease and also to evaluate the effect of treatments such as corneal collagen cross linking on these variables.

After receiving documentation relating to ethics approval for the study, headed by Professor Mark Willcox, the Association's committee of management approved the request to contact members. Emails were sent to NSW members in August and then again in December to recruit additional volunteers for the project.

Ms Mandathara sent us a copy of the findings from her initial research which were published in the *Clinical Science* journal.

We thank all members who participated in this research project and look forward to receiving further updates on its outcomes.

Centre for Eye Research Australia, Melbourne

As foreshadowed in the 2016 Annual Report, the Association held a series of discussions with researchers at The Centre for Eye Research Australia (CERA) during the past year. CERA is expanding its research into keratoconus and widening its collaboration with overseas research centres.

As mentioned previously, 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.

Its latest project involves creating an international consortium of research institutes to share data and information about keratoconus with the aim of identifying the causes of the diseases, improving diagnosis and treatments, and ultimately finding a cure for keratoconus.

The initial stage of this vast project will involve the creation of a database to collect and share clinical, genetic and risk factor data. Data analysis would hopefully identify early risk factors, best practice treatments and share these outcomes among consortium members. At this stage, some 17 research institutes in Australia, India, the UK, the US, New Zealand and Hong Kong have signed up to the project.

Keratoconus Australia strongly supports this collaborative approach to research and will provide whatever support and resources possible to advance this project.

We hope to cooperate further with CERA in 2018 on this and other projects including an update of their earlier *Cost of Keratoconus* study.

EYE-CARERS

Keratoconus Australia relies on its relationships with optometrists and ophthalmologists to keep informed of the latest developments in keratoconus treatments and management strategies. The Association also meets regularly with eye-carers to discuss issues raised by members such as access to low cost treatment options and to seek advice on problems faced by patients and their families.

These informal contacts continued during 2016-17 and the Association thanks all the eye-carers who offer their time and expertise to assist Keratoconus Australia and the keratoconus community.

University of Melbourne -
Department of Optometry and Vision Sciences (DOVS)

Since 2006, Keratoconus Australia and the University of Melbourne's Department of Optometry and Vision Sciences (DOVS) have been conducting keratoconus training clinics for optometry students. These clinics 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 and are training the next generation of specialist contact lens fitters for keratoconus.

In early 2017, the Association emailed members to ask for 8 volunteers with keratoconus and corneal transplants to attend the keratoconus and post graft contact lens fitting clinics conducted in March and April for 3rd and 4th year optometry students at the University's DOVS.

Our Victorian members again responded to the call and kindly offered their time to ensure these clinics were a success.

UoM Eyecare Keratoconus Clinic

As part of the Association's commitment to lowering the cost of contact lenses for all, the Association partnered the University of Melbourne's Eyecare optometry practice to create a keratoconus clinic. This regular clinic provides a means for all Keratoconus Australia members to obtain spectacles and contact lenses at steep discounts.

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. In fact, the clinic told the Association that more patients were required to fill available appointments, which are bulk billed.

We urge our Victorian members seeking relief from the rising cost of contact lenses for keratoconus to consider the Eyecare keratoconus clinic.

The University of NSW also offers a similar service at its Optometry Clinic.

Crosslinking Information Brochure

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.

This eye rubbing information campaign will be renewed periodically in the public arena. An information flyer on the dangers of eye rubbing is now being sent to all new members as part of our new member kit.

With the success in disseminating information about eye rubbing, the Association decided to ask for SSI's assistance in writing a brochure for patients on crosslinking using the latest information and data gleaned from the Australian Crosslinking Registry.

This project is nearing completion and we hope to have the final brochure available for distribution in early 2018. Once again, it will be included in all new member kits sent out.

Eye rubbing poster being sent to all new members of Keratoconus Australia

ABNORMAL EYE RUBBING:

What Families Need to Know

Institute for Eye Research

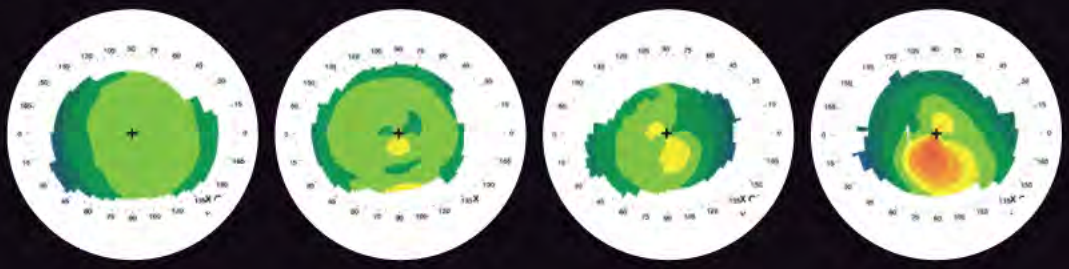
EYE RUBBING is abnormal when it lasts *too long*, or occurs *too frequently*, or uses *too much force*, or keeps recurring over a long period.

* 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).

(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]



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

Consulting Eye-carers

We again recognise 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.

Eye-carer projects *still* in-waiting…

As discussed last year, the Association remains interested in 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.

Also still on the radar, 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, further discussions were held in April 2017 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.

Medical Services Advisory Committee's advice Corneal collagen crosslinking rebate

Corneal collagen crosslinking is still not being reimbursed by Medicare or private health funds at the time of writing this report. But there has been significant progress towards the introduction of a crosslinking rebate from the Medicare Benefit Scheme (MBS).

The Australian Government's Medical Services Advisory committee (MSAC), which was reviewing an application by the Royal Australian and New Zealand College of Ophthalmologists for a $1,500 crosslinking subsidy, published its advice to The Minister for Health in its April 2017 Public Summary Document. This advice supported public funding for corneal collagen crosslinking (CCXL) "for corneal ectatic disorders with evidence of progression." It had previously accepted that crosslinking was safe and clinically effective for the proposed population of patients, although it described the quality of evidence for these conclusions as "low".

It noted that keratoconus posed challenges for conducting randomized controlled trials – the gold standard for testing new treatments – and that further data on the safety and effectiveness of crosslinking was likely to come from the recently established Australian Crosslinking Registry.

However in its advice to the Minister, MSAC queried the proposed fee and asked the Department of Health to investigate an appropriate fee and to report back to MSAC . It suggested an upper limit of $1,200 for the Medicare rebate based on international pricing and a RANZCO recommendation submitted in March 2017. It also recommended that the rebate and patient out-of-pocket-costs be reviewed two years after the Medicare rebate is introduced.

Other key findings in the MSAC advice included:

- Listing CXL with an MBS fee of $1,500 was estimated to cost Medicare $4.4 million in year one, decreasing to $648,000 by year five. In comparison, listing CXL with an MBS fee of $900 was estimated to cost the MBS $2.9 million in year one, decreasing to $421,000 by year five.
- that the MBS item descriptor should not specify details of the CCXL protocol as this may limit clinicians' ability to use the most appropriate procedure according to the best available evidence.
- That 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). This contrasts to the current approach under which a keratoconus patient is generally fitted first with glasses and then contact lenses before consideration of a corneal transplant, it noted.

At this stage, there is no further news on when a final decision on the level of rebate will be made and when a rebate for crosslinking will commence.

The full text of the MSAC statement can be found in the Annex section of the report.

As noted in previous reports, Keratoconus Australia made a submission to the MSAC inquiry into the RANZCO application. The Association supported a subsidy of around $1500 per eye in the case of progressive keratoconus. Details of the Keratoconus Australia submission were published in the 2014-15 Annual Report.

Corneal collagen crosslinking is now a routine procedure recommended by ophthalmologists to all patients with progressive keratoconus under the age of about 50. Crosslinking costs range from about $2,500 - $3,500 per eye. The procedure is being offered free through a very limited number of hospitals in Australia. (see below)

In its submission to MSAC, the Association noted that keratoconus specialists currently urge patients to undergo crosslinking, causing many patients and their families to 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. With the cost of contact lenses spiraling upwards plus sundry expenses on solutions and regular checkups, a keratoconus diagnosis can be the start of an expensive journey for many – especially those with progressive keratoconus.

A prompt decision on the Medicare rebate will ease some of this financial burden and distress and enable more patients to opt for crosslinking.

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 around the country are charging between $2,500-$3,500 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.

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

Things just become worse and worse in regard to the cost of contact lenses – the primary treatment for vision loss caused by keratoconus.

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 2016-17. Quite the contrary. The cost of optometric services for keratoconus seems to be spiraling out of control along with the price of complex new and often larger contact lenses.

The committee has decided that a priority in 2018 will now be to investigate the causes of the recent sharp rise in the cost of contact lenses and survey members as to the impact of these increases.

One concern is that patients are giving more consideration today to correcting their vision with otherwise unnecessary and sub-optimal surgery options like intra ocular lens and intracorneal rings (intacs etc) as a means of avoiding high, long term costs associated with remaining in contact lenses.

Based on a review of these inquiries, the Association would like to mount a social media campaign to raise awareness amongst eye-carers and government departments and private health insurers of the detriment to patients of contact lenses being priced out of reach.

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 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 Australia

Keratoconus Australia is currently an associate member of Vision 2020 Australia, the peak body in Australia for all eye health related organizations. In support of its goal of eliminating avoidable blindness and vision loss in Australia, Vision 2020 Australia submits position papers to the Australian Government on vision related issues on behalf of the eye health community.

Keratoconus Australia has a representative on the Vision 2020 Independence and Participation Committee.

In October 2016, members of that committee were asked to respond to two questions relating to specific problems within the current aged system:

1. What are the key issues facing people who are blind or vision impaired within the aged care system?
2. What are the key issues your organisation is facing in transitioning to a new model of aged care?

Keratoconus Australia President Larry Kornhauser responded on behalf of the Association as follows:

21 October, 2016

Dear Hayley,

Thank you for your email.

We do not have a specific policy or strategy around aged care. Keratoconus has the greatest impact on teenagers and young adults initially. We concentrate our efforts on assisting younger people make the adjustment to life with lower vision or correction aids like glasses or more commonly contact lenses.

The issue for keratoconus patients is that the main form of long term vision correction is rigid gas permeable contact lenses. These become harder to wear if dry eye develops with age. Care and insertion of these lenses can become problematic with age and particularly if older patients suffer from disease that may impact on their ability to handle such small items eg arthritis etc. They may then require carers to assist with the insertion and removal of lenses.

We would like to see a survey of our members to determine what their needs are as they age. As keratoconus generally stabilises by middle age and beyond, we would think that a general population survey of people using contact lenses in particular (or spectacles) may cover the requirements of older keratoconus patients too.

We would note that the introduction of corneal collagen crosslinking which aims to slow or halt progression at an early stage may in future reduce the number of people who arrive at old age with severe vision loss due to keratoconus.

Perhaps one question of interest would be to see if keratoconus patients have a higher rate of other eye disease (glaucoma, retinal, MD etc) later in life than the general population.

Anyway these are just some thoughts that could be raised for discussion at your roundtable.

Kind regards,

Larry Kornhauser
President
Keratoconus Australia

Following these consultations with members, Vision 2020 Australia subsequently developed a paper entitled *Position statement on meeting the needs of people who are blind or vision impaired within the aged care system.* The full paper can be found in the Annex.

After review, Keratoconus Australia endorsed the position statement.

Jess Cutter, Policy and Advocacy officer at Vision 2020 Australia, contacted us later to convey that she had passed our comments about the need for surveying the keratoconus population to the Centre for Eye Research Australia. We hope to progress a survey of the needs of older keratoconus patients in 2018.

KA Committee member Tamalii Laloulu has joined the Prevention & Early Intervention Committee as the Keratoconus Australia representative.

We request that anybody else who is interested in assisting with patient surveys or eye health policy contact the Association to participate in the Vision 2020 Australia committees during 2018. Teleconferencing is available for members unable to attend the Melbourne meetings.

The Association also plans to use its relationship with Vision 2020 Australia to publicise its activities to a wider audience in the eye health community.

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 2018.

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 https://www.keratoconus.org.au/wp-content/uploads/2017/11/KA-Insurance-letter.pdf.

International

Keratoconus Australia has enjoyed a close relationship with the US National Keratoconus Foundation (NKCF) since our creation. The NKCF provides us with booklets on keratoconus and corneal transplantation at a nominal cost which we distribute to members free of charge. These are also on sold to eye-carers at cost.

A restructuring of the NKCF has led to changes at that organization which became a program of the Department of Ophthalmology at University of California, Irvine.

We are having more trouble obtaining these booklets and ask members to be patient if delays occur in providing them.

We have been in contact with the new NKCF director, Mary Prudden, about closer cooperation in conducting international campaigns to promote awareness of keratoconus.

Last year, NKCF launched an initiative called World Keratoconus Day on November 10. The Association did not provide formal backing for this initiative. We received news of this initiative on short notice and did not have time to investigate its background or purpose. Information from the World Keratoconus Day website indicates it is largely a US-based initiative at this stage involving eye-carers and hospitals. The committee will monitor developments in this promotional activity and see how we can become involved.

Sydney Keratoconus Club launch

October 6, 2016

About 80 people with keratoconus, their families and eye professionals attended the launch of the Keratoconus Club in Sydney on October 6, 2016.

A joint initiative of Keratoconus Australia and the Save Sight Institute, the Keratoconus Club will be an informal meeting place for people with keratoconus and their families in the Sydney area.

It will provide a forum for learning more about keratoconus from the professionals, exchanging stories and experiences about living with keratoconus and discussion around the issues that interest NSW members in particular.

At the launch, Professor Stephanie Watson, a corneal specialist and head of the Australian Keratoconus Registry module of Save Sight Registries, discussed keratoconus, various treatment options currently available and research developments. She also explained the new Crosslinking registry and its importance to patients.

Margaret Lam, a Sydney optometrist with extensive experience in specialty contact lens fitting, addressed the meeting on contact lenses for keratoconus.

Ms Lam currently serves as the State President of the Cornea and Contact Lens Society of Australia for NSW, the Optometry Board of Councillors in Optometry Australia for NSW/ACT division, and is also a visiting lecturer who teaches part of the Undergraduate degree for Optometry and the Postgraduate Masters degree in Advanced Contact Lenses for the University of New South Wales.

Keratoconus Australia President, Larry Kornhauser also spoke at the meeting about the history of the Association and why patient support groups were so important.

Mr Kornhauser told the meeting that Keratoconus Australia has always contended that state-based groups can take root and flourish only if local members are prepared to assume responsibility for their organization.

“It is now up to everyone here to spread the word and make this Keratoconus Club work. Ideally it will become a forum for eye-carers and patients to meet outside of the structured environment of an eye practice. It should facilitate an exchange of information about treatments, management strategies for keratoconus and what works and what doesn’t and why,” he said.

“It should promote a culture of empowering patients with the confidence to ask their eye-carers questions and to seek evidence before agreeing to procedures that can have lifelong consequences. In doing so, it will enhance the concept of informed consent – which lies at the heart of all doctor-patient relationships, he concluded.

Ms Michelle Urquhart hosted the session and will act as the contact point for NSW patients interested in receiving support and becoming involved in the Keratoconus Club. Michelle can be contacted by email on info@keratoconus.org.au.

Free Audio and Video Podcasts

Free audio and video podcasts of recent Keratoconus Australia seminars will be soon available on the Association's new website.

Launch of the KA-SSI Kera Club in Sydney

THE ASSOCIATION

Membership

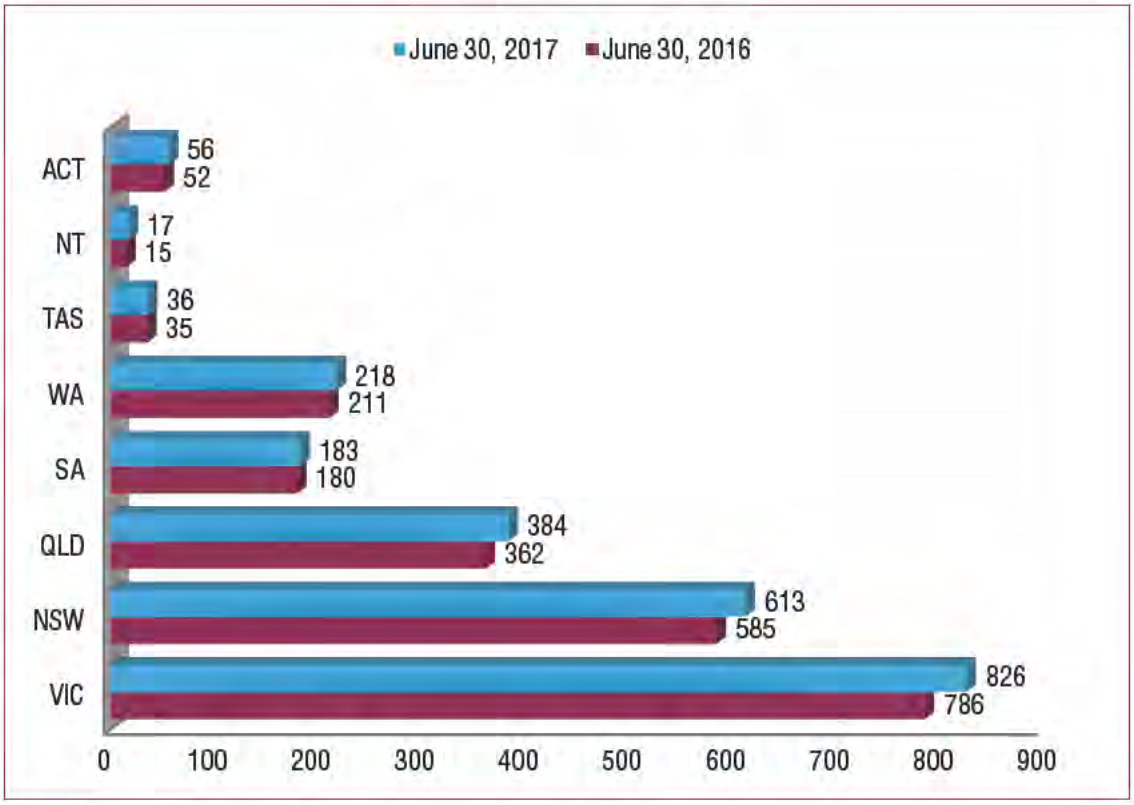
At 30 June 2017, Keratoconus Australia had 2,333 registered members. This represented an increase of 5% (adjusted) above the 2,226 members registered one year earlier.

Of the larger states, membership grew fastest in Queensland reaching 384, up 6.1% compared to the same time last year (362 members). Membership in Victoria, the Association's home state, grew strongly too and it remained the largest state with 826 members (+5.1% compared to the previous total at 30 June 2016). Then follows NSW with 613 members (+4.8%). Membership in Western Australia rose by 3.3% to 218 members, while smaller gains were made in South Australia and Tasmania

At the end of the 2016-17 financial year, Victorian members accounted for 35.4% of the total, NSW 26.3% followed by Queensland at 16.4%, and WA at 9.3% slightly ahead of South Australia at 7.8%.

(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 and institutions for their kind assistance again in 2017, notably Deloitte Private for accounting services, 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.

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.

Save Sight Institute is now a key partner of Keratoconus Australia on a number of projects including the Crosslinking Registry, the KeraClub and the Hands Off Eyes campaign to alert keratoconus patients of the dangers of eye rubbing. We are also collaborating on a patient brochure to explain crosslinking. We thank SSI's Professor Stephanie Watson for her dedication in trying to improve keratoconus patient outcomes and in providing our members with regular updates on data from the Crosslinking registry which will be posted to our new website.

Review of rules

Last year's Annual General Meeting ratified the Association's new rules which have been brought into conformity with new provisions of both 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. We thank Herbert Smith Freehills and KA committee member Neil McFarlane for their assistance in completing this review.

Fundraising and Grants

We would like to thank all donors who made significant contributions during the 2016-17 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/ and also at MyCause https://www.mycause.com.au/.

A number of members have taken advantage of this facility to run campaigns in support of Keratoconus Australia and its work.

We note that we are currently engaged in research partnerships with a number of institutions and we are considering launching major fundraising drives in 2018 to support new research into keratoconus.

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

As discussed in Events, a long overdue keratoconus patient group launched in October 2016 with the assistance of Keratoconus Australia member Michelle Urquart and the Save Sight Institute. The new group is called the Keratoconus Club or KeraClub. Over 80 patients, family members and eye-carers attended the launch which hopefully marks the first of many meetings in Sydney.

A second meeting held in November 2017 was also well attended. Speakers included Professor Watson, who presented the latest results from the Crosslinking Registry and Sydney optometrists Margaret Lam and Mark Koszek debated the merits of small versus big contact lenses for keratoconus.

Ms Urquart is seeking ideas for future Sydney-based activities during 2018. We strongly urge Sydney-based members to contact us if they would like to assist Michelle in the coming 12 months.

Despite interest from members on the Gold Coast, Tasmania, SA, and the ACT in forming local groups, none have materialized. 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.

New Logo

For some time now, the Association has been working to develop a new logo and branding.

This work was completed in August 2017 and we finally launched our new logos and colours, designed by Jorge Tarzia of Yolk design.

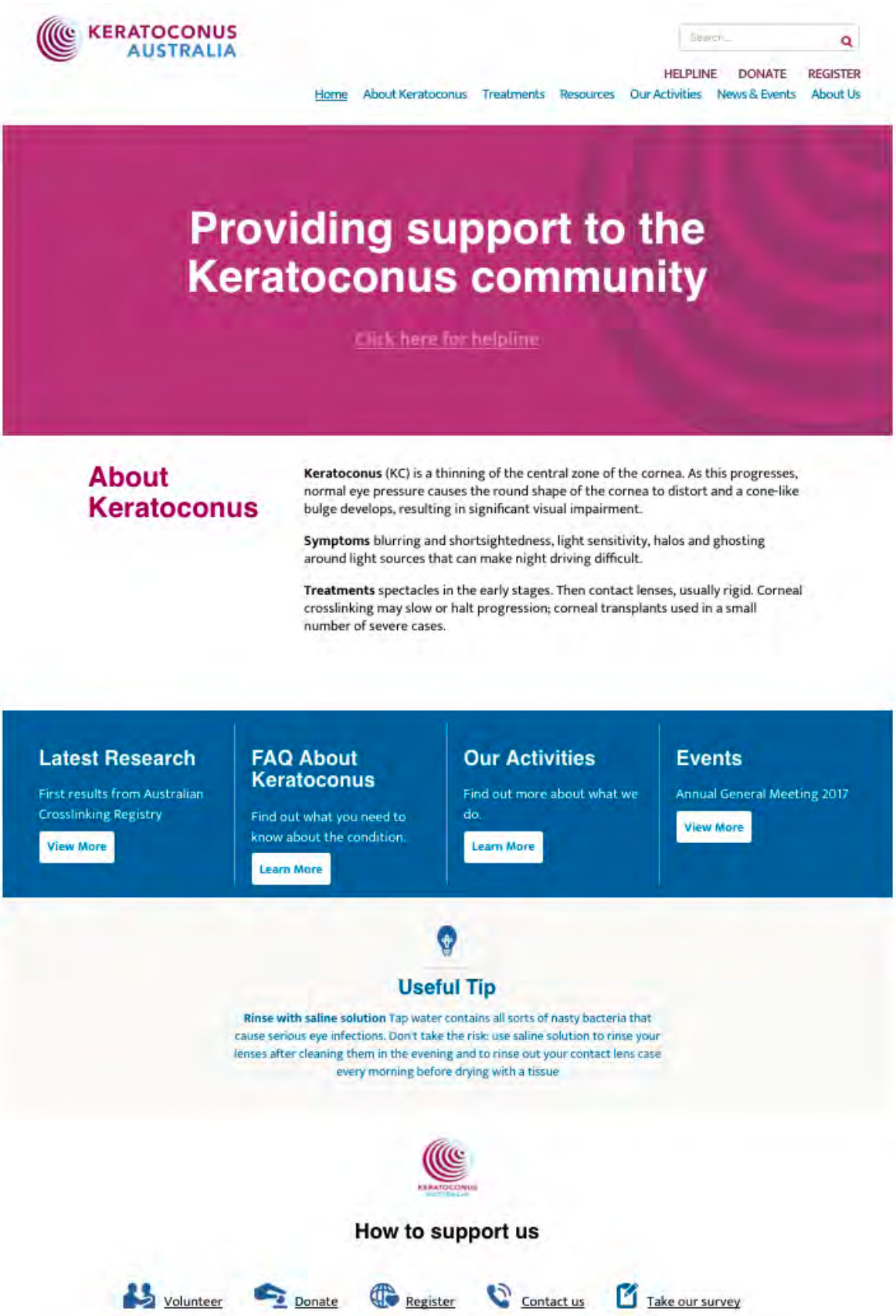
KERATOCONUS
AUSTRALIA

Let us know what you think!

Website

In early 2015, Melbourne communications agency Big Red kindly agreed to assist with the redevelopment of the Association's website and social media platform pro bono.

Despite a number of setbacks, this work was finalised in August 2017 with an enormous amount of advice and help from Matthew Blode. We greatly appreciate his assistance in fine tuning the site.



Home page of new KA Website

The new site contains the latest information about keratoconus and the various treatments and strategies for managing life with keratoconus.

It also contains a detailed Frequently Asked Questions page which we believe covers the main topics raised by members and their families when confronting the bewildering array of information about this eye disease.

Treatments have been divided between non-surgical which suit the vast majority of people diagnosed with keratoconus and surgical. Of the surgical options, corneal collagen crosslinking is given particular attention as it is the only one most people will need to consider.

We have also highlighted the need for patients considering crosslinking to ensure their surgeon will be anonymously reporting their case to the Australian Crosslinking Registry to track their outcomes for research purposes. We will also post updates on data being tracked by the Crosslinking Registry.

Where possible, we have given the pros and cons of the various treatments and provided guidance on how to decide which treatment might be appropriate given the particular circumstances facing each patient. For example, often *less is more* once you pass the age of 35 years as by then the disease tends to slow naturally in most patients.

Our News and Events page include the latest research into keratoconus from around the world and events being staged by Keratoconus Australia during the year.

The Association has also switched to the more commonly used org.au domain suffix and can now be found at https://www.keratoconus.org.au/. Our email address has also changed to reflect the move. It is now: info@keratoconus.org.au.

We thank everyone who worked on the site with us and especially Neil McFarlane for his technical assistance in launching the new site at considerable cost savings to the Association.

We are also looking for stories to populate our Living with Keratoconus pages which are not yet live. Please contact us by email if you would like to send us your story.

Members are asked to go to the new site at our new domain address of https://www.keratoconus.org.au/.

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 2016-17, the committee met four times and held informal discussions on other occasions.

The committee last year comprised:

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

Mary Veal acts as the Association's Secretary 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
	• plan major fundraisers to support keratoconus research projects. Two are being considered for 2018.
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 2017. However, you can email us over the holiday period if you would be interested in contributing in 2018 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
28 November 2017

FINANCIAL REPORTS

The Association reported a net profit in the 2015-16 financial year of $6,723. This compared to a net loss of $3,653, incurred after payment of a $10,000 gift to the Save Sight Institute in support of its Australian Crosslinking Registry project.

Otherwise, net operating profit in the two periods was largely stable, amounting to $6,723 in 2016-17 compared to $6,347 in 2015-16 (+6%). Revenues were down slightly in 2016-17 falling to $9,876 compared to $10,175 (-1%). This reflected a halving of bank interest from $1,038 in 2015-16 to only $536 last year. Donations remained steady at $9,040 ($8,980 previously). Donations have been higher recently since the Association joined a number of online giving portals which allow for credit card donations and also for people to start online fundraisers for their events.

Overall expenses were down about $1,000 to $2,854 ($3,828 previously) due to a variety of factors. Although the Association conducts most of its correspondence online these days, it is still incurring significant postage costs ($839 last year compared to $605 in 2015-16) due to the number of members who fail to notify us of their email addresses.

Domain name registration costs rose to $593 as we registered a number of keratoconus-related names for the Association. Changes to our website hosting arrangements should see a sharp reduction in these costs going forward from last year's $454. However video recording costs fell to zero last year as the Association did not hold any events in Melbourne.

The balance sheet on June 30, 2017 showed net assets of $90,396 or 8% higher than one year earlier $83,674). End-year assets totalled $90,516 ($83,944 on June 30, 2016), held mostly in cash ($90,506). Some $76,509 of this is held in a high interest-bearing deposit account at Westpac. Liabilities totalled $119 at the end of the 2016-17 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 Ltd
ACN 120 167 455
550 Bourke Street
Melbourne, VIC, 3000
Australia

Phone: +61 3 9671 7000
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 2017.

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: 4/10/2017

TO KERATOCONUS AUSTRALIA INC

PUBLIC OFFICER'S DECLARATION

The public officer declares that the incorporated association is not a reporting entity. The public officer has determined that this special purpose financial report should be prepared in accordance with the accounting policies outlined in Note 1.

The public officer of the incorporated association declares that:

1. the financial statements presents fairly the incorporated association's financial position as at 30 June 2017 and its performance for the year ended on that date in accordance with accounting policies;

2. in the public officer's opinion there are reasonable grounds to believe that the incorporated association will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the public officer:

Public Officer _____
Larry Kornhauser

Dated: 4/9/2017.

Keratoconus Australia

PO Box 1109
HAWKSBURN VIC 3142

Profit & Loss [Last Year Analysis]

July 2016 through June 2017

	This Year	Last Year
Income		
Donations	$9,040	$8,980
Seminar Entrance fees	$0	$79
Video sales	$0	$9
Booklet sales	$0	$68
Bank interest	$536	$1,038
Total Income	$9,576	$10,175
Cost of Sales		
Gross Profit	$9,576	$10,175
Expenses		
Advertising	$36	$390
Domain Name Registration	$593	$107
Bank charges	$61	$1
Catering	$0	$49
Stationery	$25	$19
Amortisation expense	$0	$670
Dues & Subscriptions	$241	$0
Late fees	$0	$15
Legal fees	$230	$0
Vision 2020	$0	$257
Postage	$839	$605
Photocopying	$159	$98
Booklets	$0	$172
PO Box rental	$124	$121
Video recording	$0	$364
Website hosting	$454	$327
Telephone and Internet	$47	$64
Travel	$0	$415
Software	$45	$0
Sundry expenses	$0	$154
Total Expenses	$2,854	$3,828
Operating Profit	$6,723	$6,347
Other Expenses		
Gifts / Contributions		
Gift - Save Sight Institute	$0	$10,000
Total Other Expenses	$0	$10,000
Net Profit / (Loss)	$6,723	($3,653)

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 2017

	This Year	Last Year
Assets		
Current Assets		
Cash On Hand		
Westpac DGF Account	$13,997	$5,738
Westpac Max-iDirect	$76,509	$75,981
Total Cash On Hand	$90,506	$81,719
GiveNow Receivables	$10	$2,225
Total Current Assets	$90,516	$83,944
Intangible Assets		
Website Development - At Cost	$6,975	$6,975
Accumulated Amortisation	($6,975)	($6,975)
Total Intangible Assets	$0	$0
Total Assets	$90,516	$83,944
Liabilities		
Current Liabilities		
GST Liabilities		
GST Collected	$267	$273
GST Paid	($148)	($2)
Total GST Liabilities	$119	$271
Total Current Liabilities	$119	$271
Total Liabilities	$119	$271
Net Assets	$90,396	$83,673
Equity		
Retained Earnings	$83,673	$87,326
Current Year Earnings	$6,723	($3,653)
Total Equity	$90,396	$83,673

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

KERATOCONUS AUSTRALIA INC

NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2017

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, optometrist

Audiovisual Solutions, Anatoly Vulikh

Matthew Blode

Big Red Communications

Belinda Cerritelli

Connecting Up

Centre for Eye Research Australia

Cameron Falt, Deloitte Private

Dr Laura Downie, optometrist

Dr Michael Loughnan, ophthalmologist

Dr Jacqueline Beltz, optometrist

Dr Elsie Chan, ophthalmologist and researcher

Dr Srujana Sahebjada, optometrist and researcher

Herbert Smith Freehills

Jessica Chi, optometrist

Margaret Lam, optometrist

Mark Koszek, optometrist

Microsoft Philanthropies

National Keratoconus Foundation

Optometry Australia

Professor Jonathan Crowther, CERA

Professor Mark Daniell, ophthalmologist and researcher

Professor Charles McMonnies, optometrist and researcher

Professor Stephanie Watson, ophthalmologist and researcher

Richard Lindsay, optometrist

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

Flinders University Keratoconus Quality of Life questionnare

1040-5488/17/9400-0000/0 VOL. 94, NO. 00, PP. 00–00
OPTOMETRY AND VISION SCIENCE

ORIGINAL ARTICLE

Development of a Keratoconus-Specific Questionnaire Using Rasch Analysis

Jyoti Khadka*, Paul G. Schoneveld†, and Konrad Pesudovs‡

ABSTRACT

Purpose. To develop and validate a keratoconus-specific quality of life (QoL) questionnaire: the Keratoconus Outcomes Research Questionnaire (KORQ).

Methods. The study was carried out in three phases. Phase I: content identifications: items were identified based on an extensive literature review, open-ended patient mail survey, and expert consultations. Each item was scored on a visual analog scale (VAS). Phase II: pilot testing using Rasch analysis. Phase III: testing psychometric properties of the final version of the KORQ.

Results. Phase I identified 44 items across 3 different content areas: activity limitation (26), symptoms (20), and convenience (8). The 44-item KORQ was self-administered to 158 people with keratoconus. The 44-item KORQ was multidimensional. Unidimensionality was restored by separating items across three content areas (subscales) as identified in phase I. The activity limitation and symptoms subscales demonstrated adequate measurement precision, but convenience (precision, 1.01) did not. Hence, the convenience subscale was discarded. Rasch analysis revealed that the VAS was disordered. The ordering of the VAS was restored by collapsing categories into 4. An iterative Rasch analysis guided item-removal resulted into a 29-item KORQ (18-item activity limitation and 11-item symptoms). The VAS was replaced by a discrete 4-option labeled categorical rating scale, and it was self-administered by 169 people with keratoconus. Both the subscales demonstrated good psychometric properties. The KORQ scores strongly correlated with visual acuity and contrast sensitivity demonstrating its construct validity.

Conclusions. The 29-item KORQ was a psychometrically robust and valid instrument to assess the impact of keratoconus on activity limitation and symptoms.
(Optom Vis Sci 2017;94:00–00)

Key Words: keratoconus, activity limitation, symptoms, quality of life, KORQ, patient-reported outcome, questionnaire

Keratoconus is a bilateral, chronic, and non-inflammatory corneal condition, which usually starts in the early teens and shows variable progression.[1] Keratoconus is characterized by progressive thinning and weakening of the cornea which leads to stretching (ectasia) and distortion of the cornea.[2] These changes cause refractive changes and optical aberrations which degrade visual performance to the extent that could severely affect an individual's day-to-day activities and overall quality of life (QoL).[3] Moreover, people with keratoconus are generally young, which means that they have to live with compromised QoL for at least 30 or 40 years.[2,4]

In the early stages of keratoconus, people experience symptoms of blurry vision. With progression, vision further deteriorates and the level of vision loss depends upon rate of the progression. At mid-stages, patients become more symptomatic and experience issues with night vision, photophobia, eye strain, etc. In advanced stages, corneal scarring may contribute to significant visual loss and the individual may need surgical intervention.[5] However, surgical intervention may come with significant QoL implications such as inconvenience caused by slow and lengthy postsurgical recovery, extended time off work, high potential of postsurgical complications, secondary complications from long-term steroid use (e.g. cataract, glaucoma), recurrence of keratoconus, residual refractive errors, etc.[6] Moreover, several treatment options are available (e.g. intrastromal corneal ring segment, corneal cross-linking, phakic intraocular lenses, femtosecond laser-assisted

*PhD
†MSc
‡PhD, FAAO
Discipline of Optometry and Vision Science, Flinders University of South Australia, Adelaide, South Australia, Australia (all authors).

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.optvissci.com).

penetrating keratoplasty, deep anterior lamellar keratoplasty, etc.) with a variable success rates in terms of limiting progression, refractive outcomes, visual outcomes, and associated complications.[7–9] In this realm, it is more insightful to comprehensively assess the impact of the disease and treatment on QoL from patients' perspectives.

In recent years, patient-reported outcome (PRO) instruments have been widely accepted to unravel the real-life impact of a disease and its treatment from patients' perspectives. Studies that have investigated the QoL impact of keratoconus have used PRO instruments developed for other conditions (e.g. cataract or refractive error).[10] This is because there is no keratoconus-specific PRO instrument. Such an instrument would be valuable as it would be sensitive to KC-specific context.[3,11–15] Furthermore, in a PRO measurement, visual analog scale (VAS) and category rating scale (CRS) are more frequently employed rating scales. The VAS is considered to allow a greater range of possible scores (i.e. 0–100 for a 100-mm VAS). The CRS is touted to be simple, easy to use, and allow a more accurate measure of the construct.[16,17] However, the benefits of using either of the rating scale in vision-specific instrument have not been explored.

Therefore, this study aimed to develop and validate a keratoconus-specific PRO instrument (Keratoconus Outcome Research Questionnaire, KORQ) by using the state-of-the art psychometric methods. The KORQ is expected to provide a valid, precise, and sensitive measure of QoL in this disease cohort. We also aim to use both the VAS and CRS in the KORQ and test which one of the rating scales provides better psychometric properties.

METHODS

This study was carried out in three phases using three separate study populations. We used a conventional content (domains and items identification) development phase followed by Rasch analysis guided iterative item culling procedure to develop and validate the KORQ.

Three phases were as follows: phase I: content development of the KORQ; phase II: piloting the KORQ and item reduction; and phase III: psychometric assessment of the final version of the KORQ. In phase I and II, participants (population 1 and 2) were recruited from the Eye Clinic at Flinders Medical Centre in South Australia. Clinical assessment details of population 1 and 2 including visual acuity and contrast sensitivity were obtained from the clinical notes. Population 1 was requested to respond to a mail out of open-ended questions seeking QoL issues in relation to having to live with keratoconus. These data were used to identify the content of the 44-item pilot KORQ. Population 2 completed the pilot KORQ. These data were used to prune the KORQ into a shorter version. In phase III, an email invitation to participate was sent out to all the members of Keratoconus Australia (population 3) who have had an established primary diagnosis of keratoconus for at least 6 months. Keratoconus Australia is a national nonprofit organization that works for the welfare of people with keratoconus in Australia. Those who responded to the initial email request and consented to participate were requested to complete the final version of KORQ sent to them in the post. The majority of the participants in population 3 did not have information on their current vision status (visual acuity and contrast sensitivity data). Therefore, visual acuity and contrast sensitivity data of population 3 are not presented in this paper.

The inclusion criteria were people with a diagnosis of keratoconus or having undergone penetrating keratoplasty for keratoconus and aged 18 years and older. People who had significant level other comorbid ocular conditions, undergone ocular surgery other than for keratoconus, any significant systemic disease, or inability to read English and understand the KORQ were excluded. This study was approved from the Southern Adelaide Clinical Human Research Committee and adheres to the Tenets of the Declaration of Helsinki. Written informed consent was obtained from all the participants.

Phase I: The KORQ Content Development (Item Identification and Selection)

The initial set of items was identified from two sources; patients' input and a comprehensive literature review. For patients' input, open-ended questions in a written questionnaire were used. There were six questions exploring the QoL impact of having to live with keratoconus. The participants' responses were analyzed using an inductive approach to identify themes of QoL impact by gathering together issues and examples to support the themes. The specific examples and issues were used to create items for an initial item pool. This item pool was supplemented from refractive error-specific QoL literature.[18–23] Identified items were then distributed across three distinct content areas based on their colloquial meaning and consensus among the researchers. An expert panel also reviewed the items. The content areas (domains) identified were activity limitation, symptoms, and convenience. These (domains) were also identified as major themes during qualitative analysis of the participants' responses. The initial set of items were culled (uncommon issues, redundant content, etc.) or merged for similar content to form the pilot instrument. The pilot KORQ had a set of representative unique items across the three domains. To cater to the three domains, we formulated three types of question syntax (how much does your vision interfere with…, how much are you troubled by…, and how much of an inconvenience is…). These three domains formed the three subscales of the KORQ.

The Pilot KORQ Questionnaire

The pilot KORQ was designed with a visual analogue scale (VAS, a 10-cm line) for patients to mark their responses. The VAS was recorded as a 101-category scale and collapsed into 11 categories (1 mm = 1 category) to simplify the analysis. The VAS was anchored at one end by 0 (Not at all) and other end by 10 (So much, I can't do it). Between 0 and 10, the VAS scale had numerical labels from 1 to 9 printed in equal spacing. A nonapplicable option was also used which was scored as missing data.

Phase II: Piloting the KORQ

Population 2 completed the postal KORQ by self-administration. Rasch analysis was used to analyze the data and each question structure (3) was allocated an Andrich rating scale

model.[24] Rasch analysis was used because it provides insight into the performance of the rating scale, fit of items to the construct, dimensionality, and overall instrument performance.[25] More importantly, Rasch analysis allows repairing and redesigning nonfunctioning response scale. We used the following given the apparent existence of three distinct domains in the KORQ, the fit of items under a single construct (QoL), and into separate subscales (activity limitation, symptoms, and inconvenience) were also investigated using Rasch analysis–based principal components analyses of residuals (PCA). PCA was also used to investigate multidimensionality of each subscale to discover any underlying variables present. A scale is considered as unidimensional if the variance explained by the measure is ≥50% and the eigenvalue for the first contrast is <3.0 (i.e. the strength of the possible second dimension should be less than three items).[26]

Item Reduction

The main aim of the item reduction was to develop a concise but sensitive instrument that could obtain all the relevant QoL impact while making it short and convenient to use by patients. Items suitable for inclusion in the pilot instrument were decided based on overall performance, fit statistics, and dimensionality assessment. The criteria used for item removal were[27,28] fit statistics mean square outside 0.7 to 1.30 high proportion of missing data (greater than 50%), ceiling and floor effect (greater than 50%), and items contributing to multidimensionality based on PCA analysis.

Phase III: Psychometric Assessment of the KORQ with Labeled Categories

Phase II resulted into a shorter version of the KORQ. Phase II also demonstrated that the use of a VAS presented difficulties for such that the rating scale did not work well. However, our previous work on rating scales has found that 4- to 5-option labeled categories is most likely to function well.[29,30] Therefore, the VAS scale was replaced by a discrete labeled 4-category rating scale (CRS) (not at all, a little, quite a bit, and a lot). The new set of response categories was selected based on the recommendation from our previous work on rating scales.[29,30] This version of the KORQ was completed by self-administration by population 3. Rasch analysis was again used to assess the psychometric properties the KORQ. This time, we particularly gave more attention to the performance of the new response categories and its effect on overall psychometric performance of the KORQ. We also assessed item bias at this stage using differential item functioning (DIF). Item bias occurs when population subgroups (e.g. males and females) respond to an item differently despite possessing equal levels of the underlying trait. We carried out DIF analysis by age (<50 years and ≥50 years), gender (male and female), and treatment (none, PRK, and corneal cross-linking). We defined DIF based on magnitude: small or absent if the difference in logits was <0.50, minimal (but probably inconsequential) if 0.50 to 1.00 logits, and notable DIF if >1.0 logit.

The construct validity of the finalized KORQ was tested by convergent validity of a hypothesized relationship between KORQ scores and clinical measures of vision. We collected visual acuity and contrast sensitivity data and analyzed the relationship with KORQ scores. We hypothesized that KORQ scores would correlate with measures of vision, but that activity limitation would show a stronger correlation than symptoms.

Statistical Analysis

Rasch analysis was performed using Winsteps v3.81.0 (Winsteps, Chicago, IL), applying single Andrich rating scale model per question format using joint maximum-likelihood estimation.[31] Sociodemographic statistics were computed using SPSS v 22 (SPSS Inc. Chicago, IL). SPSS was also used to run a linear regression analysis to assess the relationship between the KORQ and clinical measures of vision.

RESULTS

Phase I: Content Development

A total of 149 people (population 1) with keratoconus responded to the 6-item open-ended questionnaire (Table 1). A total of 145 items were identified across three domains (activity limitation, 103; symptoms, 14; inconvenience, 28). The initial item set was reviewed, culled (uncommon issues, redundant content; e.g. speed boat racing, etc.), or merged (similar content, e.g. reading small print, reading medicine bottles) to 44 items (activity limitation, 26; symptoms, 10; inconvenience, 8) for inclusion into a pilot questionnaire.

Phase II: Piloting the KORQ

The pilot instrument was completed by 158 participants (population 2) with keratoconus (mean age, 44 ± 9.16 years; range, 18–65 years; female, 43%) (Table 1). Rasch analysis revealed that 11-category VAS was disordered for all the three question formats (Fig. 1A–C). Overlapping categories were combined to arrive at a maximum number of categories with ordered thresholds which was 4 categories for each question format (Fig. 2A–C). Unidimensionality of the KORQ was put to test using the PCA of the residuals. The PCA revealed that 44-item pilot instrument was multidimensional (variance explained by the Rasch dimension, 45.1%); eigenvalue of the first contrast was 5.0 (should be less than 3 to support unidimensionality),[32] which precludes an overall score of the 44-item KORQ (Table 2). Therefore, the three content areas identified during phase I were separated and subjected to separate Rasch analysis to optimize their psychometric performance.

The activity limitation and symptoms scales performed well with person separation of 3.65 and 2.00, respectively. However, the inconvenience scale performed poorly with a person separation of 1.01; so this scale was discarded. Rasch item fit statistics showed redundancy and some misfit in both the scales; items were iteratively removed (Table 2). A total of seven activity limitation items were removed and one item (item 17: seeing in bright sunny day light) that grossly misfitting (outfit = 1.62 and infit = 1.41) the activity limitation scale was moved to the symptoms scale. The 11-item symptoms scale also demonstrated good psychometric properties (Table 2).

TABLE 1.

Demographic and clinical characteristics of the participants

Variables	Phase I (n = 149)	Phase II (n = 158)	Phase III (n = 169)
Age (yrs)			
Mean ± SD	45.7 ± 10.1	44.0 ± 9.2	45.4 ± 14.7
Range	24 71	18 65	33 58
Gender, n (%)			
Female	75 (50.4)	74 (47.0)	97 (57.4)
Correction type, n (%)			
Glasses	21 (14.0)	29 (18.5)	57 (33.7)
Contact lenses	95 (64.0)	71 (45.2)	98 (58)
Unaided	33 (22.0)	55 (34.8)	13 (7.7)
Treatment type, n (%)			
Penetrating keratoplasty	70 (46.9)	38 (24.1)	44 (26.0)
Corneal cross-linking			31 (18.3)
None	75 (51.0)	117 (74.1)	85 (50.3)
Worse eye visual acuity (logMAR)			
Mean, range (Snellen equivalent)	0.30 (6/12), −0.2 (6/4) to 0.70 (6/30)	0.30 (6/9), −0.10 (6/4.8) to 0.80 (6/38)	
Better eye visual acuity (logMAR)			
Median, range (Snellen equivalent)	0.10 (6/7.5), −0.20 (6/4) to 0.50 (6/18)	0.20 (6/9), −0.10 (6/4.8) to 0.70 (6/30)	
Worse eye contrast sensitivity (log unit)			
Mean, range	1.05, 0.05 1.80	1.05, 0.05 1.95	
Better eye contrast sensitivity (log unit)			
Mean, range	1.35, 0.75 2.00	1.30, 0.05 2.00	

Percentages of variables may not total the sum because of missing data.

Correlation with Clinical Measures of Vision

The KORQ scores were compared to clinical visual performance measures as an indication of construct validity. Linear regression showed both the activity limitation and symptoms scales were significantly related to visual acuity and contrast sensitivity. However, the activity limitation scaled demonstrated a stronger relationship to visual acuity ($r = 0.63$) and contrast sensitivity ($r = 0.76$) than for the symptoms scale (visual acuity ($r = 0.33$) and contrast sensitivity ($r = 0.26$). These indicate construct validity of the KORQ.

Phase III: Psychometric Assessment of the KORQ with Labeled Categories

A total of 169 people (population 3) with keratoconus (mean age ± SD, 45 ± 15 years; female, 57.4%) (Table 1) self-administered the final version of the KORQ with CRS (see Appendix 1, available at http://links.lww.com/OPX/A286). The 18-item activity limitation scale demonstrated excellent psychometric properties including ordered response-category thresholds (Fig. 2A), measurement precision, fit statistics, unidimensional on PCA, targeting to study population, and no DIF by age and gender (Table 3). The 11-item symptoms scale had ordered response categories (Fig. 2B), good precision, targeting, and was free of DIF. However, the PCA analysis revealed that the percent variance explained by the scale was falling slightly short of the desired value (>50%) and the first contrast had borderline eigenvalue (2.7), reflecting that there might be a suspected second dimension in the scale (Table 2). Guided by the PCA-based factor analysis, the symptoms scale was split into two item sets (set 1: four items loaded >0.4 to first contrast and set 2: rest of the seven items). However, Rasch analysis revealed that neither item set formed a valid stand-alone scale (i.e. both had measurement precision less than the acceptable threshold value of 2.00). On the other hand, all the 11 items perfectly fit into a single Rasch model (between 0.77 and 1.30). These findings together substantiate the contention that all the 11 items together could measure an overall construct of symptoms. Hence, all the items were retained in the final symptoms scale.

Ready-to-Use Scoring Spreadsheet

We have developed ready-to-use Microsoft excel scoring spreadsheets for the two scales of the KORQ (see Supplementary Digital Content 1, "KORQ Activity limitation—Rasch scoring spreadsheet" and Supplementary Digital Content 2, "KORQ Symptoms—Rasch scoring spreadsheet," available at http://links.lww.com/OPX/A287 and http://links.lww.com/OPX/A288). These spreadsheets can be used to convert respondents' raw scores into person measures in logits without having to run Rasch analysis when the study sample is similar to the present study. Each spreadsheet consists of three sheets labeled as "rawdata," "raschscore," and "raw to Rasch conversion." The users are required to register respondents' responses to items in numerical label (i.e. 1 to 4) in the "rawdata" sheet, and the corresponding Rasch scores automatically appears in the "raw to rasch conversion."

DISCUSSION

The KORQ is a psychometrically sound, valid, and reliable keratoconus-specific PRO instrument, which provides valid unidimensional measurement of activity limitation and symptoms. Multidimensionality on principal components analysis precludes

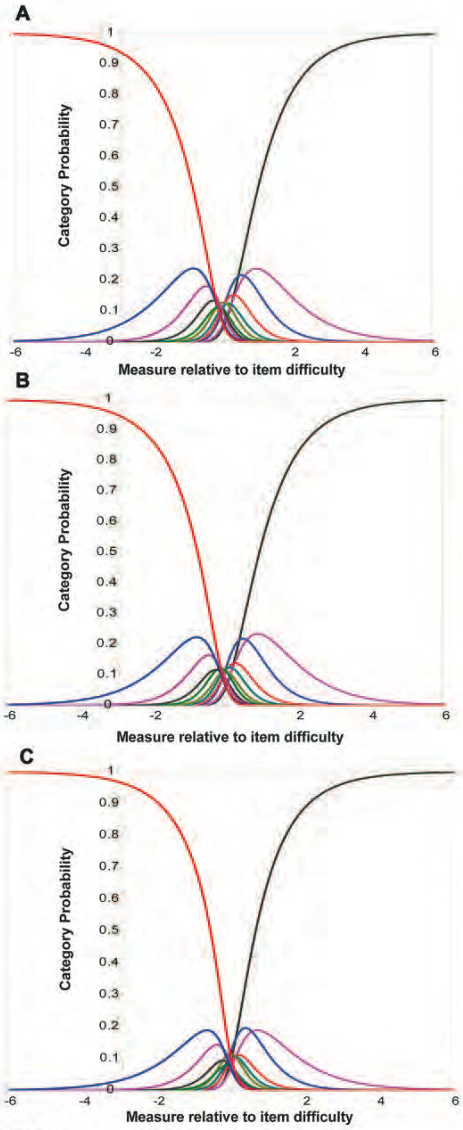


FIGURE 1.
Category probability curves illustrating the range of the visual analog scale over which each of the 11 categories (10-cm line split into 11 categories) is most likely to be chosen. Boundaries occur at points along the scale where the category most likely to be chosen changes from one to the next. A, visual disability; B, symptoms; C, convenience.

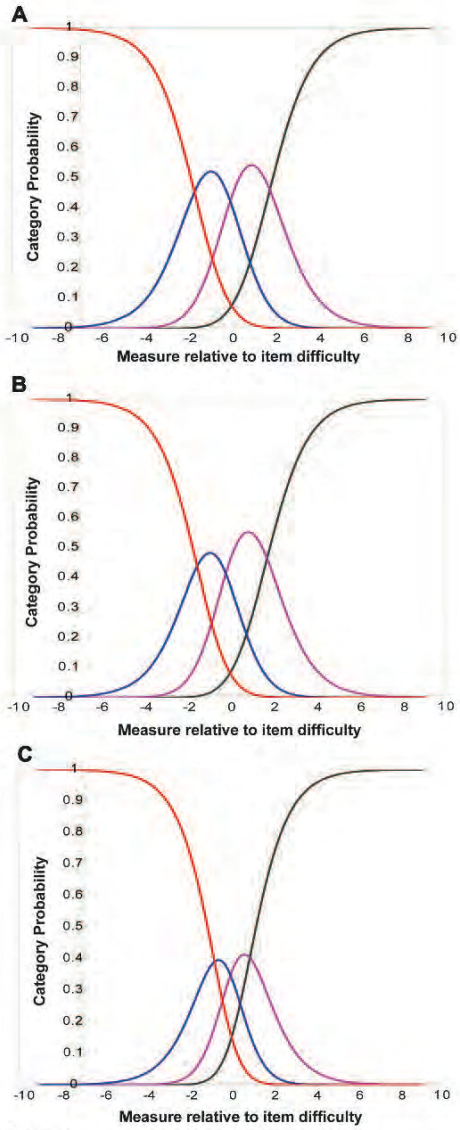


FIGURE 2.
Category probability curves after collapsing the visual analog scale into 4 categories for (A) visual disability items and (B) symptom items and 3 categories for (C) convenience items.

TABLE 2.

Psychometric properties of the pilot version of the KORQ and its scales

	Rasch model	All items	Activity limitation	Final activity limitation*	Symptoms	Final symptoms**	Convenience
No. of items		44	26	18	10	11	8
Response categories	Ordered	Ordered	Ordered	Ordered	Ordered	Ordered	Ordered
PSI	>2.00	3.81	3.65	3.24	2.00	2.10	1.01
No. of items with infit and outfit MNSQ >1.4	0	5	4	0	0	0	
PCA analysis: % variance explained by measure	>50%	45.1	54.4	56.9	45.0	43.5	
PCA analysis: eigenvalue 1st contrast	<3.0	5.1	2.8	2.1	2.4	2.4	
Targeting	<1.00 logits	−0.85	−0.99	−0.89	−0.45	−0.46	−1.59

PSI, person separation index; PCA, principal component analysis of residuals; MNSQ, mean square.

*Eight items removed based on iterative item removal criteria.

**With added item 17 "a bright sunny day interferes with your ability to see," which was *grossly misfitting* activity limitation.

combining the two KORQ scales into an overall score. The content of the KORQ was developed using a systematic qualitative phase that primarily includes patients' viewpoints. This was followed by a multiphased Rasch analysis–guided response-category optimization, item reduction, and psychometric properties optimization. The meticulous methods we adopted have not only ensured that the KORQ is highly relevant to people with keratoconus but also it has a wide content coverage with a low respondent burden.

Unlike most ophthalmic PRO instruments that are limited to measuring a single quality-of-life domain (mostly activity limitation),[32] the KORQ measures two important domains of QoL. These domains formed separate valid scales of the KORQ and in fact have been identified as significant domains of ophthalmic QoL in recent studies.[33,34] Moreover, the content of the KORQ was derived from patients, and as such, it represents important issues and concerns of the people living with keratoconus. An expert panel of clinicians also reviewed the initial set of items, and the team came to a consensus that the items were representative of QoL issues in people with keratoconus. Interestingly, three distinct content areas were identified within the initial item set initially, including a potential novel domain "convenience." We followed a systematic method to review and refine the initial item set to produce the pilot KORQ with unique set of items. The similar approaches of reviewing and refining items have been used to develop content of many health-specific PRO instruments including item banking in eye diseases.[34–37] It is noteworthy that our respondents did not raise social or psychological issues. Basically, restriction or difficulties imposed for having to live with keratoconus in their day-to-day life dominated their responses. A similar trend was also reported in studies that explored QoL issues in people with other eye conditions.[33–35] However, it is possible that more specific exploration of different content areas would identify more QoL domains of importance in keratoconus. This may have occurred if content development utilized focus groups rather than an open-ended questionnaire approach. Of particular note is the convenience domain, which may have proved valid if more items were identified during the qualitative phase. During the initial content development phase, convenience clearly emerged as an important theme for people with keratoconus. However, the resulting convenience subscale did not demonstrate an adequate measurement precision to form a standalone scale; therefore, it was dropped from further analysis. Further investigation revealed that the scale was also grossly mistargeted to the study population (Table 2), which indicates that convenience items were not adequately targeted to measure the construct. A future work that explores an additional set of targeted items could salvage the convenience scale. Owing to that, we consider this important construct as a scale under construction.

Our study shows the benefit of using a CRS over a VAS scale. We found that the original VAS scales were extremely disordered (Fig. 1A–C). The findings demonstrated the VAS was not well

TABLE 3.

Psychometric properties of the final version of the KORQ

	Rasch model expectation	Activity limitation scale	Symptoms scale
No. of items		18	11
Response categories	Ordered	Ordered	Ordered
PSI	>2.00	3.65	2.10
No. of items with infit and outfit MNSQ >1.4	0	0	0
PCA analysis: % variance explained by measure	>50%	62.7	43.2
PCA analysis: eigenvalue 1st contrast	<3.0	2.40	2.70
Targeting	<1.00 logits	−0.50	−0.01
DIF (age/gender and treatment)	<1.00 logits	0	0

PSI, Person separation index; PCA, principal component analysis of residuals; DIF, differential item functioning; treatment group = penetrating keratoplasty, corneal cross-linking, and none.

utilized by the population. This was probably because respondents might have difficulty to accurately mark their responses on a VAS scale, which basically results into spurious responses. Moreover, there is a high possibility of introducing errors in the response by allowing respondents to draw more freely on divergent frames of reference.[38] Studies have also reported that a VAS does not behave as a linear scale.[39] Furthermore, when disordered thresholds are observed, it is imperative to repair the scale to ensure optimal overall performance of the instrument is obtained.[29,40] In this study, the ordering of the VAS scale was obtained only after collapsing it into a 4-category option. This presented a dilemma about the KORQ's rating scale because the VAS by definition cannot have discrete sections. Our previous work on rating scales has clearly shown that respondents tend to find it easy to use and understand only four or five labeled categories over a numeric scale and a VAS.[29] Therefore, we replaced the VAS scale of the KORQ with a 4-option CRS and tested the psychometric properties of the new version of the KORQ. Rasch analysis confirmed that the new rating scale was functioning very well (i.e. demonstrated monotonic ordering of the thresholds steps and adequate separation) (Fig. 3 and 4). Moreover, the new rating scale provided equivalent psychometric properties with significantly better targeting in both the scales (Tables 2 and 3).

The PCA analysis showed that the symptoms scale had a lower variance explained by the measure (43%) and a higher eigenvalue attributed to the first contrast than the acceptable reference values we used in this study. This is probably because the variance explained by this scale is basically as good as the scale can provide. Moreover, Rasch analysis showed that all the 11 items perfectly fit the model (MNSQ value between 0.77 and 1.30). The four items that loaded to the first contrast more than 0.4 (items referring to symptoms associated with environmental factor) did not form a valid scale (PSI < 1.00). Moreover, the removal of those items from the symptom scale drastically reduced its measurement precision to an unacceptable value (PSI < 2.00 of the scale). Taken together, these findings indicate that the "symptoms" is a unidimensional scale.

Several studies have found no difference in PRO measures in people with keratoconus who were using a different mode of corrections (glasses vs. soft contact lenses, rigid gas-permeable contact lenses) and had different levels of the disease severity and treatment (e.g. corneal cross-linking).[10,41–43] A possible reason for this is that those studies used the PRO instruments developed for other conditions. Using non disease-specific PRO instruments may run the risk of missing measurement of the concepts important to disease and, hence, the instrument may not be sensitive to capture change in traits specific to the disease. The KORQ may be a more sensitive measure for exploring such differences. Future clinical studies and trials may benefit from the KORQ, which boasts to have relevant, informative, and targeted items for people with keratoconus. Although short-form instruments like KORQ are well suited to outcomes research, an alternative approach is item banking administered by computer adaptive testing, which is under development for many ophthalmic conditions.[30,33,34,36,44]

Studies have shown that emotional well-being (e.g. being anxious) and ocular comfort symptoms (e.g. pain, redness) are found to be responsive to change in clinical outcomes in keratoconus.[3] However, items related to these constructs of QoL are not represented in the KORQ. This is because none of the respondents in the qualitative item development phase had identified issues other than activity limitation, visual symptoms, and inconvenience important to them. Hence, the QoL constructs other than the three domains of QoL were not featured in the initial KORQ. Interestingly, the responses of our cohort were highly skewed towards activity limitation, which indicate that visual disability caused by keratoconus was the major issue.

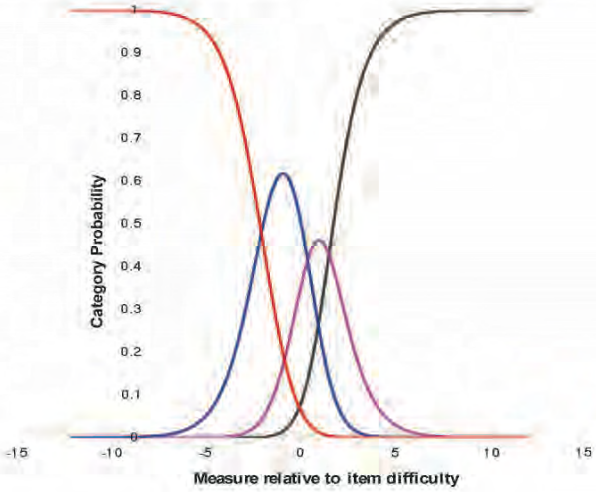


FIGURE 3.
Ordered category probability curves of 4 labeled response categories of the activity limitation scale.

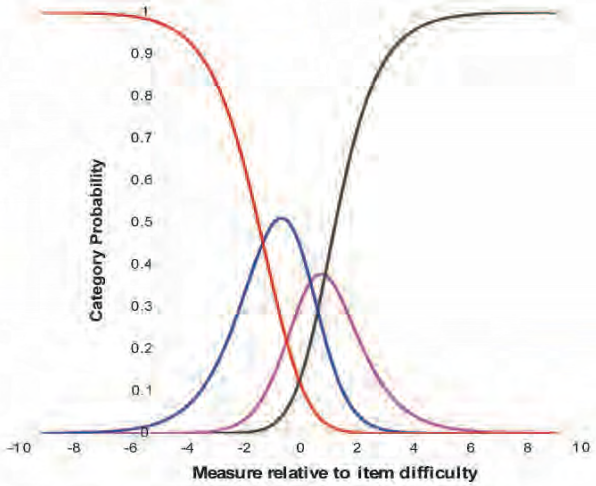


FIGURE 4.
Ordered category probability curves of 4 labeled response categories of the symptoms scale.

However, we collected qualitative data using an open-ended written survey, which might not have probed the respondents enough unlike in a face-to-face interview or a focus group. Taking together all these, we acknowledge that the KORQ is not a comprehensive measure of QoL but provides valid measures of two important domains of QoL. Another limitation of this study was that we did not measure corneal curvature in our study population. Kymes et al. have shown that, besides VA, steeper corneal curvature is highly correlated to patients' self-reports.[13] Hence, the correlation between the KORQ scores and corneal curvature was not assessed, which might have provided a strong indication of the construct validity of the KORQ. A future study that explores the relationship between corneal curvature and the KORQ would provide better insight. Furthermore, the content development phase did not have respondents who have undergone cornea cross-linking treatment; it is possible that items that are specific to cross-linking group may not have included in the development of the KORQ. However, we carried out item bias assessment in phase III by treatment. None of the items demonstrated bias, which suggests that KORQ items did not perform differently between treatment groups.

In conclusion, the KORQ is a meticulously developed and Rasch analysis tested and scaled instrument. This instrument is capable of fulfilling the need for a disease-specific instrument that is capable of measuring outcomes of treatment and intervention in keratoconus.

ACKNOWLEDGMENTS

The authors thank the president of Keratoconus Australia (KA) who allowed us to contact KA members to participate in this study. The authors also thank Ms. Susan Aldhous (research assistant, Flinders University) for collating the data for this study.

The authors have no personal financial interest in the development, production, or sale of any device discussed herein. Conflict of interest: none.

Received February 25, 2016; accepted October 6, 2016.

REFERENCES

1. Gomes JA, Tan D, Rapuano CJ, et al. Global consensus on keratoconus and ectatic diseases. The Group of Panelists for the Global Delphi Panel of Keratoconus and Ectatic Diseases. Cornea 2015;34:359–69.
2. Karamichos D, Hjortdal J. Keratoconus: tissue engineering and biomaterials. J Funct Biomater 2014;5:111–34.
3. Kymes SM, Walline JJ, Zadnik K, et al. Changes in the quality-of-life of people with keratoconus. Am J Ophthalmol 2008;145:611–7.
4. Nielsen K, Hjortdal J, Aagaard Nohr E, et al. Incidence and prevalence of keratoconus in Denmark. Acta Ophthalmol Scand 2007; 85:890–2.
5. Reinhart WJ, Musch DC, Jacobs DS, et al. Deep anterior lamellar keratoplasty as an alternative to penetrating keratoplasty a report by the American Academy of Ophthalmology. Ophthalmology 2011; 118:209–18.
6. Jones MN, Armitage WJ, Ayliffe W, et al. Penetrating and deep anterior lamellar keratoplasty for keratoconus: a comparison of graft outcomes in the United Kingdom. Invest Ophthalmol Vis Sci 2009;50:5625–9.
7. Wittig-Silva C, Chan E, Islam FM, et al. A randomized, controlled trial of corneal collagen cross-linking in progressive keratoconus: three-year results. Ophthalmology 2014;121:812–21.
8. Huang T, Hu Y, Gui M, et al. Comparison of refractive outcomes in three corneal transplantation techniques for keratoconus. Graefes Arch Clin Exp Ophthalmol 2015;253:1947–53.
9. Fahd DC, Alameddine RM, Nasser M, et al. Refractive and topographic effects of single-segment intrastromal corneal ring segments in eyes with moderate to severe keratoconus and inferior cones. J Cataract Refract Surg 2015;41:1434–40.
10. Ortiz-Toquero S, Perez S, Rodriguez G, et al. The influence of the refractive correction on the vision-related quality of life in keratoconus patients. Qual Life Res 2016;25:1043–51.

11. Khadka J, McAlinden C, Pesudovs K. Quality assessment of ophthalmic questionnaires: review and recommendations. Optom Vis Sci 2013;90:720 44.
12. Mendes F, Schaumberg DA, Navon S, et al. Assessment of visual function after corneal transplantation: the quality of life and psychometric assessment after corneal transplantation (Q-PACT) study. Am J Ophthalmol 2003;135:785 93.
13. Kymes SM, Walline JJ, Zadnik K, et al. Quality of life in keratoconus. Am J Ophthalmol 2004;138:527 35.
14. Brahma A, Ennis F, Harper R, et al. Visual function after penetrating keratoplasty for keratoconus: a prospective longitudinal evaluation. Br J Ophthalmol 2000;84:60 6.
15. McAlinden C, Khadka J, de Freitas Santos Paranhos J, et al. Psychometric properties of the NEI-RQL-42 questionnaire in keratoconus. Invest Ophthalmol Vis Sci 2012;53:7370 4.
16. Lines CR, Vandormael K, Malbecq W. A comparison of visual analog scale and categorical ratings of headache pain in a randomized controlled clinical trial with migraine patients. Pain 2001;93:185 90.
17. Svensson E. Concordance between ratings using different scales for the same variable. Star Med 2000;19:3483 96.
18. Schein OD. The measurement of patient-reported outcomes of refractive surgery: the refractive status and vision profile. Trans Am Ophthalmol Soc 2000;98:439 69.
19. Rose K, Harper R, Tromans C, et al. Quality of life in myopia. Br J Ophthalmol 2000;84:1031 4.
20. Vitale S, Schein OD, Meinert CL, et al. The refractive status and vision profile: a questionnaire to measure vision-related quality of life in persons with refractive error. Ophthalmology 2000;107:1529 39.
21. Schein OD, Vitale S, Cassard SD, et al. Patient outcomes of refractive surgery. The refractive status and vision profile. J Cataract Refract Surg 2001;27:665 73.
22. Demers L, Monette M, Lapierre Y, et al. Reliability, validity, and applicability of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) for adults with multiple sclerosis. Disabil Rehabil 2002;24:21 30.
23. Day H, Jutai J, Campbell KA. Development of a scale to measure the psychosocial impact of assistive devices: lessons learned and the road ahead. Disabil Rehabil 2002;24:31 7.
24. Pesudovs K, Gothwal VK, Wright T, et al. Remediating serious flaws in the National Eye Institute Visual Function Questionnaire. J Cataract Refract Surg 2010;36:718 32.
25. Andrich D. A model for contingency tables having an ordered response. Biometrics 1979;35:403 15.
26. Franchignoni F, Godi M, Guglielmetti S, et al. Enhancing the usefulness of the Mini-BESTest for measuring dynamic balance: a Rasch validation study. Eur J Phys Rehabil Med 2015;51:429 37.
27. Pesudovs K, Garamendi E, Elliott DB. The Quality of Life Impact of Refractive Correction (QIRC) Questionnaire: development and validation. Optom Vis Sci 2004;81:769 77.
28. Pesudovs K, Garamendi E, Keeves JP, et al. The Activities of Daily Vision scale for cataract surgery outcomes: re-evaluating validity with Rasch analysis. Invest Ophthalmol Vis Sci 2003;44:2892 9.
29. Khadka J, Gothwal VK, McAlinden C, et al. The importance of rating scales in measuring patient-reported outcomes. Health Qual Life Outcomes 2012;10:80.
30. Khadka J, McAlinden C, Gothwal VK, et al. The importance of rating scale design in the measurement of patient-reported outcomes using questionnaires or item banks. Invest Ophthalmol Vis Sci 2012;53:4042 54.
31. Andrich D. A rating scale formulation for ordered response categories. Psychometrika 1978;43:563 73.
32. Linacre JM. Winsteps® Rasch-Model Computer Programs, Beaverton, OR: Winsteps.com; 2014.
33. Fenwick EK, Pesudovs K, Khadka J, et al. Evaluation of item candidates for a diabetic retinopathy quality of life item bank. Qual Life Res 2013;22:1851 8.
34. Khadka J, McAlinden C, Craig JE, et al. Identifying content for the glaucoma-specific item bank to measure quality-of-life parameters. J Glaucoma 2015;24:12 9.
35. McCloud C, Khadka J, Gilhotra JS, et al. Divergence in the lived experience of people with macular degeneration. Optom Vis Sci 2014;91:966 74.
36. Fenwick EK, Pesudovs K, Khadka J, et al. The impact of diabetic retinopathy on quality of life: qualitative findings from an item bank development project. Qual Life Res 2012;21:1771 82.
37. DeWalt DA, Rothrock N, Yount S, et al. Evaluation of item candidates: the PROMIS qualitative item review. Med Care 2007;45:S12 21.
38. Miller GA. The magical number seven plus or minus two: some limits on our capacity for processing information. Psychol Rev 1956;63:81 97.
39. Kersten P, White PJ, Tennant A. Is the pain visual analogue scale linear and responsive to change? An exploration using Rasch analysis. PLoS One 2014;9:e99485.
40. Khadka J, Ryan B, Margrain TH, et al. Development of the 25-item Cardiff Visual Ability Questionnaire for Children (CVAQC). Br J Ophthalmol 2010;94:730 5.
41. Yildiz EH, Erdurmus M, Elibol ES, et al. Contact lens impact on quality of life in keratoconus patients: rigid gas permeable versus soft silicone-hydrogel keratoconus lenses. Int J Ophthalmol 2015;8:1074 7.
42. Wu Y, Tan Q, Zhang W, et al. Rigid gas-permeable contact lens related life quality in keratoconic patients with different grades of severity. Clin Exp Optom 2015;98:150 4.
43. Sykakis E, Karim R, Evans JR, et al. Corneal collagen cross-linking for treating keratoconus. Cochrane Database Syst Rev 2015;3:CD010621.
44. Pesudovs K. Item banking: a generational change in patient-reported outcome measurement. Optom Vis Sci 2010;87:285 93.

Jyoti Khadka
NHMRC Centre for Clinical Eye Research
Flinders University of South Australia
Adelaide, South Australia, 5001
Australia
e-mail: Jyoti.Khadka@flinders.edu.au

Public Summary Document

Application No. 1392 – Corneal Collagen Cross Linking

Applicant: **Royal Australian and New Zealand College of Ophthalmologists**

Date of MSAC consideration: **MSAC 69th Meeting, 6-7 April 2017**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website.

Purpose of application

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

MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC supported public funding of Corneal Collagen Cross Linking (CCXL) for corneal ectatic disorders with evidence of progression.

MSAC encouraged the Therapeutic Goods Administration (TGA) to continue with the Authorised Prescriber Scheme for supply of the riboflavin eye drops required to render this service.

MSAC questioned the proposed fee and requested that the Department investigate an appropriate fee and provide information to the MSAC Executive. MSAC suggested an upper limit of $1,200 for the MBS fee - with reference to international pricing and a RANZCO recommendation.

MSAC also requested a review of the utilisation, out-of-pocket costs and basis for the MBS fee two years after MBS listing begins.

Summary of consideration and rationale for MSAC's advice

MSAC noted that the proposed public funding of CCXL had been considered in July 2016. MSAC recalled that it had deferred its decision to list 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 recalled that it had previously accepted the safety and clinical effectiveness of CCXL in the proposed population (MSAC Public Summary Document (PSD) Application 1392, July 2016).

MSAC noted that both legal advice and clarification from the TGA had been sought regarding the regulatory status of riboflavin eye drops. MSAC noted that according to this information, there were no issues from either a TGA or legal perspective with the MBS listing of a service for which some, but not all, components are listed on the ARTG. MSAC noted that the TGA encourages the use of the Authorised Prescriber Scheme to access riboflavin eye drops, which allows approved prescribers to prescribe a specific therapeutic good to a class of patients under their care. MSAC concluded that this advice addressed concerns around the individual components required to render this service.

MSAC recalled that it had requested information regarding the progress of several large, well-designed clinical trials due to report in 2016–17, which have discontinued their control arms. MSAC considered a 2015 FDA briefing document of the Joint Meeting of the Dermatological and Ophthalmic Drugs Advisory Committee and Ophthalmic Device Panel of the Medical Advisory Committee, which provided follow up data for three randomised sham-controlled trials. MSAC clarified that discontinuation of the control arms was the result of very high rates of crossover from sham treatment to CCXL. MSAC also considered that the information provided by the applicant alongside its pre-MSAC response reviewing each of the CCXL trials reported in clinicaltrials.gov to be helpful in considering the relevance of these trials.

MSAC also recalled that in its pre-MSAC response for the July 2016 meeting, the applicant had noted that some data were available for ectasias other than keratoconus, though these data were not included in the response. MSAC noted that the applicant had since confirmed that non-keratoconus peripheral corneal ectasias are rare conditions and, as such, valid randomised data for these conditions would be difficult to obtain.

MSAC recalled concerns regarding the use of CCXL for post-LASIK[1] ectasia, and noted observational studies (Poli M et al 2013; Yildirim A et al 2014) which provided evidence of favourable outcomes for use in this condition or for post-radial keratotomy ectasia. MSAC considered that the use of CCXL for these patients may be appropriate. In contrast, MSAC considered that a CCXL MBS item should exclude use for the purpose of primary prevention of post-LASIK ectasia (LASIK Xtra).

MSAC noted that an assessment of the revised economic model had been undertaken by ESC. MSAC agreed with ESC that the model inputs for time horizon, age of onset of keratoconus and utility values for vision quality of life were appropriate. MSAC considered that uncertainties regarding the prevalence of keratoconus and its impact on the model had been addressed in the sensitivity analyses undertaken. MSAC noted that out-of-pocket costs were not included in the revised economic model and that these can be significant for patients accessing ophthalmologists. MSAC noted the new model:

- decreased the utility value for vision quality of life for patients with a corneal graft

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

based upon data from the Australian Corneal Graft Registry Report 2015 (0.87 in the initial model versus 0.83 in the current model);
- decreased the number of predicted procedures in 2015/2016 (2,600 versus 2,100);
- increased corneal graft costs due to inclusion of hospital and eye bank costs (~$1866 versus ~$5525); and
- assumed 2 services per patient rather than 1.5.

MSAC agreed with ESC that changes to the model were appropriate. MSAC noted that a sensitivity analysis of the MBS fee was included, with the cost of the procedure having a significant impact on the incremental cost-effectiveness ratio (ICER). MSAC concluded that revised model indicates that the CCXL treatment pathway is more effective than the current treatment pathway and is lower in cost.

MSAC considered that the number of expected procedures and the CCXL procedure fee were key drivers of the financial estimates, and that the initial surge in utilisation may be prolonged depending on the number of services provided by ophthalmologists. MSAC noted that the estimates assume that 2,426 patients are likely to access CCXL treatments in year one with the number of patients decreasing to 389 by year five. MSAC noted that the projected number of CCXL treatments is highly sensitive to an assumption that a large number of patients are currently undergoing CCXL, despite the treatment not being funded by the MBS at present. In addition, MSAC noted the assumption that listing of CCXL on the MBS would result in a reduction in corneal grafts and accepted that this was appropriate.

MSAC noted a cost sensitivity analysis was undertaken to explore the impact of variation in the MBS fee for the CCXL procedure. Listing CCXL with an MBS fee of $1,500 was estimated to cost the MBS $4.4 million in year one, decreasing to $648,000 by year five. In comparison, listing CCXL with an MBS fee of $900 was estimated to cost the MBS $2.9 million in year one, decreasing to $421,000 by year five. MSAC noted that varying the MBS fee may also result in variation to the associated out-of-pocket costs for patients.

MSAC recalled that the committee had requested a more detailed rationale for the $1,500 fee proposed by the applicant at its July 2016 meeting. MSAC noted that during public consultation, consumers advised that they are currently being charged $2,000 to $3,000 for treatment per eye. MSAC also recalled that the Protocol Advisory Sub-Committee had suggested a value between $900 and $1,300 based upon current fees for cataract surgery and corneal transplant.

In its pre-MSAC response, the applicant provided estimates of equipment and personnel input costs for the UV source, riboflavin eye drops and per treatment fee. The applicant also provided comparative estimates for the time required to perform the Dresden and accelerated protocols for CCXL (80 minutes and 65 minutes, respectively). 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. Where delivered by an ophthalmologist, CCXL treatment costs (including consumables) equated to ~$1,293 (€886) and decreased to ~$1,080 if shorter UV-A radiation exposure time (5 minutes rather than 30 minutes) via an accelerated protocol was used. MSAC noted that March 2017 correspondence from RANZCO supported an MBS rebate of $1,200.

MSAC requested that the Department investigate an appropriate fee, reviewing all reasonable cost components that contribute to setting MBS fees, and provide this information to the MSAC Executive for further consideration. Based on the information available, MSAC suggested an upper limit of $1,200 for the MBS fee. MSAC assumed that the fee would not include capital costs for the lamp, nor the cost of the riboflavin eye drops. MSAC also noted

that actual charges would be determined by the market once a MBS fee and rebate is set, especially in the out-of-hospital setting.

MSAC concluded that the MBS item descriptor should not specify details of the CCXL protocol as this may limit clinicians' ability to use the most appropriate procedure according to the best available evidence. However, given that there are variations in both the complexity and duration of the procedure, MSAC recommended it would be appropriate to review the MBS fee for CCXL two years after MBS listing. MSAC also recommended that the explanatory notes for the CCXL MBS item should stipulate the exclusion of use of this service for LASIK Xtra.

MSAC recommended that MBS listing be linked with a requirement for mandatory recording of the types of CCXL services provided and their outcomes in a CCXL register. MSAC requested that data from the Save Sight Institute's CCXL registry and the Australian Corneal Graft Registry be collated, along with out-of-pocket expenses incurred, to inform the review of CCXL two years after MBS listing.

MSAC supported MBS funding of CCXL for corneal ectatic disorders with evidence of progression. MSAC considered that, compared with corneal transplantation, CCXL has acceptable safety and clinical effectiveness, and is probably cost-effective (subject to an appropriate MBS fee). MSAC encouraged the TGA to continue with the Authorised Prescriber Scheme for supply of the associated riboflavin eye drops. MSAC also requested a review of the utilisation, registry data, out-of-pocket costs and basis for the MBS fee two years after MBS listing begins.

Background

Application 1392 was considered at the July 2016 MSAC meeting. MSAC deferred its advice 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 eye drops used in rendering this service were not registered on the 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 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.
- Progress of the several large well-developed clinical trials due to report in 2016-17 (which have discontinued their control arms).
- Data cited in the pre-MSAC response said to be available in patients with ectasias other than keratoconus.

Prerequisites to implementation of any funding advice

The UVA light source devices are registered on the Australian Register of Therapeutic Goods (ARTG).

The riboflavin eye drops are not registered on the ARTG, but may be accessed via the TGA's Authorised Prescriber Scheme or Special Access Scheme.

Proposal for public funding

The proposed MBS item descriptor for CCXL is provided in Table 1.

The applicant proposed fee is $1500. The PICO Advisory Sub-Committee suggested a fee of $900-$1300 would be appropriate (between the cost of cataract surgery and corneal transplant). During public consultation, consumers advised that they are currently being charged between $2000–3000 per eye ($4000–$6000 for both eyes).

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 [Applicant-proposed fee]. 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.*

Summary of Public Consultation Feedback/Consumer Issues

See Public Summary Document from July 2016 for Application 1392.

Proposed intervention's place in clinical management

The current approach to treating patients with corneal ectatic disorders involves, in the first instance, attempting to improve the patient's vision with glasses, if possible. If the condition progresses and the glasses 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 CCXL 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).

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.

Comparative safety

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

The assessment report stated it had not been possible to assess safety of CCXL relative to the conventional management pathway without CCXL. Therefore, at best, CCXL can be assessed to be noninferior with respect to safety.

Comparative effectiveness

The assessment report stated it was difficult to classify the therapeutic profile of CCXL in relation to the current treatment pathway, including risk of progression to a corneal transplant, as no good quality direct or indirect comparisons were identified that would allow such an assessment to be made.
Randomised trials, nonrandomised studies and meta-analyses showed that CCXL leads to improvements in corrected visual acuity, uncorrected visual acuity, Kmax and spherical equivalent refractive error, and the improvements are maintained over at least 2 years. Data were not available to inform an assessment of the risk of progression to transplant compared with management without CCXL. The relevance of these results in terms of clinical progression of the disease is, however, difficult to assess. Comparative data for children/adolescents is scarce but where this has been attempted, the outcomes have been similar to that for adults or all ages.

Some additional, but very low quality, data on quality of life was also identified that shows possible quality of life improvements in people who had undergone CCXL compared to those with contact lenses.

The complex nature of the evidence base did not lend itself to a formal GRADE analysis. All the included Randomised Control Trials and other non-randomised studies were of low quality overall, with different protocols, outcome measures and time points. There were high levels of heterogeneity in study results. Longer-term outcome measures that would be more helpful in answering the clinical question in relation to current management without CCXL, have additional quality issues with loss to followup and low patient numbers.

An evidence 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 follow up or greater

Outcomes (units)	Participants (studies)	Type of study	Quality of evidence (GRADE)	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)

Outcomes (units)	Participants (studies)	Type of study	Quality of evidence (GRADE)	Effect (summary)
	#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/preCCXL: –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 CCXL compared to those with rigid contact lenses

On the basis of this evidence profile, it is suggested that, relative to the current treatment pathway, CCXL has non-inferior safety and non-inferior (possibly superior) effectiveness. Considerable further comparative data would be required to make a more definitive conclusion relative to the conventional management pathway.

Keratoconus and other corneal ectasias present specific challenges for conducting well-designed randomised controlled trials. The disease progression of keratoconus is often slow, and 10-20 years may elapse between diagnosis and corneal transplant, which is difficult to capture in a clinical trial. The applicant has advised that additional long-term trials with an untreated control arm would be unlikely to be approved by an ethics committee, and investigators on trials that are currently under way have presented preliminary reports at ophthalmic meetings that the trials have discontinued their control arms. Further data is more likely to come from registry studies. A CCXL register has recently been set up at the University of NSW but has not yet collected any data.

Clinical claim

The complication rate of cross linking is relatively low and certainly much less than corneal transplantation. Overall visual loss from the condition should be significantly reduced.

Economic evaluation

The application presented a cost utility analysis. The model was calibrated against the number of corneal grafts currently occurring (between 300 and 400 per year) and the current number of CCXL treatments per year (around 2 000 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 Table 3. This indicates that CCXL treatment pathway has a lower cost and higher incremental benefits compared to the current treatment pathway.

Table 3 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 application noted that with respect to CCXL, the Incremental Cost Effectiveness Ratio (ICER) is an imperfect measure of value because it results in improved outcomes at a lower cost. Although the 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 showed:

- The incremental cost of the CCXL treatment pathway is highly sensitive 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 50 years).

Overall, the application stated that the service generally has incremental benefits (increased QALYs) across the range of scenarios tested.

Financial/budgetary impacts

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

The estimated potential patient population for people who might receive CCXL at some point in their lives is around 12,000. Forecasts change in line with expected population growth and changes in the stage of the disease for each person.

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 4. The estimated cost to the MBS of CCXL is $2.5 million, 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 4 Total costs to the MBS associated with CCXL

	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021
Preliminary consultations	$140,473	$38,583	$30,883	$32,338	$33,279
CCXL 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

The financial cost to the MBS depends on the listed cost of CCXL. This has been subject to sensitivity testing by increasing the listed price from $1,300 to $1,500, and reducing it to $900. This results in costs to the MBS of $4.4 million in 2016-17, falling to $648,000 in 2020-21 if the listed price is $1,500. If the listed price is $900 then the cost to the MBS is $2.9 million in 2016-17, falling to $421,000 in 2020-21.

The applicant's pre-MSAC response noted that the saving in "grafts avoided" may be underestimated. Throughout a lifetime patients may require more than one graft per eye but the corneal graft registry from which the data is derived may record failed previous graft as the graft indication rather than go back to the fundamental diagnosis of Keratoconus. Other surgery subsequent to the graft may include cataract surgery, refractive keratoplasty [for high degrees of post graft astigmatism] and glaucoma surgery [there is a significant increase in the incidence of glaucoma post corneal graft].

Key issues from ESC for MSAC

ESC noted that MSAC had previously accepted the safety and clinical effectiveness of CCXL in the proposed population at its July 2016 meeting. In addition, ESC noted that MSAC had deferred its advice on public funding and had requested the following information to enable it to finalise its advice:

- a more detailed rationale for the proposed fee;
- 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 riboflavin eye drops, used in rendering this service, not being listed on the ARTG;
- an update on why several large well-designed clinical trials have discontinued their control arms; and
- data cited in the pre-MSAC response said to be available in patients with ectasias other than keratoconus.

ESC noted that both legal advice and clarification from the TGA had been sought regarding the status of riboflavin eye drops and the consequences of the product not being registered on the ARTG. ESC noted advice that there is neither an issue with the TGA nor a legal issue with a service being listed on the MBS for which not all components are listed on the ARTG. ESC noted that the policy area also has no issues with the listing of the service without any brand of riboflavin being listed on the ARTG. ESC considered that this advice addressed concerns around the individual components required to render this service.

ESC considered the revised economic evaluation and noted concerns around the uncertainty of the prevalence of keratoconus and its impact on the model. ESC considered that these concerns were addressed in the sensitivity analysis.

ESC considered the time horizon and the age of onset of keratoconus appropriate in the revised economic model.

ESC noted that it was assumed that successful CCXL treatment halts corneal ectatic disorders' progression but does not lead to disease improvement and hence the utility weights after CCXL remain constant. ESC considered that there may be utility benefits in stopping progression but that this was hard to quantify. ESC noted the utility values for vision quality of life and considered them to be appropriate as they were closely linked to actual scores of patients reported in the data sources identified.

ESC questioned why no out-of-pocket costs were included in the revised economic model. ESC noted that out-of-pocket costs for ophthalmologists can be significant.

ESC noted that the revised economic model assumed that there was no backlog of cases and questioned the impact of this assumption on expected future financial costs.

ESC noted that the costs of glasses and other incidentals were not included in the revised economic model. ESC considered that inclusion of such costs is likely to favour CCXL.

ESC questioned the presentation of both discounted and undiscounted costs of the different treatment pathways. ESC noted that guidelines for preparing applications for MSAC specify that costs and benefits should be discounted at an annual rate of 5% which was used in the base case.

ESC noted that calculation of QALYs uses vision-related quality of life instruments rather than more global measures.

ESC noted that the revised model indicates that the CCXL treatment pathway is more effective and lower cost than the current treatment pathway.

ESC noted that the revised assessment report failed to provide comparative information on the economic model initially developed and the revised model. On manual inspection ESC noted the new model:

- decreased the utility value for vision quality of life for patients with a corneal graft based upon data from the Australian Corneal Graft Registry Report 2015 (0.87 in the initial model versus 0.83 in the current model);
- decreased the number of predicted procedures in 2015/2016 (2,600 versus 2,100);
- increased corneal graft costs due to inclusion of hospital and eye bank costs (~$1866 versus ~$5525); and
- assumed 2 services per patient rather than 1.5.

ESC considered the changes identified to be appropriate. ESC also noted that a sensitivity analysis on the MBS fee was included with the cost of the procedure having a significant impact on the model.

ESC requested that MSAC be provided with a table clearly outlining changes made to the initial model by the contracted assessment group responsible for this application. ESC advised that the table should also include responses to the information requirements specified by MSAC at its July 2016 meeting.

ESC noted that a key driver of the financial estimates is the number of expected procedures. ESC considered that this was an area of uncertainty with inputs based on estimates and prevalence and population data. ESC noted that the potential for earlier diagnosis of patients with corneal ectatic disorders may increase the number of procedures undertaken.

ESC noted that the MBS item was not restricted to a specific CCXL procedure. ESC considered that this was appropriate as the methodology for CCXL appears to be evolving with variations in the procedure performed under the same name. ESC noted that as the variations relate to both the complexity and duration of the procedure it would be appropriate to review the fee for CCXL two years post listing or if trial evidence on new procedures becomes available.

ESC noted that MSAC's question regarding the rationale for the proposed fee remained unaddressed.

ESC noted comments from the applicant in its pre-ESC response that the control arms of recent clinical trials have likely been discontinued due to investigator concern that they are denying patients potentially effective treatment. ESC considered that while further information is required to answer MSAC's question it is unlikely that the outcome will affect the cost-effectiveness of CCXL.

ESC noted that no further data on patients with ectasias other than keratoconus has been provided.

From a consumer perspective, CCXL was noted to be an important and valued procedure. ESC noted that consumers may question why riboflavin is not registered on the ARTG.

Other significant factors

Nil

Applicant's comments on MSAC's Public Summary Document

The applicant had no comments.

Further information on MSAC

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

Position statement on meeting the needs of people who are blind or vision impaired within the aged care system

Executive Summary

As a result of reforms to disability, such as the roll out of the National Disability Insurance Scheme (NDIS), there will be a greater number of older Australians who are blind or vision impaired relying on the aged care system to receive the supports and services necessary to maintain their independence and live the life they choose. It is therefore critical that the aged care system is effective for people who are blind or vision impaired, given that the majority of this population group are aged over 65 years and will therefore be ineligible for support through the NDIS.

There is therefore a need for greater Government recognition and investment to address blindness and vision impairment as an issue predominately affecting older Australians. Given the link between ageing and the increased incidence of blindness and vision loss, ensuring access to funded specialist blindness and vision impairment services for older Australians is a crucial aspect of improving the aged care system and ensuring that consumers have equal access to the right services and supports.

Vision 2020 Australia therefore considers it critical that the Australian Government address the issue of access to aged care for people who are over the age of 65 and who are blind or vision impaired by implementing the following measures:

1. Amend the *Aged Care (Living Longer Living Better) Act 2013* to include people with disability, including people who are blind or vision impaired as a special needs group.
2. Appropriately resource and inform aged care assessment to identify and respond to the needs of people who are blind or vision impaired and people with disability more broadly.
3. Ensure that co-payments do not create a barrier for people who are blind or vision impaired in accessing the most appropriate supports and services they need to remain independent and engaged in their community.
4. Develop a National Aids and Equipment Scheme for older Australians to redress the current inequitable access to aids and equipment and assistive technology.

Vision 2020 Australia position

1. Amend the *Aged Care (Living Longer Living Better) Act 2013* to include people with disability, including people who are blind or vision impaired as a special needs group.

For many years, the eye health and vision care sector has expressed concern that people with disability, including people who are blind or vision impaired, are not explicitly recognised as a special needs group within the Aged Care Legislation.

Clause 1 of Schedule 1, section 11-3 (definition of people with special needs) of the *Aged Care Living Longer Living Better Act* (the Act) defines a person with special needs as the following:

a. people from Aboriginal and Torres Strait Islander communities;

b. people from culturally and linguistically diverse backgrounds;

c. people who live in rural or remote areas;

d. people who are financially or socially disadvantaged;

e. veterans;

f. people who are homeless or at risk of becoming homeless;

g. care leavers;

h. parents separated from their children by forced adoption or removal;

i. lesbian, gay, bisexual, transgender and intersex people;

j. people of a kind (if any) specified in the Allocation Principles.

In the current definitions specified in the Act, disability acquired in older age is perceived as frailty, rather than disability. The focus on frailty creates a barrier to accessing necessary supports and services for people who are blind or vision impaired, as they are often not frail but require support relating to their requirements and their wish to remain independent.

Amending the Act to include people with disability, including people who are blind or vision impaired as a special needs group, will not only ensure that places in the Commonwealth Home Support Program (CHSP), Home Care Packages Program and residential aged care could be allocated to meet their specialist needs, but will also allow for them to be matched to professionals who hold expertise specific to the holistic needs of the individual.

2. Appropriately resource and inform aged care assessment to identify and respond to the needs of people who are blind or vision impaired and people with disability more broadly.

Regional Assessment Services (RAS) or Aged Care Assessment Teams (ACATs) assess the needs of those who wish to access aged care services in order to determine the level of support required by the individual. Given the circumstances, RAS and ACATs are accustomed to assessing the needs of those who are frail, rather than the needs of a person with disability. Assessors are therefore often not equipped with specific expertise in determining the types of services and support required for a person who is blind or vision impaired, and may not consider whether a person would benefit from specialised blindness and vision impairment services, such as orientation and mobility, literacy aids, library services or assistive technology training.

Furthermore, the National Screening and Assessment Program (NSAF) is itself limited in its capacity to respond to the needs of older people who are blind or vision impaired and people with disability more broadly. While disability is identified as a health condition that may prompt referral to an allied health professional, there is no trigger to refer an individual to

specialised support services, such as providers of blindness and vision impairment services. In relation to blindness and vision impairment, NSAF instructs assessors to refer the person to an optometrist if the person has had changes to their vision in the last three months, and does not seek any information on underlying vision impairment or consider the need for specialised blindness and vision impairment services.

It is therefore essential that specialist knowledge regarding individual need is available once an individual presents to the My Aged Care portal, the website through which available services can be identified. A specific trigger mechanism that identifies applicants who are blind or vision impaired will ensure an effective passage through the My Aged Care portal, by providing the option for a specialist assessment, undertaken by a specialist service provider in blindness and vision impairment, to substantiate the correct services and supports to meet the identified needs.

3. Ensure that co-payments do not create a barrier for people who are blind or vision impaired in accessing the most appropriate supports and services they need to remain independent and engaged in their community.

While aged care services are subsidised by the Australian Government, there is also an expectation that individuals over the age of 65 accessing the aged care system will contribute to the cost of the services that they require if they are able to do so. The amount that an individual will contribute towards their required services and supports is determined through negotiations with the service provider, and may also involve income or other forms of means testing.

As outlined by the Productivity Commission in their 2011 inquiry report on *Disability Care and Support*, the major goal of the aged care system is to minimise the loss of autonomy of those accessing it, and to allow people to live as independently and as fully as possible. This approach also recognises that people over the age of 65 have generally had lived a 'full life' to accumulate wealth during their lifetime, which can therefore be used to fund the costs of the care that they require.

However, this approach assumes that those accessing the aged care system will have had the *opportunity* to live a full life. While this assumption may be applicable to people who acquire disability, including vision loss, after the age of 65, individuals who were born with or acquired disability early in life have often experienced discrimination and exclusion through their lifetimes, and have therefore not had the same opportunities for wealth accumulation.[2]

Given that the aged care system is currently structured to accommodate the support needs of Australia's ageing population, commonly funded mainstream services that may sometimes cross over with those that are required by people who are blind or vision impaired do not sufficiently cater to the requirements of this group. As the requirements of people who are blind or vision impaired have the potential to be more cost prohibitive than

[2] BCA submission? Or email?

those of the average older person, it can be expected that co-payments paid by a person who is blind or vision impaired would be higher due to their higher support needs.

Consideration of the rules for co-payment under My Aged Care should therefore be taken, with acknowledgement of the fact that co-payments can, for some, create a barrier to the specialist services and supports uniquely required by people with disability. Exemptions to specialist services and supports required by people with permanent and severe disability could also be considered, and may include such services as mobility and support training, or adaptive technology training among others.

4. Develop a National Aids and Equipment Scheme for older Australians to redress the current inequitable access to aids and equipment and assistive technology.

Services and supports for people who are blind or vision impaired may range from assistance with orientation and mobility, training in using acentric viewing methods, training in braille or adaptive technology for literacy, occupational therapy, peer or emotional support to deal with vision loss, as well as a range of aids and equipment to assist with their mobility or literacy.[3] Under the NDIS, participants can access fully funded aids and equipment if they are eligible for a package that is individually funded.[4] However, people who acquire a disability over the age of 65 are not eligible for individually funded NDIS packages, and would be expected to access these supports through the aged care system.[5]

Further, while Home Care Packages offer some aids and equipment, as well as assistive technology, only a limited number of packages, which are often not prioritised for people who are blind or vision impaired, are available.[6] In addition, the CHSP, through which individuals can access entry-level support while on the waiting list for a Home Care Package, is not adequately funded to offer aids and equipment supports and services. It is therefore imperative that My Aged Care staff are made aware of the range of services and supports people who are blind or vision impaired may require, but also of the existing inequities that may present a barrier to accessing these supports.

Therefore, as per the recommendation put forward by the National Aged Care Alliance, the development of a National Aids and Equipment Scheme for older people, aligned with the NDIS Assistive Technology Scheme, would redress the current inequitable access to aids, equipment and assistive technology.[7] Further, a federally funded scheme with harmonised and streamlined eligibility, access and co-payment requirements across all jurisdictions would provide information and support to allow consumers to make informed choices about the aids, equipment and assistive technologies available and the related services.

[3] National Aged Care Alliance, *Improving the Interface between the Aged Care and Disability Sectors*, August 2017
[4] Ibid
[5] Ibid
[6] BCA submission? Or email?
[7] Ibid

Policy context

The proportion of people aged 65 and over in the Australian population is increasing, with the number tripling over 50 years to 3.4 million in 2014.[8] Of the total Australian population, it is estimated that more than 453,000 people are living with vision impairment or blindness, and that the majority are over the age of 65.[9] In 2010, Access Economics projected that the number of people over the age of 40 who are vision impaired will rise to almost 801,000 by 2020. It was also projected that the number of people over the age of 65 who are blind will rise to 102,750.[10] This rise reflects the ageing population and the fact that the prevalence of vision impairment and blindness doubles with each decade over the age of 60.[11]

It is estimated that on average, supporting people who are blind or vision impaired over the age of 65 requires less frequent interventions than their younger counterparts, and that they can remain engaged in their communities and live in their own homes for longer, with relatively little intervention.

However, despite the benefits associated with supporting people who are blind or vision impaired and over the age of 65, only a fraction of funding for blindness and vision impairment services is derived from Government-funded aged care streams. For example, according to the 2015 *Snapshot of Blindness and Low Vision Services in Australia* (the Snapshot Survey) conducted by Vision 2020 Australia, the National Disability Services and the Australian Blindness Forum, funding for the blindness and vision impairment services sector generated from all government sources amounted to only 30 per cent of all funding, or $56 million in 2013.[12]

Government funding streams for the sector are spread across disability, aged care, health and education, however the greatest proportion of funding for the blindness and vision impairment services sector is generated by fundraising and bequests at 43 per cent (nearly $81 million).[13] A further 18 per cent is derived from sales ($34.4 million) and nine per cent ($17.1 million) from investments, grants and other sources.[14]

As a result, many organisations within the blindness and vision impairment services sectors, who are registered providers of aged care, are only partly funded through the aged care sector. These organisations therefore provide services which are not funded from aged care to people aged 65 years and older living with blindness and vision impairment. These services include low vision clinics, information and library services, alternative formats, assistive technology training and advocacy services. Furthermore, the provision of specialist blindness and vision impairment services by these organisations is only made possible through philanthropic funding, a cost that has not been borne by the Government or aged care providers.

According to the results of the Snapshot Survey, more than one-quarter (27 per cent) of organisations reported that they have had to refuse services to clients.[15] For organisations

---

[8] http://www.aihw.gov.au/ageing/

[9] Foreman, J., et al, 2016, The National Eye Health Survey Report 2016, The Centre for Eye Research Australia and Vision 2020 Australia, Melbourne

[10] Vision 2020 Australia by Access Economics Pty Limited, Clear Focus: The Economic Impact of Vision Loss in Australia in 2009, June 2010.

[11] Foreman, J., et al, 2016, The National Eye Health Survey Report 2016, The Centre for Eye Research Australia and Vision 2020 Australia, Melbourne

[12] B. Ah Tong, G. Duff, G. Mullen and M. O'Neill, August 2015, A Snapshot of Blindness and Low Vision Services in Australia, Vision 2020 Australia, National Disability Services, Australian Blindness Forum, Sydney, page 13

[13] B. Ah Tong, G. Duff, G. Mullen and M. O'Neill, August 2015, A Snapshot of Blindness and Low Vision Services in Australia, Vision 2020 Australia, National Disability Services, Australian Blindness Forum, Sydney, page 13

[14] B. Ah Tong, G. Duff, G. Mullen and M. O'Neill, August 2015, A Snapshot of Blindness and Low Vision Services in Australia, Vision 2020 Australia, National Disability Services, Australian Blindness Forum, Sydney.

[15] Reference required

that reported that they had not been able to meet demands, the main impediments were cited as a lack of financial resources to hire staff or being unable to pay staff to work longer hours. Furthermore, with no current mechanism in place for residential aged care providers and other generalist aged care organisations to refer or pay for specialist blindness and vision impairment services, unmet demand for specialist services within nursing homes and residential care is hidden.

Reforms to aged care

Introduced in July 2012, Living Longer, Living Better is a ten year reform program intended to establish a flexible and seamless aged care system. The aim of the Living Longer, Living Better reform program is to ensure that Australians aged over 65 years have easier access to services and supports, with a focus on a model of consumer directed care that puts choice and control in the hands of consumers. Under the Living Longer, Living Better reform package, a number of initiatives have been introduced or expanded upon, including:

My Aged Care

My Aged Care was introduced in July 2013 and provides an entry point to the aged care system, offering information to consumers, service providers, as well as family members and carers. In 2015, My Aged Care was expanded to include a central client record, adoption of the National Screening and Assessment Form (NSAF) and a web-based My Aged Care portal for clients, assessors and service providers.

National Screening and Assessment Form

The NSAF is a tool used to determine eligibility level and to inform the development of support plans within the Aged Care system. In relation to eye health and vision care, the NSAF instructs assessors to refer the patient to an optometrist if they have had changes to their vision in the last three months.

The Commonwealth Home Support Program

The Commonwealth Home Support Program (CHSP) is a consolidated program that provides entry-level home support for older Australians who wish to live independently at home, but may require assistance. These supports include nursing, allied health, assistive technology, home modifications, home maintenance, food services, domestic services, personal care, social support and specialised support.

Home Care Packages

The Home Care Packages Program provides more complex support for older people who wish to stay at home, offering access to a range of ongoing personal services, support services and clinical care that can provide assistance with day-to-day activities. Under the Living Longer, Living Better reforms, the Home Care Packages Program was modified to mandate that all home care packages be delivered on a consumer directed care basis, ensuring that consumers have a choice in the types of care and services they access, how and when the services are delivered and by whom.

Vision 2020 Australia

Established in October 2000, Vision 2020 Australia is part of *VISION 2020: The Right to Sight*, a global initiative of the World Health Organisation and the International Agency for the Prevention of Blindness. Vision 2020 Australia is the peak body for the eye health and vision care sector, representing around 50 member organisations involved in local and global eye care, health promotion, low vision support, vision rehabilitation, eye research, professional assistance and community support.

The Vision 2020 Australia Independence and Participation Committee

Vision 2020 Australia's Independence and Participation Committee (the Committee) brings together a diverse group of members providing services and supports to people who are blind or vision impaired across Australia; enabling an unique platform for stakeholders to collaborate, foster consensus and develop a shared understanding on matters of significance affecting member organisations and consumers. Through drawing on the knowledge, experience, and resources of the Committee's broad and inclusive membership, the Committee is central to supporting one of Vision 2020 Australia's key roles as an effective conduit to government, offering a unified and consistent voice.