School of Optometry & Vision Science

UNSW SYDNEY

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

How often orthokeratology lenses need to be replaced?

Mark Willcox

1. What is the research study about?

You are invited to take part in this research study. This research aims to assess how Orthokeratology (OK) lenses accumulate surface deposits and scratches under regular cleaning and disinfection practices, in order to determine the optimal time for replacing the lenses. Additionally, we will evaluate the health of the front surface of the eye and the comfort of the lenses during one year of overnight use. By participating, you are contributing to research that aims to reduce the risk of eye infections and improve overall eye health for OK lens users, which may lead to better guidance for practitioners and safer lens wear for future patients.

2. Who is conducting this research?

The study is being carried out by the following researchers: Shyam Sunder Tummanapalli, Vinod Maseedupally and Mark Willcox of the School of Optometry & Vision Science

Research Funder: This research is being funded by Johnson and Johnson Vision, USA.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:

- Age between 18 to 40 years old
- Have shortsightedness or myopia between 1.00D and 4.00D (inclusive), and astigmatism ≤ 2.50D
- Good eye health with no history of eye trauma or surgery, no eye disease
- Soft contact lens wearers willing to discontinue lens wear for at least 24 hours before participation.
- Individuals with history of rigid lens wear (including orthokeratology) who have discontinued wearing them for at least one month and the duration of wear not extended beyond 3 months.
- Willing and able to comply with the research procedures and the follow-up schedule

Individuals with the following characteristics will be excluded from the study:

- Age less than 18 years or more than 40 years old
- Shortsightedness or myopia less than 1.00D or more than 4.00D and/or astigmatism > 2.50D
- Longsightedness or hypermetropia

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

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5. What does participation in this research require, and are there any risks involved?

If you agree to participate, we will assess your eligibility by conducting some routine optometric procedures at the screening visit.

Before any screening procedures you will be required to read and provide this written consent. We, the investigators will answer any questions that you may have with regards to this research study. After you have provided the consent, we will proceed with the screening visit.

Screening visit/Baseline visit: This visit will take approximately 1 hour and will involve the following tests/procedures:

- One of the investigators will ask questions relating to your eye symptoms, eye health history, past spectacle and contact lens wear, eye surgeries if any, general health history that may preclude contact lens wear.
- Distance and near visual acuities (vision) using computerised vision charts (Test Chart 2000 Pro, UK) which will involve you reading letters from a screen.
- Measurements of the spectacle power of your eye will be the eye using Shin-Nippon NVision K-5001 autorefractor (Shin-Nippon, Japan). In this test you will be asked to rest their chin and head against the machine's chin and head rest and look at a target while the measurement is taken.
- Subjective measurements of the power of the eye using standard optometric techniques which will involve you looking through various optical lenses while reading letters on a screen.
- Front eye shape measurements using the Medmont E300 corneal topographer (Medmont, Melbourne) which will involve looking at ring target inside an instrument (stored in the form of a photograph which is a magnified image of the front of the eye, that does not reveal your identity).
- An eye health check using standard optometric techniques and a high magnification clinical microscope which will involve looking at different directions of gaze while a light is directed at your eye.

If you do not meet the selection criteria, you will be informed verbally of the reasons for ineligibility*, and all data obtained during the screening visit will be discarded. If you are eligible for the study, the investigators will have appropriate OK lens parameters determined by the proprietary (Johnson and Johnson) software based on the information obtained at the screening visit. Study OK lenses will be ordered empirically, and you will be scheduled for the fitting and dispensing visit.

This study uses Menicon Z Night lenses (material: Tisilfocon A, NKL Contactlenzen BV, The Netherlands) and have been registered with Therapeutic Goods Administration (TGA) with ARTG entry: 226883 and suitable for use on the eye during sleep (overnight wear) for the correction of shortsightedness or myopia.

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Following the screening visit, you will have to attend a total of 7 study visits (approximately 1 hour each) at our research facility at the School of Optometry and Vision Science, Rupert Myers Building (North Wing), UNSW Sydney, Kensington Campus. The study visits include:

Lens fitting visit: This visit is scheduled after ordered lenses have arrived. On the day of visit the lenses will be assessed for lens spoilage before and after applying these lenses to your eyes. After lens application to your eyes, lens fit will be assessed using a high magnification clinical microscope. If the fit is clinically acceptable, you will be taught insertion, removal, cleaning and maintenance of the lenses. Lens maintenance procedures including disinfection and storing of lenses will also be explained to you. You will also be given printouts that detail lens application, removal and cleaning instructions as a reference to take home. You will also be given an "OK Wear Time Journal" where OK lens insertion and removal times, time retired to bed and waking up times to be recorded. You will be required to wear the lenses in both eyes for approximately 6-7hours during sleep with no daytime lens wear. As you are required to wear lenses overnight, you will be given contact details for the NSW Health Emergency Department in the case you experience unusual symptoms or signs with lenses and require any support after-hours. During this and subsequent visits, contact lens comfort will be assessed by administrating validated questionnaires.

This visit will take approximately 45-60 minutes. A next study visit will be scheduled after one overnight wear.

Day 1 study visit (45-60 minutes): This visit will be scheduled in the morning, and you will be asked to remove study lenses after waking and present to the research facility within 2 hours after lens removal. All the study procedures conducted during the screening visit, including administration of questionnaires and assessment of lens spoilage will be repeated in the same order.

Since it takes approximately one week for vision to be optimal with the study OK lens wear, daily disposable soft contact lenses will be provided to you, if you are expected to drive to the research facility in all the follow-up visits. These soft contact lenses will correct any expected residual power. In this case, you will be taught the insertion and removal and hygiene practices required for safe soft contact lens use by the investigators. Your "OK Wear Time Journal" will be reviewed.

Study visits: The next follow-up study visits will be scheduled after 1 week (Day 7), 3 weeks (Day 21), 6 months, and 12 months from the dispensing visit as shown in the table. At these visits, tests and measurement procedures will be the same as indicated in screening and lens fitting visits. All the visits will be scheduled for a duration of approximately 1 hour in the morning within 2 hours after waking and at these visits, lens care regimen and hygiene will be emphasised, and "OK Wear Time Journal" will be reviewed.

Day 7 study visit (45 min-60 min)	after 1-week overnight wear of study lenses from lens dispensing visit
Day 21 study visit (45 min-60 min)	after 3 weeks overnight wear of study lenses from lens dispensing visit

6 Months and 12 Months (45 min-60 min each)	after approximately 6, 9 and 12 months from lens dispensing visit
2-weeks lens cessation visit (45 min-60 min)	Occurs approximately two weeks after the 12-month visit, during which participants will cease lens wear for two weeks. This cessation period allows for the evaluation of recovery and stabilization of eye surface parameters, providing baseline comparisons. It will also help detect any eye-related events requiring further evaluation.

Risks: Possible adverse physical effects with orthokeratology lenses include those normally related to rigid contact lens wear and include possible temporary adherence of the contact lenses to the eye, mild disturbance to the front layer of cells of the eye, mild discomfort due to lens edge interaction with eyelid margin, allergic reaction to lens solution, and ocular inflammation. In the context of this closely monitored study by registered optometrists, the risks of such complications are minimal. There is an exceptionally rare but possible risk of corneal infection, however the risk of such an adverse reaction is much less in a rigid contact lens than a soft contact lens.

We will teach you appropriate techniques to safely insert, remove, clean and maintain orthokeratology lenses. You will also be taught to safely free adherent lenses and recognise signs of any potential adverse effects. You will be advised to report any symptoms experienced during lens wear. Despite our anticipation that there will be no clinically significant adverse effects in these studies from rigid contact lens wear, in the unlikely event of any clinically significant adverse response, a careful eye examination will be carried out and lens wear will be discontinued. If required, you will be referred to an appropriate health care practitioner at no cost to yourself and will be closely monitored thereafter by the investigators.

You may contact us on a 24-hour contact number on +61 2 9385 9233 if you experience any adverse side effects or have any concerns or emergencies. This number will connect you with the Chief Investigator, an Australian registered optometrist, who will be able to provide you instruction on how to receive proper care for any adverse side effects, concerns or emergencies. If required, you may be referred to an appropriate health care practitioner at no cost to yourself and be closely monitored thereafter by study investigators.

6. **Additional Costs and Reimbursement:** There are no costs associated with participating in this research project, nor will you be paid. However, you will receive a $40 digital Westfield gift card at the end of each study visit to reimburse you for your time, any reasonable travel, parking, meals and other expenses while participating in this research study.

7. **What are the possible benefits of taking part?**
   We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include clear vision without needing to wear glasses or contact lenses during

the day. The benefit of partaking in this research study also includes helping develop strategies to minimise severe form of eye disease associated with long-term use of spoiled OK lenses

8. What are the alternatives to taking part in the research?

You do not have to take part in this research project to receive OK lenses for correcting your shortsightedness. Other options are available; these include getting a comprehensive eye test at the UNSW Optometry Clinic and correction your shortsightedness by glasses, soft contact lenses, or rigid gas permeable contact lenses. Your study optometrist will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local optometrist.

9. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research study. The research team will store the data collected from you for this research project for a minimum of 15 years after the completion of the research.

The information about you will be stored in a re-identifiable format where any identifiers such as your name, address, date of birth will be replaced with a unique code.

Information collected from you in an electronic format will be stored on a UNSW password protected OneDrive only accessible to the approved research investigators. Information collected from you using paper-based measures will be stored in Rm 2.006A, Rupert Myers Building, North Wing, School of Optometry and Vision Science, UNSW Sydney, and only the approved research investigators will have access to this information.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the UNSW Privacy Management Plan.

10. How and when will I find out what the results of the research study are?

The research team intend to publish and report the results of the research. All information will be published in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

Johnson & Johnson shall have the right to review each publication and presentation (including, but not limited to, full papers, abstracts, poster presentations, and oral presentations) of results of the Study prior to its submission to anyone not affiliated with Johnson & Johnson or Institution. Such right is for the purpose of enabling Johnson & Johnson to provide peer input regarding the scientific content of such publications and to check the technical accuracy of information regarding Products.

In no case will Johnson & Johnson use the review for the purpose of influencing or amending the reported outcomes. No identifiable participant data will be disclosed to Johnson & Johnson.

11. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or Johnson and Johnson Vision, USA. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

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12. **What if I have a complaint or any concerns about the research study and will I receive compensation if suffer any injuries or have complications?**
If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
iRECS Reference Number	iRECS

13. **What should I do if I have further questions about my involvement in the research study?**
The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Dr Shyam Sunder Tummanapalli
Position	Co-Investigator
Email	s.tummanapalli@unsw.edu.au

Name	Dr Vinod Maseedupally
Position	Co-Investigator
Email	vinodm@unsw.edu.au

Name	Dr Mark Willcox
Position	Chief Investigator
Email	m.willcox@unsw.edu.au

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Consent Form – Participant providing own consent
Declaration by the participant

- I understand I am being asked to provide consent to participate in this research study;
- I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- I understand the purposes, study tasks and risks of the research described in the study;
- I provide my consent for the information collected about me to be used for the purpose of this research study only.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- I understand that I will be given a signed copy of this document to keep.
- I understand that the results of the research will be made available on the School of Optometry & Vision Science website.
- I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.

Name: _____

Address: _____

Email Address: _____

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

- I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

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Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study. All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

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I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, and the School of Optometry & Vision Science.

- I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn.
- I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.
- I am withdrawing my consent and I understand that any information already published and/or not linked to my identity cannot be withdrawn from the research.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Mark Willcox
Email:	m.willcox@unsw.edu.au
Phone:	+61 409658313
Postal Address:	School of Optometry & Vision Science, UNSW, Sydney, SYDNEY NSW 2052, AUSTRALIA