

# A Clinical Study of a Hydrogel Multifocal Contact Lens

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## Background

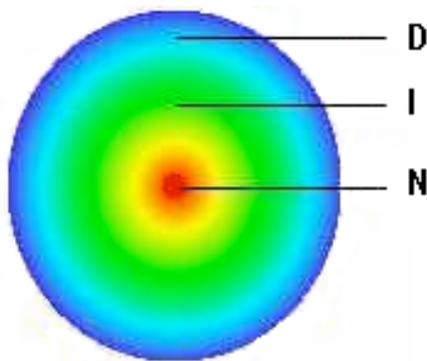
Despite the increasing number of presbyopic patients within the population, this group remain one of the greatest challenges in standard contact lens fitting. Success rates with presbyopic patients continue to be low compared to pre-presbyopic subjects. This relatively low success rate (as determined by patient satisfaction) and added complexity of fitting has not endeared contact lens practitioners to multifocal contact lenses in general. Many practitioners simply default to “monovision” fitting or glasses over the contact lenses for reading. While both these options are valid, especially in very early presbyopia, the limitations and compromises are well known by practitioners.

Modern presbyopes are healthier, more active and perhaps more demanding than their predecessors, so it stands to reason that good binocularity and convenience are important in satisfying their visual demands. Any modern design that can offer an increase in visual performance is worth investigating.

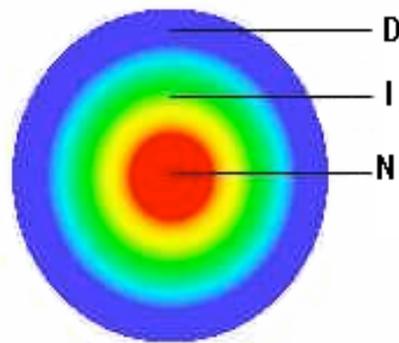
This study investigated the performance of the C2 multifocal contact lens by Precilens. The C2 lens is a new generation of simultaneous vision multifocal hydrogel contact lenses. Rather than having a continued change of power across the lens as with most near-centre multifocals, the C2 has a stabilised near zone of power centrally; a progressive intermediate zone; and a stabilised peripheral distance zone. These progressions are worked into the back surface of the lens. The front surface has a variable eccentricity aspheric surface. The C2 is also available in a front-surface toric design, although this did not form part of our study.

The Precilens C2 multifocal lenses are manufactured in Hioxifilcon B, an FDA Group1 mid-water content hydrogel material with UV filter and a dk of 15. Base curve ranges from 8.0 to 9.5mm in 0.3mm steps. Diameter is set at 14.2. Power range is -25.00 to +25.00. There are 2 different reading additions available. Progression 1 is recommended for spectacle near additions of +2.00D or less, while the Progression 2 series is for patients requiring with an addition +2.25D or more. A toric version of this lens (C2T) with a cylinder power of up to -5.50DC is also available.

Standard Design



C2 Design



## Study design

The primary purpose of this study was to determine the objective and subjective visual performance of the lens. Along with this we assessed overall comfort and recorded any adverse events. We aimed to enrol approximately 30 subjects, split between neophyte contact lens wearers, single vision contact lens wearers and existing multifocal wearers. Subjects were screened for anterior segment disease. Prior to initial dispense, existing contact lens wearers completed an assessment questionnaire regarding vision and comfort of their habitual contact lenses.

We followed the Precilens recommendations for initial lens selection. We provided Spectacle Refraction, Reading Addition, Auto-Keratometry readings and Dominant eye. The initial lens parameters were then calculated by the laboratory.

Upon delivery of the lenses they were fitted to the subjects and assessed for initial fit and vision. If deemed satisfactory, the patient was instructed in care and handling.

Followup appointments were scheduled for 2 weeks, 1 month and 3 months.

If the practitioner and patient were not satisfied with the performance of the lens, then the lens parameters were altered and a new trial set was ordered from the laboratory.

At each appointment the subjects completed a questionnaire, rating their subjective assessment of the visual and comfort performance of the trial lens.

The practitioner at each appointment assessed objective distance and near vision (both monocular and binocular), physical fit of the lenses and graded physiological response (conjunctival hyperaemia and corneal oedema). Any adverse events were noted.

At the conclusion of the study the patients were asked whether they would like to continue with the trial lenses.

We realise that the small sample of trial patients has its limitations and elected not to attempt to statistically analyse the data. However, we feel the study still provides a good amount of valuable information on the performance of the trial lenses.

## Results

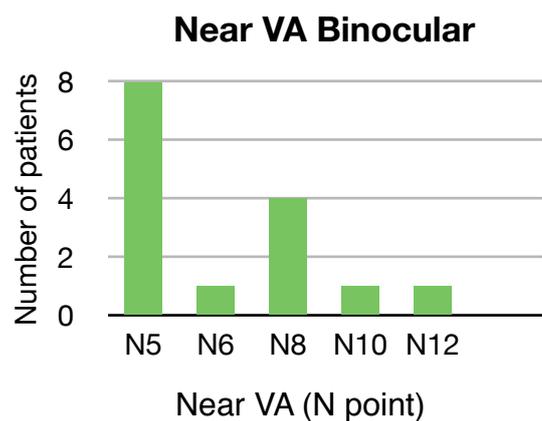
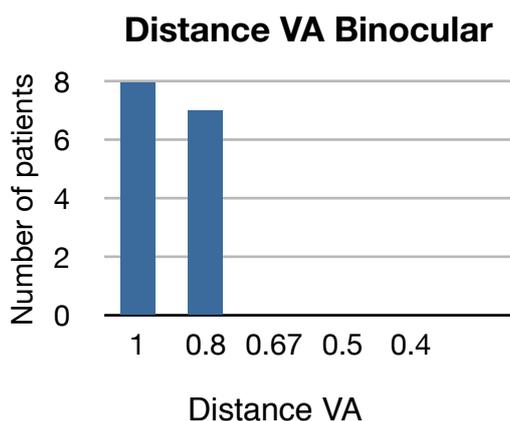
For the purposes of this study data was not included unless the subject had worn the lenses for at least 1 month of the 3 month study.

### Objective Results

Binocular distance acuity mean average was 0.91 (Snellen decimal). Range 0.8-1.0

Binocular near acuity mean average N 6.7. Range N5-N12.

Interestingly there did not appear to be any significant correlation between distance and near acuity. No significant changes in conjunctival hyperaemia were noted. No clinical detectable corneal oedema was noted with any patient. There were no adverse ocular events associated with the wear of the trial lenses.



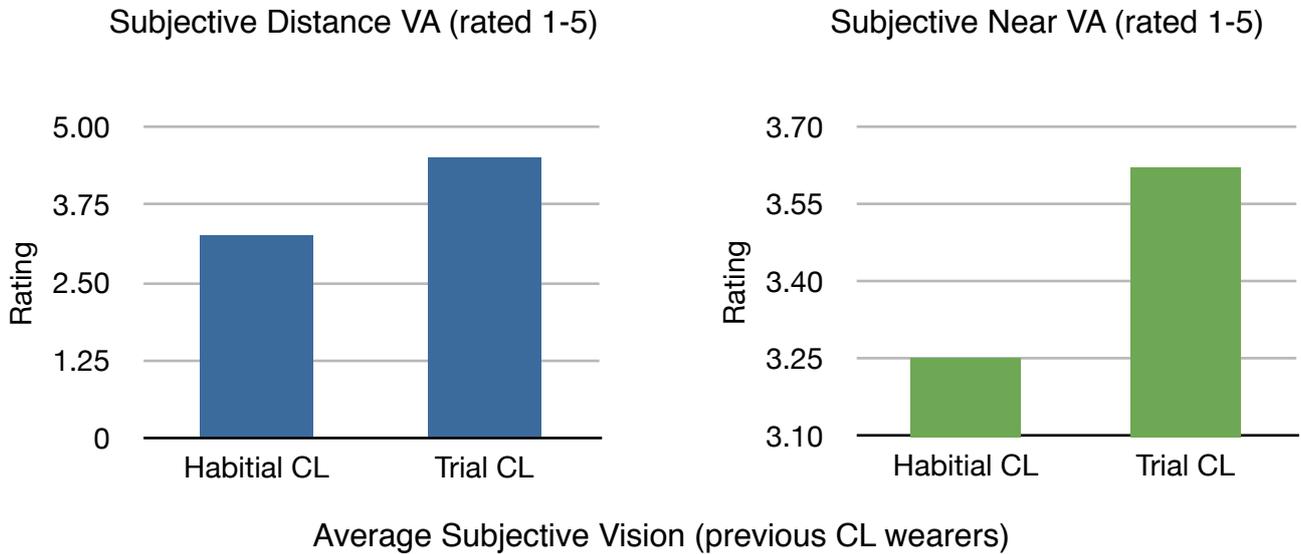
### Subjective Results

Distance and near vision with the trial lenses were graded by the subjects from poor (1) to excellent (5).

For all subjects the mean average subjective rating was 3.9 for distance and 3.2 for near.

For existing contact lens wearers the trial lens were rated at a mean average of 4.5 for distance vision, compared with 3.25 for their habitual contact lenses.

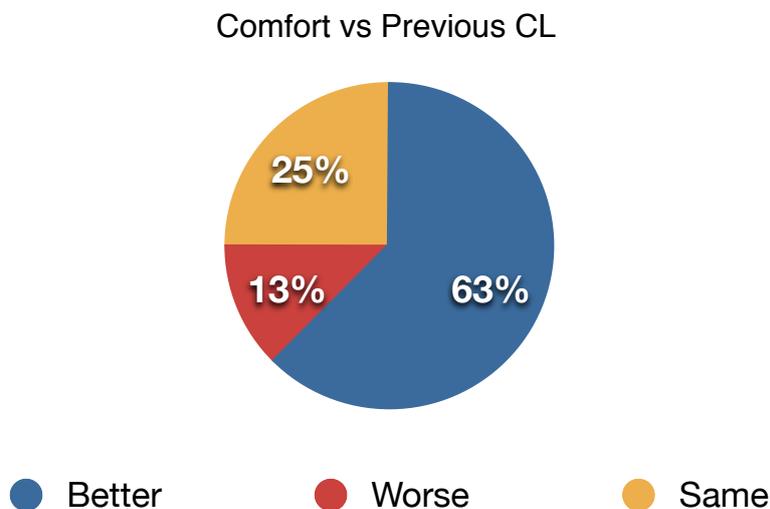
Near vision was rated at a mean average 3.6, compared with 3.2 for their habitual lenses.



A surprisingly low 13% of subjects noted day-time dryness, while this rose to 43% for end-of-day dryness.

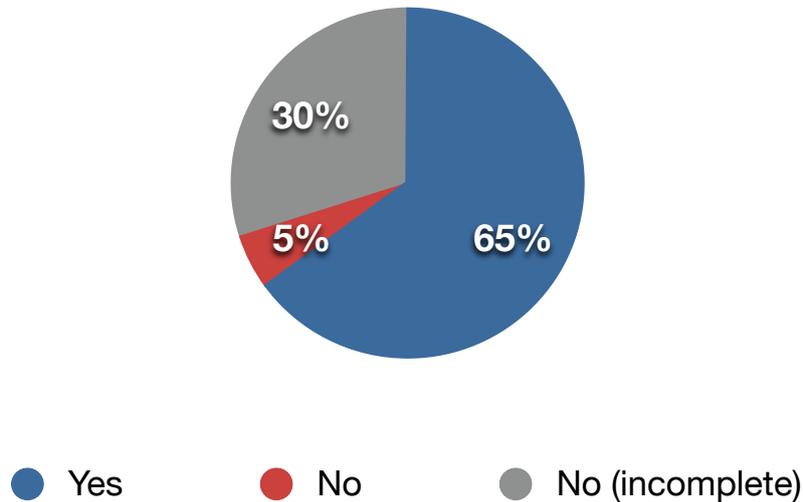
Overall comfort gained an average rating 4.2 out of 5 for all completed study subjects.

When comparing the trial lenses to their previous contact lenses 78% of subjects rated the comfort the same or better than their existing contact lenses. Only 13% preferred the comfort of their habitual contact lenses.



At the end of the study all completed subjects were asked if they would like to continue with the lenses. Subjects that were withdrawn from the study before the end of the trial period (either by the practitioner or by themselves) were considered to be a “no” in the answer to the question. Of the total subjects starting the trial, 65% stated they would like to continue with the lenses, 5% did not wish to continue and 30% did not complete the trial for various reasons.

Would you like to continue with the lenses?



## Discussion

The C2 was an extremely simple lens to fit. Our initial lenses were produced using the parameters noted earlier in this paper. At the 2 week check it was decided whether any parameters required alteration. We found we could alter the near addition without making too much compromise to the distance vision. This was probably due to the large stabilised zones of near and distance vision with this design. This is relatively unique among multifocal soft lenses, as generally significant compromise between distance and near vision is required, especially with higher reading additions. We looked at the relationship between distance and near vision obtained with the trial lenses, and plotted distance VA versus near VA. Interestingly, we found no correlation between the two. In other words it did not appear the patients that gained good distance vision did so by compromising the near vision (or vice versa).

In our view the simplicity of the fitting process is of significant benefit when fitting these potentially challenging patients. This tends to lead to reduced patient visits, which of course is beneficial for practitioner and patient alike.

One of the subjects had previously had Lasik surgery for myopia. Practitioners who have fitted a number of these patients know the challenges they can present. Our post-Lasik trial subject was no different in this respect. Fitting the peripheral cornea (with a steeper BC) gave a comfortable, stable lens with poor inconsistent acuity. Fitting the central cornea (with a flatter BC) produced improved acuity but a physically unstable and uncomfortable lens. She was withdrawn from the trial. This outlines the importance of subject selection in multifocal lens fitting.

Comfort is a significant issue with contact lens wear and probably the leading cause of patients ceasing lens wear, particularly as changes in tear chemistry with age create a more challenging ocular environment. We were surprised with the level of reported comfort with the trial lenses. Improved comfort (versus the subjects habitual lenses) was experienced by 63% of previous contact lens wearers, with only 13% rating the comfort as worse than their previous lenses.

As mentioned earlier, we asked whether the subjects would like to continue wearing the lenses they had used in the trial. 30% of subjects did not complete the trial for various reasons and therefore did not have the opportunity to answer this question. These were considered to “No” responses for our study. The reasons for incompleteness were varied but the majority were neophyte contact lens wearers. This is logical as the expectations of new wearers may be unrealistic; again patient selection is key to success.

Of the subjects that completed the trial period, the vast majority stated they would like to continue with the lenses. This of any of the measures this is perhaps the most important. What usually dictates the final success is the satisfaction of the patient.

In summary we found the Precilens C2 multifocal lens to be an excellent lens for presbyopic patients. It performed well in both objective and subjective measures and produced a high level of patient satisfaction. This combined with the ease of fitting procedure make it a lens worth considering for presbyopic patients.

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