

Results of a Multicentre European Study : Comparing subjective results in latest generation multifocal silicone hydrogel contact lenses

Some of these results were presented at the 2012 SFO (Société Française d'Ophthalmologie) in Paris, France, and at the BCLA Conference, in Birmingham, United Kingdom, in May 2012.

Comparative multicentre study performed in Germany by Thomas Harnsich (BSc Optom. FH Jena) Jenvis Research, in France by Drs Louissette Bloise, Christine Brodaty and Catherine Peyre, and in the Netherlands by Hans Kloes.

Introduction

Investigations of the demographic development in Europe and the United States show, that the amount of people of presbyopic age is very high and the number of presbyopes in the developed countries will increase over the next years. About one in two patients visiting the Eye Care Practitioner is 40 years old and upward. Therefore there is an increased demand on presbyopic correction options, especially on multifocal contact lenses.

Although this demand increases steadily, the segment of multifocal contact lenses is relatively untapped. Additionally the number of contact lens wearer's decreases in early presbyopia [1] and there is still a high drop out rate of 2.3 million people at the age of 38 and upward [2]. Physiological changes of the tear film quality and quantity plays an important role in this progress as well as the intolerable compromises regarding the vision quality in different distances. Multifocal contact lenses should meet these requirements regarding their material and their optical design. Although there was a continuous development of these lenses in the last decade the patients often complain of decreased contrast sensitivity, shadowing and ghost images.

Aim/Purpose

The primary objective of the present study was to evaluate the visual performance of two multifocal contact lenses, the C2 Multifocal (Precilens, France) in comparison to a center near progressive contact lens with the latest generation Silicone Hydrogel material, which is called for the study purpose Multifocal Test Lens (TML). The focus was on the subjective impression of vision, as well as on the objective measurement of the visual acuity in the distance and in the near.

The secondary objective was the evaluation of comfort at different stages of wearing time and the objective lens surface characteristics, especially regarding dry areas and wettability. Finally a potential preference for one of the two lenses in different categories was assessed.

Methods/Material

Three French, one German and one Dutch site enrolled 50 subjects in total (mean age 55.5 ± 8.7 years).

Multicentre European Study :

- Germany : Thomas Harnsich (BSc Optom. FH Jena) Jenvis Research, Jena
- France : Drs Louissette Bloise, Christine Brodaty and Catherine Peyre
- The Netherlands : Hans Kloes - OVN, ANVC, NCC

Prospective study, cross-over, multicentre and single-masked trial. Data provided by Precilens and analyzed by Jenvis Research at the University of Applied Sciences Jena, Germany.

Population : 38 females and 12 males - Age : at least 40 years

	Single Vision	Multifocal
Previous Contact Lens Fitting	36%	64%
Mean Age	51.2 +/-7.2	57.8 +/-8.4

Monovision was an exclusion criteria.

All subjects should have 20/40 or better distance visual acuity in each eye.

Each subject had to wear the C2 Multifocal (C2M) for two weeks and the Multifocal Test Lens (TML) for two weeks. There was no wash-out phase between the two test periods because, based on past experiences and researches, the possible secondary effects which are related to the wearing of the tested soft contact lenses (discomfort, blurred vision, distortion, etc.) are not durable and disappear as soon as the wearer remove their soft contact lenses.

A randomization was used to determine for each wearer the first lens. Subjects were randomly divided into two groups assigned to wear either C2M or TML first for two weeks and then the other multifocal soft contact lens for the next two weeks. For this purpose a randomization table for each site was generated by the study monitor according to the clinical investigation plan before the beginning of the trial.

All subjects should use their habitual lens care product for the trial period.

According to the visit schedule every subject underwent three study visits :

- **Visit 1:** Informed Consent, eligibility. Refraction, keratometry measurements, biomicroscopy evaluations. Fitting and lens performance assessment (e.g. wettability and deposits, subjective vision, biomicroscopy findings) of the first trial lenses to test.
- **Visit 2:** First trial lenses were evaluated objectively by the investigator and subjectively by the subject. Fitting and lens performance assessment of the second trial lenses to test.
- **Visit 3:** Second trial lenses were evaluated objectively by the investigator and subjectively by the subject and subjective ratings of the lenses were assessed at Trial Exit Visit.

A subjective evaluation of the current lenses was assessed by a questionnaire with a 10 points scale. Additionally there was an evaluation of a potential preference for one of the two lenses and the study completion. Patients could decide whether their preference was moderate (somewhat), strong (strongly), or if there was no preference (none). Results were rated for each evaluation criteria.

Subjective Results

Vision

In nearly all categories that refer to vision, the subjects prefer the C2M. In the case of vision of contrast the results are nearly the same for both lenses and most of the subjects had no preference. (Fig 1)

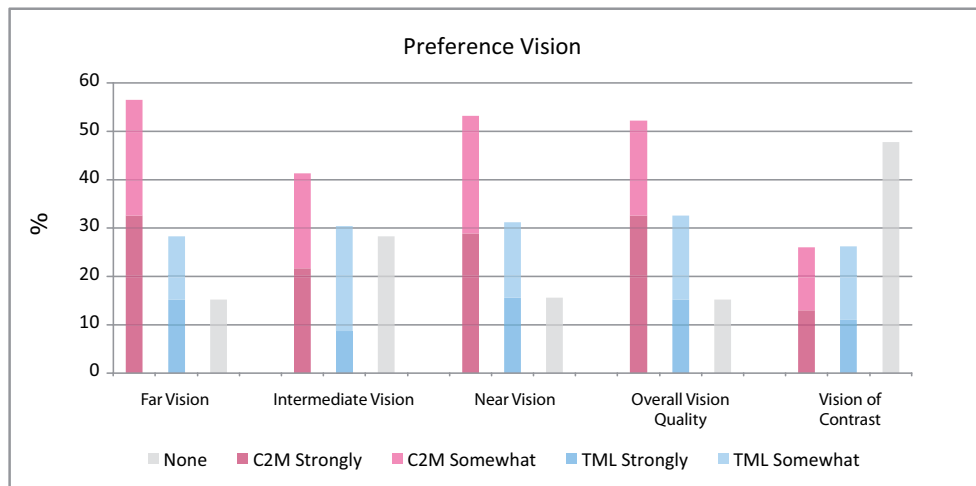


Fig 1. Preference - Vision

Comfort

Although the subjective ratings of comfort were equal for both lenses, the subjects clearly preferred the C2M in this category. A third of all subjects had no preference; nearly the same number of subjects preferred the C2M strongly. (Fig 2)

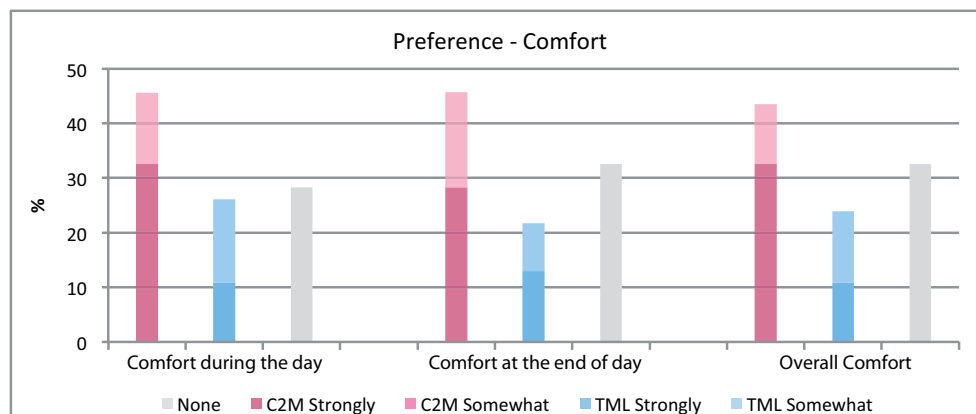


Fig 2. Preference - Comfort

Dryness

Regarding the lens dryness most of the subjects had no preference for one of the two brands. If there was any, in the majority of the cases the subjects preferred the C2M. (Fig 3)

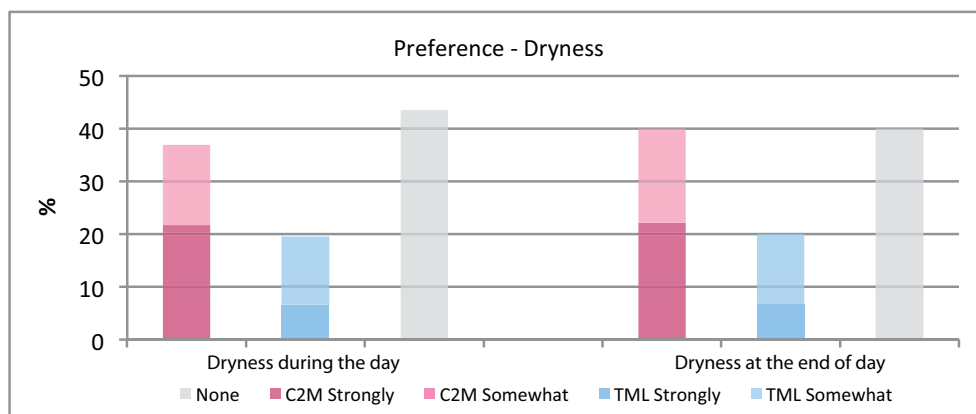


Fig 3. Preference - Dryness

Overall Satisfaction

With respect to the overall satisfaction the subjects clearly gave the C2M the preference, although the subjective rating before was almost identical. In this case most of the subjects favored the C2M even strongly. (Fig 4)

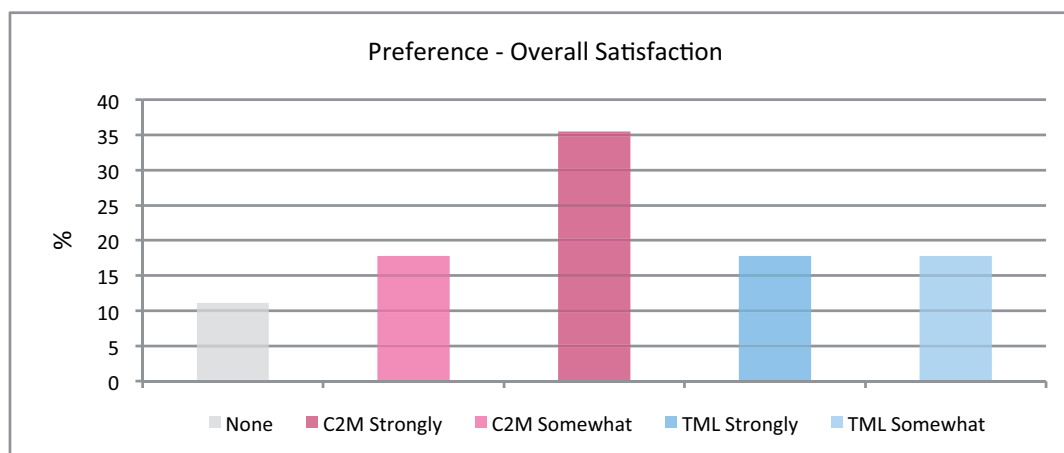


Fig 4. Preference - Overall Lens Satisfaction

Discussion

The success rate of multifocal contact lenses is still in discussion. The aim of new developed lenses is to deliver better vision and higher comfort to increase the success rate of this increasing contact lens segment.

Both lenses (study lens and control) were rated good or very good in all major criterions. Both lenses have the distinction of being comfortable over a number of hours per day. The lenses have a good visual performance with regard to both the objective measurement of the visual acuity and the subjective impression of the wearer. The comparison between the best corrected VA and the VA with the lenses shows very plainly, that the subjects have to accept only minor compromises in the distance and in the near with the lenses. Additionally it could be shown, that the lenses have very good surface characteristics especially concerning that the tear film conditions become worse with advancing age. Although the subjective ratings of the patients in different categories were almost equal there was a clear decision in favour of the C2M with respect to a potential reference for one of the two lenses.

Conclusion

The study results give an idea of the scope of the performance of the lenses. The C2M contact lens was preferred for distance, near and intermediate vision performance. As minor compromises will still remain in terms of vision performance, research and development will have to focus on more accurate visual contrasts and on simultaneous vision innovations.

References : [1] GFK data M/A 2008 – 5 Countries: UK, FR, G, I, ESP - [2] Visiontalk Study 2007 – UK, GER, F, I