# MiSight Assessment Study Spain: A Comparison of Vision-Related Quality-of-Life Measures Between MiSight Contact Lenses and Single-Vision Spectacles

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**Objectives:** Recent research has shown that concentric contact lenses (CLs) can be a way to control the progression of myopia. The purpose of the current study was to compare vision-related quality-of-life measures in children wearing distance single-vision (SV) spectacles versus MiSight CLs, a specific concentric design for myopia control.

**Methods:** Subjects aged 8 to 12 with myopia from −0.75 to −4.00 diopters (D) of sphere and astigmatism less than 1.00 D of cylinder were allocated to the lenses study group (MiSight) or control group (SV). A Pediatric Refractive Error Profile (PREP) questionnaire was administered at 12- and 24-month intervals to evaluate children's perceptions in overall vision, near vision, far distance vision, symptoms, appearance, satisfaction, activities, academic performance, handling, and peer perceptions. The mean score of all items was calculated as the overall score.

**Results:** In total, 74 children completed the study: n=41 in the MiSight group and n=33 in the SV group. In the MiSight group, the ratings at 12 and 24 months for appearance, satisfaction, effect on activities, handling, and peer perceptions were significantly better than those given by children in the SV group ($P<0.001$), as was the overall score. However, near vision was significantly better in the SV group at both 12 and 24 months ($P<0.001$).

**Conclusions:** MiSight CL wear for controlling myopia improves vision-related quality of life in children when compared with spectacle wear.

**Key Words:** MiSight—Myopia—Quality of life—Contact lenses—Children.

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Myopia typically develops and manifests itself in childhood, younger than 10 years, and progression rates are higher among younger children. Therefore, a successful myopia control treatment should target this susceptible population.[1–4] Slowing the progression of myopia in children is an issue of particular interest to parents and to the scientific community, but in most cases, childhood myopia is treated with traditional single-vision (SV) spectacles despite several studies having demonstrated that children are sufficiently mature to safely and successfully wear contact lenses (CLs).[5–10] It is also known that children are capable of wearing many types of CLs, such as daily wear Rigid Gas Permeable CLs,[5,6,11] orthokeratology (OK) CLs,[12,13] and soft CLs.[7–9,14] Contact lens wear has also been found to notably improve children's feelings about their appearance and participation in activities,[15] as well as the self-perception of 8- to 11-year-old myopic children in physical appearance, athletic competence, and social acceptance.[16] In addition, children with myopia younger than 12 years report better vision-related quality of life when wearing CLs as compared with spectacles.[17] Recent studies[18–22] have shown that different concentric soft CL designs may be successful in reducing myopia progression in children compared with control subjects. However, neither study included patient-reported visual performance. Little is understood about the visual performance of concentric CL designs for controlling myopia in children.

MiSight CL is a soft (hydrophilic) CL with a concentric design. It contains a large central correction zone surrounded by a series of treatment and correction concentric zones of alternating distant and near powers, which together produced two focal planes. The optical power of the correction zones corrected the refractive error while the treatment zones produced 2.00 diopters (D) of simultaneous myopic retinal defocus during both distance and near viewing, maintaining good visual acuity. Vision-specific quality-of-life questionnaires can be used to quantify the benefit of using CLs. The Pediatric Refractive Error Profile (PREP) questionnaire has been specifically designed to assess children's vision-specific quality of life.[23] Although other studies have compared the vision-related quality of life between children wearing OK CLs,[23] no previous studies have assessed the vision-specific quality of life in children wearing MiSight CLs and spectacles.

Therefore, the purpose of this study is to compare vision-related quality-of-life benefits between children wearing MiSight CLs and distance SV spectacles.

## METHODS

This study was part of the MiSight Assessment Study Spain (MASS), designed to assess the efficacy and subjective acceptance

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**TABLE 1.** *Comparison of Demographic and Ocular Components Expressed as Mean±SD for All Participants Who Completed the Study*

| | Completed | | |
|---|---|---|---|
| | MiSight Group (n=41) | SV Group (n=33) | *P* |
| Age, yrs | 11.01±1.23 | 10.12±1.38 | 0.005 |
| Spherical equivalent, D | −2.16±0.94 | −1.75±0.94 | 0.067 |
| Factor J0 | 0.07±0.18 | 0.00±0.12 | 0.059 |
| Factor J45 | −0.02±0.12 | 0.00±0.12 | 0.547 |
| Best-corrected visual acuity (BCVA), LogMAR | −0.06±0.06 | −0.07±0.07 | 0.627 |
| Best correct NVA, M | 0.4±0.06 | 0.39±0.03 | 0.276 |
| Axial length (AXL), mm | 24.09±0.55 | 24.00±0.86 | 0.603 |
| Anterior chamber, mm | 3.77±0.19 | 3.76±0.19 | 0.820 |
| Keratometry (KM), D | 44.24±1.25 | 44.03±1.59 | 0.533 |
| Pupil diameter (ø PUP), mm | 5.74±0.71 | 5.58±0.69 | 0.305 |

"*P* value" refers to the statistical *P* value.

SV, single-vision; D, diopters; J0 and J45, vectorial components for astigmatism; BCVA, best-corrected visual acuity measured in logarithm of the minimal angle of resolution (logMAR) units; NVAM, near visual acuity measured in M notation; AXL, axial length measured in mm; KM, mean keratometry measured in diopters; ø PUP, pupil diameter measured in mm.

of MiSight CLs versus distance SV spectacles in children with myopia for a 2-year period.

The protocol was approved by the CEI-R (Regional Research Ethics Committee of the Community of Madrid, Spain), and it adhered to the tenets of the Declaration of Helsinki. The clinical trial was registered in Clinical Trials (Clinical Trials.gov Identifier: NCT01917110) (https://clinicaltrials.gov/ct2/show/NCT01917110?term=misight+Spain&rank=1), where the outcome measures and eligibility criteria can be consulted. After explanation of the nature and possible consequences of the study, all parents provided signed permission for their children to participate, and participants provided written assent.

Healthy European subjects aged 8 to 12 with moderate levels of myopia (−0.75 to −4.00 D) and astigmatism (<−1.00 D), and free of systemic or ocular disease, were recruited for this study. At the baseline initial visit, all subjects underwent a full anterior segment examination, indirect fundus microscopy, binocular vision, and refractive evaluation. To determine whether or not they were eligible to participate in the study, eligible subjects were sequentially randomized into either the study group (MiSight CLs) or the control group (SV). Both groups were matched for age, refractive error, axial length, corneal power, pupil diameter, parental myopia, binocular and accommodative parameters, and time spent practicing sports and similar activities. Subjects in the MiSight CLs group were asked to wear their lenses for at least 6 days/week without exceeding 15-hour wear per day. It was made clear to them that they should remove their CLs if they experienced any kind of problem. They returned for follow-ups at 1 week, and at 1, 6, 12, 18, and 24 months. Subjects in the control group were prescribed standard, SV, spherocylindrical spectacles and were asked to wear the spectacles at all times. The spectacle group was asked to return for follow-ups at 6, 12, 18, and 24 months. At follow-up visits, children received new CLs or SV spectacles if overrefraction improved visual acuity by 3 letters, if there had been a change in the refractive error of −0.25 D or greater, or, at the clinician's discretion, if the child experienced visual symptoms. As in previous studies, the PREP was used to obtain qualitative information relating to the children's satisfaction with their method of compensation. The PREP survey was used in this study to compare the vision-specific quality of life between children in the MiSight and SV groups. At the baseline visit, all the subjects completed the PREP for glasses. At 12- and 24-month visits, the MiSight CLs group completed the PREP for CLs and the SV group completed the PREP for glasses. As described by Walline et al.,[15,23] the survey consisted of 26 statements, scored from 1 (negative or poor quality of life) to 5 (positive or good quality of life) and then scaled from 0 to 100 by subtracting 1 from the raw score of each question and multiplying by 25. The two surveys were identical except for the replacement of the word "glasses" with "contact lenses." Children had to read 26 statements and mark "strongly agree," "agree," "neutral," "disagree," or "strongly disagree," according to how they feel. The survey included 11 scales: overall vision, near vision, far distance vision, symptoms, appearance, satisfaction, activities, academics, handling, peer perception, and the overall score, which was calculated by averaging all the aforementioned items. The overall PREP score was the average of all 26 items. The surveys were requested to be answered by the children, and parents were asked not to participate. To administer the survey properly, children were instructed to read the question and choose only one answer for each question without skipping any of them. Children asked the examiner if they did not understand the meaning of the question.

## Statistical Analysis

Statistical analysis of data was performed using SPSS statistical software package SPSS 18 for Windows. Data corresponding to children who attended the 24-month visit were included in the analysis. The level of statistical significance was taken as 5%. Differences in each group over time (baseline vs. 24th visit) in vision-related quality-of-life measures in children were assessed. General linear model (GLM) repeated measures were applied, where the within-subjects factor is time. The assumption that the variance-covariance matrix is circular was subjected to the Mauchly test of sphericity. If this assumption is rejected, GLM repeated measures use the univariate F statistic, corrected by the epsilon index.

Differences between groups in the last visit (2-year follow-up) in vision-related quality-of-life measures in children were assessed by one-way analysis of variance (ANOVA) or Mann-Whitney *U* test, depending on the assumption of homogeneity of variances. The Levene test is performed to test for this assumption of equal variances. If this assumption is not rejected, one-way ANOVA is used.

**TABLE 2.** *Distance and NVA at 12- and 24-Month Follow-up Visits for MiSight and SV Groups*

| | 12 months | | | 24 months | | |
|---|---|---|---|---|---|---|
| | MiSight | SV | *P* | MiSight | SV | *P* |
| Best-corrected visual acuity (BCVA), LogMAR | −0.05±0.06 | −0.04±0.05 | 0.443 | −0.08±0.05 | −0.09±0.04 | 0.611 |
| Best-correct NVA, M | 0.41±0.06 | 0.43±0.09 | 0.241 | 0.39±0.03 | 0.40±0.04 | 0.234 |

BCVA, best-corrected visual acuity measured in logarithm of the minimal angle of resolution (logMAR) units; NVAM, near visual acuity measured in M notation; SV, single-vision.

Otherwise, if the assumption of equal variances is rejected, the Mann-Whitney *U* test is used. Data are expressed as mean and SD.

## RESULTS

Eighty-nine subjects were recruited for the study between September 2013 and June 2016. Forty-six children were allocated to the MiSight group and 33 to the SV correction modalities. In total, 74 children completed the study, n=41 in the MiSight group and n=33 in the SV group. There were no withdrawals in the SV group and five withdrawals in the study group.

No statistically significant differences were found in any of the baseline demographics, refractive data, and biometric data between groups except for age ($P<0.05$) (Table 1).

Table 2 shows the results of distance visual acuity (best-corrected visual acuity) and near visual acuity (NVA) for the MiSight and SV groups at 12- and 24-month follow-up visits wearing MiSight CLs and SV spectacles, respectively.

The statistical analysis was performed with the results of all the children who completed the questionnaire in each of the visits, the values of "n" being shown in Figures 1–4. The data that were not analyzed correspond to unfilled or incorrectly filled questionnaires.

At 12 months, children wearing MiSight lenses rated symptoms, appearance, satisfaction, effect on activities, handling, peer perceptions, and the total score significantly better ($P<0.05$) than those wearing spectacles (Fig. 1). At 24 months, the score with MiSight lenses was significantly better ($P<0.05$) in appearance, satisfaction, effect on activities, handling, peer perceptions, and total score than SV spectacles (Fig. 2). However, near vision was significantly better ($P<0.05$) in SV than in MiSight at both 12 and 24 months, and no statistically significant differences were found in overall vision, far vision, and academics.

We found significant differences ($P<0.05$) in appearance, satisfaction, effect on activities, handling, peer perceptions, and total score between baseline visit and 24-month visit in the MiSight CLs group, being better in the MiSight CLs group at 24 months (Fig. 3). Near vision was also significantly better ($P<0.001$) at the baseline visit with children wearing glasses than at 24-month visit with children wearing CLs. On the contrary, the SV group showed significantly worse results in far vision and handling in 24-month visit compared with baseline (Fig. 4).

## DISCUSSION

The results of this show significantly better vision-related quality of life in children wearing MiSight lenses in comparison with children wearing SV spectacles, as regard appearance, satisfaction, effect on activities, handling, peer perceptions, and the overall score. These findings could be explained by the perceived enhancement of cosmetic appearance that a CL allows in comparison with spectacles, and because of the improvement that children can feel as a result of being able to participate in activities thanks to using CLs.

By way of exception, near vision was rated better for SV spectacles versus MiSight lenses at 12 and 24 months despite the

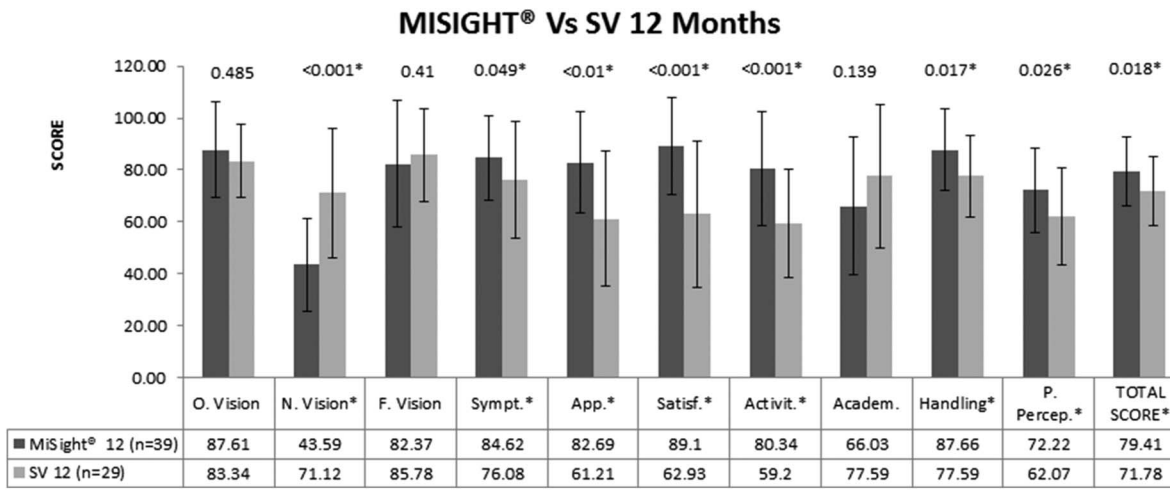
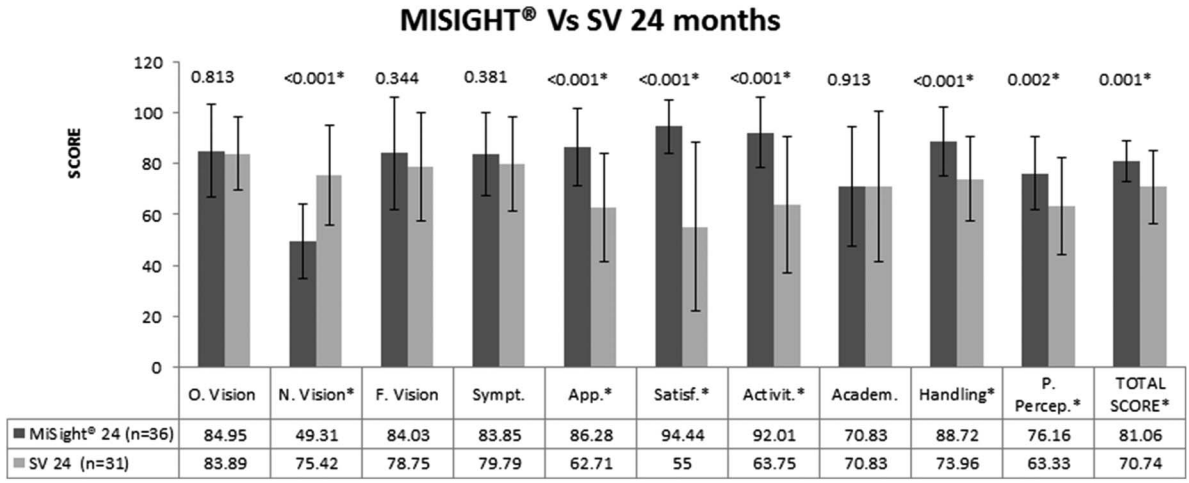



**FIG. 1.** Vision-specific quality-of-life rating for the MiSight contact lenses and single-vision (SV) spectacle groups. Twelve-month results. O. Vision, overall vision; N. Vision, near vision; F. Vision, far vision; Sympt., symptoms; App., appearance; Satisf., satisfaction; Activit., activities; Academ., academics; P. Percep, peer perception. *Statistically significant ($P<0.05$).




| | O. Vision | N. Vision* | F. Vision | Sympt. | App.* | Satisf.* | Activit.* | Academ. | Handling* | P. Percep.* | TOTAL SCORE* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| MiSight® 24 (n=36) | 84.95 | 49.31 | 84.03 | 83.85 | 86.28 | 94.44 | 92.01 | 70.83 | 88.72 | 76.16 | 81.06 |
| SV 24 (n=31) | 83.89 | 75.42 | 78.75 | 79.79 | 62.71 | 55 | 63.75 | 70.83 | 73.96 | 63.33 | 70.74 |

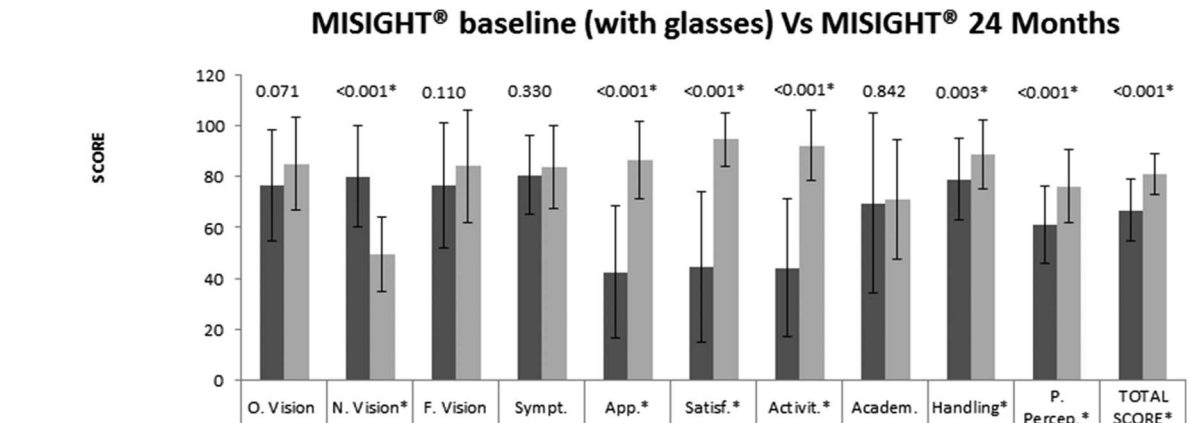
**FIG. 2.** Vision-specific quality-of-life rating for the MiSight contact lenses and single-vision (SV) spectacles groups. Twenty-four–month results. O. Vision, overall vision; N. Vision, near vision; F. Vision, far vision; Sympt., symptoms; App., appearance; Satisf., satisfaction; Activit., activities; Academ., academics; P. Percep, peer perception. *Statistically significant ($P<0.05$).

fact that there was no significant difference in NVA between both groups. It has been reported[24,25] that the quality of vision is dependent on centration of the multifocal soft CLs, so this result could be due to a possible decentration of MiSight CLs in near vision that could increase the perception of halos or light distortion due to the concentric design off-centered on the children's pupil.

The "activities" scale corresponds to the sum of the scores of four questions that refer to activities playing outdoors, playing sports, dancing, or other activities in which a good distance visual acuity is necessary. Therefore, a worse score in near vision in the MiSight group did not affect the scale "activities."

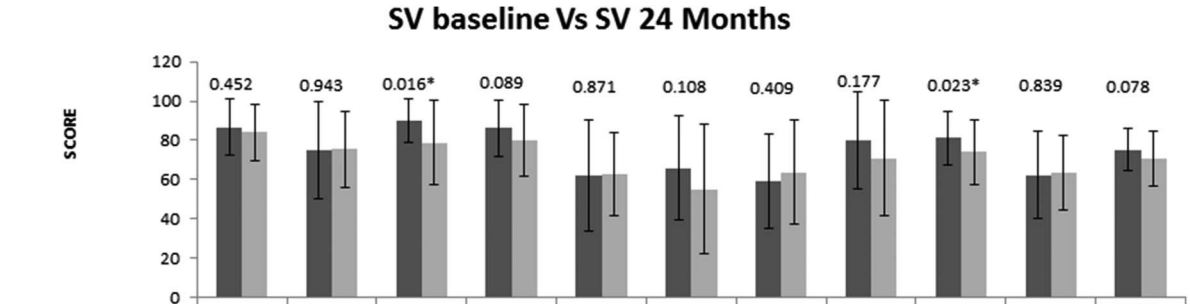
The most surprising finding was that children wearing MiSight CLs rated handling better for CLs than for SV, and the SV group even rated handling worse at 24 months. It is often assumed that spectacles are much easier to handle in comparison with CLs. However, our results show that this is not true. This can be attributed to the desire of the children in the SV group to start using CLs. These results are in agreement with previous studies that found increased vision-related quality of life in children wearing soft CLs in comparison with spectacles.

Rah et al.[17] performed a study with 484 children who wore spectacles at baseline and then were randomized to use CLs or spectacles. Their results during 3 years of follow-up show that quality of life in children who wore CLs was better in satisfaction, effect on activities, handling, peer perceptions, and the overall score. These results are similar to our results in the MiSight CLs group at 24-month follow-up. However, the study by Rah et al.[17] shows worse results for both near and far vision. On the contrary, in our study, the results for near vision are only worse in the MiSight CLs group. This could be due to the concentric design




| | O. Vision | N. Vision* | F. Vision | Sympt. | App.* | Satisf.* | Activit.* | Academ. | Handling* | P. Percep.* | TOTAL SCORE* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| MiSight® Baseline (n=36) | 76.39 | 79.86 | 76.39 | 80.56 | 42.36 | 44.44 | 44.21 | 69.44 | 78.82 | 61.11 | 66.77 |
| MiSight® 24 months (n=36) | 84.95 | 49.31 | 84.03 | 83.85 | 86.28 | 94.44 | 92.01 | 70.83 | 88.72 | 76.16 | 81.06 |

**FIG. 3.** Vision-specific quality-of-life rating for the MiSight contact lenses (CLs) baseline visit (with glasses) and MiSight CLs at 24 months. O. Vision, overall vision; N. Vision, near vision; F. Vision, far vision; Sympt., symptoms; App., appearance; Satisf., satisfaction; Activit., activities; Academ., academics; P. Percep, peer perception. *Statistically significant ($P<0.05$).




| | O. Vision | N. Vision | F. Vision* | Sympt. | App. | Satisf. | Activit. | Academ. | Handling* | P. Percep. | TOTAL SCORE |
|---|---|---|---|---|---|---|---|---|---|---|---|
| SV Baseline (n=30) | 86.67 | 75 | 90 | 86.25 | 61.94 | 65.83 | 59.17 | 80 | 81.25 | 62.22 | 75.22 |
| SV 24 months (n=31) | 83.89 | 75.42 | 78.75 | 79.79 | 62.71 | 55 | 63.75 | 70.83 | 73.96 | 63.33 | 70.74 |

**FIG. 4.** Vision-specific quality-of-life rating for the single-vision (SV) group baseline at baseline and 24-month visits. O. Vision, overall vision; N. Vision, near vision; F. Vision, far vision; Sympt., symptoms; App., appearance; Satisf., satisfaction; Activit., activities; Academ., academics; P. Percep, peer perception. *Statistically significant ($P<0.05$).

and a possible movement of the CL in relation to the center of the pupil.

As regard quality of vision with the MiSight lens design, we found that Kollobaum et al. used MiSight[26] (Dual-Focus) lenses to evaluate the visual acceptability of this lens design compared with the conventional multifocal lens design such as PROCLEAR MULTIFOCAL (MF) in a double-masked, randomized, cross-over trial with 24 subjects (aged 18–25). Their objective was to measure visual performance acquired for best-spectacle distance correction and with each CL after one week of daily use at high illumination high contrast (HIHC) at distance and low illumination low contrast (LILC) at distance, intermediate, and near. They conclude in their study that it is possible to achieve good distance visual acuity in HIHC with MF and MiSight CLs. However, like other CLs that contain multiple refractive zones, some decrease in distance and intermediate visual acuity under LILC may be experienced. These findings could explain our worst results at near vision in the MiSight CLs group, which could be due to the concentric design.

In a study using the same questionnaire as we used in ours, Santodomingo et al.[27] showed significantly better vision-related quality of life in children wearing OK CLs in comparison with children wearing SV spectacles for all survey scales with the exception of near vision and handling, which were rated better and similar, respectively, for SV in comparison with OK lenses. This may be due to differences in using, handling, replacing, and cleaning between both types of CLs. MiSight lenses are a soft (hydrophilic), daily-disposable CL, whereas OK lenses require daily cleaning, and handling may be a little more complicated.

Walline et al.[16] used a questionnaire to detect the influence of spectacles or CLs on Self-Perception for Children using a Global Self-Worth scale and as a secondary objective included the Physical Appearance, Athletic Competence, Scholastic Competence, Behavioral Conduct, and Social Acceptance Self-Perception Profile for Children scales. Although the questionnaire we used in our study is not the same as Walline et al., the results are similar. Our results are better in appearance, satisfaction, and peer perception, and Walline et al. showed that CL wear does not affect global self-worth. As regard the secondary objective of Walline et al., their study showed better results for soft CLs than for spectacles in: Physical Appearance, Athletic Competence, Scholastic Competence, Behavioral Conduct, and Social Acceptance. These results tally with our study, in that we found that in the MiSight CLs group, the ratings for appearance, satisfaction, effect on activities, peer perceptions, and the total score were better than those in the SV group.

To the authors' knowledge, the PREP survey has not previously been validated, but previous studies have demonstrated that it is a sensitive questionnaire for showing differences between children wearing CLs and spectacles.[15,17,19]

In summary, this study shows a significant improvement in vision-related quality of life in children wearing MiSight CLs versus children wearing spectacles.

## ACKNOWLEDGMENTS

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