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RESEARCH

Efficacy and safety of a soft contact lens to control myopia progression

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Clinical relevance: The control of myopia progression is currently considered an evidence-based therapeutic need.

Background: To determine the efficacy and safety of the Esencia lens, a new soft contact lens (SCL) designed to slow down myopia progression in paediatric patients.

Methods: This study was a randomised, parallel, double-masked clinical trial. Seventy myopic (−0.50 to −8.75 D) boys and girls, 7–15 years of age, were randomised and allocated to one of two groups: (i) study (n = 36) or (ii) control (n = 34). Study group patients were given the Esencia lens, a progressive multifocal and reverse geometry SCL. Control group patients were given conventional SCLs. Efficacy measurements (change in cycloplegic autorefraction and axial length) were measured at baseline and at the six-month intervals over a 12-month period. Visual performance measurements were corneal power, comfort, quality of vision and contact lens fitting. Safety measures included detection of adverse events.

Results: Mean changes in cycloplegic autorefraction after 12 months were −0.28 ± 0.35 D for study and −0.57 ± 0.52 D for control group patients (p = 0.02). A significantly lower increase in axial length was found in the study group (0.13 ± 0.12 mm) compared to control (0.22 ± 0.14 mm) patients (p = 0.03). Compared to control group patients, there was less myopia progression in the study group: 51 and 41 per cent in terms of cycloplegic autorefraction and axial length, respectively. No significant differences between groups for change in corneal power, comfort, vision quality and contact lens fitting were found (p > 0.05). Regarding safety, there were no serious and/or unexpected adverse events during the study.

Conclusions: The Esencia lens seems to be efficacious in slowing down progression of myopia in children compared to traditional SCLs in the short term, with comparable safety features and visual outcomes.

Key words: clinical trial, contact lens, myopia, myopia control, myopia progression

Myopia is a potentially injurious, and highly prevalent ocular condition, with an incidence which is increasing worldwide.[1,2] Myopia begins to develop at approximately 6–8 through 15–18 years of age,[3] proceeding even more quickly in cases of early onset and/or family background (that is, myopic parents).[4,5] Moreover, highly myopic patients are at an increased risk for serious ocular diseases,[6,7] as myopia is often associated with myopic macular degeneration, glaucoma, cataracts, and retinal detachment.

In recent years, efforts to find therapeutic modalities designed to slow down progression of myopia have globally increased, with numerous studies evaluating the efficacy of various treatments for myopic control.[8–20] In order of decreasing efficacy,[8] these treatments include atropine[9,10] and pirenzepine,[11] orthokeratology,[12,13] peripheral defocus contact lenses (bifocal[14–16] and multifocal contact lenses),[17] and bifocal and multifocal spectacles.[18–20]

Peripheral defocus soft contact lenses (SCL) are effective in slowing down the progression of myopia[8] and provide typical benefits of SCL such as comfort, good tolerance, and good quality of vision. The Esencia lens (Eurolent Servicios Ópticos S.L., Madrid, Spain) is a custom-made contact lens which

fits to the parameters of any type of patient. This is possible because radius, diameter, sphere (up to −20.00 D), and optical zone can be adjusted. In a previous unpublished randomised, double-masked, and crossover pilot study, the new peripheral defocus SCL Esencia[21] evaluated in the present study demonstrated a myopic peripheral defocus curve in the autorefraction M component ranging from −1.00 to −3.50 D (nasal to temporal), which is statistically significant compared to control SCLs and no-lens group patients (presented as a poster at the 24 Congreso Internacional de Optometría, Contactología y Óptica Oftálmica, Madrid, Spain, 2016).

A randomised, double-masked prospective two-year clinical trial was designed and conducted to evaluate the efficacy of this new progressive multifocal and reverse geometry SCL relative to conventional single vision SCLs. In this article, the results of this clinical trial during the first year of follow-up are analysed and discussed.

Methods

Study design

This clinical trial is a parallel, longitudinal, randomised, double-masked, multicentre, clinical trial with two arms: experimental and control (placebo). This design is considered the most appropriate for evaluating new treatments for regulatory purposes. The aim of the present study was to determine the efficacy and safety of a progressive multifocal SCL, the Esencia lens (Eurolent Servicios Ópticos S.L.), with respect to a conventional SCL in the control of myopia progression in paediatric patients. The study was approved by the Clinical Research Ethics Committee of the San Carlos Clinical Hospital of Madrid, Madrid, Spain, and the Virgen Macarena Hospital of Sevilla, Sevilla, Spain. The study complied with the moral, ethical, and scientific principles governing clinical research established in the Declaration of Helsinki, the International Conference on Harmonisation (ICH), and Guidelines for Good Clinical Practice, as well as with the regulatory requirements of the European and Spanish legislation for clinical trials with medicines. The research was conducted in Spain and involved seven clinical centres located in Madrid (n = 3), Andalucía (n = 3), and Murcia (n = 1).

Study population

Children aged 7–15 years who visited the investigational sites for routine ophthalmologic examinations from May 2014 to April 2017 at the different investigational sites involved were recruited according to study protocol. Inclusion criteria were cycloplegic spherical autorefraction measurements between −0.50 D to −8.75 D, and spherical component and astigmatism allowing visual acuity (VA) = 1 measured in decimals while wearing spherical equivalent in binocular trial frames. For study eligibility, children were required to have good ocular and general health and the ability to wear and handle contact lenses irrespective of previous contact lens wear status. Children not meeting these criteria and those with uncontrolled psychiatric or neurological disorders and manifest disability due to age, physical or mental conditions to wear contact lenses were excluded from the study.

Before study enrolment, parents and participants were informed of the details of the study and provided with an information sheet explaining the nature and procedures of the study. Written informed consent was obtained from parents or legal guardians and also from children aged 12 years or older, and verbal consent was obtained from all the participating children.

Once children were enrolled, they were randomised and allocated to study (Esencia) (n = 36) or control (n = 34) groups. Twelve patients – study (n = 4), control (n = 8) – were excluded from analysis due to lack of post-randomisation data although considerable efforts to obtain any information were made. Thus, a total of 116 eyes from 58 participants were analysed: study group (n = 32), control group (n = 26). Four patients discontinued participation: one study group patient and two control group patients were withdrawn owing to lack of motivation, and one study group patient due to an adverse event. Five study group patients and one control group patient did not complete the 12-month follow-up period, but their measurements provided post-randomisation data.

Lenses

The Esencia (Eurolent Servicios Ópticos S.L.) is a lathe-cut custom-made soft hydrophilic lens composed of hioxifilcon B with 50 per cent water content. It is progressive and multifocal in design, with a peripheral progressive addition of +2.00 D on the front surface of the lens. The back surface of the lens presents a central flattening and a peripheral steepening to promote lens centration and optimise the peripheral defocus effect. Control group patients were fitted with a lathe-cut hydrophilic SCL composed of the same material and parameters as the study lens, but with an aspheric one-focus design. Both lens types are daily disposable lenses with quarterly replacement schedules. To guarantee a double-masked status for investigator and participant, both lenses had the same appearance, fitting, and replacement criteria and were presented in identical coded vials. In addition, identical contact lens maintenance solutions (Aquamax multipurpose solution; Eurolent Servicios Ópticos S.L.) were provided to patients of both groups.

Outcome measures

Primary efficacy outcome measures were compared to baseline and included: (i) mean change in spherical equivalent refraction (SER) by cycloplegic autorefraction and (ii) mean change in axial length at 12 months. Visual performance data were compared to baseline, and included proportion of patients reporting good comfort, good quality of vision, lens centration, lens movement, and mean change in corneal power. Data for safety endpoints were recorded at each study visit and included detection and frequency of adverse events by slitlamp examination.

Study procedures

Cycloplegic autorefraction (Nidek ARK-1 Autorefractor; Nidek Co., Ltd, Tokyo, Japan) data comprised the mean of three measurements. Three drops of cyclopentolate hydrochloride (10 mg/ml) (Colicursí ciclopléjico; Alcon Cusí, Barcelona, Spain) were instilled into participants' eyes three times (15-minute intervals).

Axial length was measured with an IOL Master 700 (Carl Zeiss Jena GmbH, Jena, Germany) before cycloplegia five times and the mean was used for analysis.

Subjective refraction was measured for distance vision and 12 mm vertex distance using an Early Treatment Diabetic Retinopathy Study chart under photopic lighting conditions (83–85 cd/m^2), 100 per cent contrast, and trial frames, until best VA corresponding to the last line of letters that the patient could read > 50 per cent correctly. It was first conducted monocularly with the introduction of an initial +3.00 D fogging lens. This sphere was reduced until

the patient achieved VA of 0.3, and then the cylinder was determined with the horary circle test. After this, the sphere was decreased to the maximum positive providing the best VA. Then, +0.50 D was introduced, the cylinder was adjusted with Jackson cross cylinder (axis and power), and the sphere was tuned with the duochrome chart. Afterwards it was conducted binocularly; the binocular balance was performed by dissociating with three prism dioptres after +0.75 D of power addition and decreasing the positive power so that both eyes obtained best VA.

Subjective visual performance endpoints included: (i) assessment of comfort and (ii) quality of vision; both parameters were reported by the patient through a two-item questionnaire.

Contact lens fitting variables of centration and movement were assessed by the investigator via a two-item questionnaire. Central corneal power was measured with the Oculus Pentacam system (Oculus Optikgeraete GmbH, Wetzlar, Germany).

Safety was assessed through a careful and systematic slitlamp (700GL; Takagi Seiko Co., Ltd., Toyama, Japan) examination to detect the following adverse events commonly related to contact lens use: corneal epithelial oedema, corneal stromal oedema, corneal infiltration, corneal neovascularisation, conjunctival hyperaemia, conjunctival pressure or indentation, eyelid inflammation, micropapillary response, papillary conjunctivitis, superficial punctate keratitis, infection, and/or other conditions as specified by the investigator. Adverse events were classified by the investigator according to standard definitions included in the study protocol and ICH E2A Guidelines: seriousness (serious versus non-serious), anticipation (expected versus unexpected), relationships (device-related versus not device-related), and severity (mild, moderate, or severe). Measurements were assessed according to: (i) frequency of appearance of each and (ii) determination of the proportion of patients presenting with one or more adverse events.

Instruments were calibrated and re-calibrated periodically according to manufacturer instructions. Results of this clinical trial reported here are based on data from the first 12 months. Measurements were taken at baseline and every six months.

Baseline and follow-up visits

At baseline, measurements were taken and recorded, and eligibility assessed. Parents of the eligible participants provided signed informed consent. Random numbers and study group assignments were allocated.

The randomisation sequence was generated automatically by the manager of the Clinical Trial Coordination Centre by means of a computerised random-sequence generator. Block randomisations were conducted with masked fixed-length blocks and proportions of 1:1. The computer-generated sequence was printed and kept by the Coordination Centre as strictly confidential, so investigators did not know or have access to the randomisation tables. Treatment assignation was conducted after the written consent signature and the enrolment of the patient at the end of the SCL fitting.

For lens fitting, back vertex power was calculated according to subjective refraction and cycloplegic autorefraction (subjective refraction in case of discrepancy), considering vertex distance. Selection of radius for both study and control lenses was based on keratometry with the addition of 0.50 mm in the flattest meridian. Lens diameter was 14.00 mm by default and adjusted to 14.50 mm for larger visible horizontal iris diameters. Movement, centration, and over-refraction were assessed for final adjustments in the second visit. Participants were taught proper lens insertion and removal and lenses (two pairs) were provided for the next six months at the third visit.

All clinical tests were conducted at each follow-up visit (Table 1). Replacement contact lenses were provided according to investigators' assessments of test results. All SCL fittings and measurements were performed by the same experienced clinician per centre.

Statistical analyses

Sample size was calculated according to 95 per cent confidence levels and 80 per cent power for an objective SER difference

Study group	**Esencia group/control group**				
Period		**Fitting**		**Follow-up**	
Visit	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**
Study time	**Day 0**	**1 week**	**1 week**	**6 months**	**12 months**
Patient identifier	X	X	X	X	X
Informed consent	X				
Socio-demographic data	X				
General clinical data	X				
Basic optometric data	X				
Subjective refraction without cycloplegia	X			X	X
Over-refraction		X	X	X	X
Axial length (IOL Master)	X			X	X
Objective refraction (autorefractor)	X			X	X
Topography (Pentacam)	X			X	X
Objective tolerance (slitlamp)	X	X	X	X	X
Lens-fit suitability	X				
Contact lens condition				X	X
Subjective tolerance (questionnaire)	X	X	X	X	X
Drop-out reason (if applicable)		X	X	X	X

Table 1. Study procedures

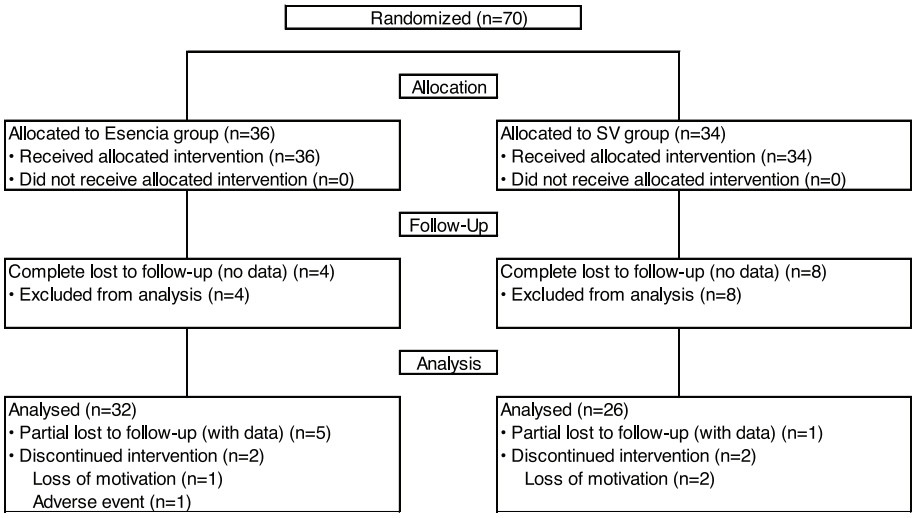

Figure 1. Flow diagram

of 0.25 D and standard deviation of 0.30, according to a previous study,[14] resulting in the requirement of 38 patients (19 patients per group). The result was adjusted afterwards, considering a drop-out rate of 40 per cent, which determined that a total of 54 patients (27 patients per group) were needed.[15]

Continuous variables are represented as mean ± standard deviation, and categorical variables as number of observations and percentages. Main assessments were evaluated by intention-to-treat analysis; that is, including all randomised patients in groups to which they were randomly allocated regardless of: (i) treatment they actually received, (ii) protocol deviations, (iii) subjects lost to follow-up, and (iv) treatment withdrawals.[22] Baseline characteristics (age, gender, race, and family background) of the two groups were analysed with an unpaired *t* test for quantitative outcomes and χ^2 test for qualitative outcomes. The intra-class correlation co-efficients were calculated given inter-eye correlations for efficacy endpoints, resulting in 0.80 and 0.95 for SER and axial length, respectively. The analysis included data from both eyes. This approach is based on the following. (i) From a clinical-scientific perspective, demonstration of a moderately high intra-subject correlation (between right and left eyes) in the progression of myopia[23] suggests inclusion of both eyes, an approach which incorporates more information than does analysis of a single eye.[24–26] (ii) From a statistical point of view, the use of both eyes (with the current models) provides greater statistical power for the available data.[25,27] (iii) From an ethical perspective, it was not deemed reasonable to reject any valid data after having subjected the patients to efforts to obtain them. Comparisons between experimental and control groups were performed at baseline and at six- and 12-month follow-ups using a linear mixed model for quantitative outcomes and generalised estimating equations for qualitative outcomes. The model included treatment group, subject, and interactions. Treatment was included as a fixed effect and subject as a random effect. Covariates were not included, as no significant differences were found at baseline. The linear mixed model allowed analysis of between-eye correlations with longitudinal and non-constant intervals between observations and was able to minimise bias derived from missing data.[28] These models are robust,[24] statistically powerful, and have the advantage of capturing both intra-subject correlations between both eyes of the same person and inter-subject differences.[14,29] Correlation between SER and axial length was analysed with a partial correlation method adjusted for eye and treatment as factors. No missing data imputation was introduced. All analyses were performed with SPSS version 24.0 (IBM Corp., released 2016; IBM SPSS Statistics for Windows, Armonk, NY, USA).

Results

Study patients

Figure 1 shows the number of patients, and reasons for losses and exclusions for each

Variable	Esencia (n = 32)		Control (n = 26)		p
Age (years)	12.20 ± 2.22	n = 31	11.90 ± 2.13	n = 22	0.620
Gender (female:male)	19:13	n = 32	18:8	n = 26	0.437
Race (Caucasian:Asiatic)	20:0	n = 20	18:1	n = 19	0.299
Family background		n = 20		n = 14	0.032
No parent with myopia	3		4		
One parent with myopia	7		9		
Both parents with myopia	10		1		
Objective cycloplegic SER (D)	−2.80 ± 1.79	n = 64	−3.31 ± 1.76	n = 52	0.273
Subjective SER (D)	−2.62 ± 1.78	n = 64	−3.28 ± 1.84	n = 52	0.177
Axial length (mm)	24.54 ± 0.89	n = 60	24.48 ± 0.78	n = 52	0.806
Steep corneal power (D)	43.24 ± 1.26	n = 54	43.62 ± 1.11	n = 46	0.260
Flat corneal power (D)	43.97 ± 1.35	n = 54	44.46 ± 1.14	n = 46	0.173

SER: spherical equivalent refraction.

Table 2. Intention-to-treat analysis. Clinical and demographic characteristics of the randomised patients per treatment group.

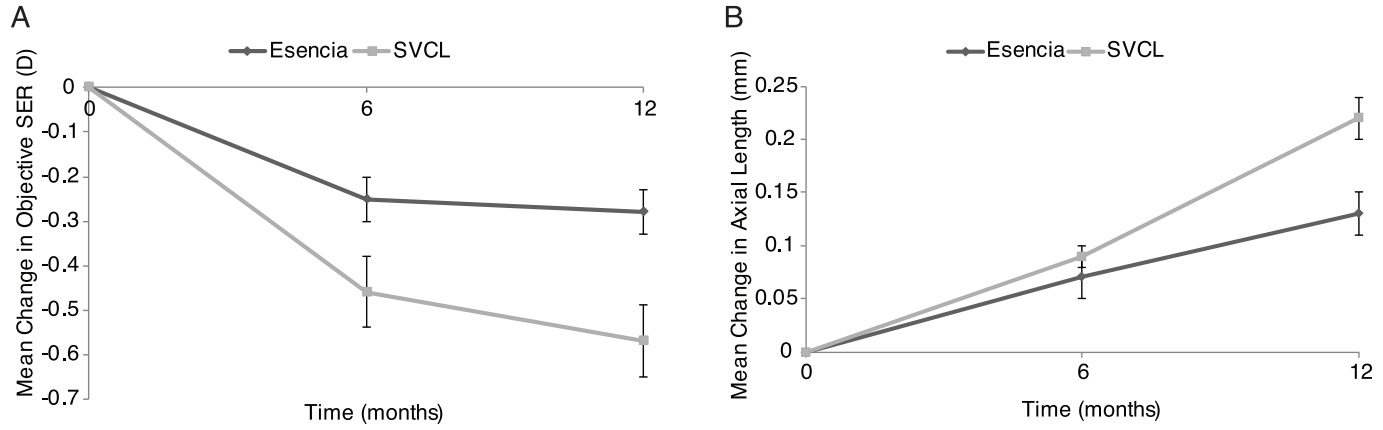

Figure 2. A: Mean change in objective refraction for the study groups. B: Mean change in axial length for the study groups. Note: the error bar represents the standard error.

phase of the study, based on Consolidated Standards of Reporting Trials recommendations.

Baseline

Demographics and clinical characteristics for patients in both groups were well-balanced. There were no significant differences in age, gender, race, axial length, objective cycloplegic SER, subjective SER, or corneal power ($p > 0.05$). Baseline measurements are shown in Table 2.

Efficacy outcomes

At six months, objective cycloplegic SER changes were -0.25 ± 0.32 D (95% CI −0.35 to −0.15) and -0.46 ± 0.53 D (95% CI −0.63 to −0.29) for the study and control groups, respectively ($p = 0.10$). At 12 months, mean changes were -0.28 ± 0.35 D (95% CI −0.38 to −0.17) and -0.57 ± 0.52 D (95% CI −0.72 to −0.41) for the study and control groups, respectively, compared to baseline ($p = 0.02$) (Figure 2A). Myopia progressed more slowly in the study group versus the control group (51 per cent).

At six months, axial length had increased by 0.07 ± 0.10 mm (95% CI 0.04–0.11) in the study group compared to the control group which showed an increase by 0.09 ± 0.10 mm (95% CI 0.06–0.12) ($p = 0.66$). At 12 months, mean changes were 0.13 ± 0.12 mm (95% CI 0.09–0.16) and 0.22 ± 0.14 mm (95% CI 0.18–0.26) for the study and control groups, respectively compared to baseline ($p = 0.03$) (Figure 2B). Study eyes had less axial length growth (41 per cent) than did control group eyes.

A statistically significant correlation was found between axial length and SER changes ($r = -0.465$, $p < 0.001$) (Figure 3).

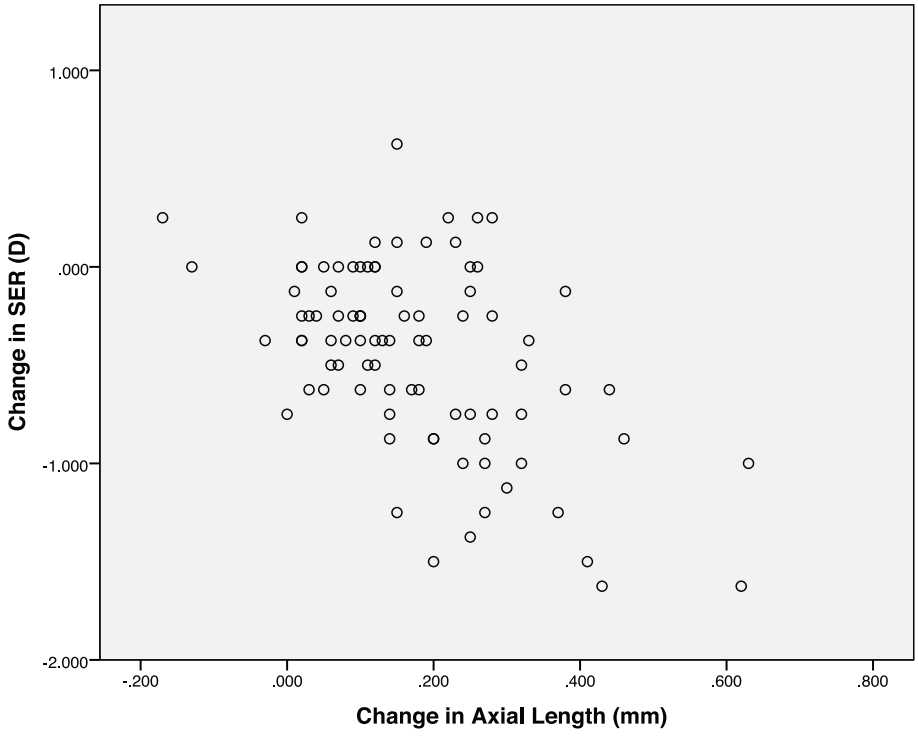

Figure 3. Relationship between changes in axial length and spherical equivalent refraction (SER)

Visual performance outcomes

Study and control lenses both provided a high degree of comfort and good quality of vision, with good centration and movement rates. There were no statistically significant differences between measurements at any study visit ($p > 0.05$) (generalised estimating equations). Rates for subjective discomfort (6.7 per cent versus 0.0 per cent) or poor quality of vision (0.0 per cent versus 4.3 per cent) were low for both study and control lenses, respectively. Longer periods of wear did not translate into increased discomfort. Contact lens fitting was adequate, with good centration and appropriate mobility attained in all fitted patients for both lens types.

There were no statistically significant differences between groups for mean

Group	Esencia (n = 32)	Control (n = 26)
Total number of patients	32 (100.0%)	26 (100.0%)
Corneal epithelial oedema	0 (0.0%)	0 (0.0%)
Corneal stromal oedema	0 (0.0%)	0 (0.0%)
Corneal infiltration	0 (0.0%)	0 (0.0%)
Corneal neovascularisation	3 (9.4%)	1 (3.1%)
Conjunctival hyperaemia	1 (3.1%)	0 (0.0%)
Conjunctival pressure	0 (0.0%)	0 (0.0%)
Eyelid inflammation	0 (0.0%)	0 (0.0%)
Micropapillary response	3 (9.4%)	2 (6.2%)
Papillary conjunctivitis	1 (3.1%)	0 (0.0%)
Superficial punctate keratitis	2 (6.2%)	1 (3.1%)
Infection	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)
Total number of patients with adverse events	8 (25.0%)	4 (15.4%)

Two patients had more than one adverse event.

Table 3. Adverse events during study period

difference in corneal power for both meridians during the study period. After 12 months, in the group treated with the Esencia lens, the mean difference in steep corneal power was -0.08 ± 0.79 D and -0.04 ± 0.54 D for the control lens ($p = 0.82$). For the flat meridian, mean differences between Esencia and control lenses were -0.23 ± 0.90 D and -0.03 ± 0.68 D, respectively ($p = 0.42$).

Safety outcomes

A total of 12 (20.7 per cent) patients presented with one or more adverse events – eight of 32 (25.0 per cent) patients from the study group and four of 26 (15.4 per cent) patients from the control group. All adverse events were classified as non-serious, expected, treatment-related, and mild during contact lens use. One study group patient discontinued intervention because of papillary conjunctivitis, and no treatment was required. No serious or unexpected adverse events were reported during this clinical trial. A summary of adverse events per group is given in Table 3.

Discussion

The present study adds to the growing compendium of randomised controlled trials evaluating peripheral addition SCLs for control of myopia. To our knowledge, eight randomised clinical trials evaluating the efficacy of peripheral defocus SCL to control progression of myopia have been published,[14–17,30–33] with only four being double-masked.[15–17,33] Complementary and additional randomised clinical studies are necessary.[34]

Baseline characteristics are consistent with those of the population benefiting from this treatment. The inclusion criteria range for refraction (–0.50 to –8.75) was set to facilitate subject recruitment. The age was set up to 15 years, but the mean ages were 12.20 and 11.90 years for the experimental and control groups respectively, and are representative of patients with progressive myopia. Regarding the age classification, 38 per cent of all patients included were between 13 and 15 years (42 per cent in the experimental group and 32 per cent in the control group). These percentages are very similar between study groups, so no bias for age is expected. This group of patients may experience slower progressions than younger patients, but they still suffer from myopia progression and have not arrived at the myopia stabilisation phase.[3,4] Additionally, we had no information on the age at myopia onset and duration of progression of myopia, or main risk factors of myopia progression, as most patients were already myopic before study enrolment.[35]

A high proportion of myopic parents was found. Statistically significant differences were found for a greater number of myopic parents in the study group than in the control group ($p = 0.03$), although this difference may be due to the fact that only 59 per cent of included patients completed this point. As it is well known that progression of myopia is positively correlated with the number of myopic parents,[36] the potential effect of this variable would be detrimental to study group data, conservatively maintaining the planned analysis.

Total post-randomisation losses (complete and partial) to follow-up and drop-outs comprised 22 patients (31.4 per cent) – 11 study and 11 control group patients. These numbers were judged adequate, considering the presence of sustained long-term interventions.[37] It is important to note that this study found a high difference in the drop-out rate between investigational sites. There were three investigational sites (which included 75 per cent of the patients) with drop-out rates of 14, 17 and 33 per cent, as opposed to two investigational sites that left the study and presented drop-out rates of 83 and 100 per cent. For this reason, the drop-out rate in this study can be considered related not to the investigational treatment but to the lack of commitment from some investigational sites. In this framework, values lost-to-follow-up were higher for those obtained by other 12-month clinical trials on myopia progression carried out for bifocal and multifocal SCLs (nine per cent in Aller et al.,[32] 16 per cent in Cheng et al.,[33] 18 per cent in Sankaridurg et al.[38]). The drop-out rate was comparable to some 24-month progression of myopia clinical trials (30 per cent in Walline et al.,[29] 42 per cent Lam et al.[15]) but significantly lower than those conducted for rigid contact lenses, where lost-to-follow-up can reach 40–50 per cent.[39] In the present study, of the 22 losses, data from 12 patients were not available because investigational sites did not send any information and were considered within the drop-out rate. If these cases are subtracted, the drop-out rate is 14 per cent, which is similar to other studies lasting one year.

The three efficacy assessments indicated the Esencia lens to be significantly more effective than the conventional SCL in stabilising the progression of myopia in children. The overall figures at 12 months were 51 and 41 per cent for objective refraction reduction and axial elongation, respectively. These results are consistent with and within the range of results reported by previous SCL clinical trials,[40] with ranges of myopia control for 12-month follow-up periods within 26–72 per cent for refraction and 29–77 per cent for axial length.[30] Additionally, the changes attained from direct

comparison of the two interventions were at the low end of the range of efficacy for axial length change compared to other 12-month studies (from −0.05 to 0.19 mm).[16]

In addition to efficacy assessments, we included several visual performance variables to evaluate lens behaviour from important clinical perspectives. Comfort and quality of vision comprised patients' subjective perceptions, while centration and movement comprised practitioners' objective indications (ease of lens fitting). No statistically significant differences for corneal power change were found, so a possible sustained corneal reshaping effect can be discarded. Our results indicate that daily long-term use of both contact lens types provides comparably good comfort and quality of vision, and that lens fitting was suitable for its intended use.

The quality of vision with the Esencia lens was subjectively assessed by the patients as being 'good'. One study had reported symptoms of poor vision for multifocal SCLs for myopic control with respect to one-focus SCLs.[41] Such a difference between results could be the consequence of: (i) the peripheral and limited nature of the defocus provided by the progressive multifocal design of Esencia; (ii) the population (children versus young adults); (iii) the diverse tests used to evaluate subjective quality of vision; and/or (iv) the smaller central optical zone of the multifocal lens used by Kang et al.[41] (2.3 mm) compared to that of the Esencia lens (4.5 mm).

The lens design introduces a reverse geometry that stabilises lens centration and provides a regular and continuous peripheral defocus during lens use. This would contribute positively to the quality of vision and efficacy of the lens.[41,42] While we could not evaluate the impact of the reverse geometry on the peripheral defocus produced, this issue will be addressed in future work.

Although a duration of two years is suggested for this type of study, the statistically significant differences obtained at one year and the increase in these differences between study groups provide ethical arguments in favour of reporting these one-year outcomes. However, some studies have found a reduction in efficacy in the second year compared with the first year of treatment in spectacles or orthokeratology, so additional long-term studies are also encouraged,[43] and we continue with the follow-up of this study. Adherence to treatment was not evaluated, as data on lens wear could not be collected. One limitation of the study is the lost-to-follow-up rate and presence of missing data; reasonable efforts were made to minimise post-randomisation losses and collect missing data. We can only hypothesise about the reasons behind the slow recruiting rate and the lack of commitment of patients. It might be the absence of economic benefit for the subjects and investigators, shortage of paediatric patients in the centres chosen, or the large number of tests conducted and the study's duration. Additionally, case report forms were collected at the end of the study period, so missing data were not found until the end of the study. Another limitation was the wide range of refraction and age set as inclusion criteria, as children with younger age tend to suffer from faster myopia progression. Additional studies are needed to: (i) evaluate the variables that can modulate treatment efficacy of peripheral addition and (ii) potentially introduce combined treatment with atropine or bifocal and multifocal glasses.

Conclusion

In summary, results from the analysis of the 12-month data of this clinical trial indicate that the Esencia SCL seems to be an efficacious option of control of myopia progression in myopic children, with similar visual performance and safety as with a conventional SCL. These results must be confirmed in the longer term, with a two-year follow-up or more.

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