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Fitting success for three multifocal designs: Multicentre randomised trial

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ABSTRACT

Purpose: To determine if the discontinuation of commercially-available simultaneous vision Multifocal Soft Contact Lenses is independent from the multifocal design. To determine causes for discontinuation and psychosocial factors involved.

Methods: Multicentre single-blinded randomised controlled trial with external blinded evaluation for a three months follow-up period for three intervention groups. 150 single-vision soft wearers were randomly assigned a spherical near centred lens (S-CN), distance centred lens (CD) or aspherical near centred lens (A-CN). Cases of discontinuation, anxiety and quality of life were measured at one week and one month.

Results: 120 females and 30 males were included with an age range of 40–62 (48.79 ± 5.23). At one month, the S-CN design had a statistically significant higher risk of discontinuation than the other two OR: 6.12 (95%CI 2.5–14.9). Twenty-eight subjects discontinued wearing S-CN at first week (56%), while discontinuation of CD and A-CD were 15 (30%) and 11 (22%), with a statistically significant difference between S-CN design and the other two ($p = 0.001$). There were not statistically significant differences when direct comparison between discontinuation of CD and A-CN was made ($p = 0.36$). Thirty-two percent discontinued the use because of poor distance vision and 28% because of both poor distance and near vision. Psychosocial factors were not statistically significant.

Conclusions: Discontinuation of Multifocal Soft Contact Lenses is dependent on the design. Most common cause for discontinuation is poor distance vision. Psychosocial factors do not impact on discontinuation rates.

1. Introduction

It is expected that 21% of the world population will be aged 60 or even older in 2050 [1]. Since the present population of economically developed countries will spend half their lives as presbyopes, most refined methods for correcting presbyopia are needed. The multifocal contact lenses market trends show that many presbyopes are not corrected with presbyopic solutions. Some data suggest that up to 63% of presbyopes are corrected with non-presbyopic solutions and only 29% use Multifocal Soft Contact Lenses (MSCL) although these data may differ across countries [2] and are confirmed by publications that report that the principal solution for presbyopes is wearing spectacles [3].

There are currently a variety of multifocal contact lens optical designs; simultaneous vision soft contact lenses are the most extended correction option for presbyopes. These lenses have a gradual change in lens power. For this reason, the contact lens performance depends on the brain's ability to select and interpret the clearest images formed simultaneously on the retina [4] and to suppress blur [5].

Soft multifocal contact lenses (SMCL) are manufactured with different multifocal designs. They can be designed with alternating power rings or with aspheric power profiles. Aspheric designs can be divided into near-centred (CN) and distance-centred (CD). The CN radius of the lens aspherically decreases for CN lenses and increases for CD lenses. Other CN and CD multifocal designs are based on alternating and concentric spherical distance and near power rings. Diffractive designs are not currently commercially available.

There are many factors that can impact on final performance of MSCL. Among them, stereoacuity [6], contrast sensitivity [7–9] and glare sensitivity [8] have been analysed. Individual tasks and visual needs are relevant as well, being almost impossible to predict success or failure rates based upon visual acuity [10]. Under these circumstances, eye care practitioners seek to meet patients' visual demands regarding multifocal contact lens use [11]. Besides, professionals need to avoid discontinuation of multifocal use and require reliable indicators of success or failure. Under the expectation of providing the eye care practitioner with criteria for initial selection of multifocal contact

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lenses, the main objective of the present study was to determine if the continuation or discontinuation of simultaneous vision MSCL is independent from the multifocal design. The secondary objectives were to determine if reasons for discontinuation were related to visual performance or to contact lens discomfort. Additionally, it was aimed to determine if psychosocial factors such as anxiety or quality of life could be related to multifocal contact lenses discontinuation.

2. Methods

2.1. Study design and ethics

The research project was a multicentre single-blinded randomised controlled trial for three intervention groups, with external blinded evaluation for a follow-up period of three months. Procedures were conducted according to the Declaration of Helsinki for experimentation on humans. A written Informed Consent was signed by all participants upon enrollment into the study. Data were collected in a Case Report Form. Every subject was assigned a code number so that the anonymisation of the collected demographic data was ensured.

2.2. Participants and study sites

Participants were recruited from 15 study sites (Optometry Centres) located throughout Spain. All of them had requested optometry services. The eligibility criteria for enrollment into the study were (1) being aged between 40 and 65 years old; (2) being monthly-disposable single-vision soft contact lens wearer; (3) refractive error between +6.00D and −8.00D (spherical equivalent) with astigmatism equal or lower than 1.25D; (4) monocular best corrected visual acuity (BCVA) with soft contact lenses being 20/20 or higher. Exclusion criteria included (1) wearing monovision contact lenses; (2) had lack of binocularity; (3) had ocular or systemic pathology that could potentially impact on contact lens wear.

2.3. Randomisation and blinding

Upon subjects' enrollment, every researcher contacted the principal investigator who assigned an intervention group by using a centralised randomisation method with a computer-based random number generator to ensure allocation concealment. Diagnostic contact lenses were inserted by an optometrist so that participants had not any information related to the multifocal designs under study.

2.4. Interventions

Participants were randomly fitted with one out of three intervention lenses, which had three different simultaneous vision designs. Multifocal design number 1 was spherical-near centred (S-CN), with a multi-concentric spherical design, and had two different additions for near: low addition (up to +1.75D) and high addition (up to +3.00D). The material was methafilcon IV and the water content was 55% (Distanza™, Tiedra). Multifocal design number 2 was CD, it had a spherical centre for distance vision, an intermediate aspherical zone and a spherical periphery in one constant optic zone for all the commercially available additions (+1.00D, +1.50D, +2.00D and +2.50D). The material was Comfilcon A and the water content was 48% (Biofinity Multifocal™, Coopervision). Multifocal design number 3 was aspherical and near-centred (A-CN), with both anterior and posterior aspherical surfaces. It had three available additions: low (up to +1.00D), med (up to +1.75D) and high (up to +2.50). The material was Iotrafilcon B and water content was 33% (Air Optix Aqua Multifocal™ Alcon Laboratories, Inc). Manufactures' fitting guides were followed except for the CD design lenses and only when the +2.00 and +2.50 adds were needed. For these cases, both right eye and left eye were CD centred, instead of CD for the dominant eye and the CN design for the non-dominant eye, as the manufacturer suggests. The reason for this was avoiding any asymmetry in the viewing conditions of both eyes.

2.5. Outcome measures and data collection

The primary outcome was the number of dropouts from wearing MSCL. Secondary outcomes were the visual relationship for discontinuation of MSCL, quality of life and anxiety levels. The research process was as follows: Each subject was supposed to attend four visits in a period of 3 months. During the first visit, a comprehensive assessment for multifocal contact lens fitting was performed by one researcher including the pupillary diameter that was measured with a Placido disc topographer. After 30 min of use of the trial lenses, they were evaluated on the eye by a second researcher at each study site. The examiner did not know what multifocal design the subject was wearing. After the ocular examination, the State-Trait Anxiety Inventory (STAI), an auto-test for measuring anxiety was performed. The self-reported STAI questionnaire is a common scoring scale for assessing anxiety in adults [12]. Researcher 2 performed all the follow-ups scheduled in the protocol. Visit number 2 was scheduled after one week of use, low and high contrast distance visual acuities were measured with Snellen and Lea Numbers respectively, and high contrast near BCVA was also measured with Lea Numbers at 40 centimetres. The National Eye Institute Refractive Error Quality of Life Instrument-42 scale (NEI-RQL-42) [13] was answered by every subject in visit 2. Since participants were previous single-vision soft contact lenses wearers, continuation of wearing MSCL was considered as success, and dropout from using MSCL was considered as failure. In case participants withdrew from the study, they were assessed for lens changes to improve their multifocal contact lens fitting experience. Visit number 3 was scheduled after one month of trial lenses use and subjects were again asked about continuation or discontinuation of MSCL wear. Finally, visit 4 was scheduled after 3 months and the assessment was equivalent to prior follow-up visits. Besides, in visit 4 both the State-STAI and the NEI-RQL 42 questionnaires were answered by participants.

2.6. Statistical analyses

For the primary variable, the number of dropouts of multifocal wear, the sample size was determined with Power and Precision Software (Biostat Inc., Englewood, NJ). For the primary variable of the study, the number of discontinuations, it was assumed a minimum clinically significant effect never inferior than a delta difference of 20%. Hence, for an alpha value being set at 0.05 (two tailed) and a null hypothesis testing, a statistical power of 80.5% for statistical significance was determined and the sample size was 130 subjects. The sample was increased in 15%, being this percentage the estimated dropouts number. This way, each of the three groups consisted of 50 subjects.

The descriptive analyses of the data were obtained from means and standard deviations for the quantitative variables, and frequencies for the qualitative data. Given the research objectives, a hypothesis testing was carried out among the study interventions for all the dependent variables.

For the categorical variables, the χ^2 test or the exact test of Fisher were used. For continuous variables, a study of the normality of the distributions was performed. This analysis determined whether the data analysis should follow parametric or non-parametric analysis models. Thus, when the data distribution was considered to achieve normality, randomness and homoscedasticity an ANOVA test was performed; the Kruskal-Wallis statistical estimator was used when the statistical analysis should follow a non-parametric model.

For the number of cases of discontinuation, as the primary variable, the Odds ratio (OR) risk estimator was determined. An increase of risk of discontinuation is established when the OR score is above 1, whereas

risk reduction is established with an OR under 1. If statistically significant differences for confusion variables existed, they were adjusted following specific statistical models. The Kolmogorov-Smirnov test was used to determine goodness of fit. An intention to treat (ITT) analysis was performed (last observation carried forward) in order to avoid attrition bias. Alpha value was set at 0.05 for statistical significance and confidence level at 95%.

All the above-mentioned analyses were made by using a Statistical Package of Social Sciences (SPSS) for Windows 20 (IBM SPSS Inc., Chicago, IL).

3. Results

The sample consisted of 150 subjects, 120 females and 30 males, the age range was 40–62 years (48.79 ± 5.23) and mean addition power 1.67 ± 0.49 D. The whole sample was randomly divided into three intervention groups. Group 1 or S-CN design group consisted of 50 subjects (41 females/9 males) with a mean age of 50.44 ± 5.18 years. Regarding refractive error, there were 37 hyperopes and 13 myopes with mean spherical equivalent of 2.32 ± 1.48 D and 1.93 ± 1.49 D respectively. Mean cylinder was 0.63 ± 0.35D. Group 2 or CD design group consisted of 39 females and 11 males with a mean age of 47.96 ± 5.03 years. There were 31 hyperopes and 19 myopes with mean spherical equivalent of 2.12 ± 1.43 and 2.04 ± 1.5 D respectively. Mean cylinder was 0.53 ± 0.33D. Group 3 or A-CN consisted of 40 females and 10 males, with a mean age of 47.98 ± 5.19 years. There were 29 hyperopes and 21 myopes, with mean spherical equivalent of 2.0 ± 1.1 and 2.27 ± 1.43 D respectively. Mean cylinder was 0.53 ± 0.39 D.

All baseline variables values are given in Table 1. Age was the only variable unbalanced among the three groups. Therefore, this variable was adjusted for statistical analyses.

For the primary variable, the number of discontinuations of MSCL, the results showed that the S-CN design lens had a statistically significant higher risk of discontinuation than the other interventions OR: 6.12 (95% CI 2.5–14.9). This determined that the risk of discontinuation at three months of use, when compared with the other two interventions, was six-fold higher p = 0.0001. Data were not statistically significant for the other two multifocal designs under study (Table 2).

From these results, a sensitivity analysis was performed to determine the time point and causes of the cases of discontinuation. Twenty-eight subjects discontinued wearing S-CN multifocal lens at first week (56%), while discontinuation of CD and A-CN lenses were 15 (30%) and 11 (22%) respectively.

These data showed a statistically significant difference between S-CN design and the other two lenses (p = 0.001). However, there were not statistically significant differences when direct comparison between discontinuation of CD and A-CN design lenses was made (p = 0.36). These comparisons are showed in Table 3.

Table 2
Risk of discontinuation for the three multifocal designs, upon completion of the study (n = 150).

Variable	B	Standard error	OR[a]	p
Age	0.0334	0.0354	1.0340 (0.9648–1.1082)	0.3443
Multifocal design				
S-CN	1.8124	0.4548	6.1251 (2.5119 − 14.9361)	0.0001
CD	0.4950	0.4491	0.06456 (0.6803 − 3.9556)	0.2704
A-CN			1	
CONSTANT	−2.7401	1.7466		

[a] Adjusted odds ratio.

Thirty-six percent of subjects discontinued multifocal use at one week of follow up. When analysing causes for discontinuation, it should be considered that 7 subjects were lost for one-week follow-up visit. However, 47 subjects reported the cause for discontinuation. Under randomization conditions, 32% of participants discontinued the use because of distance vision and 28% because of both distance and near vision (Table 4).

At one month, the discontinuation of MSCL increased up to 42%, the causes for discontinuation were similar to those at one-week follow up. Statistically significant differences were also found when comparing the three interventions under study p = 0.0001. As in the previous analysis, the statistically significance depended on the S-CN lens design (Table 3).

There were not more cases of discontinuation from the one-month visit till the end of the follow-up period at three months of use.

For the quantitative secondary variables, quality of life and anxiety levels were analysed at three months following and intention to treat (ITT) analysis, using the last observation carried forward (LOCF) model.

The mean scores were: 68.15 (95% CI 64.76–71.54) for the S-CN power profile; 71.33 (95% CI 68.06–74.60) for the CD power profile and 72.17 (95% CI 68.73–75.61) for the A-CN design. Following an ANOVA analysis, there were not statistically significant differences among the three lenses (p = 0.205). For the study of anxiety levels, the self-evaluation STAI test was used, and mean valued were S-CN: 50.10 (95% CI 42.65–57.54), CD: 45.38 (95% CI 37.87–52.88), and A-CN: 48.12 (95% CI 40.29–55.94). Since these data did not follow a normal distribution pattern, a Kruskal-Wallis analysis was used, and there were not statistically differences (p = 0.65).

4. Discussion

By measuring discontinuation rate, it was aimed to determine whether the success of simultaneous vision contact lenses fitting is dependent or not on the multifocal design of MSCL. From the results, the risk of discontinuation is high at one month of wear. This risk is even higher with S-CN design multifocal lenses. At the same time, there

Table 1
Baseline values.

Variable	Total	S-CN Design group	CD Design group	A-CN Design group	p
Gender (females)	120/150	82%	78%	80%	0.882
Age	48.79 ± 5.13	50.44 ± 5.18	47.96 ± 5.03	47.98 ± 5.19	**0.028**[a]
Refractive error (hyperopes)	97/150	74%	62%	58%	0,219
Astigmatism	0.56 ± 0.46	0.63 ± 0.35	0.53 ± 0.47	0.53 ± 0.56	0.252
Near vision at work	69/150	36%	52%	50%	0.387
Near vision at leisure time	97/150	62%	64%	68%	0.815
Pupillary diameter	3.73 ± 1.11	3.73 ± 1.22	3.87 ± 1.26	3.61 ± 0.85	0.707
Conjunctival staining (no staining)	73/150	44%	44%	58%	0,484
Bcva at distance	1.14 ± 0.08	1.13 ± 0.09	1.16 ± 0.07	1.15 ± 0.09	0.372
BCVA at near	0.96 ± 0.09	0.96 ± 0.09	0.97 ± 0.09	0.97 ± 0.09	0.378
HRQOL: NEI-RQL 42	70.55 ± 11.85	68.15 ± 11.94	71.33 ± 11.51	72.17 ± 12.10	0.451
Anxiety: STAI (E)	47.86 ± 26.39	50.10 ± 26.20	45.38 ± 26.39	48.12 ± 26.60	0.578

[a] Age was adjusted for the statistica analysis.

Table 3
Direct comparisons between lenses. Two by two lenses discontinuation analysis.

Lens Design	One week			One month		
	Discont.	Cont.	p	Discont.	Cont.	p
S-CN	28 (56%)	22 (44%)	0.009	34 (68%)	16 (32%)	0.001
CD	15 (30%)	35 (70%)	0.0001	17 (34%)	33 (66%)	0.0001
A-CN	11 (22%)	39 (78%)	0.36	12 (24%)	38 (76%)	0.27

Discont. Number of discontinuations. Cont. Number of continuations.

Table 4
Number of discontinuations and causes of discontinuations per multifocal design.

Discont.	One week				One month			
	S-CN	CD	A-CN	Total	S-CN	CD	A-CN	Total
Problems with distance vision	7	4	4	15	9	4	4	17
Problems with near vision	3	3	2	8	5	4	3	12
Problems with Distance & Near vision	10	2	1	13	10	3	1	14
Discomf.	4	4	3	11	6	4	3	13
Lost to F/U	4	2	1	7	4	2	1	7
Total	28	15	11	54 **(36%)**	34	17	12	63 **(42%)**

Discont. Discontinuation Discomf. Discomfort.

is a parallel trend of discontinuations with age; although this fact is not confirmed in the present study, it would probably have been statistically significant with a larger sample size.

In this study, the overall number of discontinuations of MSCL until the first month of use was high. In fact, especially after the first week of wear, the number of discontinuations was very significant. This finding is consistent with the results of other authors: Papas et al. reported that early multifocal assessments are not representative of later performance of the lenses [14].

After the first evaluation of the lenses, investigators did not perform any fitting adjustments from the manufacturers' fitting guide except for the CD design, and only for the +2.00 and +2.50 additions. While this is a limitation of the study, the research objectives were to assess the outcomes avoiding any asymmetry in the viewing conditions of both eyes, and focusing on the multifocal design of the lenses. Regarding asymmetry between eyes, Woods et al. [15] in 2014 found that satisfaction was better for MSCL than for monovision. In that study, 51% preferred MSCL, 37% preferred monovision and 12% declared both inacceptable. These percentages were related to subjective questions about activities such as driving or focus changing, although high contrast visual acuity and low contrast visual acuity obtained better results with monovision than with MSCL. A recent study suggests that combining both CD for the dominant eye and S-CN for the non-dominant eye could outperform other lenses [16]; but again, it was considered that different designs should be avoided on the same patient.

According to the outcomes, without achieving statistical significance, the design that caused less contact less discontinuation was the A-CN design. Some recent studies have also reported that aspherical CN designs obtain better results. García-Lázaro et al. found better visual performance results in this multifocal design [17], although their results were based on visual performance such as Binocular Distance Visual Acuity and Binocular Distance Contrast Sensitivy. Another study conducted in 2013 compared two MSCL designs in 20 presbyopes. The comparison was made between a low addition aspherical design and a concentric design. Researchers found good binocular visual acuity at different vision distances and lighting conditions, and again the performance was better with an aspherical design in mesopic conditions [4]. Under these circumstances, asphericity could be beneficial for this kind of contact lenses fitting since abrupt transitions between two refractive concentric rings could impact on diffraction and worsen the performance of the lens [18].

Regarding the reason for discontinuation of multifocal designs, most authors agree that the primary reason is not discomfort, but visual performance [19]. The most important reason for presbyopic contact lens discontinuation in the present study was poor distance vision; followed by poor vision both at distance and at near, poor vision at near and discomfort. The lack of visual performance could provide a rationale why studies quantify visual performance abilities such as contrast sensitivity, distance visual acuity and near visual acuity [20–22]. Some authors have studied the neural adaptation to simultaneous bifocal images, concluding that wearing a particular bifocal correction can improve the perception of the images provided by the correction [23]. In this study, the number of discontinuations of the three intervention lenses was greater after the first week of wear than the number of new discontinuations after the first week until one month of wear, which could be due to the fact that participants were adapting to the new presbyopic correction system.

Bennett carried out a study in 2008 and concluded that prior contact lens wearers are better candidates for using MSCL [24]. All the participants in this study had been wearing single-vision soft contact lenses upon enrollment into the study, and had been randomised to one of the three intervention trial lenses regardless the material of the lens. In the case that shifting from one material to another could impact on discontinuation, it would not be as relevant as the visual performance regarding dropouts.

Although discontinuations had been assessed subjectively after participants' common use of the contact lenses, some authors suggest that the assessment of the presbyopic vision correction should be related to specific activities such as driving [25]. By assessing the lenses in specific activities, the information obtained would enhance the patient's experience with the multifocal contact lenses. In addition, pupil size can impact on visual performance of MSCL [26], but again real pupillary diameters could be considered in relation to visual tasks in real life conditions. The in-office pupil diameter measurements in this study had a mean value of 3.73 ± 1.12. However, pupil diameter is a dynamic parameter that depends on the working distance, age and lighting levels. In-office pupillary diameter measurements may not be enough [11].

Regarding psychosocial factors, it is described in literature the importance of a positive attitude towards contact lenses wearing [23]. Psychological and psychiatric conditions are also considered to play a role in contact lens wear [27]. To the authors' knowledge, there are no

previous studies that have evaluated anxiety levels for MSCL. However, recent studies consider both subjective tolerance to blur and anxiety important factors for aspheric design MSCL success [18]. There are some studies that intend to compare quality of life with different correction solutions for refractive error, but there are not studies that compare quality of life with different MSCL [28]. In this study, however, there were not statistically significant differences in quality of life or anxiety related to multifocal designs.

5. Conclusion

From the results of the present study, there is a significant risk for discontinuation during the MSCL fitting period. The most common causes for discontinuation are poor vision at distance and poor vision both at distance and at near. The age of wearers should also be taken into account. Under this framework, there could be a greater percentage of discontinuations with one particular S-CN design when compared with specific CD and A-CN designs. However, once the patients have been fitted with MSCL; there are not statistically significant differences in quality of life and anxiety for common activities with these three designs.

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