

MULTIFOCAL CONTACT LENS F-2

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SUMMARY – PURPOSE: The objective of this study was to evaluate the safety and efficacy of the Futura-due F-2 Multifocal contact lens.

MATERIAL AND METHODS: We conducted an 18-month prospective study to evaluate the clinical performance as well as to determine the subjective factors that influence the decision to purchase a multifocal soft contact lens for correction of presbyopia. 88 patients were initially fitted with the F-2 Multifocal contact lenses.

RESULTS: All 88 patients achieved 0,9 or better visual acuity both for near and distance vision. There was no significant difference after one and six months in contrast visual acuity, retinal sensitivity and subjective symptoms using contact lenses or spectacles.

CONCLUSION: This study showed safety and efficacy of the Futura-due F-2 Multifocal contact lens in providing a high level of distance and near vision with reduced spectacle dependency, despite some increased reports of halos and glare.

Key words: *contact lenses, presbyopia*

Introduction

Amphimetropia is the condition in which a person can focus at a distance and close up. It is the natural condition of the human eye. Around the fifth decade of life the human eye begins to be unable to focus close up at 30-40 cm. This condition is called presbyopia.¹

There are 6,000 billion people in the world, and more than one third of them are presbyopes. This problem has triggered increasing interest among clinicians and researchers.^{2,3}

A normal rested human eye is focused for distance. Therefore, it needs to have a refractive power of about 60 diopteres, 42 of them provided by cornea and 18 by crystalline lens. To focus close up, this power needs to be increased with some refractive changes. This already well known process was given the name of “accommodation” by Burrow in 1841.¹

The accommodation amplitude diminishes with age in a linear fashion and many authors have published their studies on the subject. When a person is unable to maintain the accommodation of 3 diopters to see at 0,33 m for any length of time we call this the beginning of presbyopia. Evolution of presbyopia has no appreciable differences in relation with age or social class and grade of ametropia, but it appears a little earlier in women than in men.^{4,6}

The treatment for presbyopia is very simple, but is entirely dependent on the individual’s age, lifestyle, occupation, and hobbies. If the patient has good distance vision and only has difficulty seeing up close, reading glasses are usually the easiest solution. For others, bifocals (glasses with reading and distance correction) or separate pairs of reading and distance glasses are necessary. Another option is monovision: adjusting one eye for distance vision, and the fellow eye for reading vision. This can be done with contact lenses or permanently with refractive surgery. It is a good solution for presbyopic people, but not equivalent to isometric binocularity.^{7,8}

The objective of this study was to evaluate the safety and efficacy of the Futura-due F-2 Multifocal contact lens.

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We conducted an 18-month prospective study to evaluate the clinical performance as well as to determine the subjective factors that influence the decision to purchase a multifocal soft contact lens for correction of presbyopia.

Material and Methods

Study Participants

The study was conducted from February 2000 through August 2001. Eighty-eight patients were initially fitted with the F-2 Multifocal contact lenses. Prospective patients were offered the opportunity to participate in a clinical trial in which they would be fitted with multifocal contact lenses. The potential benefits of the multifocal lenses included reduced or no spectacle dependence and better-uncorrected near vision. The potential drawbacks of the multifocal lenses included increased glare and halo. Patient exclusion criteria for the study were more than 1,5 D of astigmatism, significant corneal opacities, chronic drug miosis or fundus abnormalities which could cause significant vision impairment and no indication of existing ocular pathologic characteristics other than presbyopia. 52 patients were myopic, 34 hypermetropic and 2 pseudophakic. All patients were between 44 and 56 years of age, 72 with previous experience with contact lenses.

Contact Lens

Futura-due F-2 Multifocal contact lens comes in power range from -8,00 D to +8,00 D (0,25step), with two base curve (FL or ST), 14,0 of diameter and 38% of water content.

Clinical Performance

Visual acuity measurements were always done under the same conditions with 6-m standard Snellen visual acuity charts. Near visual acuity was also measured under same condition from a distance of 25 to 40 cm, as chosen by the patient, using Jaeger charts. Conversion of the used Jaeger charts to Snellen equivalent is listed in Table 1.

Low contrast visual acuity was quantified using modified Wang & Pomerantzeff test.

Retinal sensitivity was measured by static automated perimetry using Octopus 101 ST program and Anderson's criteria were used for visual fields comparison.⁹

Quality of life Assessment

A standardized questionnaire was used to rate the patient's overall satisfaction after 1 week and 1 and 6 months.

The survey included questionnaire about color perception, distance vision and near vision both day time indoors and night time outdoors, glare, halo, dizziness and headache. The last question was if the patient would continue using this type of contact lenses.

Statistical Analyses

Group differences were tested for significance using the Student's *t* test for normal distributed and the Mann-Whitney test for non-parametric data with significance set at $P < 0,05$. Statistical comparisons concerning the subjective questionnaire were performed using chi-square test and trend analysis with significance set at $P < 0,05$.

Results

Clinical Performance

All 88 patients achieved 0,9 or better visual acuity for both near and distance vision. There was no need for choosing the "leading eye" and correcting one eye for distance vision and one for near.

There was no significant difference in contrast visual acuity with multifocal contact lenses or spectacles. The results were slightly better with spectacles but the difference was not significant.

Comparing retinal sensitivity there was also no significant difference in visual fields using contact lenses or spectacles. Each patient was corrected for near vision during perimetry in central field, and later the same Octopus program was done using multifocal contact lens. The results were even better when performing with multifocal contact lens, but difference was not statistically significant.

Quality of life Assessment

Significant differences were noted in the rating of near vision, halo and glare only after one week, and no differ-

Table 1. Conversion of the Jaeger charts to Snellen equivalent

Jaeger	Snellen
J 1+	1,0
J 1	0,9
J 2	0,7
J 3	0,5
J 4	0,3

Table 2. *Quality of life Assessment after 1 week*

	difficulty	no difficulty
color perception	0	88
distance vision	0	88
near vision	6	82
glare	6	82
halo	7	81
dizziness	0	88
headache	2	86
multifocal y/n	0	88

ences in other symptoms comparing the use of lenses or spectacles (Table 2).

There was no significant differences comparing any of the symptoms after one and six-month use of multifocal contact lenses or glasses (Table 3, Table 4).

Table 3. *Quality of life Assessment after 1 month*

	difficulty	no difficulty
color perception	0	88
distance vision	0	88
near vision	2	86
glare	0	88
halo	2	86
dizziness	0	88
headache	0	88
multifocal y/n	0	88

Table 4. *Quality of life Assessment after 6 months*

	difficulty	no difficulty
color perception	0	88
distance vision	0	88
near vision	1	87
glare	0	88
halo	2	86
dizziness	0	88
headache	0	88
multifocal y/n	0	88

Discussion

Presently, there are several investigational surgical treatments emerging for presbyopia, most of them in ex-

perimental phase and far from clinical use. The only one way to solve presbiopic problem with refractive surgery today is the so-called "monovision" concept.

Modern contactology offered several solutions for presbyopic problems. Until recently, contact lens wearers who required visual correction for reading had to use glasses over contacts to see close up. But now multifocal contact lenses offer the best of both worlds: no glasses and good vision both close up and in the distance.

The options have expanded since the first bifocal contact lenses were invented. While some contacts are still made in a bifocal design (meaning that they have two points of focus, one for distance and one for near), others are multifocals, with many points of focus for a natural visual transition from distance to close up.

The multifocal version of the concentric soft contact lens design has the distance correction in the centre, with the reading power in the periphery of the lens. But this design is not strictly limited to distance and near powers. The outer ring of the lens can contain a progressive, or gradually transitioning power for smooth vision at all distances. These lenses provide good intermediate vision for different tasks such as computer use. The inverse of this design is also available, with the centre reading power surrounded by the progressive distance correction.

Overall, F-2 Multifocal contact lenses showed good objective functional results, and all treated patients felt at least satisfied. Compared with results from newer studies we achieved similar results¹⁰⁻¹⁴. Patients who enrolled in this study were highly motivated and willing to be fitted with what was at the time almost an investigational medical device. It is possible that their desire for the potential benefits of the multifocal lens made them more tolerant of potential limitations, such as glare and halo, than a less informed, less motivated member of the public may be without adequate counseling.

For a new medical technology to be widely adopted it must not only be safe and efficacious, but it should also provide superior outcomes in terms of patient function, satisfaction, and quality of life. The results of this clinical trial suggest that the multifocal lens studied meet all of these criteria.

Conclusion

In summary, this study showed safety and efficacy of the Futura-due F-2 Multifocal contact lens in providing a high level of distance and near vision with reduced spectacle dependency. Although subjects in this study report-

ed an increase in glare and halos compared to use of spectacles, visual function remained within acceptable levels as shown by the clinical performance tests and questionnaire about subjective factors. Patient's satisfaction was high as shown in the last question where all of them decided to proceed with the use of this multifocal lens.

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Sažetak

MULTIFOKALNA KONTAKTNA LEĆA F-2

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CILJ: Cilj ovog rada bio je pokazati djelotvornost i uspješnost Futura due F-2 Multifocal kontaktne leće.

MATERIJALI I METODE: proveli smo 18-mjesečnu prospektivnu studiju s 88 pacijenata u kojoj smo pokazali kliničke rezultate, te subjektivne pokazatelje uspješnosti korekcije prezbiopije multifokalnom kontaktnom lećom F-2.

REZULTATI: Kod svih 88 pacijenata postignuta je vidna oštrina 0,9 ili bolja na daljinu kao i blizinu. Nije bilo statistički značajne razlike u kontrastnoj vidnoj oštrini, retinalnoj osjetljivosti niti subjektivnim pokazateljima nakon mjesec dana i šest mjeseci korištenja ove leće.

ZAKLJUČAK: Ova je studija pokazala djelotvornost i uspješnost Futura due F-2 Multifocal kontaktne leće u omogućavanju visokog stupnja vidne oštrine na daljinu i blizinu, smanjenu ovisnost o naočalima, te malom broju subjektivnih tegoba.

Ključne riječi: *kontaktne leće, prezbiopija*