Patients’ clinical results and visual performance after the implantation of a new multifocal lens

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The implantation of multifocal, or accommodative, intraocular lenses established itself as the new frontier of refractive surgery thanks to the improvement of the surgical techniques and the structural features of the intraocular lenses, which produced substantial and repeatable results.

Inclusion criteria and methods

✓ Patients explicitly requested to recover near and distant vision (informed consent)
✓ Absence of retinal or choroid pathologies
✓ No more than ± 1,75 D astigmatism
✓ Sample average age: 72,66 yrs (range 26-90 yrs)
✓ Pupillometry in mesopic conditions ≤ 5,2 mm
  (Colvard infrared pupillometer by Oasis Medical)
✓ Immersion biometry or interferometry (IOL Master by Zeiss)
✓ Contrast sensitivity evaluation through CRT Format Devices (ULC 800 by Unicos)
✓ 12-month follow-up
462 eyes operated on 386 patients, 76 bilaterally, using SOLEKO FIL 611 PV: a new flexible multifocal lens produced in Italy, with four supporting loops optimizing its stability.

Materials

- Multifocal lens
- 4 haptics optimize stability of the lens in the capsular bag
- Square edge design to prevent cell growth under the lens
- 5° angulation improves the posterior capsular tension
- High refractive index optimizes the profile of the lens
- UV Filter

Soleko Fil 611 PV

The central area of the lens has a +3.75 D addition for near vision (which corresponds to +3.0 D at spectacles level), while the adjoining area has a +2.1 D addition for intermediate distance vision with a +1.68 D value at spectacles level.
**Results at 6 months - Group A**

- **Sample number = 180**
- **Average age = 69.63 yrs (range 26 – 87 yrs)**
- **Standard deviation = ± 9.928**

- **20/20 BCVA whit sf ± 0.50 D**
- **20/20 UCVA for distance**

- **25%**
- **75%**

**Distant Visual Acuity**

- **68.33% read J3 characters without spectacles**
- **7.5% use spectacles for near vision**
- **Contrast sensitivity > 75%**

**Near Visual Acuity**

- **31.67%**
- **68.33%**

- **There is a 51.25% probability of having 20/22 VA pd and reading J3 characters without spectacles**

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**GROUP A**

**VA 20/20 = 180 eyes, 55 bilateral**
Sample number = 224  
Average age = 73.65 yrs (range 41 – 90 yrs)  
Standard deviation = ± 8.219

68.75% read J3 characters without spectacles  
8.88% use spectacles for near vision  
Contrast sensitivity > 75%

Distant Visual Acuity

20/22 VA pd = 72.76% - 163 eyes,  
20 bilateral – with an average age of 73.65 yrs

Near Visual Acuity

There is a 50.03% probability of having  
20/22 VA pd and reading J3 characters  
without spectacles

GROUP B

VA 20/22 = 224 eyes, 21 bilateral
Sample number = 58
Average age = 78.25 yrs (range 52 – 90 yrs)
Standard deviation = ± 8.548

62.06% read J4 characters without spectacles
9.30% use spectacles for near vision
50% < Contrast sensitivity > 75%

Distant Visual Acuity
- UCVA for distance 20/25: 29.32%
- BVCA for distance with sf/cil ± 1.75 D: 70.68%

20/22 VA pd = 70.68% - 41 eyes, with an average age of 78.25 yrs

Near Visual Acuity
- UCVA for near J4: 37.94%
- UCVA for near J4: 62.06%

There is a 43.88% probability of having 20/25 VA pd and reading J4 pv characters without spectacles

GROUP C
VA 20/25 = 58 eyes
12 months after the surgery, 45 eyes (9.74%) showed a secondary opacification of posterior capsule.

✓ Patients of the three groups A, B, C with pupillary diameter lower than 4 mm had a better visual acuity.

Applying the T-Student test to groups A, B, C, one can infer that the difference among the three populations’ average age is meaningful for p<0.01. That is to say, the recovery of visual acuity is not accidental, but it is influenced by the sample age with a probability lower than 1%.

The equation of the regression line with an incline lower than 0 (b<0) indicates that there is a negative correlation between the age and the visual acuity of the examined sample.
**Conclusion**

- As far as the subjective quality of vision is concerned, more than 67% of patients expressed a high degree of satisfaction due to the possibility of avoiding spectacles for near vision. This situation improved the life quality especially of those who regularly used spectacles before the surgery.

- In the final analysis, the idea which comes out examining all the treated patients is that the occasional reading is good, if not optimal, without the use of spectacles for near vision, though these ones cannot be completely avoided.

- SOLEKO FIL 611 pv multifocal lenses favour an optimal distant vision and a good near and intermediate vision.

- Compared with other models, these lenses do not cause statistically meaningful Glare & Halos phenomena. On the contrary, should they not allow near vision, they act as a good distant monofocal lens.

- The study of contrast sensitivity shows that a good quality of image is achieved and kept.

- The lenses result to be particularly effective if the patient is operated on both eyes.

- The lens’ stability in the capsular sac never causes decentralization phenomena.