

CLINICAL RESULTS WITH A PREMIUM MONOFOCAL IOL IN TWO EUROPEAN CLINICS

In both settings, patient satisfaction was high with the ISOPURE IOL.

Sponsored by
Beaver-Visitec International

BY RAFAEL BILBAO-CALABUIG, MD, PHD, FEBOS-CR, AND KRISTOF VANDEKERCKHOVE, MD



A LOW RISK FOR VISUAL DISTURBANCES

RAFAEL BILBAO-CALABUIG, MD, PHD, FEBOS-CR

Trifocal diffractive IOLs are currently the gold standard for lenticular presbyopia surgical correction. These lenses, however, have some undesirable visual side effects for certain patients. In my opinion, extended depth of focus (EDOF) IOLs are an exciting alternative to trifocal technologies. One lens, the ISOPURE (Beaver-Visitec International), is especially promising.

The ISOPURE is designed to provide functional intermediate vision in all conditions without compromising quality of vision. It is a nondiffractive aspheric IOL with a patented polynomial surface design across the full optic that accentuates the extended depth of focus effect without inducing photic phenomena such as halos, glare, and starbursts.

Optical bench testing has shown that the ISOPURE provides about 50% greater depth of focus than a standard aspheric

monofocal IOL (data on file with Beaver-Visitec International). Additionally, on the optical bench, contrast sensitivity with the lens is comparable to that of a standard monofocal IOL.

The ISOPURE provides a greater depth of focus compared to a standard monofocal IOL at different pupil sizes, offering a continuous increase in quality of vision between distance and intermediate.

CLINICAL STUDY

Study design. We performed a prospective clinical study to evaluate the clinical results after cataract surgery with ISOPURE implantation. Patients were followed for 6 months. The target refraction was 0.00 D when implanted monocularly and -0.50 to -0.75 D in the implanted eye when implanted binocularly.

Results. Mean distance visual acuity was 0.95, and mean intermediate vision was 0.66 monocularly and 0.75 binocularly. We obtained a widened defocus curve with a binocular visual acuity superior to 0.2 logMAR from 62 cm to distance. Contrast sensitivity curves were within the normal values for the age group.

Patient satisfaction was high in the binocular group, with 90% of patients stating they did not experience halos or glare. For the other 10%, the halos or glare were not bothersome. Additionally, 90% of patients didn't need glasses for distance or intermediate vision and 50% said they achieved uncorrected functional near vision for short durations and easy visual tasks.

With these initial promising results, our group has now implanted more than 400 ISOPURE lenses across Spain.



EXCELLENT INTERMEDIATE VISUAL ACUITY

KRISTOF VANDEKERCKHOVE, MD

Prior to introducing the ISOPURE IOL in our clinic in March 2020, about 90% of implanted IOLs were monofocal. Within 8 months, ISOPURE reached 30% of the IOL share in our practice. After 18 months, I had implanted more than 800 ISOPURE lenses. The key factors for this rapid adoption were our extensive and positive experience with the same IOL platform (Micropure, Beaver-Visitec International) and the clear positioning of ISOPURE by our team. Early data and experience from our own retrospective trial reinforced internal confidence.

We conducted a retrospective clinical trial in 50 cataract patients (100 eyes) after bilateral implantation of the ISOPURE. Patients achieved uncompromised uncorrected distance visual acuity

(≤ -0.1 logMAR) and an extended range of uncorrected vision. The defocus curve showed a smooth slope over the tested diopter range, resulting in a functional depth of focus (≤ 0.2 logMAR) of 2.40 D (Figure). Spectacle independence was 93% at intermediate and 40% at near. Quality of vision was uncompromised, with halos reported by only 7%, starburst by 14%, and glare by 18% of patients 4 to 6 weeks after surgery.

These results encouraged us to initiate a prospective head-to-head study between ISOPURE and another next-generation EDOF IOL (AcrySof IQ Vivity, Alcon). ■

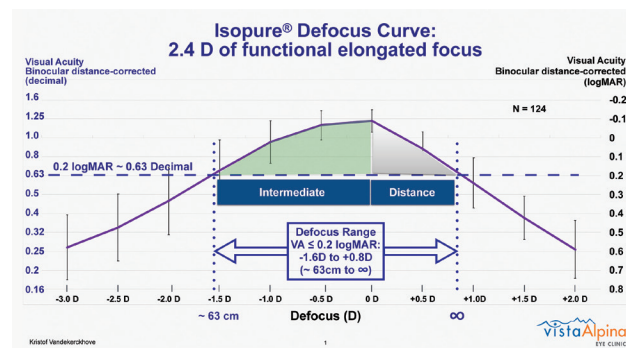


Figure. The mean functional elongation of depth of focus.

RAFAEL BILBAO-CALABUIG, MD, PHD, FEBOS-CR

- Clínica Baviera/AIER Group, Madrid, Spain
- rbilbaocalabuig@hotmail.com
- Financial disclosure: Scientific Consultant (Beaver-Visitec International/PhysIOL)

KRISTOF VANDEKERCKHOVE, MD

- Head and founder, Vista Alpina Eye Clinic, Switzerland
- vandekerckhove@vista-alpina.ch
- Financial disclosure: None