

6 Month European Study Results of Excimer-Based Treatment of Presbyopia Using the TECHNOLAS[®] Excimer Workstation

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Background

The pursuit to find optimal solutions for the treatment of presbyopia has resulted in the development of numerous different innovative technologies and approaches. Traditional methods comprise vari- or bi-focal contact lenses or glasses, surgical techniques include the implantation of accommodating or multifocal intraocular lenses, whilst mono-vision refractive correction, inlays, intrastromal femtosecond treatment (INTRACOR[®]) and presbyopic LASIK are among some of the corneal techniques.

Adopting an excimer-based presbyopic LASIK technique could be considered as one of the more attractive and practical corneal approaches for a number of reasons. This method uses the well-established LASIK procedure, incorporating some of the most advanced technologies such as multi-dimensional eyetrackers.¹ Refractive outcomes are highly predictable, with the option for easy enhancement.

The presbyopic LASIK technique does provide acceptable multi-focality. However there is always a compromise between the optimal distance and near vision achieved, which often leads to the inducement of undesired aberrations in the pupil region. These can be caused by an overlap in the optical and transition zones or by surgically induced spherical aberrations, causing a loss of distance vision and quality of vision.

Introduction to SUPRACOR

A new aberration optimized presbyopic algorithm called SUPRACOR^{™*} has been developed to treat presbyopia. The algorithm combines the TPV's learnings from the corneal approach with the excimer laser, with the growing knowledge from the

intrastromal presbyopic treatment, and applied it to the excimer platform. It has been designed to provide a presbyopic correction, whilst minimizing the induction of unwanted aberrations within the pupil region.

A simulation of how the aberration-optimized algorithm SUPRACOR provides good quality of vision across an expanded distance range, including near and distance vision, is depicted in Figure 1. The simulation of the retinal images is generated from corneal topographies integrated into Ray-Trace-Software.

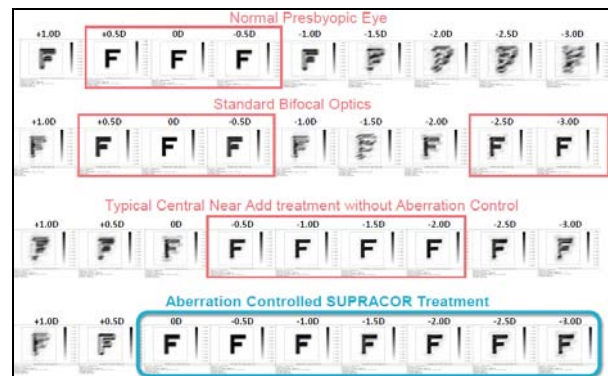


Figure 1: Simulation of SUPRACOR vision quality over an expanded distance range

Developed for use on the TECHNOLAS[®] Excimer Workstation 217P (Figure 2), SUPRACOR is intended to treat the full refractive treatment range.

(*) SUPRACOR is Not for Sale in the United States.



Figure 2: TECHNOLAS Excimer Workstation 217P

This article summarises the results of a European multicentre clinical study evaluating the SUPRACOR algorithm in presbyopic hyperopes.

Study Objectives and Methods

In this prospective, multicentre, clinical study, 46 eyes of 23 presbyopic hyperopic patients underwent the SUPRACOR treatment. The procedure was carried out on the TECHNOLAS[®] Excimer Workstation 217P (Technolas Perfect Vision), using the system's iris recognition and eyetracker technology (Advanced Control Eyetracker).

The study participants were Dr Jean-Jacques Chaubard, Nice (Principal Investigator), Dr Jorge Castanera, Barcelona, Dr Dominique Pietrini, Paris and Dr Antoine Roure, Nice.

Patients had good ocular health and thorough patient selection and counselling prior to the procedure. All patients were at least 50 years old and required a near addition of least 1.50D. LASIK SUPRACOR treatment was always bilateral, using an optical zone of 6.0mm. Both eyes received the same algorithm aiming for a slight residual myopia; this is not a monovision treatment. A nomogram adjustment for sphere was made after 6 patients.

Primary measured outcomes were manifest refraction, uncorrected near visual acuity (UCNVA), uncorrected distance visual acuity and distance best spectacle corrected visual acuity (BSCVA) obtained by means of Snellen readings under photopic conditions. A subjective patient questionnaire was also conducted. Post-operative follow-up was at 1 day, 1 week, 1, 3 and 6 months.

Results

The mean patient age was 55.5, ranging from 50 to 62 years. Pre-operative spherical equivalent, sphere and cylinder were $1.67 \pm 0.77D$, $1.90 \pm 0.80D$ and $-0.45 \pm 0.30D$, respectively. Mean refractive spherical equivalent (MRSE) remained stable after 1 month. At 6 months postoperative follow-up, MRSE was $-0.41D$, whilst sphere and cylinder were $-0.22D$ and $-0.37D$.

Safety

In terms of safety, all patients see binocular BSCVA of 1.0 at 6 months postoperatively, and 34.8% of patients see 1.25 compared with 21.7% pre-operatively (Figure 3).

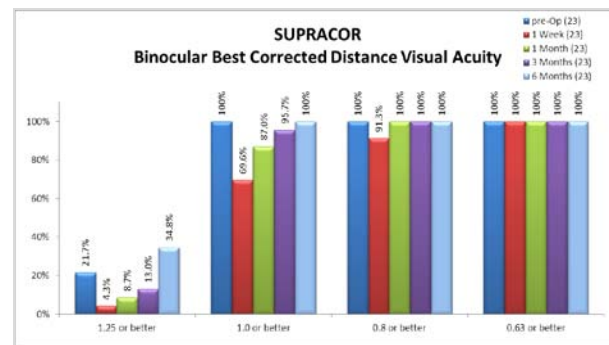


Figure 3: Safety of SUPRACOR algorithm – Binocular Best Spectacle Corrected Visual Acuity

Efficacy

Looking at efficacy data, 84.8% of patients achieve monocular uncorrected near visual acuity of 0.8 at 6 months follow-up, with 93.5% at 0.63 or better. Binocularly, 91.3% of patients have an UCNVA of 0.8 or better (Figure 4).

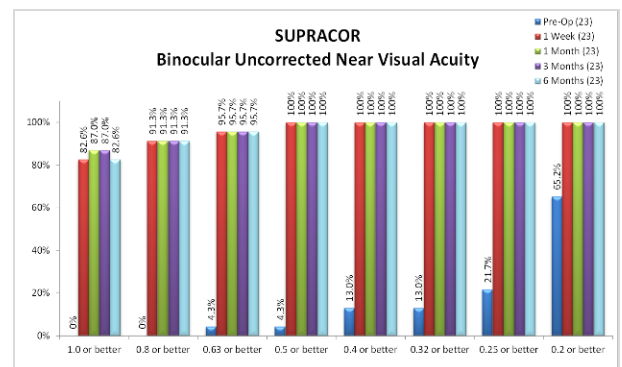


Figure 4: Efficacy of SUPRACOR algorithm - Binocular Uncorrected Near Visual Acuity

Six month postoperative results for distance vision find 78% of patients have a monocu-

lar UCDVA of 0.8 or better. Binocularly, 96% have an UCDVA of 0.8 or better (Figure 5).

Comparisons of the pre- and post-operative binocular uncorrected near and distance visual acuities when displayed as 3-dimensional plots (Figures 6a and 6b), show a significant improvement in visual acuity. Eighty-seven percent achieve a minimum J2 and 20/25 at 6 months follow-up.

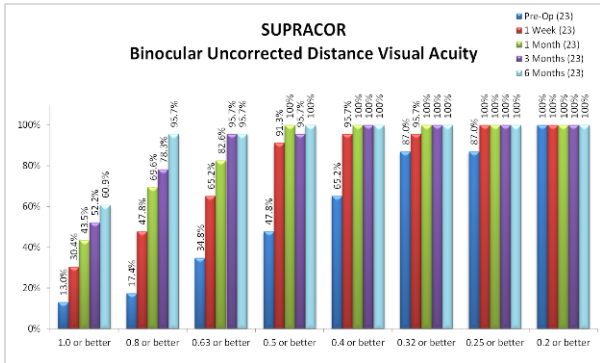


Figure 5: Efficacy of SUPRACOR algorithm - Binocular Uncorrected Distance Visual Acuity

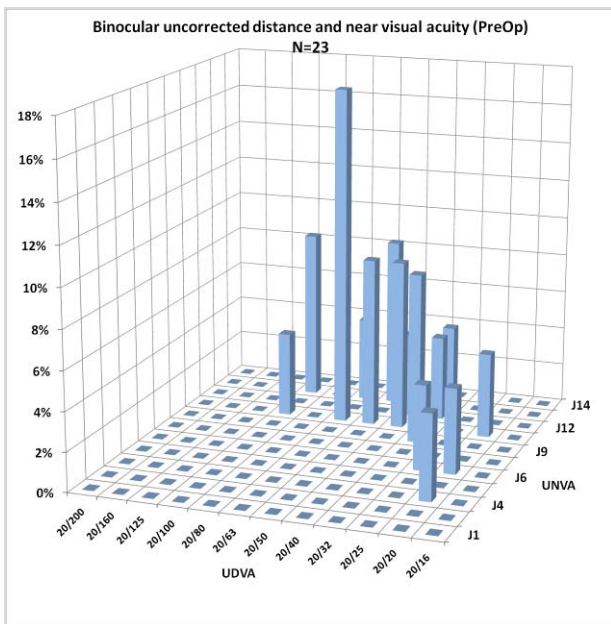


Figure 6a: 3D plot of pre-operative near and distance uncorrected visual acuities

Patient questionnaire

The subjective patient questionnaire, which was conducted at all of the post-operative follow-ups, showed a high level of patient satisfaction and spectacle independence with the SUPRACOR procedure. At 6 months follow-up, 96% of patients could read the text in the newspaper, short mobile phone messages and menus, compared with only 39% being able to read the headlines pre-operatively. Seventy-eight percent of patients also reported being able to read the package inserts of prescription medication (Figure 7).

When asked if they have the feeling they live a life without glasses, all patients gave a positive response, as they feel their life was led without glasses (Figure 8). Ninety-six percent of patients no longer require glasses for computer work. All of the patients would recommend the SUPRACOR procedure to their friends.

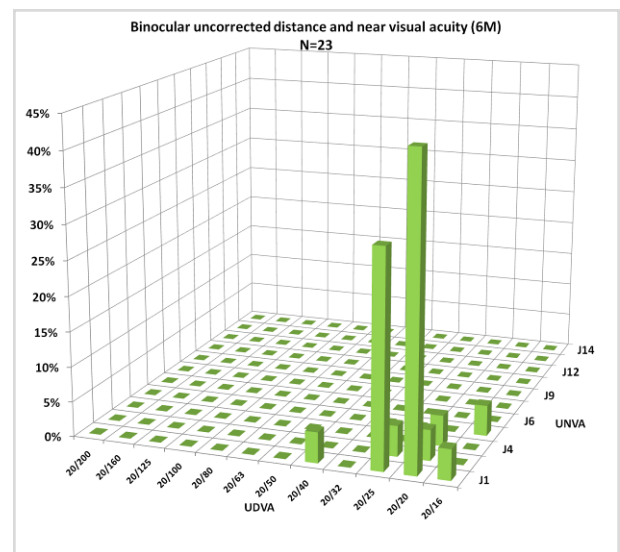


Figure 6b: 3D plot of 6 month post-operative near and distance uncorrected visual acuities

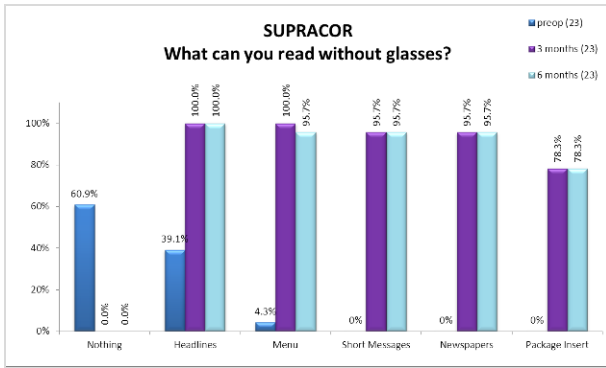


Figure 7: Patient questionnaire results at 6 months follow-up – reading without glasses



Figure 8: Patient questionnaire results at 6 months follow-up – life without glasses

Summary

According to the 6 month follow-up data obtained from this multicentre European evaluation of the SUPRACOR algorithm, the procedure provides a very safe and effective treatment for presbyopia. There is minimal loss of lines of BSCVA, with only 2 eyes losing 1 line at 6 months postoperatively. All patients gain a significant improvement in near vision, whilst maintaining and controlling very good distance vision. All patients report high levels of satisfaction and spectacle independence for daily activities using near, intermediate and distance vision.

The bilateral approach applied with the SUPRACOR procedure without monovision provided easy patient adaptation and good intermediate vision, avoiding the compromises associated with a monovision technique.

Following an initial nomogram adjustment, the treatment can be tailored to suit a patient's needs and the surgeon's technique. This procedure also benefits from using a

well-established LASIK technique which many surgeons are already using comfortably.

Outlook

The 6 month data on this hyperopic patient cohort shows the SUPRACOR procedure provides a promising treatment for presbyopia. Further longer term data with larger patient numbers are needed to confirm these findings.

Other clinical studies into myopic, emmetropic and post-LASIK patients are ongoing. Preliminary results of these patient groups are promising. This technique also offers the option for easy enhancements and treatment reversal.

As with all multifocal treatments, careful patient selection and counseling is imperative to provide optimal outcomes and patient satisfaction.

In conclusion, the SUPRACOR algorithm offers the possibility to treat a full refractive range, including the possible suitability for post-LASIK patients, with good near, intermediate and distance vision. This represents an important advance in the search for the optimal solution to presbyopia.

References

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Further information

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