Journal of Clinical & Experimental Ophthalmology

Doyle et al., J Clin Exp Ophthalmol 2016, 7:5
DOI: 10.4172/2155-9570.1000601

Research Article Open Access

Retreatment Rate Following Supracor Treatment of Hyperopic Presbyopia

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Received date: August 15, 2016; **Accepted date:** September 21, 2016; **Published date:** September 24, 2016

Abstract

Objective: To report the retreatment rate and safety of presbyopia treatment using the corneal laser in situ keratomileusis (LASIK) procedure, Supracor.

Methods: In this case series, bilateral LASIK using the Supracor algorithm was performed on consecutive hyperopic presbyopic patients. All patients were followed for a minimum of six months postoperatively. The principal outcome measures were retreatment rate, safety, efficacy in terms of uncorrected distance visual acuity (UDVA) and uncorrected reading ability (vocational reading test), patient satisfaction, stability and predictability.

Results: 76 eyes of 38 patients were treated. 42% of patients (16 patients) that were treated required at least one re-treatment. The mean preoperative manifest refractive spherical equivalent (MRSE) was +1.90 D ± 1.01 D. The mean MRSE following all treatments was -0.24 D ± 0.62 D. The UDVA was 20/20 or better in 38%, and was 20/30 or better in 91% of eyes following all treatments. 12% of eyes lost 1 line of Snellen corrected distance visual acuity (CDVA), and 3% lost 3 lines of Snellen CDVA following the primary treatment. 14% of eyes had lost 1 line of Snellen CDVA, and 4% of eyes had lost 3 lines of Snellen CDVA following all treatments. 92% of patients had uncorrected binocular near reading of J5 or better following the primary treatment. 97% of eyes had uncorrected binocular near reading of J5 or better following all treatments. Following all treatments, 82% of patients that underwent Supracor were pleased they had had the procedure performed. The mean follow-up period of patients in the study was twelve months.

Conclusion: While there was a high level of near vision spectacle independence, the high retreatment rate with reduced CDVA in some cases is a cause for concern. The high retreatment rate with potentially reduced CDVA following Supracor may be due to a combination of blend zone, centration, and hyperpositive central zone issues.

Keywords: Supracor; Presbyopia; Retreatment; Laser; LASIK; Satisfaction; Refraction; Surgery

Introduction

Accommodation in the human eye is a complex process which is exceptionally difficult to replicate following the onset of presbyopia. A number of operative techniques have been developed to address the issue of presbyopia, including insertion of pseudo-accommodating intraocular lenses [1], multifocal intraocular lenses [2] and corneal inlays [3], laser blended vision [4] and monovision [5-7]. A corneal approach may be a preferable option to intraocular surgery, involving less perceived risk to the patient (in patients with no cataract).

A number of corneal refractive procedures have been used for the correction of presbyopia. These include laser multifocal ablation [8-10], peripheral presbyLASIK [11], laser blended vision [4] and INTRACOR laser [12]. The central presbyLASIK approach named PresbyMAX (Schwind Eye-Tech-Solutions GmbH and Co. KG, Kleinostheim, Germany) is based on the creation of a multifocal central area for near vision and a surrounding area for distance emmetropia [13,14]. Some patients find it difficult to tolerate the loss of distance visual acuity that may be associated with multifocal laser ablation [4]. Artola et al. found evidence for delayed presbyopia after photorefractive keratectomy for myopia. The induced aberrations reduced the quality of the retinal image for distance but enhanced near acuity by means of a multifocal effect [15].

Correction of presbyopia with monovision has been carried out using LASIK with a high degree of patient satisfaction and spectacle independence [5-7]. Monovision correction may be associated with a significant loss of stereopsis and contrast sensitivity [7], increased higher order aberrations [16], intolerance [17], and need for retreatment [17]. The existence of so many types of technique for corneal correction of presbyopia suggests that an entirely satisfactory laser correction technique remains to be found.

In this retrospective case-series study, we report on the retreatment rate, safety, efficacy and predictability of Supracor in the correction of hyperopic presbyopia.

Patients and Methods

This retrospective study included a consecutive series of 76 eyes of 38 hyperopic presbyopic patients undergoing Supracor multifocal excimer LASIK for correction of presbyopia in the Galway Clinic Hospital, Galway, Ireland. Inclusion criteria were a manifest refractive spherical equivalent (MRSE) of between +0.50 diopters (D) and +4.50 D, mean keratometry readings of 41.0 to 45.0 dioptres, age 46 years or

older, central corneal thickness of 500µm or greater, and a corrected distance visual acuity (CDVA) of 20/40 or better.

Exclusion criteria were the presence of ocular surface disease, abnormal corneal topography, and clinically significant lenticular opacity.

Each subject underwent biomicroscopy of the anterior and posterior segments preoperatively. The monocular CDVA was recorded on a logMAR (log minimum angle of resolution) chart. Near vision was taken to be the smallest print the patient could read on the Vocational Reading Test (Keeler Instruments, Inc.) at 40 cm without correction. The corresponding Jaeger print sizes are N5=J2, N6=J3, N8=J5, N10=J7, N12=J8, and N18=J12.

Surgeries were all performed by the same surgeon (F.K.) with the Technolas 217P excimer laser (Technolas Perfect Vision GmbH). Superior-hinged corneal flaps were created with the Zyoptix XP microkeratome (Technolas Perfect Vision GmbH).

The flaps were of 120 µm thickness and 8.5 to 9.5 mm diameter. The ablation was centered over the center of the pupil. Dynamic rotational eye tracking using Zyoptix ACE technology and iris recognition were used during the ablation. The Zyoptix tissue-saving algorithm was used to perform the correction (adjusted according to a nomogram) in a 6.0 mm optical zone. This was followed by the Supracor component, which involves an additional 2000 pulses to create a hyperpositive area in the central 3.0 mm zone. The treatment targets emmetropia in the dominant eye and 0.50 dioptres of myopic defocus in the non-dominant eye.

The postoperative drops regimen was chloramphenicol 1.0% (Chloromycetin Redidrops) 4 times daily for 5 days, and prednisolone acetate 1.0% (Pred Forte) 4 times daily for 2 weeks.

Patient satisfaction reflected the patients' response to a number of questions following the primary treatment and following all treatments (as recorded in clinical notes). Patients were asked the following questions. 1) Are you pleased you had the procedure performed? 2) Are you pleased with your distance vision? 3) Do you need to wear reading glasses to read a label, use a laptop, use a mobile phone, read a menu in a restaurant?

Statistical analyses were performed using SPSS for Windows, Version 20.0 using a t test for normally distributed data and a Wilcoxon signed-rank test for non-normally distributed data. Differences were considered significant if p was less than 0.05. Data are given as mean ± standard deviation.

Results

76 eyes of 38 patients were treated. The mean age was 55 years (range 47 to 66 years); 21 patients (55%) were female, and 17 patients (45%) were male.

Forty-two percent of patients (16 patients) that underwent the Supracor procedure initially required at least one further corrective procedure. Mean follow-up time was 12 months.

Safety

The preoperative mean CDVA was 20/20. Six months after the primary treatment, 92% of eyes had a CDVA of 20/20, and 8% had a CDVA of 20/25. Following all treatments, 89% of eyes had a CDVA of 20/20, 7% of eyes had a CDVA of 20/25, and 3% of eyes had a CDVA of 20/40.

Six months following the primary treatment, 7 (9%) of eyes had lost 1 line of Snellen CDVA, and 1 (1%) eye had lost 2 lines of Snellen CDVA, in comparison to preoperative CDVA. Following all treatments, 9 (12%) eyes had lost 1 line of Snellen CDVA, and 2 (3%) eyes had lost 2 lines of Snellen CDVA, in comparison to preoperative CDVA.

Efficacy

The mean unaided distance visual acuity (UDVA) six months following the primary treatment was logMAR 0.11 (20/25.8). Following all treatments, the mean UDVA was logMAR 0.11 (20/25.8). The UDVA was 20/20 or better in 45% of eyes six months following the primary treatment and 20/20 or better in 38% of eyes following all treatments. Six months following the primary treatment, the UDVA was 20/30 or better in 92% of eyes. Following all treatments, the UDVA was 20/30 or better in 91% of eyes. Figure 1 shows unaided distance monocular visual acuity outcomes following treatment in the context of preoperative monocular corrected distance visual acuity (Figure 2).

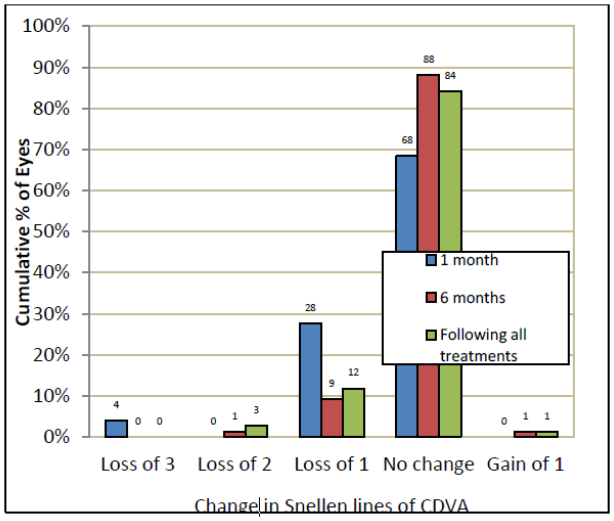

Figure 1: Loss or gain of lines of Snellen corrected distance visual acuity (CDVA) following the primary treatment and following all treatments.

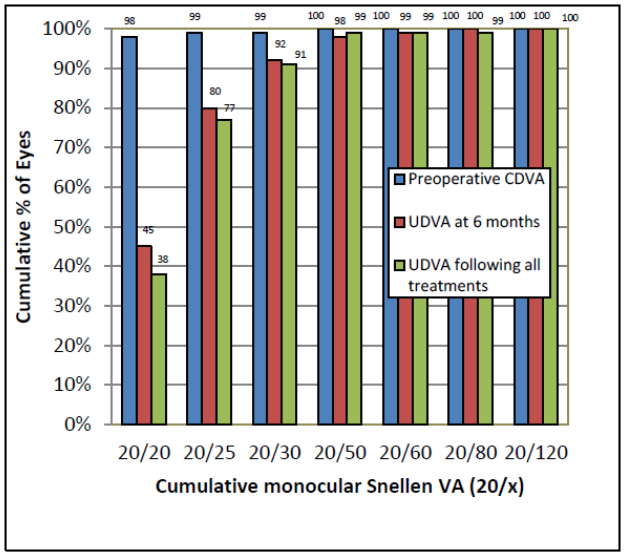

Figure 2: Efficacy of distance vision correction. Cumulative monocular unaided distance visual acuity (UDVA) six months following the primary treatment, and following all treatments, in the context of preoperative monocular corrected distance visual acuity (CDVA).

Figure 3 shows the cumulative uncorrected binocular vocational reading test ability following the primary treatment, and following all treatments.

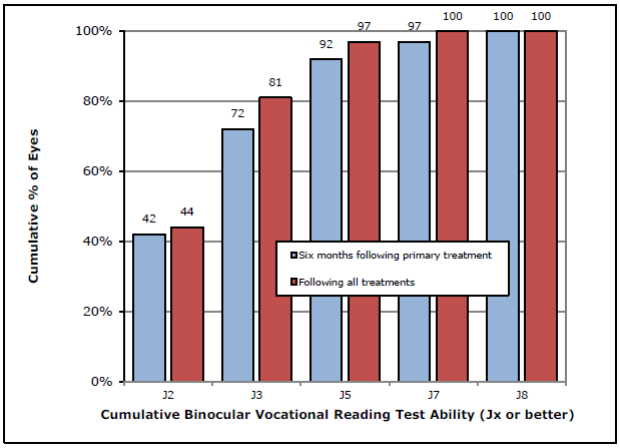

Figure 3: Efficacy of near vision correction. Cumulative monocular uncorrected reading ability (displayed as smallest J print read at 40 cm on the Vocational Reading Test).

Postoperative refraction

The overall mean preoperative manifest refractive spherical equivalent (MRSE) was +1.90 D ± 1.01 D.

The mean MRSE six months following the primary treatment was -0.05 D ± 0.60 D. The mean MRSE following all treatments was -0.24 D ± 0.62 D.

Astigmatism

Mean preoperative astigmatism was +0.36 ± 0.30 D. Mean astigmatism six months following the primary treatment was +0.17 ± 0.30 D. Mean astigmatism following all treatments was +0.20 ± 0.25 D (Figures 4-7).

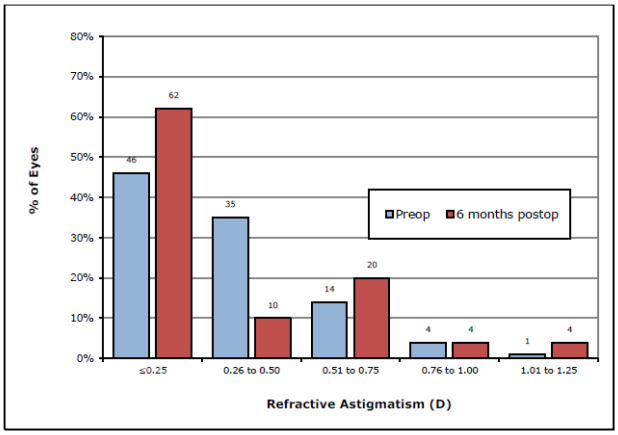

Figure 4: Refractive astigmatism six months following the Supracor treatment in the context of preoperative refractive astigmatism. Mean preoperative astigmatism was 0.39 ± 0.33 (median 0.38, range 0 to 1.25). Mean postoperative astigmatism was 0.16 ± 0.58 (median 0.0, range 0 to 1.25).

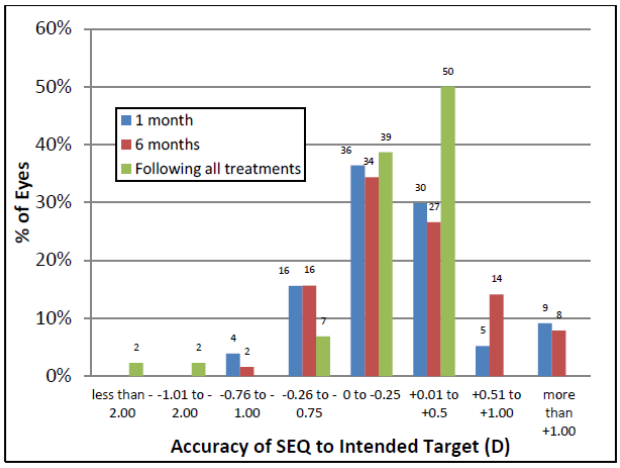

Figure 5: Spherical equivalent refractive accuracy following the primary treatment and following all treatments.

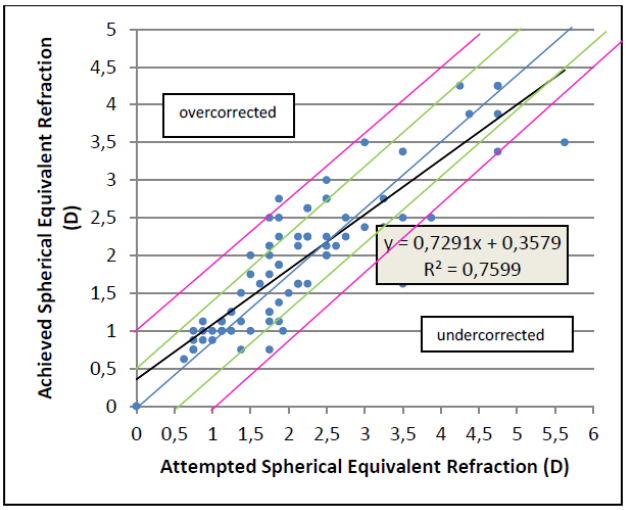

Figure 6: Scatterplot of attempted versus achieved spherical equivalent refraction six months after the primary treatment.

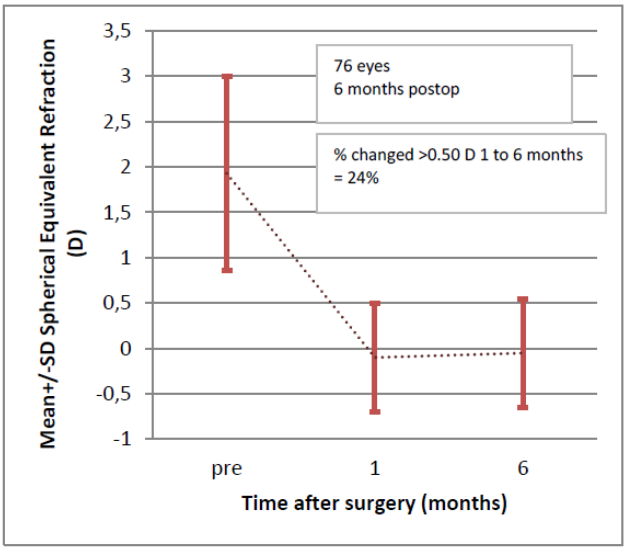

Figure 7: Stability of the SE refraction up to 6 months after the Supracor treatment.

Safety and postoperative refraction

The mean CDVA in eyes six months following the primary treatment that were over-corrected by 0.50 D or more was logMAR 0.00 (20/20), and was logMAR 0.00 (20/20) in eyes that were under corrected by 0.50 D or more.

The mean CDVA following all treatments in eyes that were overcorrected by 0.50 D or more was logMAR 0.00 (20/21.4), and was logMAR 0.02 (20/20.9) in eyes that were under corrected by 0.50 D or more.

Patient satisfaction

Three discrete groups of patients were retreated because of dissatisfaction with their outcome six months following the primary procedure. 13% of patients (5 patients) were not satisfied with their distance vision and underwent retreatment to correct this issue. 18% of patients (7 patients) were not satisfied with their near vision and underwent enhancement to improve near vision. 11% of patients (4 patients) underwent retreatments because of dissatisfaction with both near and distance vision. 14 of the 16 patients who were retreated were pleased that they had undergone the procedure (following all treatments). One patient had had retreatment because of dissatisfaction with near vision on two occasions in the non-dominant eye, once with +0.5 D, and once with +1.25 D; the binocular unaided near vision was J5 (N8) before retreatment; the final binocular unaided near visual acuity was J3 (N6); this patient remained persistently unhappy with near vision following all treatment. A second patient underwent one retreatment with +0.75 D in the nondominant eye because of dissatisfaction with near vision; the unaided binocular near vision before enhancement was J5 (N8), and the final binocular unaided near visual acuity was J3 (N6); this patient remained unhappy with their near vision following all treatment.

Following all treatments, 82% (31 patients) of patients were happy they had had the procedure performed.

Aberrations

Median total HOA RMS increased from 0.32 µm preoperatively to 0.46 µm postoperatively (p=0.004). The median total coma RMS did not significantly increase (0.12 µm to 0.14 µm) (p=0.35). Total trefoil did not increase (0.10 µm to 0.09 µm) (P=0.28). Spherical aberration changed from positive 0.18 µm preoperatively t negative 0.17 µm postoperatively, as anticipated (p<0.0001).

Discussion

In this study, we report the outcomes of a series of hyperopic presbyopes treated with Supracor. Using LASIK for presbyopia correction comes with the disadvantage of using mixed ablation profiles, which may create unwanted transition zones and so may harm distance visual acuity [13]. The proposed unique benefit of Supracor is that it avoids the creation of transition zones. In common with other studies [18,19], binocular unaided reading was excellent following Supracor treatment in this study. Postoperative uncorrected reading was J5 or better in in 93% of patients following the primary treatment, and J5 or better in 97% of patients following all treatments.

Our cohort of patients had a high retreatment rate relative to other users of the Supracor algorithm, despite using similar settings for Supracor, including the tissue saving algorithm, pupil centration, optical zone diameter and use of a mechanical microkeratome [18,19]. Other researchers have reported a retreatment rate of approximately 20% [13,18]. 42% of eyes in our study required at least one retreatment. In addition, we found that 12% of eyes lost one line of Snellen acuity and 3% of eyes lost 2 lines of Snellen corrected distance acuity following all treatments.

There is a variety of potential explanations for this high retreatment rate and loss of lines of corrected Snellen acuity.

In Supracor the line of sight is used routinely as the centration point of the ablation-there is debate as to whether the pupil is the most advantageous centration point. A number of studies report good

outcomes following ablations centred on the coaxially sighted corneal light reflex [20-22]. Other work suggests that outcomes are equally good following ablations centred on the line of sight [23] or on the pupil [24].

It is known that the tissue saving algorithm may cause there to be an increase in higher order aberrations because of its small blend-zone [25]. There have been a number of studies, however, in which small ablation zones combined with a large blend zone do not lead to an increase in higher order aberrations [26].

A combination of pupil-centred treatment, along with increased visual phenomena perhaps exacerbated by a small blend zone, in association with spherical aberration related to hyperpositive central Supracor treatment, may be responsible for the improvement in reading ability at the expense of distance vision.

Perceived or potential limitations of this study include reliance on clinical notes for patient satisfaction, rather than a questionnaire. Also, further studies may explore the risk factors for retreatment in supracor, as well as strategies for retreatment.

In conclusion, we report a high enhancement rate and loss of corrected distance vision in a cohort of patients undergoing Supracor refractive surgery. This may be related to a small blend zone, the hyperpositive central zone, and pupil centration.

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