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New technique for femtosecond laser creation of clear corneal incisions for cataract surgery

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Purpose: To evaluate the changes in corneal topography and corneal higher-order wavefront aberrations with the use of a new technique in which clear corneal incisions (CCIs) for cataract surgery are created with a femtosecond laser.

Setting: IRCCS Fondazione G.B. Bietti, Rome, Italy.

Design: Prospective randomized case series.

Methods: Cataract surgery patients were randomized into 2 groups. In the study group, a 3-plane CCI was created with a femtosecond laser. In the control group, the single plane-angled CCI was created manually using disposable knives. Simulated keratometry (K) values and corneal higher-order wavefront aberrations with 3.5 mm and 6.0 mm pupils were compared between groups.

Results: Each group comprised 10 eyes. At 6 months, the mean change in K values from preoperatively was 0.16 diopter (D) $\pm$ 0.14 (SD) in the study group and 0.34 $\pm$ 0.16 D in the control group, with no differences between groups ($P > .05$). The manual CCI significantly increased corneal higher-order wavefront aberrations with 3.5 mm and 6.0 mm pupils (both $P < .05$). In the study group, corneal higher-order wavefront aberrations increased significantly with a 6.0 mm pupil only ($P \leq .02$). The induced changes in corneal higher-order wavefront aberrations were significantly different between groups over both pupil sizes ($P < .05$).

Conclusions: The femtosecond laser–created CCI did not induce significant changes in simulated K or corneal higher-order wavefront aberrations over the mesopic pupil size. The lower amount of induced corneal higher-order wavefront aberrations with the new technique than with manual CCI could be related to the different geometry of the 2 techniques.

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Several commercial femtosecond laser platforms have been developed to perform clear corneal incisions (CCIs), the continuous curvilinear capsulorhexis, and cataract nucleus fragmentation.[1–5] In a previous laboratory study,[6] we assessed the changes induced by femtosecond laser–assisted CCIs on the corneal curvature of donor eye-bank eye globes. We found minimal changes in the anterior and posterior corneal topography with no induced corneal astigmatism after surgery in which a CCI was created with a commercial 150 kHz femtosecond laser (Intralase iFS, Abbott Medical Optics, Inc.). In subsequent clinical studies,[7,8] we compared the influence of femtosecond laser–created CCIs and manually created CCIs on corneal topography and corneal higher-order wavefront aberrations in the early postoperative period (up to 1 month follow-up). We created the CCIs with the same femtosecond laser platform as in our laboratory study. However, for the clinical studies, we developed a custom mask that was placed above the applanation cone immediately after corneal applanation. This approach was required because when the other studies were performed, that particular femtosecond laser did not permit one to select the corneal posterior and lamellar cut positions and angles.

Significant differences in corneal topography and corneal higher-order wavefront aberrations have been found only at the CCI site, with no clinically significant differences over the central cornea between the 2 techniques. Mastropasqua et al.[9] have shown that compared with the manual CCI technique, a femtosecond laser–created CCI results in less of a decrease in the endothelial cell count 7 days and 30 days postoperatively and less of an increase in corneal

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thickness at the site of CCI 30 days and 180 days postoperatively. Masket et al.[10] found that a single-plane, angled, 3.00 mm × 2.00 mm CCI is more stable than narrower incisions (from >1.00 to <2.00 mm), with less leakage at various levels of indentation pressure performed with an ophthalmodynamometer.

Recently, the Intralase iFS 150 kHz software added the Laser Cataract Suite, a new algorithm for creating CCIs with a femtosecond laser in cataract surgery. Here, we present the technique using this algorithm and report the 6-month outcomes in patients having cataract surgery with the CCI created using the new femtosecond laser algorithm or created manually.

PATIENTS AND METHODS

The study followed the tenets of the Declaration of Helsinki and was approved by the local ethical committee (Complesso Ospedaliero San Giovanni Addolorata, Roma, Italy). All patients signed an informed consent form after receiving an exhaustive explanation of the nature and risk of the procedure.

The inclusion criteria were a vision-impairing senile cataract, preoperative manifest refraction ranging from +4.00 to −6.00 diopters (D), and manifest astigmatism of 1.50 D or less. The exclusion criteria were previous ocular surgery, ocular hypertension or glaucoma, and corneal pachymetry thinner than 700 μm at the site of CCI, which was placed at 12 o'clock (superior) in all cases.

Group Allocation

Eligible patients were randomized after enrollment with an allocation ratio of 1:1 into the study group or the control group. Assignment of patients to either group was performed using the random number generator for simple randomization in the SPSS software program (version 17.1, SPSS, Inc.). In the study group, the CCI was created using 150 kHz Intralase iFS femtosecond laser. In the control group, the CCI was created manually with disposable knifes.

Surgical Technique

All surgeries were performed by the same surgeon (D.S.L.). Patients had phacoemulsification through a 2.75 mm incision.

In the study group, the CCI was created at the 12 o'clock position using the new algorithm of the femtosecond laser. A 3-plane CCI was programmed with the anterior and posterior cuts intersecting the lamellar cut at 30 μm from its anterior edge and posterior edge, respectively. The following laser parameters were used: anterior and posterior width, 2.75 mm; total length, 2.50 mm; anterior side cut, 30 degrees; depth of lamellar cut, 300 μm; posterior side cut, 30 degrees; energy level, 1.25 μJ; spot separation, 4 μm; and layer separation, 3 μm. A single-plane side port was positioned at 60 to 90 degrees with respect to the CCI, with an anterior width and posterior width of 1.00 mm and 0.95 mm, respectively; anterior side angle at 30 degrees; 1.25 μJ energy level; 4 μm spot separation; and 3 μm layer separation.

Each eye was applanated using the disposable flat interface contact lens of the system and the suction ring provided by the manufacturer. The suction ring was applied to visualize 1.0 mm of bulbar conjunctiva at 12 o'clock (Figure 1) to allow the placement of the CCI and side-port incision in clear cornea close to the corneal limbus. After the CCI was created, the patient was moved to the operating microscope for the phacoemulsification procedure (Infiniti, Alcon Laboratories, Inc.) and intraocular lens (Acrysof, Alcon Laboratories, Inc.) implantation.

In the control group, a single-plane angled CCI was created manually using a disposable 2.75 mm knife (Clear Cut, Alcon Laboratories, Inc.). Phacoemulsification was performed as in the study group.

Patient Assessment

All patients had a complete ocular evaluation preoperatively and postoperatively. The evaluations included logMAR corrected distance visual acuity (CDVA) using the Early Treatment Diabetic Retinopathy Study chart at 4 m, manifest refraction (expressed as spherical equivalent [SE] in diopters), corneal thickness measurement obtained with an ultrasound portable pachymeter (Pachmate DGH55, DGH Technology, Inc.), and corneal topography and aberrometry using a Placido disk topographer (Keratron, Optikon 2000). Corneal pachymetry was performed at the site of the CCI immediately before surgery. Corneal topography and aberrometry were performed preoperatively and 1 week, 1 month, 3 months, and 6 months postoperatively.

Postoperatively, a minimum of 3 topographic acquisitions were performed for each eye at each time interval. If the value varied by more than 10% between the acquisitions, another measurement was obtained. The best image was selected for analysis. All the preoperative and postoperative topographies were taken by the same expert observer (D.S.L.). The preoperative and postoperative tangential curvature values and the corneal higher-order wavefront aberrations values were exported and analyzed as described in previous studies.[11,12]

The analysis of corneal topography data included the simulated keratometry (K) and the anterior corneal curvature values at the site of main incision as previously described.[11,12] Curvature data were expressed as the mean ± SD and measured in diopters. The corneal higher-order wavefront aberrations were evaluated over simulated pupils of 3.5 mm and 6.0 mm diameters. The root mean square (RMS) of the higher-order corneal wavefront aberrations up to the 7th order was computed from the Zernike coefficients, and the recommended notation was used.[13,14] Further parameters analyzed included the RMS of coma (the square root of the sum of the squared coefficients of Z[3,−3] and Z[3,3]), the RMS of trefoil (the square root of the sum of the squared coefficients of Z[3,−3] and Z[1,3]), and the RMS of spherical aberration (the square root of the sum of the squared coefficients of Z[0,4] and Z[0,6]). The RMS data were expressed as the mean ± SD in micrometers.

Vector analysis of corneal cylinder was performed using adjusted axes for the left eye (adjusted axis = 180 degrees − original axis) and double angles to determine the changes in both direction and magnitude of cylinder from the preoperative visit to the postoperative visits.[8,11,12,15,16]

Statistical Analysis

Statistical analysis was performed using SPSS software (version 17.1, SPSS, Inc.) and R software (version 3.2.3, Alcatel-Lucent S.A.). The Wilcoxon signed-rank test was used to determine the changes in simulated K, the vector magnitude and vector angle of corneal astigmatism, and corneal higher-order wavefront aberrations at each postoperative time interval with respect to baseline in both groups and to assess the differences between the 2 CCI techniques. Sample-size calculation was performed to detect mean induced differences of 0.10 μm ± 0.12 (SD) between the average changes in corneal higher-order aberrations in the study group and control group at a significance level of 5% and a power of 80%. Differences with a *P* value of 0.05 or less were considered statistically significant.

RESULTS

Twenty patients (20 eyes) were recruited in the study. Ten eyes (study group: 4 men, 6 women) had a femtosecond laser–created CCI, and 10 eyes (control group: 5 men, 5 women) had a manually created CCI. The mean age was