Several factors can lead to poor incision architecture during phacoemulsification. These include incorrect construction by an inexperienced or even an experienced surgeon and stretching of the wound during difficult surgical cases.  

A study showed that when experienced surgeons attempted three-plane incisions only 32% were three-plane tunnels, 64% were two-plane tunnels, and 4% were one-plane tunnels.  

Studies using anterior segment optical coherence tomography (AS-OCT) after cataract surgery for corneal assessment at the incision site disclosed the most frequent architectural features of the cornea.  

Although contact ultrasound pachymetry is widely considered the gold standard for measurement of central corneal thickness, AS-OCT presents advantages in corneal imaging over ultrasonic devices, including two-dimensional imaging of the anterior segment that allows measurements from a cross-sectional image through a precise selected corneal location and the absence of any contact with the surface of the eye during examination.  

Recently, the use of femtosecond laser was introduced in cataract surgery to perform corneal incisions, capsulorhexis, and nuclear fragmentation.  

In a preliminary study on cadaver eyes, Masket et al. demonstrated that femtosecond laser-assisted cataract incisions were reproducible and stable, particularly for corneal incisions with a length of 2.0 mm.  

Femtosecond laser performance of CCI could potentially improve incision architecture by increasing the precision with which the automated incision is made and reducing

**ABSTRACT**

**PURPOSE:** To compare functional and morphological outcomes of femtosecond laser clear corneal incision (CCI) versus manual CCI during cataract surgery.

**METHODS:** Sixty eyes of 60 patients who underwent CCI during cataract surgery were randomized into two groups: femtosecond laser CCI (30 eyes) and manual CCI (30 eyes).

**RESULTS:** There were no significant between-group differences in uncorrected distance visual acuity, corrected distance visual acuity, surgically induced astigmatism, and corneal aberrations. Keratometric astigmatism was significantly lower in the femtosecond laser CCI group compared to the manual CCI group at 30 and 180 days ($P < .05$). Central endothelial cell count was significantly higher in the femtosecond laser CCI group compared to the manual CCI group at 7 and 30 days postoperatively ($P < .05$). A lower increase of corneal thickness at the incision site was observed at 30 and 180 days postoperatively in the femtosecond laser CCI group compared to the manual CCI group ($P < .05$). In addition, femtosecond laser CCI showed a better morphology (lower percentage of endothelial and epithelial gaping and endothelial misalignment) compared to manual CCI at different time points. Total phacoemulsification time was significantly lower in the femtosecond laser CCI group ($P < .05$).

**CONCLUSIONS:** The femtosecond laser procedure was safe, efficient, and less damaging, as evidenced by lower central endothelial cell loss, lower increase of corneal thickness at the incision site, and better tunnel morphology compared to the manual technique.

mechanical and thermal stress at the incision site during surgery. This greater precision should be associated with a more predictable surgically induced astigmatism, which is particularly important when implanting advanced technology intraocular lenses. Moreover, the use of femtosecond laser to perform some surgical steps lessens the need for other surgical instruments and reduces the overall cumulative dissipated energy by reducing or eliminating the need to implement ultrasound energy during lens extraction. Overall, this should also contribute to sparing tunnel anatomy.

In this study, we compared functional and morphological outcomes of femtosecond laser CCI and manual CCI during cataract surgery.

**PATIENTS AND METHODS**

The prospective study was performed at the Department of Ophthalmology of the Medical University of “G. d’Annunzio” after obtaining approval from our local ethics board, and adhered to the tenets of the Declaration of Helsinki. Sixty right eyes of 60 consecutive patients with cataract who were candidates for phacoemulsification and intraocular lens implantation and who met the inclusion and exclusion criteria were enrolled after informed consent was obtained.

The inclusion criteria were: age between 65 and 75 years, axial length between 23.0 and 24.0 mm, corneal astigmatism less than 2.00 diopters (D), nuclear cataract of grade 2 to 3 (nuclear opalescence 3/4) (Lens Opacities Classification System III), and corneal endothelial cell count greater than 1,200/mm. The exclusion criteria were: pathological alterations of the anterior segment (eg, corneal opacities, keratoconus, chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma, and diabetes mellitus), other ocular pathologies impairing visual function, previous anterior or posterior segment surgery, and intraoperative or postoperative complications.

The enrolled patients were randomized into two groups: femtosecond laser CCI (30 eyes of 30 patients) and manual CCI (30 eyes of 30 patients). Before cataract surgery, patients had a complete ophthalmologic examination including manifest refraction, corneal tomography by means of a Pentacam Scheimpflug System (Oculus Optikgeräte, Wetzlar, Germany), slit-lamp examination, applanation tonometry, cataract grade/type assessment, and ophthalmoscopy through dilated pupils. In addition, corneal endothelial cell count (cells/mm²) centrally and at the tunnel site was measured in all patients by a corneal confocal laser scanning microscope (HRT II Rostock Cornea Module, diode-laser 670 nm; Heidelberg Engineering GmbH, Heidelberg, Germany). The technical characteristics of the HRT II laser scanning confocal microscope and the procedure of endothelial cell count assessment have been previously described.

In all cases, the corneal thickness at the incision site was measured with anterior segment optical coherence tomography (AS-OCT) (Model 1000; Carl Zeiss Meditec, Inc., Dublin, CA). Corneal higher-order aberrations were measured using OPD-Scan II and OPD-Station software (NIDEK Co. Ltd., Gamagori, Japan) based on retinoscopic principles using infrared light. Aberration measurements were obtained at the baseline preoperative visit and during scheduled follow-up examinations after pupil dilation. In each patient, 5.0-mm pupil diameter was chosen as reference to obtain comparable data. The corneal root mean square of total higher-order aberrations and of single third-order coma (Z₁²), third-order trefoil (Z₁³, Z₃²), and fourth-order spherical (Z₄⁰) aberrations were calculated at each evaluation for each patient as the mean value of three reliable consecutive measurements.

**SURGICAL PROCEDURE**

One experienced surgeon (LM) performed both femtosecond laser-assisted and manual procedures. All surgical procedures were performed using standard surgical equipment.

**FEMTosecond LASer PROCEDURE**

In the femtosecond laser CCI group, the corneal incisions were performed using a LensX platform (Alcon Laboratories, Inc., Fort Worth, TX). The setting parameters for the primary corneal incision were a two-plane corneal incision at 130° with an incision width of 2.8 mm and incision length of 2.0 mm. An energy setting of 6.50 µJ, a spot separation of 5 µm, and a layer separation of 4 µm were used. The setting parameters of the secondary incision were one-plane corneal incision at 40° with an incision width of 1.0 mm. An energy setting of 7.0 µJ, a spot separation of 4 µm, and a layer separation of 4 µm were used.

The CCIs were performed at the end of the femtosecond laser procedure. Lens fragmentation was performed after the capsulotomy. The capsulotomy diameter was 4.6 mm. The upper and lower deltas of the capsule were set at 330 µm. The energy was 13 µJ with a spot separation of 3 µm and a layer separation of 3 µm. The lens was fragmented using a mixed chop (two chops using an energy of 15 µJ with a spot separation of 6 µm and a layer separation of 6 µm) and a cylindrical pattern (three cylinder using an energy of 15 µJ with a spot separation of 8 µm and a layer separation of 6 µm). The anterior and posterior offsets for lens fragmentation were 500 and 800 µm, respectively.
Manual Procedure

In the manual procedure, a temporal two-plane corneal incision (at approximately 130°) was made with a disposable keratome knife (2.75-mm ClearCut dual-bevel; Alcon Laboratories, Inc.) with a 2.75-mm width. A 2.0-mm long incision was made using the etched 2.0-mm mark on the ClearCut blade. The secondary incision was a one-plane corneal incision, located at approximately 40° with an incision width of 1.0 mm. The manual capsulorhexis was performed using the continuous curvilinear capsulorhexis technique with an intended diameter ranging between 5.0 and 5.5 mm. In all cases, lens fragmentation was performed with a “divide and conquer” technique.

Standard Surgical Procedures for Femtosecond Laser and Manual CCI

In both groups, standard phacoemulsification was used to complete the surgery with combined longitudinal/torsional ultrasound mode (longitudinal ultrasound linear power, 40% limits; continuous torsional phacoemulsification with linear amplitude, 100% limits; and vacuum limit fixed 300 mm Hg) using the Alcon Constellation System (Alcon Laboratories, Inc.). Intraocular lenses (AcrySof SN60WF; Alcon Laboratories, Inc.) were implanted in the capsular bag with a Monarch III injector and Monarch D Cartridge. The incision was not hydrated and was not sutured. Postoperative therapy consisted of ofloxacin 0.3% and dexamethasone 0.2% eye drops four times daily for 3 weeks.

Main Outcome Measures

The main outcome measures were uncorrected and corrected distance visual acuity (UDVA and CDVA, respectively), keratometric astigmatism, and corneal endothelial cell count centrally and at the tunnel site, corneal thickness at the incision site, and higher-order corneal aberrations.

The amount and axis of astigmatic change induced by the cataract surgery were assessed by calculating the surgically induced astigmatism. Power vector analysis of keratometric astigmatic change between preoperative and postoperative values was performed according to the Alpins method.10-12 To visualize the change in astigmatism induced by surgery, the astigmatic components of the power vector were analyzed by the two-dimensional vector (J_x, J_y).10

Intraoperative measurements included mean torsional and lateral mean phacoemulsification time, total time, and mean cumulative dissipated energy. The scheduled follow-ups of the main parameters evaluated in the study were set at 1, 7, 30, and 180 days postoperatively.

Statistical Analysis

This study was designed to show the differences of functional and morphological outcomes between groups. The main outcome was the difference in corneal thickness at the incision site at 180 days postoperatively. Assuming a difference of at least 0.25 mm with a standard deviation of 0.3 mm between the two groups, a minimum of 25 patients per group were required for an 90% power and 0.05% significance.

Shapiro-Wilk’s test was performed to detect departures from normality distribution. The results were reported separately for each group. The Student’s t test and chi-square analysis or Fisher’s exact test were performed where appropriate. Repeated measures analysis of variance was applied to analyze the differences between groups during the follow-up period for visual acuity parameters, keratometric parameters, endothelial cell count, and corneal thickness.

All statistical analyses were performed using SPSS Advanced Statistical 11 software (SPSS, Inc., Chicago, IL) software package and the “polar.plot” function of R open source software.

Results

Demographics and Preoperative and Intraoperative Data

The mean age was 70.2 ± 2.9 years (range: 65 to 75 years) in the femtosecond laser CCI group and 70.5 ± 3.2 years (range: 65 to 75 years) in the manual CCI group (P = .705).

The intraoperative surgical system parameters such as mean cumulative dissipated energy, total time, and mean torsional time were significantly different between the two groups, whereas statistically significant differences were not found for mean phacoemulsification time (Table 1).

The nuclear opalescence was not significantly different between the two groups (66.7% of Nuclear Opalescence grade 3 in the femtosecond laser CCI group vs 63.3% in the manual CCI group) (P = .996). There were no statistically significant differences between the groups according to UDVA and CDVA, preoperative keratometric topographic cylinder, endothelial cell count, and corneal thickness (Tables 2-3, Figures 1-2, and Figure A [available in the online version of this article]).

Visual and Refractive Outcome

UDVA and CDVA increased significantly postoperatively in both groups during the follow-up period (P < .001) but were not significantly different between the two groups at different time points (Table 2, Figure 1). Changes in the astigmatic power vector during
the follow-up period were statistically significantly different in the femtosecond laser CCI group and the manual CCI group (P < .001) (Table 3). Contrast analysis showed that the between-group differences were significantly different at 30 days for J₀ and at 180 days after surgery for J₄₅ (Table 3).

In vector analysis, the mean surgically induced astigmatism was 0.64 ± 0.32 D in the femtosecond laser CCI group and 0.69 ± 0.50 D in the manual CCI group. The between-group difference was not statistically significant (P = .779) (Figure B, available in the online version of this article).

**ENDOTHELIAL CELL COUNT AND CORNEAL THICKNESS AT INCISION SITE**

Postoperatively, there was a significant decrease of endothelial cell count at the center of the cornea in both groups compared with preoperative values (P = .05), with statistically significant differences between the two groups at 7 and 30 days (P < .05) (Figure A).
Endothelial cell count also decreased at the tunnel site in both groups compared with preoperative values without statistically significant differences between the two groups (Figure A).

Figure 2 shows the variation of corneal thickness for the two groups at different postoperative visits. The analysis of variance for repeated measures demonstrated the variation of corneal thickness during time ($P < .001$) and showed that the variation was significantly different depending on the group ($P = .007$). After 1 day postoperatively, the corneal thickness at the incision site significantly increased in both groups compared with preoperative values (114% increase in the femtosecond laser CCI group and 131% increase in the manual CCI group; $P = .006$) without showing statistically significant differences between groups. At 7 days postoperatively, there was a reduction of incisional corneal thickness in both groups compared to the previous time point without statistically significant differences between the two groups ($P > .05$, contrast analysis). At 30 and 180 days postoperatively, corneal thickness was significantly thicker in the manual CCI group compared to the femtosecond laser CCI group ($P < .05$, contrast analysis) (Figure 2).

**AS-OCT Features**

All corneal incisions in the femtosecond laser CCI and manual CCI groups were biplanar as planned preoperatively. AS-OCT showed different tunnel architectures: endothelial and epithelial gaping, misalignment at epithelial and endothelial sides, localized detachment of Descemet's membrane, and loss of coaptation along tunnel margins. Significantly lower percentages of endothelial and epithelial gaping and endothelial misalignment were found in the femtosecond laser CCI group compared to the manual CCI group at 30 days postoperatively (Table 4). Overall, the different AS-OCT patterns had similar modifications over time.
independent of femtosecond laser CCI or manual CCI. The extension of endothelial gaping usually reduced over time and was not present at 180 days after surgery. Epithelial gaping and localized detachment of Descemet’s membrane disappeared during the first month. Complete adhesion along tunnel margins was observed after 7 days in all cases.

CORNEAL HIGHER-ORDER ABERRATIONS

Postoperatively, the root mean square of corneal total higher order and root mean square of coma, trefoil, and spherical aberrations did not increase significantly and did not show significant differences between the two groups (Table A, available in the online version of this article).

DISCUSSION

In our study, 100% of patients in both groups showed biplanar CCI, as planned preoperatively. Nevertheless, the manual CCI group showed a significantly greater corneal thickness at the site of the incision compared to the femtosecond laser CCI group at 30 and 180 days postoperatively. This group also showed a significantly higher percentage of epithelial gaping at 1 and 7 days postoperatively compared to the femtosecond laser CCI group, a significantly higher percentage of endothelial gaping up to 30 days postoperatively, and endothelial misalignment at 180 days postoperatively.

Previous studies demonstrated that incision integrity was mainly affected by two factors: mechanical injury and thermal injury.1,13-15 Mechanical injury is caused by surgery instruments and thermal injury is usually due to ultrasonic energy. The use of femtosecond laser technology to perform CCI could produce a more precise incision profile. In addition, the use of this type of laser to perform the capsulorhexis and lens fragmentation could have reduced the mechanical trauma due to conventional instruments.

We also demonstrated a significant reduction of the cumulative dissipated energy and total phacoemulsification time in the femtosecond laser CCI group compared to the manual CCI group. In the former, this could have reduced the thermal injury at the incision site. Other studies have demonstrated a reduction of the effective phacoemulsification time using femtosecond laser cataract surgery.16,17 Takács et al. also demonstrated less corneal swelling and endothelial cell damage in patients undergoing femtosecond laser-assisted cataract surgery compared to a conventional phacoemulsification technique.18 In accordance with their results, we also found a lower central endothelial cell loss at 7 and 30 days in the femtosecond laser CCI group compared to the manual CCI group.

The CCI is related to the surgically induced astigmatism that influences the visual outcome after cataract surgery, particularly when planning to implant a toric or multifocal intraocular lens. Surgically induced astigmatism depends on several factors, including incision size, incision location, incision distortion, and healing. In our study, a significant difference was found at 30 days for J0 and at 180 days for J45 between the two groups with the lower variability of surgically induced astigmatism in the femtosecond laser CCI group compared to the manual CCI group.

The size and site of incision were the same for the two groups; thus, it can be argued that this difference could be due to the different tunnel morphology between the two groups at different time points. A possible explanation is that the use of femtosecond laser technology provided a more precise and reproducible tunnel architecture compared to the manual incision. Moreover, morphological modifications of the incision due to mechanical and thermal damage during the surgical cataract procedure could have influenced corneal astigmatism.

### Table 4

<table>
<thead>
<tr>
<th>Parameter (%)</th>
<th>1 Day</th>
<th>7 Days</th>
<th>30 Days</th>
<th>180 Days</th>
</tr>
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<tbody>
<tr>
<td>Endothelial gaping</td>
<td>85.7</td>
<td>88.9</td>
<td>.680</td>
<td>85.7</td>
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<tr>
<td>Epithelial gaping</td>
<td>28.6</td>
<td>33.3</td>
<td>.822</td>
<td>0.0</td>
</tr>
<tr>
<td>Endothelial misalignment</td>
<td>100.0</td>
<td>100.0</td>
<td>–</td>
<td>100.0</td>
</tr>
<tr>
<td>Epithelial misalignment</td>
<td>28.6</td>
<td>33.3</td>
<td>.822</td>
<td>14.3</td>
</tr>
<tr>
<td>Descemet membrane detachment</td>
<td>50.0</td>
<td>66.7</td>
<td>.721</td>
<td>14.3</td>
</tr>
<tr>
<td>Loss of coaptation along tunnel</td>
<td>14.3</td>
<td>11.1</td>
<td>.680</td>
<td>0.0</td>
</tr>
</tbody>
</table>

AS-OCT = anterior segment optical coherence tomography; FEMTO = femtosecond laser

*Chi-square test or Fisher’s exact test, when appropriate.*
In our patients there were no differences in the corneal higher-order aberrations after surgery and no significant differences of UDVA and CDVA. Femtosecond laser procedures were safe and efficient in inducing lower central endothelial cell loss, lower increase of corneal thickness at the incision site, and better tunnel morphology compared to manual technique.

**AUTHOR CONTRIBUTIONS**

Study concept and design (MD, LM, LT, RM); data collection (AM, EP, LV); analysis and interpretation of data (AM, LT); drafting of the manuscript (LT); critical revision of the manuscript (MD, AM, EP, LV, RM); statistical expertise (MD); supervision (LM)

**REFERENCES**


Figure A. Postoperative mean ± standard error (SE) of corneal endothelial cell counts (ECC) (A) central and (B) tunnel by group at different visits. A: \(P = .093\) for time effect, \(P = .050\) for treatment effect and \(P = .845\) for interaction. B: \(P = .219\) for time effect, \(P = .285\) for treatment effect and \(P = .942\) for interaction. FEMTO = femtosecond laser clear corneal incision group; Manual = manual clear corneal incision group.

*\(p<0.05\) Contrast analysis FEMTO vs Manual

Figure B. Individual vectors in vector analysis of surgically induced astigmatism for the femtosecond laser clear corneal incision group (upper panel) and for the manual clear corneal incision group (lower panel).
<table>
<thead>
<tr>
<th>Corneal Wavefront</th>
<th>Preoperative</th>
<th>Postoperative 7 Days</th>
<th>Postoperative 30 Days</th>
<th>Postoperative 180 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOA</td>
<td>0.25 ± 0.11</td>
<td>0.30 ± 0.05</td>
<td>0.37 ± 0.09</td>
<td>0.45 ± 0.19</td>
</tr>
<tr>
<td>Coma</td>
<td>0.14 ± 0.07</td>
<td>0.15 ± 0.10</td>
<td>0.16 ± 0.07</td>
<td>0.17 ± 0.10</td>
</tr>
<tr>
<td>Trefoil</td>
<td>0.13 ± 0.09</td>
<td>0.16 ± 0.12</td>
<td>0.24 ± 0.14</td>
<td>0.33 ± 0.19</td>
</tr>
<tr>
<td>Spherical</td>
<td>0.11 ± 0.06</td>
<td>0.11 ± 0.07</td>
<td>0.09 ± 0.10</td>
<td>0.11 ± 0.06</td>
</tr>
</tbody>
</table>

FEMTO = femtosecond laser-assisted clear corneal incision
*Contrast analysis, FEMTO vs manual