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Comparison of wound architecture in implantable collamer lens surgery: Self-sealing single-plane opposite clear corneal incision versus main surgical incision

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Abstract

Purpose: Incision architecture can play an important role in corneal astigmatism management through peripheral corneal relaxing incisions. The aim of this study was to compare the incision architecture of single-plane opposite clear corneal incisions (OCCIs) and main surgical incisions (MSIs) in patients undergoing implantable collamer lens (ICL) surgery.

Methods: A retrospective cross-sectional tomographic analysis of MSI and OCCI architectures was performed 6 months after ICL surgery. Image acquisition was performed using spectral-domain anterior segment optical coherence tomography.

Results: A total of 31 OCCIs and 24 MSIs were evaluated. The mean incision angle was 42.83 ± 5.69 degrees for MSIs and 48.26 ± 6.07 degrees for OCCIs ($p < 0.01$), and the mean MSI and OCCI length was 1146.70 ± 150.48 μm and 976.68 ± 140.19 μm, respectively ($p < 0.01$). The mean increase in epithelium depth in the wound was 37.63 ± 11.91 μm in the MSI group and 47.64 ± 15.45 μm in the OCCI group ($p = 0.02$). Endothelial misalignment was observed in both types of incisions. However, the misalignment with MSI was greater than with OCCI, 106.67 ± 31.84 μm versus 83.75 ± 23.39 μm ($p = 0.01$), respectively.

Conclusion: Both types of incisions, OCCI and MSI, were shown to be safe with complete wound sealing and healing 6 months postoperatively. The MSIs performed in the temporal position were more angled and longer, with greater endothelial retraction and minor epithelial thickening in the wound area compared with astigmatic incisions without manipulation.

Keywords

Wound architecture, opposite clear corneal incision, main surgical incision

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Introduction

Management of corneal astigmatism in intraocular lens (IOL) surgery is crucial to achieve excellent postoperative refractive outcomes. Peripheral corneal relaxing incisions have been shown to be a safe and effective method to reduce pre-existing corneal astigmatism in IOL cataract surgery,[1–3] as well as in phakic refractive IOL surgery.[4] The opposite clear corneal incision (OCCI), in particular, is a technique that is relatively easy to perform and no additional technology or equipment is needed.

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Some authors, however, have suggested that there is a greater theoretical risk of endophthalmitis when making additional corneal incisions compared to conventional surgery.[5,6] The study of incision architecture in the early postoperative period is critical to understand the role that wound tightness plays in endophthalmitis. In addition, it is known that postoperative astigmatism can change during the wound healing process and stabilizes around 3 months after surgery.[3] Consequently, it is important to have a thorough knowledge of the characteristics of astigmatism incision architecture over the mid-to long-term to understand their influence on astigmatism management when using OCCIs. The architecture of the main surgical incision (MSI) in cataract surgery has been extensively studied.[7–14] In the early post-operative period, a certain degree of epithelial and endothelial gap,[8,15] local Descemet's membrane detachment (DMD)[8] and subsequent misalignment of the endothelial incision or endothelial retraction can be observed using anterior segment optical coherence tomography (AS-OCT).[12] The total sealing surface damage of the incision and local DMD tend to appear spontaneously during the first few weeks after surgery, disappearing several months later.[8,12] Nevertheless, it seems that endothelial misalignment persists and increases in the late postoperative period.[12] Although there appears to be a consensus in the literature on the changes that occur in the architecture of main cataract surgery incisions, to the best of our knowledge, no studies have been published on the changes produced by astigmatic incisions without manipulation. In addition, we found no studies of corneal incision architecture assessed by AS-OCT in posterior chamber phakic lens surgery (implantable collamer lens, ICL). Therefore, the main objective of this study was to analyze the architectural features of the main incision and the astigmatic incisions in phakic ICL implantation once the healing process is complete.

Methods

Design and subjects

A retrospective cross-sectional tomography analysis of MSI and OCCI architectures was performed 6 months after phakic ICL surgery. All patients included in the study were informed in detail about the surgical procedure before providing written informed consent. The study conformed to the standards of the Declaration of Helsinki and the research was approved by the Research Ethics Committee of Reina Sofia Hospital, Córdoba, Spain. All consecutive patients undergoing phakic refractive ICL surgery combined with OCCI to manage preoperative corneal astigmatism at La Arruzafa Ophthalmology Institute, Cordoba, Spain, between January and March 2021 were included. The inclusion criteria were: (1) healthy eyes, (2) anterior chamber depth greater than 2.8 millimeters, (3) intraocular pressure between 10 and 21 mmHg, (4) endothelial cell count greater than 2000 cell/millimeter2 (5) refractive cylinder power less than 1.50 diopters and (6) regular corneal astigmatism less than 2.00 diopters (Pentacam sim K). The exclusion criteria were: (1) previous ocular surgery, (2) signs of inflammation or moderately dry eyes evaluated by slit lamp and (3) irregular corneal astigmatism (non-orthogonality between both the main corneal meridian and asymmetric bow-tie topography). An exhaustive preoperative analysis was performed to ensure the appropriate selection of patients for this type of refractive surgery. This analysis comprised a complete anamnesis, cycloplegic and non-cycloplegic refraction, corneal tomography using two devices: OCULUS Pentacam® AXL (Wetzlar, Germany) and AS-OCT Tomey CASIA 2 (AJL Ophthalmic, Spain), static pupillometry using a Colvard infrared pupillometer (OASIS Medical, Inc. Glendora, California), endothelial cell count (Specular Microscope CEM-530, Nidek, CO., LTD. Gamagori, Japan), anterior segment slit lamp examination and retinal evaluation. All patients were informed of the surgical alternative to the spherical ICL implant along with the implementation of OCCI for the correction of their ametropia, such as toric ICL implantation or bioptics (a combination of two surgeries: spherical phakic IOL implantation and corneal refractive surgery to compensate for the residual astigmatism).

Surgical technique

All procedures were performed by the same experienced refractive surgeon (A.C.O). Topical (double anesthetic, tetracaine 0.1% and oxybuprocaine 0.4%, Colircursi®, ALCON, Fort Worth, Texas, United States) and 0.3 mL intracameral anesthesia (balanced salt solution, BSS PLUS®, and 5% lidocaine hydrochloride, B. Braun, Melsungen, Germany) injection through the MSI was used. Before surgery, and after complete mydriasis was achieved with application of one drop of tropicamide (Colircursi® tropicamide, ALCON, Fort Worth, Texas, United States) every 15 min, the 0–180 meridian was marked with the patient sitting in an upright position to avoid the risk of misalignment of the steep meridian during surgery due to possible torsional eye movement. A Gimbel/Mendez-Koch 135° fixation ring (Mastel Precision Surgical Instruments, South Dakota, United States), aligned with the previously made marks on the horizontal meridian, was used to identify the steep meridian. The main incision was created in the temporal clear cornea (in right and left eyes) close to the limbus using a 3.00-mm keratome ophthalmic surgical knife (OPHTEC, Groningen, Netherlands). A 1 mm paracentesis was performed 90 degrees from the main incision. All astigmatic OCCIs were performed on the steep meridian using a

3.2 mm incision size independent of the amount and orientation of the corneal astigmatism meridian. All wounds were constructed using a self-sealing single-plane clear corneal incision located 1 mm into the limbus. Lastly, the wounds were hydrated with balanced salt solution (BSS).

The phakic Visian ICL (STAAR Surgical, California, United States) was implanted horizontally in all patients. The STAAR Surgical Online Calculation and Ordering System was used to calculate the sizing. The parameters necessary for this calculation, including white-to-white, keratometry, refraction, anterior chamber depth and central cornea thickness, were measured with an OCULUS Pentacam® AXL (Wetzlar, Germany) Scheimpflug-based tomography system in the preoperative visual measurements. Postoperative topical corticosteroid and antimicrobial therapy with Maxidex® 1 mg/mL and Vigamox® 5 mg/mL (ALCON, Fort Worth, Texas, United States) was prescribed every 8 h for one week. The non-steroidal anti-inflammatory Yellox® 0.9 mg/mL (PharmaSwiss S.A., Prague, Czech Republic) was used twice daily for the first few months after surgery.

Measurements

Image acquisition was performed using spectral domain AS-OCT, Spectralis (Heidelberg Eng. Heidelberg, Germany). Image captures of 11 B-scans 6 mm in length were taken centered on each incision and all of them were located perpendicular to the limbus (Figure 1(a)). Subsequently, the following parameters were measured with a caliper: epithelial thickness at and adjacent to the incision (Figure 1(b)), angle to the anterior surface of the cornea (Figure 1(c)), endothelial retraction (Figure 1(d)), wound length and corneal thickness at the incision (Figure 1(e)) and the distance between the wound and the limbus line. OCCI diameter was measured as the distance between the two intersections of both astigmatic CCIs and the anterior corneal surface (AS-OCT tomograph CASIA 2, Tomey GmbH, Nuernberg, Germany). All measurements were performed by a single examiner. To avoid the risk of bias in manual quantification using the caliper, 3 measurements were made, and the mean value was recorded. The angle, pachymetry and length of the incision were measured in central B-Scan number 6 (Figure 1(a)), while the epithelial thickness of the incision as well as the degree of endothelial retraction were measured in the cut representing its greatest extent. External online software (RULER software developed by the Polytechnic University of Valencia) was used to measure the angle since the Spectralis SD-OCT software does not have an angle meter (Figure 1(c)).

Statistical analysis

The data analysis was performed using IBM® SPSS Statistics software version 26.0. The normal distribution was analyzed with the Shapiro-Wilk test, and parametric (*t*-test) or non-parametric (Mann-Whitney U test) inferential tests were applied depending on the nature of the different quantitative continuous variables. The chi-square test was used for qualitative parameters. Pearson's correlation (r) was used to evaluate the relationship between different variables. The statistical power was calculated when significant differences were obtained in the hypothesis contrast. A p-value <0.05 was considered statistically significant.

Results

A total of 55 clear corneal incisions (CCIs) performed on 24 eyes belonging to 24 patients were evaluated. Of these, 31 CCIs were unopened astigmatic keratotomies, not manipulated during surgery, while 24 were MSIs performed on the temporal side. Of the total non-manipulated astigmatic CCIs (31), 71% (22) were made in the vertical meridian, 19% (6) in the oblique meridian and 10% (3) in the horizontal meridian. The mean patient age was 34.64 ± 9.30 years (range: 23–49 years).

The MSI was made with a 3.0 mm blade while all astigmatic incisions were performed systematically with a 3.2 mm blade positioned on the steepest corneal meridian independent of the preoperative astigmatism.

All CCIs were made close to 1 mm into the corneoscleral limbus. The mean distance between the wound and the limbus line was 0.69 ± 0.16 mm (range: 0.46–1.14 mm) for astigmatic incisions versus 0.54 ± 0.16 mm for MSIs ($p = 0.02$). A positive linear correlation was observed between the white-to-white measurement and the OCCI diameter, $r = 0.83$, $p < 0.001$ (Pearson's correlation).

The measurements for the two types of incisions are shown in Table 1. The mean angle of incision was 42.83 ± 5.69 degrees for MSIs versus 48.26 ± 6.07 degrees for OCCIs. This discrepancy between both types of incision was significant ($p < 0.01$; statistical power 92%). Since all wounds were created through a single-plane incision, the clear corneal incision length was measured as a straight line. The mean incision length was 1146.70 ± 150.48 µm for the MSIs and 976.68 ± 140.19 µm for the OCCIs ($p < 0.01$; statistical power 100%). A decrease in the angle of the incision with respect to the tangent line of the anterior surface of the cornea was highly correlated with an increase in incision length, $r = -0.86$, $p < 0.001$.

The increased depth of epithelium in the wound was measured as the difference between the depth of the epithelium over the wound minus the depth of the surrounding anterior epithelium (within two millimeter of the wound). The MSIs had a mean increase in epithelium depth of 37.63 ± 11.91 µm while the mean increase in epithelium depth in the astigmatic incisions was 47.64 ± 15.45 ($p = 0.02$). There was no significant difference in pachymetry

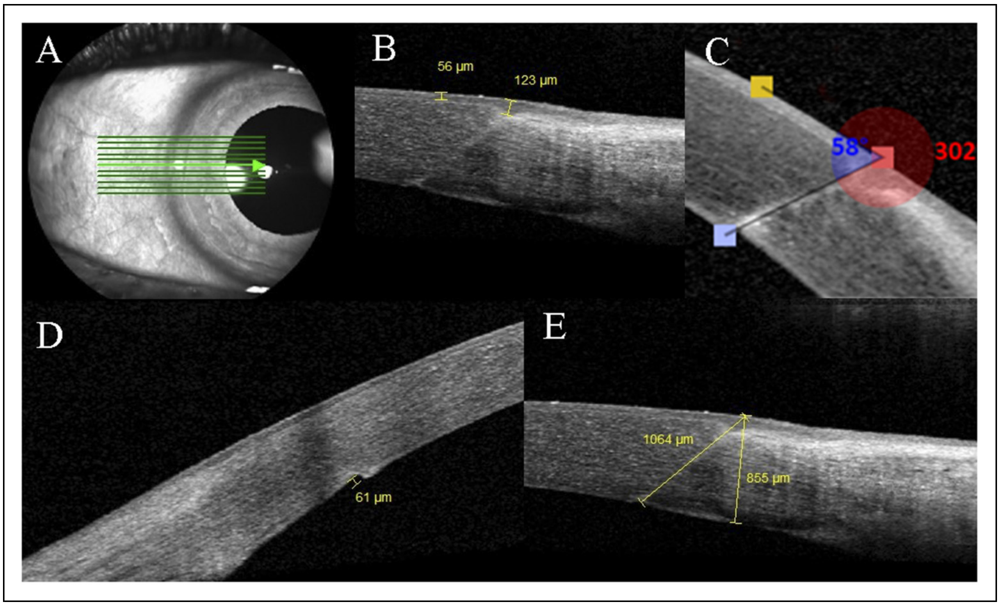

Figure 1. Central B-scan image of the limbus (6/11) perpendicular to the incision (a); epithelial thickness at the incision (123 µm) and adjacent anterior to the incision (56 µm) (b); angle to the anterior surface of the cornea (58°) (c); slight endothelial misalignment (61 µm) (d); incision length (1064 µm) and pachymetry (855 µm) (e).

Table 1. Incisional architecture features: MSI vs OCCI.

	MSI (n = 24)	OCCI (n = 31)	P-Value
Incision length (µm)			
Mean ± SD Range	1146.70 ± 150.48 (825 to 1393)	976.68 ± 140.19 (755 to 1215)	<0.01
Incision pachymetry (µm)			
Mean ± SD Range	786.92 ± 60.97 (681 to 900)	757.06 ± 78.73 (628 to 996)	0.13
Incision angle (degree)			
Mean ± SD Range	42.83 ± 5.69 (38 to 58)	48.26 ± 6.07 (33 to 60)	0.01
Incision increased epithelium (µm)			
Mean ± SD Range	37.63 ± 11.91 (13 to 63)	47.64 ± 15.45 (20 to 73)	0.02
Endothelial retraction (µm)			
Mean ± SD Range	106.67 ± 31.84 (55 to 166)	83.75 ± 23.39 (55 to 160)	0.01
Endothelial retraction %	70.0%	67.7%	0.56

MSI: Main surgical incision; OCCI: opposite clear corneal incision; µm: microns; SD: standard deviation.

measured at the wound site, 786.92 ± 60.97 µm for MSIs versus 757.06 ± 78.73 for astigmatic incisions ($p = 0.13$) (Table 1).

A certain degree of endothelial misalignment was observed in both types of incisions. Endothelial retraction occurred in 75.0% of the cases in MSIs while in astigmatic incisions this occurred in 67.7% ($p = 0.56$). In addition, the misalignment seen in the main incision was greater than in the OCCIs, 106.67 ± 31.84 compared to 83.75 ± 23.39 ($p = 0.01$; statistical power 87%). Spearman rho (ρ) was used to assess the relationship between endothelial retraction and wound length. The endothelial retraction was correlated with the wound length, $\rho = 0.65$, $p = <0.001$. All incisions were well sealed by stromal hydration, and none required sutures. There was no indication of epithelial or endothelial gaping in any of the cases. Local DMD, often seen in the immediate postoperative period, was noted in only one case in the 6 months after surgery (Figure 2(e)).

Discussion

Research using AS-OCT to study CCIs has provided remarkable insight into wound architecture. Early preoperative wound analysis using AS-OCT is crucial for understanding the risks of postsurgical endophthalmitis associated with loss of wound tightness.[16,17] Regarding incisional astigmatic surgery, wound architecture could

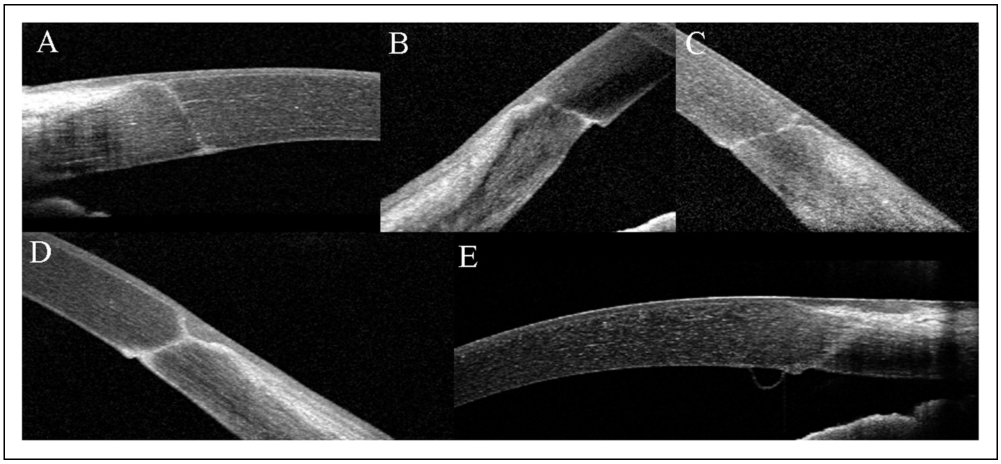

Figure 2. Good endothelial alignment in a single-plane self-sealing clear corneal incision (a); high resolution AS-OCT image showing an endothelial wound retraction (b); epithelial growth at the wound site in an astigmatic incision (c); large epithelial growth softening a large irregularity at the anterior aspect of the incision (d); local detachment of Descemet's membrane (e).

influence the flattening of the steep meridian.[18] The refractive stability of the incision occurs from the third month.[19,20] Therefore, our research team considers it necessary to evaluate the corneal architecture at this follow-up, when the healing process has concluded, and incision morphology is stable.

Two types of clear corneal incisions can generally be distinguished: triplanar incisions and single-plane incisions. The former is more effective in terms of controlling aqueous humor leakage and the incision remains better sealed.[21] However, it is a more difficult incision to construct even for experienced surgeons.[21] Calladine et al. observed that only 32% of the wounds visualized postoperatively had a 3-plane incision despite their intention to perform this incision in all cases.[22] Triplanar incisions are more accurate and effective when using the femtosecond laser, achieving good wound coaptation without the need for additional hydration.[8,23] Single-plane incisions are easier to make; however, their tightness can be compromised in wide and shorter incisions. Arched single-plane incisions in which the length of the arcuate incision is longer than its incision chord appear to be safer in terms of wound tightness and the sliding of one lip over another.[22,24] Despite this, in our study we found correct wound sealing in all cases by performing a sutureless single-plane incision of up to 3.2 mm.

A statistically significant difference was found when comparing the angle of the OCCI with that of the MSI. The main incision was performed at a smaller angle to the corneal surface. The authors believe that the systematic execution of the main incision in the temporal zone allows for greater angulation of the knife because this zone is free of ocular appendages. However, the angle of the incisions located outside the temporal area may be limited by the nose, cheekbone or upper orbital ridge, leading to greater angulation of the incision by the surgeon. Furthermore, in line with the study by Calladine et al.,[22] we found a negative correlation between incision angle and incision length (smaller angles produce longer incisions than more vertical angles). Due to this close relationship, angulation is of vital importance in maintaining the tightness of the incision in a single-plane incision. Fine et al.[24] suggested that incisions with a chord length of at least 2000 μm are recommended for the construction of self-sealing corneal incisions. However, in our study, a good level of wound tightness was found in both the main incision and the astigmatic incisions, despite having a mean length of 1146.70 ± 150.48 μm and 976.68 ± 140.19 μm, respectively.

In relation to epithelial changes in the wound area, we found greater epithelial thickness in the astigmatic incisions compared to the main incisions: 47.64 ± 15.45 μm versus 37.63 ± 11.91 μm, respectively ($p = 0.02$). It is well known that the corneal epithelium has a restorative ability in the presence of an alteration in the normal morphology of the cornea. The epithelium is therefore a tissue composed of restorative cells with a great capacity for migration and localization of altered areas. The authors hypothesize that the greater changes that occur in OCCI compared to MSI are due to the greater angle of the astigmatic incision producing increased indentation of the wound edges thus resulting in a more pronounced accumulation of epithelial cells (Figure 2(c) and (d)). This assumption is supported by the fact that when the angle of the incision is more perpendicular, gaping tends to occur at the epithelial side.[22] In MSIs, which are less angled, there is greater alignment between the outer edges of the wound, which makes this irregularity smoother.

Concerning the morphology of the posterior part of the wound, in most incisions, endothelial misalignment occurs, caused by a retraction of the distal lip and a protrusion zone in the most central part (Figure 2(b)). Several authors have described endothelial misalignment in the main incision in cataract surgery in both the short and long term[7,22,25] that is greater in the first few weeks after surgery.[14,17] The authors, in agreement with the suggestions made by Calladine et al.[22] and Fukuda et al.,[14] hypothesize that the anterior lip protrusion results from increased stromal hydration in the roof of the incision. This may be due to less resistance to the edema in the area more distal to the limbus. Although incisional stromal swelling due to hydration with balanced salt solution has been shown to disappear within two weeks,[14,26] its effect on wound architecture could be permanent. Furthermore, an elevated IOP can promote pressure from the floor of the wound towards its roof.[22] In the present study, greater misalignment of the main incision was found in comparison with astigmatic incisions that were not manipulated during surgery: 106.67 ± 31.84 µm versus 83.75 ± 23.39 µm, respectively ($p < 0.05$). Edema of the MSI due to its manipulation together with posterior wound hydration could explain these results. Indeed, endothelial misalignment in the MSI from incisional edema has been described in cases where no additional wound hydration was applied.[14,22] Moreover, MSIs may require more hydration than astigmatic incisions.

Regarding epithelial and endothelial gaping, none was found in either of the two groups, and local DMD occurred in only one case (Figure 2(e)). These findings usually appear in the early postoperative period within the first week, tend to resolve, and are not found after about three months of surgery.[12,14] Some authors suggest that an inappropriate incision angle and low intraocular pressure at the end of the surgery may increase the likelihood of incision gaping.[10,14]

The present study has some limitations, such as the small sample size and cross-sectional design. However, despite the small sample size, high statistical power was obtained in the hypothesis contrast. Furthermore, to the best of our knowledge, this is the first study to compare the corneal architecture in MSIs and OCCIs without manipulation during surgery. In addition, although analyses of corneal incisions by AS-OCT in cataract surgery have been published previously, ours is the first study performed in ICL. Our outcomes in ICL implantation should be contrasted with those found in the scientific literature on cataract surgery, as some authors suggest that the results found in phacoemulsification surgery may be due to the size of the phacoemulsification instruments, pressure fluctuations during surgery or the energy transmitted during ultrasound.[9,17] Further research with a larger sample is needed to confirm our findings.

In conclusion, both the self-sealing hydrated single-plane OCCI and the MSI were shown to be safe, with complete sealing and healing of the wound 6 months postoperatively. The main incision made in the temporal position is a more angled and longer incision, with greater endothelial retraction and a minor epithelial increase in the wound area compared with astigmatic incisions without manipulation. No local DMD, endothelial gaping or epithelial gaping was found in either group.

Declaration of conflicting interests

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