Corneal incision width after lens implantation: comparing delivery systems

Carlo Cagini, Maria Teresa Perri, Anna Pia Di Napoli, Tito Fiore, Marco Messina, Leopoldo Spadea, Gian Maria Cavallini

PII: S2452-4034(17)30011-0
DOI: https://doi.org/10.1016/j.xjec.2018.04.001
Reference: XJEC 3

To appear in: *Journal of EuCornea*

Received Date: 29 June 2017
Revised Date: 26 February 2018
Accepted Date: 2 April 2018

Please cite this article as: C. Cagini, M.T. Perri, A.P.D. Napoli, T. Fiore, M. Messina, L. Spadea, G.M. Cavallini, Corneal incision width after lens implantation: comparing delivery systems, *Journal of EuCornea* (2018), doi: https://doi.org/10.1016/j.xjec.2018.04.001

Corneal incision width after lens implantation: comparing delivery systems

Corneal incision width and injector systems

Carlo Cagini MD[1], Maria Teresa Perri MD[1], Anna Pia Di Napoli MD[1], Tito Fiore[1], Marco Messina[1], Leopoldo Spadea MD[2], Gian Maria Cavallini MD[3]

1. Ophthalmology Section, Dept. of Surgery and Biomedical Science, University of Perugia, Italy
2. Dept. of Biotechnology and Medical-Surgical Science, "Sapienza" University of Rome, Latina, Italy
3. Ophthalmology Institute, University of Modena, Modena, Italy.

The authors declare no conflict of interest.

Corresponding author:

Prof. Carlo Cagini, M.D.

Ophthalmology Section, Dept. of Surgical and Biomedical Science,

University of Perugia, Ospedale S. Maria della Misericordia, S. Andrea delle Fratte, Perugia, Italy 06156

E-mail: carlo.cagini@unipg.it; carlocagini@hotmail.com

Tel.: +39 75 5783944, Fax: +39 75 5783951

Abstract

Purpose: to compare corneal incision width after phacoemulsification and intraocular lens implantation (IOL) using different delivery systems.

Methods: one hundred and seventeen patients with cataract and no other anterior segment pathological features or previous eye surgery underwent cataract surgery with IOL implantation through a 2.2 mm incision. Three foldable IOL were implanted with their recommended delivery systems: Acrysof© SN60WF with Monarch© III/cartridge D (Group A, 38 patients); Tecnis© ZCB00 with Unfolder Platinum/cartridge easy load (Group B, 38 patients); Acrysof© SN60WF with Ultrasert™ preloaded system (Group C, 42 patients). Incision width was measured before and after phacoemulsification and IOL implantation.

Results: Before and after phacoemulsification incision width was, respectively, 2.21 ± 0.02 mm and 2.34 ± 0.08 mm in group A; 2.20 ± 0.02 mm and 2.31 ± 0.06 mm in group B; 2.20 ± 0.02 mm and 2.30 ± 0.07 mm in group C. Incision width was not significantly enlarged after phacoemulsification. Before and after IOL implantation incision width was, respectively, 2.34 ± 0.07 mm and 2.47 ± 0.07 mm in group A; 2.32 ± 0.06 mm and 2.45 ± 0.08 mm in group B; 2.30 ± 0.07 mm and 2.39 ±0.07 mm in group C. Incision widths in group C were significantly different to groups A and B. No relationship was found between incision sizes and phacoemulsification time, ultrasound energy and IOL powers.

Conclusion: In cataract surgery Ultrasert™ enlarges the corneal incision less than other delivery systems.

Key words: incision width; cataract surgery; phacoemulsification; intraocular lens; delivery system

Introduction

Cataract surgery has made considerable progress in recent decades. The development of surgery through small incisions, which was undoubtedly a major step forward, has provided several benefits such as no main incision sutures, less induction of lower and higher order aberrations, rapid wound healing and faster visual rehabilitation [1,2,3,4]. In this type of operation, incision architecture plays a major role in post-operative stability and wound water-tightness [5]. To facilitate intraocular lens (IOL) insertion through small incisions in conformity with lens morphology, most major companies developed injector systems for IOL implantation. Compared with forceps implantation, these devices ensure smaller incisions, more sterile procedures and better protection of the corneal endothelium [6]. A new pre-loaded IOL injector system, called Ultrasert™ (Alcon Laboratories, Inc.), recently came on to the market. IOL insertion was expected to be smooth as its cartridge tip is equipped with a stop to limit its entrance into the anterior chamber and reduce its impact upon incision architecture.

The present study analyzed and compared corneal incision widths after cataract phacoemulsification surgery with IOL implantation using Ultrasert™ and other injective systems. It also investigated relationships between incision size and some intra-operative parameters.

Material and methods

This prospective, randomized study recruited patients aged ≥18 years with cataract who were referred to the Section of Ophthalmology of the Department of Biomedical and Surgical Sciences of University of Perugia. All underwent phacoemulsification and posterior chamber IOL implantation. Exclusion criteria were: any relevant eye disease such as corneal pathologies, hypertension, uveitis, previous ocular surgery and glaucoma; pregnancy or breastfeeding; inability to understand study procedures. Ethics committee approval was obtained (CEAS Umbria, Prot n. 2632/15) and the principles outlined in the Declaration of Helsinki were followed in this study.

Immediately before surgery patients were randomly divided into three groups. Group A was assigned to receive the hydrophobic acrylic aspheric intraocular lens Acrysof© SN60WF (Alcon Laboratories, Inc.) which was implanted with Monarch© III D cartridge. Group B received the hydrophobic acrylic aspheric intraocular lens Tecnis© ZCB00 (Abbott Medical Optics Inc.) which was implanted with Unfolder© Platinum cartridge easy load. Group C received the hydrophobic acrylic aspheric intraocular lens Acrysof© SN60WF who was implanted with Ultrasert™ preloaded system. One experienced surgeon (CC) performed all operations using a Centurion© Phacoemulsification System (Alcon Laboratories, Inc.) under topical and intra-cameral anesthesia. A temporal limbal incision was made with a pre-calibrated 2.2 mm sharp. Two side-port incisions were made with a 15° knife and after continuous curvilinear capsulorrhexis, lens emulsification was performed with various cracking

procedures based on the cataract grade. An Intrepid© Balanced Tip 30° 0.9 mm and an Ultra Sleeves were used. Surgical phacoemulsification times and power were recorded in every case. Cortical material was removed through the side-port incisions by means of bimanual irrigation and an aspiration system. In patient of group A and group B IOLs were implanted after proper IOL loading and using the cartridge-insertion technique [7]; in group C through-the-wound technique was used; incisions were left sutureless. Internal incision width was measured by a caliper (Incision Gauge Set, Bausch+Lomb, Storz) and a caliper larger than the expected size was tested and in a second time smaller gauges were used until the caliper just passed completely through the incision. This was done in order to avoid manoeuvres that can enlarge the incision width. Incision width was measured at 4 time-points: before and after phacoemulsification, and before and after IOL implantation. All procedures were completed without any intraoperative complications and there were no reports of postoperative surgery-related adverse events as wound leaking, or infections.

Statistical Analysis

Between-group comparisons of width incision were made using a chi-square test and an analysis of variance. If differences were significant ($P<0.05$), the Turkey Kramer tests subsequently compared the groups two by two. Spearman's correlation test evaluated relationships between incision size, phacoemulsification

time, ultrasound energy and IOL power. All statistical analyses were performed with SAS statistical software (System for Windows release 9.1, SAS Institute Inc., Cary, NC, USA).

Results

This study enrolled 117 patients (78 females, 39 male; mean age 76.6 ± 8.2 years, range 47-94 years). Group A included 38 patients, Group B had 38 and Group C had 41.

Table 1 shows demographic data and the major surgical procedure parameters in the three groups, with no significant inter-group differences. Before and after phacoemulsification incision width was, respectively, 2.21 ± 0.02 mm and 2.34 ± 0.08 mm in group A; 2.20 ± 0.02 mm and 2.31 ± 0.06 mm in group B; 2.20 ± 0.02 mm and 2.30 ± 0.07 mm in group C. After phacoemulsification, tunnel width was enlarged by 6% in Group A eyes, by 5% in Group B eyes and by 4.4% in group C eyes. No significant difference emerged (X^2 =10.75 P <0.0963) **(Table 2)**. No relationship was detected between wound size, phacoemulsification time, ultrasound energy that was used during surgery or IOL power. IOL power was homogeneous in the three groups (group A: 21.1±2.8 D; group B: 20.9±3.7 D; group C 20.4±4.1 D. No low power IOL (< 13 D) were implanted in the three groups. A similar medium (between 13 and 23 D) and high power IOLs (> 23.5D) were implanted, respectively 30 and 8 in group A, 29 and 9 in group B, and 33 and 8 in group C.

Before and after IOL implantation incision width was, respectively, 2.34 ± 0.07 and 2.47 ± 0.07 mm in group A; 2.32 ± 0.06 mm and 2.45 ± 0.08 mm in group B; 2.30 ± 0.07 mm and 2.39 ± 0.07 mm in group C. Tunnel width enlargement after IOL implantation was 5.6% in group A, 5.8% in group B and 3.6% in group C. Analysis of variance showed a significant inter-group difference ($F=7.91$ $P<0.0001$). Although the difference in incision width after implantation between Groups A and B was not significant, a significant difference ($P<0.05$) emerged between Groups A and B vs Group C (The Tukey Kramer Test) **(Table 3).** After the Ultrasert™ preloaded system implanted IOL (Group C), 29.3% of eyes did not show incision enlargement, compared with 10.6% of eyes in Group A and 13.2% of eyes in Group B **(table 4).** No statistically significant difference in preoperative and postoperative corneal astigmatism and surgical induced astigmatism was identified between two groups. Moreover, we did not report in postoperative period any complications as wound leaking, or infections

Discussion

In cataract surgery there is a growing trend towards smaller incisions because size impacts greatly upon outcome in terms of induced astigmatism and visual rehabilitation and from many years the self-healing wound of about 2.2 mm represents the gold standard. The width and morphology of the main wound are crucial: in order to avoid to stitch the wound it has to allow a smooth cataract

surgery. Also, in the postoperative period it has to maintain its impermeability avoiding the wound leak and reducing the endophthalmitis risks. In fact, it has widely shown that during a postoperative wound leak the efficacy of topical or systemic antibiotics in controlling an eventual postoperative bacterial infection is reduced [8, 9, 10]. It has been shown that during the cataract surgery an increase of the main wound width can be induced. [8, 9]. Some authors suggested that corneal incision enlargement was due to instrument manipulation. Older studies reported that keratome type, IOL type and dioptric power might affect incision width, but cartridge insertion undoubtedly may contribute to its enlargement [10,11,12]. More recently, maximum incision stretch was observed to occur during IOL implantation [13,14].

In the present study, IOL insertion with D Monarch III and Unfolder Platinum cartridges widened the corneal incision by 0.13 mm in about 90% of patients with no significant differences emerging between devices. Our data concur with observations that, with diverse cartridge types, IOL implantation through a 2.2-mm clear corneal incision, was associated with incision enlargement in the majority of cases [6,14,15]. The ideal incision size was held to be 2.3 mm for the D cartridge with Monarch III with the wound assisted implantation technique, while 2.4 mm was believed to be the smallest incision the D cartridge tip could be fully inserted into [6,14,16]. In fact, the D cartridge tip size measures 1.56 mm in the vertical diameter and 2.03 mm in the horizontal.

The present analysis showed the Ultrasert™ device provided the smallest post-implantation incision enlargement of all the injection systems we tested. It did not change incision size in approximately 1/3 of cases and enlarged the incision by ≥ 2.4 mm in only 12.2% of eyes, perhaps because cartridge shape prevented excessive penetration through the corneal tunnel. Unique to Ultrasert™ is a guard, close to the cartridge tip, which limits penetration to a maximum of 2 mm in order to preserve the incision structure. Indeed, one crucial step in IOL delivery is cartridge tip penetration of the corneal incision, which may become larger since the cartridge diameter is bigger in the middle than at the tip. For example, corneal incisions are smaller [7,13] with cartridge tip insertion only into the internal incision and not into the anterior chamber. In line with similar findings in other studies, present results show that IOL insertion by means of the Ultrasert™ system compared well with the wound assisted technique, because both approaches limit tip penetration into the corneal wound.

Concurring with present data, injector width and IOL insertion speed were found to be the only factors significantly affecting incision enlargement [17,18]. In comparing IOL implantation through a 2.2-mm clear corneal incision by means of a motorized injector vs a standard manual injector, Khokhar et al found incisions were enlarged in 100% of cases after the D cartridge with manual injector was used and not enlarged in about 90% of eyes after Autosert assisted implantation [6].

No correlation emerged between incision width and implanted IOL power in the present study. In fact, with injector systems, the tip diameter, which is inserted into the corneal incision, is the same for each IOL power. Concurring with our data, previous studies by Kohen et al, reported that IOL material, IOL power and total optic diameter had no direct influence on incision sizes [18]. On the other hand, Mamalis et al found that IOL power did affect incision size [19]. Using the wound-assisted technique, Guarnieri observed incision width was larger when IOLs were implanted with a high dioptric power. The increase in the incision's final diameter could be due to IOL passage through the cartridge, or to IOLs with higher dioptric powers requiring more pressure for injection and thus exerting more friction on the incision [7].

Furthermore, heat produced during phacoemulsification in cataract surgery may produce direct corneal thermal damage [20]. Present findings showed incision size was not linked to phacoemulsification time or to ultrasound energy, possibly because phacoemulsification times were short and little energy was dissipated.

Limitations of the present study include evaluating only incision size but not morphology as Fukada et al. observed alterations in wound architecture by means of optical coherence tomography [21]. Secondly, using a calliper with 0.1 mm increments could have led to measurement underestimates. Finally, we did not consider IOL implantation speed since rapid insertion is known to be associated with

less incision damage than slow insertion and Ultrasert™ ensures rapid injection with constant IOL progression.

Conclusion

IOL implantation through incision may lead to corneal damage and improper wound healing. In the immediate post-operative follow-up, obtaining a stable, self-sealing incision is crucial because leakage from the main incision can predispose to post-operative infection [22]. Thus the use of devices permitting safer wound architecture in the postoperative period is essential. Our study shows that, compared with other devices, Ultrasert™, a preloaded IOL delivery system, seems to maintain the corneal incision better during insertion. Studies on larger cohorts of patients warrant being conducted to analyze factors influencing the course of post-operative wound stability.

References

1. Kohnen T, Dick B, Jacobi KW. Comparison of the induced astigmatism after temporal clear corneal tunnel incisions of different sizes. J Cataract Refract Surg 1995; 21:417–424
2. Hayashi K, Yoshida M, Hayashi H. Postoperative corneal shape changes: microincision versus small-incision coaxial cataract surgery. J Cataract Refract Surg 2009; 35:233–239
3. Elkady B, Piñero D, Aliò JL. Corneal incision quality: microincision cataract surgery versus microcoaxial phacoemulsification. J Cataract Refract Surg 2009; 35:466–474
4. Nikhil S Gokhale, Saurabh Sawhney. Reduction in astigmatism in manual small incision cataract surgery through change of incision site. IJO, 2005; 53, 201-203.
5. Haldipurkar SS, Shikari HT, Gokhale V. Wound construction in manual small incision cataract surgery. IJO, 2009; 57, 9-13
6. Khokhar S, Sharma R, Patil B, Aron N and Gupta S. Comparison of new motorized injector vs manual injector for implantation of foldable intraocular lenses on wound integrity: an ASOCT study. Eye 2014; 28, 1174-1178
7. Guarnieri A, Moreno-Montañés J, Sabater AL, Gosende-Chico I, Bonet-Farriol E. Final incision size after cataract surgery with toric intraocular lens implantation using 2 techniques. J. Cataract Refract Surg 2013;39:1675-1681.
8. Cagini C, Piccinelli F, Lupidi M, Messina M, Cerquaglia A, Manes S, Fiore T, Pellegrino RM. Ocular penetration of topical antibiotics: study on the penetration

of chloramphenicol, tobramycin and netilmicin into the anterior chamber after topical administration. Clin Experiment Ophthalmol 2013;41(7):644–647.

9. Cagini C, Dragoni A, Orsolini G, Fiore T, Beccasio A, Spadea L, Moretti A & Mencacci A (2017): Aqueous Humor Antimicrobial Activity: In Vitro Analysis after Topical 0.5% Chloramphenicol Application. Curr Eye Res 2017 Jun;42(6):847-851
10. Moreno-Montañés J, Garcia-Layana A, Aliseda D, Munuera JM. Variation in clear cornea incision size after phacoemulsification and foldable lens implantation. J Cataract Refract Surg 1998; 24: 931-934.;
11. Radner W, Menapace R, Zehetmayer M, Mallinger R. Ultrastructure of clear corneal incisions. Part I: effect of keratomes and incision width on corneal trauma after lens implantation. J Cataract Refract Surg 1998; 24: 487—492.
12. Moreno-Montañés J, Maldonado MJ, García-Layana A, Aliseda D, Munuera JM. Final clear corneal incision size for AcrySof intraocular lenses. J Cataract Refract Surg 1999; 25: 959—963.
13. Kohnen T, Klaproth OK. Incision sizes before and after implantation of SN60WF intraocular lenses using the Monarch injector system with C and D cartridges. J Cataract Refract surg 2008; 34: 1748-1753
14. Espiritu CR, Bernardo Jr JP. Incision sizes at different stages of phacoemulsification with foldable intraocular lens implantation. J Cataract Refract Surg 2009; 35: 2115—2120

15. Osher RH. Microcoaxial phacoemulsification. Part 2: clinical study. J Cataract Refract Surg 2007; 33: 408—412

16. Allen D, Habib M, Steel D. Final incision size after implantation of a hydrophobic acrylic aspheric intraocular lens: new motorized injector versus standard manual injector. J Cataract Refract Surg 2012; 38:249–255

17. Ouchi M. Effect of intraocular lens insertion speed on surgical wound structure. J. Cataract Refract Surg. 2012;38:1771-1776.

18. Kohnen T, Kasper T. Incision sizes before and after implantation of 6-mm optic foldable intraocular lenses using Monarch and Unfolder injector systems. Ophthalmology 2005; 112: 58-66.

19. Mamalis N. Incision width after phacoemulsification with foldable intraocular lens implantation. J Cataract Refract Surg 2000; 26:237–241.

20. Buschschlüter S, Koch C, von Eicken J, Höh H. Computation of the temperature rise at the corneal endothelium during cataract surgery by modeling of heat generation inside the anterior chamber. Ultrasound Med Biol. 2014 Oct;40(10):2431-44.

21. Fukuda S, Kawana K, Yasuno Y, Oshika T. Wound architecture of clear corneal incision with or without stromal hydration observed with 3-dimensional optical coherence tomography. Am J Ophthalmol 2011; 151:413–419

22. Bergamasco VD, Antunes VA, Hida RY, Malavazzi GR. Grooved and nongrooved clear corneal incisions in phacoemulsification: permeability study. Eur J Ophthalmol. 2016 May-Jun;26(3):248-51.

Table 1. Demographic data

	Group A	**Group B**	**Group C**
N. of patients	38	38	41
Age (years) (m±SD)	75.5 ± 10.0	75.9 ± 7.2	77.8 ± 7.4
Sex (M/F)	25/13	26/12	27/14
Phaco time (seconds) (m±SD)	54.4 ± 20.0	54.7 ± 18.4	50.1 ± 19.8
Energy (%) (m±SD)	9.3 ± 2.6	9.1 ± 2.5	8.8 ± 3.1
IOL	Acrysof© SN60WF	Tecnis© ZBC00	Acrysof© SN60WF
Power IOL (D)	20.6 ± 5.9	20.6 ± 3.6	22.8 ± 2.6
Injector system	Monarch© III D	Unfolder© Platinum/easy load	Ultrasert™
Corneal astigmatism preoperative (D)	0.93±0.59	0.89±0.63	0.91±0.48
Corneal astigmatism postoperative (D)	1.02±0.57	0.86±0.57	0.93±0.62
Surgical induced astigmatism	0.28±0.09	0.27±0.09	0.28±0.08

Table 2. Incision width before and after phacoemulsification.

		Group A	Group B	Group C
Before Phaco (mm)		2.21 ± 0.02	2.20 ± 0.02	2.20 ± 0.02
After Phaco (mm)		2.34 ± 0.08	2.31 ± 0.06	2.30 ± 0.07
Incision enlargement	**mm.**	0.13 ± 0.08	0.11 ± 0.06	0.10 ± 0.08
	%	6%	5%	4.4%

Table 3. Incision width before and after IOL implantation

		Group A	Group B	Group C
Before IOL (mm)		2.34 ± 0.07	2.32 ± 0.06	2.30 ± 0.07
After IOL (mm)		2.47 ± 0.08	2.45 ± 0.08	2.39 ± 0.07
Incision enlargement	**mm.**	0.13 ± 0.08	0.13 ± 0.08	0.09 ± 0.06
	%	5.6%	5.8%	3.6%

Table 4. Incision width after IOL implantation: % of eyes

	Group A	**Group B**	**Group C**
2.2 mm.	10.6%	13.2%	29.3%
2.3 mm.	52.6%	50.0%	58.5%
≥ 2.4 mm.	36.8%	36.8%	12.2%