Corneal Endothelial Cell Loss between the Kongsap Manual Phacofragmentation and Phacoemulsification†

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Objective: *To compare corneal endothelial cell loss between the Kongsap manual phacofragmentation and phacoemulsification.*
Material and Method: *One hundred two eyes with age-related cataract were randomized to undergo either the Kongsap manual phacofragmentation (Group 1, 52 eyes) or phacoemulsification surgery (Group 2, 50 eyes) with implantation of a posterior chamber, foldable, acrylic intraocular lens performed by one surgeon. The main parameters were corneal endothelial cell density (ECD), best corrected visual acuity (BCVA), and intraoperative and postoperative complications. Follow-up visits were scheduled at 1, 4, and 12 weeks.*
Results: *Pre-operatively, the mean ECD in Group 1 was 2,350 $\pm$ 229 cells/mm^2 and in Group 2 was 2,429 $\pm$ 263 cells/mm^2 ($p = 0.112$). Mean ECD decrease was 7.61% in Group 1 and 7.19% in Group 2 at the end of 12 weeks. The 95% confidence intervals of the mean differences of the endothelial cell loss at 4 weeks and 12 weeks after surgery were -1.87 to 2.04% and -2.77 to 3.63%, respectively. Mean best-corrected visual acuity at the end of 4 weeks was 0.88 $\pm$ 0.22 in Group 1 and 0.82 $\pm$ 0.24 in Group 2 ($p = 0.117$). There was no statistical difference between the groups in intra-operative and postoperative complications ($p > 0.05$).*
Conclusion: *The corneal endothelial cell loss after cataract surgery with the Kongsap manual phacofragmentation is equivalent to those of phacoemulsification and both surgical techniques allowed excellent visual results.*

Keywords: *Cataract surgery, Endothelial cell loss, Endothelial cell count, ECD, Corneal endothelium, Small-incision cataract surgery, Phacoemulsification, Intraocular lens implantation*

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Cataract is the leading cause of blindness worldwide, particularly within developing countries. Therefore, with rapid developments in surgical techniques in cataract surgery, small-incision techniques in particular have become increasingly popular. The use of smaller incisions has the following advantages: less surgical trauma, minimal postoperative induced astigmatism, and faster rehabilitation enabling patients to more quickly return to regular daily occupations[1-3]. Consequently, this has led to phacoemulsification becoming the preferred technique when resources are available. However, phacoemulsification machines are both expensive to purchase and maintain, adds relatively high costs to surgical consumables and subsequently places phacoemulsification beyond the reach of many ophthalmic surgeons working in developing countries.

Alternative techniques of small incision cataract surgery presently available involve manual

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fragmentation of the nucleus into small pieces or reducing the size of the nucleus. These include the quarters extraction, phacosection, manual multiphacofragmentation, the nylon loop technique, and prechop manual phacofragmentation[4-10]. These techniques are economical and do not require costly and complicated mechanical instrumentation.

The Kongsap technique is a manual small-incision cataract surgery in which the lens nucleus is divided into 3-4 fragments prior to manual removal through a relatively small incision, using inexpensive instrumentation (Fig. 1A, 1B)[11]. The foldable IOL is placed in the capsular bag and the wound is closed with no suture. Endothelial mosaic alterations are considered important parameters of surgical trauma and are essential in estimating the safety of various surgical techniques[12-14]. The author performed a prospective, randomized clinical trial to compare the corneal endothelial cell loss and visual results of the Kongsap manual phacofragmentation (KMPF) with those of phacoemulsification (PE).

Material and Method

One hundred and two eyes of 102 cases with age-related nuclear cataract (grade 2 to 3)[15] were recruited from patients at Prapokklao Hospital, Chanthaburi, Thailand. All consenting patients were admitted for cataract surgery. The criteria for inclusion in the present study stated that patients had to be residents within the region and both willing and able to attend regular follow-ups for at least 3 months. The patients with diabetes, uveitis, glaucoma, retinal detachment, previous trauma or surgery, and a dislocated or subluxated lens were excluded from the present study. The present study was approved by the institutional review board. A sample size of 102 patients was estimated from an alpha error of 0.025 (2-tailed), 90% power, equivalence range of $\pm$4% of the endothelial cell loss, the standard deviation from internal pilot data of 6.05%.

The patients were assigned randomly to receive either the KMPF (Group 1, 52 eyes) or PE (Group 2, 50 eyes) with a foldable intraocular lens. Randomization of treatment was done in sample random technique. The sequence was generated by random number table.

A pre-operative examination including best-corrected visual acuity (BCVA), slitlamp biomicroscopy, tonometry, retinal evaluation, and non-contact specular microscopy was performed.

The outcome measures were as follows:

The primary outcome was the endothelial cell loss by both techniques.

The secondary outcomes were:

1) Best corrected visual acuity (BCVA) from both techniques. Visual data was obtained using the Snellen chart, which was then transformed into decimal units for adequate statistical analysis.

2) Complications (both intra-operative and post-operative) from either technique.

3) The surgical time for each technique. The surgical time was measured from the start to the completion of the procedure (from the putting on to removing the lid speculum) and was measured with a stopwatch in minutes and seconds.

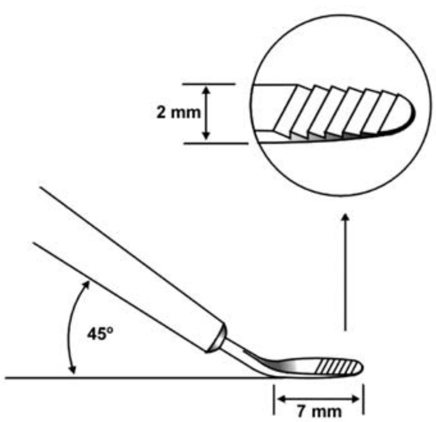

Fig. 1A Nuclear supporter made from the crescent knife or 3-mm keratome

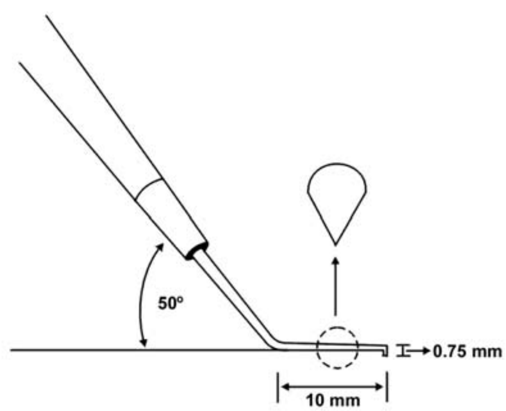

Fig. 1B Demontrated the sharpness of the nuclear cutter made from a Sinskey hook

All surgeries were performed by one surgeon [P.K.] using local anesthesia. The surgeon had reasonable experience in both the KMPF and in PE. Local retrobulbar anesthesia was a mixture of 1 mL lidocaine 2% (Xylocaine®) and 1 mL bupivacaine HCL 0.5% (Marcaine®). A Honan balloon was applied for 10 minutes before surgery. In all cases Viscoat® (3% Sodium Hyaluronate/4%Sodium Chondroitin Sulfate, Alcon) was used as the viscoelastic agent and Ocusol® (Balanced salt solution, A.N.B.Laboratories) was used as the infusion fluid. A three-piece acrylic foldable AcriSof® (Alcon) lens was implanted in all cases.

For PE, a clear corneal incision was made using a 3-mm keratome. Continuous curvilinear capsulorhexis (CCC) was performed, followed by hydrodissection and hydrodelineation. Posterior chamber phacoemulsification with an Alcon Universal phacoemulsification machine was performed using the stop and chop technique and automated irrigation and aspiration was performed. The anterior chamber was deepened using a viscoelastic agent. The original incision was extended to 4.0 mm and a foldable intraocular lens (IOL) was implanted in the capsular bag. The incision was left unsutured.

For KMPF[11,16], two side port was performed with a 15 degree stab knife (one for the anterior chamber maintainer and the other for the instruments). The CCC, hydrodissection was undertaken and followed by the anterior cortical debris removal. A 4.0-mm temporal corneal incision was made using a 3.0-mm keratome. The viscoelastic was injected into the anterior chamber and the nucleus was dislocated out of the bag using a spatula and a Sinskey hook. The nucleus was divided into 3-4 fragments using the nuclear supporter and the nuclear cutter. Each fragment was extracted through the corneal incision using the same instruments. The epinucleus and lens cortex were removed through the side port incision by a cortex extractor. Viscoelastic was then injected into the anterior chamber and a foldable intraocular lens was implanted into the capsular bag. The wound was then closed with no suture.

Postoperative medication included an antibiotic steroid combination of dexamethasone 0.1% and neomycin 0.5% four times a day for the first two weeks and then tapered down over the following two weeks. The follow-up examination was carried out at 1- day, 1- week, 1-month and 3- month visits.

On the first post-operative day, only visual acuity and slitlamp biomicroscopy were recorded. During subsequent examinations, all patients had a complete clinical evaluation including Snellen best-corrected visual acuity (BCVA), slitlamp biomicroscope, tonometry, and keratometry. The specular microscopy was done at the 1-month and 3- month visit. Corneal endothelial cell counts were undertaken in the central part of the cornea using a non-contact confocal specular microscope (Nidek SEM Technologies 2005). The measurements were performed in an automated, masked manner.

The primary outcome, corneal endothelial cell loss, was analyzed by 95% mean $\pm$ standard deviation (SD) and confidence interval approach. For the secondary outcomes, the Student t test or their non-parametric equivalents were used when appropriate. A p-value of $\leq$ 0.05 was considered statistically significant for all the outcome measures.

Results

Baseline characteristics of the 52 patients in KMPF and the 50 patients in the PE groups were comparable (Table 1). The sample size of 102 was the number of patients who met the inclusion criteria and all of them completed the present study. Mean patient age was 66.13 years $\pm$7.95 (SD) in Group 1 (KMPF) and 67.06 $\pm$ 9.55 years in Group 2 (PE). Group 1 was comprised of 22 men and 30 women while Group 2 had 27

Table 1. Baseline characteristics of patients undergone cataract surgery (n = 102)

Variable	Group 1-KMPF	Group 2-PE	p-value
Total	52 (100%)	50 (100%)	
Male	22 (42.31%)	27 (54.0%)	0.237
Average age	66.13	67.06	0.596
Visual acuity	0.1294	0.1092	0.150
Average cell count $\pm$ SD (cells/mm^2)	2350 $\pm$ 229	2429 $\pm$ 263	0.112

KMPF = the Kongsap manual phacofragmentation
PE = phacoemulsification

men and 23 women. Preoperative visual acuity was similar in both groups. The mean preoperative corneal endothelial cell count was 2350 ± 229 cells/mm^2 in Group 1 and 2429 ± 263 cells/mm^2 in Group 2. There were no significant differences between the two groups in the baseline characteristics (Table 1). Nuclear hardness was grade 2 to 3 in both groups. The mean surgical time was 13.39 minutes for the KMPF and 11.50 minutes for PE ($p = 0.001$).

Mean visual acuity 7 days after surgery was slightly higher after the KMPF (0.86 ± 0.24) than after PE (0.82 ± 0.23) but the difference between groups was not statistically significant ($p = 0.329$). Thirty days postoperatively, visual acuity was 0.89 ± 0.22 in Group 1 and 0.82 ± 0.24 in Group 2 ($p = 0.117$). There was no statistically significant difference during subsequent examination ($p > 0.05$) (Table 2).

Mean final postoperative endothelial cell density (ECD) was 2172 ± 285 cells/mm^2 in the KMPF group and 2263 ± 312 cell/mm^2 in the PE group. When the corneal endothelial cell loss was expressed as a percentage of preoperative endothelial cell count the author found that the patients in the KMPF group lost an average of 7.61% of cells, whereas patients after phacoemulsification lost an average of 7.18%. The 95% confidence intervals of the mean differences of the endothelial cell loss at 4 weeks and 12 weeks after surgery were -1.87 to 2.04% and -2.77 to 3.63%, respectively.

The most common complications were iris prolapse and corneal edema. Iris prolapse in two cases and transient intracameral bleeding in one case were the complications seen only in Group 1. Corneal wound edema was also noted in two eyes in Group 1. This corneal edema cleared after 5 days. There was no statistical difference between groups in intra-operative and post-operative complications ($p > 0.05$). There was no endophthalmitis, uveitis, glaucoma, and corneal decompensation noted in either groups.

Table 2. Postoperative Snellen best-corrected visual acuity (n = 102)

Follow-up	Group 1-KMPF (mean ± SD)	Group 2-PE (mean ± SD)	p-value
1 week	0.86 ± 0.24	0.82 ± 0.23	0.329
1 month	0.89 ± 0.22	0.82 ± 0.24	0.117
3 months	0.90 ± 0.20	0.84 ± 0.22	0.066

KMPF = the Kongsap manual phacofragmentation
PE = phacoemulsification

Table 3. Post-operative endothelial cell loss (n = 102)

Endothelial cell	Group (Mean ± SD)	
	KMPF	PE
Mean count (cells/mm^2) ± SD		
4 weeks	2249 ± 235	2330 ± 275
12 weeks	2172 ± 285	2263 ± 312
Mean loss (%) ± SD		
4 week	4.54 ± 5.01	4.46 ± 4.95
12 weeks	7.61 ± 9.00	7.18 ± 7.15

KMPF = the Kongsap manual phacofragmentation
PE = phacoemulsification

Discussion

Major advances in the techniques used for cataract surgery during the last decades have made it possible to decrease the size of the incision through which the surgery is performed. Incision size was reduced when the shift occurred from intracapsular to extracapsular extraction[17]. A major step forward took place when phacoemulsification and foldable intraocular lens (IOLs) were developed, accompanied by the further decrease in the incision size to 3.5 mm[18]. This decrease in the incision size has proved to be associated with a significant decrease in postoperative intraocular inflammation, less wound-related complications, less surgical time[19], and shorter postoperative rehabilitation. Because of these advantages, phacoemulsification has become the routine procedure for cataract extraction in industrialized countries. However, in developing countries it has played a limited role due to the expense of equipment and consumables. Therefore, manual techniques have been developed to achieve benefits similar to those achieved by phacoemulsification.

The Kongsap manual phacofragmentation refers to small incision surgery, in which the lens nucleus is divided into 3-4 fragments using simple instruments prior to removal, a relatively small incision, and foldable IOLs being placed in the capsular bag. It has been shown to provide rapid visual recovery and a lower rate of complications in the first 40 eyes. The mean central endothelial cell loss was 8.15% at 1 month after surgery[16]. For the safety of the procedure, there was no comparative study relating to the endothelial cell loss by this manual small incision cataract surgery.

Vajpayee and co-authors[20] in a comparative study found that the endothelial cell loss at 3 months with small incision cataract surgery (Phacofracture) was 17.66% and with phacoemulsification, it was 12.03%. Jongsareejit[21] reported the endothelial cell loss at 3 months with small incision cataract surgery (Phaco-drainage) was 15.44% and with phacoemulsification was 6.35%.The differences in the endothelial cell loss between MPF and phacoemulsification in both reports were statistically significant. In the present study, the endothelial cell loss at 3 months after surgery was 7.61% in KMPF group and 7.18% in phacoemulsification group. The pre-specified equivalence limit of 4% was determined to compare with the mean difference between the groups. The author has demonstrated that with 95% confidence intervals for the differences, the confidence interval located within the range of equivalence. It has shown that the endothelial cell trauma in the Kongsap manual phacofragmentation surgery is no higher than that identified in phacoemulsification when the surgery is performed by an experienced surgeon. Although mean endothelial cell loss was lower than those in Phacofracture and Phacodrainage, two eyes in the first-10 cases had the endothelial cell loss of 14 and 15%. The author believes that the viscoelastics used in the present study is one reason for less endothelial cell loss. This is due to Chondroitin sulfate (Viscoat®) rather than hydroxypropyl mehylcellulose being used in the present study. The quality of endothelial protection in Chondroitin sulfate is higher than that in mehylcellulose.

The postoperative BCVA was not significantly different between this technique and phacoemulsification after 1 week, 1 month, and 3 months. The postoperative BCVA was 0.86, 0.89, and 0.90 at 1 week, 1 month, and 3 months respectively. There was not a poor outcome (visual acuity < 6/60) in any of the patients of either group.

The Kongsap manual phacofragmentation group had a greater incidence of the intraoperative and postoperative complications. Iris prolapse (2 cases) and transient intracameral bleeding (1 case) were the most common intra-operative complications. Corneal edema (2 cases) was the most common major postoperative complication. The intraoperative and postoperative complications were seen only in the KMPF group, but there was no statistical difference between the groups. The author believes that the complications occurred only in the KMPF group because of the surgeon's chronological hands on experience. Ten years of post-residency experience had led to some ten years experience of phacoemulsification and only two years of KMPF surgery. That is in real terms a minimum of 2000 phacoemulsification procedures and 200 KMPF surgical procedures. Increasing knowledge and experience of this surgical technique will ensure that the surgeon remains on a productive learning curve and subsequently ensures the continuing development of this procedure together with a decrease in intra-operative and postoperative complications.

There was more iris prolapse in the KMPF group, 2(3.85%) compared with none in the PE group and these usually occurred during the removal of the nucleus. Early perforation into the anterior chamber of the wound and incomplete luxation of the lens fragment into the anterior chamber may have caused this problem. A single case of transient intracameral bleeding was seen in the KMPF group caused by accidental capture of the iris during IOL implantation but it did not result in increased poor postoperative outcome.

Because this technique is performed mostly in the anterior chamber, corneal endothelial damage may occur during nuclear luxation, nuclear fragmentation, and nuclear removal through the clear corneal incision. Damage can be avoided if a good viscoelastic is frequently injected into the anterior chamber and the surgeon holds the instruments still. Patient selection is also important for surgical success. The guidelines are similar to the ones used for phacoemulsification. Nuclear hardness of grade 2 to 3 according to the Lens Opacities Classification System II allows easier nuclear fragmentation. The author does not recommend this technique for cataract surgery with a hard cataract and a large nucleus because there is a narrow space for manipulation in the anterior chamber and thus the nucleus is hard for nucleus fragmentation and the central fragment is thick.

In conclusion, corneal endothelial cell loss between the KMPF and PE is equivalent. Both surgical techniques achieved excellent visual outcome with low complication rates. However, these results were based on short term follow-up. The author will continue to develop the surgical technique to decrease the complications and continue to study endothelial cell loss for one year with the goal of increasing the safety of this manual phacofragmentation.

Acknowledgement

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Conflicts of interest

The author declares no conflicts of interest.

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***การสูญเสียเซลล์กระจกตาชั้นใน จากการผ่าตัดต้อกระจกโดยวิธี** Kongsap manual phacofragmentation **และ** phacoemulsification*

พิพัฒน์ คงทรัพย์

***วัตถุประสงค์**: เพื่อศึกษาเปรียบเทียบการสูญเสียเซลล์กระจกตาชั้นในจากการผ่าตัดต้อกระจก โดยวิธี Kongsap manual phacofragmentation และ phacoemulsification*

***วัสดุและวิธีการ**: ผู้นิพนธ์ทำการศึกษาในผู้ป่วยที่มารับการผ่าตัดต้อกระจกจำนวน 102 ราย โดยผู้ป่วยได้รับการแบ่งแบบสุ่มเป็นกลุ่ม ๆ กลุ่มแรกได้รับการผ่าตัด แบบแผลเล็กด้วย Kongsap technique จำนวน 52 ราย กลุ่มที่สองได้รับการผ่าตัดโดยการสลายต้อกระจก จำนวน 50 ราย ผู้ป่วยทุกรายได้รับการผ่าตัดโดยแพทย์ผู้ผ่าตัดคนเดียวกัน และได้รับการใส่เลนส์แก้วตาเทียมชนิดนิ่มพับได้ ผู้ป่วยได้รับการประเมินเซลล์ กระจกตาชั้นใน, ระดับสายตา และภาวะแทรกซ้อนจากการผ่าตัด โดยนัดตรวจ 1 สัปดาห์, 1 เดือน และ 3 เดือน หลังผ่าตัด*

***ผลการศึกษา**: ค่าเฉลี่ยความหนาแน่นของเซลล์กระจกตาในกลุ่มแรกเท่ากับ 2,350 $\pm$ 229 เซลล์/มิลลิเมตร^2 กลุ่มที่สองเท่ากับ 2,429 $\pm$ 263 เซลล์/มิลลิเมตร^2 ($p = 0.112$) ค่าเฉลี่ยการสูญเสียเซลล์กระจกตาชั้นในหลังการผ่าตัด 3 เดือนในกลุ่มที่ 1 เท่ากับ 7.61% และกลุ่ม 2 เท่ากับ 7.19% ความแตกต่างของการสูญเสียเซลล์กระจกตาชั้นในเฉลี่ยทั้งสองกลุ่ม มีค่าความเชื่อมั่นที่ระดับ 95% ณ เวลา 4 สัปดาห์และ 3 เดือนหลังผ่าตัดอยู่ระหว่าง -1.87 ถึง 2.04% และ -2.77 ถึง 3.63% ตามลำดับ ค่าเฉลี่ยระดับสายตาที่ 4 สัปดาห์หลังผ่าตัดในกลุ่มที่ 1 เท่ากับ 0.88 $\pm$ 0.22 และกลุ่มที่สองเท่ากับ 0.82 $\pm$ 0.24 ($p = 0.117$) ในการศึกษาครั้งนี้ไม่พบความแตกต่างของภาวะแทรกซ้อนระหว่างผ่าตัดและหลังผ่าตัด ในผู้ป่วยทั้งสองกลุ่ม ($p > 0.05$)*

***สรุป**: การผ่าตัดต้อกระจกแผลเล็กโดย Kongsap technique มีการสูญเสียเซลล์กระจกตาชั้นใน และผลการผ่าตัดใกล้เคียงกับการสลายต้อกระจก*