

Safety and efficacy of manual small incision cataract surgery

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Abstract

• Manual small incision cataract surgery (MSICS) has widely been used in clinical operation, especially in developing countries. This article aims to compare the efficacy and safety (intraoperative and postoperative complications) among conventional extracapsular cataract extraction (ECCE), MSICS and phacoemulsification. By using the PubMed search engine, we collected the relevant literatures on MSICS, ECCE and phacoemulsification. Meanwhile, the relevant literatures published in Chinese journals were also referred to. Compared with phacoemulsification, both MSICS and ECCE achieved excellent visual outcomes with low complications. MSICS does not depend on expensive instrument, and is significantly faster, less expensive, and requires less technology; therefore, MSICS is especially suitable to hard nucleus cataract surgery. Though MSICS demands skill and patience during cataract surgery, it is a safe, effective and economical treatment and is used as an alternative to phacoemulsification in developing countries.

• **KEYWORDS:** cataract surgery; manual small incision cataract surgery; phacoemulsification; extracapsular cataract extraction

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INTRODUCTION

Cataracts typically progress slowly to cause vision loss and remain the most common treatable cause of blindness. Surgery is the most effective method for treating cataract. Currently, the three main types of cataract surgery extraction performed by the ophthalmologists, phacoemulsification, conventional extracapsular cataract extraction (ECCE) and manual small incision cataract surgery (MSICS) are the most popular forms of cataract surgery in the world^[1]. Phacoemulsification is the preferred technique for cataract surgery in developed countries, and became more acceptable over the open chamber extracapsular cataract surgery, but large-scale implementation in developing countries may prove to be a challenge because of its expensive fund input. Meanwhile, phacoemulsification is difficult in hard brown cataracts and not friendly to the corneal endothelium^[2]. ECCE involves manual expression of the lens through a large (usually 10-12mm) incision made in the cornea or sclera, and it is a better choice for the cataract patients with hard nucleus. However, because of large incision, many procedures of surgery, serious astigmatism and slow visual rehabilitation after surgery to ECCE, small incision cataract surgery has also been an alternative method to ophthalmologists.

Small incision cataract surgery refers to a small incision made in the sclera and then performed cataract extraction, including phacoemulsification, laser emulsification and MSICS. In MSICS, a 6.5-7.5mm scleral tunnel is created with a straight or frown incision and a side port to facilitate intraocular manipulations. Then the capsule was opened with continuous curvilinear capsulorhexis and the nucleus is dislocated into the anterior chamber, or may be by simple picked up by a bent cystitome, usually a 26-gauge needle. When viscoelastic injected around the nucleus and an irrigating vectis inserted below it, the nucleus is then delivered in parts through the scleral tunnel. To date, small incision cataract surgery has been increasing in popularity^[3] and many techniques have been used in MSICS such as two-knife chopping^[4], double nylon loop^[5], snare technique^[6], sandwich technique^[7], selective hydrodissection^[8], capsulotomy and hydroprocedures for nucleus prolapse technique^[9] and so on to fit the requirements of personalized surgeon.

EFFICACY

Phacoemulsification has been proved a safe and effective technique to cataract surgery^[10-12]. In comparison with phacoemulsification, MSICS does not require expensive instrument, but the vision rehabilitation outcomes are similar. Hitherto, the comparison of efficacy and safety between MSICS and phacoemulsification had done by using randomized controlled trials in the world. A prospective, randomized trial found that both phacoemulsification and MSICS achieved excellent visual outcomes with low complication rates. In the phacoemulsification group, 12 of 54 patients (22.2%) had an uncorrected visual acuity of hand motions or worse, compared with 13 of 54 patients (24.1%) in the small incision cataract surgery group ($P=0.819$). The average visual acuity of the 42 remaining patients in the phacoemulsification group was 20/300. The average visual acuity of the remaining 41 patients in the SICS groups was 20/353 ($P=0.681$)^[13]. Similarly, in a randomized controlled clinical trial of 6-week follow-up, MSICS was also proved that it is as safe and effective as phacoemulsification. The study showed that 68.2% patients in the phacoemulsification group and 61.25% patients in the small-incision group had uncorrected visual acuity better than or equal to 6/18 at 1 week ($P=0.153$). 81.08% patients of the phacoemulsification group and 71.1% patients of the small-incision group ($P=0.038$) were better than or equal to 6/18 at the 6-week follow-up for presenting visual activity. Visual acuity improved $\geq 6/18$ with best correction in 98.4% and 98.4% patients ($P=0.549$), respectively^[14]. Another single masked randomized controlled clinical trial was conducted to compare safety and efficacy of phacoemulsification *vs* MSICS techniques for rehabilitation of the cataract patients, and found that visual result of phacoemulsification and MSICS techniques is comparable, both techniques are effective and safe, MSICS is far more economical than phacoemulsification^[15]. Nevertheless, in terms of hard nucleus during cataract surgery, phacoemulsification needs more ultrasonic energy and longer microsecond-long cycles of burst and rest to divide hard nucleus into parts, it's difficult to complete the phacoemulsification of white hard cataract^[16], so phacoemulsification might increase the risk of severe endothelial cell loss and extracapsular cataract extraction should be preferred^[17, 18]. Because MSICS does not require expensive instrument, MSICS is far more economical than phacoemulsification^[3, 13-15].

In ECCE, the surgeon makes a tiny incision near the outer edge of the cornea. The size of this opening depends on whether the nucleus of the lens is to be removed all in once piece or whether it will be dissolved into tiny pieces and then removed out. Conventional ECCE makes a large incision in the cornea or sclera and usually results in serious

complications to the patients. Thus, small incision cataract surgery becomes an alternative because of its less complication and faster rehabilitation after surgery. A single masked randomized trial was used to compare the safety, efficacy, time, and patient satisfaction of surgery by both ECCE and MSICS, the result showed that MSICS is economical and gives better uncorrected visual acuity in a greater proportion of patients^[19]. Another single masked randomized controlled clinical trial had found that MSICS and ECCE are both safe and effective techniques for treatment of cataract patients in community eye care settings. MSICS needs similar equipment to ECCE, but gives better uncorrected vision^[20]. Moreover, in a district hospital in West Africa, MSICS yielded faster visual rehabilitation and had a lower incidence of fibrinous iritis than in standard ECCE surgery^[21]. In addition, much more clinical trials have also proved that MSICS offers faster visual recovery^[22], lower cost than ECCE or phacoemulsification^[23]. The MSICS is the technique that under the nucleus prolapsed into the anterior chamber and then removed through an incision made in the sclera. Because it is also a type of ECCE surgery, the complications of the MSICS are similar compared with conventional ECCE, although there are certain unique ones. More maneuvers in the anterior chamber operation were involved during the MSICS, e. g., first the capsulotomy, then dislodging the nucleus from the posterior to the anterior chamber and finally removing the nucleus from the scleral tunnel. Unlike the phacoemulsification where it is performed with the machine equipped with ultrasonic power and vacuum, the MSICS have to be done manually, hence, such the techniques are much more demanding in terms of manual skill of the ophthalmologists, and are also associated with the occurrence of complications, therefore, the principles of a good ECCE surgery, such as not to handle the cornea, to touch the iris rarely, and to preserve the posterior capsule, all hold good for MSICS and phacoemulsification, as they are all variants of the conventional ECCE technique^[1]. Although the final efficacy of both techniques seems to be similar, however MSICS is recommended only in hard nucleolus and when phaco-machine is not in access.

INTRAOPERATIVE COMPLICATIONS

The intraoperative complications during MSICS usually involve maneuvers ophthalmologists perform, including posterior capsule rupture^[18, 24-26], vitreous loss^[7, 21, 27, 28], zonular dialysis^[18, 27, 28], iris prolapse^[29, 30], transient intracameral bleeding^[29], and capsulorhexis tear^[29]. The good maneuvers need patience and expertise of ophthalmologists and can reduce the occurrence of complications intraoperatively or postoperatively. The 95 eyes of 95 patients underwent manual sutureless cataract surgery, and the most common intraoperative complication was iris prolapse (7.37%). Other intraoperative complications were posterior capsule rupture

(2.11%), transient intracameral bleeding (2.11%), and capsulorhexis tear (2.11%)^[29]. To compare the safety and efficacy of phacoemulsification and MSICS in treating white cataracts, the randomized prospective study was carried out. Consecutive patients with white cataract were randomly assigned to have phacoemulsification or MSICS by 1 of 3 experienced surgeons in both techniques. Surgical complications, operative time, uncorrected distance visual acuities (UDVA) and corrected distance visual acuities (CDVA), and surgically induced astigmatism were compared. The results showed that on the first postoperative day, the UDVA was comparable in the 2 groups ($P=0.805$) and the MSICS group had less corneal edema (10.2%) than the phacoemulsification group (18.7%, $P=0.047$). At 6 weeks, the UDVA was 20/60 or better in 99 patients (87.6%) in the phacoemulsification group and 96 patients (82.0%) in the MSICS group ($P=0.10$) and the CDVA was 20/60 or better in 112 patients (99.0%) and 115 patients (98.2%), respectively ($P=0.59$). The mean time was statistically significantly shorter in the MSICS group (8.8 ± 3.4 minutes) than in the phacoemulsification group (12.2 ± 4.6 minutes) ($P < 0.001$). Posterior capsule rupture occurred in 3 eyes (2.2%) in the phacoemulsification group and 2 eyes (1.4%) in the MSICS group ($P=0.681$)^[31]. In another single masked randomized controlled clinical trial, 741 patients with operable cataract were randomly assigned to receive either MSICS or ECCE and operated upon by one of eight participating surgeons. The surgical results indicated that there were no significant differences between the two groups for intraoperative and severe postoperative complications^[20]. Using MSICS technique, even to the cataract patients with phacomorphic glaucoma, no significant intraoperative complications were noted, indicating that MSICS is safe and effective in achieving good functional visual acuity with minimal complications^[32]. Regarding the applications of MSICS, it is used not only in hard nucleus, but also in areas where the phaco-machine is not in access.

POSTOPERATIVE COMPLICATIONS

Cataract surgery usually accompanies the occurrence of astigmatism, and is associated with maneuvers of ophthalmologist^[33]; the smaller wound incision produces less astigmatism^[34] even does not induce astigmatism^[35]. In a randomized, comparative clinical trials, changes in corneal astigmatism and shape after 2.0mm corneal incision cataract surgery are virtually the same as those after 2.0mm scleral incision cataract surgery, whereas those occurring after 3.0mm corneal incision cataract surgery are significantly greater than those occurring after 3.0mm scleral incision cataract surgery^[36]. The average astigmatism was 0.7 diopter (D) in the phaco and 0.88D in the MSICS ($P=0.12$) in the Nepal study^[13]. Another clinical trial showed that the mode of astigmatism was

0.5D for the phacoemulsification group and 1.5D for the small-incision group, and the average astigmatism was 1.1D and 1.2D, respectively^[14]. One study on surgically induced astigmatism following conventional extracapsular cataract surgery, MSICS and phacoemulsification was carried out and found that mean surgically induced astigmatism was 1.77D (± 1.61 D) for the ECCE group, 1.17D (± 0.95 D) for the MSICS group and 0.77D (± 0.65 D) for the phacoemulsification group ($P=0.001$). The magnitude of the difference between the MSICS and the phacoemulsification group was 0.4D^[37]. Additionally, another clinical randomized comparison showed that the average keratometric astigmatism was 0.88D in the MSICS group and 0.70D in the phacoemulsification group ($P=0.12$), indicating there was no statistical difference in astigmatism between MSICS group and phacoemulsification group^[13]. After MSICS, the most common complication was high intraocular pressure (IOP)^[27,28,38], and a comparative study of postoperative intraocular pressure changes in small incision *vs* conventional extracapsular cataract surgery has proved that IOP rises significantly on day 1 in ECCE and small incision cataract surgery and thereafter comes down slightly by day 2 and rapidly by day 7. IOP rise is more pronounced in ECCE than in small incision cataract surgery. After 1 week to 3 months, IOP decline is very gradual and thereafter ceases to decrease^[39]. During MSICS, using different viscoelastic agents could cause a significantly higher IOP increase in the early postoperative period^[40,41]. To find out the pattern of changes in intraocular pressure after the MSICS, consecutive patients were prospectively evaluated for change in IOP measured at day 1, 1st, 2nd, 4th, 6th, 8th and 12th week. The results indicated that the mean postoperative IOP in eyes where sutures were not applied (12.59 ± 3.02 mmHg, 12.54 ± 2.19 mmHg and 12.40 ± 2.99 mmHg at day 1, 2 weeks and 4 weeks, respectively) was lower than that where sutures were used to close the wound (15.57 ± 3.86 mmHg, 14.05 ± 2.52 mmHg, 14.43 ± 3.39 mmHg at day 1, 2 weeks and 4 weeks respectively). There was a drop of IOP from the preoperative IOP in both suture (1.15 ± 3.29 mmHg) and non suture (3.29 ± 3.07 mmHg) group at 3 months of follow-up, indicating that eyes where sutures are applied are more likely to have higher IOP than those without sutures at the initial postoperative period^[42].

Cataract surgery is known to change the corneal endothelial cell density and morphology. The small incision performed during cataract surgery also causes endothelial loss. A clinical trial has performed to compare the surgically induced endothelial cell loss following ECCE, MSICS and phacoemulsification and found that there was no significant difference in endothelial cell loss for all three techniques ($P=0.855$). ECCE induced a loss of 4.72% (SD: 13.07); MSICS 4.21% (SD: 10.29) and phacoemulsification 5.41%

(SD: 10.99)^[36], respectively. In a randomized control trial, the mean preoperative endothelial cell count by the manual counting method was 2950.7 cells/mm² in the phaco-emulsification group and 2852.5 cells/mm² in the MSICS group and by the automated counting method, 3053.7 cells/mm² and 2975.3 cells/mm², respectively. The difference at 6 weeks was 543.4 cells/mm² and 505.9 cells/mm², respectively, by the manual method ($P=0.44$) and 474.2 cells/mm² and 456.1 cells/mm², respectively, by the automated method ($P=0.98$), this result has also shown that there were no clinically or statistically significant differences in endothelial cell loss between phacoemulsification and MSICS^[43]. A prospective cohort study was conducted to assess and compare the endothelial cell loss and change in central corneal thickness (CCT) after MSICS in patients with diabetes *vs* age-matched patients without diabetes and the results showed there was a steady drop in the endothelial density in both the groups postoperatively, with the percentage of endothelial loss at 6 weeks and 3 months being 9.26 ± 9.55 and 19.24 ± 11.57 , respectively, in patients with diabetes 7.67 ± 9.2 and 16.58 ± 12.9 , respectively, in controls. The percentage of loss between 6 weeks and 3 months was found to be of significant difference ($P < 0.023$). In both the groups, an initial increase in CCT till the second postoperative week was followed by a reduction of CCT in the subsequent follow-up (6th week) and a further reduction in the last follow-up (3 months). The change in CCT between the 2nd and 6th weeks was significantly higher in the diabetic group ($P=0.045$)^[44]. Posterior capsular opacification (PCO) is the most frequent complication of cataract surgery. Advances in surgical techniques, intraocular lens materials, and designs have reduced the PCO rate or, at least, have prolonged its onset^[45]. A clinical trial has been proved that clinical grading of PCO varied significantly between manual sutureless small-incision extracapsular cataract surgery and phacoemulsification groups. At the 6th month follow-up visit, 26 of 46 patients (56.5%) in the MSICS group *vs* 41 of 48 patients (85.4%) in the phacoemulsification group had no PCO ($P=0.203$). Of the remaining 20 patients in the MSICS group, 12 patients were graded as 1+ PCO, and 8 patients were graded as 2+ PCO. In the phacoemulsification group, 7 patients were graded as 1+ PCO, and no patients were found to have 2+ PCO^[13]. Macular edema after cataract surgery occurred primarily in the central region of the macula and was associated with the presence of leaking sites^[46], and appropriate agent could effectively prevent cystoid macular edema following MSICS^[47]. The conjunctival inclusion cysts following MSICS occurred and no recurrence was noted at 3 months follow-up. Careful reflection of conjunctiva during tunnel construction and posterior chamber intraocular lens implantation may prevent

their occurrence^[48]. The comparison between MSICS and phacoemulsification has found that the incidence of anterior chamber contamination in the MSICS group (4%) did not significantly differ from that in the phacoemulsification group (2.7%, $P=0.65$)^[49]. Of the 102 eyes with brunescant and black cataract, MSICS was performed and, the main intraoperative complication was posterior capsule rupture in two patients (2.0%). Postoperatively, 20 eyes (19.6%) developed corneal edema. Mild iritis was seen in six eyes (5.9%) and moderate iritis with fibrin membrane formation occurred in three eyes (2.9%)^[50]. Similarly, the main complication of small-incision surgery was moderate corneal edema, which persisted until at least the 1-week visit in 14 eyes (7%) and 1 eye in the small-incision group (0.5%) had bullous keratopathy^[21]. To compare macular thickness following uncomplicated phacoemulsification and MSICS, a prospective study was carried out and, in spite of the greater theoretical risk of increased postoperative inflammation following MSICS, there was no evidence of cystoid macular edema. However, chance of sub-clinical increase in central subfield mean thickness was more following MSICS compared to phacoemulsification^[51]. Another study has proved that uneventful small incision cataract surgery using peribulbar anesthesia did not affect ocular blood flow in patients with senile cataract between 1 day and 1 month postoperatively^[52]. A retrospective data analysis after small incision cataract surgery was conducted and the incidence of pigment precipitates was 0.35% ($n = 23/6519$), mean time to occurrence was 5.5 months^[53].

CONCLUSION

The MSICS is one of the cataract surgical techniques commonly used in developing countries, usually results in a good visual outcome and is useful for high-volume cataract surgery^[3,13,21,54-57]. It is a safe and effective surgery^[9,14,18,20,22,25,27,50] and is far more economical than phacoemulsification^[3,13,15,22,23,31]. MSICS needs similar equipment to conventional extracapsular cataract surgery, but gives better uncorrected vision and has a lower complications intraoperatively and postoperatively. MSICS may be the more appropriate surgical procedure for the treatment of advanced cataracts in the developing world^[13]. MSICS has similar advantages of phacoemulsification in the rehabilitation of the cataract blind, and is also easier for a surgeon trained in ECCE surgery to master MSICS than to phacoemulsification. Thus, among small incision surgeries, the MSICS is ideal for developing countries.

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手法小切口白内障手术的安全性和治疗效果评价

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摘要

手法小切口白内障术(manual small incision cataract surgery, MSICS)特别是在发展中国家已广泛应用于临床手术。本文旨在比较传统白内障囊外摘除术(extracapsular cataract extraction, ECCE)、MSICS以及超声乳化白内障吸除术治疗效果以及安全性(术中并发症以及术后并发症)。通过使用PubMed搜索引擎,我们收集了传统ECCE、MSICS以及超声乳化白内障吸除术的相关文献,以评价其安全性和治疗效果。同时,也参考了国内出版的相关文献。结果发现,与超声乳化白内障吸除术相比,传统ECCE以及MSICS也取得了很好的治疗效果,并且具有并发症少等优点。MSICS不需要依赖昂贵的仪器,并且具有手术快速、费用低廉以及技术门槛低等特点,特别适用于硬核白内障的治疗。虽然在白内障手术治疗过程中MSICS需要一定的技术和耐心,但它仍然是一种安全、有效、经济治疗手段,特别是在发展中国家可以替代超声乳化进行白内障的治疗。

关键词: 白内障手术;手法小切口白内障术;超声乳化白内障吸除术;白内障囊外摘除术