

Clinical Trial of Manual Small Incision Surgery and Standard Extracapsular Surgery

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Introduction

Manual small incision cataract surgery (MSICS) is used increasingly for cataract extraction and intraocular lens implantation. It is thought that the small wound heals faster than a conventional incision, leading to less astigmatism and a better uncorrected visual acuity. This is important as many patients do not wear or cannot afford spectacles after surgery, which means that their uncorrected visual acuity is what they rely on to carry out their every day functions. Often this is less than 6/18 on the Snellen's chart, which would fall below the WHO 'good outcome' category for post-operative visual impairment. A post-operative vision of 6/18 or better without spectacles is a goal which appears to be within the reach of small incision techniques for cataract surgery. However, there are concerns that the method used to remove the nucleus in MSICS may be more traumatic to the corneal endothelium than conventional ECCE surgery.

Irritation and infection from sutures, which necessitates their removal, are arguments against conventional ECCE/IOL surgery. This is particularly problematic in large community eye care programmes where the expertise and equipment for suture removal may not be available in remote villages and the number of visits to an eye centre may increase the costs. It seems likely that patients without sutures would be more comfortable, less likely to rub their eyes and more satisfied with surgery.

When changing from one technique to another, we also need to consider costs of surgery, both to the provider and to the patient. An operation that gives better results but which costs much more may lead to unequal opportunities as only the wealthy could afford the better surgery. These issues (i.e., visual outcome, quality of life, patient satisfaction and cost) have

been studied in a randomised clinical trial to compare conventional ECCE/IOL surgery with MSICS / IOL surgery in Pune, India.^{1,2} Key findings are summarised in this article.

Methods

The purpose of the trial was to compare MSICS with conventional ECCE in terms of safety, effectiveness, costs and quality of life. A total of 741 patients aged 40–90 years with operable cataract were randomly assigned to receive either MSICS or ECCE, and they were operated on by one of eight experienced surgeons. In ECCE, the cataract nucleus was removed through a 10mm limbal incision followed by cortex aspiration and posterior chamber IOL implantation. The wound was closed with 8–0 or 10–0 interrupted sutures. In MSICS, a scleral tunnel was constructed using a keratome and the lens nucleus delivered into the anterior chamber. It was then removed with visco-elastic. Cortex aspiration and lens implantation was similar to ECCE, but no sutures were needed as the wound was self-sealing. Patients were followed up at 1 week, 6 weeks, and 1 year after surgery when they were examined and had their visual acuity recorded before and after refraction.

Questionnaires developed for the Madurai intraocular lens implant study³ were used in the trial in Pune to compare patient satisfaction, vision function and quality of life. These questionnaires were designed for use in trials of cataract patients who were blind in both eyes.

To compare the cost of MSICS with conventional ECCE, the fixed facility and recurrent cost for the two procedures was calculated. Average cost per procedure was calculated by dividing the total cost by the number of procedures performed. The average personnel cost for a procedure was calculated using the time required to perform it. A stopwatch was used to measure the surgery time in minutes and seconds.

Results

Safety and Effectiveness

The study found that MSICS gave an uncorrected visual acuity of 6/18 or better in a higher proportion of patients than ECCE at 6 weeks. Corrected visual acuities

of 6/18 or better were also slightly higher in MSICS, but this was not statistically significant. Poor outcomes (post-operative visual acuity of <6/60) was 1.7% in MSICS and 1.1% in ECCE at 6 weeks.

The rates of intra-operative and post-operative complications were similar in the two groups, except for transient post-operative corneal oedema which was more common following MSICS. However, by 6 weeks there was no difference between the two types of surgery.

Costs

This trial found MSICS to be marginally more economical than ECCE, and although the cost of keratome blades was high this was offset by savings on sutures.² The cost of the fixed facility was the same for both the techniques (\$11.34 for the service provider) and the consumable costs for MSICS was marginally less than for the conventional ECCE technique (\$4.34 and \$4.48 respectively). Surgical time was similar, with MSICS generally requiring less time as no suturing was required. The average surgical time for the eight surgeons using MSICS was 12 minutes (range: 6 min 19 sec – 27 min 25 sec) and for ECCE was 12½ minutes (range: 7 min – 25 min 40 sec). MSICS may work out to be cheaper in the long term because of fewer post-operative visits, fewer post-operative drugs and fewer patients needing spectacles.

Quality of Life

There was no significant difference between conventional ECCE and MSICS in the scores of visual function and quality of life. There was a small difference in the patient satisfaction scores, with MSICS scoring better.

Conclusions

The findings of this trial show that MSICS gives better short term visual results than standard ECCE, particularly before correction, without a higher rate of complications or adverse outcomes, and at a marginally lower cost. Concerns about endothelial damage were not substantiated clinically in this trial. A study in Madurai found endothelial cell loss to be only 6% following MSICS.⁴ Most problems in MSICS arise with very hard cataracts and small pupils,¹ and ECCE may be an alternative in such cases.

Ultimately, the choice of technique of surgery for uncomplicated cataract depends on the type of cataract, the surgeon's skills and available resources. Phacoemulsification provides excellent

and immediate visual rehabilitation, but the cost of equipment, consumables and maintenance make it unaffordable in many settings. The majority of ophthalmologists in developing countries are being trained in conventional ECCE surgery. The change to MSICS is easier than learning phacoemulsification, as anterior chamber dynamics in MSICS are similar to conventional ECCE. More trials are needed to compare the different techniques and their variations, to

provide better evidence of the costs and benefits.

References

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Author's Abstract

Sutureless cataract surgery with nucleus extraction: outcome of a prospective study in Nepal

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Aim: To report the short and medium term outcome of a prospective series of sutureless manual extracapsular cataract extractions (ECCE) at a high volume surgical centre in Nepal.

Methods: Cataract surgery was carried out, on eyes with no co-existing diseases, in 500 consecutive patients who were likely to return for follow up. The technique involved sclerocorneal tunnel, capsulotomy, hydrodissection, nucleus extraction with a bent needle tip hook, and posterior

chamber intraocular lens (PC-IOL) implantation according to biometry findings. Surgical complications, visual acuity at discharge, 6 weeks, and 1 year follow up, and surgically induced astigmatism are reported.

Results: The uncorrected visual acuity at discharge was 6/18 or better in 76.8% of eyes, and declined to 70.5% at 6 weeks' follow up, and 64.9% at 1 year. The best corrected visual acuity was 6/18 or better in 96.2% of eyes at 6 weeks and in 95.9% at 1 year. Poor visual outcome (<6/60) occurred in less than 2%. Intraoperative complications included 47 (9.4%) eyes with hyphaema, and one eye (0.2%) with posterior capsule rupture and vitreous in the anterior chamber. Surgery led to an increase in against the rule astigmatism, which was the major cause of uncorrected

visual acuity less than 6/18. Six weeks postoperatively, 85.5% of eyes had against the rule astigmatism, with a mean induced cylinder of 1.41 D (SD 0.8). There was a further small increase in against the rule astigmatism of 0.66 D (SD 0.41) between 6 weeks and 1 year. The mean duration of surgery was 4 minutes and the average cost of consumables, including the IOL, was less than \$10.

Conclusion: Rapid recovery of good vision can be achieved with sutureless manual ECCE at low cost in areas where there is a need for high volume cataract surgery. Further work is required to reduce significant postoperative astigmatism, which was the major cause of uncorrected acuity less than 6/18.

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Examination	Applications and Fees Due	Essay and/or MCQ Papers	Clinicals/Orals/OSES ⁺ /OSCES ⁺
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	31 August 2004	11–12 October 2004	None
Part 2 MRCOphth	4 May 2004	14 June 2004	14–18 June 2004
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Part 2 MRCOphth	31 August 2004	13 October 2004	13–14 October 2004
Part 3 MRCOphth	31 August 2004	14 October 2004	14–15 October 2004

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