Meta analysis to compare the safety and efficacy of manual small incision cataract surgery and phacoemulsification

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African proverb:

If you have to travel fast: Travel alone;

If you have to travel far: Travel together

Introduction

Cataract is still the leading cause of avoidable blindness worldwide and what is the most safe, effective and economical technique for its amelioration is still a matter of debate. (1,2) Manual small incision cataract surgery (SICS) has become an established cataract surgery technician over the past decade as an alternative to phaco emulsification (Phaco), the technique of choice in the developed world and tertiary centers of developing countries. [3-8] Numerous randomized controlled clinical trials (RCTs) have proved both the techniques to be safe and effective to rehabilitate the vision of the cataract patient. [9-14] Both have advantages of being sutureless, having a smaller incision and giving quicker visual rehabilitation. The Phaco technique has a much smaller incision (3.2mm) but is dependent on the machine. A meta-analysis published last year had presented comparable results with both techniques with phaco giving better unaided visual acuity. (15) However its results were drawn from the six randomized control trials (RCTs) which were selected using the Jadad composite scale. [16] While the study discussed unaided and aided visual acuity after surgery, it did not go into the details of complications [during and after surgery], learning curves, astigmatism and surgeon time for SICS and phaco. There is a huge backlog of cataract blind individuals which makes cataract the leading cause of avoidable blindness globally, including Africa.(1) The reasons for this backlog is lack of access to eye care and lack of resources, especially trained surgeons, to deliver it safely and reliably. We thus performed a meta-analysis comparing SICS with phaco using a wider publication base, stressing more on safety, learning curves and resource inputs and tried to get a more holistic picture about the two techniques. The surgery should be such that it is safe, reliable, effective and affordable to all, including low and middle income countries and poor communities of relatively well off societies. This manuscript presents our results.

Method

Permission was requested from the ethical committee of Africa Vision Research Institute. As the study involved review of published manuscripts, each of which had an ethics approval, the committee opined that permission was not necessary. The data bases of pub med, Cochrane and Scopus were searched with key words manual small incision cataract surgery and phaco emulsification. Search was also made for Non-English language manuscripts and those that were not indexed, on SICS and its comparison with Phaco.

Individual data from each study was grouped for following objectives.

1. Unaided and best corrected visual acuity $\geq$ 6/18
2. Unaided and best corrected visual acuity $\geq$ 6/9
3. Unaided visual acuity <6/60.
4. Astigmatism
5. Intra operative complications.
6. Post – Operative complications.
7. Endothelial cell loss.
8. Time taken for surgery.
9. Cost of surgery

The cut-off of 6/9 was taken as this is the driving license vision standard in most developed countries. But the vision of 6/9 should be in better eye and can be with spectacle correction.

The 6/18 and better is normal vision by WHO standards. 6/60 is considered severe visual impairment by WHO standards (economic blindness) and is the legal norm for blindness in the United States and India (<6/60 in the better eye with available correction). Unaided vision results were considered as many may not have or afford a pair of spectacles. Astigmatism only was considered, as the post-operative refractive spherical error was taken care by A-scan biometry and proper intra-ocular lens implantation. The post-operative cylinder depended on the size, site and type of incision which differed in the two techniques.

The Oxford Cataract Treatment and Evaluation Team (OCTET) grading was used to compare the intra operative and postoperative complications depending on their severity. [17] Complications were graded as per severity so that they were compared not just by their frequency but also by their ability to affect the final visual acuity. Endothelial cell loss though not always obvious during surgery has the ability to affect corneal transparency in long term. This too was compared for both techniques. Intra operative complications like posterior capsular rent (PCR), vitreous loss, zonular dialysis and iridodialysis were compared as also post operative complications like endophthalmitis, retinal detachment, posterior capsular opacification, post-operative corneal edema that has potential for corneal decompensation. Also calculated was the time taken for surgery and the cost for surgery. This was because surgeon time was a factor of cost in high volume African settings where surgeons are scarce. We also compared the two techniques with respect to their learning curves as new surgeons would need to be trained for combating and eliminating the cataract backlog.

Statistical analyses were performed using STATA (version 10; StataCorp, College Station, Texas). Randomized control trials or parallel arms (one with PE and one MSICS) design studies were included in the meta analysis. Primary outcomes were presented either as binary or continuous variables. For Binary variables, a pooled Odds ratio (OR) with 95% confidence interval (CI) was calculated. . For the continuous outcomes, the standardized mean difference (SMD) with 95% CI was calculated. Statistical heterogeneity was tested using the chi-square and I2 statistic. Fixed-effects models were used unless significant evidence of statistical heterogeneity or clinical diversity was found. However, for results showing higher heterogeneity (I2 >□25%), a random-effects meta-analysis was performed using DerSimonian-Laird method. (18) A P-value <0.05 was considered significant.

For missing data that could not be obtained from the published reports or author communication, an attempt was made to calculate or estimate values (e.g. standard deviations, mean age of combined groups, mean treatment effects) using the formulas supplied in the Cochrane handbook. (19) Studies were excluded from the meta-analysis portion of the review when values for missing data could not be obtained or estimated.

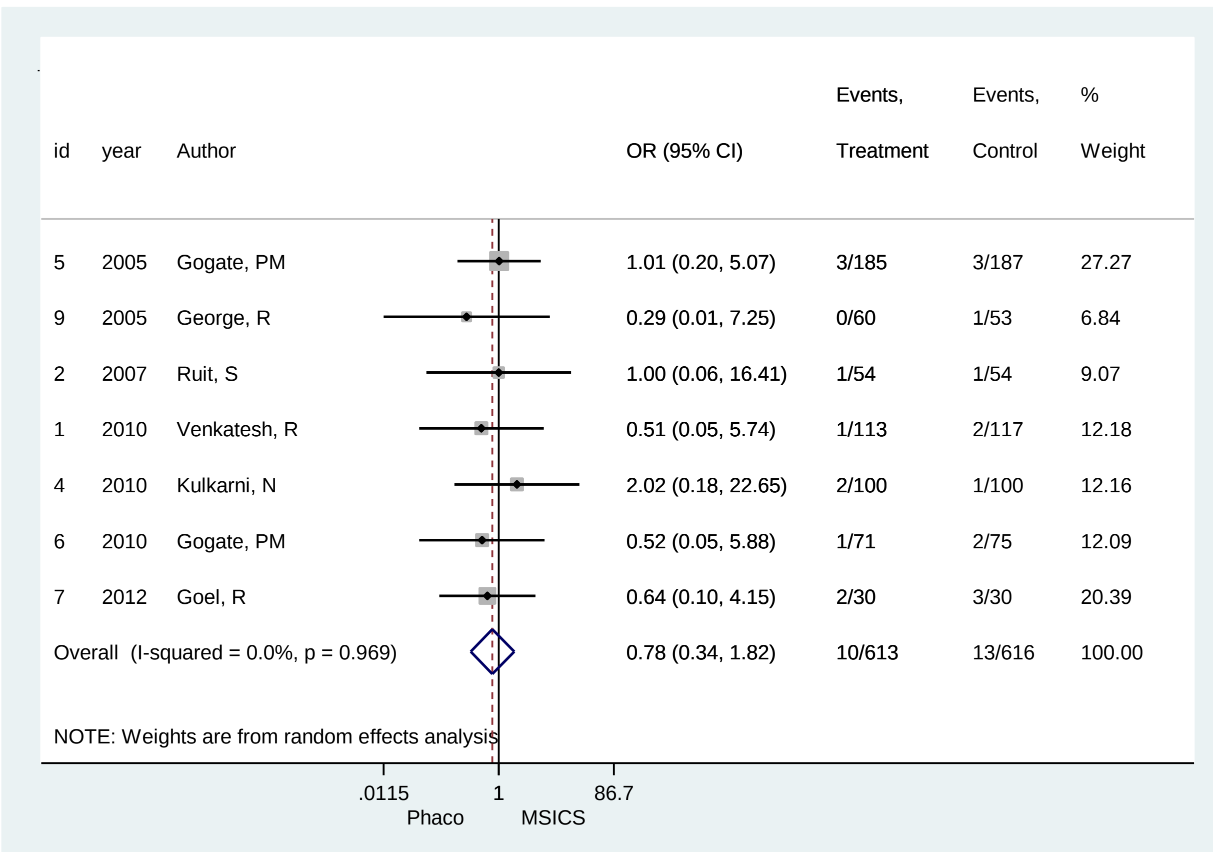
Results :

The literature search revealed 84 studies which fulfilled the inclusion criteria. One each involved comparison of phaco and SICS with conventional extra capsular cataract surgery (ECCE). 38 had been published in pub med indexed journals, 30 in other indexed journals, 2 in local journals while one was published in the proceedings of the All India Ophthalmology Society’s Annual Conference. (20) 11 studies involved direct comparison between phaco and SICS, of which 6 were RCTs. Of these six were randomized control trials, [9-14] and three others were direct comparison, one with near vision data, the second comparing subluxated cataracts while the third compared immature cataract surgery by both techniques in Nepal. (20-22)

A study by Khanna et.al. compared the safety and efficacy of both techniques during their learning curves in a large residency and fellowship training program. (23) It had a large sample size and variety of complications and dominated the forest plots comparing intra and post-operative complications. It was thus not included in the meta-analysis but discussed in parallel, especially in view of safety and complications. Another study by Haripriya et al dealt with comparison between SICS and phaco in a high volume setting. [24]

1. **Comparison of best corrected visual acuity ≥ 6/18**

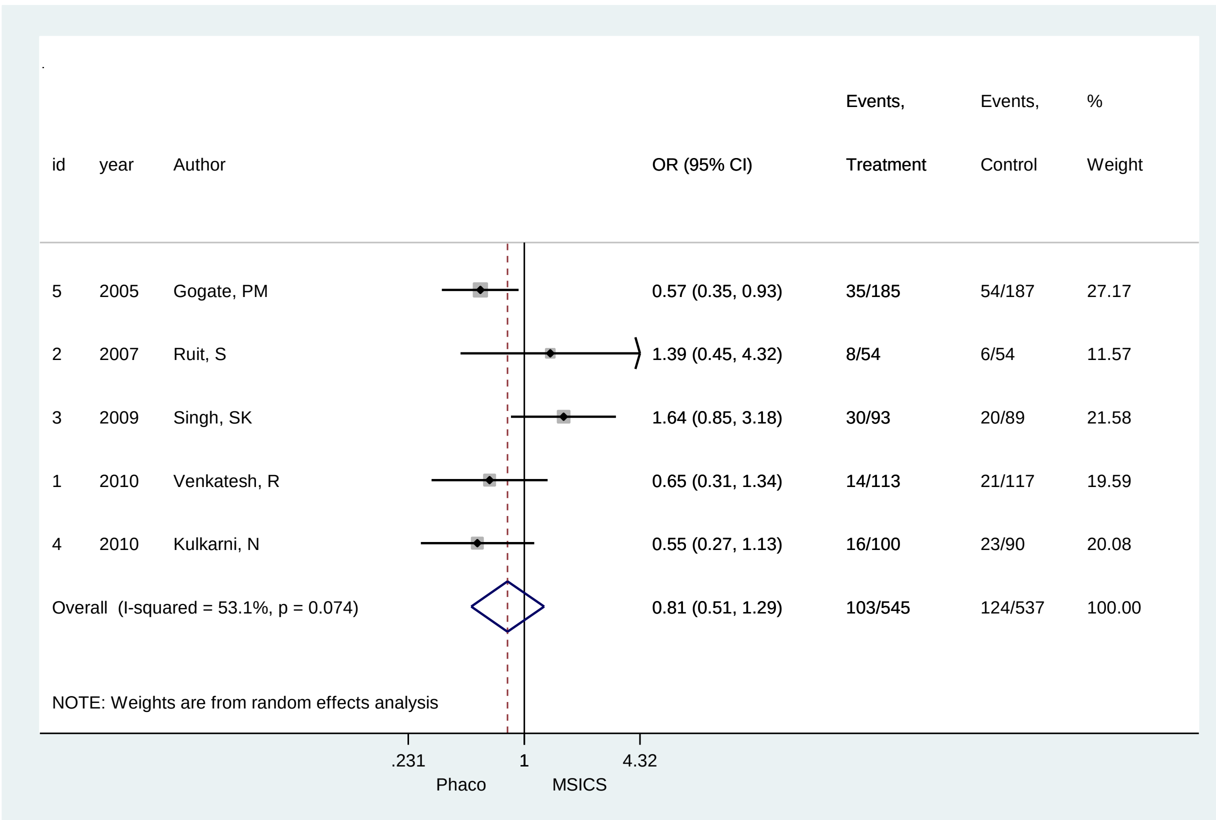
   Figure 1: Comparison of best corrected visual acuity < 6/18, relatively poor or borderline and poor outcome by phaco vs SICS



Seven publications including BCVA data on 1229 eyes, reported the proportion of patients having BCVA <6/18 vs. BCVA of 6/18 or better at (around 6 weeks ± 2 weeks) follow-up after the surgery. Heterogeneity among study results was detected to be (I^2 = 0.0%). A random effect modeling was used. Analysis of these data revealed that the difference in the proportion of participants having BCVA < 6/18 after surgery between the PE and MSICS groups was not

Comparison of unaided corrected visual acuity > 6/18

Figure 2: Comparison of unaided visual acuity < 6/18, relatively poor or borderline and poor outcome by phaco vs SICS

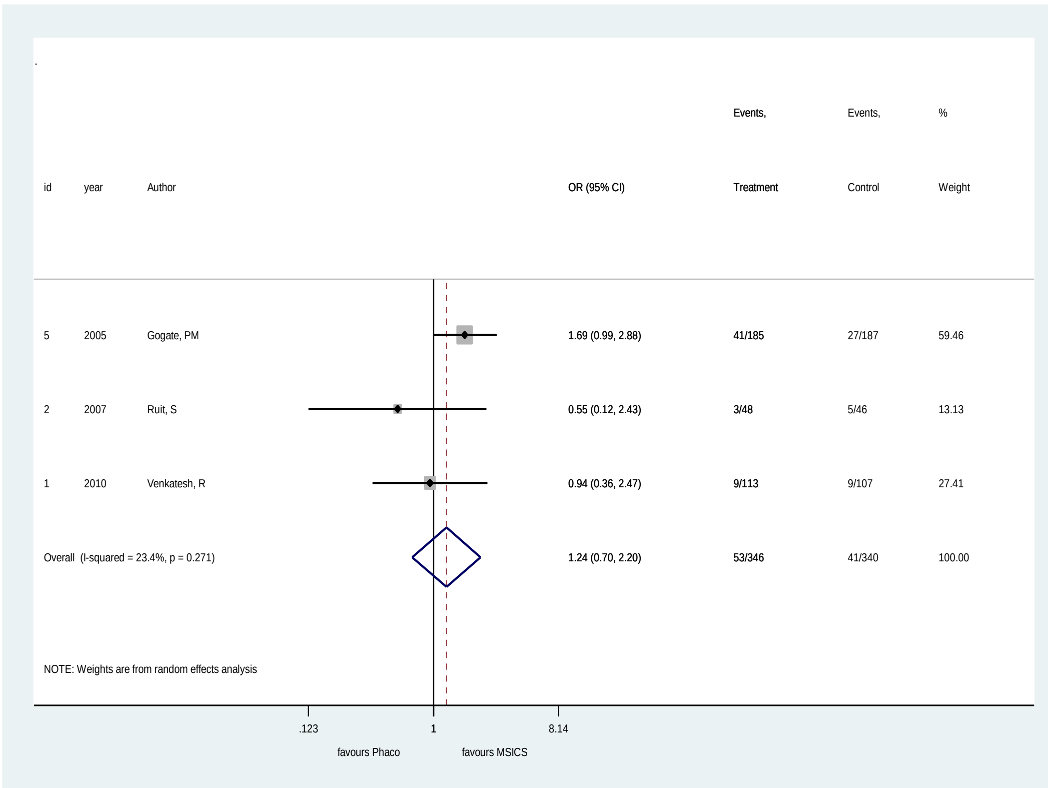


Five publications including unaided visual acuity data on 545 eyes, reported the proportion of patients having unaided visual acuity <6/18 vs. unaided visual acuity of 6/18 or better at (around 6 weeks + 2 weeks) follow-up after the surgery. Heterogeneity among study results was detected to be (I^2 = 53.10%). A random effect modeling was used. Analysis of these data revealed that the difference in the proportion of participants having unaided vision < 6/18 after surgery between the PE and MSICS groups was not statistically significant (OR,0.81; 95% CI,0.51-1.29; *P* = 0.373; Fig. 2). It favors phaco, but only slightly.

Comparison of best corrected visual acuity > 6/9

Figure 3: Comparison of best corrected visual acuity >6/9 by phaco vs SICS.

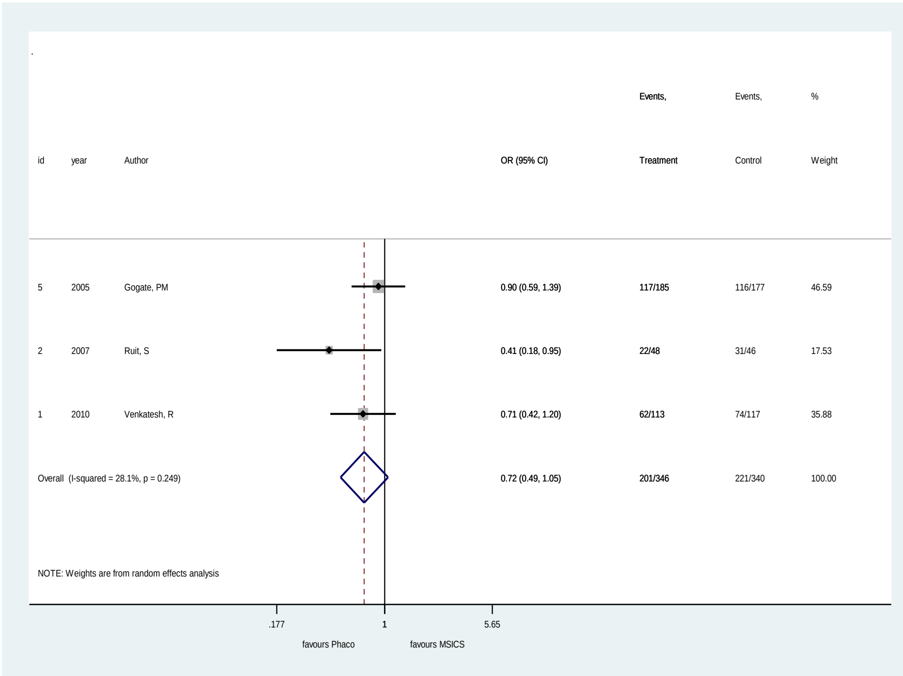
Only 3 papers were available for comparison of this endpoint.



Three publications reported the proportion of patients having best-corrected visual acuity >6/9 vs. BCVA of <6/9 at around 6 weeks ± 2 weeks follow-up after the surgery. Heterogeneity among study results was detected to be (I^2 = 23.4%). A random effect modeling was used. Analysis of these data revealed that the difference in the proportion of participants having unaided vision < 6/18 after surgery between the PE and MSICS groups was not statistically significant (OR,1.24; 95% CI,0.7- 2.2; P = 0.460; Fig. 3)

Comparison of unaided visual acuity $\geq$ 6/9

Figure 4: Comparison of unaided visual acuity >6/9 by phaco vs SICS



Heterogeneity chi-squared = 2.78 (d.f. = 2) p = 0.249

I-squared (variation in OR attributable to heterogeneity) = 28.1%

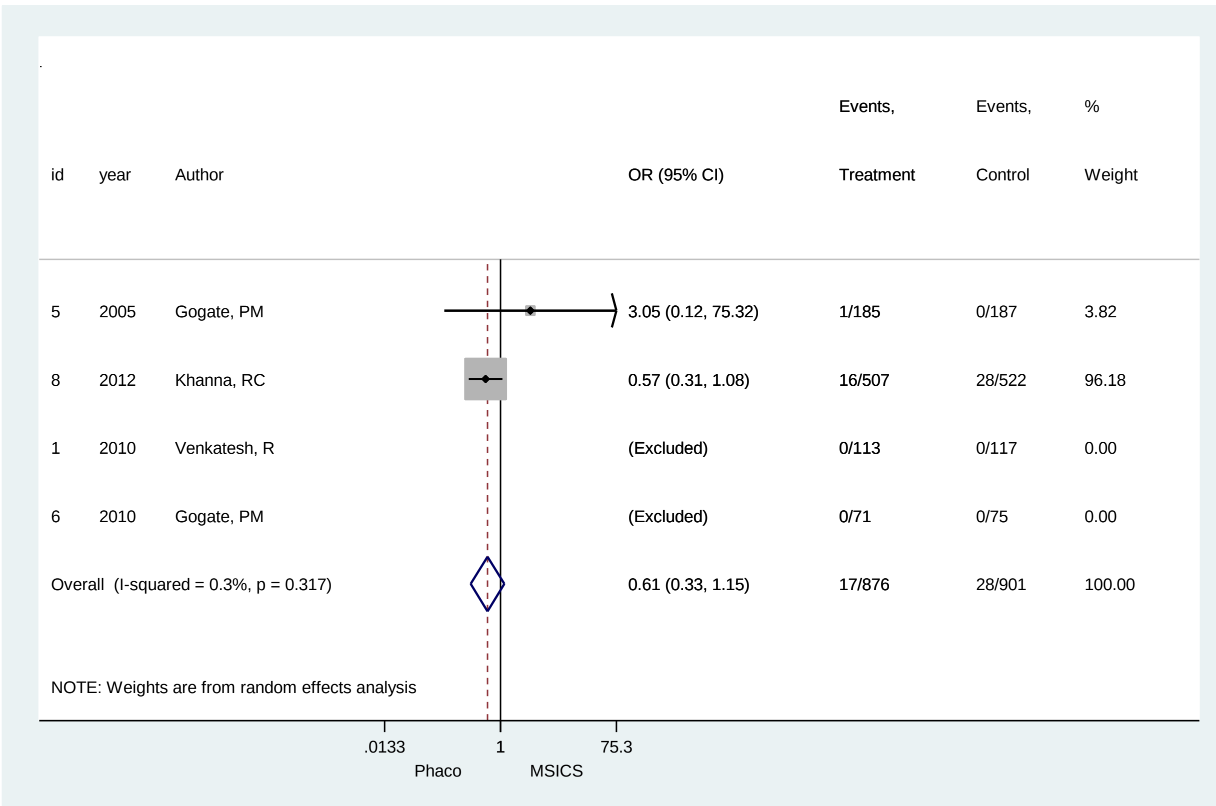
Estimate of between-study variance Tau-squared = 0.0329

Test of OR=1 : z= 1.69 p = 0.092

Phaco was better than SICS with borderline significance with OR=0.720(95% CI: 0.49, 1.055) and p value as 0.092.Three publications reported the proportion of patients having unaided visual acuity >6/9 vs. unaided visual acuity of <6/9 at around 6 weeks $\pm$ 2 weeks follow-up after the surgery. Heterogeneity among study results was detected to be (I^2 = 28.1%). A random effect modeling was used. Analysis of these data revealed that the difference in the proportion of participants having unaided vision >6/9 after surgery between the PE and MSICS groups was not statistically significant (OR, 0.72; 95% CI,0.49- 1.1; *P* = 0.092; Fig. 4)

Comparison of best corrected visual acuity <6/60

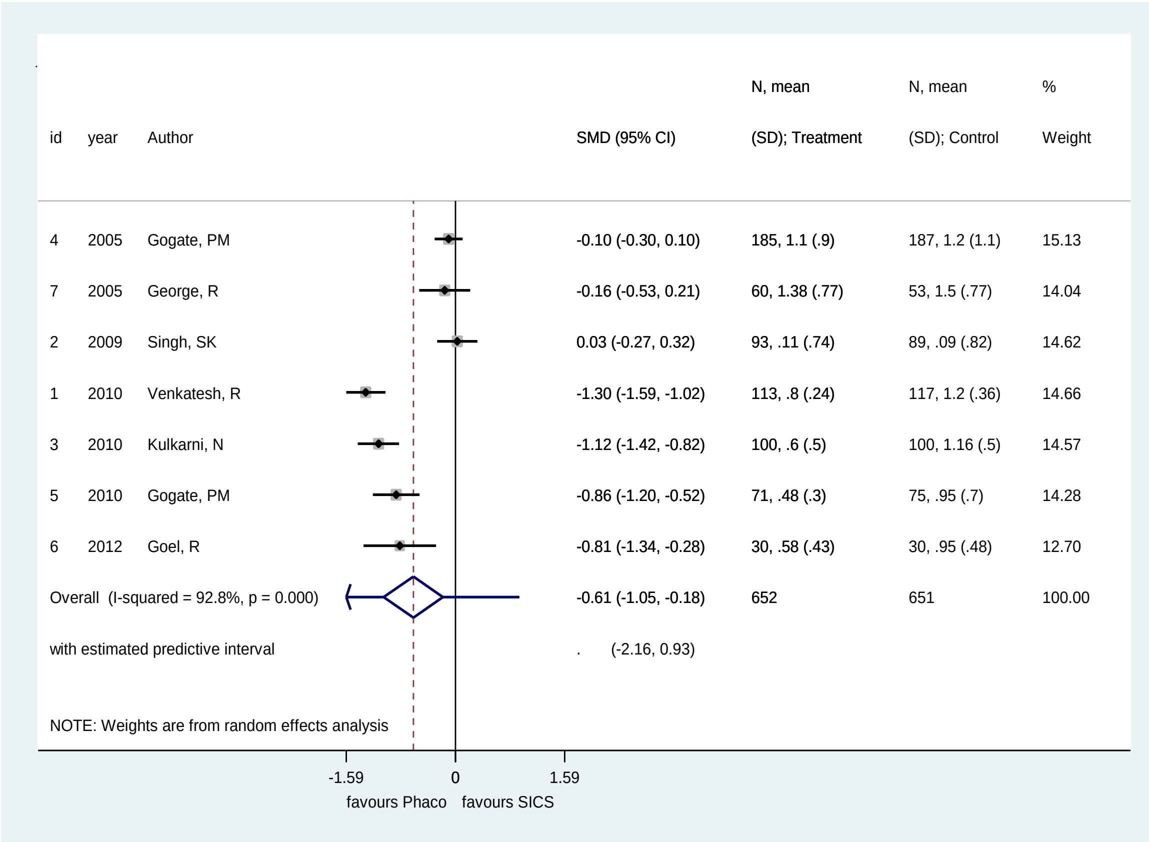
Figure 5: Comparison of best corrected visual acuity < 6/60, poor outcome by phaco vs SICS



Two publications for unaided vision <6/60 had data on 876 (692) eyes, reported the proportion of patients having unaided vision <6/60 vs. UNVA of 6/60 or better at (around 6 weeks $\pm$ 2 weeks) follow-up after the surgery. Khanna et.al. also was used for this analysis. Heterogeneity among study results was detected to be (I^2 = 0.3%). A random effect modeling was used. Analysis of these data revealed that the difference in the proportion of participants having unaided vision <6/60 after surgery between the PE and MSICS groups was not statistically significant (OR, 0.61; 95% CI, 0.33-1.15; *P* = 0.126; Fig. 5).

Comparison of astigmatism by both techniques

Figure 6: Comparison of astigmatism by phaco vs SICS



Heterogeneity chi-squared = 83.33 (d.f. = 6) p = 0.000

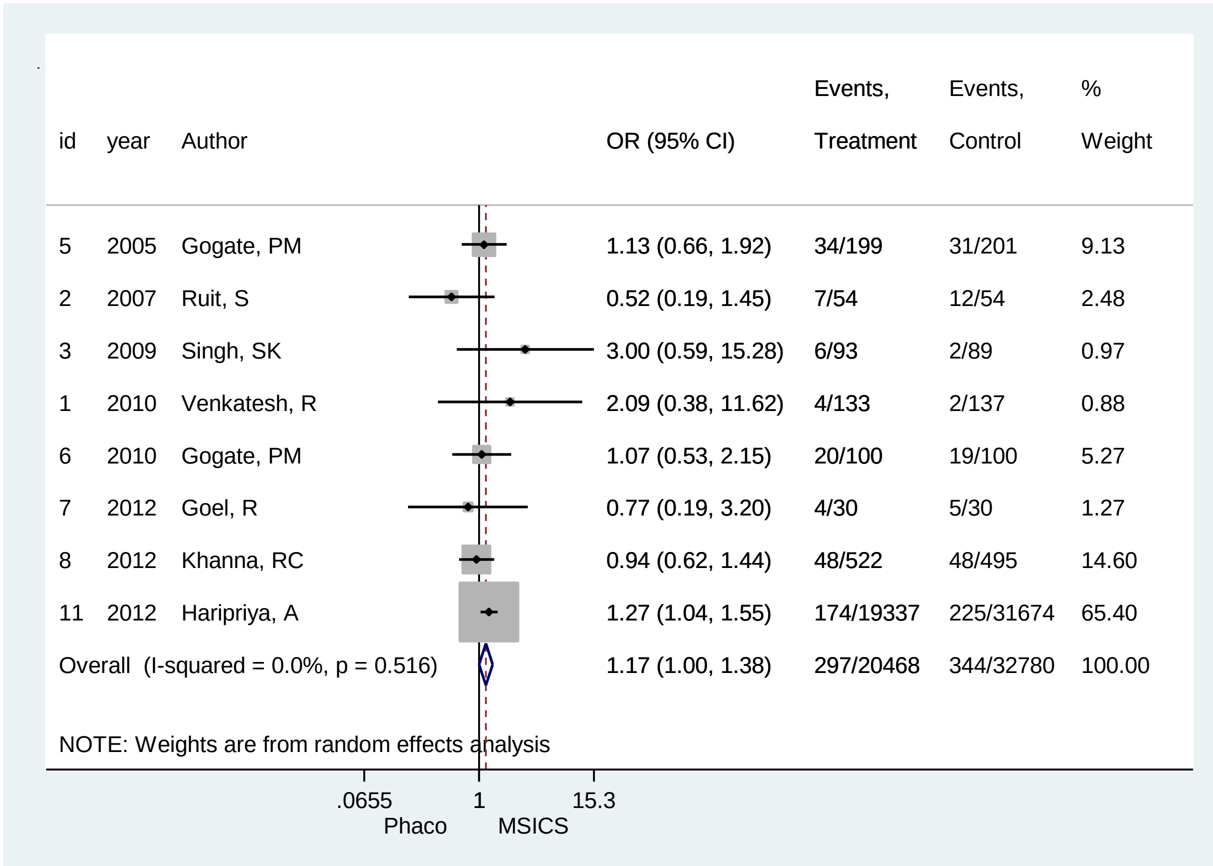
I-squared (variation in SMD attributable to heterogeneity) = 92.8%

Estimate of between-study variance Tau-squared = 0.3111

Test of SMD=0 : z= 2.78 p = 0.005

Seven studies involving 1303 eyes compared surgically induced astigmatism after surgery using PE and MSICS. Analysis of these data showed that PE group was significantly better than MSICS group (SMD=-0.614, 95% CI –-1.05, -0.18, p=0.005). The smaller incision size in PE led to significantly lesser astigmatism than SICS.

Comparison of complications by both techniques



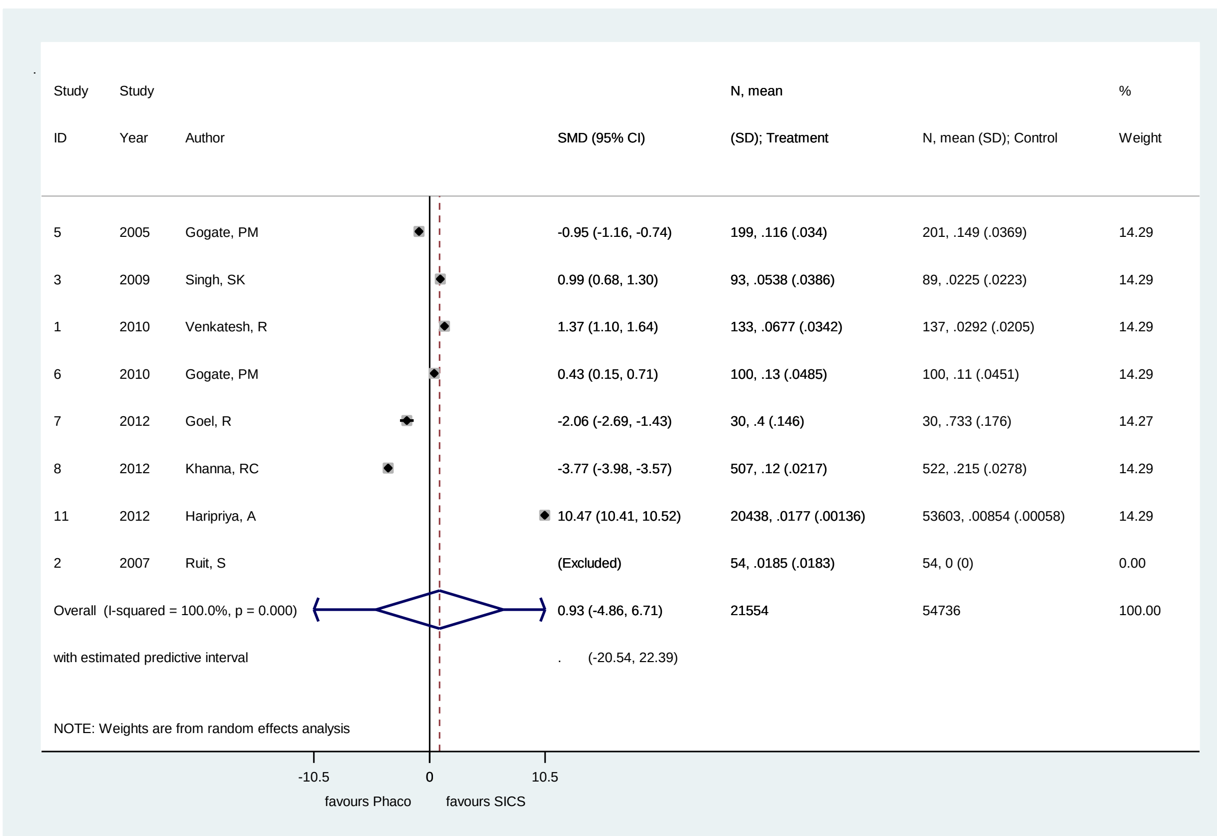
Eight publications with data on intra-operative and post-operative complication on 20,468 eyes, reported the proportion of patients having OCTET complication scores for intra-operative and post-operative complications, including surgeries by residents and trainees. Heterogeneity among study results was detected to be (I^2 = 0.0%). A random effect modeling was used. Analysis of these data revealed that the difference in the proportion of participants having complications between the PE and MSICS groups was not statistically significant (OR, 1.17; 95% CI, 1.00 to 1.38; *P* = 0.516 / 0.054). SICS was safer with lesser complications as far as beginner surgeons were concerned.

As Khanna et. Al. was a manuscript comparing the results while learning of both techniques, while Haripriya A et.al was on high volume surgery we analyzed the intra and post-operative complications separately, with and without these to manuscripts.

Comparison of intra-operative complications by both techniques

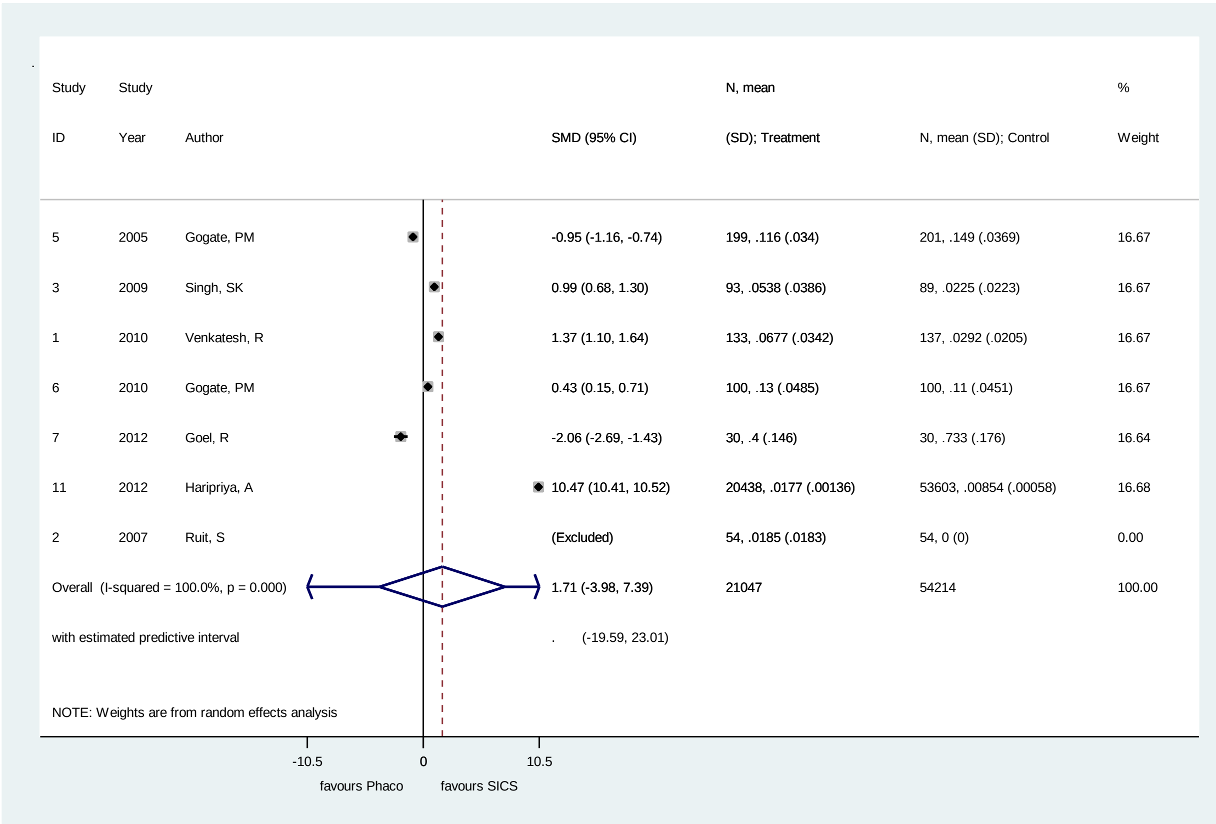
Six publications with data on intra-operative and post-operative complication on 609 eyes, reported the proportion of patients having OCTET complication scores for intra-operative and post-operative complications at around 6 weeks follow-up after the surgery. Heterogeneity among study results was detected to be (I^2 = 0.0%). A random effect modeling was used. Analysis of these data revealed that the difference in the proportion of participants having complications between the PE and MSICS groups was not statistically significant (OR, 1.06; 95% CI, 0.74 to 1.52; *P* = 0.509 / 0.739; Fig. 7).

Figure 7a: Comparison of intra-operative complications including studies with learning curves and high volume surgery.



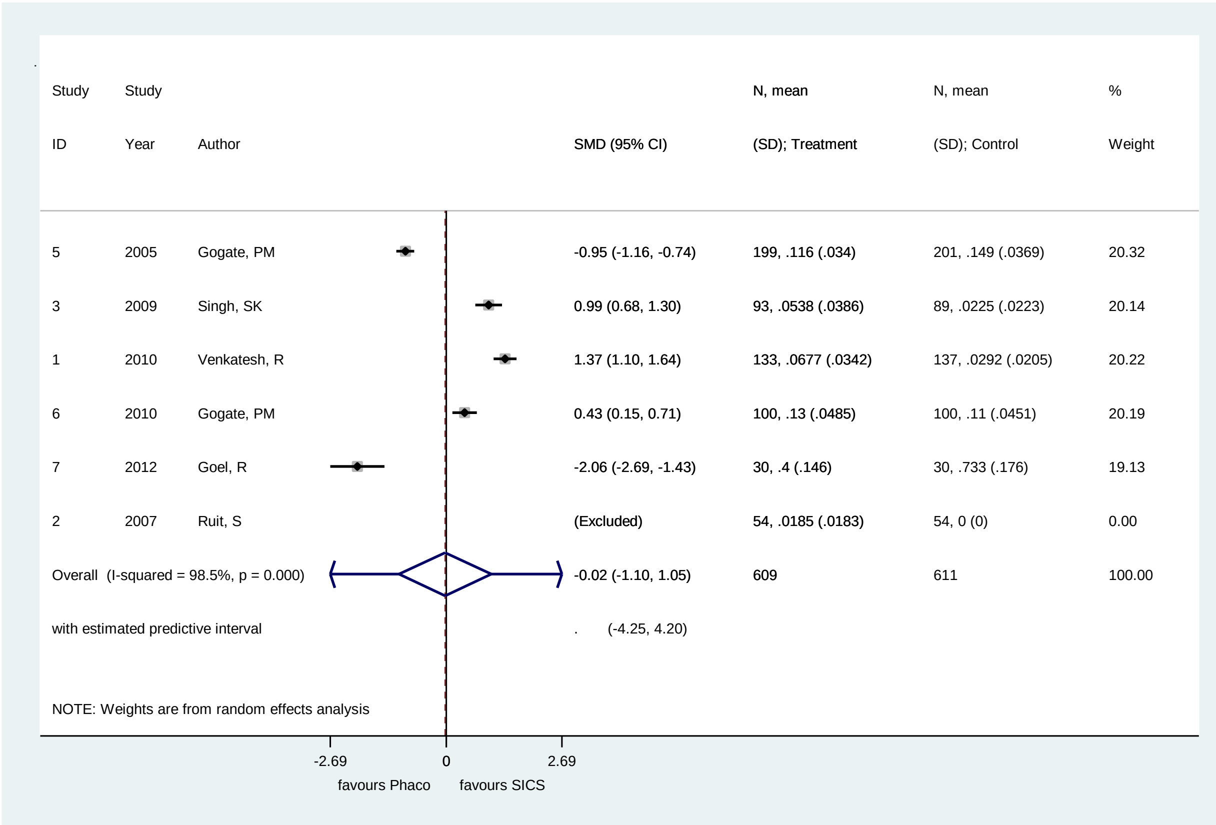
SICS is safer.

Figure 7b: Comparison of intra-operative complications excluding studies with learning curves, but includes high volume setting.



SICS is safer

Figure 7c: Comparison of intra-operative complications excluding studies with learning curves and high volume surgery



Heterogeneity chi-squared = 269.00 (d.f. = 4) p = 0.000

I-squared (variation in SMD attributable to heterogeneity) = 98.5%

Estimate of between-study variance Tau-squared = 1.4629

Test of SMD=0 : z= 0.05 p = 0.964

The line is almost parallel to zero, there is no difference in intra-operative complications between both techniques.

Comparison of post-operative complications by both techniques

Figure 8a: Comparison of post-operative complications including studies with learning curves and high volume surgery.

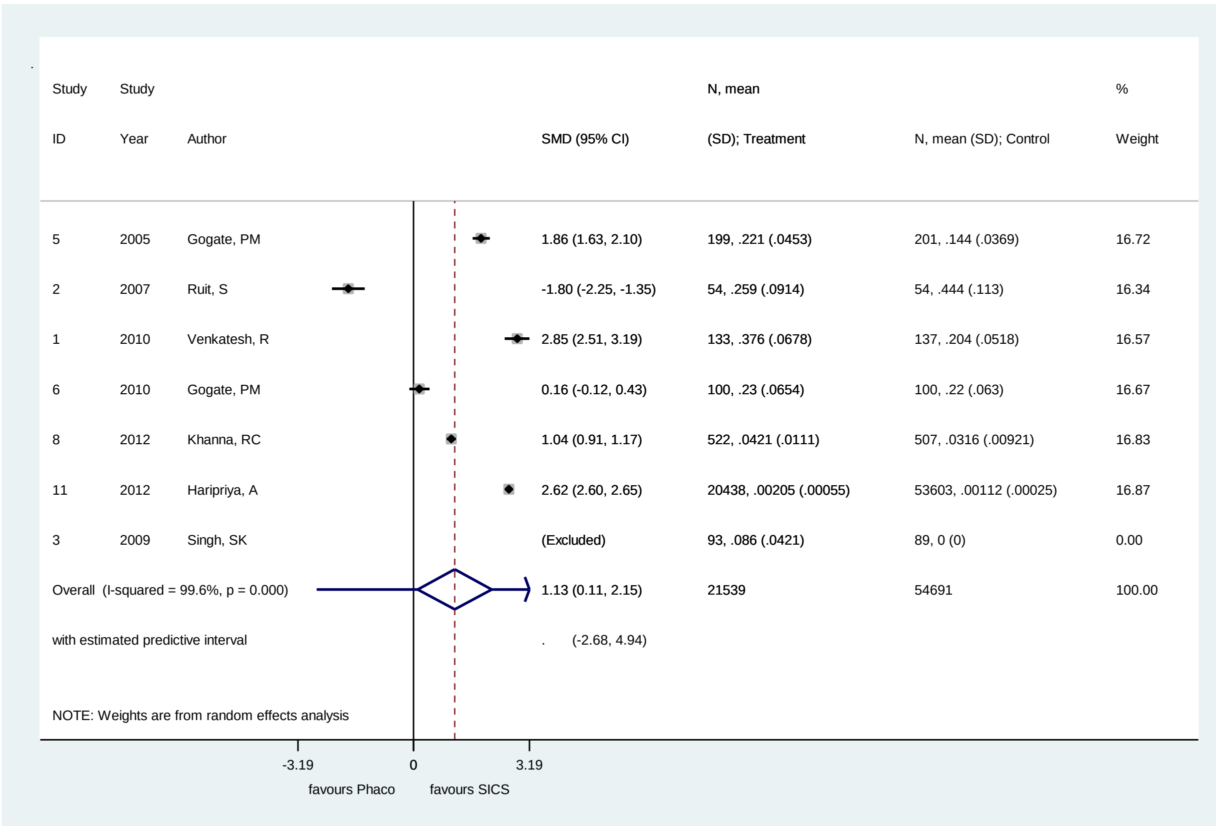
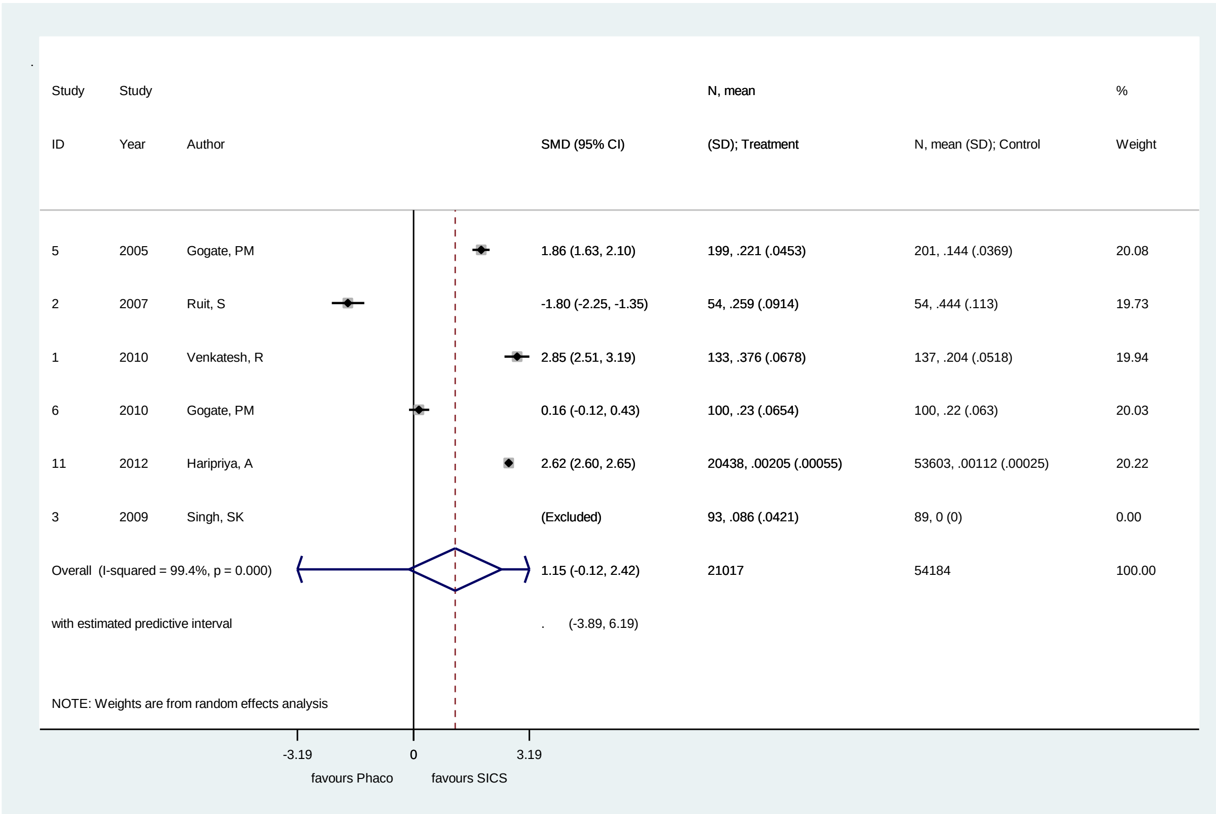


Figure 8b: Comparison of post-operative complications excluding studies with learning curves.



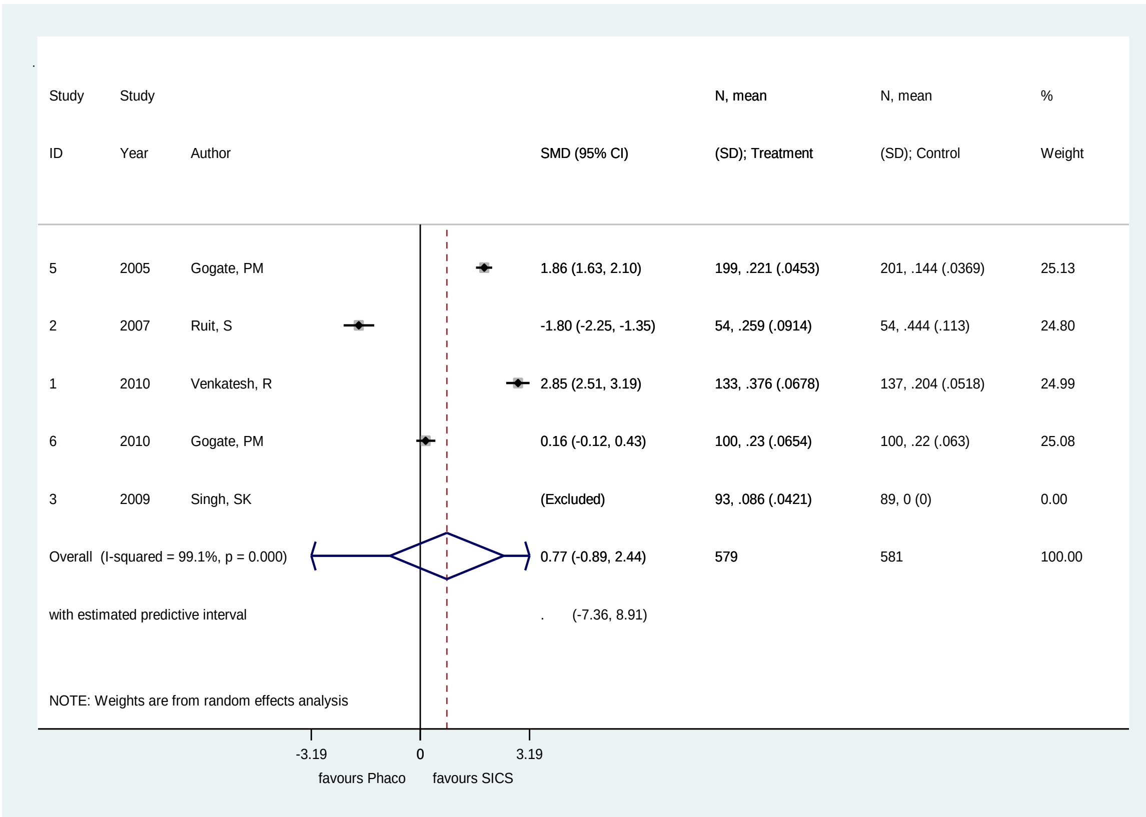
Heterogeneity chi-squared = 713.24 (d.f. = 4) p = 0.000

I-squared (variation in SMD attributable to heterogeneity) = 99.4%

Estimate of between-study variance Tau-squared = 2.0883

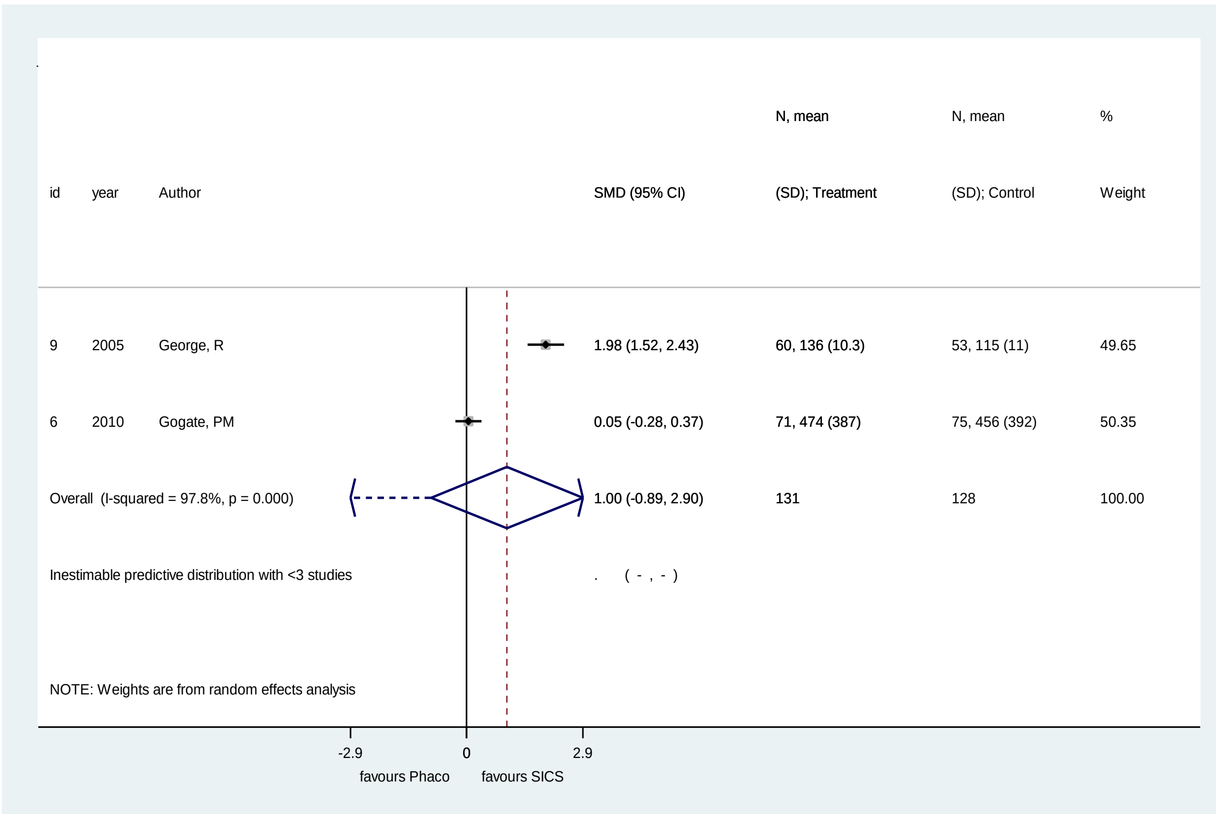
Test of SMD=0 : z= 1.77 p = 0.077

Figure 8c: Comparison of post-operative complications excluding studies with learning curves and high volume surgery.



Comparison of endothelial cell loss by both techniques

Figure 9: Comparison of endothelial cell count reduction after phaco and SICS



Heterogeneity chi-squared = 46.25 (d.f. = 1) p = 0.000

I-squared (variation in SMD attributable to heterogeneity) = 97.8%

Estimate of between-study variance Tau-squared = 1.8227

Test of SMD=0 : z= 1.04 p = 0.298

Only two studies had compared endothelial cell loss after PE and SICS, each having similar weight in the meta-analysis. One study had shown higher loss with SICS while the other had shown no difference, even though sodium hyaluronate and foldable lenses were used for PE and methyl cellulose and PMMA lenses were used for SICS.

Table 10: Average time taken for each technique in minutes

Author	Journal, year	Phaco	SICS
Venkatesh [12]	2010	8.8 (3.4)	12.2
Ruit S [11]	2007	15.5	9.0
Singh SK [22]	2009	7.0	5.4
Kulkarni AN [20]	2010	15.0	7.0
Gogate PM [25]	2005	15.0	7.0

A meta-analysis could not be performed as the published manuscripts did not have the standard deviations along with the mean time for surgery. However all the five publications had the average time for SICS surgery nearly half of that for phacoemulsification.

Table 11: Cost comparison between the two techniques

Country	**Study (Year) (Reference)**	**SICS**	**PHACO**	**ECCE - IOL**
India	Gogate (2003) [26]	US $ 15.68		US $ 15.82
India	Gogate (2007) [25]	US$15.34	US$ 42.10	-
India	Muralikrishnan et al (2004) [27]	US$17.03	US$ 25.55	US$ 16.25
Nepal	Ruit et al (2007) [11]	US$ 15	US$ 70	-

Discussion

The meta-analysis revealed no difference between Phaco and SICS on best corrected visual acuity, unaided vision, vision <6/60, endothelial cell loss and intra-operative and post-operative complications scores. PE was better for lesser astigmatism while SICS was safer for beginner surgeons.

There was no difference between the two techniques with respect to corrected vision. Even the difference in unaided, presenting vision without spectacles was very small and not statistically significant. Phaco gives lesser astigmatism which was confirmed on the meta-analysis. However this did not translate into greatly improved unaided vision. 6/18 is considered to be normal vision by WHO for most tasks. There were equally good results with both SICS and Phaco. While considering safety and looking at the other end of visual spectrum, vision <6/60, again there was no difference. This was after considering manuscripts for white, hard cataracts and immature cataracts also which were not a part of meta-analysis done earlier which was solely based on the RCTs.

Limitations of this study: Limitations of individual studies and their designs. Most have short follow up (<4months). Larger follow up would lead to delay in astigmatism but perhaps increased posterior capsular opacification. We have considered series which were not randomized control trial to make the meta-analysis more broad based.

There was no difference in unaided visual acuity at the 6/18 cut-off, which is the WHO standard for normal vision. So even if phaco resulted in less astigmatism it did not have a significant advantage of unaided vision. *In fact the astigmatism led to better unaided near vision in the study from Miraj, India.* [20] *So while astigmatism is an issue differentiating the two techniques, it does not seem to have much impact on functional vision*. In fact the increased astigmatism in SICS in one series from Miraj, India was responsible for better unaided near vision as compared to Phaco, where the astigmatism-free improved unaided distance vision was associated with impaired unaided near vision. The unaided near vision was important even in illiterate, rural communities for needle work, working and cleaning, answering mobiles and differentiating currency and not just for reading and writing.

While comparing complications using OCTET scores there was no difference in safety. SICS was also safer during its learning phase in residents and trainees across two large, reputed training programs in India. [23,24] But some complications like nucleus drop was observed in Phaco while iridodialysis was seen in SICS. Endothelial cell count decrease was comparable; in fact it was slightly more in phaco even with use of high density viscoelastic devices. The two large studies from India showed SICS to be safer for residents in their training programs. Use of SICS had also improved the visual outcomes in a large community eye care centre. [28]

But a cursory look at the cost comparison between the two techniques shows that SICS is almost half the cost of phaco with easier learning curves.

The meta analysis again underlines the similarity of results between Phaco and SICS – even after considering white, black, hard and sub-luxated cataracts and not just randomized clinical trials as was done in the study from China. Some randomized trials give better unaided vision in the Phaco arm of the study[9], but the meta analysis demonstrates that this difference was not significant.

The comparable results of unaided and aided visual acuity, intra and post-operative complications, endothelial cell loss make SICS a comparable technique to phacoemulsification. After considering the surgeon time saved, the easier and safer learning curves and the cost of the procedure, SICS is the most suitable surgery to tackle to backlog of cataract blindness in Africa.

The lesser time and equipment needed for SICS meant the surgeon would be more productive with a higher turnover in communities where there is large backlog of blindness and trained human resource is scarce as in many African countries. More economical cost would mean that the same budget could be used for more number of beneficiaries. **In a limited resource setting with large number of beneficiaries awaiting cataract surgery/ backlog of cataract blind, manual SICS is the technique of choice over Phaco, as in Africa. In any public funded program it would give the most cost-effective results. Only when surgery is self-paid would the small, certainly not significant, advantage of phaco for unaided vision be justified. But in all settings SICS was safer and more economical and almost as effective.**

As the African proverb says if you have to travel fast, travel alone (phaco); but if you have to travel far, travel together (SICS)

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