Clinical Ophthalmology Dovepress

Open Access Full Text Article ORIGINAL RESEARCH

The Cutting Efficiency of a Hybrid Phacoemulsification Tip Using High and Low Intraocular Pressure Settings in Different Grades of Cataract

Justin Spaulding[1], Brad Hall[2]

[1]Cataract & Laser Institute, Medford, OR, USA; [2]Sengi, Penniac, NB, Canada

Correspondence: Justin Spaulding, Cataract & Laser Institute, 1408 E Barnett Road, Medford, OR, 97504, USA, Tel +1-541-779-2020, Email justinophtho@gmail.com

Purpose: To evaluate the efficiency of a hybrid tip in removing cataract grade 3 and 4 in high and low intraocular pressure (IOP) settings.

Methods: This was a randomized, prospective, double-arm contralateral eye study. One randomized eye of each subject had phacoemulsification with high IOP settings (50 mmHg) while the other eye had phacoemulsification with low IOP settings (20 mmHg). Operative endpoints included phaco time, aspiration time, fluid use, cumulative dissipated energy (CDE), total case time, total torsional time, and total longitudinal time. Postoperative endpoints included central corneal thickness (CCT), and IOP.

Results: A total of 102 eyes (51 patients) completed the study. Phaco time in grade 3 and grade 4 cataracts were 38.4 ± 9.6 s and 44.1 ± 9.9 s in the high group, respectively, and 38.9 ± 8.6 s and 46.3 ± 11.0 s in the low group, respectively. Aspiration time in grade 3 and grade 4 cataracts were 95.3 ± 21.2 s and 111.8 ± 32.8 s in the high group, respectively, and 105.4 ± 27.0 s and 108.6 ± 23.1 s in the low group, respectively. Fluid volume used in grade 3 and grade 4 cataracts were 39.2 ± 6.8 mL and 45.2 ± 10.8 mL in the high group, respectively, and 38.3 ± 7.3 mL and 43.2 ± 8.0 mL in the low group, respectively. The CDE in grade 3 and grade 4 cataracts were 7.8 ± 2.6 and 10.2 ± 3.2 in the high group, respectively, and 7.7 ± 2.2 and 9.9 ± 4.5 in the low group, respectively.

Conclusion: Results suggest that a hybrid phacoemulsification tip was efficient in removing cataracts of grade 3 and grade 4 with high and low IOP settings.

Plain Language Summary: Phacoemulsification involves emulsifying the natural lens during cataract surgery with an ultrasonic handpiece and removing the lens from the eye. An important facet for safety and good postoperative outcomes is the phacoemulsification tip. Traditional tips have used a metal cutting edge. A new hybrid tip is available that utilizes a soft polymer on the metal tip. The purpose of this study was to assess the efficiency of the hybrid tip to remove different grades of cataract. The results of this study suggest that a hybrid tip was efficient in removing grade 3 and grade 4 cataracts at both low and high intraocular pressure settings.

Keywords: active sentry, phacoemulsification, intrepid hybrid

Introduction

Phacoemulsification is the gold standard method to remove the natural lens during cataract surgery. An important facet for safety and good postoperative outcomes is the phacoemulsification tip, with differences in design or materials reportedly influencing surgical outcomes.[1] Traditional tips have used a metal cutting edge at the distal end of the phacoemulsification handpiece. In contrast, the Intrepid hybrid tip (Alcon Vision, LLC) utilizes a soft polymer on the metal tip, which is designed to reduce posterior capsular rupture (PCR) compared to a conventional tip.[2–4]

Received: 25 July 2024
Accepted: 29 October 2024
Published: 13 November 2024

Cataract surgery is typically performed with intraocular pressure (IOP) settings much higher than physiological IOP. Using these high IOP settings may increase the risk of postoperative complications such as corneal edema (including epithelial edema, stromal edema, and endothelial edema) and endothelial cell loss.[5,6] Studies have reported a correlation between increased postoperative central corneal thickness and endothelial cell loss.[7,8]

Active Sentry technology (Alcon Vision, LLC) has an integrated pressure sensor in the handpiece, which can detect the onset of post-occlusion surge, and a Quickvalve within the cassette that can supply solution into the aspiration line when a surge event occurs.[9] Combined with Active Fluidics, which adjusts flow to maintain target IOP, Active Sentry can provide a stable target IOP.[9] This handpiece also facilitates operation at lower IOP settings, which may reduce the risk of postoperative complications.

The use of Centurion with Active Sentry handpiece and the Intrepid hybrid tip has been reported to potentially improve clinical safety.[10] However, to date there is minimal data on the cutting efficiency when using IOP settings that are closer to physiological IOP. The purpose of this study was to assess the efficiency (as measured by phaco time, aspiration time, and fluid use) of a hybrid tip in removing cataract grades 3 and 4 in high and low IOP settings.

Methods

This prospective, observational, randomized, contralateral eye study enrolled was reviewed and approved by an independent institutional review board (Salus IRB, approval JS-22-001). An independent IRB was used as this study was conducted in private practice. All participants gave written informed consent, and the study was registered in a clinical trials registry (NCT05868772). The study followed good clinical practice, the tenets of the Declaration of Helsinki, and International Harmonization (ICH) guidelines.

Inclusion criteria were adults (age 50 years or older), who were candidates for uncomplicated bilateral cataract surgery with IOL implantation and had a grade 3 or 4 cataract (classified using LOCS III). Exclusion criteria were pseudoexfoliation syndrome, zonular dehiscence, history of eye trauma, rheumatoid arthritis, prior refractive surgery, or posterior capsular tear.

One experienced surgeon performed all surgeries (JS). The Centurion Vision System with Active Sentry Handpiece and hybrid tip (Alcon Vision, LLC) were used in all eyes. One eye was randomized (using simple randomization) to have phacoemulsification using high IOP settings (50 mmHg), and the other eye had phacoemulsification using low IOP settings (20 mmHg). Aspiration and vacuum settings were also different for each group. A summary of the settings used for each group is shown in Table 1.

The primary endpoint was to compare efficiency (as measured by phaco time, aspiration time, and fluid use) of the hybrid tip in removing cataract grades 3 and 4 using high and low IOP settings. The secondary endpoint was to compare changes in central corneal thickness (CCT). Exploratory endpoints included cumulative dissipated energy (which is a measure of ultrasonic exposure during surgery), total case time, total torsional time, total longitudinal time, and IOP.

We estimated that the study would require 54 eyes, assuming a pooled standard deviation of 10.3 mL, difference in means between the high and lower IOP groups of 7.8 mL, power of 80% and a level of significance of 5% (two sided). For additional power, a total of 100 eyes was targeted. The software environment R (version 4.3.1; The R Foundation for

Table 1 Settings for High and Low Intraocular Pressure Groups

	High IOP Settings Group			Low IOP Settings Group		
	IOP (mmHg)	Vacuum (mmHg)	Aspiration (cc/min)	IOP (mmHg)	Vacuum (mmHg)	Aspiration (cc/min)
Sculpt	50	110	26	20	110	20
Quad	65	550	41	20	400	20
Cortex	55	700	40	20	700	30
Visco	55	700	60	20	700	40

Abbreviation: IOP, intraocular pressure.

Statistical Computing, Vienna, Austria) was used for statistical analysis. An analysis of variance model, adjusted for any bias when using 2 eyes from the same patient, was used for comparisons between groups. A $p \leq 0.05$ was considered significant.

Results

A total of 51 subjects (102 eyes) completed the study. Demographic and preoperative data are summarized in Table 2. Preoperative CCT and IOP were similar between groups. Three adverse events occurred relating to the surgery. Each was related to elevated IOP and resolved within a week.

The efficiency of removing cataracts grade 3 and 4 is summarized in Table 3. The efficiencies (as measured by phaco time, aspiration time, and fluid use) under high and low IOP settings were similar overall, and when specifically comparing grade 3 and grade 4 cataracts ($p > 0.05$). Other operative data are also summarized in Table 3. The results for high and low IOP settings were similar for cumulative dissipated energy, torsional time, and longitudinal time ($p > 0.05$). Total case time appears lower for the high IOP settings group compared to the low IOP settings group, but this difference was not significant ($p > 0.05$).

Table 4 summarizes the postoperative data. At day 1 and day 7, IOP was similar for eyes in the high IOP settings group compared to the low IOP settings group. Change in central corneal thickness compared to preoperative appeared slightly elevated in the low IOP settings group at both postoperative days, but this was not significant ($p > 0.05$).

Table 2 Preoperative Patient Demographics

Parameter	High IOP Settings	Low IOP Settings
Age (years)	75.8 ± 6.7 (61 to 92)	
Sex Female Male	 31 (61) 20 (39)	
Cataract Grade 3 4	 31 (61) 20 (39)	
CCT (μm)	546.5 ± 36.2 (470 to 627)	547.1 ± 35.3 (474 to 623)
IOP (mmHg)	16.5 ± 3.6 (10.5 to 29.5)	16.0 ± 2.8 (10 to 21.5)

Note: Data presented as Mean ± SD (Range) or n (%).
Abbreviations: CCT, central corneal thickness; IOP, intraocular pressure; SD, standard deviation.

Table 3 Efficiency of Cataract Removal and Other Operative Data

Parameter	Cataract Grade	High IOP Settings	Low IOP Settings
Total Phaco Time (s)	Overall 3 4	41.6 ± 10.0 (27.3 to 65.8) 38.4 ± 9.6 (27.3 to 65.8) 44.1 ± 9.9 (32.5 to 61.9)	41.8 ± 10.2 (21.4 to 77.2) 38.9 ± 8.6 (21.4 to 58.5) 46.3 ± 11.0 (32.1 to 77.2)
Total Aspiration Time (s)	Overall 3 4	101.7 ± 27.2 (61 to 204) 95.3 ± 21.2 (61 to 135) 111.8 ± 32.8 (74 to 204)	106.7 ± 25.3 (69 to 186) 105.4 ± 27.0 (69 to 186) 108.6 ± 23.1 (71 to 168)
Total Fluid Volume (mL)	Overall 3 4	41.6 ± 9.0 (30 to 75) 39.2 ± 6.8 (30 to 52) 45.2 ± 10.8 (32 to 75)	40.2 ± 7.8 (29 to 64) 38.3 ± 7.3 (29 to 59) 43.2 ± 8.0 (30 to 64)

(*Continued*)

Table 3 (Continued).

Parameter	Cataract Grade	High IOP Settings	Low IOP Settings
Cumulative Dissipated Energy	Overall 3 4	8.7 ± 3.1 (4.2 to 18.9) 7.8 ± 2.6 (4.2 to 14.5) 10.2 ± 3.2 (6.8 to 18.9)	8.6 ± 3.4 (1.8 to 22.2) 7.7 ± 2.2 (2.8 to 13.5) 9.9 ± 4.5 (1.8 to 22.2)
Total Case Time (s)	Overall 3 4	246.9 ± 62.9 (171 to 454) 236.1 ± 52.3 (172 to 449) 236.7 ± 74.8 (171 to 454)	267.9 ± 71.4 (169 to 657) 260.8 ± 48.8 (169 to 388) 279.0 ± 97.2 (215 to 657)
Total Torsional Time (s)	Overall 3 4	36.0 ± 9.5 (4.7 to 56.9) 33.6 ± 9.5 (4.7 to 56.9) 39.7 ± 8.4 (27.6 to 54.9)	36.5 ± 9.8 (4.3 to 64.9) 33.3 ± 9.0 (4.3 to 50.1) 41.3 ± 9.1 (28.6 to 64.9)
Total Longitudinal Time (s)	Overall 3 4	4.6 ± 5.2 (0.8 to 38.7) 4.8 ± 6.6 (0.8 to 38.7) 4.3 ± 1.9 (1.9 to 8.9)	5.3 ± 4.6 (1.6 to 34.4) 5.5 ± 5.7 (1.6 to 34.4) 5.0 ± 2.3 (2.3 to 12.3)

Note: Data presented as Mean ± SD (Range).
Abbreviations: IOP, intraocular pressure; SD, standard deviation.

Table 4 Postoperative Data

POSTOPERATIVE DAY 1			
Parameter	**Cataract Grade**	**High IOP Settings**	**Low IOP Settings**
CCT Change from Preop (μm)	Overall 3 4	18.2 ± 15.1 (−3.1 to 62.9) 14.9 ± 13.6 (−3.1 to 59.4) 23.0 ± 16.2 (0.8 to 62.9)	20.4 ± 21.2 (−4.1 to 93.5) 16.3 ± 13.0 (−4.1 to 49.1) 26.7 ± 29.2 (−2.8 to 93.5)
IOP (mmHg)	Overall 3 4	22.7 ± 7.2 (9 to 43) 21.2 ± 7.4 (9 to 43) 25.0 ± 6.3 (13 to 36.5)	22.6 ± 7.5 (10 to 45) 20.9 ± 6.5 (11 to 39) 25.1 ± 8.2 (10 to 45)
POSTOPERATIVE DAY 7			
Parameter	**Cataract Grade**	**High IOP Settings**	**Low IOP Settings**
CCT Change from Preop (μm)	Overall 3 4	5.4 ± 5.1 (−3.8 to 18.0) 4.6 ± 4.5 (−3.8 to 16.0) 6.7 ± 5.7 (−3.8 to 18.0)	8.1 ± 8.9 (−1.2 to 53.8) 8.5 ± 10.4 (−0.5 to 53.8) 7.6 ± 6.2 (−1.2 to 23.5)
IOP (mmHg)	Overall 3 4	15.4 ± 3.9 (10 to 26) 15.5 ± 3.5 (10 to 26) 15.3 ± 4.7 (11 to 26)	15.2 ± 3.8 (8 to 27) 14.5 ± 3.0 (8 to 22) 16.4 ± 4.7 (9 to 27)

Note: Data presented as Mean ± SD (Range).
Abbreviations: CCT, central corneal thickness; IOP, intraocular pressure; SD, standard deviation.

Discussion

In this study, we compared the efficiency of a hybrid tip in removing cataract grades 3 and 4 using high and low IOP settings. To the best of our knowledge, this is the first study to compare efficiency of the hybrid tip in high and lower IOP settings. The efficiency (as measured by phaco time, aspiration time, and fluid use) was similar between the two groups, with no significant differences identified overall or in grade 3 or 4 cataracts. Sabur and Unsal[10] reported similar efficiency results to ours for Active Sentry and the Intrepid hybrid tip in eyes (62% of which were grade 3 or 4 cataract) with high IOP settings. Minor differences between their results and ours may be explained by surgical technique, settings on the

Centurion Vision System, and the differences in cataract grade. The results of our study suggest that there is no significant loss in efficiency of grade 3 or 4 cataract removal with lower IOP settings when using the hybrid tip.

Using lower IOP settings may decrease the risks of postoperative complications.[5,6] One indicator of corneal endothelial damage is an increase in CCT postoperatively. We observed no significant differences in postoperative CCT between high and low IOP settings overall or in grade 3 or grade 4 cataracts. This could be due in part to the differences in vacuum and aspiration flow rate used between the groups. Indeed, Liu et al[9] reported lower postoperative day 1 CCT using low IOP settings with an Active Sentry handpiece compared to high IOP settings with a handpiece that does not have an integrated pressure sensor (Ozil), with the vacuum and aspiration flow rate kept constant between groups. Though it is not clear whether the difference is from the IOP settings, the handpieces, surgical technique or a combination of these. However, Cyril et al[11] observed no significant differences in corneal edema (percentage of none, mild, moderate) using an Active Sentry handpiece compared to an Ozil handpiece, both with high IOP settings.

The findings from this study have important implications for surgical practice and patient safety in cataract surgery. The demonstrated efficiency of the hybrid tip at both high and low IOP settings suggests that surgeons may safely employ lower IOP levels during phacoemulsification without sacrificing operational efficiency. The high IOP settings group used higher vacuum and aspiration flow rate, which could decrease the total case time and potential stress to ocular structures. Despite this, the low IOP settings group was similarly efficient and did not significantly increase CCT from baseline at days 1 or 7 postoperatively. This is particularly relevant in the context of minimizing postoperative complications associated with elevated IOP, such as corneal edema and endothelial cell loss, which can significantly affect long-term visual outcomes. In our study, there were 3 instances of IOP spikes immediately postoperatively (which all resolved within a week). Elevated IOP can be influenced by various factors, including but not limited to residual viscoelastic at the end of the procedure, over-infiltration of balanced salt solution, and steroid response. However, we do not believe that the choice of handpiece or the intraocular pressure (IOP) settings significantly contributed to post-operative spikes in IOP.

Future studies should aim to explore the long-term effects of using lower IOP settings, including the impact on endothelial health and visual acuity over extended follow-up periods. Additionally, investigating the performance of the hybrid tip across a broader spectrum of cataract grades and varying surgical conditions could further clarify its role in enhancing safety and efficacy in cataract surgery. Ultimately, optimizing IOP settings alongside advancements in phacoemulsification technology may contribute to improved patient outcomes in cataract surgery.

A limitation of this study of this study was the relatively short follow-up period. We are not able to draw conclusions about the long-term outcomes between the two IOP settings; however, the primary outcome for the study was to measure the efficiency of cataract removal. The follow-up period was sufficient to accomplish this goal. In addition, the vacuum and aspiration flow rate settings were different between the groups. The high IOP settings group used higher vacuum and aspiration flow rate, which would decrease the total case time and potential stress to ocular structures. Despite this, the low IOP settings group was similarly efficient.

In conclusion, the results of this study suggest that a Hybrid tip was efficient (as measured by phaco time, aspiration time, and fluid use) in removing grade 3 and grade 4 cataracts with high and low IOP settings.

Acknowledgment

This paper was presented at the 2024 American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting as a conference talk. The paper's abstract was published in ASCRS Paper Sessions: https://ascrs.confex.com/ascrs/23am/meetingapp.cgi/Paper/88523.

Funding

This study was supported with an investigator-initiated study grant (74989267) from Alcon Vision LLC, Fort Worth, TX, USA.

Disclosure

The authors report no other conflict of interest for this work.

References

1. Demircan S, Atas M, Goktas E, Baskan B. Comparison of 45-degree Kelman and 45-degree balanced phaco tip designs in torsional microcoaxial phacoemulsification. *Int J Ophthalmol*. 2015;8(6):1168–1172. doi:10.3980/j.issn.2222-3959.2015.06.16
2. Khokhar S, Aron N, Sen S, Pillay G, Agarwal E. Effect of balanced phacoemulsification tip on the outcomes of torsional phacoemulsification using an active-fluidics system. *J Cataract Refract Surg*. 2017;43(1):22–28. doi:10.1016/j.jcrs.2016.11.034
3. Solomon KD, Lorente R, Fanney D, Cionni RJ. Clinical study using a new phacoemulsification system with surgical intraocular pressure control. *J Cataract Refract Surg*. 2016;42(4):542–549. doi:10.1016/j.jcrs.2016.01.037
4. Zacharias J. In vitro analysis of clinically relevant aspects of a polymer-coated phacoemulsification tip vs a traditional tip. *J Cataract Refract Surg*. 2023;49(12):1264–1269. doi:10.1097/j.jcrs.0000000000001267
5. Suzuki H, Oki K, Shiwa T, Oharazawa H, Takahashi H. Effect of bottle height on the corneal endothelium during phacoemulsification. *J Cataract Refract Surg*. 2009;35(11):2014–2017. doi:10.1016/j.jcrs.2009.05.057
6. Ti SE, Yang YN, Lang SS, Chee SP. A 5-year audit of cataract surgery outcomes after posterior capsule rupture and risk factors affecting visual acuity. *Am J Ophthalmol*. 2014;157(1):180–185e181. doi:10.1016/j.ajo.2013.08.022
7. Perone JM, Boiche M, Lhuillier L, et al. Correlation between postoperative central *corneal* thickness and endothelial damage after cataract surgery by phacoemulsification. *Cornea*. 2018;37(5):559–587. doi:10.1097/ICO.0000000000001502
8. Lundberg B, Jonsson M, Behndig A. Postoperative corneal swelling correlates strongly to corneal endothelial cell loss after phacoemulsification cataract surgery. *Am J Ophthalmol*. 2005;139(6):1035–1041. doi:10.1016/j.ajo.2004.12.080
9. Liu Y, Hong J, Chen X. Comparisons of the clinical outcomes of Centurion((R)) active fluidics system with a low IOP setting and gravity fluidics system with a normal IOP setting for cataract patients with low corneal endothelial cell density. *Front Med Lausanne*. 2023;10:1294808. doi:10.3389/fmed.2023.1294808
10. Sabur H, Unsal U. The efficacy and safety profile of cataract procedures performed with a sensor-embedded handpiece and a new hybrid phaco tip. *Eur J Ophthalmol*. 2022;32(6):3438–3443. doi:10.1177/11206721221084764
11. Cyril D, Brahmani P, Prasad S, et al. Comparison of two phacoemulsification system handpieces: prospective randomized comparative study. *J Cataract Refract Surg*. 2022;48(3):328–333. doi:10.1097/j.jcrs.0000000000000769