

# Safety and efficacy of 8-and 10-sector ultrasound cycloagulation: a retrospective study

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## Research Article

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# Abstract

**Purpose:** To measure the efficacy and safety of ultrasound cycloplasty (UCP) in sectors 8 and 10.

**Methods:** Thirty-four patients with various types and degrees of glaucoma (43 eyes) underwent UCP at the Aier Eye Hospital of Tianjin University. Primary outcomes included intraocular pressure and visual acuity. Secondary outcomes included corneal endothelium, pupil area, cornea (Surface asymmetry index SAI and (Surface regularity index) SRI, ciliary body detachment, and the safety and efficacy of UCP after trabeculectomy.

**Results:** Twelve months postoperatively, intraocular pressure (IOP) decreased from 28.4 mmHg to 14.4 mmHg ( $P < 0.05$ ). On average, IOP decreased by 44.7%, and the success rate was 55.8%. At the final follow-up, IOP decreased by 43.46% on average, and the success rate was 62.8%. There was a significant difference in the postoperative pupil area of the eight sectors ( $P = 0.016$ ) within six months and no significant difference after six months. There was a significant difference in SRI between baseline and one month after UCP ( $P = 0.016$ ) and no significant difference in the remaining months. There was no significant difference in corneal endothelium from the preoperative baseline. Ciliary body detachment occurred in sectors 8 and 10, and it was removed and reduced one month after surgery. The success rate of UCP after trabeculectomy was 91%, and there were no follicle-related complications.

**Conclusion:** UCP is safe and significantly lowers IOP, with few short-term complications and no long-term complications. It is safe and effective to select sectors 10 and 8 for IOP reduction; however, there is no advantage in IOP reduction compared with sector 6.

## Introduction

Glaucoma is the leading irreversible blinding eye disease worldwide; pathological increases in intraocular pressure (IOP) cause glaucoma optic nerve and visual field damage, and IOP is the only controllable risk factor [1–3]. The imbalance of aqueous humor production and outflow leads to increased IOP. The treatment of IOP includes medications and surgery, and surgery may be invasive or non-invasive [29]. Non-invasive surgery balances the side effects of medication-induced reduction of IOP with the risk of severe complications of invasive surgery. Non-invasive surgery includes laser, condensation, ultrasound destruction of ciliary body non-pigment epithelial cells, and reduction of aqueous fluid secretion [4–8]. The application of laser and condensation damage to the ciliary body non-pigment epithelial cells is limited due to the damage inflicted on surrounding tissues and various severe postoperative complications [9–12]. Ultrasonic circular cyclocoagulation was introduced in the 1980s. Following the emergence of EyeOP1 (a UCP device), the use of the procedure has increased. UCP reduces IOP by selectively acting on the ciliary body non-pigment epithelial cells and avoiding adjacent structures to reduce aqueous fluid generation and increase aqueous outflow [13–15]. Most studies are conducted on six sectors, and there is a lack of studies on 8 or 10 sectors [16–19]. In the present study, we used the

EyeOP1 probe with an 8-s duration in 8 or 10 sectors depending on baseline IOP and glaucoma severity. We also assessed the safety and efficacy of the procedure.

## Materials And Methods

### *Patients*

This retrospective non-comparative study included 34 patients (43 eyes) who underwent UCP at the Aier Eye Hospital of Tianjin University from January 2019 to December 2020. All patients provided verbal and written informed consent before enrollment. The procedures complied with the ethical standards of the Ethics Committee of Aier Eye Hospital of Tianjin University and the Helsinki declaration. Inclusion criteria were as follows: age 18 or above; average baseline IOP of 21 mmHg or more while on more than three types of medical treatment; intolerance to medication; inability to tolerate adverse effects of medication; contraindications to filtration surgery; glaucoma types, including primary open-angle glaucoma, primary angle-closure glaucoma, the filtration of postoperative IOP out of control, neovascular glaucoma, and absolute glaucoma. Exclusion criteria were as follows: systemic medication that affects IOP monitoring; normal tension glaucoma; ocular infection within the past month; history of refractive surgery; retinal detachment; ocular tumor

### *Procedures and follow-up*

All high-intensity focused ultrasound (HIFU) cyclocoagulation procedures were performed by the same physician under peribulbar anesthesia and short-term sedation. The probe size was determined based on the anatomy of each eye using computer-assisted UBM pictures taken by the same engineer and white-to-white distance measured using IOL Master. The following parameters were measured: probe diameters (11, 12, and 13 mm), operating frequency 21 MHz; sectors 8 and 10 activated; acoustic power 2.45 W; duration of each shot 8 seconds; the time between each shot 20 seconds. Each probe has six sectors activated in turn, and then it is rotated clockwise to activate two or four sectors to complete the procedure. Postoperatively, tobramycin and dexamethasone were applied topically four times per day in the first week, then minus one time in one week, totaling three weeks. For example, change to 3 times a day in the second week after surgery. Atropine sulfate eye gel was prescribed three times a day for one week, and prednisone acetate eye drops four times a day for four weeks. Postoperative IOP-lowering medications were reduced according to whether the target IOP was achieved.

The study lasted for one year, and the follow-up interval was one week after surgery and every month within one year after surgery. Some patients completed follow-ups for 26 months. Slit lamp bio-microscopy with mydriatic fundus examination corneal probing (Medmont E300 Corneal Topographer), Goldman applanation tonometry, and best corrected visual acuity was performed one day prior to surgery and postoperatively at one day, one week, one month, two months, three months, four, six months seven months, eight months, nine months, ten months, 11 months, and 12 months. Ultrasound bio-microscopy was performed preoperatively and postoperatively at one week, one month, and three months. Optical coherence tomography (OCT) (Heidelberg Engineering GmbH, Spectralis OCT, Germany), specular

endothelial cell microscope, SP.3000P, Auto Optometry system OS-1500, Optical Biometry IOL Master 700, Visual field (Humphrey Field Analyzer; 24-2 SITA-standard program; Carl Zeiss Meditec) were performed preoperatively and postoperatively.

### *Outcome measures and statistical analysis*

The primary outcomes were IOP reduction at six months postoperatively and the final follow-up and complications of ocular structural integrity (i.e., pupil area, corneal parameters, corneal endothelium, and ciliary body detachment). The secondary outcomes were some postoperative complications and safety of UCP after trabeculectomy. Surgical success was defined as IOP reduction from baseline  $\geq 20\%$  and  $> 5$  mmHg, with or without adding hypotensive medications and possible HIFU re-treatment. Extrapolated 2.6, 2.7, 2.8, and 2.9 logMAR represented the vision of counting fingers, hand motion, light perception, and no light perception, respectively [30].

We used SPSS Software Version 26.0. Demographic and ocular baseline characteristics were expressed using descriptive statistics. Paired t-tests were used to compare the preoperative and postoperative pupil area, corneal endothelium, SAI, and SRI mean values. Statistical significance was set at P 0.05.

## **Results**

### **Table 1.**Demographic characteristics

Category	Values
Patients/eyes, n	33/43
Age±SD range	60.28±11.08 35-82
Male/female, n	15/18
Type of glaucoma	
PACG	15(34%)
POAG	18(40.9%)
Absolute glaucoma	4(9%)
Neovascular glaucoma	4(9%)
Secondary glaucoma	2(4.5%)
Ocular hypertension	1(2%)
Lens status, n	
Phakic	40(93%)
Pseudophakic	3(7.0%)
Type of glaucoma surgeries	
Filtering surgery	11
Cryotherapy	1
activated sectors	
8sectors	34
10sectors	9

Thirty-three patients with primary and secondary glaucoma of varying severity (43 eyes) were enrolled. Demographic and ocular characteristics are listed in Table 1, with the best corrected visual acuity ranging from no light perception to 1.0. In secondary glaucoma, two patients with scleritis and uveitis and one patient with ocular hypertension chose UCP because of medication refusal.

#### *Efficacy Data from patients*

**Table 2.** Data from patients from baseline of each follow-up

	IOP(MD±SD )	DV	Drops	VA (logMAR)
baseline	28.4 ±14.7	0	5.18	1.00
1day	17.4 ± 7.2	11	3.88	0.91
7day	14.5 ± 5.4	13.9	3.29	1.04
1m	15.7 ± 4.3	12.7	3.21	0.83
2m	15.1 ± 4.2	13.3	2.59	0.80
3m	15.4 ± 4.1	13.0	2.14	0.88
4m	15.9 ± 3.5	12.5	2.28	0.83
5m	14.4 ± 3.1	14	2.24	0.95
6m	15.7 ± 3.2	12.5	2.19	0.91
7m	17.2 ± 3.9	11.2	1.06	0.53
8m	16.7 ± 6.3	11.7	1.59	0.87
9m	18.3 ± 6.8	10.1	1.7	0.41
10m	14.3 ± 3.3	14.1	2.2	1.05
11m	15.0 ± 4.0	13.4	2.31	0.88
12m	14.4 ± 3.9	14	1.8	0.77

DV, different value: IOP every time-baseline; B, baseline; M, the month; No,number; The Va, visual acuity

The mean IOP decreased from 28.4 mmHg to 14.4 mmHg 12 months after UCP. The surgical success rate was 55.8%, and IOP decreased by 44.7% on average. The surgical success rate was 62.8% at the final follow-up, with an average decrease in IOP of 43.46%. For patients whose preoperative IOP was < 20 mmHg under the control of one to six drops of IOP-lowering medications, the IOP decreased less than 5 mm Hg after the withdrawal of medications or two drops of IOP-lowering medications. Three patients with primary glaucoma had IOP less than 15 mmHg with one medication before surgery, and their IOP increased by 3–6 mmHg one year after surgery. Visual acuity six months after surgery was 0.91 logMAR, compared with 1.00 logMAR before surgery, showing no significant difference (P = 0.425). The visual acuity at the final follow-up showed no significant difference compared with that before surgery (P = 0.218) (Table 2)

### *Safety*

Corneal endothelial cell count, ciliary body detachment, pupil area, corneal SAI and SRI were statistically analyzed, among which corneal endothelial cell count, pupil area, corneal SAI and SRI were paired T test

### *pupil area*

**Table 3.** Pupil area in different sectors at different time periods mean±SD

Number	3-6months	DV 95%CI	t value	P value
	7-12months			
8sectors	24.85 ± 10.79※	-9.81 -17.17- -2.46	-3.155	0.016
	17.75 ± 8.70※	-2.71 -6.21-0.78	-1.834	0.109
10 sectors	20.84 ± 8.36*	-0.34 -6.21-5.54	-0.136	0.896
	19.42 ± 8.09*	1.09 -3.29-5.46	0.576	1.09

※ Compared with the baseline mean 15.04±8.08; \* Compared with the baseline mean of 20.5 ± 10.98; units:mm<sup>2</sup>

The pupil area was measured using corneal topography. In eight activated sectors, the mean pupil area of 24.85 ± 10.79 mm<sup>2</sup> 3 to 6 months after UCP was significantly different from the 15.04 ± 8.08 mm<sup>2</sup> before UCP (P = 0.016, 95% confidence interval [CI] -17.17 to -2.46). The mean values of eight activated sectors at 7–12 months and ten activated sectors at 3–6 months and 7–12 months were not significantly different from the mean values preoperatively (P > 0.05; Table 3).

Atropine sulfate ophthalmic gel was used within one month of surgery. Data over three months were collected and analyzed to avoid the interference of medications in the pupil area. Eight samples were selected from sectors 8 and 10, and the pupil areas obtained at the corresponding periods were compared with their baseline. The preoperative pupil area, IOP, sector, and probe size were incorporated into the multi-factor linear regression equation. Preoperative pupil area was significantly different from 3–6 months after surgery (B = 0.68, T = 3.11, P = 0.010). IOP (P = 0.381), sector (P = 0.149), and probe size (P = 0.866) had no significant effect on the pupil area 3–6 months after surgery.

Simple linear regression analysis was performed for the pupil area 3–6 months after surgery. The simple linear regression equation was Y = 13.195 + 0.543 X. X and Y are the preoperative pupil area and the pupil area 3-6 months after surgery respectively), For every 1 unit increase in preoperative pupil area, the pupil area changed about 0.543 units 3 to 6 months postoperatively

#### Corneal endothelium

Seven patients had measurements of the preoperative and 3-month postoperative corneal endothelium. The mean value of the preoperative corneal endothelium was 2059.29/mm<sup>2</sup>, and the mean value of the postoperative corneal endothelium was 2366.00/mm<sup>2</sup>. There was no significant difference in the overall mean value between the groups (difference = -306.71, 95% CI -1045.15 to 431.72, P = 0.349)

## SAI and SRI

We measured SAI and SRI for thirteen patients one day before surgery, and seven days, one month, three months, six months, ten months, and twelve months after surgery (Figure 1). The SRI was  $1.01 \pm 0.31$  before UCP and  $1.34 \pm 0.44$  one month after UCP. There was a significant difference in the overall mean between the groups (the difference was 0.33, 95% CI  $-0.60$  to  $0.75$ ,  $P = 0.016$ ). There was no significant difference in the other months compared with the preoperative mean (Figure 1).

## Ciliary body detachment

UBM showed 12.5% ciliary body detachment at one week postoperatively in eight of 16 patients with eight sectors and 12.5% ciliary body detachment at one week postoperatively in eight of 16 patients with ten sectors, which returned to normal at one month postoperatively.

## UCP after trabeculectomy

All eleven patients underwent trabeculectomy. One patient underwent UCP after three months of uncontrolled IOP, and the other ten patients underwent UCP after more than one year of uncontrolled IOP (Table 4).

**Table.4** Hypotensive therapy evolution after Ucp after trabeculectomy

	IOP-pre	IOP reduction(%)	Drop reduction	last follow-up
1	31	2(6)	3	9months
2	60	41(68)	2	6months
3	60	49(82)	5	10months
4	60	45(75)	7	17months
5	25	10(40)	4	15months
6	22	10(45)	2	7months
7	28	12(43)	6	26months
8	21	4(19)	5	24months
9	36	11(31)	0	6months
10	34.7	14.7(42)	1	21months
11	29	9(31)	2	4months

At the final follow-up visit, no follicular leakage, ciliary body detachment, or choroid detachment were observed, and 81% of patients undergoing UCP after trabeculectomy had a reduction in IOP of more than 20% with hypotensive medications.

## Discussion

Controlling IOP by reducing the aqueous humor generation pathway is essential to control glaucoma. The principle of surgery is to reduce aqueous humor generation by photocoagulation, condensation, and ultrasound on the ciliary body without pigment epithelial cells. Reducing IOP by photocoagulation and condensation due to poor predictability and control limits the use of these technologies. UCP (especially the second-generation probe) represents a breakthrough for predictability and controllability [20] and has made the technology more widely used to treat glaucoma. The present study included primary angle-open glaucoma, primary angle-closure glaucoma, and multiple refractory glaucoma (including neovascular glaucoma and uncontrolled IOP after filtration). Another study found that UCP for glaucoma types was well-tolerated [21]. Other studies found that IOP decreased by 30–40% at the final follow-up after exposure of sectors 8 for 4 s, 6 s, or 8 s for six months [22–25]. In the present study, the ultrasonic exposure time was 8 s. The surgical success rate was 62.8% at the final follow-up, with an average decrease in IOP of 43.46%. The IOP-lowering effect is consistent with previous research, suggesting that increasing the activation sector to sectors 8 and 10 may not affect IOP reduction. Prospective randomized controlled trials are needed to confirm this finding. Preoperative IOP was less than 20 mmHg, and the effect of postoperative IOP reduction was not ideal; some medical records revealed increasing instead of decreasing IOP. It is not clear why this phenomenon occurred.

Sousa et al. evaluated how UCP (EyeOP-1®) affected pupil dynamics [26]. The present study was the first to explore the safety of UCP from the perspective of changes in pupil area measured by corneal topography. The mean pupil area in sector 8 was  $24.85 \pm 10.79$  3 to 6 months after surgery, significantly different from before surgery ( $P = 0.016$ ). There was no significant difference in the overall mean pupil area between 7 to 12 months after surgery and baseline ( $P = 0.109$ ), suggesting that it took more than six months for UCP to restore the pupil to the baseline level, similar to Sousa et al. [26, 27]. There was no significant difference in the overall mean of pupil area at three to six months and seven to twelve months in sector 10 compared with baseline ( $P > 0.05$ ), suggesting that the change in pupil area might not increase with the increase of the active sector. Whether the other ten sectors will cause changes in pupil area still needs to be further confirmed by expanding the sample size. Including preoperative pupil area, IOP, sector, and probe size into multi-factor linear regression equation analysis revealed that postoperative pupil area was affected by preoperative pupil area. Univariate linear regression analysis showed that, with every 1-mm increase in preoperative pupil area, the pupil area changed about 0.543 mm 3–6 months after surgery. This study is the first to analyze the factors influencing postoperative pupil area and its linear relationship with preoperative pupil area. Nevertheless, the influence of changes in pupil area on subjective feelings such as photophobia and visual function and the degree of influence need to be further studied.

Eleven patients who underwent HIFU after trabeculectomy had an ideal effect on reducing IOP, and no postoperative complications related to filter bubble were found, consistent with Marques et al. [28]. Although there were follicles after trabeculectomy, these findings suggest that UCP is safe and effective.

This study was the first to assess corneal parameters measured by SRI and SAI based on corneal topography. The overall mean of pre-and postoperative corneal SRI showed no significant difference ( $P > 0.05$ ). The regularity of corneal SRI, corneal scar and epithelial defect affect corneal SRI. There was a significant difference in the overall mean value of SRI between the groups ( $P < 0.05$ ); however, there was no significant difference in the overall mean value of SRI from baseline after three months ( $P > 0.05$ ). The regularity of the cornea was affected in the early postoperative period. Over time, topical corneal medications could restore IOP to baseline after three months. The influence of corneal regularity changes within three months on subjective sensation requires further study.

There were limitations in this study. This simultaneous control study was carried out in sectors six, eight, and ten. Due to incomplete follow-up examination of some patients, the sample size of some postoperative complications is small, making it challenging to detect some rare complications. Finally, the sample size of some indicators was small. These limitations affect the reliability of the results.

## Conclusion

UCP is safe and significantly lowers IOP, with few short-term complications and no long-term complications. It is safe and effective to select sectors 10 and 8 for IOP reduction; however, there is no advantage in IOP reduction compared with sector 6.

## Declarations

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**Conflicts of interest:** The authors have no conflicts of interest to declare.

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**Ethics approval:** The Ethics Committee of Hospital Aier Eye Hospital of Tianjin University

**Author contributions:** Rong Zhang, the first author, was responsible for the conception and design of the study, analyzing the data, drafting the paper, and ensuring the accuracy and completeness of the entire research process.

Fuhua Li, the second author, was responsible for the data collection and modification of the paper.

**Data availability:** Available from the corresponding author upon reasonable request.

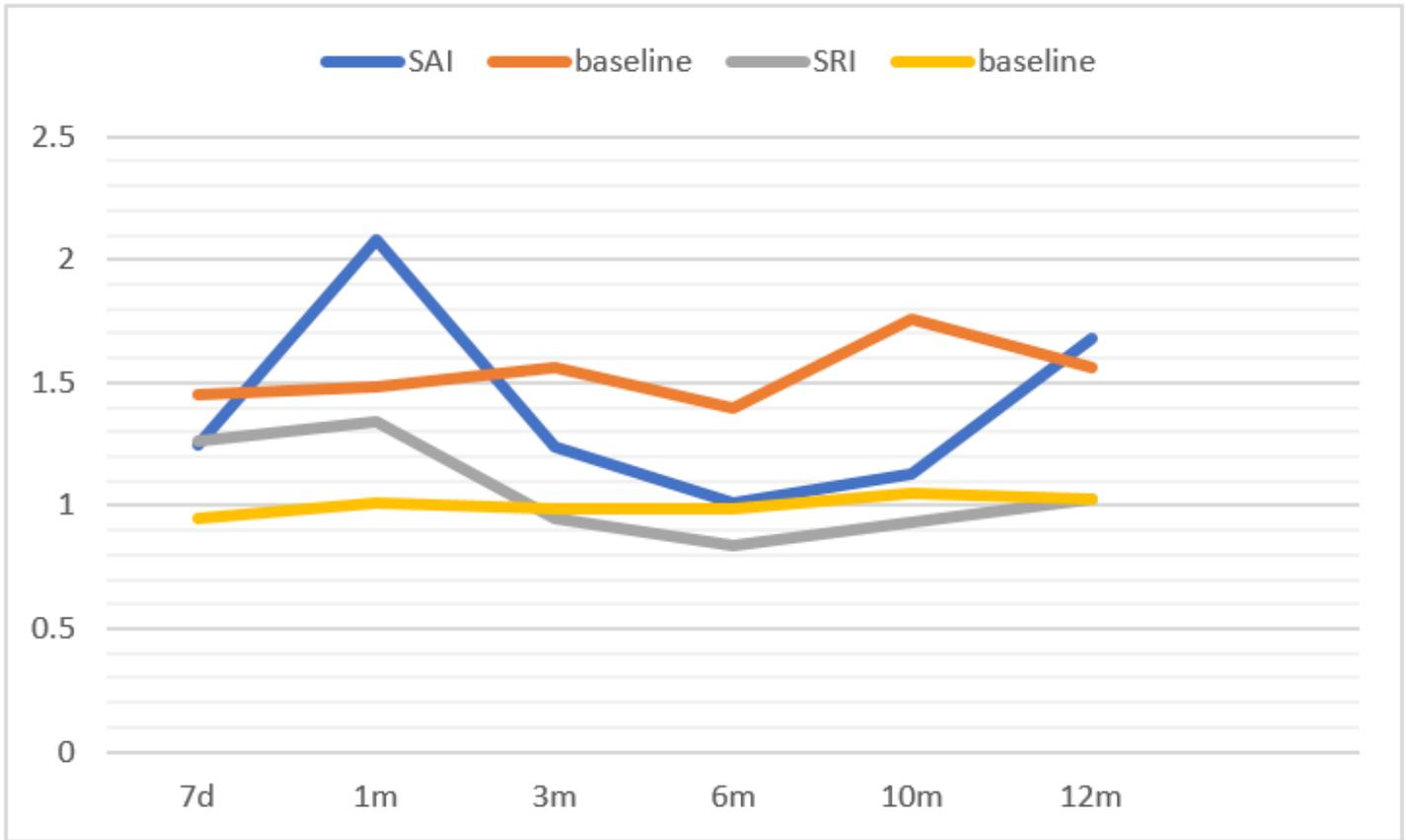
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## Figures



**Figure 1**

SAI and SRI at each follow-up visit with the comparison of baseline. Datum collected from 13 patients at each time point and compared with their preoperative baseline mean