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Evaluation of deep sclerectomy and trabeculectomy in the treatment of glaucoma

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Abstract

Purpose: This study aims to compare the clinical outcomes of deep sclerectomy and trabeculectomy surgeries, both utilizing 5-fluorouracil.

Methods: In this study, 11 eyes of 10 patients (14.3%) in the deep sclerectomy group and 66 eyes of 61 patients (85.7%) in the trabeculectomy group were retrospectively examined. Success in intraocular pressure (IOP) was defined as being below 21 mmHg without medication, partially successful if achieved below 21 mmHg with a single molecule, considered less successful with two to four molecules for maintaining IOP below 21 mmHg, and deemed unsuccessful if IOP exceeded 21 mmHg.

Results: The deep sclerectomy group showed a success rate of 81.8% on post-operative day 1, with 18.2% considered unsuccessful; at post-operative 6 months, the success rate was 12.5%, with 50% partially successful and 37.5% less successful. In the trabeculectomy group, the success rate was 97% on post-operative day 1, with 3% considered unsuccessful; at post-operative 6 months, the success rate was 60.8%, with 15.7% partially successful, 13.7% less successful, and 9.8% unsuccessful. Trabeculectomy patients experienced complications such as choroidal detachment (6.1%), shallow anterior chamber (4.5%), tight suturing (3%), internal ostium occlusion (3%), posterior synechia (3%), bleb failure (1.5%), cyclodialysis/iridodialysis (1.5%), and hyphema (1.5%). In the deep sclerectomy group, tight suturing (36.3%), and dellen (9.09%) were observed, with no other complications reported.

Conclusion: Trabeculectomy surgery has been observed to be superior to deep sclerectomy in follow-ups up to 48 months postoperatively. However, it is noted that there is a higher risk of post-operative complications.

Keywords: 5-Fluorouracil; deep sclerectomy; non-penetrating glaucoma surgery; trabeculectomy.

Glaucoma ranks among the preventable causes of blindness worldwide.^[1] The most significant and modifiable risk factor for glaucomatous damage is the elevation of intraocular pressure (IOP).^[2] The goal of treatment is to lower IOP, and there are medical, laser, and surgical treatment options available. Surgical treatment is employed in patients who fail to reach the

target IOP with medical and/or laser therapy or in those who cannot tolerate these treatments. Trabeculectomy surgery is considered the gold standard surgical technique. However, it is associated with post-operative complications related to penetrating surgery.^[3] Hypotony, shallow anterior chamber, hypotensive maculopathy, choroidal detachment, bleb leakage, endophthalmitis, bleb failure



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or overfiltration, post-operative visual acuity loss, and increased cataract progression are possible complications. The high rates of complications highlight the prominence of non-penetrating, minimally invasive glaucoma surgeries. Deep sclerectomy is a non-penetrating surgical method.[4] This study compares the success and complication rates of trabeculectomy and deep sclerectomy.

Materials and Methods

In this study, a retrospective analysis was conducted on a minimum of 48-month follow-up of 11 eyes (14.3%) from 10 patients who underwent deep sclerectomy using 5-fluorouracil (5-FU) between 2016 and 2020, and 66 eyes (85.7%) from 61 patients who underwent trabeculectomy with the use of 5-FU during the same period. The study included glaucoma patients who underwent surgery due to the inability to achieve IOP reduction despite medical treatment. Success in the post-operative period was defined as IOP below 21 mmHg without medication, partially successful if achieved below 21 mmHg with a single molecule, considered less successful with two to four molecules for maintaining IOP below 21 mmHg, and deemed unsuccessful if IOP exceeded 21 mmHg.

The study participants provided informed consent for the publication of their data. Ethical approval for this study was obtained from the Ethics Committee of Istanbul Medeniyet University Göztepe Training and Research Hospital clinical research on February 05, 2020 Decision number: 2020/0037. The study was conducted within the rules of the Declaration of Helsinki.

Statistical Analysis

The analysis of research data was conducted using the 22.0 version of the (Statistical Package for the Social Sciences, Chicago, IL, USA) program. Descriptive statistics were

presented as mean±standard deviation for data showing normal distribution and as median with interquartile range for data not showing normal distribution. The normality of variables was examined using Shapiro–Wilk tests. For variables showing normal distribution, the Student's t-test was employed for statistical significance between two independent groups, whereas the Mann–Whitney U test was used for variables that did not conform to normal distribution. The Wilcoxon test was used for the comparison of two dependent groups that did not follow normal distribution. The Chi-square test was utilized for comparing categorical data. A statistical significance level of 95% confidence interval was considered, with $p < 0.05$.

Exclusion Criteria

Patients with congenital glaucoma, high myopic refractive error, active intraocular infection, and those with optic neuropathy secondary to neurological diseases were excluded from the study.

Results

Among the patients in the deep sclerectomy group, 4 were male (34.6%), and 7 were female (63.6%). In the trabeculectomy group, 43 patients were male (65.2%), and 23 were female (34.8%). No statistically significant differences were observed between the groups in terms of age, gender distribution, age at diagnosis, and duration of follow-up ($p=0.114, 0.139, 0.678, 0.311$, respectively) (Table 1). Statistically significant differences were not observed in the best-corrected visual acuity before and after surgery, pachymetry values, and gonioscopic examination findings of the patients ($p=0.438, 0.588, 0.285, 0.730$, respectively) (Table 2).

A statistically significant difference was found in the

Table 1. Demographic characteristics and follow-up durations of study groups

	Trabeculectomy Group (n=66)	Deep Sclerectomy Group (n=11)	p
Age	64.48±17.17*	73.00±10.06 *	0.114 β
	66.00 (20.3) ¥	78.00 (19.0) ¥	
Gender (M/F) (%)	43/23	4/7	0.139α
Age at Diagnosis	65.2/34.8	36.4/63.6	
Disease Follow-up (months)	58.51±16.64*	62.90±11.32*	0.678β
	62.00 (22.00)¥	61.00 (21.0) ¥	
Duration (months)	44.79–47.70*	70.18–81.64*	0.311β
	29.50 (40.0) ¥	36.00 (79.0) ¥	
Post-operative Follow-up Duration (months)	17.63±14.36 *	24.90±9.97*	
	14.00 (14.5) ¥	24.00 (20.0) ¥	0.023β

*: Mean±Standard Deviation; ¥: Median (Interquartile Range); α: Chi-square test; β: Mann–Whitney U test; M: Male; F: Female.

Table 2. Comparison of visual acuity and anterior segment measurements in study groups

	Trabeculectomy Group (n=66)	Deep Sclerectomy Group (n=11)	p
Pre-operative Best-Corrected Visual Acuity (log MAR)	0.64±0.92* 0.22 (0.60)¥	0.47±0.57* 0.30 (0.25)¥	0.438β
Post-operative Best-Corrected Visual Acuity (log MAR)	0.69±0.98* 0.22 (0.60)¥	0.47±0.57* 0.30 (0.25) ¥	0.588 β
Pachymetry (µm)	547.22±39.68*	533.63±32.33*	0.285α
Gonioscopy (Shaffer Grade)	3.39±0.94* 4.00 (1.0) ¥	3.36±0.92* 4.00 (1.0) ¥	0.730β

*: Mean±Standard Deviation; ¥: Median (Interquartile Range); α: Chi-square test; β: Mann–Whitney U test.

comparison of pre-operative, post-operative 1-week, and 1-month IOP between trabeculectomy and deep sclerectomy study groups ($p < 0.05$). However, no statistically significant difference was observed in the comparison of post-operative 1-day, 3-month, and 6-month IOPs between the study groups. ($p = 0.154, 0.290, 0.991$, respectively) (Table 3). A statistically significant difference was observed in the comparison of pre-operative medication count with post-operative medication counts at 1 day, 1 week, 1 month, 3 months, and 6 months between the trabeculectomy and deep sclerectomy groups ($p < 0.05$) (Table 4).

In the trabeculectomy group, 72.7% of patients did not experience complications during the post-operative period. However, complications were observed in 1.5% of patients

for bleb failure, 6.1% for choroidal detachment, 3.0% for tight suturing, 4.5% for shallow anterior chamber, 1.5% for peripheral anterior synechia, 1.5% for cyclodialysis, 1.5% for iridodialysis, 1.5% for hyphema, 3.0% for internal ostium occlusion, and 3.0% for posterior synechia. In the deep sclerectomy group, 54.5% of patients did not experience complications. However, 36.3% exhibited tight suturing, and 9.1% showed the presence of dellen. While 86.3% of trabeculectomy patients did not require additional interventions in the post-operative period, 7.58% needed bleb revision, 1.52% required re-operation, and another 1.52% needed laser suture lysis. Among deep sclerectomy patients, 63.6% did not require additional interventions, whereas 36.36% required reoperation.

Table 3. Comparison of Intraocular Pressure (IOP) Values in Study Groups

	Trabeculectomy Group (n=66)	Deep Sclerectomy Group (n=11)	p
Preoperative IOP (mmHg)	29.67±7.56 * 28.00 (8.0) ¥	23.00±4.17 * 23.00 (7.1) ¥	0.002 β
Postoperative 1. day IOP (mmHg)	13.09±3.55 * 12.00 (5.0) ¥	15.27±4.81 * 13.00 (8.0) ¥	0.154 β
p ¹	<0.01 α	0.004 α	
Postoperative 1. week IOP (mmHg)	14.52±6.24 * 14.00 (7.0) ¥	20.18±5.56 * 19.00 (9.0) ¥	0.004 β
p ²	<0.01 α	0.074 α	
Postoperative 1. month IOP (mmHg)	18.11±6.58 * 17.00 (9.0) ¥	23.70±8.82 * 23.50 (12.0) ¥	0.040 β
p ³	<0.01 α	0.838 α	
Postoperative 3. months IOP (mmHg)	16.95±5.03 * 16.00 (4.0) ¥	18.13±3.94 * 17.00 (4.0) ¥	0.290 β
p ⁴	<0.01 α	0.127 α	
Postoperative 6. months IOP (mmHg)	16.79±3.78 * 17.00 (4.0) ¥	17.00±2.56 * 16.00 (4.0) ¥	0.991 β
p ⁵	<0.01 α	0.012 α	

*: Mean±Standard Deviation; ¥: Median (Interquartile Range); β: Mann-Whitney U test; α: Wilcoxon test; p1: Statistical result of preoperative vs. postoperative day 1 comparison, p2: Statistical result of preoperative vs. postoperative week 1 comparison, p3: Statistical result of preoperative vs. postoperative month 1 comparison, p4: Statistical result of preoperative vs. postoperative month 3 comparison, p5: Statistical result of preoperative vs. postoperative month 6 comparison.

Table 4. Comparison of Number of Medications in Study Groups

	Trabeculectomy Group (n=66)		Deep Sclerectomy Group (n=11)		p
	Number of Medications	Success Rates	Number of Medications	Success Rates	
Preoperative	3.35±0.51 *		2.82±0.75 *		0.018 β
	3.00 (1.0) ¥		3.00 (0.0) ¥		
Postoperative 1. Day	0.08±0.50 *	97.0% Successful	0.00±0.00 *	81.8% Successful	0.561 β
	0.00 (0.0) ¥	3.0% Unsuccessful	0.00 (0.0) ¥	18.2% Unsuccessful	
p ¹	<0.01 ^α		0.002 ^α		
Postoperative 1. Week	0.09±0.42 *	90.6% Successful	0.45±1.03 *	54.5% Successful	0.157 β
	0.00 (0.0) ¥	9.4% Unsuccessful	0.00 (0.0) ¥	45.5% Unsuccessful	
p ²	<0.01 ^α		0.04 ^α		
Postoperative 1. Month	0.51±0.84 *	65.1/ Successful	0.45±1.03 *	30.0/ Successful	0.015 β
	0.00 (1.0) ¥	9.5/ Partially successful	0.00 (0.0) ¥	10.0/ Less successful	
		25.4/ Unsuccessful		60.0/ Unsuccessful	
p ³	<0.01 ^α		0.04 ^α		
Postoperative 3. Months	0.63±0.94 *	61.0/ Successful	1.25±0.88 *	12.5/ Successful	0.025 β
	0.00 (1.0) ¥	10.2/ Partially successful	1.00 (1.0) ¥	62.5/ Partially successful	
		10.2/ Less successful		12.5/ Less successful	
		18.6 / Unsuccessful		12.5/ Unsuccessful	
p ⁴	<0.01 ^α		0.015 ^α		
Postoperative 6. Months	0.75±0.92 *	60.8/ Successful	1.38±0.91 *	12.5/ Successful	0.055 β
	0.00 (1.0) ¥	15.7/ Partially successful	1.00 (1.0) ¥	50.0/ Partially successful	
		13.7/ Less successful		37.5/ Less successful	
		9.8 / Unsuccessful			
p ⁵	<0.01 ^α		0.015 ^α		

*: Mean±Standard Deviation; ¥: Median (Interquartile Range); β: Mann-Whitney U test; α: Wilcoxon test; p1: Statistical result of preoperative vs. postoperative day 1 comparison; p2: Statistical result of preoperative vs. postoperative week 1 comparison, p3: Statistical result of preoperative vs. postoperative month 1 comparison, p4: Statistical result of preoperative vs. postoperative month 3 comparison, p5: Statistical result of preoperative vs. postoperative month 6 comparison.

Discussion

In our study, statistically significant reductions were observed in IOP and the number of antiglaucomatous medications following trabeculectomy and deep sclerectomy surgeries. Studies have reported a reduction in IOP and the number of antiglaucomatous medications in the post-operative period consistent with this study.^[5-9]

In this study, a statistically significant difference was observed in the comparison of pre-operative and post-operative 1-week and 1-month IOPs following trabeculectomy and deep sclerectomy surgeries ($p < 0.05$). However, no statistically significant difference was found in the comparison of post-operative day 1, post-operative month 3, and post-operative month 6 IOPs. The main reason for the statistical difference in IOP values between the two groups over the months was thought to be the difference in pre-operative IOP values of the groups. The absence of a difference on post-operative day 1 might be attributed

to the increase in IOP due to the use of viscoelastic agents during surgery. In post-operative months 3 and 6, it was considered that the gap in IOP between the groups might have closed due to bleb failure in the trabeculectomy group.

In our study, regarding the comparison of trabeculectomy and deep sclerectomy surgeries in terms of their reducing effect on the number of antiglaucomatous medications, there was no statistically significant difference in the comparison of post-operative day 1 and post-operative week 1 medication numbers. However, a statistically significant difference was observed in the comparison of pre-operative medication numbers and post-operative month 1, month 3, and month 6 medication numbers. This indicates that deep sclerectomy surgery is effective in the early post-operative period, but its effect diminishes over time, leading to an increased need for antiglaucomatous medications to lower IOP.

There are numerous studies demonstrating that trabeculectomy is a more effective surgical method compared to other glaucoma surgeries. In a study, 55 medically uncontrolled glaucoma patients with a mean age of 68.6 were included in the study, and 65 eyes were retrospectively followed. Trabeculectomy and deep sclerectomy surgeries were performed on the patients, and both groups showed a decrease in IOP. However, statistically significant IOP reduction and higher success rates were associated with trabeculectomy compared to deep sclerectomy in this study.^[10]

A study was conducted where they performed trabeculectomy and deep sclerectomy surgeries on 34 eyes of 17 patients with medically uncontrolled primary open-angle glaucoma, similar to our study. In this study, IOP, and the number of antiglaucomatous medications decreased in both groups, but these results have shown the superiority of trabeculectomy over deep sclerectomy.^[11]

In a meta-analysis of 945 eyes from 18 studies conducted until 2013, which involved trabeculectomy and non-penetrating glaucoma surgeries (deep sclerectomy, canaloplasty, and viscocanaloplasty) and were written in any language, they compared IOPs and complications. Studies with patients with open-angle glaucoma who were followed for at least 6 months were included. Similar to our study, in this meta-analysis, the trabeculectomy group was superior to other surgeries in reducing IOP, but the frequency of choroidal effusion, hypotony, cataract, and shallow anterior chamber increased.^[12]

In a study where implant-assisted deep sclerectomy surgery was performed on 157 eyes with medically uncontrolled IOP in open-angle glaucoma, a decrease in IOP and the need for antiglaucomatous medication was observed in the post-operative period. The observed complications were as follows: 27 eyes (10.5%) with pre-operative microperforation, 2 eyes (0.8%) with the shallow anterior chamber, 2 eyes (0.8%) with hyphema, 5 eyes (2%) with cataract, and 1 eye (0.4%) with Dellen. There were no cases of endophthalmitis or choroidal detachment. After surgery, 23 eyes (8.9%) underwent a new filtration surgical procedure, and 2 eyes (0.8%) underwent diode laser cyclophotocoagulation. This study demonstrates that non-penetrating glaucoma surgery is an effective procedure for reducing IOP and provides the advantage of having fewer complications compared to trabeculectomy.^[4]

Studies have shown that deep sclerectomy has a lower complication rate compared to trabeculectomy.^[13,14] In addition, they have reported similar IOP reduction.^[15] In

this study, we observed that the complication rates in the post-operative period were in line with or even lower than the existing literature. This was attributed to the surgeries being performed by experienced surgeons and careful perioperative care and follow-up.

In this study, we observed that the complication rates during the post-operative period were consistent with or even lower than those reported in the literature. This was attributed to the surgeries being performed by experienced surgeons, and the careful perioperative care and follow-up. Our study had certain limitations that should be acknowledged. First, the low sample size of our deep sclerectomy group is a notable limitation; however, we still demonstrated significant differences between the two groups in terms of certain parameters. Second, the inclusion of both eyes of some patients in the study is another limitation. Third, the use of 5-FU instead of mitomycin as an antifibrotic agent might be considered a limitation; nevertheless, using the same antimetabolite in both groups helps prevent confusion in the comparison. Fourth, the presence of various types of glaucoma within the study groups and the fact that surgeries were performed by different surgeons are additional considerations.

Conclusion

Trabeculectomy surgery has been observed to be superior to deep sclerectomy in follow-ups up to 48-month postoperatively. However, it is noted that there is a higher risk of post-operative complications. For more reliable results, further studies with longer follow-up periods and prospective designs are necessary.

Ethics Committee Approval: Ethical approval for this study was obtained from the Ethics Committee of Istanbul Medeniyet University Göztepe Training and Research Hospital clinical research on February 05, 2020 Decision number: 2020/0037. The study was conducted within the rules of the Declaration of Helsinki.

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