Original Article

Modified Deep Sclerectomy for the Surgical Treatment of Glaucoma

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Abstract

Purpose: To report the short-term outcomes of modified deep sclerectomy (MDS) in the management of open angle glaucoma.
Methods: This prospective, non-randomized, controlled study included 105 eyes (105 patients) with open angle glaucoma. Eyes were categorized as follows: trabeculectomy (30 eyes), MDS (27 eyes), phacotrabeculectomy (28 eyes), and phaco-MDS (20 eyes). The MDS technique involved removal of a third scleral flap to expose the suprachoroidal space and excision of a trabecular block. A two-site approach was used for combined surgeries. Main outcome measures included intraocular pressure (IOP), number of glaucoma medications, and complications. Treatment success was defined as an IOP of 6–15 mmHg and/or a 30% reduction in IOP.
Results: All groups showed significant decrease in IOP and number of medications (both *P*s < 0.001). The MDS group had a higher IOP (13.9 ± 3.8 vs. 12.4 ± 2.5 mmHg, *P* = 0.080) and required more medications (*P* = 0.001) than the trabeculectomy group at 1 year. The MDS group had a higher baseline IOP than the trabeculectomy group (*P* = 0.004) and both the groups showed similar IOP reductions (33.3% vs. 25.7%, *P* = 0.391). The phaco-MDS and phacotrabeculectomy groups had comparable IOP (13.3 ± 3.1 vs. 12.4 ± 3.1 mmHg, *P* = 0.354), number of medications (*P* = 0.594), and IOP reduction (*P* = 0.509) at 1-year follow-up visit. The trabeculectomy and phacotrabeculectomy groups developed more wound leaks (*P* = 0.043) and required more bleb needling during the early postoperative period (*P* < 0.001).
Conclusion: The MDS technique seems to be slightly inferior to trabeculectomy, but when combined with phacoemulsification, is safer and results in similar IOP outcomes.

Keywords: Glaucoma; Glaucoma Surgery; Modified Deep Sclerectomy; Trabeculectomy

J Ophthalmic Vis Res 2019; 14 (2): 144-150

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Received: 27-10-2017 Accepted: 18-08-2018

Access this article online
Quick Response Code:
Website: www.jovr.org
DOI: 10.4103/jovr.jovr_228_17

INTRODUCTION

Since the first description of trabeculectomy in 1968 by Cairns,[1] this technique has become the gold standard for the surgical management of glaucoma. Therefore, the

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How to cite this article: Sharifipour F, Yazdani S, Asadi M, Saki A, Nouri-Mahdavi K. Modified deep sclerectomy for the surgical treatment of glaucoma. J Ophthalmic Vis Res 2019;14:144-50.

success rates of other procedures are compared to that of trabeculectomy. However, despite its efficacy in reducing intraocular pressure (IOP), trabeculectomy is far from ideal because of high complication rates and a low safety profile.[2] Glaucoma drainage devices (GDDs) have been shown to be effective and have low complication rates.[3] However, they have not replaced trabeculectomy[4] and are generally used in eyes with conjunctival scars or a history of failed trabeculectomy.[5]

Nonpenetrating glaucoma surgery (NPGS) was introduced in 1984 as a potentially safe and effective method for lowering IOP and was associated with fewer complications than was trabeculectomy.[6] Deep sclerectomy (DS), viscocanalostomy and, more recently, canaloplasty are commonly performed NPGS procedures.[6] Studies have shown IOP reduction provided by these procedures is equivalent to or slightly lower than that provided by trabeculectomy, but they have significantly lower rate of complications such as hypotony, cataract, wound leak, choroidal effusion, and late endophthalmitis.[7] However, these techniques have not gained widespread popularity as replacements for trabeculectomy. Additionally, NPGS is time consuming, technically more challenging, and has a steeper learning curve. The inadvertent rupture of trabeculo-Descemet's membrane during surgery may necessitate conversion to a trabeculectomy.[7]

All NPGS procedures aim to augment the natural drainage pathway through Schlemm's canal, and to a lesser extent, through conjunctival and choroidal vessels.[7] The suprachoroidal space is a virtual space into which a portion of the aqueous humor normally drains via uveoscleral outflow.[8] Choroidal effusions can build up in this space and spontaneously resolve, indicating the high resorptive capacity of this space. There has been great interest in diverting aqueous humor to this space with the aim of reducing IOP using a procedure that has a low complication rate. Surgical techniques, including cyclodialysis, gold microshunts (GMS), and the Cypass suprachoroidal shunt, have been used to augment suprachoroidal outflow.[9,10] Additionally, modifications in trabeculectomy and NPGS have been efficacy of a modified deep sclerectomy (MDS) procedure and trabeculectomy performed with and without cataract surgery.

METHODS

This prospective, non-randomized, controlled study was performed at a tertiary eye center was performed at the Department of Ophthalmology, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. The study protocol was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences and adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from all patients. Patients with open angle glaucoma scheduled for glaucoma surgery alone or combined with cataract surgery were considered for study enrollment. Preoperative diagnoses included primary open angle and pseudoexfoliative glaucoma. Patients with neovascular glaucoma, uveitic glaucoma, angle closure glaucoma (ACG), monocular glaucoma, or a history of ocular surgery were excluded from the study. Only eyes with a best corrected visual acuity (BCVA) <20/200 were considered for MDS or phaco-MDS. All patients underwent a complete ocular examination and ultrasound pachymetry (Pachymeter SP 3000, Tomey, Nagoya, Japan) to measure central corneal thickness. IOP was also measured twice using a calibrated Goldmann applanation tonometer (GAT BQ 900, Haag-Streit, Konitz, Switzerland). The average of the two measurements was used in analyses if they were within 2 mmHg of each other, otherwise a third reading was obtained.

Patients were categorized into the following study groups: trabeculectomy, MDS, phacotrabeculectomy, and phaco-MDS. All surgeries were performed by a single surgeon. Trabeculectomy was performed as follows: corneal traction suture (7-0 silk) placement, fornix-based conjunctival flap creation, 3.5 × 3.0 mm half-thickness scleral flap dissection, and 0.02% mitomycin C application. Mitomycin C was applied for 2-3 minutes on surgical sponges based on conjunctival and Tenon's capsule thickness and degree of vascularity. Finally, a 1.0 × 1.5 mm trabecular block was excised before performing peripheral iridectomy. The scleral flap was secured using two 10-0 nylon releasable sutures, and the conjunctiva was reapproximated with 10-0 nylon sutures. Following the completion of the procedure, the surgeon verified the absence of wound leaks.

Modifications were made to the standard DS technique for patients in the MDS groups. After creating a fornix based conjunctival flap, a 5 × 5 mm parabolic 1/3 thickness scleral flap was created. Next, a 4 × 4 mm deep scleral flap was fashioned and removed. A trabeculo-Descemet's membrane was not created. Paracentesis was then performed to decompress the eye and a 3 × 3 mm window was created into the suprachoroidal space by removing a thin layer of sclera overlying uveal tissue. More specifically, a small scleral incision was made and ophthalmic viscosurgical device (OVD; Visicrome, Croma Pharma GmbH, Leobendorf, Austria) was injected under the sclera to push back the uveal tissue and protect it from inadvertent damage. Next, a thin layer of sclera was removed using Vannas scissors or a 15-degree blade with the cutting edge facing upward. A 1.0 × 1.5 mm trabecular block was removed, and peripheral iridectomy was performed in a manner similar to trabeculectomy. The iris attachment to the scleral spur was left intact so that aqueous humor drainage into the suprachoroidal space would only occur via the uveal window and not a cyclodialysis cleft. A small amount of OVD was injected into the suprachoroidal space to maintain space and facilitate subsequent aqueous humor drainage. The superficial scleral flap was then repositioned and sutured (10-0 nylon watertight sutures) in a shoelace fashion to the cut edge of the deep scleral flap. This created more space for the intrascleral lake. The anterior chamber (AC) was reformed, the conjunctival wound was closed (10-0 nylon sutures), and the wound was checked for leakage [Figure 1a-h]. All combined procedures were 2-site surgeries that included temporal clear corneal phacoemulsification, which was performed before glaucoma surgery.

All the patients received chloramphenicol eye drops 4 times a day for 1 week following surgery and betamethasone eye drops every 3 hours with a gradual taper over 4-6 weeks. Cycloplegic medications were used in eyes with a shallow AC. Postoperative eye examinations were performed at 1 and 3 days; 1 and 2 weeks; and 1, 2, 3, 6, and 12 months after surgery. At each examination, the wound was checked for leakage using fluorescein strips. Leaks were first managed conservatively with therapeutic contact lens and decreasing the frequency of topical steroids. Re-suturing was performed for sustained leaks. Patients were specifically monitored for choroidal effusions if the pupil remained dilated 1 week after surgery, if IOP was low (<6 mmHg), or if the AC was shallow. In the trabeculectomy and phacotrabeculectomy groups, releasable sutures were removed depending on bleb morphology. Needling and a 5-fluorouracil (5 mg) subconjunctival injection were performed on eyes with failing blebs. Anterior segment optical coherence tomography (OCT; Topcon 3D OCT-1000, Topcon Corp, Tokyo, Japan) was used to postoperatively evaluate intrascleral blebs. Main outcome measures included intraocular pressure (IOP), number of glaucoma medications, and complications. Power calculations with an α error of 0.05 revealed that 16 eyes were needed in each group to obtain 80% power for detecting a between group IOP difference of 1 mmHg. Assuming 20% dropout during the follow-up period, a sample size of 20 eyes was chosen for each group. However, recruitment was continued until enrollment of the last group was complete.

Statistical analyses were performed using SPSS software version 17 (SPSS, Inc., Chicago, IL). Data are presented as mean ± standard deviation and 95% confidence intervals (CI). To compare within and between group differences, paired sample and independent samples *t*-tests, respectively, and Mann-Whitney U test for non-normally distributed parameters were used. Kaplan–Meier curves were created for cumulative failure rates. Success was defined as an IOP between 6 and 15 mmHg and/or a 30% reduction in IOP. Failure was defined as an IOP >15 mmHg (with glaucoma medication use) or <6 mmHg or a visual acuity decline to no light perception that was attributable to glaucoma or surgical complications. The log-rank test was used to compare success rates between groups. *P* values <0.05 were considered to be statistically significant.

RESULTS

Overall, 105 eyes of 105 patients were included in this study. Patients were assigned to intervention groups as follows: trabeculectomy (n = 30 eyes),

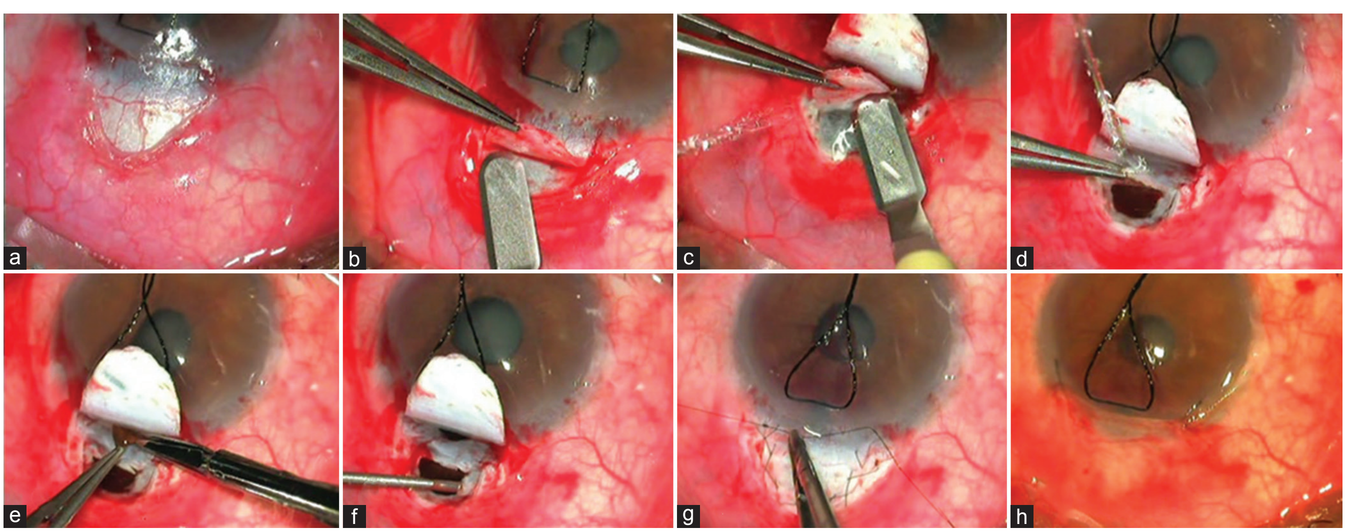

Figure 1. Surgical steps of modified deep sclerectomy. (a) A fornix based conjunctival flap was created. (b) A 5 × 5 mm parabolic 1/3 thickness scleral flap was created. (c) A 4 × 4 mm deep scleral flap was created and removed. (d) After paracentesis, a 3 × 3 mm window into the suprachoroidal space was created by removing a thin layer of sclera over the uveal tissue. This step was aided by the injection of ophthalmic viscosurgical device (OVD) under the sclera. (e) A 1.0 × 1.5 mm trabecular block was removed, and a peripheral iridectomy was performed. (f) A small amount of OVD was injected into the suprachoroidal space. (g) The superficial scleral flap was repositioned and sutured with 10-0 nylon. (h) The conjunctival wound was closed with 10-0 nylon sutures.

MDS (n = 27 eyes), phacotrabeculectomy (n = 28 eyes) and phaco-MDS (n = 20 eyes). Baseline characteristics of the study groups are presented in Table 1. Preoperatively, the MDS and trabeculectomy groups were similar in terms of age, sex, central corneal thickness (CCT), and number of glaucoma medications. However, the MDS group had a higher preoperative IOP (P = 0.004) and a lower BCVA (P = 0.001). At baseline, the phaco-MDS group used more medications (P = 0.031) and had a lower BCVA (P = 0.012) than the phacotrabeculectomy group, but age, sex, IOP, and CCT were similar between groups [Table 1]. After surgery, IOP and the number of glaucoma medications significantly decreased in all study groups (all Ps < 0.001; [Table 2 and Figure 2a and b]). Although the MDS group had higher pre- and postoperative IOP values than the trabeculectomy group, (P = 0.004 and 0.080, respectively) both groups had a similar percent reduction in IOP from baseline (P = 0.381). The MDS group required more medications at 1 year than the trabeculectomy group (P = 0.001, [Table 2]). The phaco-MDS group required significantly more medications at baseline than the phaco-trabeculectomy group (P = 0.031), but mean IOP (P = 0.324) at baseline, mean IOP at 1 year (P = 0.354), the number of medications at 1 year (P = 0.594), and IOP reduction (P = 0.509) were similar between groups.

The trabeculectomy and phacotrabeculectomy groups had higher rates of needling bleb revision than the MDS and phaco-MDS groups, respectively (both Ps < 0.001), in the early postoperative period because of more wound leaks and choroidal effusions [Table 3]. These complications were managed medically. The BCVA was significantly lower in the MDS and phaco-MDS groups before surgery because of the inclusion criteria. The BCVA remained unchanged in the MDS and trabeculectomy groups but significantly improved

Table 1. Baseline characteristics of the study groups

Group	MDS	Trabeculectomy	*P*	Phaco-MDS	Phacotrabeculectomy	*P*
Number	27	30		20	28	
Age (yr) Mean (SD)	58.6 (11.9)	57.3 (15.3)	0.710	68.7 (10.3)	68.4 (9.7)	0.928
Gender F (%)	9 (33)	6 (20)	0.332	9 (45)	14 (50)	0.713
IOP (mmHg) Mean (SD)	22.2 (7.3)	17.6 (4.4)	**0.004**	19.2 (6.1)	18.1 (5.8)	0.324
Medication (N) Mean (SD)	3.1 (1.4)	3.1 (1.4)	0.822	3.5 (1.3)	2.6 (1.4)	**0.031**
CCT (µm) Mean (SD)	526 (41)	533 (45)	0.586	536 (38)	537 (25)	0.931
BCVA (LogMAR) Mean (SD)	1.4 (0.9)	0.7 (0.6)	**0.001**	1.6 (0.9)	1 (0.5)	**0.012**

SD, standard deviation; MDS, modified deep sclerectomy; IOP, intraocular pressure; Medication, number of glaucoma medications; CCT, central corneal thickness; BCVA, best corrected visual acuity; LogMAR, logarithm minimum angle of resolution; yr, years; N, number

Table 2. Inter- and intra-group comparisons of the study parameters

Group	MDS	Trabeculectomy	*P*	Phaco-MDS	Phacotrabeculectomy	*P*
Pre Op. IOP (mmHg) Mean (SD)	22.2 (7.3)	17.6 (4.4)	**0.004**	19.2 (6.1)	18.1 (5.8)	0.324
IOP at 1 yr (mmHg) Mean (SD)	13.9 (3.8)	12.4 (2.5)	**0.08**	13.3 (3.1)	12.4 (3.1)	0.354
P	**<0.001**	**<0.001**		**<0.001**	**<0.001**	
IOP change (%) Mean (SD)	33.3 (21.7)	25.7 (22.3)	0.381	24.6 (22)	24.6 (22)	0.509
Pre Op. Medication (N) Mean (SD)	3.1 (1.4)	3.1 (1.4)	0.822	3.5 (1.3)	2.6 (1.4)	**0.031**
Medications at 1 yr (N) Mean (SD)	1.6 (1)	0.6 (1)	**0.001**	0.9 (0.7)	0.8 (0.9)	0.594
P	**<0.001**	**<0.001**		**<0.001**	**<0.001**	

SD, standard deviation; MDS, modified deep sclerectomy; Pre Op., preoperative; IOP, intraocular pressure; yr, year

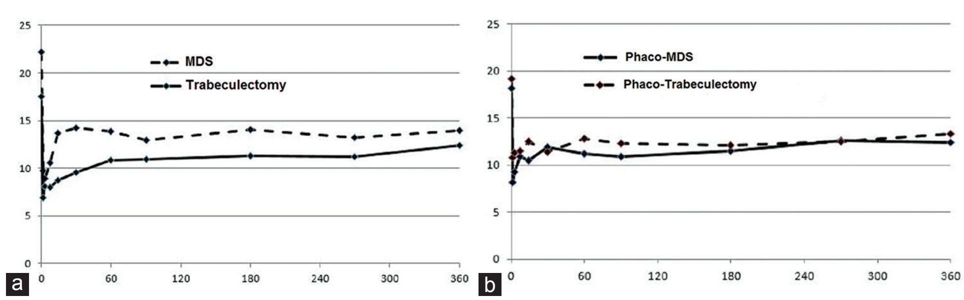

Figure 2. Line graph showing intraocular pressure (IOP) values before and after glaucoma surgery in the trabeculectomy and modified deep sclerectomy (MDS) groups (a) and the phacotrabeculectomy and phaco-modified deep sclerectomy (Phaco-MDS) groups (b).

in both the phaco-MDS and phacotrabeculectomy groups. No patient experienced loss of BCVA. Anterior segment OCT revealed an intrascleral lake in the eyes in the MDS group [Figure 3], which had a lower success rate than the trabeculectomy group (64.6% vs. 71.5%, respectively, *P* = 0.131; [Figure 4a]). However, the phaco-MDS and phacotrabeculectomy groups had similar success rates (61.9% vs. 60.4%, respectively, *P* = 0.581; [Figure 4b and Table 4]).

DISCUSSION

The current study demonstrated that our new MDS technique, which also targets the suprachoroidal space for aqueous humor drainage, results in a percent reduction in IOP similar to that of trabeculectomy and has a higher safety profile when combined with cataract surgery. Reducing IOP is currently the main therapeutic approach for the treatment of glaucoma. Surgery for glaucoma is usually performed to prevent disease progression or when medical and/or laser therapies fail to control IOP or prevent disease progression. Even though newer surgical techniques have been developed,[9] trabeculectomy has remained the gold standard surgical treatment for more than 40 years. Even though it has a reasonable efficacy, trabeculectomy is not an ideal procedure because of high complication rates and a low safety profile. Early and late complications associated with trabeculectomy included hypotony, overfiltration, bleb leaks, bleb fibrosis and encapsulation, overhanging blebs, corneal endothelial cell loss, dellen, aqueous humor misdirection, cataract, blebitis, and bleb related endophthalmitis.[11]

Various surgical procedures have been developed to augment normal outflow pathways (i.e., conventional and uveoscleral) in an effort to improve the safety of glaucoma surgery. Laser goniopuncture[12] and newer goniosurgical procedures [e.g., trabecular microbypass (iStent),[13] trabectome microelectrocautery,[14] the Eyepass implant,[15] and canaloplasty[16] have been used to enhance conventional outflow pathways. Surgical procedures to augment suprachoroidal outflow include cyclodialysis,[17] suprachoroidal implants,[18-20] seton devices,[21] and GMS placement in the suprachoroidal space.[10,22] Studies have shown better safety profiles and similar short-term efficacy with these techniques. However, some studies have shown that fibrosis can cause suprachoroidal devices to gradually fail.[23,24] Although there has been some success with suprachoroidal tube implantation,[18-20,21,25] a gradual loss of efficacy may occur.[18,19] In one study, ultrasound biomicroscopy revealed that some cases of shunt failure were caused by fibrotic obstruction of the posterior tube lumen.[18] In fact, fibrotic reactions and scarring are most likely the main cause of failure of glaucoma surgeries that divert aqueous humor to the suprachoroidal space.

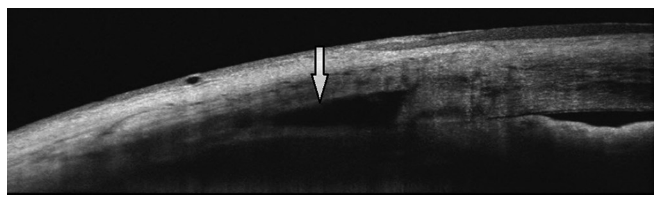

Figure 3. Representative anterior segment optical coherence tomography image in a subject that underwent modified deep sclerectomy. An intrascleral lake (arrow) is readily visible.

Table 3. Postoperative complications/interventions during one year of follow-up in the study groups

Group	Number	Wound leak *n* (%)	Shallow AC *n* (%)	Choroidal effusion *n* (%)	Needling *n* (%)
MDS	27	0 (0)	2 (8)	1 (4)	0 (0)
Trabeculectomy	30	2 (7)	3 (10)	3 (10)	17 (57)
P		0.186	0.768	0.382	**<0.001**
Phaco-MDS	20	0 (0)	0 (0)	0 (0)	0 (0)
Phacotrabeculectomy	28	4 (14)	2 (7)	2 (7)	12 (43)
P		**0.043**	0.161	0.161	**<0.001**

MDS, modified deep sclerectomy; AC, anterior chamber

Table 4. Treatment outcomes after one year of follow up in the study groups

Group	Number	Complete success *n* (%)	Qualified success *n* (%)	Failure *n* (%)
MDS	27	12 (44)	13 (48)	2 (8)
Trabeculectomy	30	25 (83)	5 (17)	0 (0)
P		**<0.001**	**0.006**	0.211
Phaco-MDS	20	12 (60)	8 (40)	0 (0)
Phaco- trabeculectomy	28	16 (57)	12 (43)	0 (0)
P		0.712	0.712	

MDS, modified deep sclerectomy. Complete success, IOP ≤16 mmHg without additional glaucoma medications; qualified success, IOP ≤16 mmHg with glaucoma medications; failure, IOP >16 mmHg with glaucoma medications

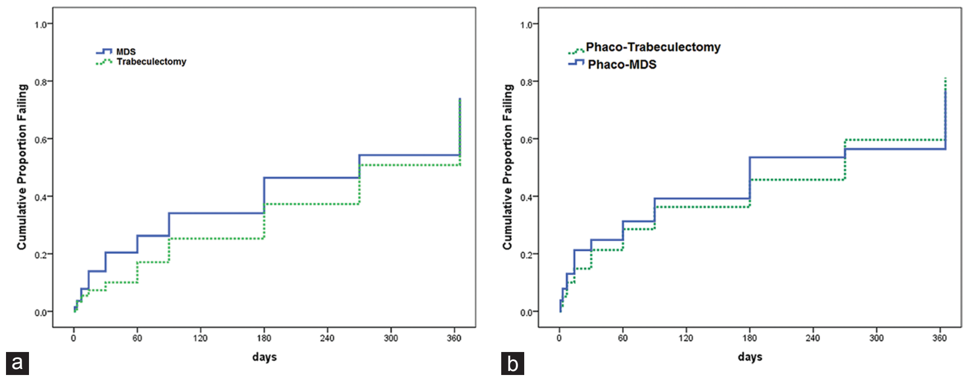

Figure 4. Kaplan–Meier curves showing cumulative success rates. Surgical success was defined as an IOP between 6 and 15 mmHg and/or a 30% reduction in IOP. Higher cumulative failure rates occurred in the modified deep sclerectomy (MDS, a) and phaco-modified deep sclerectomy (phaco-MDS, b) groups than in their respective trabeculectomy counterparts.

Non-penetrating glaucoma surgery (NPGS) was introduced approximately 30 years ago as a new filtering surgery that did not require globe penetration and had a better safety profile than trabeculectomy.[6] Modifications to this technique include the use of antimetabolites,[26] placement of various implant types to improve surgical success,[7,27] viscocanalostomy, and canaloplasty.[28,29] While most studies show lower complication rates with NPGS than with trabeculectomy, procedural efficacy remains somewhat controversial, especially the complete success rate.[7] Additionally, NPGS is technically difficult, has a long learning curve, and has a high conversion rate to trabeculectomy, particularly when inexperienced surgeons rupture the trabeculo-Descemet's membrane. Furthermore, NPGS has more contraindications than trabeculectomy and the technique is not recommended for eyes with ACG unless it is combined with cataract surgery.[7]

The current study examined novel modifications in the DS technique in an attempt to negate some NPGS limitations. This new technique makes surgery easier to perform because the difficult part of DS is creating a *trabeculo-Descemet's* membrane. Our technique changes this to a block excision, as in trabeculectomy, which also makes it an option for treating ACG. Our results showed a similar percent reduction in IOP between MDS and trabeculectomy (P = 0.381) and between phaco-MDS and phacotrabeculectomy (P = 0.509). However, survival curves showed higher failure rates in the MDS group, which also had a greater need for medication. This finding was likely due to fibrous tissue formation in the suprachoroidal space. However, the technique had fewer early postoperative complications than the trabeculectomy and phacotrabeculectomy groups, which resulted in fewer postoperative visits and the need for further intervention (e.g., needling bleb revision). Patients also had greater comfort, less bleb dysesthesia, and fewer bleb related complications. Antimetabolites are not used in this technique and aqueous humor can only access the suprachoroidal space via the fistula and not a cyclodialysis cleft. The technique does not use an implant or shunt, making it less expensive. The modified technique presented here has many common procedural steps with DS, trabeculectomy, and suprachoroidal drainage. It is also easy to perform and was associated with few complications. Neither intraoperative uveal damage nor hemorrhage was observed in any of the patients. However, vigorous control of inflammation at the suprachoroidal level may increase technique efficacy.

This study showed promising results for glaucoma surgeries that target the suprachoroidal space, although suprachoroidal space inflammation and scarring is a concern. In summary, the proposed deep sclerectomy modification was safer and had comparable efficacy to trabeculectomy, especially when combined with phacoemulsification. However, longer follow up is needed to evaluate intermediate- and long-term results and potential complications.

Financial Support and Sponsorship

Nil

Conflicts of Interest

There are no conflicts of interest.

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