Efficacy and safety of non-penetrating deep sclerectomy surgery in Saudi patients with uncontrolled open angle glaucoma

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ABSTRACT

الأهداف: تحقيق فعالية وسلامة تطبيق جراحة إختراق الصلبة العميق على المرضى السعوديين المصابين بداء الزرق المفتوح الزاوية الأولى والثانوى.

الطريقة: في هذه الدراسة الجيلية الإسترجاعية تم إدراج عدد 194 عين لعدد 152 مريض مشخصين بمعاناة مرض الزرق مفتوح الزاوية ، وتم إخضاعهم لجراحة إختراق الصلبة العميق مع إضافة مادة المايتومايسين – سى فى مستشفى الملك عبد العزيز الجامعى خلال الفترة من يناير 2002م وحتى سبتمبر 2010م. جمعت بيانات ديموجرافية وإكلينيكية عن المرضى تشمل العمر وقت الجراحة، والنوع ، والتشخيص الدقيق، وضغط العين، وعدد الأدوية، والتعرض لجراحات سابقة ، ونسبة مقياس الكأس لقرص العصب البصرى، كما سجلت المضاعفات القريبة والبعيدة الأمد.

النتائج: تمت متابعة الحالات إلى متوسط 60.9 (±49.7) شهر، لوحظ خلالها إنخفاض ضغط العين من متوسط 25.6 (±10.3) قبل الجراحة إلى 13.5 (±4) فى آخر زيارة، فى حين إنخفض متوسط أدوية الزرق المستخدمة من 2.95 (±0.93) قبل الجراحة إلى 0.22 (±0.63) فى آخر زيارة، وكان كلا الإنخفاضين ذو دلالة معنوية (p<0.0001). كما تحقق النجاح الجراحى الكامل فى 159/194 عين بنسبة (82%) والنجاح الشامل بنسبة 175/194 (90.2%). كانت محددات الفشل المعنوية هى ورود المرضى فى سن أقل من 50 سنة (p=0.039) ، إرتفاع ضغط العين عن 21 (p=0.003) مم زئبق عند الحضور، بالإضافة إلى التعرض لجراحات سابقة. بينما كان الجمع بين جراحة المياه البيضاء والجلوكوما (p=0.047)، والتحول إلى الجراحة الإختراقية أثناء الجراحة من عوامل زيادة النجاح بشكل ملحوظ (p=0.037).

خاتمة: تعتبر جراحة إختراق الصلبة العميق جراحة فعالة وآمنة لخفض إرتفاع ضغط العين إلى المستوى الطبيعى ، كما تتميز بندرة المضاعفات التى تؤدى إلى تهديد حدة الإبصار بين مرضى الزرق المفتوح الزاوية.

Objectives: To investigate the efficacy and safety of deep sclerectomy (DS) in Saudi patients with primary and secondary open-angle glaucoma (OAG).

Methods: In this retrospective cohort study, a total of 194 eyes of 152 patients with OAG were consecutively enrolled to undergo DS with Mitomycin-C (MMC) at King Abdulaziz University Hospital, Jeddah, Kingdom of Saudi Arabia between January 2002 and September 2010. Age at surgery, gender, type of glaucoma, operated eye, previous ocular surgery, type of implant, pre and final visit visual acuities, intraocular pressure (IOP), number of anti-glaucoma medications, optic nerve cup/disc ratio, and complications were recorded.

Results: Cases were followed up to a mean of 60.9 (±49.7) months. The IOP reduced from a preoperative mean of 25.6 (±10.3) to final visit of 13.5 (±4), whereas the mean number of anti-glaucoma medication also reduced from 2.95 (±0.93) to 0.22 (±0.63), which was statistically significant (p<0.0001). Complete success was 82%, while overall success was 90.2%. Patients <50 years (p=0.003), high IOP (≥21) at baseline (p=0.039), and being exposed to previous surgeries (p=0.047) were significant risk factors for failure, while combining cataract and converting to penetrating surgery have significantly improved the success rate (p=0.037).

Conclusions: Deep sclerectomy provides significant IOP reduction with low rate of visual threatening complications in Saudi patients with open angle glaucoma.

Saudi Med J 2013; Vol. 34 (1): 54-61

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Received 30th September 2012. Accepted 26th November 2012.

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Deep sclerectomy (DS) is a non-penetrating surgical procedure for treatment of open-angle glaucoma (OAG), while trabeculectomy is a penetrating filtration surgery widely used for surgical treatment of medically uncontrolled glaucoma. The penetrating nature of trabeculectomy results in several postoperative complications.[1] In an attempt to lower the incidence of such complications, non-penetrating glaucoma surgery (NPGS) was developed. It was first described by Epstein in the late 1950s[2] and Krasnov in the late 1960s.[3] They suggested deroofing of the Schlemm's canal (SC) as a mean to lower intraocular pressure (IOP). However, the effect of the procedure was short-term and it required a long learning curve. Modified non-penetrating deep sclerectomy (NPDS) gained momentum for OAG surgeries.[4] Non-penetrating glaucoma surgery involves removal of a deep scleral flap that leads to the formation of an empty scleral space called 'decompression space', where the aqueous will be collected before its drainage.[5] It was demonstrated previously that aqueous outflow resistance occurring in the juxtacanalicular trabecular meshwork (TM) and inner wall of SC.[6] Non-penetrating glaucoma surgery is designed to address this area of resistance by deroofing SC and peeling its floor, together with the juxtacanalicular and part of corneoscleral layers of TM. Trabecular meshwork acts as an outflow resistance site, allowing a progressive decrease in IOP without penetration into the anterior chamber, which in turn precludes the sudden hypotony that occurs after trabeculectomy.[7] To facilitate IOP lowering efficacy, space-maintaining devices in NPDS were introduced. They are used to reduce scar formation and to keep the decompression space open during the time of maximal healing. Different absorbable and non-absorbable; expensive and low cost; animal, synthetic and chemical-based devices are used nowadays.[1] Examples of the commonly used devices are aqua-flow collagen implant staar surgical AG (Nidau, Switzerland), reticulated hyaluronic acid implant (Sk-Geltm, Corneal Laboratories, Paris, France), non-absorbable hydrophilic acrylic implant (T-flux®, loltech, La Rochelle, France), viscoelastic implant (namely Healaflow, Anteis Ophthalmology, Geneva, Switzerland), and Viscoplus® (Biomedical, Aschaffenburg, Germany). In some patients, the trabecular meshwork membrane (TDM) may present an increased resistance to aqueous outflow, either early or later following the NPDS, and when the filtration through the membrane is considered to be insufficient because of elevated IOP, a goniopuncture (trabeculo-Descement's membranotomy) can be performed with a Neodymium: Yttrium-Aluminum-Garnet (Nd:YAG) laser through a gonio-lens.[8] The insufficient passage of aqueous humor through the TDM is usually due to fibrosis as part of the healing process at the TDM, or due to excessive deposition of debris and or pigments. Goniopuncture is effective when under-filtration is due to poor function of the TDM and not due to other causes such as poor dissection plane, excessive bleb fibrosis or other more serious causes.[9] It is considered as a minor follow up procedure equivalent to Yag laser posterior capsulotomy. Laser gonio puncture (LGP) converts deep sclerectomy from being a non-penetrating procedure to a penetrating one, but with fewer complications compared with penetrating glaucoma surgery. Except for Al Sayyad et al[10] study, there are no previous studies that investigated the efficacy and safety of NPDS in OAG in this country and in such a large cohort with a long term follow-up. The aim of this study is to investigate the efficacy and safety of deep sclerectomy with MMC in Saudi patients with OAG.

Methods. We retrospectively reviewed 152 charts of patients who underwent DS for medically uncontrolled primary or secondary OAG between January 2002 and September 2010. Exclusion criteria included cases of congenital glaucoma, angle closure glaucoma and neovascular glaucoma. Surgical indications included: high intraocular pressure (>21 mm Hg) with maximum tolerated medical treatment, progressive glaucomatous visual field loss calculated as slopes of mean deviation (MD) over time in automated field analyzer with pattern standard deviation that eliminate media opacity including cataract cases and/or progressive optic disc cupping detected by increase in cup disc ratio (Cup/Disc ≥0.7 vertical elongation and increased by at least 0.1 in 2 successive visits) documented in files or in disc photography and confirmed by optical coherence tomography (OCT) disc analysis even with normal range of IOP (10-21 mm Hg) or poor compliance to medical therapy or confirmed diagnosis as open angle with normal ocular tension. The procedures were performed by 2 of the glaucoma consultants (SO & EAO) in the Glaucoma Unit, Ophthalmology Department at King Khalid University Hospital, Riyadh, Saudi Arabia.

Ethical approval was sought from the Institutional Research Board, College of Medicine, King Saud University. The study adhered to the tenets of the declaration of Helsinki for research involving humans. Brief description of the NPDS technique: a fornix-based conjunctival flap was fashioned, and a 5x5 mm one-third sclera thickness superficial flap was created, which extended 1.5 mm into the clear cornea. A sponge soaked in MMC solution (0.2 mg/ml) was placed

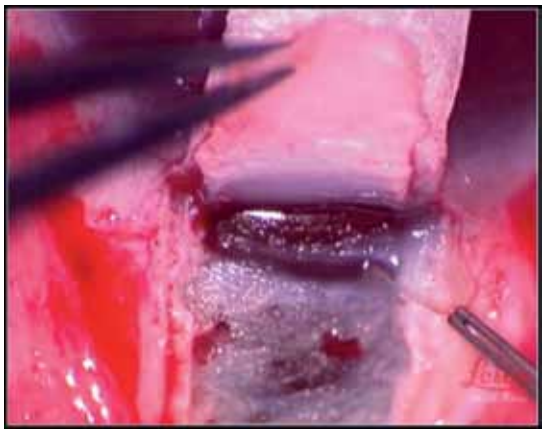

Figure 1 - Peeling of the floor of the Schelmn's canal with double plated forceps.

under the superficial scleral flap and Tenon's capsule for 2 minutes, then thorough irrigation with balanced salt solution. A 4x4 mm deep scleral flap was created leaving only a very thin layer of scleral tissue over the uvea. Dissection was carried out from the posterior part of the flap and extended anteriorly to deroofing Schlemm's canal (SC), spontaneously. Dissection was continued anteriorly to create the TDM. The floor of SC was peeled off with double plated forceps (**Figure 1**) and the deep flap was excised. Different implants were used (in most of patients) and placed in the floor of the excised deep flap such as T-flux,® SK-GELTM, Healaflow® or Viscoplus®. The superficial scleral flap was then closed loosely with 10-0 nylon sutures at the posterior corners. The conjunctival flap was closed in a water-tight fashion with 9-0 vicryl suture. Postoperatively, all patients received topical antibiotic eye drop for 2 weeks and topical steroid to be tapered gradually in 4-12 weeks. The following data were collected: age at time of surgery, gender, type of OAG, the eye to undergo surgery, previous ocular surgeries, type of implant device used, preoperative and at final visit, visual acuity, IOP, number of anti-glaucoma medications and optic nerve cup-to-disc ratio. Intraoperative and postoperative complications where recorded.

In this study, complete success is defined as achieving IOP >6 and ≤21 mm Hg at all times without the use of additional medications or the need for further surgical procedures. While qualified success is defined as IOP ≤21 mm Hg with anti-glaucoma medication and failure was defined as eyes requiring further surgery to control IOP (>21 mm Hg). Moreover, overall success was calculated combining both complete and qualified success rates.

Statistical analysis. Data were collected in a specially designed questionnaire form that included both demographic and clinical indices, which was reviewed and corrected by the researchers. All records with missing data, inconvenient conflictions and/or outlier results were removed before the analysis. Data were then entered into a specifically designed database using Microsoft Access 2007® where necessary data management was conducted. Data analysis was conducted using SPSS (Statistical Package for Social Sciences) version 19.0 by IBM® incorporation (IBM Inc.®, Chicago, Illinois) and MedCalc version 11.4.2 by MedCalc® (MedCalc Software bvba, Mariakerke, Belgium). Descriptive statistics including: mean, standard deviations, average (min-max) were calculated to both numerical and categorical variables. Inferential analysis was conducted to compare means for pre- and post- intervention indices using Student's paired T test for continuous variables (Wilcoxon signed rank test whenever appropriate), while Chi-square was conducted to investigate the potential associations between other categorical variables. Binary logistic regression was conducted to adjust for confounding variables and achieve the best set of significant risk factors. A p-value <0.05 was considered as statistically significant, while a standardized 95% confidence intervals were set as standard for conduct of the statistical tests.

Results. A total number of 194 eyes of 152 patients were recruited. The sample was equally distributed by gender (n=76 (50%) males and n=76 (50%) females). Bilateralism was found in 43 (28.3%) while the other 108 (71.7%) were unilateral where the frequency of diseases was almost equally distributed per eye (right eye: 99; 51%, left eye: 95; 49%). The mean (±SD) age of patients was 44.9 (±20.3); range 8-90 years. Cases were followed up to a mean of 60.9 (±49.7) months ranging from 6 month to 9 years. The clinical baseline data showed that patients presented with a mean IOP of 25.6 (±10.3), Log MAR visual acuity of 0.45 (±0.51), cup/disc ratio of 0.78 (±0.21) and the mean number of anti-glaucoma medication of 2.95 (±0.93). Most cases were primary OAG as the main diagnosis followed by uveitic glaucoma and juvenile OAG (**Table 1**).

Out of 194 cases, 13 (6.7%) eyes had previous surgeries: argon laser trabeculoplasty (n=3), deep sclerectomy (n=2), trabeculectomy (n=2), extra capsular cataract extraction (n=1), retinal reattachment surgery (n=1), laser intervention plus lensectomy (n=1), strabismus, penetrating keratoplasty (n=1), and phacoemulsification (n=1). Non-penetrating deep sclerectomy was the intervention procedure of choice in most cases while 31 (16%) cases were converted

to penetrating technique whenever necessary or due to accidental perforation. Along with the surgical procedure, 29 (14.9%) eyes had no implant, 50 (25.8%) had healaflow, 59 (30.4%) had Sk-Gel, 55 (28.4%) had T-flux, and Viscoplus was used in 2 (1%) cases. Combined phacoemulsification and DS surgery was performed in 31 (16%) of eyes. The intraocular pressure (SD) reduced from preoperative mean value of 25.6 (±10.3) to a mean value of 13.5 (±4) at final visit with a mean reduction of 12.1 (95% CI: -0.014 to -0.098), whereas the mean number of anti-glaucoma medication also reduced from preoperative of 2.95 (±0.93), (range 1-4) to 0.22 (±0.63), (range 1-3). Both improvements in IOP and the number of used medications were highly statistically significant (p=0.0001). Cataract extraction using phaco emulsification plus intraocular lens insertion (IOL) was combined with 31 (16%) of the cases. The mean Log MAR visual acuity has improved from preoperative of 0.45 (±0.51) to 0.41 (±0.46) at final visits; however, insignificantly. Nevertheless, this slight improvement may be due to combined cataract-glaucoma cases. Among the 31 cases combined with cataract, the mean LogMAR has significantly improved from preoperative value of 0.69 (0.46) to postoperative value of 0.39 (0.29), p<0.0001, while among non-combined cases, the mean LogMAR has almost kept unchanged (preoperative; 0.4 (0.5), postoperative; 0.41 (0.48), p=0.822).

Complete success rate (as defined in the methods section) was achieved in 159/194 (82%) eyes, while overall success rate was 175/194 (90.2%) eyes. Meanwhile, further intervention was needed in 21 (10.8%) of eyes. Repeated deep sclerectomy 2 (1%), bleb revision 2 (1%), trabeculectomy 5 (2.5%), trabeculectomy plus phacoemulsification 4 (2%), and tube surgery 3 (1.5%). Most cases were carried out successfully without any intra-operative or postoperative complications (145 eyes; 74.7%) whereas complications were recognized in 49 eyes (25.3%). Some eyes had single or multiple complications. Complications are demonstrated in details in **Table 2**.

Among cases with implant, the overall success rate was 133/166 (80.1%) eyes, which is very close to those without implant; 26/28 (92.9%) eyes (p=0.119). Furthermore, among cases with implant, the success rate with Healaflow was 43/50 (86%) eyes, SKGel 47/59 (79.7%) eyes, TFlux 41/55 (74.5%) eyes, and Viscoplus 2/2 (100%) eyes. These differences were not of statistical difference (p=0.638). Comparing cases with primary and secondary glaucoma in terms of the complete and overall success rate yielded that cases with primary glaucoma were more successful; (complete: 103/120; 85.8%, overall: 111/120; 92.5%) than those with secondary glaucoma; (complete: 56/74; 75.7%, overall: 64/74; 86.5%). However, this difference was not statistically significant on both aspects (p=0.113 for complete and p=0.171 for overall rates). Despite the majority of secondary glaucoma cases being uveitic in nature (47/194; 24.2%). Among the group with combined phaco, the mean IOP significantly reduced from pre-operative value of 19.2 (±6.4) to postoperative value of 13.4 (±3.8), with a reduction of 5.8 (±7.2), [95% CI: 3.121-8.247], p<0.0001. Meanwhile, among the group with no cataract, the mean IOP has significantly reduced from preoperative value of 26.8 (±10.4) to 13.6 (±4.1) postoperatively, with a reduction value of 13.3 (±11.1), (95% CI: 11.52-14.97), p<0.0001. In terms of reduction value of IOP, the mean difference in reduction was 6.8 (±1.5) (statistically significant p<0.0001) (95% CI: -9.89 to -3.76). The conduct of univariate analysis revealed that age <50 years (p=0.003; 95% CI: 1.39-9.19) and elevated preoperative IOP (≥21; p=0.039; 95% CI: 0.166-1.024) were significant risk factors for failure; however, combining phaco-emulsification with DS and converting to penetrating surgery have improved the probability of success (p=0.037; 95% CI: 0.017-0.960) (**Table 3**). Moreover,

Table 1 - Diagnosis at presentation of 152 patients.

Diagnosis	n	(%)
POAG	86	44.3
Uveitic	47	24.2
Juvenile	24	12.4
Pseudoexfoliation	11	5.7
Normal Tension	10	5.2
Steroid Induced	7	3.6
Pigmentary	5	2.6
Angle Recession	4	2.1
Total	**194**	**100.0**

POAG - primary open angle glaucoma

Table 2 - Intraoperative and postoperative complications.

Complications	n	(%)
Microperforation	15	(7.7)
Hyphema	12	(6.2)
Bleb leak	6	(3.1)
Macroperforation	8	(4.1)
Hypotony	5	(2.6)
Iris adhesion to trabeculo-descemet's membrane	5	(2.6)
Decompression retinopathy	4	(2.1)
Choroidal detachment	2	(1.0)
Hypotony maculopathy	2	(1.0)
Descemet's membrane detachment	1	(0.5)
Small scleral flab tear	1	(0.5)
SK gel implant migration	1	(0.5)

Table 3 - Risk factors associated with failure in 152 charts of patients.

Factors	Failure		Success		*P*-value	95% confidence intervals
	n	(%)	n	(%)		
Age					0.003	1.39 - 9.19
<50	27	(25.5)	79	(74.5)		
≥50	8	(9.1)	80	(90.9)		
Preoperative IOP					0.039	0.166 - 1.024
<21	9	(11.3)	71	(88.8)		
>21	26	(22.8)	88	(77.2)		
Preoperative (number of medications)					0.481	0.127 - 2.78
<2	2	(11.8)	15	(88.2)		
≥2	33	(18.6)	144	(81.4)		
Type of glaucoma					0.074	0.230 - 1.152
Primary	17	(14.2)	103	(85.8)		
Secondary	18	(24.3)	56	(75.7)		
Occurrence of complications					0.175	0.71 - 4.0
Yes	12	(24.5)	37	(75.5)		
No	23	(15.9)	122	(84.1)		
Combined phaco with DS					0.037	0.017 - 0.960
Yes	1	(3.2)	30	(96.8)		
No	34	(20.9)	129	(79.1)		
NPDS converted to PDS					0.037	0.017 - 0.960
Yes	1	(3.2)	30	(96.8)		
No	34	(20.9)	129	(79.1)		
Type of implant					0.240	
Healaflow	7	(14)	43	(86)		
SK-GEL	12	(20.3)	47	(79.7)		NA
T-Flux	14	(25.5)	41	(74.5)		
Viscoplus	0	(0)	2	(100)		
No implant	2	(7.1)	26	(92.9)		
Cup:disc ratio					0.283	0.211 - 1.576
<0.5	7	(13.2)	46	(86.8)		
≥0.5	28	(19.9)	113	(80.1)		
Having previous surgery					0.047	0.750 - 11.720
Yes	5	(38.5)	8	(61.5)		
No	30	(16.6)	151	(83.4)		

IOP - intraocular pressure, Phaco - phacoemulsification, DS - deep sclerectomy, NPDS - non-penetrating deep sclerectomy, PDS - penetrating deep sclerectomy, MMC - mitomycin C.

Table 4 - Results of non-penetrating deep sclerectomy in primary and secondary open angle glaucoma with and without adjuvant.

Authors	Year	Design	No. of eyes	Procedure	Mean F/U (months)	Mean IOP (mm Hg)		Definition of success	Success (%)	
						Pre-op	Post-op		Complete	Overall
Mousa[5]	2007	Prospective	20	DS+SC	12	33.1±6.2	14.6±3.8	<18	50.0	85.0
Bissig et al[7]	2008	Prospective	105	DS+CI	101.5±43.1	26.8±7.7	12.2±4.7	≤21	47.7	89.0
Khairy et al[11]	2006	Prospective	43	DS	28.1±8.2	24.6±5.5	18.5±4.6	<22	18.9	NA
Shaarawy et al[9]	2004	Prospective	105	DS+implant	43.2±14.3	26.8±7.7	12.24±4.6	<21	57.0	91.0
El Sayyad et al[10]	2000	Prospective	39	DS+implant	12	27.9±5.9	15.6±4.2	<21	79.0	92.3
Devloo et al[18]	2005	Retrospective	69	DS	16	23.8±5.82	16.1±5.05	21	41.0	83.0
			24	DS+SC	15	25.6±7.31	15.8±6.21		54.0	75.0
Shaarawy et al[17]	2005	Prospective	13	DS	49±20	24.1±7	16±3	≤21	38.0	69.0
			13	DS+implant	56.5±14	25.3±6	10±4		69.0	100.0
Ravinet et al[14]	2004	Prospective	11	DS+healon GV	24	23.5±8.3	12.2±8.3	≤21	95.4	100.0
			11	DS+implant		28.1±14.4			100.0	100.0
Present study	2012	Retrospective	194	DS+implant	60.9±49.7	25.6±10.3	13.5±4	<21	82.0	90.2

DS - deep sclerectomy, IOP - intraocular pressure, NA - not available, F/U - follow-up, Preop - pre-operative, Post-op - post-operative, CI - collagen implant, SC - scleral, GV - viscoelastic, Chl - chromic suture implant

the conduct of binary logistic regression analysis revealed that age (p=0.02) and preoperative cup/disc ratio (p=0.009) were the persistent risk factors even after adjustment.

Discussion. Non-penetrating glaucoma surgery (NPGS) has been modified in the last 2 decades to improve the safety of filtering procedures by avoiding penetration into the anterior chamber.[9,11] Several routes have been shown to drain aqueous from the decompression space, such as through supra-choroidal space. Other route in non-penetrating deep sclerectomy may include filtration through the trabeculo-descemato-window to subscleral space or sclera leak and through trans-scleral pathway to suprachoroidal space. Delarive et al[12] have shown newly formed scleral aqueous veins around decompression space in animal study.[12] Furthermore, aqueous may enter the SC to be drained by the episcleral venous plexus.[13] In this study, 194 eyes of 152 patients were followed up to a mean of 60.9 (±49.7) months ranging from 6 months and 9 years. The current data set is the largest on the literature. Shaarawy et al and Bissig et al[7] have demonstrated the largest data set to date (105 eyes each). Bissig et al[7] provided the longest average of follow up (101.5 [43.1]), but with relatively low complete success rate (47.7%), while the overall success rate was 89%. Mousa et al[5] reported findings for one year follow up (12-month) with complete success rate of 50%, while the overall success rate was 85%, which is more or less similar to Bissig et al.[7] Moreover, Mousa et al[5] demonstrated the highest reduction in IOP 18.5 mm Hg, while in 2006, Khairy et al[11] demonstrated only 6.1 mm Hg reduction. In this study, the IOP was reduced from preoperative of 25.6 (±10.3) to mean value of 13.5 (±4) at final visit with a 12.1 (47.3%) mm Hg reduction. The definition of IOP threshold for success was homogenous in the majority of reported series at 21 mm Hg. However, some authors have identified either lower IOP (18 mm Hg) threshold such as Mousa[5] or higher IOP threshold (22 mm Hg) such as Khairy et al[11] (**Table** 4). Our complete success rate with the long follow-up duration was considerably high (82%) and the overall success was 90.2%. We did not find any differences in success rate across different implants. In 2004, Ravinet et al[14] demonstrated the highest complete and overall success rates ever (95.4% and 100%) in a follow up mean of 24 months; however, the number of operated eyes was relatively small (22 eyes). On the other hand, Khairy et al[11] have reported the lowest complete success rate ever (18.9%) in a follow up duration of 28.1 (8.2) months. In this study, the preoperative mean IOP was 25.6 (±10.3) mm Hg. In previous studies (**Table** 4), the mean preoperative IOP ranged from 24-33 mm Hg, which was comparable to the current study.

In the current study, the intraocular pressure reduced from preoperative mean value of 25.6 (±10.3) to final mean value of 13.5 (±4) which was statistically significant (p<0.0001). Other studies showed a postoperative IOP ranging from 12-18 mm Hg and therefore our final IOP (13.5) was toward the lower end of the range and this may be attributed to the use of MMC. The average number of anti-glaucoma medication also reduced from preoperative of 2.95 (±0.93; range 1-4) to 0.22 (±0.63; range 1-3) at final visit. The mean Log MAR visual acuity has a slightly but, insignificantly improved from preoperative of 0.45 (±0.51) to 0.41 (±0.46) at final visit; this may be due to the combination of cataract extraction with glaucoma surgeries.

Findings from Saudi Arabia by El Sayyad et al[10] show similar reduction in IOP (12.3) mm Hg and number of anti-glaucoma medications (2.1) which are more or less similar to our findings. Likewise, both complete (82%) and overall (90.2%) success rates in our study were in line with Al Sayyad study (79% and 92.3%) as well as the rate of complications. Another study by Hassan et al[15] investigated 30 consecutive eyes of 22 patients with uncontrolled pseudo exfoliation glaucoma (PEXG) and cataract. Phacoviscocanalostomy achieved a complete surgical success (IOP <21 mm Hg without anti-glaucoma medications) of 90%, while an overall success (IOP <21 mm Hg with or without glaucoma medication) was achieved in 100% of cases.[15] Several studies have showed that the use of anti-metabolites improves success rates. Kozobolis et al[16] compared NPDS to PDS (augmented by MMC) has been associated with a lower IOP reduction and improved success rate. It was reported that the use of implants improves the long-term surgical success rate for long term results. In this study, the success rate was similar in cases with and without implant, and also similar regardless the type of implant used. Shaarawy et al[17] comparing DS in one eye and DS with collagen implant in the other eye, their complete success at 48 months was 38.5% of DS eyes and 69.2% of eyes after DS with collagen implant. Neodymium:Yttrium-Aluminum-Garnet LGP was performed when the target IOP for each patient was not achieved because of insufficient filtration through the TDM. In this study, LGP was performed in 24.4% of eyes that had NPDS. Mean IOP prior to Nd:YAG LGP was 23.3 (±5.9) mm Hg and decreased to 14.6

(±4.4) mm Hg at the last follow-up after the procedure. The mean interval between surgery and LGP was 9.78 (± 11.16) months and the mean follow up after LGP was 16.7 (±16) months with success rate of 53.2% (25 eyes). Previous studies indicated that success rate of goniopuncture ranged from 45-80%.[5,14,18,19] Moreno-Montanes et al[20] showed that LGP rate increased from 17.6% during the first year to 69.6% with follow up longer than 2 years.

In this study, the complete success rate was 159/194 (82%), while overall success rate was 175/194 (90.2%), such rates were more or less in the same line compared to most reported series in the literature as demonstrated in details in **Table 4**. Most cases went successfully without any pre or postoperative complications (145 eyes; 74.7%). Complications were recognized in 49 eyes (25.3%). Macro and microperforation in 23 eyes (11.8%), hyphema in 12 eyes, bleb leak in 6 eyes, transient hypotony in 5 eyes, iris incarcerated to trabeculo-Descemet's window in 5 eyes, 4 eyes developed decompression retinopathy, 2 eyes with choroidal detachment, hypotony maculopathy in 2 eyes, one case had SK-Gel migration to sub-conjunctival space,[21] one case of small scleral flap tear, and one case of total descemet membrane detachment (DMD) where UBM was highly effective in documenting such total DMD.[22] None of the cases developed bleb related infection. Some of the eyes had single while some other eyes had multiple complications. Complications are demonstrated in details in **Table 2**. Risk factors for failure were analyzed using univariate analysis and logistic regression revealed that age <50 years (p=0.003), high preoperative IOP (p=0.039), and having previous surgeries (p=0.047) were significant risk factors for failure as shown in **Table 3**. Moreover, the conduct of binary logistic regression analysis revealed that age (p=0.02) and pre-operative cup/disc ratio (p=0.009) were the persistent risk factors even after adjustment. Although it was anticipated that the reduction in IOP among the combined cataract group would exceed the non-combined group. The reduction was significantly higher among the glaucoma group. This may be due to 2 plausible reasons; one is that the non-combined group is almost 5 folds greater than the combined group, and this may have widened the IOP range at this group; hence, it affects the mean reduction. The other reason is that the combined group had lesser mean IOP at baseline, which has definitely reduced the marginal reduction in the postoperative assessment.

One of the limitations of this study is being a retrospective study with the inherently known limitations of such type of study design. Although, the use of implant has shown significantly better long-term success rate in literature, the current study did not support this finding, a prospective clinical trial in the Saudi population is required to investigate this issue.

In conclusion, deep sclerectomy provides significant IOP reduction with low rate of visual threatening complications in Saudi patients with uncontrolled OAG. Although penetrating deep sclerectomy show better success rate, it may lead to a higher rate of potential complications.

Acknowledgment. *We would like to gratefully acknowledge the full support of the Glaucoma Research Chair, King Saud University, which facilitated the fulfillment of the current study in its final shape. The authors would also like to express deep thanks and appreciation to Ms. Priscilla W. Gikandi, Research Assistant, Research Unit, Department of Ophthalmology, King Saud University for her outstanding efforts in data management, reviewing, editing, and finalization of the manuscript.*

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