

Comparison of deep sclerokeratodissection, a new variant of nonpenetrating glaucoma surgery, with deep sclerectomy

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Purpose: The aim of this study was to evaluate the safety and efficacy of deep sclerokeratodissection (DSKD), a new nonpenetrating technique in glaucoma surgery. **Materials and Methods:** Retrospective comparison between patients treated with DSKS or deep sclerectomy (DS) between 2013 and 2014. In DSKD, the first and only flap is dissected directly into clear cornea with unroofing Schlemm's canal. Beside routine clinical follow-up (visual acuity, intraocular pressure [IOP] readings, slit lamp and fundus examination), postoperative ultrasound biomicroscopy (UBM) investigation and quality of life (QoL) assessment were performed. Statistically significant differences were determined by parametric or nonparametric tests, depending on normality. **Results:** Twelve (38.7%) DSKDs and 19 (61.3%) conventional DS' were included in this analysis. IOP decreased significantly from 21.5 ± 9.2 mmHg to 6.2 ± 5.4 mmHg on day 1, 13.4 ± 7.7 at 1 month, 12.0 ± 4.1 at 3 months, 12.5 ± 3.1 mmHg at 6 months, and 13.4 ± 4.3 mmHg at 12 months ($P < 0.01$). No significant difference in the IOP was observed between the two groups at any follow-up ($P > 0.1$). There was no significant difference in intra- and post-operative complications, the morphology of the surgical site in the UBM as well as in the QoL assessment. **Conclusion:** The results indicate that DSKD is a safe and efficient new variant of nonpenetrating glaucoma surgery. IOP can be lowered as effectively compared to conventional DS, with a similarly low rate of complications. Further reports are necessary to confirm these results.

Key words: Deep sclerectomy, deep sclerokeratodissection, glaucoma, nonpenetrating glaucoma surgery, safety

Glaucoma surgeries can be divided into penetrating and nonpenetrating surgeries, including the deep sclerectomy (DS). The principle of DS is based on unroofing the Schlemm's canal and juxtacanalicular trabecular meshwork, presenting the structures responsible for most of the outflow resistance. A trabeculo-Descemet's membrane (TDM) is left intact to control the amount of flow. Thereby, DS avoids full-thickness penetration, leading to a more controlled pressure reduction compared to penetrating procedures.^[1-3] The purpose of this study was to introduce and evaluate the deep sclerokeratodissection (DSKD) as a novel modification of DS.

Materials and Methods

Between June 2013 and July 2014, 44 eyes of 36 patients underwent either DS or DSKD. Twenty-seven patients (31 eyes) gave their consent to participate. All patients were white Caucasians. Male to female ratio was 7:24. The mean age of the included patients was 70.9 ± 12.6 years. In all, 15 eyes (48.4%) had primary open-angle glaucoma, 7 had pseudoexfoliation glaucoma (22.6%), 4 had normal-tension glaucoma (12.9%), 2 had pigment dispersion glaucoma (6.5%), 1 had juvenile

glaucoma, 1 had uveitic glaucoma, and 1 had a narrow chamber angle (each 3.2%). Mean time between surgery and the last follow-up examination was 550.2 ± 119.0 days (range between 370 and 730 days). An ultrasound biomicroscopy (UBM) examination of the treated eye was performed and patients were asked to fill in a quality of life (QoL) questionnaire at last follow-up. The study protocol was reviewed and approved by the local ethics committee and all included patients gave written informed consent. All conducted research and measurements followed the tenants of the Declaration of Helsinki.

DSKD has been developed by one of the authors. Surgeries were performed under general anesthesia by one of three experienced surgeons. The conjunctiva was opened fornix-based to expose the sclera. At this stage, mitomycin C (0.02 mg/ml) was applied through impregnated sponges to the scleral bed for 2–3 min, followed by intense irrigation. When doing the conventional DS, a superficial 5 mm × 5 mm scleral flap of two-third sclera-thickness was cut and extended approximately 1–1.5 mm into clear cornea. Subsequently, a second scleral flap of 4 mm × 4 mm was resected, allowing

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the deroofing of the Schlemm's canal with formation of the TDM. Once this dissection was completed, the deep flap was excised [Fig. 1a].

When performing the DSKD, only one scleral flap is dissected, deep enough to allow an uveoscleral outflow and to directly unroof Schlemm's canal [Figs. 1b and 2]. No excision of scleral tissue is necessary in this procedure. After incision of the Schlemm's canal, aqueous humor can be observed percolating through the trabeculum. The canal's inner wall and the juxtacanalicular trabecular meshwork are grabbed and peeled off. The superficial scleral flap was closed with two 10.0 nylon single button sutures. Finally, the conjunctiva was closed using 8.0 vicryl sutures.

Follow-up was performed 1 day, 1 month, 3 months, 6 months, 1 year after surgery and when the UBM investigation was performed. The main outcome parameters were intra- and post-operative complications and the intraocular pressure (IOP) at the defined visits with comparison between DSKD and DS. Postoperative hypotension was defined as an IOP <5 mmHg. Additional outcome parameters were the number of antiglaucomatous drops (AGDs), achieved visual acuity, evaluation of the surgical site by UBM investigation, and patients' satisfaction evaluated by means of a QoL questionnaire.

UBM can be used to examine anterior chamber, ciliary body, and filtering blebs.^[4,5] We used the Aviso® system (Quantel, France), producing high-frequency (50 MHz) ultrasonic scan images. Scans and assessments were performed by an experienced investigator, using the technique developed by Pavlin *et al.*^[4] The investigator was masked to the IOP and the surgical procedure. Biometric measurements of the surgical site were performed using the electronic calipers of the onboard software. Parameters evaluated were (1) presence, (2) maximum length, and (3) height of the intrascleral lake; (4) minimum thickness of the TDM; (5) presence of a suprachoroidal hyporeflexive space as a sign for additional drainage; (6) presence and (7) type of the subconjunctival filtering bleb. The type of the bleb was described according to the model of Yamamoto *et al.* who defined four types.^[6] L-type stands for

low reflective blebs, in contrary to the H-type (high reflective). E-type characterizes an encapsulated bleb and F-type a flattened bleb. In one patient (one eye), the UBM examination was not feasible due to the anatomical configuration of the orbit.

We used a slightly modified version of a questionnaire that was recently presented by Klink *et al.* to assess the influence of surgery on QoL [Supplementary File 1].^[7]

Yttrium-aluminum garnet laser goniopuncture (YAG-GP) can be used to augment filtration after nonpenetrating glaucoma surgery by rupture of the TDM. It is a common procedure after DS.^[8] In this study, effectiveness of YAG-GP following DS or DSKD was compared by its pressure-lowering effect. GP was executed with a neodymium-doped: YAG laser (VISULAS; Carl Zeiss Meditec GmbH; Jena, Germany).

Statistical analysis was performed with SPSS software version 23.0 (PASW/SPSS IBM Corporation, New York, NY, USA). Descriptive values are given in mean \pm standard deviation (SD). Figures with depiction of statistical results were created with SPSS. Data were tested for normal distribution by means of the Kolmogorov-Smirnov test and qualitatively checked with a Q-Q plot. Comparison of means was analyzed using Mann-Whitney U-test for nonparametric data (IOP, number of AGDs, height of intrascleral lake, and TDM thickness UBM and metric QoL data). Student's *t*-test was used for comparison of metric data (length and area of the intrascleral lake in the UBM, pressure reduction achieved by YAG-GP, and operation time). Repeated measures ANOVA with Bonferroni correction were used for comparison of more than two groups of parametric data (visual acuity). Analysis of frequencies of nominal scaled parameters (intra- and post-operative complications, use of YAG-GP and nominal UBM and QoL parameters) was performed by means of Chi-square test. For statistical significance, we defined a level of $P \leq 0.05$.

Results

Thirty-one eyes of 27 patients were included in this series. Twelve procedures were performed as DSKD (39%), 19 surgeries (61%) were performed as conventional DS. Two eyes had to undergo additional surgery after DSKD during follow-up. The first eye was subjected to cyclophotocoagulation

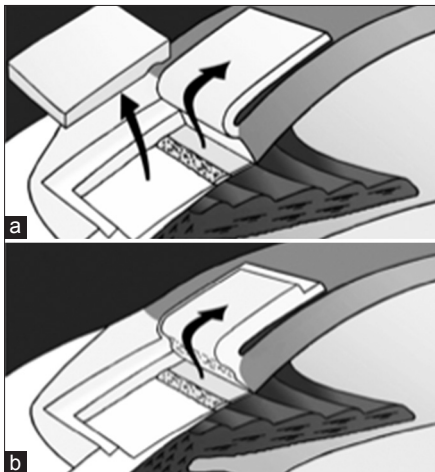


Figure 1: (a) Procedure of deep sclerectomy with excision of the deep scleral flap. (b) Depiction of deep sclerokeratodissection with direct unroofing of the Schlemm's canal

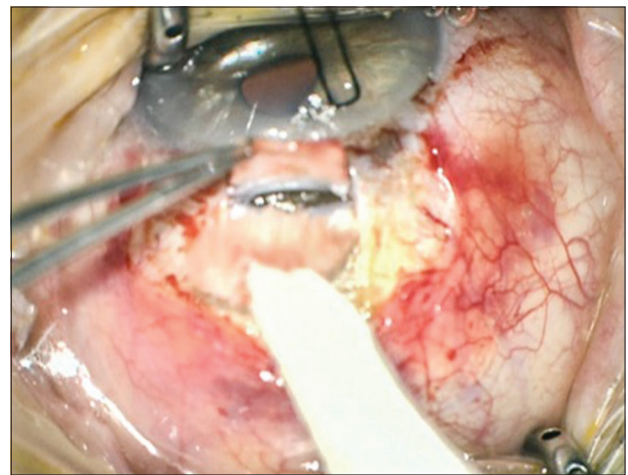


Figure 2: Picture of deep sclerokeratodissection with direct unroofing of the Schlemm's canal

because of insufficient IOP reduction, the second eye had to undergo trabeculectomy because of an iris capture. There was no significant difference in the occurrence of intraoperative complications [Table 1].

IOP decreased significantly from 21.5±9.2 mmHg to 6.2±5.4 on day 1, 13.4±7.7 at 1 month, 12.0±4.1 at 3 months (*P* < 0.01), 12.5±3.1 mmHg at 6 months, 13.4±4.3 mmHg at 12 months, and 14.4±4.5 at the last follow-up (*P* < 0.01).

No significant difference in IOP was observed between DSKD and DS at any follow-up [Fig. 3].

The number of AGDs did not vary significantly between DSKD and DS [Table 2]. Seven eyes (one in DSKD group, six in DS group) were pretreated additionally with oral acetazolamide, 250 mg. AGDs were reduced significantly in both groups after surgery (*P* < 0.01). Mean time between surgery and represcription of pressure lowering eye drops was 13.1 ± 5.5 months in DSKD group and 15.5 ± 6.8 months after DS (*P* = 0.38).

Visual acuity collected as decimal fractions by Early Treatment Diabetic Retinopathy Study charts was 0.57 ± 0.3 in the DSKD group and 0.49 ± 0.4 in the DS group before surgery. In both groups, no statistically significant reduction in visual acuity after surgery was seen at any time (*P* > 0.1).

Operation time was shorter when doing DSKD (61.7±18.0 min vs. 77.1 ± 25.2 min), but the difference did not reach statistical significance (*P* = 0.056).

Concerning the UBM data, no statistical significant differences were found between DSKD and DS [Table 3].

According to the QoL questionnaire, no significant differences were found between DSKD and DS [Table 4].

In the DSKD group, YAG-GP was performed in five eyes (42%), and in the DS group in 13 eyes (68%). In both groups, the pressure reduction achieved by GP was rated statistically significant. In the DSKD group, IOP was reduced from 21.6 ± to 15.8 (*P* = 0.04); in the DS group, from 19.1 ± 3.5 to

12.9 mmHg (*P* = 0.01). No significant difference in IOP reduction achieved by YAG-GP was shown between the groups (*P* = 0.5).

Discussion

DS is generally thought to be the safer procedure, compared to penetrating glaucoma surgery as it precludes the sudden hypotension that occurs by creating full-thickness penetration into the anterior chamber.^[9] In this preliminary study, we present a new approach for nonpenetrating glaucoma surgery, DSKD, which allows for performing a DS without the need for scleral tissue removal and at the same time achieving the same level of pressure reduction as with conventional DS. Therefore, we believe that the DSKD is especially suitable

Table 1: Occurrence of intra- and post-operative complications after deep sclerokeratodissection and deep sclerectomy

| | Time after surgery | DSKD (eyes; %) | DS (eyes; %) | <i>P</i> |
|--------------------|--------------------|----------------|--------------|----------|
| Microperforation | Intraoperative | - | 2; 10.5 | 0.2 |
| Iris capture | Intraoperative | 1; 8.3 | - | 0.2 |
| Hypotension | 1 day | 4; 33.3 | 9; 47.4 | 0.4 |
| | 1 month | 1; 8.33 | 2; 10.5 | 0.8 |
| Choroidal effusion | 1 day | 4; 33.3 | 3; 15.8 | 0.3 |
| | 1 month | 3; 25 | - | 0.1 |

No statistically significant differences were observed between the groups (*P* > 0.1). DSKD: Deep sclerokeratodissection, DS: Deep sclerectomy

Table 2: Number of antiglaucomatous drugs before surgery (baseline) and at follow-up in both groups

| | DSKD | DS | <i>P</i> |
|-------------------------|----------|----------|----------|
| BL | 3.25±1.3 | 3.05±1.2 | 0.58 |
| 1 month after surgery | 0.83±1.6 | 0.26±0.8 | 0.48 |
| 3 months after surgery | 0.64±1.4 | 0.32±0.7 | 0.83 |
| 6 months after surgery | 0.3±0.9 | 0.58±1.1 | 0.54 |
| 12 months after surgery | 0.5±1.0 | 0.58±1.0 | 0.91 |
| LF | 0.8±1.2 | 1.0±1.4 | 0.95 |

Differences between the groups were tested for significance. BL: Baseline, LF: Last follow-up, DSKD: Deep sclerokeratodissection, DS: Deep sclerectomy

Table 3: Comparison of ultrasound biomicroscopy findings between deep sclerokeratodissection and deep sclerectomy

| | DSKD | DS |
|---|-----------|-----------|
| Intrascleral lake visible (eyes; %) | 8; 66.7 | 17; 89.5 |
| Length of intrascleral lake (mean±SD) | 4.5±0.21 | 2.83±1.46 |
| Height of intrascleral lake (mean±SD) | 0.34±0.21 | 0.7±1.08 |
| Area of intrascleral lake (mean±SD) | 1.26±0.93 | 1.23±0.89 |
| Suprachoroidal, hyporeflexive space visible (eyes; %) | 2; 16.7 | 3; 15.8 |
| TDM thickness (mean±SD) | 0.18±0.06 | 0.21±0.09 |
| Subconjunctival bleb visible (eyes; %) | 8; 66.7 | 17; 89.5 |

No statistically significant differences were observed (*P* > 0.1). TDM: Trabeculo-Descemet's membrane, DS: Deep sclerectomy, SD: Standard deviation, DSKD: Deep sclerokeratodissection

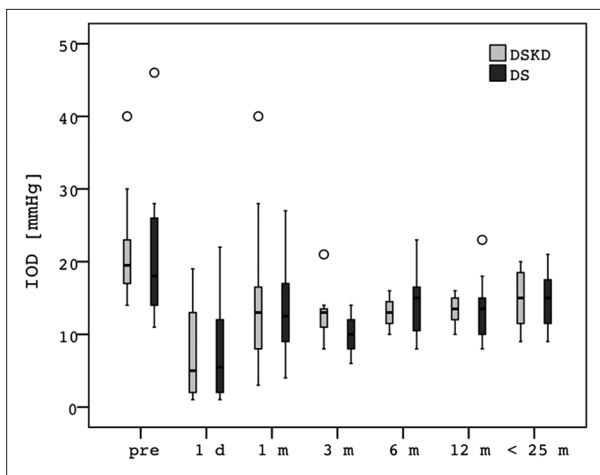


Figure 3: Box-whiskers-plot of the intraocular pressure before surgery (pre) and at every follow-up of deep sclerokeratodissection and deep sclerectomy. Intraocular pressure was significantly reduced until the last follow-up. No significant differences were shown between the groups (*P* > 0.1)

Table 4: Comparison of the scaled variables (mean±standard deviation) of the quality of life questionnaire

| Question number | Category | DSKD | DS |
|-----------------|--|-----------|-----------|
| 1 | Change in VA | 3.0±1.86 | 3.47±1.39 |
| 2a | Reading newspapers | 3.83±1.34 | 3.26±1.45 |
| 2b | Watching television | 3.67±1.37 | 3.67±1.57 |
| 2c | Seeing at night | 3.83±1.03 | 3.11±1.73 |
| 2d | Driving | 1.27±1.74 | 1.63±1.92 |
| 3 | Glare | 4.0±1.41 | 3.63±1.38 |
| 4 | Pain | 4.08±1.38 | 3.79±0.92 |
| 5 | Foreign body sensations | 4.17±1.19 | 4.26±0.73 |
| 6 | Tearing | 4.0±1.28 | 4.05±1.08 |
| 7 | Redness | 3.5±1.45 | 3.74±0.65 |
| 8 | Dry eye | 4.0±1.35 | 3.63±1.07 |
| 9 | Fulfillment of expectations not to use eye drops anymore | 3.42±1.78 | 3.68±1.45 |
| 11 | Stress caused by surgery | 3.82±1.17 | 4.37±0.68 |
| 12 | Stress caused by follow-ups | 4.0±1.26 | 4.47±0.77 |
| 13 | Restriction of social contacts | 4.42±1.08 | 4.26±0.87 |
| 14 | Loss of independence | 4.42±1.08 | 4.58±0.61 |
| 16 | Satisfaction with results of surgery | 7.5±3.15 | 8.53±2.41 |

For exact meaning of the values, see the questionnaire (supplemental). No statistically significant differences between DSKD and DS were observed ($P>0.1$). DS: Deep sclerectomy, DSKD: Deep sclerokeratodissection, VA: Visual acuity

for nonpenetrating glaucoma surgery in cases where the preparation of two flaps is difficult such as in revision surgeries or eyes with thin sclera. As resection of the deep scleral flap increases, the risk of scleral rupture in trauma eyes could be less susceptible to injuries after blunt trauma, after DSKD compared to eyes treated with DS.^[10]

Both DS and DSKD were proven safe procedures with only minor complications. The number of intra- and post-operative complications was comparable between the procedures. We observed no differences between DSKD and DS with respect to IOP reduction. The average effectiveness results of both groups were comparable to findings of other studies published.^[5,11]

Within all UBM parameters, there were no significant differences between DSKD and DS. This result shows that also the ultrastructural outcome following DSKD was comparable with DS'. No difference was shown in the thickness of the TDM, implicating that its preparation was as successful after DSKD as after DS.

To evaluate patients' satisfaction after surgery, we used a questionnaire that was recently introduced by Klink *et al.* to analyze other glaucoma surgeries.^[7] Since DSKD/DS and canaloplasty both belong to the subgroup of nonpenetrating glaucoma surgeries and all of the questions are generally asked unspecific, we deemed it reasonable to use the questionnaire in the present study. We could not find any statistically significant difference in the patient's answers. It is to assume that DSKD does not influence patients QoL more than the conventional DS does.

There was no difference in the pressure reduction achieved by YAG-GP between the two groups; thus, we conclude that GP is an effective treatment for decreasing IOP levels in the postoperative period not only after DS but also after DSKD.

Although results are encouraging, the limited number of patients treated in this study, and the retrospective design of

the analysis may impede detection of minor variances. Thus, larger studies with longer observation periods will be necessary to confirm that DS and DSKD are equivalent procedures. Nonpenetrating glaucoma surgeries are generally reserved for open-angle glaucoma.^[12] Subgroup analysis on DSKD efficacy in different glaucoma types was not reasonable in our study because of the small population thus further analysis are needed.

Conclusion

DSKD is a safe and effective new surgical version of conventional DS, a nonpenetrating glaucoma surgery. IOP can be lowered sufficiently with only little risk for intra- or post-operative complications. There is no difference in the formation of an intrascleral lake or subconjunctival bleb when investigated by UBM. YAG-GP can sufficiently lower IOP after DSKD as well as after DS. Patient's satisfaction did not vary between DSKD and DS. Operation time is reduced in DSKD and no scleral tissue has to be removed; thus, it can be considered a less invasive method.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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