

# NON PENETRATING DEEP SCLERECTOMY (NPDS) WITH SKGEL<sup>®</sup> IMPLANT AND/OR 5-FLUOROURACILE (5-FU)

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## ABSTRACT:

**Purpose:** to assess effectiveness and safety of DS with reticulated hyaluronic acid implant (SKGEL<sup>®</sup>) and/or 5-Fluorouracile (5-FU)

**Material-Methods:** 61 eyes (48 patients) (mean age: 64,5 ± 10,5 years) with medically uncontrolled open angle glaucoma and comparable surgical risk failure were included in this retrospective non randomized study and were categorized into DS+SKGEL<sup>®</sup> (10 eyes), DS +5-FU (25 eyes) and DS+SKGEL<sup>®</sup> +5-FU simultaneously (26 eyes). The 3 groups were comparable in respect of age of patients, diagnosis, severity of VF defects, and bleb failure risk factors. All procedures were performed according to the Kozlov's and Mermoud's technique. Complete ocular examination was carried out preoperatively and at day 1, 7, at 1,2 and 3 months and every three months thereafter.

**Results:** Mean follow up was 11 ± 4,9 months and was significantly shorter in group C. For all 61 eyes, mean IOP was significantly decreased from 27,8 ± 8,6 mm Hg to 15,1 ± 3,5 mm Hg. Complete (target IOP reached without medication or YAG laser goniopuncture) and qualified (target IOP reached with medication and/or YAG laser goniopuncture) final success rates were respectively of 54% and 90%. Complete success probability was 95% at 6 months and 72% at 12 months. Qualified success probability increased to 89,5% at 12 months.

The IOP results, the distribution of success rates and complications were similar within the first postoperative year whatever using SKGEL<sup>®</sup> or intra-oper-

ative 5-FU application or both. The need for additional glaucoma medication and the percentage of YAG goniopuncture appeared to be lower in the SKGEL group. Success probability appeared to be improved in SKGEL<sup>®</sup> group comparatively with the other 2 groups.

**Conclusions:** NPDS is a valid, effective and relatively safe alternative to trabeculectomy although adjunctive medications and/or Nd:YAG goniopuncture are frequently needed.

Considering the limitations of our study, we can conclude that the IOP results, success rates and complications are similar within the 1<sup>st</sup> postoperative year whatever using peroperative 5-FU or SKGEL<sup>®</sup> implant. A longer follow up is needed to confirm that SKGEL<sup>®</sup> implant seems to improve the IOP control and the long term patency of the sclerectomy site by comparison with intra-operative application of 5-FU.

## RÉSUMÉ:

**Objectifs:** le but de notre étude est d'apprécier l'efficacité et l'inocuité de la sclérectomie profonde non perforante (SPNP) associée à la mise en place d'un implant d'acide hyaluronique réticulé (SKGEL<sup>®</sup>) et/ou l'application peropératoire de 5-Fluorouracile (5-FU).

**Matériel-Méthodes:** 61 yeux (48 patients) (âge moyen: 64,5 ± 10,5 ans) porteurs d'un glaucome à angle ouvert et présentant un risque chirurgical comparable ont été inclus dans cette étude rétrospective non randomisée. Notre série se compose de 3 groupes: groupe A avec implantation d'un SKGEL<sup>®</sup> (10 yeux), groupe B avec application de 5-FU uniquement (n= 25 yeux) et groupe C combinant la mise en place d'un SKGEL<sup>®</sup> et une application peropératoire de 5-FU (26 yeux). La technique chirurgicale employée a été celle de Kozlov et de Mermoud. Nous avons procédé à un examen pré-

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pératoire complet et avons revu les patients dans le décours opératoire à 1 jour, 1 semaine, 1,2 et 3 mois puis trimestriellement.

**Résultats:** le recul moyen actuel est de  $11 \pm 4,9$  mois et se révèle significativement plus court dans le groupe C. Tous les yeux regroupés, la PIO moyenne est réduite significativement d'une valeur moyenne préopératoire de  $27,8 \pm 8,6$  mm Hg à une valeur de  $15,1 \pm 3,5$  mm Hg. Les taux de succès complet (PIO cible atteinte sans traitement médical d'appoint et sans gonopuncture au laser YAG) et relatif (PIO cible atteinte avec traitement médical d'appoint et/ou gonopuncture) sont respectivement de 54% et de 90% au dernier contrôle. La probabilité de succès complet est de 95% et de 72% à 6 et 12 mois. La probabilité de succès relatif passe à 89,5% à 1 an.

Les résultats tensionnels, la distribution des taux de succès et des complications se révèlent comparables dans les 3 groupes durant la 1<sup>ère</sup> année postopératoire. La fréquence des traitements médicaux d'appoint et des gonopunctures au laser YAG est moindre dans le groupe SKGEL<sup>®</sup>. La probabilité de succès apparaît meilleure dans le groupe SKGEL<sup>®</sup> que dans les deux autres groupes

**Conclusions:** la SPNP nous apparaît comme une alternative efficace et relativement sûre à la trabéculotomie. Un traitement médical d'appoint et/ou des gonopunctures au laser YAG sont fréquemment nécessaires. Compte tenu des limites de notre étude, nous pouvons conclure que les résultats tensionnels, les taux de succès et les complications postopératoires sont comparables dans la 1<sup>ère</sup> année postopératoire qu'on ait eu recours à une application per-opératoire de 5-FU ou à la mise en place d'un implant de type SKGEL<sup>®</sup>. Un recul plus long est nécessaire pour confirmer que le SKGEL semble améliorer le contrôle de la PIO à plus long terme par rapport au 5-FU seul

#### KEY-WORDS:

non penetrating deep sclerectomy- SKGEL<sup>®</sup> implant- open angle glaucomas

#### MOTS-CLÉS:

sclérectomie profonde non perforante - implant SKGEL<sup>®</sup> - glaucomes à angle ouvert

By decreasing the incidence of postoperative complications compared with standard trabeculectomy, non penetrating deep sclerectomy (DS) has been meeting with increasing interest during the past few years for the surgical management of medically uncontrolled open angle glaucoma. Because the inhibition of the healing process and the maintenance of the patency of the intra-scleral space is a major concern, intraoperative application of antimetabolites or placement of a collagen or a cross-linked sodium hyaluronate implant (SKGEL<sup>®</sup>) in the centre of the deep sclerectomy dissection had been most often proposed in order to enhance the passage of aqueous from the anterior chamber to the subconjunctival space and to lower the risk of scleral fibrosis. (2, 3, 6, 7, 10, 15, 16, 19, 20, 22, 23) However the exact benefits of these different adjuvant procedures still remain controversial. (3, 4, 5, 7, 9, 10, 12, 13, 14, 16, 18, 20)

The purpose of this present study was to analyze the midterm effectiveness and safety of DS with reticulated hyaluronic acid implant (SKGEL<sup>®</sup>) or adjuvant intra-operative application of 5 Fluoro-uracile (5-FU) or combined SKGEL<sup>®</sup> and 5-FU simultaneously.

## PATIENTS AND METHODS

### Patients

Our first sixty one consecutive eyes of 48 Caucasian patients (22 male, 26 female with a mean age of  $64,5 \pm 10,5$  years) with medically uncontrolled open angle glaucoma and comparable surgical risk factors were included in this retrospective non randomized study in which DS was associated with SKGEL<sup>®</sup> implant and/or intraoperative 5-FU application.

DS procedures were categorized into 3 groups: **Group A** with placement of a SKGEL<sup>®</sup> implant included **10 eyes**.

**Group B** with intra-operative application of 5-FU included **25 eyes**

**Group C** with combination of SKGEL<sup>®</sup> and 5-FU included **26 eyes**.

Except for the preoperative IOP which was significantly lower in the group C ( $p < 0,05$ ), the

different groups were quite well matched whether regarding to the age of patients, the type of glaucoma, the history of previous cataract, filtering or laser surgery, the mean number of glaucoma medications, the duration of medical treatment, the severity of glaucomatous damage or the distribution of the target IOP's (chi-square  $p > 0,05$ ).

In the 61 eyes, previous laser or cataract surgery was performed within more than the 3 months preceding the deep sclerectomy. The 6 pseudophakic eyes were implanted in posterior chamber.

Table 1 summarizes the different preoperative characteristics for the 61 eyes and for the different groups with the p-value relative to the frequency of the distribution of the preoperative characteristics between the 3 groups.

The mean **follow-up time was  $11 \pm 4,9$  months** (range: 2 to 23 months) and was respectively of  $11,3 \pm 6,0$  months in group A,  $12,9 \pm 5,0$  months in group B and  $9,0 \pm 3,5$  months in group C ( $p$ -value  $< 0,05$ ).

## Surgical procedure

All procedures were performed according to the Kozlov's and Mermoud's technique.

In all cases, a 9-0 superior peripheral corneal traction vicryl was used. A limbus-based conjunctival flap was dissected superiorly and the sclera was exposed. A one third scleral thickness limbus based scleral flap measuring  $5 \times 5$  mm was dissected anteriorly into clear cornea for about 1,5 mm. A second triangular deep scleral flap was then dissected leaving only a

Table 1: *Demographics*

	Total (n=61)	A NPDS+ SKGEL® (n=10)	B NPDS + 5-FU (n=25)	C NPDS + 5-FU + SKGEL® (n=26)	p-value
Mean Age (mean years SD)	64,5 (10,5)	65,5 (5,4)	66,4 (9,8)	62,4 (12,1)	$> 0,05$
Diagnosis					
POAG	51	6	21	23	$> 0,05$
Pigm.	6	2	3	1	
PExG	1	0	1	1	
other secondary	3	2	0	1	
Pseudophakic	6	0	3	3	$> 0,05$
VF defect (HFA)					
mild ( $MD \leq -6$ dB) moderate	16	3	8	5	
( $MD > -6$ & $\leq -12$ dB) severe	19	3	6	10	$> 0,05$
( $MD > -12$ dB)	26	4	11	11	
Target UIO (mm Hg)		max 16 max 21 7 3	max 16 max 21 18 7	max 16 max 21 21 5	$> 0,05$
Mean preop VA (SD)	0,68 (0,31)	0,73 (0,32)	0,55 (0,35)	0,77 (0,23)	$< 0,05$
Preop meds (SD)	2,1 (0,81)	1,7 (0,7)	2,2 (0,8)	2,2 (0,8)	$> 0,05$
Duration meds months (SD)	70,5 (59)	58 (61)	82 (65)	64 (52)	$> 0,05$
Previous laser	24	10	6	8	$> 0,05$
Previous glaucoma surgery	14	0	7	7	$< 0,05$
Mean Preop IOP mmHg (SD)	27,8 (8,6)	29,7 (5,7)	31,4 (11,4)	23,5 (2,8)	$< 0,05$
Follow-up (months) (SD)	11,0 (4,9)	11,3 (6,0)	12,9 (5,0)	9,0 (3,5)	$< 0,05$

very thin layer of deep sclera over the choroid. Anteriorly, the dissection was carried down to unroof and remove Schlemm's canal and juxtacanalicular trabeculum. More anteriorly, the excision of corneal stroma was carried down to Descemet's membrane. At this stage of the procedure, aqueous humor was seen to percolate through the thin remaining trabeculo-Desce-metic membrane.

After excision of the deep triangular scleral flap, a triangular 3,5×3,5 mm SKGEL® implant (CORNEAL®, Paris, France) was placed in the center of the deep sclerectomy dissection site. The rectangular superficial scleral flap was then repositioned over the SKGEL® implant and closed with 10-0 monofilament nylon sutures with buried knots. The conjunctiva and Tenon capsule were carefully closed with a running 10-0 Biosorb suture.

When needed, a sponge soaked with 5-FU (50 mg/ml) was applied beneath the superficial scleral flap during 3 minutes.

Postoperative management included topical treatment with dexamethasone 0,1%, geomy-cine three times daily for 3 to 4 weeks and then with topical diclofenac sodium three times a day during the next following month.

If the filtering bleb showed signs of failure, sub-conjunctival injections of 5 mg of 5-FU were given into the inferior fornix or in the vicinity to the bleb. These injections were repeated up to 7-8 times. Argon laser suture lysis was also performed when needed in order to improve the filtration.

Goniotomy with Nd:YAG laser was performed at the site of surgery through the trabeculo-Desce-metic membrane when failure with raised IOP was documented.

### Pre- and postoperative monitoring

Full preoperative baseline data were collected for each patient and included age, sex, ocular history, best corrected visual acuity assesment, anterior biomicroscopy, gonioscopy, aplanation tonometry, automated perimetry using the Central 30-2 threshold Sita Standard program of the Humphrey Field Analyzer or Goldmann kinetic perimetry in advanced visual field defects, fundus examination.

After surgery and except for visual fields which were repeated every 6 months, the same examinations were performed at day 1, 7, at 1, 2, 3, 4, 5, 6 months, every 3 months thereafter until the final examination.

### Success criteria

Complete success was defined as a clinical target IOP reached without antiglaucoma medication(s) or Nd: YAG goniotomy for each patient at the last examination; qualified success was defined as a target IOP reached with medication and/or Nd:YAG goniotomy. Failure was considered when target IOP was not reached with medication or laser goniotomy or when a further glaucoma surgery was required.

The need for post-operative 5-FU sub-conjunctival injections or laser suture lysis was not considered in the final success.

The calculation of target IOP was performed using H. Jampel's formula (11):

Target IOP = maximum IOP - maximum IOP % - Z

(Z = optic nerve damage severity factor).

When "maximum" IOP (which is the value of IOP at which glaucomatous damage presumably occurred) was unknown, the calculation was based on the severity of optic nerve damage and the associated risk factors for glaucomatous neuropathy.

### Statistical analysis

Student's and Anova tests for comparison of means, chi-square analysis for 2×2 tables, Kaplan-Meier survival curves for medium term success rate analysis and Log-Rank test for comparison between groups were used.

A p-value < 0,05 was considered significant.

## RESULTS

### IOP results and success rates (Table 2)

From a mean preoperative value of 27,8±8,6 mm Hg, the IOP was significantly reduced by 46 % (15,0±3,8 mm Hg) at 3 months, by 42,8% at 6 months (15,9±6,6 mm Hg) and by 41,7% at 12 months (16,2±5,5 mm Hg) (p < 0,05).

Table 2: Final results: IOP results and success rate

	Total n=61	SKGEL® A (n=10)	5-GU B (n=25)	SKGEL® + 5-FU C (n=26)	p-value
Mean final IOP (mm Hg) (SD)	15,1 (3,5)	14,3 (2,2)	15,8 (4,8)	14,8 (2,3)	> 0,05
Mean decr. IOP (mmHg) (SD) (%)	12,7±9,1 45,7%	15,4±16,9 52,5%	15,6±12,2 49,7%	8,8±3,2 37,4%	< 0,05
Complete success	33	8	11	14	> 0,05
Qualified success	55	10	20	25	
Add. Meds	21	2	9	10	
Mean nb meds (SD)	0,46 (0,77)	0,2 (0,63)	0,56 (0,91)	0,46 (0,64)	> 0,05
Mean final VA (SD)	0,66 (0,33)	0,72 (0,31)	0,51 (0,351)	0,78 (0,25)	> 0,05 in each group

The mean IOP was  $15,1 \pm 3,5$  mm Hg at the last visit for the 61 eyes and was not significantly different between groups A ( $14,3 \pm 2,2$  mm Hg), B ( $15,8 \pm 4,8$  mm Hg) and C ( $14,8 \pm 2,3$  mm Hg) ( $p > 0,05$ ).

The percentage of IOP reduction was respectively of 52,5% in group A, 49,7 % in group B and 37,4 % in group C, corresponding to a mean IOP decrease of  $15,4 \pm 6,9$  mm Hg in group A,  $15,6 \pm 12,2$  mm Hg in group B and  $8,8 \pm 3,2$  mm Hg in group C. ( $p < 0,05$ )

The graph of fig. 1 details the mean IOP results (mm Hg±SD) in the 61 NPDS eyes with associated sample size at each time interval.

Mean final IOP was  $15,4 \pm 3,5$  mm Hg in the mild,  $14,5 \pm 1,5$  mm Hg in the moderate and  $15,4 \pm 4,5$  mm Hg in the severe visual field defects ( $p > 0,05$ )

Antiglaucoma medications were significantly reduced at the last visit from a mean preoperative number of  $2,13 \pm 0,81$  to a mean final number of  $0,46 \pm 0,77$  ( $p < 0,05$ ) No significant difference was found in the number of postoperative glaucoma medications between groups A, B and C ( $p$  value  $> 0,05$ ). Twenty per cent of the eyes received additional glaucoma medications in group A comparatively to 36% in group B and 38,5% in group C.

According to the previously defined success criteria, 33 eyes (54,1%) presented with complete success at the last visit. Qualified and

complete success concerned 90,2% (55 eyes) of the eyes.

The frequency of distribution of final success was not significantly different between the three groups ( $p > 0,05$ ) but the rate of complete and qualified success was respectively 100% and 96% in both group A and C with SKGEL® comparatively to 80% in group B with 5-FU alone.

### Visual acuity

Mean final visual acuity reached  $0,66 \pm 0,33$  (range: 0,05 to 1,0). It was not significantly altered compared with preoperative level ( $0,68 \pm 0,31$ ) and was not significantly altered in each group ( $p > 0,05$ )

### Complications (Table 3)

A iatrogenic microperforation of the trabeculo-Descemetic membrane without iris prolapse occurred at the time of surgery in 16 eyes (2 in group A, 9 in group B and 6 in group C. ( $p > 0,05$ ).

Postoperative complications occurred in 38/61 eyes ( 52,3%) and are listed on table 3. Their distribution did not significantly differ between the different groups. ( $p > 0,05$ )

One month postoperative complications included shallowing of the anterior chamber in 6 eyes associated or not with localized choroidal detachment, iris prolapse in 4 eyes which was successfully treated by laser in all 4 eyes and a mild hyphema in 2 eyes.

Transient wound leaks were observed in 9 eyes and were easily repaired by suture (4 eyes) and/

Figure 1: Decrease of IOP (mmHg±SD) in the 61 NPDS with associated sample size at each time interval

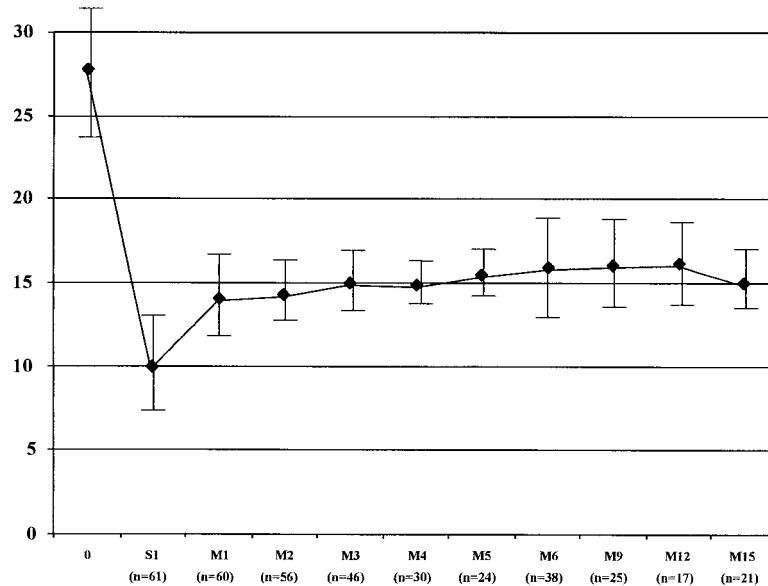


Table 3: Complications

	Total (n=61)	number of eyes			%	p value between A-B-C
		A (n=10)	B (n=25)	5 (n=26)		
<b>Peroperative</b>						
microperforation of the trabeculo-Descemetic membrane	16	2	9	6	21	>0,05
<b>Early (1st month)</b>						
hyphema	2	2	0	0	3,2	
shallow AC with/without choroidal detachment	6	0	2	4	9,8	
wound leak	9	1	5	3	14,8	>0,05
iris prolapse	4	1	3	0	6,5	
fibrosis/encysted bleb	16	2	9	5	23	
5-FU injections	14	2	9	3		
mean number:	6,8	5,5	6,9	7,3		
<b>Late</b>						
Nd:YAG goniopuncture	18	1	11	6	29,5	>0,05
surgery - related astigmatism	1		1			
cataract progression	5	2	3		8,2	
infection - hypotony	0				0	

or application of a megasoft contact lens (Procornea®, The Netherlands).

Bleb fibrosis and encapsulation were the most frequent complications and were treated by 5-FU subconjunctival injections in 14 eyes (22,6%). The mean number of 5-FU injections per patient was  $6,8 \pm 1,2$  (4 to 11) and was not sig-

nificantly different between the 3 groups (p-value > 0,05) but 20% and 11,5% in group A and C received postoperative 5-FU injections compared to 36% in group B.

YAG goniopuncture was performed in 18 eyes (29,5%) at various times after DS with 10% in group A, 44% in group B and 23% in group C (p > 0,05). It was effective to control IOP in

14/18 eyes (77,8%) The mean time between surgery and goniopuncture was  $7,5 \pm 4,7$  months (0,5 to 17 months). Iris prolapse was observed 3 months after YAG goniopuncture in one eye (group B)  
No bleb related endophthalmitis and no surgery induced cataract was observed.

**Medium term cumulative complete and qualified success probability in all 61 NPDS and in the 3 groups (Kaplan-Meier life-table analysis)**

For the 61 procedures, complete success probability was 95% at 6 months and 72% at 12 months. Qualified success probability increased to 98% at 6 months and 89,5% at 12 months. (fig. 2)

The complete success probability seemed to be improved in SKGEL<sup>®</sup> group compared with the other 2 groups. (fig. 3) whereas the qualified success probability tended to be higher in SKGEL<sup>®</sup> group A and C (SKGEL<sup>®</sup> + 5-FU) group compared with group B with 5-FU at about 12 months postoperatively. (fig. 4)

## DISCUSSION

DS allows aqueous filtration from the anterior chamber to the subconjunctival space through a thin trabeculo-Descemetic membrane. This membrane avoids a sudden IOP drop, thus lowering the incidence of postoperative complications, such as hypotony, flat anterior chamber and choroidal detachment encountered in trabeculectomy.

DS was first proposed by Zimmerman et al. (22, 23) Different techniques such as ab externo trabeculectomy and viscocanalostomy were described by others with success rates ranging from 77% to 90% of patients (1, 21). Fyodorov et al (9) and Kozlov et al (13) reported the use of a collagen drainage implant in the scleral bed to promote filtration. With a mean follow-up of 18 months and a maximum follow-up of 36 months, Karlen, Sanchez, Mermoud et al confirmed the better surgical outcome when a collagen drainage implant was used during NPDS. (12, 16, 18). With UBM studies, they concluded that IOP lowering is obtained by aqueous filtration through the thin remaining trabeculo-Descemetic membrane to an area under the scleral flap, which was maintained open by the collagen implant. (4, 5) However, Demailly et al concluded retrospectively and with a

Figure 2:  
NPDS with SKGEL<sup>®</sup> implant and/or 5-FU Medium term cumulative complete and qualified success probability in all 61 NPDS (Kaplan-Meier life-table analysis)

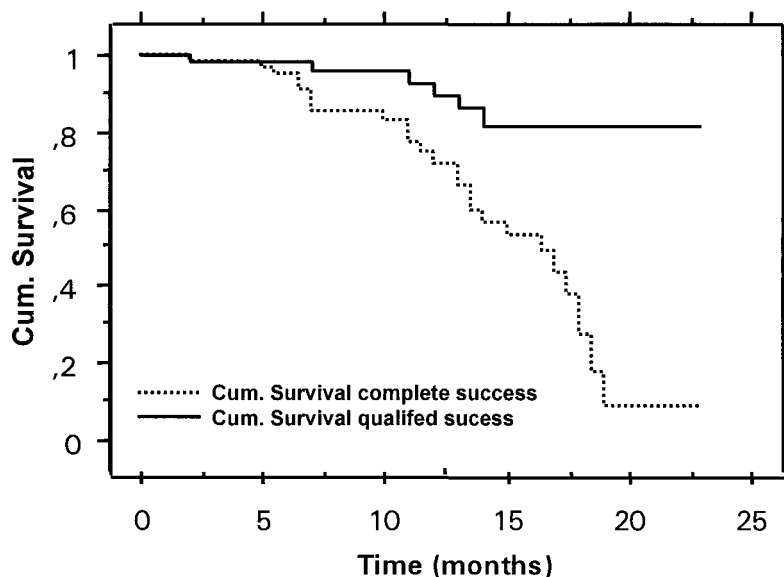


Figure 3:  
 NPDS with SKGEL® implant and/or 5-FU. Medium term cumulative complete and qualified success probability in all 61 NPDS (Kaplan-Meier life-table analysis)

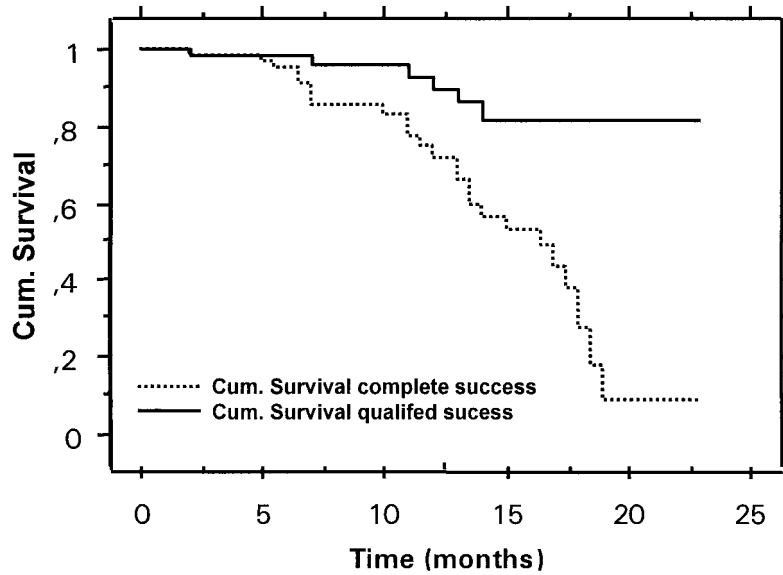
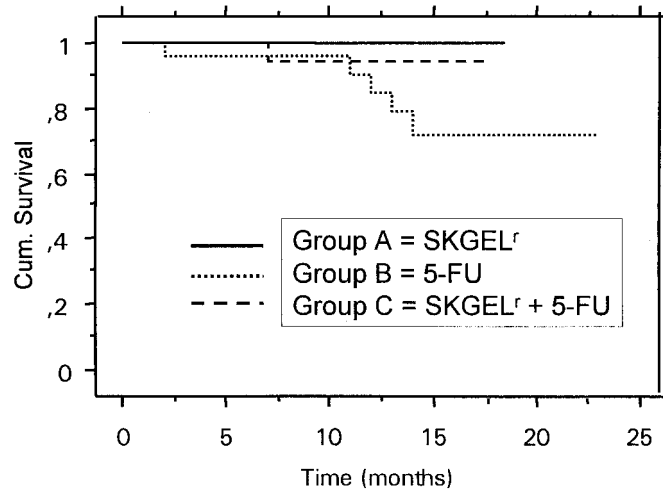


Figure 4:  
 NPDS with SKGEL® implant and/or 5-FU Medium term cumulative qualified success probability in groups A,B,C (Kaplan-Meier life-table analysis)



mean follow up of 13 months, that the collagen device with or without 5-FU did not seem to improve tonometric results. (7, 8) With a mean follow up of 8,8 months, Hamard et al also concluded that the use of a collagen device did not lead to a better control in IOP compared to the use of a sponge soaked of 5-FU. (10)

In this retrospective study, we compared the midterm effectiveness and safety of DS associated with adjuvant intra-operative 5 Fluorouracile (5-FU) or placement of a reticulated hyaluronic acid implant (SKGEL®) or combined SKGEL® and 5-FU peroperatively in our first consecutive 61 eyes that underwent DS.



Firstly, we confirmed that DS was an effective and relatively safe procedure in patients with a comparable surgical risk. (2,6, 7, 9, 14, 18). The mean IOP was significantly decreased from  $27,8 \pm 8,6$  mm Hg to  $15,1 \pm 3,5$  mm Hg at the last visit corresponding to a mean decrease in IOP of 45,6% compared to the preoperative IOP values. Simultaneously, the glaucoma medications could be significantly alleviated.

Our overall complete and qualified success rates were respectively of 54% and 90 % at the last visit. These results were comparable or slightly lower than those previously reported, but our success criteria were based on a clinical target IOP and not on a final IOP equal or less than 21 mm Hg which could explain this discrepancy. (2, 3, 6, 7, 8, 10, 12, 14, 15, 18, 19)

The retrospective non randomized nature of our study, the lack of control group, the differences in the sample size of the groups, in the follow-up duration and in the preoperative IOP values between the 3 groups compromise the reliability of our comparative analysis between the different adjuvant methods used to attempt to improve the IOP control.

With a mean follow-up of 11 months, we found that the IOP results, the final success rates and the observed complications were similar whatever using SKGEL<sup>®</sup>, intra-operative 5-FU or both. The mean final IOP appeared to be relatively independent of the preoperative IOP value. Interestingly the need for postoperative 5-FU injections, additional glaucoma medications and laser goniopuncture appeared to be lower in the SKGEL group compared with the other 2 groups. Both these results and the probability of success which seemed to be higher in the SKGEL<sup>®</sup> group in the late follow-up tend to confirm the benefits of the placement of an implant and suggest that SKGEL<sup>®</sup> implantation could lengthen the patency of the deep sclerectomy comparatively to 5-FU application alone

## CONCLUSIONS

In our experience, NPDS revealed to be a valid, effective and relatively safe alternative to trabeculectomy in return for which additional glaucoma medications and/or Nd:YAG goniopuncture are frequently needed to reach a clinical success.

puncture are frequently needed to reach a clinical success.

A close postoperative monitoring appears to be mandatory to detect frequent insidious IOP increases overtime, particularly in patients with moderate to severe glaucomatous damage.

Considering the limitations of our study, we can only conclude that the IOP results, the distribution of success rates and complications were similar within the 1<sup>st</sup> post operative year whatever using peroperative 5-FU or SKGEL<sup>®</sup> implant or both simultaneously. Certainly we need a longer follow-up to confirm that SKGEL<sup>®</sup> implant actually improves the IOP control, reduces the need for additional glaucoma medication or YAG laser gonipuncture and increases the long term patency of the sclerectomy site by comparison with intraoperative application of 5-FU.

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