
UNIVERSITE DE LAUSANNE - FACULTE DE BIOLOGIE ET DE
MEDECINE
HOPITAL OPHTALMIQUE JULES GONIN
SERVICE D'OPHTALMOLOGIE

TEN YEARS FOLLOW-UP AFTER DEEP
SCLERECTOMY WITH COLLAGEN
IMPLANT

THESE

préparée sous la direction du Professeur associé André Mermoud

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DOCTEUR EN MEDECINE

par

Alexandre BISSIG

Médecin diplômé de la Confédération Suisse
Originaire de Isenthal (URI)

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Rapport de synthèse

BUT

Le but de ce sujet de recherche est d'évaluer le taux de succès et les complications à long terme de la sclérectomie profonde non pénétrante avec implant de collagène (SPIC) chez les patients atteints de glaucome à angle ouvert.

METODES ET PATIENTS

Il s'agit d'une étude clinique, prospective, monocentrique, non-randomisée, effectuée sur 105 patients atteints d'un glaucome à angle ouvert médicalement non-contrôlé. Ces patients ont tous bénéficiés d'une SPIC, effectuée selon le geste chirurgicale standard (technique décrite dans l'article). Dans le cadre de cette étude, nous avons effectué un bilan ophtalmologique complet avant l'acte chirurgical puis un suivi postopératoire à 1 et 7 jours ; 1,2,3,6,9,12 mois et ensuite tous les 6 mois durant les dix années suivantes.

RESULTATS

Le suivi moyen de cette étude s'étend sur 101.5 ± 43.1 , [3-144] mois (moyenne \pm écart type, [étendue]). La pression intraoculaire (PIO) préopératoire était élevée à 26.8 ± 7.7 , [14-52] mmHg, et l'acuité visuelle corrigée à 0.71 ± 0.33 , [0.02-1.5]. Au terme des dix années après le traitement chirurgical, le nombre de patients suivi était de 52 avec une pression intraoculaire abaissée à 12.2 ± 4.7 , [6-20] mmHg et une acuité visuelle corrigée de 0.63 ± 0.34 , [0.01-1.2]. Le nombre de médicaments par patient a diminué de 2.3 ± 0.7 , [1-4] à 1.3 ± 1.1 , [0-3].

Dix ans après la SPIC, une pression intraoculaire ≤ 21 mmHg sans médicaments (succès complet) était obtenue chez 47.7 % des patients et 89 % avec ou sans traitement médicamenteux (succès relatif). Les gestes postopératoires additionnels par goniotomie ont été effectués sur 61 yeux (59.8%) et les injections sous-conjonctival de 5-fluorouracil ont été pratiquées sur 25 yeux dont 5 incluant un needling.

CONCLUSIONS

Le suivi à long terme sur une période de dix ans, démontre que la sclérectomie profonde avec implant de collagène (SPIC) est efficace dans le contrôle de la pression intraoculaire et présente peu de complications postopératoires.

Ten years follow-up after deep sclerectomy with collagen implant

Alexandre Bissig, MD*;¹ Delphine Rivier, MD;¹ Marc Zaninetti, MD, PhD;¹
Tarek Shaarawy, MD, MSc;^{1, 2} André Mermoud, MD;³ Sylvain Roy, MD,
PhD*;¹

*: These authors have equally contributed to this work.

1: Jules Gonin Eyes Hospital, Glaucoma Unit, Lausanne University, Lausanne, Switzerland.

2: Ophthalmology Clinic, Department of Clinical Neurosciences, Geneva University
Hospitals, Geneva, Switzerland.

3: Glaucoma Center, Clinique de Montchoisy, Lausanne, Switzerland

Address for correspondence:

Sylvain Roy, MD, PhD

Jules Gonin Eyes Hospital

Glaucoma Unit

Lausanne University

Av. de France 15

CH-1004 Lausanne

Switzerland

Tel. +41 21 626 82 24

Fax +41 21 626 82 46

E-mail: sylvain.roy@epfl.ch

Abstract

Purpose:

To evaluate the long term success rate and complications of non penetrating deep sclerectomy with collagen implant (DSCI) in open-angle glaucoma.

Patients and Methods:

Clinical, prospective, monocentric, non-randomized, unmasked study on 105 patients with medically uncontrolled glaucoma. A standard procedure DSCI was performed. Complete examinations were performed before surgery and postoperatively at 1 and 7 days; 1, 2, 3, 6, 9, 12 months and then every 6 months during the 10 following years.

Results:

The mean follow-up was 101.5 ± 43.1 , [3-144] months (mean \pm SD, [range]). The preoperative intraocular pressure (IOP) was 26.8 ± 7.7 , [14-52] mmHg and the best corrected visual acuity (BCVA) 0.71 ± 0.33 , [0.02-1.5]. Ten years after surgery IOP was 12.2 ± 4.7 , [6-20] mmHg and BCVA 0.63 ± 0.34 , [0.01-1.2] (number of remaining patients = 52). The mean number of medications per patient went from 2.3 ± 0.7 , [1-4] down to 1.3 ± 1.1 , [0-3]. An IOP ≤ 21 mmHg without medication was achieved in 47.7 % patients and in 89% with or without treatment. One major complication was reported. Goniopuncture was performed in 61 eyes (59.8%), 5-fluorouracil treatment given to 25 patients postoperatively and included needling (n=5).

Conclusions:

Based on a 10 year follow-up deep sclerectomy with collagen implant demonstrated its efficacy in controlling IOP with few postoperative complications.

Key words:

glaucoma – glaucoma drainage implant - filtering surgery

Introduction

Deep sclerectomy with collagen implant (DSCI) is a non-penetrating filtration procedure used for the surgical treatment of medically uncontrolled open-angle glaucoma. It was first described by Fyodorov et al in 1989.¹ It was conceived in an attempt to lower the incidence of early postoperative complications of conventional trabeculectomy (such as hypotony, hyphema, flat anterior chamber, choroidal detachment, choroidal effusion or hemorrhage, surgery-induced cataract and endophthalmitis)²⁻⁸, without compromising on the success rate of intraocular pressure (IOP) reduction.⁹⁻¹¹

Medium term studies of this surgical procedure have already been reported in our previous reports.^{12-14, 25} In this study we present the long-term results (10 years) of DSCI. The IOP control, the rate of complications and the reduction of glaucoma treatment for the initial 102 patients were studied.

Patients and Methods

Case selection

This clinical, prospective, monocentric, non-randomized, unmasked study was performed on 105 eyes of 105 patients with open-angle glaucoma. All operations were performed by the same surgeon (A.M). Surgeries were performed between June 1994 and January 1997. These were the initial patients who underwent DSCI for this diagnosis at the Jules Gonin Eyes Hospital in Lausanne, Switzerland.

Inclusion criteria were: medically uncontrolled primary open-angle, pseudoexfoliative, pseudophakic, normal tension, pigmentary, aphakic, traumatic and open angle uveitic glaucomas (table 1). Medically uncontrolled glaucoma was defined as an IOP higher than 21 mmHg under a maximal tolerable glaucoma therapy with evidence of progression of visual fields defects and or optic nerve cupping. Previous ocular surgery such as filtering or cataract extraction was not a criterion for excluding patients from this study. Exclusion criteria were: angle-closure, neovascular, congenital or juvenile glaucomas, known allergy to porcine collagen, previous argon laser trabeculectomy or eye surgery within 6 months prior to enrollment in the study, unwillingness to participate in the study, and pregnant or breast feeding women. Patients with operative perforation of the trabeculo-Descemet's membrane were purposely removed from this study.

The study was approved by the Ethics Committee of the University of Lausanne. Every patient gave written informed consent before surgery. None of the authors have any financial interest in the study.

Preoperative examination

The data were obtained from the medical records of the patients. Every patient underwent complete ophthalmic examination that included best corrected visual acuity (BCVA) measured at 6 meters on Snellen's chart, biomicroscopy, Goldmann applanation tonometer IOP measurements, anterior chamber angle assessment using a 4 mirrors contact lens, and fundus examination. The visual fields were tested using the Octopus 123 program G1 (Interzeag AG, Schlieren, Switzerland).

Postoperative follow-up

Postoperative evaluation which included all preoperative examinations except for the visual fields were performed at 1 and 7 days; 1, 2, 3, 6, 9, 12 months and then every 6 months thereafter to complete a 10 years follow-up. The visual field examination was repeated every year. Complications are defined on table 3. Mains outcomes were the IOP, the BCVA, the number of medications, and the nature and rates of complication.

Surgical technique

All surgeries were performed under retrobulbar anesthesia. The technique has been described in details elsewhere.¹² Briefly a superficial scleral flap was created. A deep scleral flap dissected down to the Schlemm's canal and a trabeculo-Descemet's membrane was performed. The inner wall of Schlemm's canal was peeled off and a collagen implant sutured in the deep scleral bed. The superficial scleral flap was repositioned over the implant and secured with 2 untight sutures (Figure 1 A-F).

Postoperatively patients were treated with topical 6000 U/ml polymyxin, 0.35 % neomycin and 0.1 % dexamethasone tid for 4 weeks and with topical fluorometholone 1 mg/ml tid for 3 months thereafter.

Glaucoma collagen implant

The collagen implant is a cylindrical device (length: 2.5 mm; diameter: 1 mm) made from lyophilized porcine scleral collagen¹² (Aquaflow® Staar Surgical AG, Nidau, Switzerland). This bio-compatible material is not known to induce systemic immunologic reactions.¹⁵ Acting as a space maintainer after hydration the implant is progressively degraded roughly 6 to 9 months after surgery.^{16, 17}

Additional procedures

The additional procedures are reported on table 2 and were indicated based on the clinical aspect of the filtering bleb. Laser goniopuncture (Microruptor II; Lasag AG, Thun, Switzerland) in Q-switch mode (5 to 8 mJ) creates microscopic holes in the trabeculo-Descemet's membrane allowing a direct passage of aqueous humor from the anterior chamber to the intra-scleral space. This procedure transforms a non-penetrating filtration procedure into a penetrating one.^{18, 19} After laser treatment, topical prednisolon acetate 1% was administered tid for three days. Glaucoma medications was reintroduced when IOP > 18 mmHg.

Success rate

Surgery was considered as a complete success when IOP was ≤ 21 mmHg without glaucoma medication at last follow-up, as a qualified success when IOP was ≤ 21 mmHg including medication. It was defined as a failure when IOP was < 6 mmHg or > 21 mmHg despite glaucoma medication, the eye required further glaucoma drainage surgery, developed phtisis bulbi, or lost light perception.

Statistical analysis

Results were analyzed using the Student's t test for comparison of means, chi-square analysis for 2 x 2 tables, and Kaplan-Meier survival curves for long term success rate analysis. P was considered significant when <0.05 .

Results

One hundred and five eyes from 105 patients were enrolled in the study. The mean age of the patients at the time of surgery was $68.0 \text{ years} \pm 12.6$, [43-102] (mean \pm SD, [range]), and 21 patients (20%) had previous ocular surgeries. The mean follow-up was 101.5 ± 43.1 , [3-144] months and the median was 120 months. During the study 29 patients died, while 24 were lost of follow-up. Preoperative diagnoses are presented on table 1.

Mean preoperative IOP was 26.8 ± 7.7 , [14-52] mmHg, mean postoperative IOP at 1 day was 5.1 ± 3.3 , [0-15] mmHg (reduction from preoperative value of 80.9 %), at 3 months 12.3 ± 3.7 , [5-27] mmHg (-54.1 %), at 3 years 13.3 ± 3.7 , [6-24] mmHg (-50.4 %), at 5 years 12.5 ± 3.6 , [6-21] mmHg (-53.4 %), at 8 years 11.9 ± 3.9 , [4-21] mmHg (-55.6 %) and at 10 years 12.2 ± 4.7 , [6-20] mmHg (-54.5 %). Figure 2 shows a steep reduction in IOP on the first postoperative day that gradually stabilized through the first month at around 12 mmHg. The mean IOP remained at that level for the next 10 years, with concurrent medication when necessary.

The mean number of medications per patient went from a preoperative value of 2.3 ± 0.7 , [1-4] down to 1.3 ± 1.1 , [0-3] at last follow-up, representing a reduction of 43.5 %. This reduction was more pronounced shortly after surgery but showed slow and gradual increase overtime (Figure 3). At 120 months and without antiglaucoma medication 47.7% of patients had an IOP < 21 mm Hg and 43.2% achieved an IOP < 15 mmHg. With medication, 88.9% and 85.6% of the patients achieved the same targets, respectively.

Based on cumulative survival curve the success rate at 10 years was 44.6 % and 77.6 % for complete and qualified success, respectively (Figure 4). One patient was defined as a failure due to IOP > 21 mmHg (mean IOP 22.5 mmHg) that was stabilized with medication. Eighteen patients had failed procedure and required further glaucoma drainage surgery. This second deep sclerectomy was performed on average 60.4 months [1 month-10 years] after the

initial DSCI. These patients were then all well controlled after the second procedure (IOP at 10 years: 12.6 ± 3.7 , [8-15] mmHg).

The BCVA decreased on the first postoperative day from 0.71 ± 0.33 , [0.02-1.5] (preoperatively) to 0.53 ± 0.28 , [0.02-1.25]. It returned just below preoperative level during the first month after surgery and remained stable for the following 10 years (Figure 5). When lens opacities induced a drop in BCVA, cataract extraction was proposed and performed during the follow-up (n=42).

Preoperatively mean defect and corrected lost variance were 13.1 ± 7.4 , [0.2-29] [dB] and 45.0 ± 35.0 , [1.4-149] [dB²], respectively, and went to 9.1 ± 6.8 , [0.1-18] [dB] and 36.8 ± 27.9 , [0.5-110] [dB²], respectively, 10 years later.

There was only one significant complication during surgery that consisted in a malignant glaucoma due to ciliary bloc. This complication was treated with cycloplegia medication, the IOP at the end of the follow-up period was 11 mmHg. Table 3 shows the postoperative complications. Minor complications such as transient (< 5 days) hypotony, limited filtering bleb leakage, and subtle choroidal detachment were not comparable in respect to severity with the long-term trabeculectomy-related complications such as prolonged shallow or flat anterior chamber, surgery-induced cataract, or bleb-related endophthalmitis.

Twenty-five patients (24.5 %) required subconjunctival 5-FU injections to treat bleb fibrosis or encapsulation. The mean number of injections per patients was 2.9 ± 1.9 , [1-7] and the mean time between DSCI and injection was 1.8 ± 2.6 , [0.25-12] months. From these 25 patients, 5 (4.9 %) had additional procedures, such as needling (n=5), to treat encysted blebs. No needling alone was performed without 5-FU injection.

Goniopuncture with the Nd:YAG laser was performed in 61 patients (59.8 %). The mean number of goniopunctures per patient was 1.1 ± 0.4 , [1-3]. Delay between DSCI and

goniopuncture was ranging from 1 to 119 months, with the median at 29 months. The mean IOP before goniotomy was 19.8 ± 5.5 , [14-46] mmHg. The IOP decreased to 12 ± 6.4 , [5-20] mmHg 15 minutes after laser treatment, thus representing a 39.4 % IOP reduction.

For the assessment of success, patients undergoing either 5-FU and/or needling and/or Nd:YAG goniotomy were considered a failure only if the IOP after such additional procedures was not lowered < 21 mmHg.

Discussion

Trabeculectomy is a penetrating filtration surgery widely used for the surgical treatment of medically uncontrolled glaucoma. The penetrating nature of this procedure leads to several postoperative complications such as hypotony, hyphema, flat anterior chamber, choroïdal detachment, choroïdal effusion or hemorrhage, endophthalmitis and surgery-induced cataract. Even with a modified trabeculectomy²⁰ the predictability of the first day IOP is variable and additional procedures may have to be performed (e.g. laser suture lyses, injection of viscoelastics in the anterior chamber, needling, releasable sutures). In an attempt to lower the incidence of such complications, non-penetrating filtration surgery was developed.^{1,21} DSCI allows a progressive filtration of aqueous through the thin remaining trabeculo-Descemet's membrane into the intrascleral reservoir. In their ultrasound biomicroscopy study, Chiou et al^{16,17} speculated that aqueous, shunted into this intrascleral room, was filtered to the subconjunctival and scleral space, then eventually through the thin remaining scleral wall and into the suprachoroidal space, which offers 2 new aqueous outflow mechanisms compared to trabeculectomy. To enhance filtration and to prevent the collapse of the intrascleral space Koslov et al²¹ proposed the use of a collagen implant placed within the scleral bed. Similarly, Sanchez et al²² and Shaarawy et al^{26,27} confirmed that the surgical outcome was better when the deep sclerectomy was performed with the insertion of a collagen implant.

The major advantage of DSCI over standard trabeculectomy is the non-perforation of the anterior chamber, allowing a progressive decrease in IOP, thus lowering the occurrence of complications often seen after trabeculectomy. In an experimental model, Vaudaux et al²³ studied the aqueous dynamics through the remaining thin trabeculo-Descemet's membrane and found that the outflow resistance was significantly lower but still sufficient to control a progressive filtration and thus to avoid the trabeculectomy-related postoperative

complications. This surgery requires a good surgical skill and the long-term results might differ depending on the surgeon's talent. The main difficulty lies in performing the dissection of the deep sclera and avoiding perforation of the thin trabeculo-Descemet's membrane. In this series, perforation of the membrane occurred in 3 patients that were not included in the study. In cases of perforation into the anterior chamber, DSCI was converted into trabeculectomy. Sanchez et al.²⁴ reported that in this particular condition the success rate and complications were similar to that of trabeculectomy.

Short, medium-term successes of DSCI have been reported to be favorable. Based on the same patient database, Karlen et al¹² reported a 55.4 % IOP reduction 3 months after DSCI and 53.2 % at 3 years, the mean number of medications per patient being reduced by 90 %. Demailly et al¹¹ reported a complete success rate of 89 % at 6 months and 97 % with or without glaucoma medication. Shaarawy et al¹³ demonstrated that DSCI was reaching, 5 years after surgery, a 61.9 % complete success. Mermoud et al²⁸ have compared the results after DCSI with a match group after trabeculectomy. At 24 months, they concluded that the success rate of DSCI may be comparable to that of trabeculectomy, with fewer complications. Similar conclusions were presented by El Sayyad et al²⁹ while Chiselita³⁰ was reporting that trabeculectomy lowers the IOP more than the NPDS technique. However, the complication rate seems to be lower in NPDS. In a comparative study with DSCI on one eye and trabeculectomy in the other eye Ambresin et al¹⁰ reported similar success rates with both procedures. Complications rates were significantly lower with DSCI than with trabeculectomy. However, additional procedures such as 5-FU injection or goniopuncture were more frequently performed in the DSCI group. To compare the effect of such additional procedure, Cillino et al³¹ have compared the long-term effects of low-dosage mitomycin C (MMC) in both deep sclerectomy and trabeculectomy. At the 48 months end-point either

procedure controlled IOP efficaciously, a low-dosage MMC can be considered a mild enhancement of deep sclerectomy IOP-lowering effect.

This paper presents the first study with a 10 year follow-up after DSCI. Our results indicate that DSCI remains a long-term successful procedure in stabilizing the IOP with low postoperative complication rates and a rather stable visual acuity. These outcomes confirm, on a long-term perspective, the results from previous papers in respects to efficacy and rate of complications compared to trabeculectomy.^{10-13, 28-31} In this context the reduced complication rates would present some benefice in preventing further sight degradation in eyes with significant glaucoma damages, and in reducing the duration, costs and extension of the postoperative managements. The DSCI shall be considered, in that respect, as a safer technique compared to trabeculectomy, and we shall advocate this surgery when a filtering procedure is indicated in eyes at high risks for sight threatening complications.

In addition the visual field also remained stable for the majority (63%) of patients. When comparing the results at 96 months in Shaarawy study²⁵, reporting a 57% complete success rate, with our 47% success at 10 years, we have to take into account some elements. Seven patients had a failure at a mean of 109 months after surgery. Seven other patients died and 2 other were lost of follow up before the 10 years outcome. In a study on 436 patients with a mean age of 71.1 years, Sharma found that 29.8% of the patients with glaucoma died within 10 years of diagnosis.³² This figure compares with the 27.6% of mortality reported in this study. One of the problems mentioned by Sharma about published studies on the long-term outcome of chronic glaucoma is that they are undertaken on patients who are recruited from the practices of glaucoma subspecialists whose patient profile tends to be skewed in the direction of difficult cases and include those with advance disease. The Kaplan-Meier curve that is generally used to demonstrate progression over time should therefore be interpreted in such cases with caution.³² Altogether these long term events might explain the decrease in

success when analyzing the surgical results on patients from the same database for 5, 8 and 10 years follow up.

In conclusion, DSCI offers satisfactory results after 10 years of follow-up in controlling IOP in patients with primary and secondary open-angle glaucoma. The success rates were comparable with other filtration techniques while the immediate postoperative complication rates were low, and visual acuity remaining fairly stable. However, careful postoperative examinations are required to early recognize and treat bleb fibrosis or encapsulation with 5-FU injection or needling, as well as to identify and treat an increased outflow resistance through the trabeculo-Descemet's membrane by performing a goniotomy. Our results indicate that DS is a viable option for the surgical therapy of open-angle glaucoma.

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Legends for figures

Figure 1.

A) One third thickness (300 μm) limbus based superficial scleral flap measuring 5 x 5 mm is dissected and extended 1 mm further into clear cornea. A rectangle or square of deep sclera is dissected leaving a thin layer of deep sclera covering the choroid on the posterior plane. Schlemm's canal is exposed.

B) Descemet's membrane exposure is performed with a ruby knife.

C) The deep sclera is carefully extended further into the corneal stroma to expose at least 1-2 mm of Descemet's membrane.

D) The deep sclera is excised using a diamond blade.

E) A toothed forceps is peeling off the inner wall of the Schlemm's canal.

F) The collagen implant is placed radially (in the center of the deep sclerectomy dissection) and secured with a single 10.0 nylon suture to the thin remaining scleral layer.

Figure 2. Mean postoperative intraocular pressure (IOP) evolution. ($p < 0.005$). Preop indicates preoperative, and n the number of patients; M, month; Y, year. Bar: SD.

Figure 3. Mean number of antiglaucoma medications per patient before and after surgery. ($p < 0.05$). Preop indicates preoperative, and n the number of patients. Bar: SD.

Figure 4. Cumulative complete and qualified long-term success rate using Kaplan-Meier survival curve; n indicates the number at risk.

Figure 5. Mean postoperative Snellen best corrected visual acuity (BCVA) evolution. ($p = 0.23$). Preop indicates preoperative, and n the number of patients; M, month; Y, year. Bar: SD.

Table 1. Preoperative glaucoma diagnosis

Type of Glaucomas	Number of patients	Percentage (%)
Primary open angle glaucoma	53	50.5
Pseudoexfoliative glaucoma	22	20.9
Pseudophakic glaucoma	14	13.3
Normal tension glaucoma	5	4.8
Pigmentary glaucoma	4	3.8
Aphakic glaucoma	2	1.9
Other glaucoma *	5	4.8

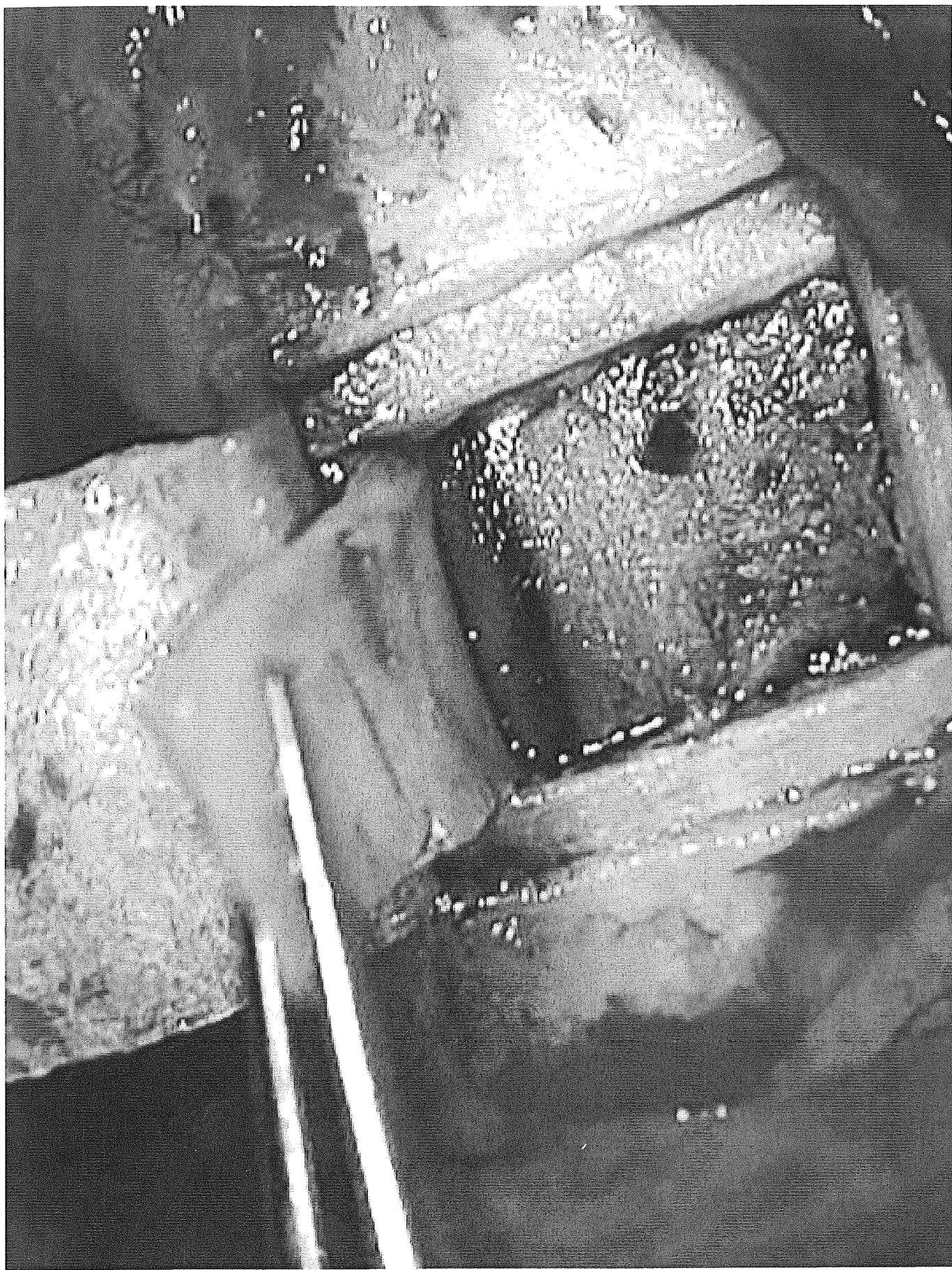
*Other glaucoma includes 1 inflammatory glaucoma (Posner-Schlossman Syndrome), 2 traumatic glaucomas, 1 corticosteroid induced glaucoma and 1 iridocorneal dysgenesis.

Table 2. Definitions of postoperative complications and additional procedures

Complications	Definition
Hyphaema	Erythrocytes in the anterior chamber
Hypotony	Postoperative IOP < 4 mmHg for > 2 weeks
Shallow anterior chamber	Iridocorneal touch in the periphery
Flat anterior chamber	Lens-cornea touch
Anterior chamber inflammation	Flare or/and cells seen in the anterior chamber
Choroidal detachment	Seen in the peripheral retina using an indirect ophthalmoscope
Surgery-induced cataract	Rapid decrease (1 month) in the visual acuity; mainly cortical opacities
Progressive cataract	Slow progressive decrease in visual acuity of > 2 lines (Snellen chart), essentially due to nuclear sclerosis
Additional procedures	Indication
Subconjunctiva injections of 5 mg of 5-fluorouracil (administered in the lower quadrant opposite to the deep sclerectomy)	When filtering blebs were encysted or showed signs of fibrosis
Needling	When filtering blebs were encysted or showed signs of fibrosis
Nd: YAG laser Goniopuncture	When filtration through the trabeculo-Descemet's membrane was clinically suspected to be insufficient reflected by an increasing IOP > 18 mmHg

Table 3. Postoperative complications after DSCI

Postoperative complications	Number of patients	Percentage (%)
Flat anterior chamber	0	0
Hyphaema	9	8.6
Dellen	6	5.7
Transient hypotony	2	1.9
Bleb leakage	9	8.6
Subtle choroidal detachment	8	7.6
Malignant Glaucoma	1	0.9
Surgery related cataract	0	0
Encysted bleb	24	22.8
Bleb fibrosis	12	11.4
Encysted bleb + bleb fibrosis	3	2.8





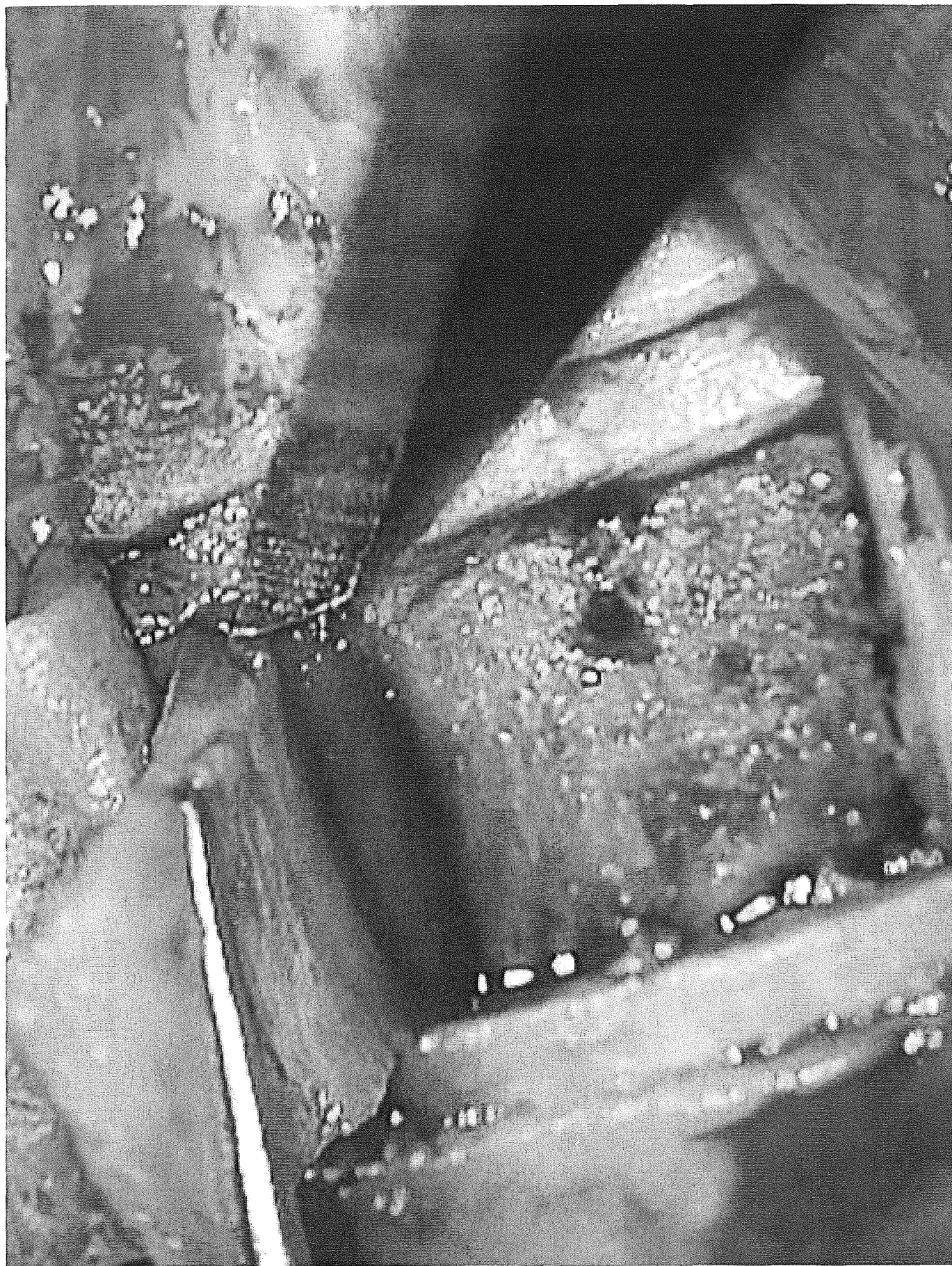








Figure 2

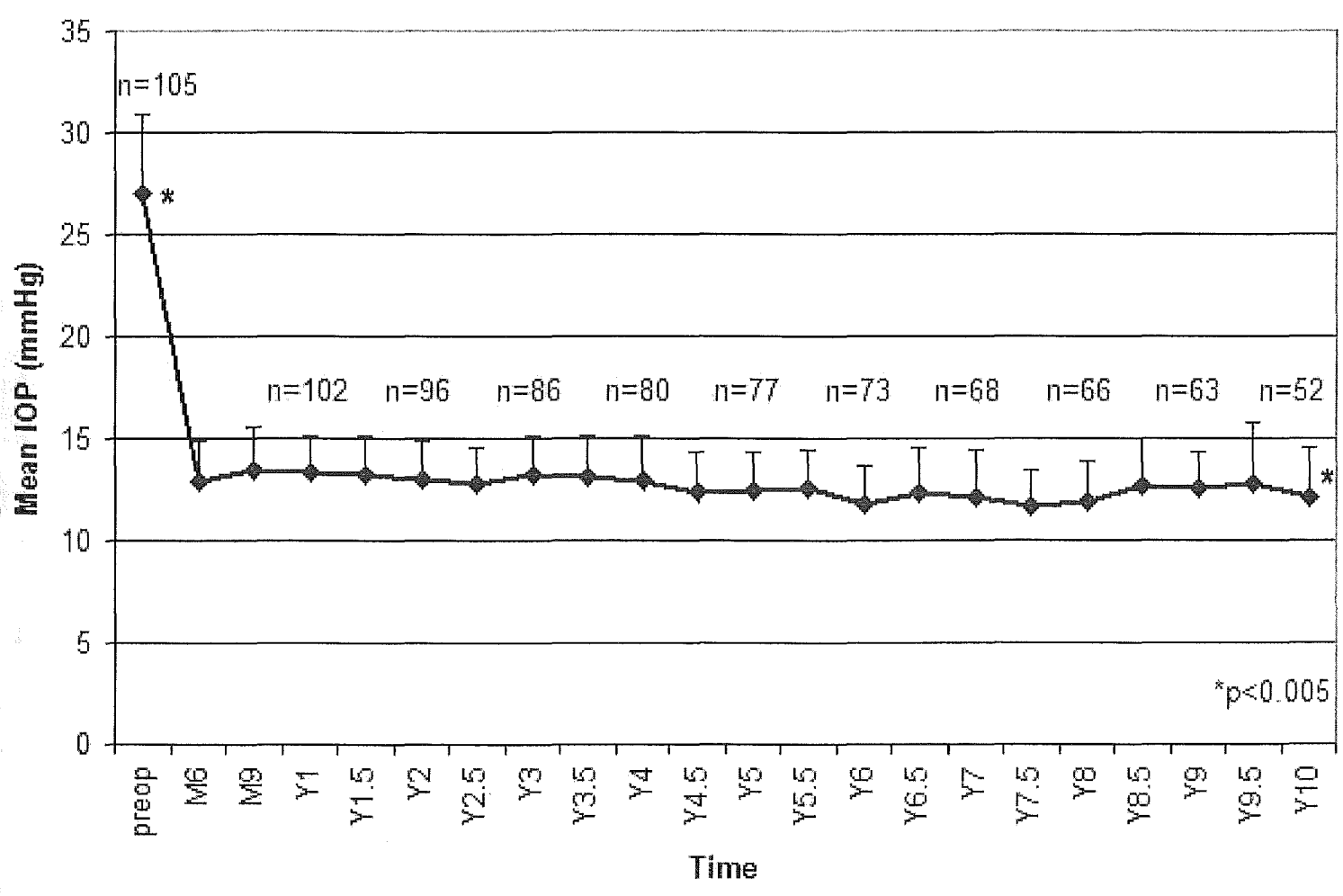
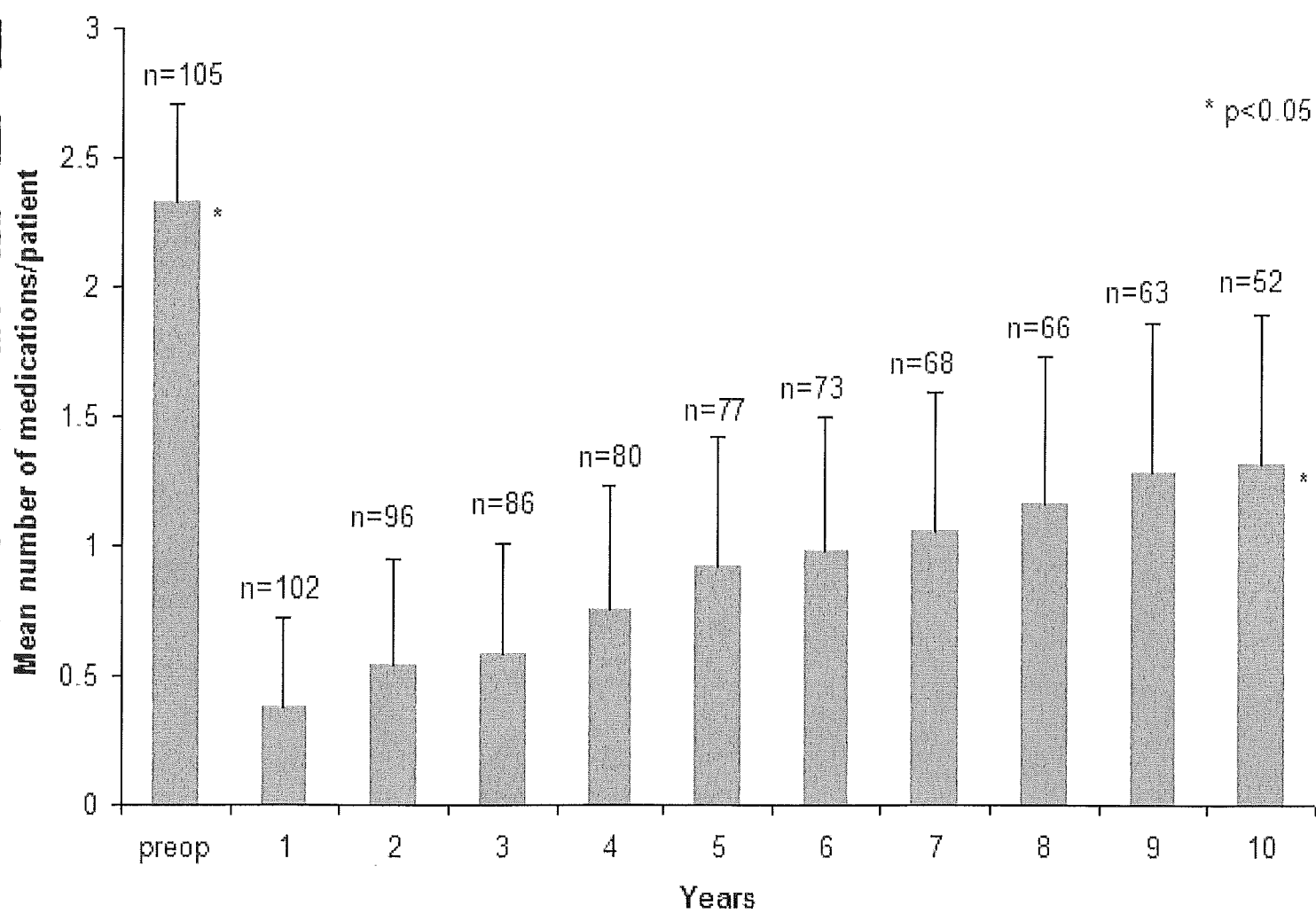


Figure 3



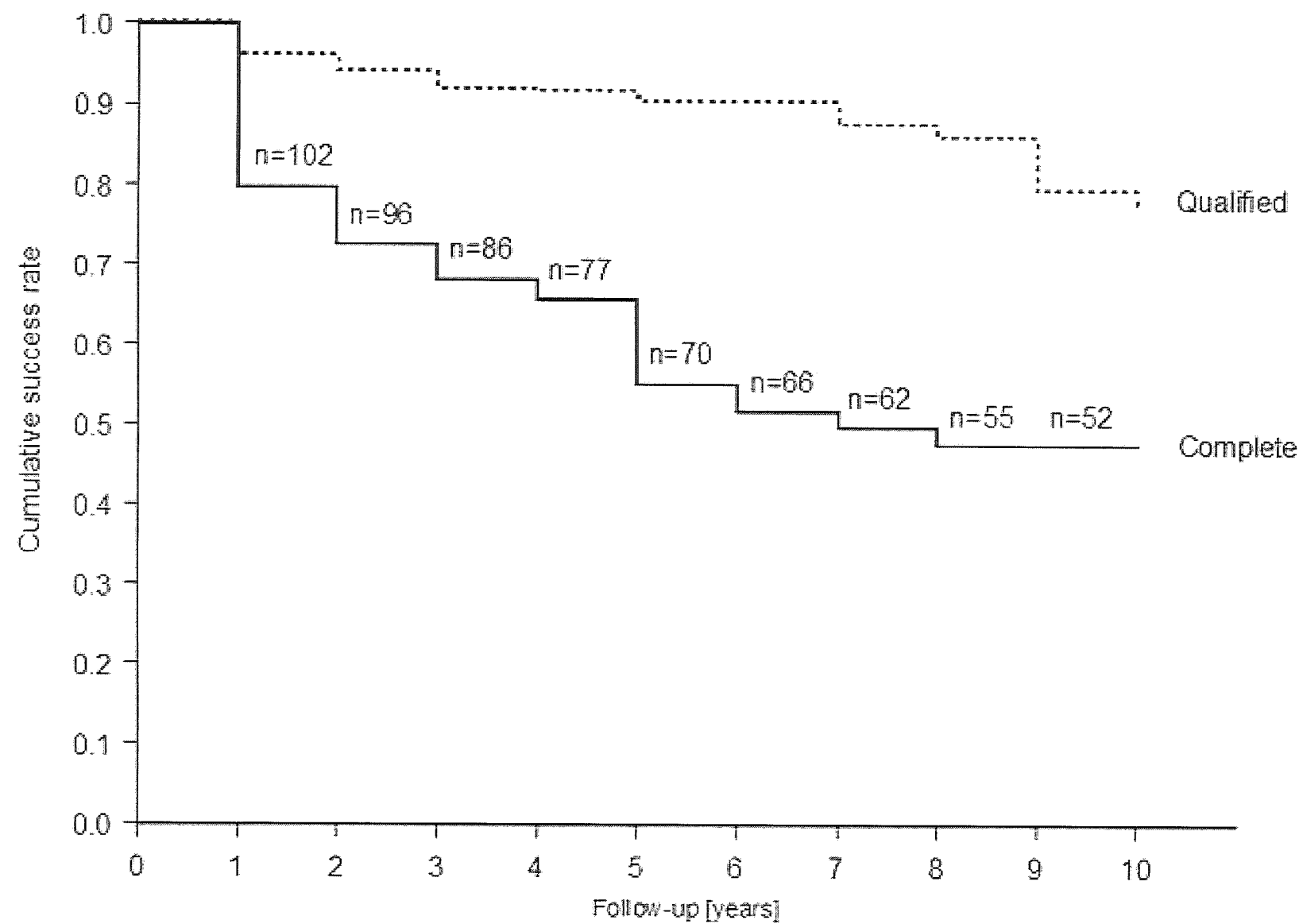


Figure 5

