EXTENDED REPORT

Low first postoperative day intraocular pressure as a positive prognostic indicator in deep sclerectomy

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Aim: To study the possibility of using intraocular pressure (IOP) in the first postoperative day after sclerectomy as a prognostic indicator.

Methods: Non-randomised prospective trial involving 105 eyes of 105 patients with medically uncontrolled primary and secondary open angle glaucoma. Visual acuity, IOP, and slit lamp examinations were performed before and after surgery at 1 and 7 days, and 1, 3, 6, 9, 12, 18, 24, 30, 36, 48, 54, 60, and 66 months. Visual field examinations were repeated every 6 months. A split point on day 1 IOP of less than or equal to 5 mm Hg (61%) versus more than 5 mm Hg (39%) was used. The first postoperative day IOP was examined in relation to the need for subsequent Nd:YAG goniopuncture, the subsequent use of postoperative antiglaucoma medications, and as a stratification variable in the Kaplan-Meier analyses.

Results: The mean follow up was 43.2 (SD 14.3) months. The mean preoperative IOP was 26.8 (SD 7.7) mm Hg; the mean postoperative IOP was 5.1 (3.3) mm Hg at day 1 and 11.8 (3.1) mm Hg at month 60. Patients with IOP $\leqslant$5 mm Hg had significantly fewer Nd:YAG goniopunctures ($p=0.0478$). A significant (log rank test 0.0122) improvement for those with IOP $\leqslant$5 mm Hg in terms of survival was detected using the most stringent criterion (IOP $\leqslant$15 mm Hg with no medications). For patients with first postoperative day IOP $\leqslant$5 mm Hg, the median time to failure was 24 months (95% CI: 12 to 30), but for those with an IOP >5 mm Hg, the median time to failure was only 6 months (CI 2 to 9). No significant difference in postoperative antiglaucoma medications was observed.

Conclusion: First postoperative day IOP can be considered to be a significant prognostic indicator in deep sclerectomy.

Deep sclerectomy (DS) and viscocanalostomy are filtration procedures for the surgical treatment of open angle glaucoma. The more classic trabeculectomy, with or without antimetabolites, has a well documented complication rate.[1–12] In the literature there is an agreement that from the point of view of safety, DS seems to surpass trabeculectomy.[13–15] Efficacy, nevertheless, is a different issue. Controversial, often contradictory, results[13 14 16] are available in the literature reporting on success rates of DS, as well as levels of intraocular pressure (IOP) reduction that can be achieved.

On close examination of the literature, variability of results is associated with differences in mean IOP achieved in the first postoperative day.[13 17–24] Studies showing unfavourable results of DS seem to report higher mean IOP in the first postoperative day[13 20 22 24] (table 1).

This study was designed to test the hypothesis that mean postoperative IOP could be utilised as a prognostic indicator in DS.

PATIENTS AND METHODS

Case selection

One hundred and five eyes of 105 white patients with medically uncontrolled primary and secondary open angle glaucoma underwent deep sclerectomy with collagen implant (DSCI). The study patients were enrolled consecutively, after the approval of the ethics committee of the University of Lausanne. Uncontrolled glaucoma was defined as uncontrolled IOP >21 mm Hg under maximal tolerable medical treatment and with well documented progression of visual field defects and optic nerve morphology.

Exclusion criteria were unwillingness to participate, unique eyes, advanced lens opacities, and previous eye surgery or laser trabeculoplasty less than 6 months before enrolment.

On the day before surgery, patients underwent best corrected visual acuity assessment and IOP was measured using a Goldmann applanation tonometer.

After surgery, previously mentioned examinations were conducted on the first and the seventh day and at 1, 3, 6, 9, 12, 18, 24, 30, 36, 48, 54, 60, and 66 months.

Surgical procedures

The surgical procedure has been previously described[18] in detail. A one third scleral thickness scleral flap measuring 5×5 mm was dissected. A rectangle of deep sclera measuring 4×4 mm was then delineated. The incision was deepened to the level of the choroid. When the choroid was identified, dissection was started just above this level and advanced anteriorly. Schlemm's canal (SC) was bisected and deroofed, and the deep flap of sclera with a portion of corneal stroma was excised leaving in place the remaining trabeculo-Descemet's membrane (TDM).

The collagen implant was then placed on the remaining scleral tissue and secured with a single 10–0 nylon suture (fig 1). The superficial scleral flap was repositioned and secured with two loose single 10–0 nylon sutures.

When a perforation of the thin TDM occurred during the corneal stroma dissection, the surgery was converted into a standard trabeculectomy. The results of the surgery undergone by patients who experienced perforation of the TDM (six patients) are not analysed in this paper because they have already been reported.[25]

Goniopuncture with the Nd:YAG laser was performed when IOP was elevated, and the reason was thought to be the lack of filtration through the TDM; in other words goniopuncture was performed when IOP did not reach the

Table 1 Studies showing unfavourable results

Reference	Procedure	Mean IOP in the 1st PO day	Complete success
O'Brart *et al*[22]	Viscocanalostomy	9.2	64% (12 months)
Drusedau *et al*[20]	Viscocanalostomy	18.6 (SD 7.5)	36% (12 months)
Chiselita[13]	DS	9.8 (SD NA)	44.5% (18 months)
Luke *et al*[24]	Viscocanalostomy	15.7 (SD 3.6)	30% (at 12 months)

PO = postoperative.

preset target range, even if IOP was within the statistically normal range.

Glaucoma collagen implant

The collagen implant measures 2.5 mm in length and 1 mm in diameter. Chiou *et al*[26] reported ultrasonic biomicroscopy findings consistent with IOP lowering by aqueous filtration through the thin remaining TDM to an area under the scleral flap, which was hypothetically maintained open by the presence of the collagen implant.

Other available implants are the reticulated hyaluronic acid implant[27 28] and the hydrophilic acrylic non-absorbable implant (Dr Elie Dahan, personal communication).

Statistical analysis

Patients were divided into two groups according to their IOP in the first postoperative day. The cut-off level was set to $\leqslant$5 mm Hg for the low IOP group and $>$5 mm Hg for the high IOP group. The splitting at that level was empirically derived, being close to the halfway point in the distribution of IOP, as well as being close to mean IOP in the first postoperative day given by most studies reporting positive results of DS in terms of efficacy.

Patients in the two groups were compared to see if differences existed in the proportion of men and women, age, preoperative IOP, and previous use of medications. Preoperative IOP, age, and number of medications used were compared with *t* tests and the distribution of patient sex was compared by Fisher's exact test.

The proportion of patients in the low and high IOP groups undergoing Nd:YAG goniopuncture or starting medications postoperatively was compared using Fisher's exact tests. The grouping classification of day 1 IOP was used as a stratification variable to examine time to failure defined in three ways: IOP $\leqslant$15 mm Hg with no medications; IOP $\leqslant$21 mm Hg with no medications; and IOP $\leqslant$21 mm Hg, regardless of medication use.

Statistical analyses were performed using SAS, Version 8.2.

Figure 1 Photograph of collagen implant placed after deep sclerectomy dissection. SC was unroofed, anterior trabeculum and Descemet's membrane were exposed, and aqueous was seen filtering through the remaining membrane.

RESULTS

Mean follow up time was 43.2 (SD 14.3) months. The mean preoperative IOP was 26.8 (SD 7.7) mm Hg. The mean IOP at the first postoperative day was 5.1 (SD 3.3) mm Hg. The IOP at 3 months was reduced by 55.5% (12.2 mm Hg (SD 3.4) versus 26.8 mm Hg), and at 48 months IOP was reduced by 55.4% (12.24 mm Hg (SD 4.6) versus 26.8 mm Hg) thus showing stability of IOP postoperatively (fig 2), detailed results have been previously described.[18]

Goniopuncture with ND:YAG laser was performed on 48 (46%) patients. The mean time between laser and DSCI was 13.5 (SD 13.0) months, the mean IOP before goniopuncture was 20.6 (SD 6.0) mm Hg and the mean IOP after goniopuncture was 10.7 (SD 6.3) mm Hg.

Comparison of the two groups yielded no significant differences in terms of their preoperative IOP ($p = 0.5704$), age ($p = 0.2940$), or number of medications used ($p = 0.1671$). The proportion of males to females in each group was consistent ($p = 0.4278$). Therefore, the two groups appear to be reasonably similar. Coincidental characteristics in the two groups would therefore not be expected to be the cause of subsequent differences in the course of their disease.

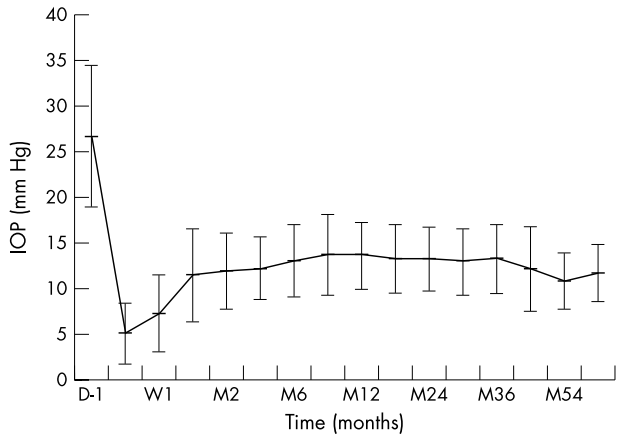

Figure 2 Intraocular pressure before and after deep sclerectomy with collagen implant.

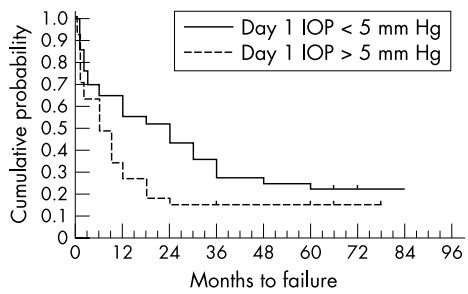

Figure 3 Long term cumulative success of DSCI, stratified by day 1 IOP using Kaplan-Meier life table analysis.

Table 2 Studies showing favourable results

Reference	Procedure	Mean IOP in the 1st PO day	Complete success
Shaarawy *et al*[23]	Viscocanalostomy	5.6 (SD 6.1)	60% (60 months)
Mermoud *et al*[15]	DSCI	6.1 (SD 4.5)	69% (24 months)
El Sayyad *et al*[14]	DS	8.4 (SD 2.7)	92% (12 months)
Shaarawy *et al*[18]	DSCI	5.1 (SD 3)	62% (60 months)
Ambresin *et al*[17]	DSCI	5.0 (SD 4.3)	40% (24 months)

PO = postoperative; DS = deep sclerectomy; DSCI = deep sclerectomy with collagen implant.

Patients with IOP ⩽5 mm Hg had significantly fewer Nd:YAG goniopunctures (p = 0.0478) (Goniopuncture with ND:YAG laser was performed on 48 (46%) patients, 26 patients of whom were among the patients with IOP ⩽5 mm Hg). We detected significant improvement for those with IOP ⩽5 mm Hg in terms of the survival using most stringent criterion (IOP ⩽15 mm Hg with no medications). The p value for the log rank test was 0.0122. For patients with first postoperative day IOP ⩽5 mm Hg, the median time to failure was 24 months (95% CI: 12 to 30), but for those with an IOP >5 mm Hg, the median time to failure was only 6 months (CI 2 to 9). A graphic display of time to failure is provided (fig 3). When examining less stringent criteria of success (IOP ⩽21 with no medications, or IOP ⩽21 mm Hg with or without medications), the two groups did not show significant differences in time to failure. However, these analyses had substantially less power to detect differences, because of the large number of censored eyes in these analyses (the definition of failure was such that many eyes simply did not experience an event). No significant difference in postoperative antiglaucoma medications was observed.

DISCUSSION

Recently, deep sclerectomy and viscocanalostomy have been a topic of discussion and controversy in numerous published editorials.[29] These editorials point, righteously, to the controversial, often contradictory, results in the literature regarding the efficacy of DS.

On close examination of the literature we can find a mean IOP in the first postoperative day of about 5.9 (SD 3.6) mm Hg in studies reporting favourable results of DS[14 17–19 23] (table 2). On the other hand, studies with unfavourable results show a mean IOP in the first postoperative day of 13.3 mm Hg[5 13 20 22 24] (table 1). Of course success criteria differ slightly from one source to another—for example cut-off level of IOP is slightly different and duration of follow up is also different. Nevertheless this would probably not account for the significant differences in reported success rates if they are classified according to mean IOP in the first postoperative day.

We have examined our series of consecutive 105 patients[18] to test our hypothesis that mean IOP in the first postoperative day could be utilised as a prognostic factor. Our results clearly and significantly show that success is more likely to be achieved, using a stringent cut-off level of ⩽15 mm Hg, with a low mean IOP in the first postoperative day. Patients were also significantly less likely to require Nd:YAG goniopuncture if low IOP was achieved in the first postoperative day.

Lower mean IOP in the first postoperative day can possibly occur with perforations of the TDM, but in our series no identifiable perforations were observed. Microperforations are a possibility, but again it is impossible intraoperatively to identify or test for microperforations. Histopathological examinations of the TDM in enucleated eyes[30] have not shown microperforations but have demonstrated that the main aqueous percolation occurs at the level of the trabeculum and to a much lower extent at the Descemet's membrane. Whether microperforations do occur or not, and their overall responsibility for drop of IOP is a topic of much debate,[31] and concerns to a major extent the study of mechanisms of function of DS.

One can argue that mean postoperative IOP is an indicator of correct depth of dissection achieved intraoperatively. This is in line with the work of Rossier and co-workers[32] and Vaudaux and co-workers,[30] who have shown that the remaining TDM provides reproducible outflow resistance, and thus can account for reproducibility of results in properly dissected deep sclerectomies.

This could be explained by the work of Zimmerman *et al*[33] and Grant,[34] more than 40 years ago, who had shown that the maximum site of outflow resistance resides in the inner wall of SC and the juxtacanalicular trabeculum.

There is, admittedly, a long learning curve of this technically demanding procedure. This is mainly related to developing an understanding of the technique and observation of anatomical landmark of proper dissection.[35] Results tend to improve with experience as has been shown by two recent consecutive studies.[5 16] The two studies have provided an increase of success rates from 0% in the first group to 30% in the following group of viscocanalostomy.

The hypothesis that mean postoperative IOP is an indicator of correct depth of dissection achieved intraoperatively could only be proved, beyond doubt, if a correlation was made between mean IOP in the first postoperative day and histopathological examination of the excised deep sclera, corneal stroma, and the peeled inner wall of SC, which unfortunately was not done in our study.

What this study seems to indicate is that the IOP in the first postoperative day could be utilised as a prognostic factor in DS. Lower IOP in the first postoperative day could be correlated with higher success probabilities. What this study could not prove, owing to lack of histopathological examinations, is that first postoperative day IOP is directly related to proper intraoperative dissection. Our study should encourage research in this field.

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