Donor sclera versus bovine pericardium as patch graft material in glaucoma implant surgery and the impact of a drainage suture

Milo van Hoefen Wijsard D Michiel Haan, Eelco Rietveld and Laurentius J. van Rijn

Department of Ophthalmology, VU University Medical Center, Amsterdam, the Netherlands

ABSTRACT.

Purpose: To compare the use of human donor sclera with bovine pericardium as patch graft material for a glaucoma drainage device (GDD), with respect to the incidence of tube exposure, and to study the role of a drainage suture.

Methods: All GDD surgeries between 2010 and 2014 performed at the VU Medical Center were examined in this comparative, retrospective cohort study. A total of 244 cases were included; 163 in the human donor sclera cohort and 81 in the bovine pericardium cohort with a median follow-up of 31 and 36 months, respectively. The primary outcome measure was occurrence of tube exposure. Survival analysis for tube exposure was carried out and Kaplan–Meier curves compared. Secondary outcomes were postoperative intraocular pressure (IOP), number of glaucoma medications and the effect of a drainage suture.

Results: In the bovine pericardium cohort, eleven (13.6%) eyes developed tube exposure compared to none in the human donor sclera cohort. Their Kaplan-Meier survival curves differed significantly from each other ($\chi^2 = 21.1$, p < 0.001, log-rank test). Mean IOP and number of glaucoma medications did not differ significantly between patch graft materials at three months of follow-up. The use of a drainage suture directly lowered IOP after surgery in both cohorts. Within the bovine pericardium cohort, eyes with a drainage suture experienced more tube exposure, although this difference was not statistically significant (p = 0.09).

Conclusion: Human donor sclera leads to less tube exposure than bovine pericardium. A drainage suture directly lowers IOP after surgery. With bovine pericardium, but not with donor sclera, exposure tends to be enhanced by a drainage suture.

Key words: Baerveldt implant – glaucoma drainage device – intraocular pressure – tube erosion – tube exposure – tutopatch

Acta Ophthalmol. 2018: 96: 692-698

© 2018 The Authors. Acta Ophthalmologica published by John Wiley & Sons Ltd on behalf of Acta Ophthalmologica Scandinavica Foundation.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.

doi: 10.1111/aos.13721

Introduction

The use of glaucoma drainage devices (GDD) is becoming increasingly more

popular in the surgical management of glaucoma. Where trabeculectomy used to be the first-line surgical treatment, now, the trend in practice patterns towards the implantation of glaucoma drainage devices. (Desai et al. 2011; Wright et al. 2016). GDD surgery has been shown to have a lower failure rate than trabeculectomy with similar reduction in intraocular pressure, fewer early complications and less need for additional glaucoma surgery (Vass et al. 2007; Van Aken et al. 2010; Gedde et al. 2012a,b).

Because of the nature of the procedure, glaucoma drainage device surgery has some unique complications. A known risk of surgically installing a foreign device into the human body is erosion of the overlying tissue leading to exposure of that device. In GDD surgery, reported as one of the main complications is transconjunctival tube erosion leading to tube exposure outside the conjunctiva (Bailey & Sarkisian 2014).

Tube exposure is a serious complication that requires surgical repair as it increases the risk of infection and malfunction of the drainage device with a risk of rapid change in intraocular pressure. Furthermore, after initial surgical revision due to exposure, the implant is more prone to repeated conjunctival erosions (Gedde et al. 2012a,b; Huddleston et al. 2013; Ng et al. 2015). During GDD surgery, most clinicians use a tissue patch to cover the tube. Different materials can be used as patch grafts such as human donor cornea, dura mater, sclera and bovine pericardium, of which the latter two are used most frequently (Brandt 1993; Spierer et al. 2016). The use of these patch grafts leads to a decrease in implant exposure (Byun et al. 2009; Ng et al. 2015; Trubnik et al. 2015; Lind et al. 2016). Currently, the association between patch graft material and tube exposure is not yet fully explored, and limited literature is available comparing these materials. While bovine pericardium is available worldwide and has a better shelf life, human donor sclera is less expensive and seems to be more biocompatible (Smith et al. 2002; Tsoukanas et al. 2016).

The Baerveldt glaucoma implant is one of the most commonly used GDDs and the only glaucoma implant used in this study. A drawback of implant surgery using a Baerveldt implant is that little immediate pressure decrease is being achieved (Budenz et al. 2011). One of the authors (ER) suggested using a drainage suture technique to combat this problem and presented this at the ARVO Annual Meeting in 2009 (Rietveld et al. 2009). While already in use due to good preliminary effects, results of this technique have not been fully analysed.

This study was designed to compare the use of human donor sclera with bovine pericardium as graft materials in GDD surgery with respect to the incidence of tube exposure. As a secondary aim, the role of the drainage suture for immediate pressure decrease was evaluated.

Materials and Methods

Patient selection

For this historical cohort study, all glaucoma drainage device (GDD) surgeries between 2010 and 2014 performed at the VU University Medical Center, Amsterdam (VUmc), were retrospectively evaluated. After having used bovine pericardium as a patch graft for several years at the VUmc, there was a switch in 2012 to human donor sclera because it became more readily available in the Netherlands again. Cases were identified by a computerized search of the procedural terminology code for implantation of GDDs. Without taking revisions, removals and replacements into account, a total of 248 GDD surgeries were performed by two surgeons (ER and LJR) in the selected time period.

Cases were included when either donor sclera or bovine pericardium was used as a patch graft.

At the VUmc, GDDs are first and preferably placed in the superior

quadrants of the eye. Three cases were excluded from this study in whom placement in these quadrants was not possible due to conjunctival scarring from (multiple) previous GDD surgeries suggesting a poorer outcome. If a patient had GDD surgery in both eyes, these eyes were included as individual cases

Medical records were retrospectively reviewed. Preoperative data included study eye, gender, age at time of implantation, type of glaucoma according to national registration guidelines, history of systemic hypertension and diabetes mellitus, history of smoking and previous intraocular surgeries in the study eye. No cases were excluded based on type of glaucoma. Ethnicity was only reported in a small number of medical records (<2%) and consequently could not be included as a variable. Baseline values were recorded from the hospital visit when device implantation was deemed necessary and included preoperative intraocular pressure (IOP), best-corrected visual acuity (BCVA) and type and number of glaucoma medications used (both topical and oral). Each class of medication was counted as one. A visual acuity (VA) of LP+ (only light perception) was recorded as LogMAR +2.80 and LP- (no light perception) extrapolated to LogMAR +2.90 (Roberts et al. 2002). In most young children, measuring an accurate vision on a VA scale was not always possible so they were excluded from analysis of mean VA. Intraoperative data collected included type of the GDD, quadrant of implantation, operating surgeon, patch graft material, concomitant surgery and whether a drainage suture (see below) were placed through the tube. Data from follow-up visits were recorded from around one week (mean 8.3 ± 4.9 days) and around three months (mean 76.9 \pm 27.9 days) after surgery and included IOP and glaucoma medications. During the followup of up to 3 years, medical charts were reviewed for postoperative complications, specifically the occurrence of tube exposure.

Surgical technique and materials

Only Baerveldt 101-350 glaucoma implants (Abbott Medical Optics, USA) were used. Surgical techniques were standardized between surgeons. The conjunctiva and Tenon's capsule were opened in the fornix, the horizontal (medial or lateral) rectus muscle hooked and the inferior wing of the GDD was placed underneath. Thereafter, the superior rectus muscle was hooked, and the superior wing of the GDD was placed underneath. The GDD was fixed to the sclera using either nylon 9.0 or vicryl 8.0 sutures. A limbal tunnel was created using a 27-gauge surgical stiletto, and the tube was inserted into the anterior chamber. Then, the tube was ligated with a 7.0 vicryl suture and tested for watertightness. The tube and, often, the proximal part of the plate were covered with the patch material, and Tenon's capsule and the conjunctiva were closed in layers. Patch materials used were bovine pericardium (Tutopatch, RTI Surgical USA) and human donor sclera which was processed by the Dutch Sclerabank, a division of the Euro Tissue Bank. The human donor sclera, kept in C₂H₅OH, was rinsed in three baths of sterile irrigation solution without antibiotics (for five minutes each time) before implantation according to Eurotransplant protocol.

Drainage suture

In the majority of cases, prior to closing Tenon's capsule and the conjunctiva, a single nylon 9.0 drainage suture was placed through the tube during surgery (Rietveld et al. 2009). It creates an opening in the tube and accommodates the outflow of aqueous humour from the anterior chamber, see Figure 1, thereby lowering the IOP almost instantaneously after surgery. When installing a nonvalved GDD such as the Baerveldt implant, due to the ligation of the tube, early postoperative hypertony may occur. A drainage suture may prevent this by lowering IOP in this early postoperative phase. The drainage suture is looped at the limbus and ordinarily will be removed at the slit lamp when the ligation suture has dissolved and the tube is fully open at around two months after surgery. It can also be easily removed in the case of hypotony. Removal results in closure of the additional opening due to elasticity of the tube (as we tested in an *in vitro* setting). At the time of introduction, the drainage suture was used in eyes with high

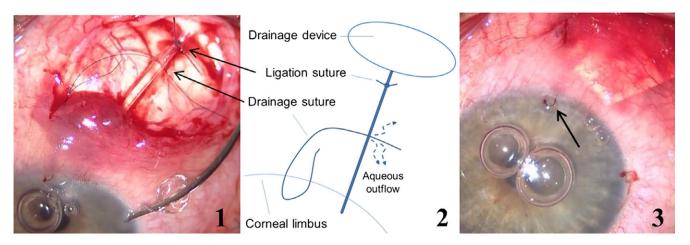


Fig. 1. A *drainage suture* creates an opening in the tube of a glaucoma drainage device and accommodates the outflow of aqueous humour lowering intraocular pressure. The suture is looped through the corneal limbus and, if necessary, will be removed at the slit lamp when intraocular pressure becomes too low and when the ligation suture has dissolved. [1] During surgery. [2] Schematic. [3] Postsurgery, looped at the limbus (arrow). [Colour figure can be viewed at wileyonlinelibrary.com].

preoperative IOP to achieve immediate pressure reduction. Later, the use was extended to include eyes with advanced glaucomatous damage or severe risk of postoperative pressure rise, for example, due to steroid response.

Analysis

The primary outcome measure of this study is the occurrence of tube exposure following GDD implantation. Secondary outcome measures are postoperative intraocular pressure, the number of glaucoma medications needed and the role of the drainage suture on former outcomes.

Comparisons between patient characteristics were performed using chisquare test or Fisher's exact test for categorical variables. Continuous variables are presented with N. mean \pm SD or N% and analysed by an independent t-test. A survival analysis for tube exposure based on a Kaplan-Meier curve and log-rank test was carried out. Regression analysis between both cohorts to assess confounding and effect modification could not be performed as there were no events in one of the cohorts. Another survival analysis and a Cox regression analysis were carried out for patients within the bovine pericardium cohort to compare tube exposure between cases with or without a drainage suture. All statistical analyses were 2-sided, and p < 0.05 was considered significant.

Results

A total of 245 cases were identified in 239 eyes of 212 patients. The cases were

divided into two cohorts based on patch material used: 81 received bovine pericardium and 164 received donor sclera. Difference in cohort size was due to gradually more GDD surgeries being performed over time together with the shift to donor sclera. One case (donor sclera, no tube exposure) was lost to follow-up within the first month due to emigration and was excluded from analyses. Median follow-up times were 31 months (range: 13-36 months) in the donor sclera cohort and 36 months (range 21-36 months) in the bovine pericardium cohort. Table 1 presents the patient characteristics and baseline values. There were eight eyes from children ≤ 6 years of age in the donor sclera group and four eyes in the bovine pericardium group. Smoking status could be assessed in 53.3% of cases. No significant differences in any of the demographic or clinical features were observed between treatment groups.

Table 2 lists the surgical characteristics. In the donor sclera cohort, significantly, more drainage sutures were used. This was due to increased use of drainages sutures each year because of good preliminary results together with the increase in use of donor sclera.

Tube exposure

In the bovine pericardium cohort, tube exposure occurred in 11 cases (13.6%). In the donor sclera cohort, none of the operated eyes experienced tube exposure. Characteristics of patients with tube exposure are listed in Table 3. None of these eyes developed endophthalmitis. Figure 2 shows the Kaplan–Meier curves for both cohorts, where cumulative survival is the nonoccurrence of tube exposure. The bovine pericardium curve shows a steady descent, and the log-rank test shows this differs significantly from the donor sclera curve ($\chi^2 = 21.1$, p < 0.001). One of the surgeons operated more within the bovine pericardium cohort where all tube exposures for each of the eye surgeons was calculated within the bovine pericardium cohort, ER (2/23) and LJR (9/58), but the difference was not significant (p = 0.72, Fisher's exact test).

To see whether drainage sutures had any effect on tube exposure, Kaplan-Meier curves were constructed for those within the bovine pericardium cohort with and without a drainage suture (Fig. 3). Two (6.1%) of the eyes without drainage suture experienced tube exposure, while tube exposure occurred in nine (19.6%) eyes with a drainage suture. The log-rank test showed no significant difference between the survival curves (p = 0.09). Cox regression analysis for tube exposure comparing cases with a drainage suture and those without showed an odds ratio of 3.45, however, also not significant (p = 0.11).

Of note are two patients in which one eye was treated with bovine pericardium, and in their another eye, donor sclera was used. The two eyes treated with pericardium experienced tube exposure, after 16 and 33 months, while no tube exposure occurred during follow-up in their other eyes where human donor sclera was used. What is more, in all four eyes, a drainage suture was applied.

Table 1. Patient characteristics and baseline values.

	Donor sclera $(n = 163)$	Bovine pericardium $(n = 81)$	p-value
Age in years, mean \pm SD, range 0-93	59.1 ± 18.3	56.9 ± 20.7	0.11
Sex, male	96 (58.9%)	54 (66.7%)	0.24
Systemic Hypertension	55 (35.9%)	29 (38.2%)	0.74
Diabetes Mellitus	38 (24.2%)	17 (22.1%)	0.72
Smoking	14 (17.1%)	12 (25.0%)	0.28
Preoperative IOP, mean \pm SD	32.9 ± 10.3	33.4 ± 10.6	0.72
Preoperative logMAR visual acuity, mean \pm SD	0.76 ± 0.84	0.79 ± 0.75	0.80
Preoperative glaucoma medications, mean \pm SD	3.0 ± 1.2	3.3 ± 0.9	0.21
Diagnosis			
Primary open-angle glaucoma	64 (40.3%)	25 (30.9%)	0.20
Angle-closure glaucoma	11 (6.9%)	3 (3.7%)	0.40
Neovascular glaucoma	19 (11.9%)	15 (18.5)	0.15
Congenital glaucoma	3 (1.9%)	6 (7.4%)	0.06
Uveitic glaucoma	16 (10.1%)	12 (14.8%)	0.25
Post-traumatic	5 (3.1%)	4 (4.9%)	0.49
Postvitreoretinal surgery	6 (3.8%)	6 (7.4%)	0.22
Postcataract surgery	8 (4.9%)	3 (3.7%)	1.00
Other secondary glaucoma*	27 (16.6%)	7 (8.6%)	0.09
No. of previous intraocular surgeries, mean \pm SD	1.2 ± 1.2	1.4 ± 1.4	0.26
No. of previous intraocular surgeries (grouped)			
0	58 (35.6%)	26 (32.1%)	0.49
1	55 (33.7%)	24 (29.6%)	
≥2	50 (30.7%)	31 (38.3%)	

Values are described by N (%).

* Other secondary glaucoma includes the following: pigmentary, pseudoexfoliative, Fuchs heterochromic, steroid induced, postcorneal surgery and phacomorphic glaucoma.

Table 2. Glaucoma device implantation.

	Donor sclera ($n = 163$)	Bovine pericardium $(n = 81)$	p-value
Tube location (quadrant)			
Superotemporal	140 (86.4%)	66 (81.5%)	0.31
Superonasal	22 (13.6%)	15 (18.5%)	
Operating surgeon			
ER	71 (43.6%)	23 (28.4%)	0.02
LJR	92 (56.4%)	58 (71.6%)	
Drainage suture	133 (83%)	46 (58.2%)	< 0.001
Concomitant eye surgery	0	0	-
Previous Baerveldt implantation in study eye	13 (8.0%)	6 (7.4%)	0.88

Values are described by N (%).

Statistically significant results are highlighted in bold.

Intraocular pressure

Table 4 presents measurements at baseline and one week and three months of follow-up. A significant reduction in IOP was observed after three months in both cohorts with an average reduction of 15.7 mmHg (95% CI, 13.8–17.6; p < 0.001, paired *t*-test) in the donor sclera group and 17.9 mmHg (95% CI, 15.3-20.6; p < 0.001) in the bovine pericardium group.

Mean IOP one week after surgery was significantly different between the cohorts. This difference can be explained by the large proportion (83%) of drainage sutures in the donor sclera cohort. This is shown in Figure 4 where the mean IOP of all cases is clustered for drainage suture use. Mean IOP was significantly lower at one-week follow-up in eyes when a drainage suture was used (p = 0.001, independent *t*-test). At three months, no significant difference in mean IOP was observed, apparently as the tubes in all of the drainage implants opened up and lowered the IOP equally in all cases.

Medical therapy

Surgical intervention in both cohorts caused a significant reduction in the use

of medical therapy (Table 4). After three months, the average number of glaucoma medications decreased from baseline by 1.35 (95% CI, 1.12–1.57; p < 0.001, paired *t*-test) in the donor sclera cohort and by 1.67 (95% CI, 1.34–1.99; p < 0.001) in the bovine pericardium cohort.

Discussion

This retrospective cohort study compares the use of donor sclera with bovine pericardium as patch graft material in glaucoma drainage device surgery. In the bovine pericardium cohort, 13.6% (n = 11) of the cases experienced tube exposure, while in the donor sclera cohort, none of the operated eyes developed tube exposure.

This is the first study to compare tube exposure rates between two relatively large groups using these patch graft materials. All patients were operated within the same facility by the same two surgeons. Consequently, with the surgeries being performed in one institution under the same circumstances, a better comparison between patch materials could be made.

The number of tube exposures in our bovine pericardium cohort was higher than reported in the most literature. Reported percentages vary from 2.0%, 5.0% and 8.3% to 8.5% (Gedde et al. 2012a,b; Ng et al. 2015; Trubnik et al. 2015; Chaku et al. 2016). In one paper, the authors aimed at decreasing the rate of tube exposure by applying a double layer of bovine pericardium during 59 GDD surgeries (Lankaranian et al. 2008). They reported no tube exposure during an average follow-up of 18.6 months. However, another study comparing single and double pericardium as patch material reported a tube exposure rate of 8.9% when using double pericardium with a mean minimum follow-up of 4.3 years (Ng et al. 2015).

Few studies report tube exposure rates specifically for human donor sclera as a patch graft. Authors have found tube exposure to occur in one of 23 (4.3%) donor sclera eyes when mean follow-up was 5.5 years (Smith et al. 2002). In a more recent study, where human donor sclera was used during 64 GDD surgeries, tube exposure occurred in 1.6% of the cases after an average follow-up of 18 months (Tsoukanas et al. 2016). Notably, the donor

Table 3.Tube exposures.

	Gender	Age (years)	Type of glaucoma*	Previous surgery**	IOP at baseline	Systemic Hypertension	Diabetes Mellitus	Smoking	Drainage suture	Time to tube exposure (in days)
1.	Female	66	Uveitic glaucoma	CA	20	No	Yes	No	Yes	267
2.	Female	85	POAG	CA	32	Unknown	No	Unknown	Yes	497
3.	Female	54	Postvitreoretinal surgery	CA + VR	34	No	No	No	Yes	11
4.	Male	59	POAG	CA + TE	23	Yes	No	No	Yes	1016
5.	Female	63	POAG	TE + BV	32	Yes	Yes	No	Yes	472
6.	Male	60	POAG	None	44	Yes	Yes	No	Yes	855
7.	Female	34	Fuchs heterochromic	TE	40	No	No	No	Yes	133
8.	Female	35	Fuchs heterochromic	TE + BV	32	No	No	No	Yes	36
9.	Male	27	POAG	None	34	No	No	Yes	No	496
10.	Female	50	PACG	CA + TE	35	No	No	No	No	39
11.	Male	54	POAG	TE + COR	34	No	No	No	Yes	114

Characteristics of patients with tube exposure.

* PACG = primary angle-closure glaucoma, POAG = primary open-angle glaucoma.

** Previous surgery: BV = Baerveldt implant, CA = cataract surgery, COR = corneal surgery, TE = trabeculectomy, VR = vitreoretinal surgery.

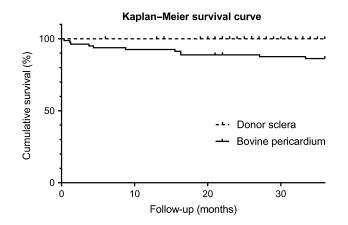


Fig. 2. Kaplan–Meier plots of the cumulative survival (nonoccurrence of tube exposure) in donor sclera cohort (n = 163) and bovine pericardium cohort (n = 81).

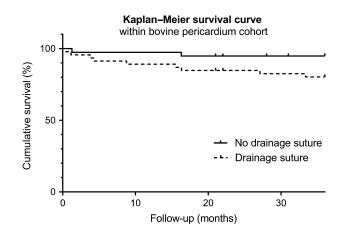


Fig. 3. Kaplan–Meier plots of the cumulative survival (nonoccurrence of tube exposure) of cases with and without a drainage suture within bovine pericardium cohort (n = 81).

sclera used in this study was fresh heterologous sclera that was left over after keratoplasty performed earlier the same day as the GDD surgery. While studied in smaller groups, these reported tube exposure rates are low, similar to our findings. When comparing the number of tube exposures from our donor sclera cohort to the exposure rates reported in other studies using other patch graft materials, we observed a substantially lower rate (Gedde et al. 2012a,b; Trubnik et al. 2015).

The rate of tube exposure when using bovine pericardium reported by other authors is still significant but lower than the 13.6% in our study. The reason for the increased number of tube exposures within our bovine pericardium cohort is not entirely clear. A difference between GDD surgery in our study and in other research is that, in the majority of cases in our study, a drainage suture was placed through the tube. Within the bovine pericardium, 58% received a drainage suture. It is being observed that bovine pericardium material functions as a matrix for the ingrowth of the bodies' own connective tissue (van Rijn et al. 2016). A drainage suture could cause intraocular fluid to accumulate around the patch graft material and in the case of bovine pericardium limit the ingrowth of connective tissue leading to melting of the patch graft. This hypothesis is supported by our observation that the drainage suture tends to increase the rate of tube exposure. As in instances where bovine pericardium is not surrounded by intraocular fluid, melting of the material is not being observed (van Rijn et al. 2016). In this current study, despite a trend in the survival analysis and an odds ratio of 3.45, a significant association between tube exposure and drainage sutures within the bovine pericardium cohort could not be demonstrated, however. This is possibly due to a limited sample size. One may suspect that the nylon of the drainage suture itself may have enhanced the tube erosion, particularly

 Table 4. Intraocular pressure and medical therapy.

	Donor sclera	Bovine pericardium	p-value
Baseline			
IOP (mmHg)	32.9 ± 10.3	33.4 ± 10.6	0.72
Glaucoma medications	3.0 ± 1.2	3.3 ± 0.9	0.21
One week			
IOP (mmHg)	15.8 ± 9.4	19.2 ± 11.7	0.03
Glaucoma medications	1.5 ± 1.5	2.1 ± 1.4	0.01
Three months			
IOP (mmHg)	17.1 ± 6.7	15.3 ± 6.3	0.06
Glaucoma medications	1.7 ± 1.2	1.6 ± 1.2	0.51

Data presented as mean \pm standard deviation.

Statistically significant results are highlighted in bold.

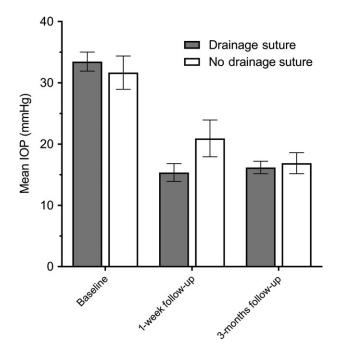


Fig. 4. Mean intraocular pressure (IOP) at baseline, one week and three months of follow-up clustered for drainage suture. Error bars: 95% CI.

in those cases where the bovine pericardium had melted. We think that this did not play a role, as in most cases, the drainage suture was removed long before melting (if any) of the patch material occurred.

As there was no tube exposure in the human donor sclera cohort, a drainage suture does not seem to have a negative effect on donor sclera, especially when considering that significantly more drainage sutures where placed in this cohort compared to the bovine pericardium cohort. Therefore, also the difference in tube exposures between our two cohorts can therefore not be explained by the difference in drainage sutures per se.

Other research demonstrated that black race was associated with a worse

outcome after GDD revision surgery caused by initial tube exposure (Huddleston et al. 2013). It is unclear whether black race leads to more tube exposure in the same way after the initial implantation of a GDD. Due to the retrospective nature of this study, we could not examine whether ethnicity was associated with such an outcome because of insufficient data in medical records. However, a difference in ethnicity between cohorts was not to be expected. As the choice of patch material was not determined by anything other than the moment in time, it is not likely that ethnicity differs significantly in time (months) within the same hospital.

Other studies demonstrated that a higher number of previous intraocular

surgery were a possible risk factor for tube exposure (Byun et al. 2009) and that concomitant intraocular surgery with GDD implantation may be a potential risk factor for future exposure (Trubnik et al. 2015).

In this study, the number of intraocular surgeries before GDD implantation did not differ significantly between the two cohorts, and no concomitant intraocular surgery was performed during any of the 244 operations. Consequently, these characteristics are not expected to have influenced the outcome of this study.

One of the surgeons performed more operations within the bovine pericardium cohort; however, no statistical relation was found between a specific operating surgeon and tube exposure. Difference in operating surgeon between cohorts therefore is not expected to be of great influence on the difference in rate of tube exposure between the two cohorts.

Regression analysis to assess confounding and effect modification between cohorts could not be performed as there were no events in the donor sclera cohort. However, no statistical differences were observed in patient characteristics and baseline values. This supports the conclusion that the lower rate of tube exposure in the donor sclera cohort might be caused mainly by the difference in patch graft material used.

With this study, we also demonstrated the effect of the drainage suture in a relatively large group of 179 eyes. Using a drainage suture through the tube results in a lower IOP immediately after surgery. When used together with human donor sclera as a patch graft, a drainage suture appears to be safe. It can be of assistance in protecting the eye from further glaucomatous damage by avoiding or dampening the postoperative hypertonic phase which up until now was characteristic for a nonvalved GDD such as the Baerveldt implant.

Of the eleven cases that experienced tube exposure, none of the eyes developed endophthalmitis during followup. This might contradict the idea that exposure of the tube inevitably leads to serious infection.

All data were collected by retrospective chart review, and an obvious limitation is that certain patient demographics could not be collected for all patients and that the effects of patch graft and drainage suture could not be studied independently of each other.

In conclusion, a significantly lower occurrence of tube exposure was observed in patients who received human donor sclera as a patch graft material in comparison with patients who received bovine pericardium. No differences in intraocular pressure and medical therapy were seen between patch materials at three months of follow-up. A drainage suture lowers IOP directly after surgery. Tube exposure tends to be enhanced by a drainage suture when bovine pericardium is used, but not when donor sclera is used. Based on these results, using human donor sclera is preferred above bovine pericardium in GDD surgery.

References

- Bailey AK, Sarkisian SR Jr (2014): Complications of tube implants and their management. Curr Opin Ophthalmol 25: 148–153.
- Brandt JD (1993): Patch grafts of dehydrated cadaveric dura mater for tube-shunt glaucoma surgery. Arch Ophthalmol **111**: 1436– 1439.
- Budenz DL, Barton K, Feuer WJ, Schiffman J, Costa VP, Godfrey DG, Buys YM & Ahmed G Baerveldt Comparison Study (2011): Treatment outcomes in the Ahmed Baerveldt Comparison Study after 1 year of follow-up. Ophthalmology 118: 443–452.
- Byun YS, Lee NY & Park CK (2009): Risk factors of implant exposure outside the conjunctiva after Ahmed glaucoma valve implantation. Jpn J Ophthalmol **53**: 114– 119.
- Chaku M, Netland PA, Ishida K & Rhee DJ (2016): Risk factors for tube exposure as a late complication of glaucoma drainage implant surgery. Clin Ophthalmol **10**: 547–553.
- Desai MA, Gedde SJ, Feuer WJ, Shi W, Chen PP, Parrish RK 2nd (2011): Practice preferences for glaucoma surgery: a survey of the

American Glaucoma Society in 2008. Ophthalmic Surg Lasers Imaging **42**: 202–208.

- Gedde SJ, Herndon LW, Brandt JD, Budenz DL, Feuer WJ, Schiffman JC & G Tube Versus Trabeculectomy Study (2012a): Postoperative complications in the Tube Versus Trabeculectomy (TVT) study during five years of follow-up. Am J Ophthalmol 153: 804–814.
- Gedde SJ, Schiffman JC, Feuer WJ, Herndon LW, Brandt JD, Budenz DL & G Tube versus Trabeculectomy Study (2012b): Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. Am J Ophthalmol 153: 789– 803.
- Huddleston SM, Feldman RM, Budenz DL et al. (2013): Aqueous shunt exposure: a retrospective review of repair outcome. J Glaucoma **22**: 433–438.
- Lankaranian D, Reis R, Henderer JD, Choe S & Moster MR (2008): Comparison of single thickness and double thickness processed pericardium patch graft in glaucoma drainage device surgery: a single surgeon comparison of outcome. J Glaucoma 17: 48–51.
- Lind JT, Shute TS & Sheybani A (2016): Patch graft materials for glaucoma tube implants. Curr Opin Ophthalmol **28**: 194–198.
- Ng JY, Sng CC, Liao J, Aquino MC & Chew P (2015): Glaucoma drainage device exposure in Asian eyes. Clin Exper Ophthalmol **43**: 85–88.
- Rietveld E, Jansonius NM & Muskens RPHM (2009): Immediate pressure reduction with baerveldt glaucoma implants. Invest Ophthalmol Vis Sci 50: 445–445.
- van Rijn LJ, van De Ven SJ, Krijnen JS, Jansen SM, Bakels AJ & Langenhorst AM (2016): Tendon elongation with bovine pericardium (Tutopatch(R)) when conventional strabismus surgery is not possible. Eur J Ophthalmol 26: 193–202.
- Roberts MF, Fishman GA, Roberts DK, Heckenlively JR, Weleber RG, Anderson RJ & Grover S (2002): Retrospective, longitudinal, and cross sectional study of visual acuity impairment in choroideraemia. Br J Ophthalmol 86: 658–662.

- Smith MF, Doyle JW, Ticrney JW Jr (2002): A comparison of glaucoma drainage implant tube coverage. J Glaucoma 11: 143–147.
- Spierer O, Waisbourd M, Golan Y, Newman H & Rachmiel R (2016): Partial thickness corneal tissue as a patch graft material for prevention of glaucoma drainage device exposure. BMC Ophthalmol 16: 20.
- Trubnik V, Zangalli C, Moster MR, Chia T, Ali M, Martinez P, Richman J & Myers JS (2015): Evaluation of risk factors for glaucoma drainage device-related erosions: a retrospective case-control study. J Glaucoma 24: 498–502.
- Tsoukanas D, Xanthopoulou P, Charonis AC, Theodossiadis P, Kopsinis G & Filippopoulos T (2016): Heterologous, fresh, human donor sclera as patch graft material in glaucoma drainage device surgery. J Glaucoma 25: 558–564.
- Van Aken E, Lemij H, Vander Haeghen Y & de Waard P (2010): Baerveldt glaucoma implants in the management of refractory glaucoma after vitreous surgery. Acta Ophthalmol 88: 75–79.
- Vass C, Hirn C, Sycha T, Findl O, Bauer P & Schmetterer L (2007): Medical interventions for primary open angle glaucoma and ocular hypertension. Cochrane Database Syst Rev (4): CD003167.
- Wright C, Tawfik MA, Waisbourd M & Katz LJ (2016): Primary angle-closure glaucoma: an update. Acta Ophthalmol 94: 217–225.

Received on July 9th, 2017. Accepted on January 10th, 2018.

Correspondence

Laurentius J. van Rijn, MD Department of Ophthalmology VU University Medical Center PO Box 7057 1007 MB Amsterdam, the Netherlands Tel: +31204444795 Email: vanrijn@vumc.nl