Ocular motility changes and diplopia in sutured versus unsutured implantation of the Baerveldt glaucoma device

Esma Islamaj,¹ Caroline P. Jordaan-Kuip,¹ Peter W.T. De Waard,² Koen A. Vermeer¹ and Hans G. Lemij²

¹Rotterdam Ophthalmic Institute, Rotterdam Eye Hospital, Rotterdam, the Netherlands ²Glaucoma Department, Rotterdam Eye Hospital, Rotterdam, the Netherlands

ABSTRACT.

Purpose: To investigate the effect of two surgical techniques in primary Baerveldt glaucoma implant (BGI) surgery, that is the sutured technique and the unsutured (free) plate technique, on the ocular motility and prevalence of diplopia. We hypothesize that the free plate technique results in a lower diplopia prevalence.

Methods: We performed a prospective study of patients who underwent BGI surgery with the free plate technique and compared them with patients from a previous study who had undergone BGI surgery with the sutured technique. Their ductions, ocular alignment and fusion range and the prevalence of diplopia were measured before surgery and at 3 months, 6 months and 1 year postoperatively. *Results:* We analysed 57 free plate and 51 sutured plate patients. One year postoperatively, we found no statistically significant difference in the prevalence of diplopia between the two techniques. All duction changes between baseline and 1-year follow-up were restrictions and occurred statistically significantly more frequently in the free plate than in the sutured plate group (p = 0.03; 60% versus 34%). About the ocular alignment, in the horizontal direction, a change in exodirection was more common in both groups, while in the vertical direction, a hyperdeviation of the operated eye was more common. The vertical ocular alignment change was smaller in the free plate group than in the sutured plate group (p = 0.04 at near and p = 0.02 at distance).

Conclusions: One year postoperatively, the prevalence of diplopia was not significantly different between patients with the sutured plate and patients with the free plate technique. Both surgical techniques induce diplopia and changes in ocular motility and/or in ocular alignment.

Key words: baerveldt - diplopia - glaucoma surgery - surgical technique

doi: 10.1111/aos.14707

Introduction

A commonly reported long-term complication after the implantation of a glaucoma drainage device such as the Baerveldt glaucoma implant (BGI) is a restriction of the ocular motility (Rauscher et al. 2009; Bailey & Sarkisian 2014; Desai 2017; Sun et al. 2017). Reduced ocular motility may in turn lead to persistent strabismus and diplopia – the simultaneous perception of two images of a single object or double vision (Ansons & Davis 2014). We have previously reported that 35% of the patients with the sutured technique showed reduced ocular motility 1 year after primary BGI surgery (Islamaj et al. 2018b). In the same study, 1 year postoperatively, diplopia was still reported by approximately 28% of patients with a BGI.

We speculated that a reduction in the prevalence and severity of this diplopia might be achieved by applying a different surgical technique, which we refer to as the free plate technique. The conventional implantation procedure of BGI surgery involves securing the plate to the sclera by two sutures, posterior to the insertions of two extraocular muscles, typically the superior and lateral rectus muscles. We speculate that the extraocular muscles might then be restricted in their contraction and relaxation due to the development of fibrotic adhesions between the fibrotic capsule surrounding the BGI plate and (parts of) the extraocular muscles. In addition, we speculated that the fibrotic capsule itself, notably once filled with aqueous, might sit in the way of free movements by its sheer volume. By not suturing the plate to the globe, that is placing the plate 'freely', it would find a position in which the plate and its encompassing bleb would minimally restrict normal

Acta Ophthalmol. 2021: 99: e949-e955

^{© 2021} 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-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is noncommercial and no modifications or adaptations are made.

eye movements. Furthermore, by placing the plate quite posteriorly, any fibrotic adhesions between the capsule and the extraocular muscles should be less likely to come about. In a preliminary, unpublished and retrospective review, we interviewed 87 patients with a sutured plate and 86 patients with a free plate about the presence of diplopia after their primary BGI surgery. A fewer of the patients with the free plate technique appeared to suffer from diplopia compared to the patients with the sutured plate technique (20% versus 41%, respectively).

Therefore, we hypothesized that the free plate surgical technique in primary glaucoma surgery leads to a lower prevalence of (persistent) diplopia than the conventional, sutured technique.

Methods

Study design

We performed a prospective, cohort study of patients who underwent primary BGI surgery with the free plate technique and compared them with patients from a previous cohort study who underwent BGI surgery with the conventional sutured technique. This study was approved by the medical research ethics committee of the Erasmus Medical Center (Rotterdam, The Netherlands) and was registered at www.trialregister.nl (identifier NTR4826). The research followed the tenets of the Declaration of Helsinki. Patients were selected at the outpatient glaucoma department of the Rotterdam Eye Hospital. Written informed consent was collected from all patients after a detailed explanation of the study procedures involved was provided.

Patients who were scheduled for a Baerveldt implantation were asked to join the study. Inclusion and exclusion criteria were similar for both surgical techniques. Inclusion criteria included age (18-75 years), Caucasian origin, binocular single vision and primary open-angle glaucoma, normal-tension glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma. Exclusion criteria consisted of a history of best-corrected strabismus, Snellen visual acuity less than 20/200 in one or both eyes or previous ocular surgery in the study eye, for example cataract surgery, trabeculectomy or BGI surgery. Other exclusion criteria were

a history of active uveitis or diabetic retinopathy, pregnancy or lactation, anticipated glaucoma surgery combined with other ocular procedures (i.e. cataract surgery) and a narrow anterior chamber angle interfering with tube implantation.

Surgical procedures

Eighty-four patients underwent BGI surgery (BG-101-350, Advanced Medical Optics Inc. Santa Ana, CA, USA) with the free plate technique. The BGI plate was placed in all patients in the superotemporal quadrant, with its wings sitting under the lateral and superior rectus muscles. It was slid posteriorly over the sclera so that the plate was thought to have less contact with any of the extraocular muscles.

The tube was occluded with a single vicryl 7.0 ligature and sized to fit in the anterior chamber of the operated eye. The surgeon made an entry into the anterior chamber behind the limbus and positioned the tip of the tube at a maximal distance of the corneal endothelium, anterior to the iris. The tube was sutured close to the limbus with a 9.0 nylon suture, to prevent the tube from slipping either into or out of the anterior chamber. The nylon suture passed through the tube lumen, which allowed some egress of aqueous out of the tube during the early postoperative phase to avoid any intraocular pressure spikes. The tube was then covered with a graft of donor sclera with a size of approximately 4 by 12 mm, which was sutured to the recipient sclera with interrupted vicryl 7.0 sutures. The surgeon closed the conjunctiva and Tenon's capsule with a running suture (vicryl 7.0). At the end of the surgery, Dexamytrex (Dexamethasone/gentamycin) eye ointment was applied to the eye before padding it with an eye bandage. The postoperative regimen also consisted of local steroids that were tapered over a period of 3 months. No postoperative antibiotics or subconjunctival injections were administered. Intraocular pressure (IOP)-lowering medication was prescribed as required at the surgeon's discretion.

We compared the results of this patient group to the results of a study in which 59 patients received the plate sutured in a standard fashion to the sclera, positioned with its wings just behind the insertions of the rectus muscles (Islamaj et al. 2018a; Islamaj et al. 2018b). The closing visits of this comparative group had finished just a few weeks prior to the start of the current study. By using the data from this comparative group, the time for recruiting was reduced for the current study. Apart from suturing the plate to the sclera just underneath the rectus muscles, the surgical procedures had been similar to those in the free plate group.

Study procedures and outcome measures

The goal of this study is to reduce the incidence of persistent diplopia after primary BGI surgery. Therefore, measurements started after the adapting period of 3 months postoperatively. All patients were measured before surgery, as well as 3 months, 6 months and 1 year after surgery.

To quantify any diplopia, we first asked patients about the presence of any diplopia 3 months, 6 months and 1 year after surgery. If diplopia was reported, we determined the severity of this side-effect by using the diplopia severity scale introduced by Paridaens et al. (2006). The severity was graded according to its effect on the patient's daily activities, ordered from mild to severe: diplopia experienced in one or more gaze directions (gaze-evoked diplopia), intermittent diplopia in the primary and/or reading position and continuous diplopia in the primary and/or reading position. This scale was only used to point out that there are several levels in severity of this complaint and in literature every level was not always taken into account. For analysis, the presence or absence of (any form of) diplopia was used.

To quantify any ocular motility changes after surgery, an orthoptist measured the ductions, ocular alignment and fusion range of the two eyes in each patient.

The ductions of both eyes were measured in eight gaze directions by means of a synoptophore; these were elevation, depression, adduction, abduction, elevation in 25° abduction, depression in 25° abduction, depression in 25° abduction and depression in 25° adduction. A significant duction change between baseline and postoperative follow-up visits was defined as 2° or more; this threshold of 2° was based on the repeatability of motility measurements (Rauscher et al. 2009; Jellema et al. 2011). The maximum range of a synoptophore is 40° (in abduction and adduction) and 30° (all other directions). We assumed that there were no duction limitations beyond these extremes, if no restrictions had been found within the tested range. A change could occur in more than one direction.

We evaluated the patient's ocular alignment at near fixation with the alternate prism cover test with the patient fixating at 30 cm distance. A significant change in ocular alignment between preoperative and postoperative follow-up visits was defined as 4 prism dioptres (PD) or more (Rauscher et al. 2009). Additionally, ocular alignment while fixating at distance was measured with the synoptophore. The horizontal and vertical fusion ranges were also determined with the synoptophore.

We examined the visual fields by white-on-white standard automated perimetry with the Humphrey Field Analyser 24-2 SITA standard programme (HFA; Carl Zeiss Meditec, Dublin, CA, USA) for each eye to asses any visual field loss. Afterwards, the patient's mean deviation (MD) was classified into three visual field loss Hodapp-Parrishcategories after Anderson (Hodapp et al., 1993); mild (MD > -6 dB),moderate (-6 dB > MD > -12 dB) or advanced (MD < -12 dB).

Statistical analysis

A univariate analysis was performed by using the unpaired *t*-test for independent samples and a paired t-test for dependent samples with a normal distribution. For independent samples with a non-normal distribution, such as motility changes, the Mann-Whitney U test was performed. Categorical variables, such as diplopia, were evaluated with Fisher's exact test when comparing the groups, and Wilcoxon and Friedman's ANOVA test when comparing the results over time within the group. We analysed the results before and after surgery within the free plate group (paired test, repeated measures ANOVA) and between the free plate and sutured group (unpaired test). The Bonferroni correction was applied. To identify any predictors, a logistic regression analysis was executed. A

Kendall's tau-b correlation was used to determine the relationship between the prevalence of diplopia and motility variables. The Kendall's tau-b is a nonparametric correlation for small data sets with a large number of tied ranks. All statistical calculations were done in SPSS (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY, USA: IBM Corp.).

Results

Between January 2015 and December 2017, we included 84 patients who were scheduled for a BGI implantation with the free plate technique. During follow-up, five patients withdrew their informed consent before completing all visits. After excluding those patients that had already had a BGI in their fellow eye (eight) or received a BGI in either eye during follow-up (13), 57 patients remained for analysis (Table 1).

At baseline, the free plate patients 66 ± 9 years were of age (mean \pm SD). We found 26 patients (46%) with limited ductions before surgery. Furthermore, the group consisted of 54% men and 46% women, 44% right eyes and 56% left eyes. The most common diagnosis was primary open-angle glaucoma (79% and 82% in the free plate group and the sutured group, respectively). Other diagnoses were normal-tension glaucoma (13% and 6%), pigmentary glaucoma (5% and 6%) and pseudo-exfoliative glaucoma (3% and 6%). No significant

Table 1. Number of patients before and after exclusions.

| | Free plate group | Sutured plate group |
|-----------------------------------------------------------------------|------------------------|---------------------------|
| Before exclusions Exclusions due to | 84 | 59 |
| Diplopia at screening | -1 | -1 |
| Withdrawn informed | -5 | 0 |
| consent BGI in fellow eye | -8 | 0 |
| BGI in fellow eye within first year of | -12 | -7 |
| follow-up 2 nd BGI in study eye within first year of | -1 | 0 |
| follow-up Final group size after exclusions | 57 | 51 |

difference was found in the distribution of diagnoses between the two groups (p = 0.66; chi-square test).

When comparing the baseline characteristics of the two groups, we found no difference between the groups in gender, study eye or MD of the visual field. However, the age was statistically significantly differently distributed between the two study groups (p < 0.004; Kolmogorov–Smirnov test; range 27-82 years in the sutured group and 40-85 years in the free plate group). Patients in the free plate group were slightly older than the patients in the sutured plate group (60 \pm 11 years; p = 0.002; independent *t*-test). As for the orthoptic measurements at baseline, there was a statistically significant difference in ductions between the study groups (46% free plate patients versus 10% sutured plate patients with restricted ductions; p < 0.001; Fisher's exact test). We did not look into possible reasons for these differences as we focused on the surgically induced changes between before and after surgery. The ocular alignments and fusion ranges were similar for the two groups.

Diplopia

Diplopia occurred in both groups at all postoperative visits (Figs 1 and 2). At 1 year postoperatively, both study groups reported the same prevalence of diplopia, namely 28% of the patients. Within the two groups, the prevalence of diplopia did not change statistically significantly between 3 months and 6 months and 6 months and 1 year of follow-up (p = 0.2 for)the free plate group and p = 0.7 for the sutured plate group; Friedman's ANOVA test). In total, 38 patients developed diplopia at some point during our follow-up. In nine of these patients, the diplopia disappeared after 3 and 6 months postoperatively. There were seven of these cases that newly developed diplopia at 6 months after surgery. No new cases were reported at 1 year postoperatively.

When comparing the study groups, we found no statistically significant difference in prevalence of diplopia between the free plate and the sutured technique at 3 months (p = 0.15; Fisher's exact test), 6 months (p = 0.60) and 1 year after surgery (p = 0.81).









Ductions

One year after surgery, the ductions in both study groups were statistically significantly reduced compared to baseline. At 1 year of follow-up, the ductions in the free plate group became statistically significantly more restricted in abduction (p = 0.017), (p < 0.001), adduction elevation (p = 0.001), elevation in 25° abduction (p < 0.001) and in elevation in 25° adduction (p = 0.005). As for the sutured group, the changes in ductions were mostly restricted in elevation (p < 0.001), in elevation in 25° adduction (p = 0.044) and in elevation in 25° abduction (p < 0.001).

When comparing the duction change (i.e. baseline versus 1 year postoperatively) between the two study groups, statistically significantly more patients with the free plate technique developed (more) reduced ductions (p = 0.03;duction changes were observed in 60% of the free plate patients versus 34% of the sutured patients; Table 2). Furthermore, the free plate technique showed statistically significantly greater duction changes than the sutured technique, especially in abduction (p = 0.002), adduction (p = 0.007) and depression (p = 0.014; Table 2).

Ocular alignment

In the free plate group, no statistically significant change was found in horizontal or vertical ocular alignment between baseline and 1 year after surgery. By contrast, in the sutured group, the change between baseline and 1 year after surgery in near ocular alignment was statistically significant both horizontally, with a change of -0.7 ± 4.8 PD (p = 0.04) and vertiof cally with a change -0.7 ± -2.5 PD (p = 0.01). The horizontal near-ocular alignment change was more common in the exodirection than in the esodirection in both groups; seven patients developed a horizontal change in ocular alignment in the exodirection $(-2.6 \pm 3.7 \text{ PD})$ and three patients in the esodirection $(4.6 \pm 1.4 \text{ PD})$ in the sutured group, as compared to 10 patients in the exodirection (-5.7 ± 5.6 PD) and six patients in the esodirection $(2.1 \pm 1.7 \text{ PD})$ in the free plate group. In the total group, a change in vertical direction was seen in 18 patients. We

Table 2. Orthoptic changes of the overall group between the two groups 1 year after surgery.

| | Free plate $n = 57$ | Sutured plate $n = 51$ | p-value between study groups | |
|-----------------------------------------------------------------------------------------------------------|---------------------|------------------------|------------------------------------|--|
| No diplopia <i>n</i> (%) | 41 (72) | 37 (72) | 0.81 [†] | |
| Diplopia n (%) | 16 (28) | 14 (28) | | |
| In gaze direction | 11 (19) | 6 (12) | | |
| Intermittently in primary and/or reading position | 4 (7) | 7 (14) | | |
| Continuously in primary and/or reading position | 1 (2) | 1 (2) | | |
| No duction change n (%) | 20 (35) | 26 (51) | 0.03 [†] | |
| Duction change n (%) | 34 (60) | 18 (35) | | |
| Unknown (%) | 3 (5) | 7 (14) | | |
| Duction changes Δ overall group (mean \pm SD) (°): (a patient can have a change in >1 direction) | | | | |
| Δ abduction | -2.4 ± 4.5 | -0.5 ± 2.1 | 0.002 [‡] | |
| Δ adduction | -1.9 ± 5.9 | 0.3 ± 1.8 | 0.007 [‡] | |
| Δ elevation | -2.9 ± 5.9 | -1.9 ± 4.2 | 0.223 [‡] | |
| Δ depression | 0.9 ± 3.9 | 0.0 ± 0.0 | 0.014 [‡] | |
| Δ elevation in 25° abduction | -3.6 ± 6.2 | -2.3 ± 4.0 | 0.093 [‡] | |
| Δ elevation in 25° adduction | -2.4 ± 6.8 | -1.4 ± 4.5 | 0.076^{\ddagger} | |
| Δ depression in 25° abduction | -0.0 ± 1.3 | 0.0 ± 0.3 | 0.561 [‡] | |
| Δ depression in 25° adduction | -0.1 ± 1.2 | 0.1 ± 0.9 | 0.458 [‡] | |
| Ocular alignment deviation (mean \pm SD) | | | | |
| Δ near, horizontal (PD) | -0.5 ± 2.7 | -0.7 ± 4.8 | 0.664 [‡] | |
| Δ distance, horizontal (°) | -0.1 ± 1.4 | -0.1 ± 3.0 | 0.308 [‡] | |
| Δ near, vertical (PD) (R/L) | -0.1 ± 1.1 | -0.7 ± 2.5 | 0.044 [‡] | |
| Δ distance, vertical (°) (R/L) | -0.1 ± 0.6 | -0.5 ± 1.2 | 0.021 [‡] | |
| Δ near, vertical (PD) (study/fellow eye) | 0.5 ± 2.5 | 0.1 ± 1.0 | 0.041 [‡] | |
| Δ distance, vertical (°) (study/fellow eye) | 0.2 ± 1.3 | -0.1 ± 0.7 | 0.023 [‡] | |
| Change in fusion range (mean \pm SD) | | | | |
| Δ horizontal (°) | -5.4 ± 9.9 | -4.1 ± 13.2 | 0.500^{\ddagger} | |
| Δ vertical (°) | -0.3 ± 1.2 | -0.3 ± 1.7 | 0.731 [‡] | |

Duction changes with a negative sign express a reduction. Similarly, for the change in fusion range, a negative sign represents a reduction of the range, while a positive sign shows an increase of the range. About the horizontal ocular alignment deviations, a negative sign represents a shift in exodirection, while a positive sign represents a shift in esodirection. In the first vertical ocular alignment, a negative sign represents a shift in elevation of the left eye relative to the right eye (L/R or R/L), a positive sign a shift in elevation of the right eye relative to the left eye. In the second vertical alignment, a positive sign refers to a shift in elevation of the study eye, while a positive sign refers to a shift in elevation of the study eye.

Bold values indicate significance level at p < 0.05.

n = number of patients.

* Wilcoxon signed-rank test.

[†] Chi-squared test.

[‡] Wilcoxon rank-sum test.

found a hyperdeviation of the operated eye in 72% of the patients (13 patients) with a change in the vertical alignment of operated eyes over the non-operated eyes (1 year after surgery).

When comparing the two study groups, there was no statistically significant difference in the magnitude of the change in horizontal ocular alignment following surgery (Table 2). Vertically, however, the sutured group developed a statically significantly larger ocular alignment change than the free plate group (p = 0.04 at near and p = 0.02 at distance; when looking at the change in study eye over fellow eye

p = 0.04 at near and p = 0.02 at distance; Table 2).

Fusion range

In the free plate group, 36 out of 57 patients (63%) showed a statistically $9.9 \pm 8.7^{\circ}$ of significant loss (mean \pm SD) in their horizontal fusion range (p < 0.001; Wilcoxon signedrank test), while 11 out of 57 free plate patients (19%) showed a statistically of $2 \pm 0.5^{\circ}$ significant loss (mean \pm SD) in their vertical fusion range (p = 0.04; Wilcoxon signed-rank test). In the sutured plate group, 23 out of 51 patients (45%) showed a statistically significant loss of $12.5 \pm 10.3^{\circ}$ (mean \pm SD) in their horizontal fusion range (p = 0.01). Vertically, 15 out of 51 sutured plate patients (29%) showed a loss of $1.9 \pm 1.1^{\circ}$. However, this loss was not statistically significant (p = 0.31).

When comparing the study groups, no significant difference was found between the prevalences in the horizontal fusion range (p = 0.08) nor in vertical fusion range (p = 0.26). Also, the magnitude of change was not statistically significantly different for the two groups (p = 0.50 in horizontal fusion range and 0.73 in vertical fusion range; Table 2).

Visual field

The mean deviation of the visual field did not change statistically significantly throughout the follow-up period in the two groups (p = 0.54 for the study eye and 0.21 for the fellow eye). Patients with diplopia had less severe visual field loss than patients without diplopia (p = 0.04; Figure 3). Of the free plate patients that experienced diplopia, 87% (14 of the 16 patients) had mild glaucomatous visual field loss in one or both eye(s), while this was observed in 77% of the patients without diplopia. These findings were similar to those in the sutured plate group. In the latter group, 86% of the patients that experienced diplopia (12 of the 14 patients) had mild glaucomatous visual field loss in one or both eye(s), while this was observed in only 57% of the patients without diplopia.

Discussion

Contrary to the results of our previous, unpublished retrospective review, we did not find a difference in prevalence of diplopia between the two surgical techniques, that is with the plate sutured to the sclera or left unsutured (free plate). The results of our study showed that both techniques result in about a quarter of all patients reporting diplopia at 1 year after surgery.

Furthermore, the free plate did not lead to fewer duction restrictions. On the contrary, 1 year after surgery, in the free plate group more patients had reduced ductions (60%) than in the sutured plate group (35%). The sutured technique induced a larger change in the vertical ocular alignment of the patient than the free plate technique.

Whenever an ocular alignment change developed in our patients, it occurred most frequently in the exodirection. The change in exodirection may be explained by the extraocular muscles' function. A possible explanation can be found at the level of the lateral rectus muscle. When placing the plate under the muscle, the muscle will probably be restricted in its relaxation, turning the eye in exodirection. This hypothesis was confirmed by a consistent hyperdeviation of the operated eye. The restricted ductions as well as the possible esodeviations may be explained by the posterior adhesion of the muscle to the BGI plate and/or its capsule, like after Faden surgery (weakening of the muscle in its field of action without much slackening and alteration in de primary position) (Jayakumar et al. 2019).

At baseline, there was a difference in age. This might have affected the preoperative ductions. Shechtman et al. (2005) showed a gradual decrease in horizontal and vertical gaze directions with advancing age with a steep decline after the age of 60 years. In our study, the free plate patients were on average 6 years older than the sutured patients. We suspect that a difference of 6 years in age between the two groups might have had a small effect on the changes in ductions that we observed.

To our knowledge, no study into the effects of a BGI on ocular motility and diplopia has mentioned various grades of diplopia such as gaze-evoked or intermittent diplopia. Therefore, only continuous diplopia in the primary position and or reading position can be compared. At 1 year after surgery, our results (2%), concerning the prevalence of persistent diplopia, are in agreement with the results of Abdelaziz et al. (2013) (1.4%) and Rauscher et al. (2009) (5%).

Abdelaziz et al. (2013) stated in their retrospective study that 18.8% of the patients developed diplopia between 3 and 9 months after surgery. In our



VISUAL FIELD LOSS

Fig 3. Glaucoma stage of the two eyes of patients with and without diplopia of the two study groups combined (n = 108).

study, however, the prevalence of diplopia at 3 months was higher than reported by Abdelaziz (41% in the sutured group and 23% in the free plate group). This difference between our and their results could be explained by the retrospective nature of their study.

We should point out that the answer to the question about the presence of any diplopia is of a subjective nature. Looking at the magnitude and the prevalence of the measured motility disturbances, we would expect that these disturbances result in a higher prevalence of diplopia than is reported by our study patients. A possible explanation for this difference in prevalence of diplopia and motility disturbances is that glaucoma patients often have visual field loss. In both our study groups, patients with diplopia often had less severe visual field loss than patients without diplopia. In the TVT study (Rauscher et al. 2009), the authors found the same discrepancy; motility disturbances were detected in 28% of their patients, while only 5% of the patients reported persistent diplopia. An interesting future topic would be to investigate the relationship between the overlapping intact visual field of the two eyes and diplopia.

A limitation of this study is that the groups were not randomized. Instead, a new group of patients received the free plate technique and was compared with an existing group with the conventionally sutured technique of a study carried out immediately prior to the present one. Although this approach obviously speeded up the inclusion of patients, a selection bias - due to the significant age difference may have been introduced. Furthermore, in the sutured group, the orthoptic measurements were executed by several orthoptists at the orthoptic department of the eye hospital, while the ductions of the free plate group were measured by one orthoptist and her back-up orthoptist at the Rotterdam ophthalmic institute, which could

explain the difference in ductions at baseline between the study groups. Finally, measuring stereo acuity at baseline could have provided us with more detailed information about the binocular vision.

In conclusion, at 1 year after surgery, the prevalence of diplopia was similar for the two study groups. However, as with the free plate technique the plate is placed significantly more posteriorly, far away from the extraocular muscles, we should question whether the plate could be traced when resurgery is necessary. Another concern could be whether the freely placed plate could move towards the optic nerve. Therefore, we suggest that the surgeon needs to weigh up these advantages and disadvantages with a critical eye and consider the situation of each patient individually whether the plate should be sutured or placed freely.

Diplopia is a serious complication of BGI surgery which needs proper attention. In future work, we aim to investigate the underlying mechanisms of these changes, to reduce the occurrence of diplopia following BGI surgery.

References

- Abdelaziz A, Capó H, Banitt MR, Schiffman J, Feuer WJ, McKeown CA, Spencer NE & Parrish RK (2013): Diplopia after glaucoma drainage device implantation. J AAPOS 17: 192–196.
- Ansons AM & Davis H (2014): Diagnosis and management of ocular motility disorders.4th edn. West Sussex: Wiley-Blackwell.
- Bailey AK & Sarkisian SR (2014): Complications of tube implants and their management. Curr Opin Ophthalmol 25: 148–153.
- Desai P (2017): Diplopia common after glaucoma drainage device surgery. Am Acad Opthalmol.
- Hodapp E, Parrish RKI & Anderson D (1993): Clinical decisions in glaucoma, 1st edn. London: Moby.
- Islamaj E, Jordaan-Kuip CP, Vermeer KA, Lemij HG & de Waard PWT (2018a): Motility changes and diplopia after baerveldt glaucoma drainage device

implantation or after trabeculectomy. Transl Vis Sci Technol 7: 7.

- Islamaj E, Wubbels RJ & de Waard PWT (2018b): Primary Baerveldt versus trabeculectomy study after one-year followup. Acta Ophthalmol **96**: e740–e746.
- Jayakumar M, Vel S & Agarwal A (2019): Modified Faden operation –a new surgical technique. Indian J Ophthalmol **67**: 264– 266.
- Jellema HM, Baader A, Pitz S, Prick L, Wiersinga WM & Mourits MP (2011): Comparison of cyclodeviation and duction measurement in Graves' orbitopathy patients using different devices. Strabismus 19: 43–51.
- Paridaens D, Lie A, Grootendorst RJ & van den Bosch WA (2006): Efficacy and side effects of 'swinging eyelid' orbital decompression in Graves' orbitopathy: a proposal for standardized evaluation of diplopia. Eye 20: 154–162.
- Rauscher FM, Gedde SJ, Schiffman JC, Feuer WJ, Barton K & Lee RK (2009): Motility disturbances in the tube versus trabeculectomy study during the first year of followup. Am J Ophthalmol 147: 458–466.
- Shechtman D, Shallo-Hoffmann J, Rumsey J, Riordan-Eva P & Hardigan P (2005): Maximum angle of ocular duction during visual fixation as a function of age. Strabismus 13: 21–26.
- Sun PY, Leske DA, Holmes JM & Khanna CL (2017): Diplopia in medically and surgically treated patients with glaucoma. Ophthalmology **124**: 257–262.

Received on April 8th, 2020. Accepted on November 9th, 2020.

Correspondence:

Esma Islamaj Rotterdam Ophthalmic Institute (ROI), Rotterdam Eye Hospital Schiedamse Vest 160d 3011 BH Rotterdam the Netherlands Tel: +31 (0) 615916399 Fax: +31 (0) 104023449 Email: e.islamaj@oogziekenhuis.nl

Gratitude goes to the patients that participated in this study and also to the clinical research unit of the Rotterdam Ophthalmic Institute for collecting the data. The study was financially supported by ZonMw Topzorg (projectnr 842005004), Rotterdamse Stichting Blindenbelangen and Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO) prof. Dr. H.J. Flieringa.