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Changes in macular thickness after trabeculectomy with or without adjunctive 5-fluorouracil

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Background. The aim of the study was to assess changes in macular thickness after trabeculectomy in respect to the use of 5-fluorouracil (5-FU) as well as to analyse possible associations between the postoperative changes in macular thickness and intraocular pressure (IOP).

Materials and methods. The prospective observational study included 106 eyes (100 patients) with glaucoma who underwent trabeculectomy with or without 5-FU. Subsequently 5-FU needling was performed if failure of the filtrating bleb occurred. Macular thickness and the IOP were evaluated before, one week, and six months after the surgery. The mean and sectoral macular thickness was assessed using spectral domain optical coherence tomography.

Results. The mean (±SD) IOP reduced from 27.71 (±6.88) mmHg at baseline to 18.3 (±8.1) mmHg one week ($p < 0.001$) and 15.1 (±7.6) mmHg six months ($p < 0.001$) after trabeculectomy. One week postoperatively, the mean macular thickness increased from 285.19 (±15.98) µm to 288.9 (±16.31) µm ($p < 0.001$); macular thickening was significant in all subfields ($p < 0.001$) and correlated positively with IOP reduction (*rho* = 0.312, $p = 0.001$ for central subfield). After six months, macula remained thicker only at the central and inner nasal subfields ($p < 0.05$). The changes in macular thickness were not affected by the use of 5-fluorouracil.

Conclusions. Trabeculectomy may induce a slight macular thickening which is more pronounced in the early postoperative period. The IOP reduction plays an important role in this process and is associated with thicker postoperative macula. However, the use of adjunctive 5-FU has no influence on macular thickness after glaucoma surgery despite its potential hypotonic, inflammatory and cytotoxic effects.

Keywords: retinal thickness, macula, trabeculectomy, 5-fluoruracil, intraocular pressure

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INTRODUCTION

Structural changes in ocular posterior pole such as shortening of axial length, anterior displacement of lamina cribrosa, reversal of the optic nerve cupping, and thickening of macular and parapapillary choroid have been reported after acute reduction in intraocular pressure (IOP) following glaucoma filtering surgery (1–7). However, few studies have evaluated central retinal changes after trabeculectomy, especially with respect to the use of antifibrotic agents. A reversible central macular thickening has been described after glaucoma surgery revealing no association between the reduction of intraocular pressure and retinal changes (8, 9). Still, prospective studies evaluating the long term effects on total macular thickness are lacking.

Macular oedema following intraocular surgery including trabeculectomy has been shown to cause visual impairment even in uncomplicated surgical cases (10–13). The use of antimetabolites, including 5-fluorouracil (5-FU), in glaucoma surgery or a failed filtering bleb needling increases the risk of early postoperative complications such as bleb leakage, hypotonic maculopathy, uveitis, and infectious endophthalmitis (14–19). We hypothesize that anti-scaring substances used in glaucoma surgery could enhance the postoperative structural changes in macula because of their association with a marked IOP reduction, postoperative inflammation, as well as a possible subclinical toxic effect on retinal cells. Therefore we evaluated macular changes after trabeculectomy with or without the use of adjunctive metabolite and its relation with intraocular pressure changes.

The aim of our study was to assess macular thickness after an acute reduction of IOP following trabeculectomy and to analyse possible associations between the postoperative changes in retinal thickness and intraocular pressure. In addition, we investigated whether the use of 5-FU may alter this response.

MATERIALS AND METHODS

A prospective longitudinal study adhering to the principals of the declaration of Helsinki was performed at Vilnius University Hospital Santaros klinikos Centre of Eye Diseases from May 2014 to December 2016. The permission of the local bioethics committee was received and written informed consent was obtained from the participants. Patients with glaucoma who underwent trabeculectomy because of an uncontrolled IOP were enrolled in the study. Exclusion criteria were defined as: prior intraocular surgery except phacoemulsification with intraocular lens implantation; refractive error beyond –6.0 D and +6.0 D of sphere and ±3.0 D of cylinder; poor image quality because of opaque ocular media; age-related macular degeneration of AREDS (Age-Related Eye Disease Study) category 4; uveitis, cystoid macular oedema, and hypotony maculopathy. In total, 106 eyes of 100 patients were included in the study. All patients underwent a limbal-based trabeculectomy with or without 5-FU. Subsequently, 5-FU needling was performed if failure of the filtrating bleb occurred.

The baseline examination included applanation tonometry (Goldmann tonometer, Haag-Streit AG, Switzerland), slit-lamp biomicroscopy, indirect ophthalmoscopy, autorefractometry (Topcon KR-1 Auto Kerato-Refractometre, Topcon medical Systems, USA), and spectral domain optical coherence tomography (SD-OCT) (Heidelberg Spectralis, Heidelberg Engineering, Dossenheim, Germany). The intraocular pressure and mean and sectoral macular thickness were compared preoperatively, one week, and six months after the surgery.

The retina was imaged by SD-OCT enhanced depth imaging mode. The images were generated using the posterior pole scan pattern centered at the fovea at equally spaced angular orientations and 61 raster lines spaced 120 μm apart. We selected the macular map analysis protocol on Spectralis to display numeric averages of the measurements for each of the nine subfields as defined by the Early Treatment Diabetic Retinopathy Study (ETDRS) (Fig. 1). The standard retinal subfields included central, inner superior, inner nasal, inner inferior, inner temporal, outer superior, outer nasal, outer inferior, and outer temporal sectors (Fig. 1). The central foveal subfield, inner and outer macular subfields are bounded by the innermost 1-mm diameter, 3-, and 6-mm diameter circles, respectively. The mean macular thickness was averaged from all nine subfields.

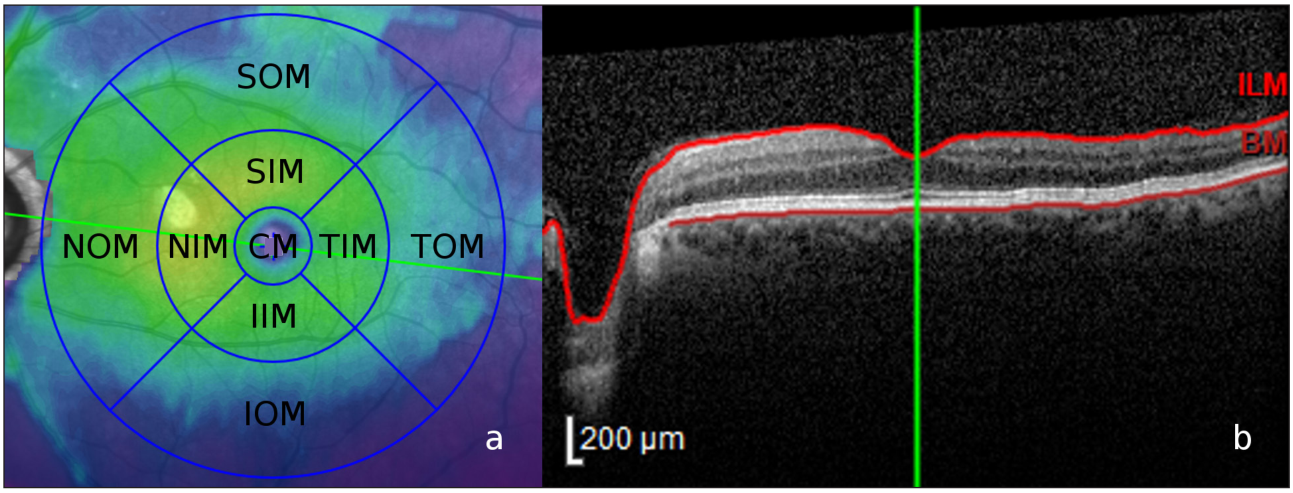

Fig. 1. Measurements of macular thickness with spectral domain optical coherence tomography

Macular thickness was measured using enhanced depth imaging optical coherence tomography at 9 subfields (a): CM, central macula ; SIM, superior inner macula, TIM, temporal inner macula, IIM, inferior inner macula; NIM, nasal inner macula SOM, superior outer macula; TOM, temporal outer macula; IOM, inferior outer macula, NOM, nasal outer macula. The retinal thickness was defined as distance between hyperreflective internal limiting membrane (ILM) and Bruch's membrane (BM) (b).

The data were analyzed using R commander software (R program software version 3.1.2, CRAN Project). Continuous variables were checked for normal distribution and expressed by mean and standard deviation (SD). Repeated measures ANOVA analysis was used to compare the mean value of preoperative and postoperative measurements, p value was adjusted for multiple comparisons using Bonferroni correction. The correlation and univariate regression analysis were performed. $p < 0.05$ was considered statistically significant.

RESULTS

In total, data of 106 eyes (100 patients) were analyzed. The demographic and clinical characteristics of the patients are presented in Table 1.

Table 1. Demographic and clinical characteristics of the patients

Parameter	Value
Age, years (mean, range)	66.43 (30–83)
Male/Female	47/53
Visual acuity, Snellen chart (mean ± SD)	0.67 ± 0.26
Refraction*, diopters (mean ± SD)	–0.47 ± 2.02
Glaucoma type (eyes)	
Pseudoexfoliative glaucoma	78
Primary open angle glaucoma	18
Primary angle closure glaucoma	8
Juvenile glaucoma	1
Pigmentary glaucoma	1
Total	106

Abbreviations: SD, standard deviation; *, spherical equivalent.

The mean preoperative IOP (±SD) under topical medications was 27.71 (±6.88) mmHg. After surgery a significant reduction at both follow-up visits was observed to values of 18.3 (±8.1) mmHg after one week ($p < 0.001$) and 15.1 (±7.6) mmHg after six months ($p < 0.001$). The IOP reduction did not differ significantly between the patients with or without adjunctive 5-FU ($p > 0.05$).

Macula thickness at all measured ETDRs sectors and the mean macular thickness increased one week after trabeculectomy ($p < 0.001$) (Table 2). During the early postoperative period the mean change in thickness of the central macular subfield was 4.17 (±6.95) µm ($p < 0.001$). Six months after the surgery a small yet significant macular thickening was observed in central and inner nasal macular subfields only ($p = 0.002$, $p = 0.016$) (Table 2). The thickness of the outer nasal segment reduced –1.95 (±7.78) µm half a year after the surgery ($p = 0.034$).

A total of 38 eyes (35.85%) received 5-FU during trabeculectomy and 32 eyes (30.19%) underwent needling with 5-FU because of failed filtering blebs. There was no significant difference in the change in macular thickness at all measured locations, neither regarding the use of 5-FU during the trabeculectomy nor during the filtering blebs needling ($p > 0.05$).

There was a mild correlation between the magnitude of the macular thickening and the IOP reduction at all macular subfields one week postoperatively ($p < 0.05$) (Fig. 2). However, at the later follow-up only outer nasal and superior subfields correlated significantly with the IOP (*rho* = –0.321, $p < 0.001$ and rho = –0.273, $p = 0.002$, respectively). In univariate regression models, a greater IOP reduction was associated with central and average macular thickening one week after trabeculectomy ($p = 0.0095$, regression coefficient: 0.214 µm/mmHg, 95% CI 0.053 to 0.375; $p = 0.0007$, regression coefficient: 0.167 µm/mmHg, 95% CI 0.072 to 0.262, respectively).

Table 2. Central retinal thickness measurements at baseline and after trabeculectomy

Macular subfields	**Macular thickness µm, mean (±SD)**				
	Baseline	**1 week after surgery**	**6 months after surgery**	**Change 1 week postoperatively**	**Change 6 months postoperatively**
CM	268.10 (±19.90)	272.27 (±20.46)	270.13 (±20.33)	4.17 (±6.95)†††	2.03 (±5.88)††
SIM	310.85 (±18.59)	315.02 (±18.63)	311.21 (±20.41)	4.17 (±4.75)†††	0.36 (±11.07)
TIM	298.25 (±18.69)	301.32 (±18.49)	298.96 (±18.63)	3.08 (±5.14)†††	0.72 (±5.21)
IIM	305.42 (±19.67)	309.36 (±20.25)	306.34 (±20.10)	3.93 (±4.92)†††	0.92 (±6.57)
NIM	316.08 (±19.42)	320.06 (±20.39)	317.68 (±19.91)	3.97 (±5.93)†††	1.59 (±5.76)†
SOM	269.40 (±15.80)	272.92 (±15.82)	269.61 (±15.73)	3.52 (±4.03)†††	0.22 (±6.41)
TOM	259.32 (±15.34)	262.54 (±15.37)	261.81 (±17.28)	3.22 (±4.65)†††	2.49 (±10.86)
IOM	255.56 (±15.22)	258.32 (±15.34)	255.56 (±16.07)	2.76 (±4.28)†††	0.00 (±9.26)
NOM	283.75 (±18.16)	288.28 (±19.17)	281.79 (±18.13)	4.54 (±5.17)†††	–1.95 (±7.78)†
Mean macular thickness	285.19 (±15.98)	288.9 (±16.31)	285.9 (±16.02)	3.71 (±4.21) †††	0.71 (±5.55)

Abbreviations: SD, standard deviation; CM, central macula; SIM, superior inner macula, TIM, temporal inner macula, IIM, inferior inner macula; NIM, nasal inner macula SOM, superior outer macula; TOM, temporal outer macula; IOM, inferior outer macula, NOM, nasal outer macula. †††, $p < 0.001$; ††; $p < 0.01$; †, $p < 0.05$

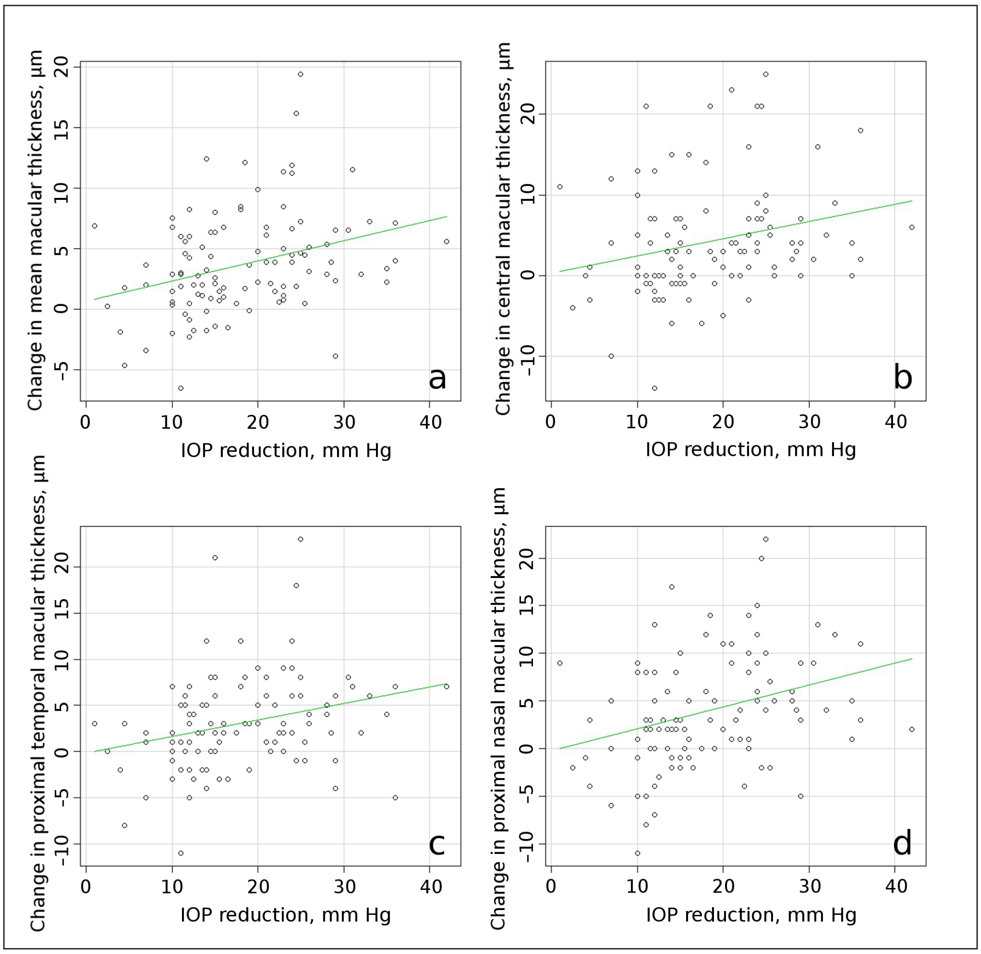

Fig. 2. Correlation between the macular thickening and IOP reduction one week after trabeculectomy

A positive correlation between magnitude of change in mean, central, proximal temporal and proximal nasal macular thickness and IOP reduction (*rho* = 0.352, $p < 0.001$; *rho* = 0.312, $p = 0.001$; *rho* = 0.346, $p = 0.001$ and *rho* = 0.352, $p < 0.001$, respectively.

DISCUSSION

Only few studies have previously referred to the changes in macular thickness following trabeculectomy. We set out to evaluate the effect of uncomplicated trabeculectomy with or without 5-FU on the central retina in the short- and long-term postoperative periods. The thickening of all macular subfields was observed one week after the surgery. Six months after trabeculectomy this effect stayed significant in central and inner nasal macular sectors, but was less pronounced. Our early postoperatively results are consistent with several previous studies. Sesar et al. reported a thicker central macular one week after trabeculectomy in 34 glaucomatous eyes (8). A modest thickening of fovea after filtrating surgery with or without anti-scarring agents was also described by Karasheva et al. (9). The authors revealed the largest increase of retinal thickness one month after surgery. Foveal thickness did not, however, differ significantly from the preoperative value three months after trabeculectomy. Contrarily, in our study the slight retinal thickening remained significant in the late postoperative period at the central and inner nasal macular subfields. These results agree with work of Pitale et al., who showed a trend toward a total macular thickness increase as a result of a surgical IOP reduction after an average of 10.8 ± 5.3 months follow-up (20). A small retinal thinning of the outer nasal subfield in our study could be explained by the progressive glaucomatous damage to the retinal nerve fibre layer which is the thickest in this peripapillary region.

We also evaluated the relationship between the IOP and the retinal changes after trabeculectomy. The results revealed a mild correlation between the magnitude of macular thickening and the IOP reduction at all macular sectors one week postoperatively, yet the relationship stayed significant after six months in outer nasal and superior sectors only. In contrast, no significant correlation was found between the changes of retinal thickness and a surgery-induced IOP reduction in previous studies (8, 9). Potentially, a greater surgical IOP reduction and a bigger sample size in comparison with the mentioned studies permitted us to prove a significant association between the IOP reduction and mild early macular changes.

Several mechanisms may contribute to the central retinal thickening after trabeculectomy. An acute IOP reduction may affects macular thickness directly since the inner force of the IOP on the retina is reduced allowing to re-gain its original shape. Moreover, the indirect effect of the IOP lowering via subsequent scleral deformations transmitted to compliant adjacent intraocular tissues appears to play a role (21). Additionally, an IOP lowering leads to the reduction of the retinal interstitial pressure and an increase in the gradient of the capillary/intercellular pressure leading to enhanced filtration and fluid accumulation in the intracellular retinal space (8, 22). It has been suggested that the thickening of the retinal nerve fibre layer observed after glaucoma filtration surgery is due to a parapapillary swelling (23). Finally, inflammation may play a role in the thickening of the retina, because the inflammatory mediators from the anterior chamber are reported to reach the posterior pole of the eye and increase the permeability of the blood–aqueous barrier associated with vascular leakage (24–26).

In the present study we also investigated the effect of 5-FU on the macular thickening. The antimetabolite is used as an adjunctive therapy to trabeculectomy, as well as for needling of failed filtering bleb to suppress conjunctival fibroblast proliferation and to inhibit scarring of ocular tissues (27, 28). Several studies have shown that in the long term the use of antimetabolites may be associated with higher rates of bleb leaks, blebitis, scleral melting, uveitis, endophthalmitis, hypotony, hypotony maculopathy, and choroidal effusions (12, 29, 30). The subconjunctival administration of a 5-FU dose not only induces ocular surface toxicity but also has toxic effects on corneal endothelium, ciliary body, and retina (31–34). Furthermore, the inhibition of protein synthesis in photoreceptors and ganglion cells of rabbit retina was demonstrated following subconjunctival 5-FU injections after a trephine filtering procedure (35). Therefore 5-FU may be associated with a larger IOP reduction and hypotony as well as with toxic or imunomodulating effects and have a potential impact on the postoperative macular changes. In our study, however, we found no significant impact of the use of 5-FU on the change in macular thickness.

The strengths of our study were the prospective design, relatively large sample size, long follow-up, and the wide macular area measured. The limitations include potential segmentation errors of retinal layers, which were, however, minimized by manually checking all the OCT scans and the heterogeneity of the study population since different types of glaucoma were included.

We conclude that trabeculectomy may induce a slight macular thickening which is more pronounced in the early postoperative period. The IOP reduction plays an important role in this process and is associated with the thicker postoperative macula; still, the inflammatory mechanism may be considered. Despite the potential hypotonic, inflammatory and cytotoxic effects on the eye, the adjunctive antimetabolite 5-FU has no influence on the central retinal thickness after glaucoma surgery.

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TINKLAINĖS GELTONOSIOS DĖMĖS STORIO POKYČIAI PO TRABEKULEKTOMIJOS BE ARBA SU 5-FLUOROURACILU

Santrauka

Įvadas. Tyrimo tikslas – įvertinti tinklainės geltonosios dėmės storio pokyčius po trabekulektomijos atsižvelgiant į 5-fluoruracilo naudojimą bei rasti galimas struktūrinių centrinės tinklainės dalies pokyčių sąsajas su akispūdžiu.

Medžiaga ir metodai. Prospektyvinėje stebimojoje studijoje dalyvavo 100 glaukoma sergančių pacientų (106 akys), kuriems atlikta trabekulektomija be arba su papildomu 5-fluoruracilu. Pooperaciniu periodu nefunkcionuojančios filtracinės pagalvėlės atveju taikytos 5-fluoruracilo injekcijos. Akispūdis ir tinklainės geltonosios dėmės storiai vertinti prieš operaciją bei 1 sav. ir 6 mėn. po operacijos. Vidutinis ir sektoriniai tinklainės geltonosios dėmės storiai matuoti atliekant spektro domeno optinę koherentinę tomografiją.

Rezultatai. Pooperaciniu periodu stebėtas reikšmingas akispūdžio sumažėjimas nuo bazinio 27,71 (±6,88) mmHg iki 18,3 (±8,1) mmHg po vienos savaitės (p < 0,001) ir 15,1 (±7,6) mmHg po 6 mėn. (p < 0,001). Praėjus vienai savaitei po trabekulektomijos, vidutinis geltonosios dėmės storis padidėjo nuo 285,19 (±15,98) μm iki 288,9 (±16,31) μm (p < 0,001). Ankstyvame pooperaciniame periode tinklainė sustorėjo visuose geltonosios dėmės sektoriuose (p < 0,001), rasta teigiama geltonosios dėmės centrinio ir sektorinių storių pokyčių, taip pat akispūdžio sumažėjimo koreliacija (centrinio tinklainės storio: *rho* = 0,312, p = 0,001). Vėlyvuoju pooperaciniu periodu statistiškai reikšmingas geltonosios dėmės sustorėjimas rastas tik centriniame ir vidiniame nazaliniame sektoriuose (p < 0,05). 5-fluoruracilo naudojimas trabekulektomijos metu ar pooperaciniu periodu neturėjo reikšmingos įtakos tinklainės geltonosios dėmės dalies storio pokyčiams.

Išvados. Trabekulektomija lemia tinklainės geltonosios dėmės sustorėjimą, ypač ankstyvajame pooperaciniame periode. Iš dalies padidėjusį centrinės tinklainės dalies storį po glaukomos operacijos galima paaiškinti akispūdžio sumažėjimu, kuris koreliuoja su struktūriniais tinklainės pokyčiais. Tuo tarpu antimetabolito 5-fluorouracilo vartojimas, nepaisant jo galimo hipotenzinio, imunomoduliuojančio ir citotoksinio poveikio, geltonosios dėmės storio pokyčiams įtakos neturi.

Raktažodžiai: tinklainės storis, geltonoji dėmė, trabekulektomija, 5-fluorouracilas, akispūdis