A comparison of intrascleral bleb height by anterior segment OCT using three different implants in deep sclerectomy

R Fernández-Buenaga^{1,2}, G Rebolleda¹, P Casas-Llera^{1,2}, FJ Muñoz-Negrete¹ and M Pérez-López¹

Abstract

Purpose To compare intrascleral blebs characteristics after deep sclerectomy (DS) with three intrascleral implants using the Visante anterior segment optical coherence tomography.

Methods This is a cross-sectional study including 60 eyes of 51 patients that underwent DS with Sk-Gel, Esnoper, and Aquaflow implant. Intraocular pressure (IOP) measurement, slit-lamp examination, and Visante scans were performed the same day in all the patients. Visante scans were done through the intrascleral bleb at 45°, 90°, and 135° and the bleb height was measured. Results Sk-Gel was used in 19 eyes (31.66%), Esnoper in 22 eyes (36.66%), and Aquaflow in 19 eyes (31.66%). The median time lapsed from the surgery was 15.50 months 25th and 75th percentiles (p^{25} 8.25; p^{75} 20). The median IOP was 13 mm Hg (p^{25} 10; p^{75} 15), with no significant differences among implants (P = 0.232). Overall, the correlation between the scleral bleb height and the IOP was statistically significant at 45° (*r* = -0.359; *P* = 0.004), 90° (r = -0.410; P = 0.001), and 135° (r = -0.417; P = 0.001). However, Sk-Gel did not show any statistically significant correlation between the scleral height and IOP whereas the other two groups (Esnoper and Aquaflow) showed a significant correlation. There were no differences in the bleb height among implants. Conclusion There was a moderate inverse correlation between the scleral bleb height and the IOP measurement after DS with Esnoper and Aquaflow implants. There were no differences in bleb height among the three implants.

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Introduction

The principles of optical coherence tomography and its application in imaging the anterior segment (AS) have been properly described.¹ Anterior segment optical coherence tomography (AS-OCT) has been used to evaluate blebs after filtrating glaucoma surgery.^{2–6}

Glaucoma surgery long-term success is determined by the development of an adequate filtering bleb in both trabeculectomy and deep sclerectomy (DS).

DS was designed to decrease the complications associated to trabeculectomy without compromising the success rate and intraocular pressure (IOP).⁷ The use of the implants or antimetabolites has been advocated to maintain the scleral space, created by the removal of the deep sclerocorneal flap.^{8,9}

The existing classifications^{10,11} for evaluating glaucoma filtering blebs rely mostly on external bleb characteristics and the postoperative control of IOP. As DS has four possible mechanisms of IOP reduction (subconjuctival bleb, intrascleral bleb, suprachoroidal, and episcleral vein outflow of aqueous from Schlemm's canal),¹² DS external bleb appearance could not correlate necessarily with IOP because the intrascleral bleb cannot be seen or evaluated by slit-lamp examination.

The purpose of this study was to evaluate the relationship between intrascleral bleb height and

¹Hospital Ramón y Cajal, Madrid, Spain

²Vissum Corporation-Instituto Oftalmológico de Alicante, Alicante, Spain

Correspondence: R Fernández-Buenaga, Vissum Corporation-Instituto Oftalmológico de Alicante, C/Cabañal 1, 03016 Alicante, Spain Tel: + 34 90 2333344; Fax: + 34 96 5260038. E-mail: rfernandezbuenaga@ gmail.com

Received: 3 October 2011 Accepted in revised form: 30 November 2011 Published online: 13 January 2012 IOP following DS using the Visante (Carl Zeiss Meditec, Dublin, CA, USA) AS-OCT. We used three kinds of implants: hyaluronic acid (Sk-Gel, Corneal Laboratories, Paris, France), 2-hidroxietilmethacrilate (Esnoper, AJL Ophthalmic SA, Álava, Spain), and collagen implant (Aquaflow, STAAR surgical, Nidau, Switzerland). To the best of our knowledge, no AS-OCT approach to compare several implants in DS has been reported.

Materials and methods

The current study is a cross-sectional study including 60 eyes of 51 patients that underwent uneventful DS with intrascleral implant.

The indication for DS surgery was medically uncontrolled glaucoma defined as well-documented progression of visual field defects and optic nerve morphology with maximal tolerable medical treatment.

Exclusion criteria were the previous eye filtering surgery and laser trabeculoplasty.

All surgeries were performed using retrobulbar anaesthesia by two experienced surgeons (GRF and FJMN). A fornix-based conjunctival flap was created, the sclera was exposed, and haemostasis by wet-field cautery was performed. A one-third scleral thickness superficial flap $(5.0 \times 5.0 \text{ mm})$ was dissected at the 12-o'clock position at least 1.0 mm into the clear cornea. A second deep scleral flap was dissected, Schlemm's canal was deroofed, and a TDM window was created. The deep scleral flap was excised; the juxtacanalicular trabeculum and Schlemm's endothelium were removed using small blunt forceps (ab externo trabeculectomy). An implant was placed on the sclera bed: Sk-Gel implant was used in 19 eyes (31.7%), Esnoper in 22 eyes (36.7%), and Aquaflow in 19 eyes (31.7%). Esnoper and Aquaflow implant were sutured with a 10-0 nylon suture. The superficial scleral flap was sutured with two to four interrupted 10-0 nylon buried sutures.

Goniopuncture using a Nd:YAG laser was performed in the anterior portion of the trabeculo-descemet's membrane when the IOP did not reach the preset target.

The IOP measurement and an analysis with the Visante AS-OCT were performed by the same expert investigator (RF-B) the same day.

Visante-OCT (Carl Zeiss Meditec) was used to evaluate the height of the postoperative intrascleral blebs. The patient was asked to look downwards at an angle from the horizontal of about 30°. The upper eyelid was gently retracted by the examiner to expose the superior bulbar conjunctiva as fully as possible without pressing on the globe.

To measure the bleb height (Figure 1), high-resolution scan protocols at 45° , 90° , and 135° were performed. Using a two-dimensional image recorded by the Visante-OCT,



Figure 1 Measurement of intrascleral bleb height. The maximum height of the intrascleral bleb in each scan was manually measured with the OCT caliper tool and automatically calculated with the device's software.

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Because AS-OCT was performed for routine clinical care in our department, and no additional procedure was performed for research purposes alone, no specific consent was required by the Ethics Committee of Ramon y Cajal Hospital. However, all patients were informed of the aims of recording these data and their oral consent was obtained before undergoing AS-OCT.

Statistical analysis

Normality was verified using the Kolmogorov–Smirnoff test. Data are presented as mean and SD, or as median and 25th and 75th percentiles (p^{25} ; p^{75}). Pearson's correlation test was used to analyze the overall correlation between scleral bleb height and IOP. When this analysis was repeated separately by the group of implant, Spearman's correlation test was elected. Differences among implants were tested with Kruskal–Wallis and Mann–Withney *U* test. Differences or correlations were considered statistically significant if *P* was less than 0.05.

Results

Demographic and clinical data are shown in Table 1. The median time lapsed from the surgery to the AS-OCT examination was 15.50 (p^{25} 8.25; p^{75} 20).

The median time from the surgery in the Sk-Gel group (21 months) was longer than the Esnoper group (8 months; P < 0.000) and the Aquaflow group (12.5 months; P < 0.000). No differences in median time from surgery were found between the Esnoper group and the Aquaflow group (P = 0.487).

Overall, the median preoperative IOP was 19 (p^{25} 17; p^{75} 23) and median postoperative IOP was 13 (p^{25} 10; p^{75} 15; P < 0.001). The median preoperative and postoperative

Table 1	Demographic	and	clinical	data
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	Sk-Gel	Esnoper	Aquaflow	P-value
Eyes (<i>n</i> , %)	19 (31.66)	22 (36.66)	19 (31.66)	
Sex (n, %)				0.920
Male	9 (15)	12 (20)	11 (18.33)	
Female	10 (16.66)	10 (16.66)	8 (13.33)	
Median preoperative IOP (p^{25} ; p^{75})	18 (18; 21)	20 (17; 23)	20 (16; 25)	0.462
Mean age (SD)	74.42 (9.46)	70.09 (12.84)	75.60 (9.42)	0.379
Median time lapsed from surgery (months; p^{25} ; p^{75})	21 (19; 24)	8 (1; 19)	12.5 (8.5; 16.5)	0.000
Median postoperative IOP $(p^{25}; p^{75})$	14 (12; 15)	11.50 (9; 15.50)	14 (11; 16)	0.232
Goniopunctured eyes (n, %)	1 (5.26)	1 (4.54)	2 (10.52)	0.835
Type of glaucoma $(n, \%)$				0.619
POAG	16 (26.66)	15 (25)	13 (21.66)	
PEXG	1 (1.66)	4 (6.66)	6 (10)	
Other	2 (3.33)	3 (5)	0 (0)	

Abbreviations: IOP, intraocular pressure; Others, pigmentary glaucoma, corticosteroid induced glaucoma; PEXG, pseudoexfoliation glaucoma; POAG, primary open angle glaucoma.

Table 2 Bleb heights at 45°, 90°, and 135° for the three implants

	Sk-Gel (mm)	Esnoper (mm)	Aquaflow (mm)	P-value
45°	0.650	0.570	0.660	0.297
90°	0.630	0.630	0.650	0.760
135°	0.670	0.650	0.670	0.611

Table 3 Spearman's correlation between IOP and bleb heights at 45° , 90° , and 135° with the three implants

Sk-Ge	el Esn	ıoper	Aquaflow
45° 0.000 (P = 90° 0.072 (P = 135° 0.021 (P =	0.998) -0.459 (0.770) -0.603 (0.931) -0.516 (P = 0.032) -0.5 P = 0.003) -0.5 P = 0.017) -0.4	$\begin{array}{l} 83 \ (P = 0.009) \\ 69 \ (P = 0.011) \\ 25 \ (P = 0.070) \end{array}$

IOP in each group are shown in Table 1 without differences among them.

The median bleb height was 0.65 (p^{25} 0.44; p^{75} 0.76), 0.63 (p^{25} 0.442; p^{75} 0.827), and 0.66 (p^{25} 0.42; p^{75} 0.84) for 45°, 90°, and 135° scans, respectively. There was not any statistically significant difference in the median scleral bleb height among the three groups of implants (Table 2) at 45°, 90°, and 135°.

Overall, an inverse correlation was found between the scleral bleb height and the IOP at 45° (r = -0.359, P = 0.004), 90° (r = -0.410, P = 0.001), and 135° (r = -0.417, P = 0.001). However, when comparing among implants (Table 3), Sk-Gel did not show any statistically significant correlation between the scleral bleb height and IOP at any angle of analysis whereas the other two groups (Esnoper and Aquaflow) showed this correlation at every angle of analysis.

Discussion

Deep selerectom creates a trabeculo-descemet window by removing the juxtacanalicular tissue of the Schlemm's canal avoiding the perforation of the anterior chamber. A space maintainer (implant) is frequently utilized to enhance the intrascleral lake and to improve long-term success.^{9,13} External bleb classifications^{10,11} have been described to address the glaucoma surgery functionality and prognosis but they cannot assess the intrascleral bleb. Recently, the AS-OCT has been used to evaluate filtering blebs after trabeculectomy²⁻⁴ and DS with collagen scleral implant.^{5,6} The objective of this study was to perform an analysis of the relationship between DS blebs height with three different intrascleral implants and IOP using the Visante AS-OCT.

Muller *et al*¹⁴ used slit-lamp-adapted OCT to study filtering blebs in the glaucoma surgery, including DS. They concluded that AS-OCT can assess internal structure of a filtering bleb improving the clinical external classifications. Likewise, Labbe *et al*⁶ using Visante-OCT after a heterogeneous filtering surgery group, found Visante assessment can complement the clinical evaluation after glaucoma surgery.

Mavrakanas *et al*⁵ investigated a homogenous group of 25 eyes, all having DS with collagen implant and MMC and postoperatively clinically flat blebs. They measured the intrascleral bleb height with the Visante-OCT. They found a significant positive inverse correlation between the intrascleral bleb height and postoperative IOP.

In the current study, we included patients following DS with different external blebs appearances, not only flat blebs. Our median time lapsed from the surgery to the Visante examination and the IOP measurement was



longer than that reported by Mavrakanas *et al*⁵ (15.5 *vs* 8 months). We also found an inverse significant correlation between the scleral bleb height at 45°, 90°, and 135°, and the IOP measurement after uneventful DS not only with collagen implants but also with 2-hidroxietilmethacrilate implant (Esnoper). However, these correlations although statistically significant were moderate and slightly weaker than that described by Mavrakanas.⁵ In our opinion, the reason of these differences could be the heterogeneous appearance of our blebs and shows that, as it is perfectly known, the intrascleral lake is not the only mechanism of filtration after DS.

In spite of there being no difference in bleb height among implants, Sk-Gel group did not show correlation between the bleb height and IOP at any angle of analysis. This evident finding may be explained by the longer time that lapsed from the surgery in this group. Further longitudinal studies are needed to check if AS-OCT bleb height correlation with IOP turns weaker with time or if it is an implant-related finding. The aforementioned varied mechanisms of filtration might evolve to a different bleb functionality, less bleb-height dependence.

In addition, we did not found any significant difference in terms of IOP control among groups (Table 1). There is no well-designed study that has demonstrated the superiority of any commercialized implant. Wiermann et al,¹⁵ found no significant differences in the short- and mid-term IOP lowering effects of DS, whether or not it was combined with the cataract surgery, between the non absorbable T-flux and the Sk-Gel implants. Rekas et al16 did not found differences between these two implants although the qualified success rate in the case of phaco-DS with T-flux was significantly lower after a 24-month follow-up. They hypothesized that the nature of the intrascleral lake created by the implants used may be essential in the IOP regulation role. Studies comparing implants are lacking and are necessary to address the safer and the most efficient space maintainer to improve DS results.

Ultrasound biomicroscopy (UBM) has been also studied to evaluate the thickness of TMD and intrascleral space in DS. Blumen-Ohana *et al*¹⁷ or Cabrejas *et al*¹⁸ described a relationship between TDM thickness and low-reflectivity blebs measured by UBM and good surgical prognosis. UBM has a lower resolution (axial $25 \,\mu$ m and transverse $50 \,\mu$ m) than Visante, which has an optical axial resolution of up to $18 \,\mu$ m and optical transverse resolution of up to $60 \,\mu$ m.¹⁹ Also, minimal experience is required for non-contact image acquisition in AS-OCT unlike UBM that needs an experienced observer and it is a contact technique.

Our study has some limitations. First, this is a crosssectional study within a variable period after DS (median time lapsed 15.50 months (p^{25} 8.25; p^{75} 20)) and one group with longer time lapsed from surgery than the others. Second, as previously described by Mavrakanas,⁵ a validated approach for OCT pixel intensity measurement is needed to assess intrableb reflectivity, so we could not measure bleb wall reflectivity that might be related to bleb functionality. Third, the differences between implants were only evaluated in IOP control terms and its bleb height correlation. Complications or incidence of goniopuncture are crucial issues to be addressed in a further study.

In conclusion, we found that the Visante- OCT is an interesting tool to adequately evaluate DS filtering blebs. We found a moderate significant correlation between the IOP and bleb height with Esnoper and Aquaflow intrascleral implants. There was no difference in bleb height among the three implants. In Sk-Gel group with a median of 21 months lapsed from the surgery, there was no correlation between IOP and bleb height at any angle of analysis. Further prospective longitudinal studies are needed in order to confirm these results.

Summary

What was known before

• Muller *et al*¹⁴ and Labbe *et al*⁶ described in a heterogeneous group of the glaucoma surgery patients including deep sclerectomy that anterior-segment OCT can assess internal structure of a filtering bleb improving the clinical external classifications. Mavrakanas *et al*⁵ described a significant positive inverse correlation between intrascleral bleb height and postoperative IOP in deep sclerectomy with collagen implant in 25 patients with flat blebs.

What this study adds

• This is the first paper to assess intrascleral blebs in a group of deep sclerectomy patients with three different intrascleral implants. We included patients following deep sclerectomy with different external blebs appearances not only flat blebs. There was no difference in bleb height among the three implants. There is a moderate inverse correlation between intrascleral bleb height and postoperative IOP in 22 Esnoper and 19 Aquaflow deep sclerectomy patients. In Sk-Gel implant group with a median of 21 months lapsed from the surgery there was no correlation between IOP and bleb height.

Conflict of interest

The authors declare no conflict of interest.

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