

Research Article

Surgically Induced Astigmatism after Deep Sclerectomy with Esnoper Clip Device Implantation

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Abstract

Purpose: The aim of the study was to evaluate the level of Surgically Induced Astigmatism (SIA) after deep sclerectomy with Esnoper Clip device implantation.

Method: We retrospectively evaluated 48 eyes of 41 patients with glaucoma, who underwent deep sclerectomy with Esnoper Clip device (AJL Ophthalmics) implantation between the years 2018-2020 in our clinic. One experienced surgeon performed all surgeries. The main parameters observed were keratometry readings measured with autorefracto keratometer (Nidek ARK 510-A) and Pentacam HR (Oculus) preoperatively and one, three and six months postoperatively. Corneal surgically induced astigmatism was calculated with a corneal SIA Tool (ascrs.org) and evaluated with the use of centroid values, mean absolute values and double-angle plots. Intraocular pressure (IOP) and best-corrected visual acuity (BCVA) were also evaluated.

Results: The centroid of SIA (autorefracto keratometer data) was 0,21@85° (SD ±0,86D), 0,06@57° (SD ±0,81D) and 0,09@71° (SD ±0,75D) one, three and six months after the surgery. The centroid of SIA (Pentacam HR, Cornea front map data) was 0,32@88° (SD ±1,29D), 0,12@152° (SD ±0,72D) and 0,18@63° (SD ±1,36D) respectively. The centroid of SIA (Pentacam HR, True net power map data) was 0,36@90° (SD ±1,47D), 0,05@133° (SD ±0,84D) and 0,18@53° (SD ±1,33D) respectively. The maximal and minimal mean absolute value of corneal astigmatism preoperatively was 0,84D (SD ±0,49D) and 0,80D (SD ±0,62D). The maximal and minimal mean absolute value of SIA from all measured values postoperatively was 0,98D (SD ±1,13D) and 0,58D (SD ±0,47D).

The average preoperative IOP was 19,4 (SD ±5,9) mmHg. The average postoperative IOP was 12,6 (SD ±3,3) mmHg 6 months after the surgery. The average BCVA prior the surgery was 0,16 (SD ±0,2) logMAR, the average BCVA six months after the surgery was 0,07 (SD ±0,14) (p=0,13) logMAR.

Conclusion: In our study, deep sclerectomy with implantation of Esnoper Clip device did not induce any relevant corneal astigmatism postoperatively.

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Introduction

Glaucoma still belongs among one of the most common eye diseases, having high impact on visual functions of patients worldwide [1]. Important risk factor, being at the same time the only directly influenceable parameter, is the intraocular pressure (IOP). It can be reduced conservatively or surgically. The surgical gold standard currently is trabeculectomy used since the 1960s [2]. Another surgical option, which theoretically has a lower risk of postoperative complications is deep sclerectomy (DS) [3-5].

To increase the success rates of DS, different types of space-maintainer devices were designed. The first one, which was a purified porcine collagen was tried by Kozlov in 1990 [6]. Since then, non-absorbable, absorbable, and autologous implants were the main kinds being used till now. New implants have been developed in the past few years with promising results, such as the non-absorbable 2-hydroxyethyl-methacrylate implant Esnoper (AJL Ophthalmics, SA, Miñano, Alava, Spain) used in our study [7]. It was developed by group at the Glaucoma Unit of the Hospital Universitari Germans Trias i Pujol (Universitat Autònoma de Barcelona, Barcelona, Spain). The implant has been designed with 2 footplates, one placed in the intrascleral space and the other in the supra-ciliary space. The shape of the device has been designed to maintain the patency of both spaces and the aqueous humor outflow in the long postoperative period. Its safety and efficacy to lower IOP was described for example by Romera-Romero P. et al or Loscos-Arenas J. et al [8,9].

One of the possible side effects of filtration glaucoma surgery is induction of corneal astigmatism and thus the effect on uncorrected visual acuity. There are reports demonstrating occurrence of significant postoperative induced astigmatism after both trabeculectomy and deep sclerectomy [10-14]. The aim of our study was to evaluate the changes in postoperative corneal topography by calculating Surgically Induced Astigmatism (SIA) after deep sclerectomy with Esnoper Clip device implantation, which could potentially deteriorate postoperative visual acuity and visual rehabilitation.

Method

A retrospective evaluation of 48 eyes of 41 patients with glaucoma (24 women, 17 men) of an average age of 73 years $\pm 8,5$ (SD) (min 59, max 93) was done. Twenty were right eyes, 28 left eyes. Thirty-one eyes (64,5%) suffered from a primary open-angle glaucoma (of this three normal tension glaucoma), nine eyes from pseudoexfoliation glaucoma, four eyes were diagnosed with secondary glaucoma (of this three steroid-induced glaucoma), and one with angle-closure glaucoma. Thirty eyes of 26 patients already underwent cataract surgery in their medical history (29 PC IOL, 1 AC IOL implantation), 18 patients had their own lens (14 cataracts, four clear lens). All patients underwent single-procedure DS with EsnoperClip device implantation between 2018-2020 in our clinic. Complex ophthalmological examination, including visual acuity test (Snellen chart, converted to the logMAR scale), IOP measuring (Goldmann applanation tonometry), keratometry measuring with autorefractometer (Nidek ARK 510-A) and Pentacam HR (Oculus) analysis, were performed prior the surgery. The same parameters were measured one, three and six months after the surgery.

One experienced surgeon (PS) performed all surgeries. Local

anaesthetic drops (oxybuprocaini hydrochloridum) combined with the instillation of local subconjunctival anaesthesia (lidocaine) into the superior quadrant were used. The bulbus was fixed with two conjunctival stitches and the conjunctiva was then opened superiorly approximately 10 mm above the corneal limbus. A superficial scleral square-shaped flap of a size 4x4mm in a depth of approximately one third of the scleral thickness was created with the use of a crescent blade. Underneath, second scleral flap having a size of 3 x 3mm was cut away. After opening the Schlemm's canal and creating trabeculo-Des-cemet's window, the Esnoper Clip device was inserted into the scleral bed. Subsequently, the remaining sclera was perforated, approximately 1 mm from the scleral spur, and the peripheral part of the implant was inserted into the suprachoroidal space. The device was then covered with the superficial scleral flap and fixed with two sutures (10-0 nylon) in its upper part. At the end, the conjunctiva was fixed with a continuous suture (8-0 Vicryl) and local antibiotic therapy was applied. Antimetabolites were used neither preoperatively nor postoperatively. All patients used combination of antibiotics and corticosteroid drops (tobramycin/dexamethasone) five times a day for three weeks after the surgery, which was then replaced with fluorometholon drops three times a day for two months after the surgery.

The corneal SIA was evaluated using data obtained from autorefractometer (ARK) and Pentacam HR one, three and six months after the procedure. The evaluation of each eye separately and both eyes together was performed. Anterior corneal curvature values (Cornea Front) centered on apex, calculated in three-zone diameter were used from the Pentacam HR measurements. To evaluate eventual astigmatism changes of the posterior corneal surface were also analysed the data from the True Net Power map (TNP). The results were calculated with a corneal SIA Tool (ascrs.org), based on a publication by Koch DD et al in 2015 [15]. This tool generates double-angle plots of the corneal SIA, centroid values and standard deviations, mean values (without considering axis) and 95% confidence ellipses of the dataset and of the centroid values. The double-angle plot allows the display of the magnitude and axis of the average astigmatism (centroid) and the confidence ellipse [15]. Values of BCVA, IOP and absolute values of SIA data in all observed time intervals are given as means and standard deviations. Analysis of BCVA data among the all time periods was performed using the non-parametric Kruskal-Wallis test To find the difference in measured SIA data among time intervals repeated measures analysis of variance ANOVA followed by multiple comparison Bonferroni's test were calculated. StatSoft's STATISTICA version 9 was used for statistical analysis. A p-value less than 0.05 is considered to be statistically significant.

Results

The preoperative and postoperative keratometric data from ARK were available for 39 eyes (81%) one month after the surgery and for 33 eyes (69%) three and six months after the surgery. The preoperative and postoperative keratometric data from Pentacam HR were available for 33 eyes (69%) one month after the surgery, for 23 eyes (48%) three months after the surgery and for 31 eyes (65%) six months after the surgery. The remaining data were not available or had poor quality and so were excluded. The centroid of SIA (autorefractometer data) was 0,21@85° (SD $\pm 0,86$ D), 0,06@57° (SD $\pm 0,81$ D) and

0,09@71° (SD ±0,75D) one, three and six months after the surgery (Figure 1). The centroid of SIA (Pentacam HR, Cornea front map data) was 0,32@88° (SD ±1,29D), 0,12@152°(SD ±0,72D) and 0,18@63°(SD ±1,36D) respectively (Figure 2). The centroid of SIA (Pentacam HR, True net power map data) was 0,36@90°(SD ±1,47D), 0,05@133°(SD ±0,84D) and 0,18@53°(SD ±1,33D) respectively (Figure 3). The maximal and minimal mean absolute value of corneal astigmatism preoperatively was 0,84D (SD ±0,49D) and 0,80D (SD ±0,62D). The maximal and minimal mean absolute value of SIA from all measured values postoperatively was 0,98D (SD ±1,13D) and 0,58D (SD ±0,47D). There were no statistically significant difference between absolute values of SIA among the all time periods (ARK p=0,53, PNT CF p=0,48, PNT TNP p=0,58, ANOVA).

The preoperative mean absolute values of corneal astigmatism are summarised in table 1. All postoperative centroid values of SIA and mean absolute values of SIA measured with ARK

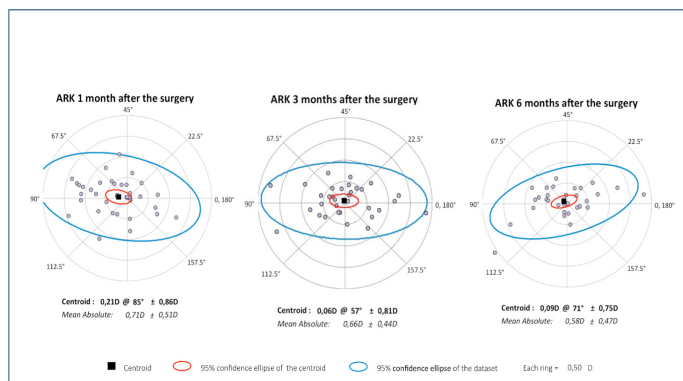


Figure 1: Double-angle plots of SIA and centroid values: one, three and six months after the surgery, ARK.

and Pentacam HR in single periods are digestedly summarised in tables 2-4. All postoperative mean absolute values of SIA measured with ARK and Pentacam HR in single periods are digestedly summarised in tables 5-7. The right eye, the left eye and both eyes together are described separately.

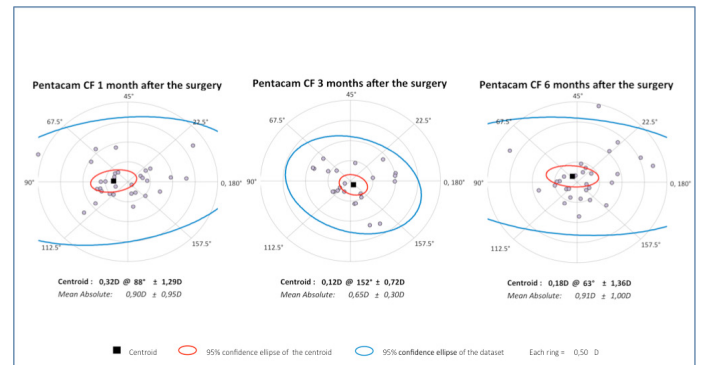


Figure 2: Double-angle plots of SIA and centroid values: one, three and six months after the surgery, Pentacam CF map.

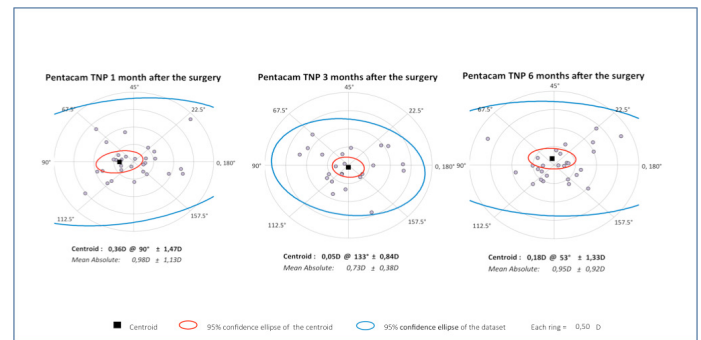


Figure 3: Double-angle plots of SIA and centroid values one, three and six months after the surgery, Pentacam TNP map.

Table 1: Preoperative absolute values of corneal astigmatism – means, standard deviations (SD) and ranges.

	ARK			Pentacam HR CF			Pentacam HR TNP		
	OD	OS	ODS	OD	OS	ODS	OD	OS	ODS
Mean absolute value (D)	0,75 ± 0,69	0,85 ± 0,56	0,80 ± 0,62	0,81 ± 0,35	0,81 ± 0,44	0,81 ± 0,41	0,83 ± 0,44	0,84 ± 0,51	0,84 ± 0,49
Min – Max (D)	0-2,5	0-2,5	0-2,5	0,2-1,6	0,3-2,3	0,2-2,3	0,1-1,7	0,2-2,6	0,1-2,6

OD: right eye, OS: left eye, ARK: autorefracto keratometer, CF: Cornea front map, TNP: True Net Power map, Min: minimum, Max: maximum

Table 2: Centroid values of SIA, ARK data – means and standard deviations (SD).

	ARK (NidekARK 510-A), Centroid values		
	1 month	3 months	6 months
OD	0,27D@94° ± 0,74D	0,07D@50° ± 0,75D	0,22D@91° ± 0,85D
OS	0,19D@73° ± 0,98D	0,06D@64° ± 0,89D	0,12D@35° ± 0,67D
OD+OS	0,21D@85° ± 0,86D	0,06D@57° ± 0,81D	0,09D@71° ± 0,75D

OD: right eye, OS: left eye, ARK: Autorefracto keratometer

Table 3: Centroid values of SIA, Pentacam HR CF map data – means and standard deviations (SD).

	Pentacam HR (Oculus), CF map, Centroid values		
	1 month	3 months	6 months
OD	0,42D@105° ± 1,53D	0,14D@141° ± 0,70D	0,33D@10° ± 0,90D
OS	0,34D@73° ± 1,08D	0,12D@170° ± 0,78D	0,46D@82° ± 1,58D
OD+OS	0,32D@88° ± 1,29D	0,12D@152° ± 0,72D	0,18D@63° ± 1,36D

OD: right eye, OS: left eye, CF Cornea Front

Table 4: Centroid values of SIA, Pentacam HR (Oculus), TNP map data – means and standard deviations (SD).

	Pentacam HR (Oculus), TNP map, Centroid values		
	1 month	3 months	6 months
OD	0,48D@105° ± 1,8D	0,08D@128° ± 0,77D	0,41D@9° ± 1,01D
OS	0,35D@76° ± 1,19D	0,02D@154° ± 0,97D	0,46D@77° ± 1,48D
OD+OS	0,36D@90° ± 1,47D	0,05D@133° ± 0,84D	0,18D@53° ± 1,33D

OD: right eye, OS: left eye, TNP: True Net Power

Table 5: Mean absolute values of SIA, ARK data – means and standard deviations (SD).

	ARK (NidekARK 510-A), Mean absolute values		
	1 month	3 months	6 months
OD	0,66D ± 0,41D	0,61D ± 0,39D	0,65D ± 0,55D
OS	0,78D ± 0,60D	0,72D ± 0,48D	0,54D ± 0,39D
OD+OS	0,71D ± 0,51D	0,66D ± 0,44D	0,58D ± 0,47D

OD: right eye, OS: left eye, ARK: Autorefracto keratometer

Table 6: Mean absolute values of SIA, Pentacam HR (Oculus), CF map data – means and standard deviations (SD).

	Pentacam HR (Oculus), CF map, Mean absolute values		
	1 month	3 months	6 months
OD	0,98D ± 1,18D	0,63D ± 0,27D	0,78D ± 0,50D
OS	0,83D ± 0,73D	0,67D ± 0,34D	0,73D ± 0,65D
OD+OS	0,90D ± 0,95D	0,65D ± 0,30D	0,91D ± 1,0D

OD: right eye, OS: left eye, CF: Cornea Front

Table 7: Mean absolute values of SIA, Pentacam HR (Oculus), CF map data – means and standard deviations (SD).

	Pentacam HR (Oculus), TNP map, Mean absolute values		
	1 month	3 months	6 months
OD	1,12D ± 1,41D	0,68D ± 0,31D	0,87D ± 0,06D
OS	0,87D ± 0,84D	0,8D ± 0,45D	1,01D ± 1,12D
OD+OS	0,98D ± 1,13D	0,73D ± 0,38D	0,95D ± 0,92D

OD: right eye, OS: left eye, TNP: True Net Power

The average preoperative intraocular pressure (IOP) was 19,4 (SD ±5,9) mmHg.

The average IOP one month after the surgery was 13,5 (SD ±4,5) mmHg, 14,7 (SD ±6,6) mmHg three months after the surgery and decreased to 12,6 (SD ±3,3) mmHg six months after the surgery.

The mean preoperative best-corrected visual acuity (BCVA) was 0,16 (SD ±0,2) logMAR. It stayed stable without any statistically significant worsening in 1 and 3 months and improved to 0,07 (SD ±0,14) (p=0,13) logMAR 6 months after the surgery. The mean BCVA one month after the surgery was 0,13 (SD ±0,15) (p=0,32) logMAR. The mean BCVA 3 months after the surgery was 0,11 (SD ±0,15) (p=0,94) logMAR.

Discussion

Surgical treatment of glaucoma still remains challenging because of postoperative complications, which include worsening of vision and dissatisfaction of the patients [16,17]. Reasons of the worsening of the visual acuity are miscellaneous. A study published by Costa et al in 1993 concluded that the main reasons for such early visual acuity loss after trabeculectomy were lens opacification followed by hypotony maculopathy [18].

Non-penetrating surgery is considered as less invasive, as the globe is not opened during the procedure and the loss of anterior chamber and severe postoperative hypotony should be herewith avoided. There are different types of glaucoma filtration implants, which can be used to increase the effect of deep sclerectomy and help to maintain the space created after the removal of the deep scleral flap [9,19]. One of them is the Esnoper Clip implant used in our study.

There are some studies reporting significant corneal topographic changes after glaucoma surgeries [10-14,20,21]. The reason of its origin remains unclear. One of the theories is that they are caused by removing of piece of the tissue during the glaucoma surgery and by sinking of the unsupported corneal edge [22].

The trabeculo-Descemet's window made up to 1,5-2 mm into clear cornea beyond the scleral spur could in our opinion

possibly induce postoperative corneal astigmatism. On the other hand, there are almost no sutures except final conjunctival sutures needed during the procedure, which should influence corneal topography less than for example sutures used during trabeculectomy.

Egrilmez et al. compared the level of induced astigmatism after nonpenetrating trabecular surgeries versus trabeculectomy. Nonpenetrating trabecular surgeries (viscocanalostomy, deep sclerectomy with T-flux implant) induced less astigmatism than trabeculectomy [23]. On contrary El Saied et al compared 60 eyes undergoing trabeculectomy with mitomycin-C (MMC) versus 60 eyes undergoing deep sclerectomy with MMC and reported that in both groups occurred statistically significant and similar with the rule astigmatism six months after the procedure [11]. One of the study comparing SIA among different glaucoma surgeries (trabeculectomy group, EX-PRESS shunt group, ab externo trabeculotomy group and microhook ab interno trabeculotomy group) was retrospective study of Tanito et al. The authors reported that trabeculectomy group induced more corneal astigmatism than other three groups in early postoperative period (three months postoperatively). The mean SIA vectors between the first two groups (trabeculectomy group, EX-PRESS shunt group) were significantly higher than centroid of SIA in our study. The mean SIA vectors of ab externo trabeculotomy group and microhook ab interno trabeculotomy group were similar to our results [20].

No antimetabolites were used during the procedure performed in our study. The possible impact of using the MMC on the postoperatively induced astigmatism is discussed. A study published by Hong YJ et al. compared the effects on postoperative astigmatism after trabeculectomy with those after a triple procedure (trabeculectomy with extracapsular cataract extraction with intraocular lens implantation) with and without the use of MMC.

Authors concluded that the MMC induced less with-the-rule astigmatism in early postoperative periods and continuous against-the-rule shift three months after trabeculectomy or a triple procedure was performed [24].

According to systemic review of Chan et al. the corneal topographic changes appear to stabilise at three months [10]. We observed a little bit higher values of centroids of SIA one month after the surgery in compare to three months values, but there were no statistically significant difference in SIA absolute values among the all follow-up periods.

Our study has some limitations. First, because of the retrospective evaluation of the data, not all the patients had good quality of the scans, which could be evaluated. Second, all the surgeries were performed by one experienced surgeon, which could in our opinion influence the level of final SIA.

The level of average surgical induced astigmatism in our study was low and consistent during the whole follow-up period. There was no statistically significant difference among the absolute values of SIA in early postoperative period and six months period. We did not observe any higher occurrence of topographical changes of the posterior surface of cornea. There was also no noticeable trend in the axis of induced astigmatism across the group. We did not notice any significant difference in values of SIA between right and left eye.

In our study, deep sclerectomy with implantation of Esnoper Clip device did not induce any relevant corneal astigmatism

postoperatively, which could influence postoperative rehabilitation and visual acuity.

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