Graefe's Archive for Clinical and Experimental Ophthalmology (2018) 256:773–781
https://doi.org/10.1007/s00417-018-3916-x

GLAUCOMA

The STARflo glaucoma implant: preliminary 12 months results

Sofia Fili[1] · Peter Wölfelschneider[1] · Markus Kohlhaas[1]

Received: 27 September 2017 / Revised: 9 January 2018 / Accepted: 19 January 2018 / Published online: 1 February 2018

Abstract

Purpose The STARflo glaucoma implant is a drainage-free system designed for the operative treatment of refractory open-angle glaucoma. The purpose of this study is to investigate the safety and efficacy of the STARflo implant. The results of 12 months follow-up are presented in patients with open-angle glaucoma, PEX–glaucoma, and congenital glaucoma.

Methods A prospective study with a total of over 29 patients (36 eyes), in which the suprachoroidal implantation of the STARflo was indicated for long-term intraocular pressure reduction, is still in process and evaluation.

Results The reduction of intraocular pressure was satisfying after 12 months with an average intraocular pressure of 15.0 (± 2.5) mmHg in comparison to 21.08 (± 7.29) mmHg preoperatively. There was a significant 66.7% reduction in local glaucoma drops 12 months postoperatively ($p < 0.001$). Twenty-five percent of the eyes needed further surgery to regulate the intraocular pressure. No intraoperative complications have been reported after the implantation of STARflo. Postoperative complications include hyphema and fibrin formation in the anterior chamber, which were completely resorbed after the first postoperative month. A postoperative intraocular pressure (IOP) elevation was the most common complication after the first 3 months.

Conclusions The STARflo implant appears to be a safe and effective alternative treatment method for patients with refractory open-angle glaucoma compared to conventional glaucoma surgery.

Keywords STARflo implant · Refractory glaucoma · Suprachoroidal pathway · Intraocular pressure

Introduction

Glaucoma surgery intends to reduce the intraocular pressure (IOP), when the target IOP cannot be reached through medical therapy (local or systemic) or laser treatments (Yag-Iridotomy, Iridoplasty, Laser-Trabeculoplasty) so that the optic nerve and the visual fields remain protected from further damage due to elevated IOP. Conventional glaucoma surgeries including the trabeculectomy and the glaucoma drainage devices such as Ahmed-valve Implant and Baerveldt Implant aim to create an alternative aqueous pathway, but they lead frequently to postoperative challenges such as early ocular hypotonia, blebitis, endophthalmitis, bleb leakage, overfiltration, bleb encapsulation, fibrosis, tube migration, plate exposure, and tube lumen occlusions [1–3]. As a result, many efforts have been directed to create new anti-glaucoma surgical procedures that have equal efficacy with a lower risk of complications compared to traditional glaucoma surgeries. The suprachoroidal space has been identified as an alternative pathway that can be modified to increase the outflow of the aqueous humor [3].

Nowadays, the uveoscleral pathway provides the opportunity for micro-invasive glaucoma surgery (MIGS), which offers a satisfactory reduction of IOP and local medications as well as an excellent safety profile. Suprachoroidal MIGS techniques also belong to this category with very promising results. Blebless ab-externo glaucoma surgery (BAGS) is another technique that tends to reform the suprachoroidal space in order to lower the IOP in patients with more advanced glaucoma that require lower target IOP [3, 4].

The STARflo is a new permanent implant, produced from iSTAR medical company in Belgium, routing the aqueous humor from the anterior chamber to the suprachoroidal space and therefore enhancing the uveoscleral outflow through a bleb-free drainage system. It is designed as a silicone, microporous, and tissue-friendly material, which is composed of a body and a head segment, and its size is 5 × 8 mm with a thickness of 275 μm [3, 5] (Fig. 1).

✉ Sofia Fili
sofia.fili@joho-dortmund.de

[1] Clinic of Ophthalmology at St. Johannes Hospital in Dortmund, Johannesstraße 9-13, 44137 Dortmund, Germany

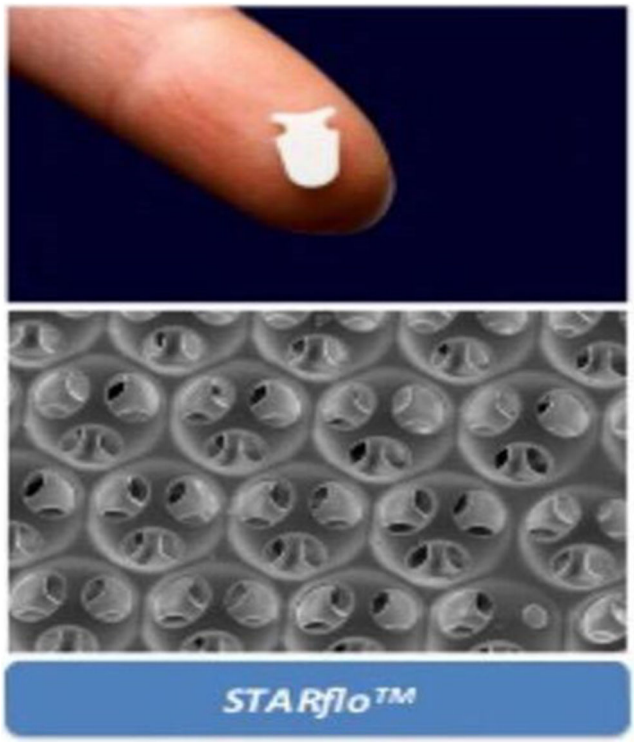

Fig. 1 Macroscopic representation of the STARflo implant

The Star biomaterial derives from NuSil med-6215 (a silicone elastomer) and its unique structure consists of an organized network of hollow spheres, which enables drainage. This multi-porous geometry is designed to promote biointegration from the surrounding tissues into the material, thereby maintaining the drainage efficiency in a long-term. The porous design promotes a natural flow rate that reduces the incidence of fibrosis and minimizes scarring, thus increasing the implant durability and maximizing the long-term performance. It is shown an exceptional biointegration of the device with surrounding tissue colonizing the porous structure while preserving in vivo drainage efficacy. No encapsulation is observed in experimental studies with rabbits. More specifically, an absence of a continuous surrounding fibrous capsule or of a continuous presence of macrophage or of a continuous fibroblast layer is shown [3–5] (Fig. 2).

The safety and efficacy of the STARflo glaucoma implant in patients with refractory open-angle glaucoma (OAG) are still under evaluation. The STARflo feasibility clinical study was completed in 2012 leading to CE-marking approval. A prospective, multi-center, clinical trial started in September 2014 in several European countries, including Belgium, Bulgaria, France, Germany, and Switzerland. Patient follow-up is still on-going. The study primary endpoint is the reduction of IOP at 12 months. Other study endpoints include the reduction of the IOP, changes of the glaucoma eye drops, and

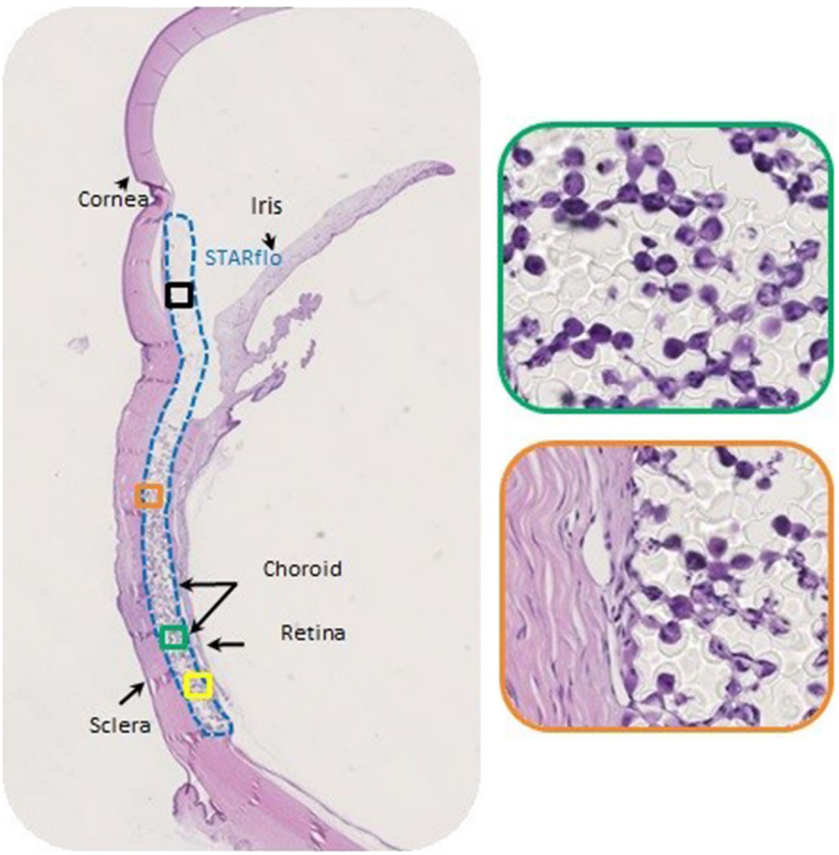

Fig. 2 Histological representation of the STARflo after a 6-month rabbit study. Source: Prof. Nathalie Collignon (CHU of Liège, Liège, Belgium); In-vivo: CER Group (Marloie, Belgium); Histology: GIGA-ULg Immunohistology Platform (University of Liège, Liège, Belgium). March 2013

safety endpoints up to 24 months. The inclusion criteria are the diagnosis of primary open-angle glaucoma (POAG) and intraocular pressure (IOP) between 21 and 40 mmHg [3, 5].

The objective of this prospective clinical study is to present our experience of glaucoma surgical procedure with the STARflo implant, the reduction of IOP, and changes in local and systemic IOP lowering medications as well as the incidence of postoperative complications including subsequent surgical procedures.

Materials and methods

This prospective STARflo implantation study is ongoing in the department of ophthalmology in St. Johannes Hospital in Dortmund since October 2016. Between October 1, 2016 and September 26, 2017, 29 patients with POAG, pseudoexfoliation (PEX) glaucoma, and congenital glaucoma were examined and STARflo was implanted in 36 eyes in total. Our patient population consists of 13 men and 16 women with an average age of 64.3 ± 12.9 years and a range of age between 30 and 82 years. Twelve months follow-up data are being presented here.

The main inclusion criteria are the diagnosis of moderate to advanced therapy-resistant open-angle glaucoma, and intraocular pressure above 20 mmHg. As advanced open-angle glaucoma is defined, the glaucoma is consisted of baseline IOP between 16 and 40 mmHg, CDR 0.9–1.0, Shaffer Grade 3–4 as result of the gonioscopy, visual fields Humphrey MD between −10.00 and −25.00 and is responding neither to the maximal local therapy (three to four glaucoma eye drops) nor to the systemic therapy (acetazolamide), although the requested target IOP is in all cases under 13 mmHg. All the included 29 patients in the study fulfilled the above criteria, and no patient was excluded in the follow-up of 12 months of the study.

The patients were controlled in scheduled postoperative visits in the following intervals: 1 week, 1 month, 2 months, 3 months, 6 months, and 1 year. The patients that presented satisfying results (IOP till 13 mmHg under one to two local glaucoma medications without postoperative complications) and could not attend all the scheduled visits in our clinic because of poor general health condition were controlled further from ophthalmologists in the private practices. This condition refers to three patients in total. The Kaplan-Meier curve is presented the number of the patients that received a STARflo implant and came to the scheduled visits till now. (Fig. 3).

As complete success criterion is considered the achievement of the target IOP after the implantation of STARflo without medications. The achievement of the target IOP after the surgery under topical medications is regarded as a qualified success. Eight cases (seven cases with advanced primary open-angle glaucoma-POAG and one case with congenital glaucoma) showed no satisfying response to the implantation of STARflo and a further glaucoma surgery was needed because of an uncontrolled postoperative IOP even under conservative therapy with local and systemic glaucoma medication. These cases were excluded from the further follow-up so that the results remain unaffected from this factor. The exclusion of these eyes from the follow-up is done from the time point that they received a following glaucoma surgery.

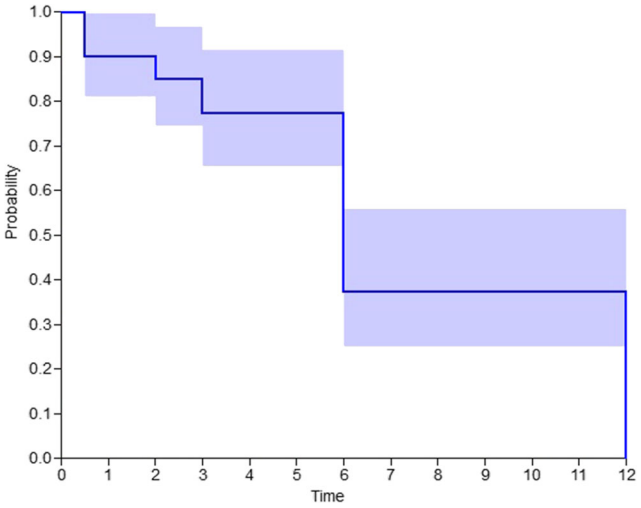

Fig. 3 Kaplan-Meier survival curve of the patients that received a STARflo implant and participated in the study

All patients were admitted to the clinic and the surgical treatment with the STARflo implant was stationary. The ocular surgery was performed under general anesthesia for all patients.

The surgical procedure was performed by experienced surgeons in the eye department and strictly followed the STARflo instruction for use of the manufacturer. At first, a fornix based conjunctival flap is created, followed by hemostasis of the episcleral vessels. Then, a scleral lamella of 7 × 3 mm is prepared, and a limbus-parallel incision is made down to the choroid 1.5 mm from the blue-white border. Then, a 3 mm long and 5 mm wide pocket is prepared between choroid and sclera with a blunt spatula. Subsequently, the body of the implant is placed in the suprachoroidal space and its head in the anterior chamber. At the end, the sclera and the conjunctiva are sutured watertight. (Fig. 4).

The statistical calculations were carried out with R Project: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. In all the statistical processes was used the niveau of significance $\alpha = 0.05$ (5%). When the p value becomes less than the α value, then the corresponding zero hypothesis can be rejected to level 5%. The results were checked for normal distribution using the histogram as a graphical method. Because the examined values could not be derived from a normal distribution, the Wilcoxon sign rank test was used for connected

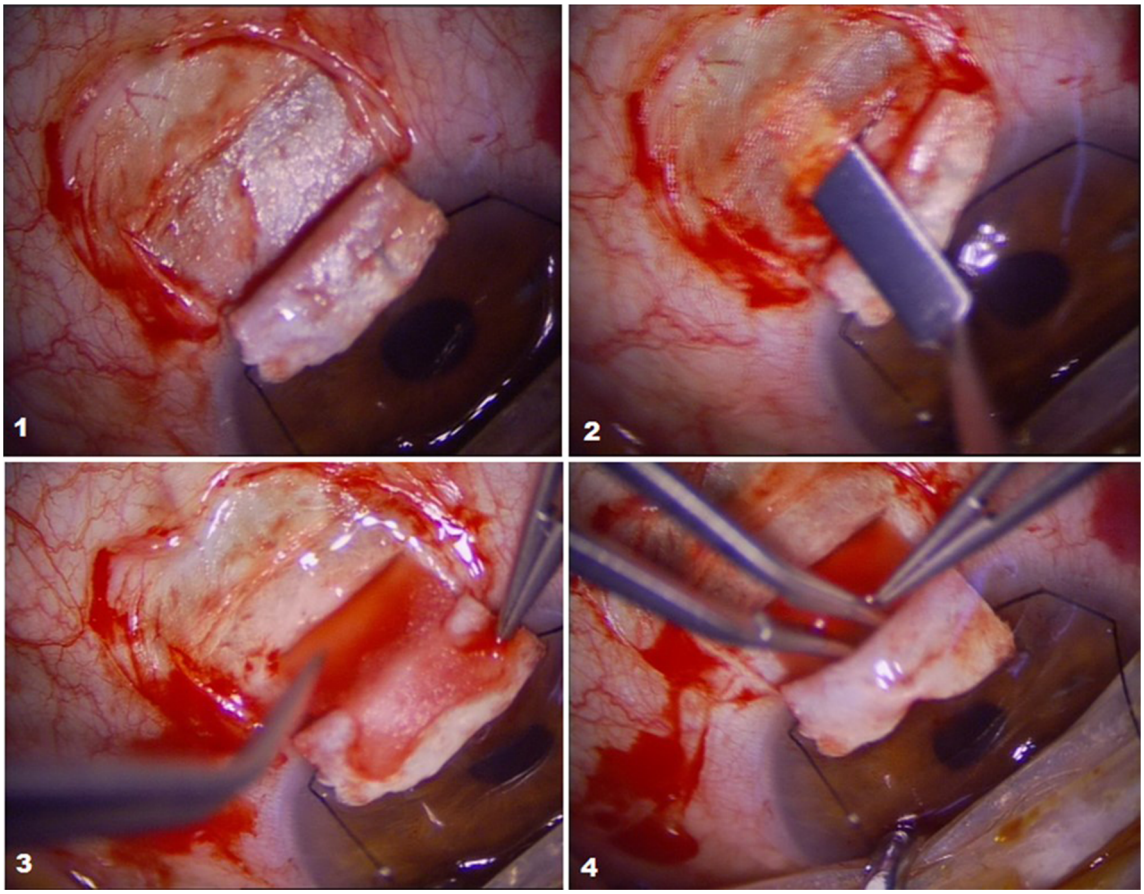

Fig. 4 Presentation of the most important steps of the operative procedure

samples. Thus, the test could be made for significant differences in the values between the different time periods.

Results

The majority of eyes and more specifically 66.6% of the cases had a moderate to advanced primary open-angle glaucoma (POAG). Five patients had PEX glaucoma and three patients had congenital glaucoma.

The 86.1% of the patients were pseudophakic and 27 of the 36 eyes (75%) had already undergone glaucoma surgery (Table 1).

Baseline IOP of patients under maximal local therapy (three to four substances as eye drops) that were included in the study was 19.81 ± 5.2 mmHg. The 38.9% of patients had an IOP of 22.92 ± 9.5 mmHg under local therapy with one to two eye drops. The 27.8% of patients were systemically treated with acetazolamide per os due to multiple intolerance against eye drops or treatment-refractory IOP decompensation.

The preoperative IOP fluctuated between 16 and 39 mmHg, and the mean preoperative intraocular pressure (IOP) was 21.08 (± 7.29) mmHg. The average intraocular pressure on the discharge-day was 9.25 (± 6.89) mmHg. The follow-up IOP 1 month postoperatively was 14.97 (± 7.23) mmHg and 3 months postoperatively was 16.57 (± 2.51) mmHg, which represents a satisfactory short-term result. Twelve months postoperatively, a significant IOP pressure reduction was noticed and the average IOP was 15.0 (± 2.51) mmHg. This corresponds to a reduction of the IOP of 28.8% compared to the preoperative condition (Fig. 5).

The number of the local medications that were administered on average 12 months after the ocular surgery was 0.9, a significant reduction ($p < 0,05$) compared to the 2.7 administered prior to the surgery. This represents a reduction of the local glaucoma therapy of 66.7%. (Fig. 6). In 15.2% of patients, oral acetazolamide has been added due to a significant increase in IOP after the first postoperative month. After 12 months, the IOP regulation was achieved in all patients without any systemic administration of acetazolamide.

Regarding the best-corrected visual acuity, we observed that the visual acuity reached within 12 months the preoperative strength and showed no significant change ($p = 0.1$) (Fig. 7).

The early complications postoperatively include a transient ocular hypotonia in 13.9%, hyphema in three eyes, and

Table 1 Preoperative findings and history of the patients and eye surgeries before the STARflo™ implantation. *IOP* intraocular pressure, *CDR* cup-to-disc ratio, *MD* mean deviation, *PSD* pattern standard deviation, *PC-IOL* posterior chamber intraocular lenses, *ALT* argon laser trabeculoplasty, *SLT* selective laser trabeculoplasty

Preoperative findings			Eye surgeries before the STARflo implantation		
	Average	Standard deviation (SD)	Type of surgery	Eyes in %	Eyes (*n*)
Visus	0.41	0.35	Phacoemulsification/PC--IOL	86.11	31
IOP (mmHg)	21.08	7.28	Trabeculectomy+mitomycin	22.22	8
CDR	0.97	0.05	Kanaloplasty	8.33	3
Pachymetry (μm)	563.2	39.86	Transscleral Cyclophotocoagulation	27.27	8
Gonioscopy (Shaffer Grade)	3.64	0.57	Cypass implant	2.78	1
Visual fields Humphrey MD	− 17.22	8.51	Ahmed-valve implant	0	0
Visual fields Humphrey PSD	7.68	4.15	ALT/SLT	5.56	2
			Goniotomy/trabeculotomy	13.88	5

vitreous hemorrhage in one patient. To-date, there was no IOP elevation as an early postoperative complication. The hyphema and vitreous hemorrhage resorbed completely within 2 weeks. After 3 months, 30.6% of patients showed a hypertensive tendency, which was resolved in all cases in the following 6 months. One patient developed uveitic reaction combined with macular edema on the third postoperative month which resolved completely after the intravitreal application of triamcinolone. The most severe early postoperative complication was an expulsive hemorrhage on the second postoperative day in a young female patient with congenital glaucoma and a long list of previous glaucoma operations. No other device-related serious adverse events were reported during the follow-up period. (Table 2).

In case of unsatisfactory postoperative intraocular pressure, we have indicated an additional operative measure within the 12 postoperative months. In 13.9% of the eyes (five cases) was performed a mild transscleralcyclophotocoagulation. In two cases with refractory IOP decompensation in conservative therapeutic measures, we implanted an Ahmed-valve drainage mechanism respectively in the third postoperative month and after 12 months. In another one patient, the target IOP was not reached even within 6 months postoperatively, and we decided for a trabeculectomy combined with mitomycin C 0.2 mg/ml and a biodegradable and implantable collagen artificial extracellular matrix (Ologen®).

The 71.4% of the eyes that received the STARflo implant 1 year ago reached the target IOP with two or less glaucoma eye drops, and 7.2% of them reached the target IOP without any postoperative reduction of the glaucoma eye drops. The rest 21.4% of the eyes were excluded from the follow-up controls after the secondary glaucoma surgery by decompensated and not regulated IOP despite the glaucoma eye drops.

Discussion

BAGS including the STARflo implant have been introduced to lower IOP in patients with advanced open-angle glaucoma as an alternative to reduce the risk profile of conventional glaucoma surgeries.

Challenging cases were included in our study, with advanced open-angle glaucoma and a long story of past ocular surgeries. The majority of eyes (77.1%) had at least one previous glaucoma surgical procedures and 86% of the eyes were pseudophakic. Even on three eyes with congenital glaucoma

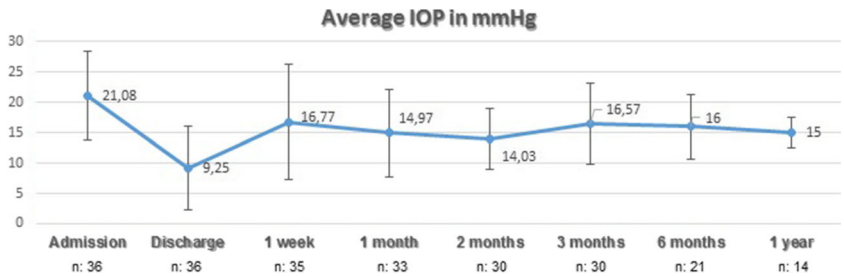

Fig. 5 Graph of the average IOP curve (mmHg) with the standard deviation up to 12 months

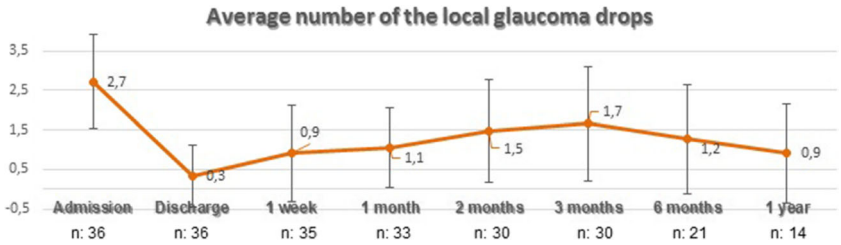

Fig. 6 Graph of the number of local antiglaucoma substances with the standard deviation up to 12 months

was performed the implantation of STARflo without any special difficulties, although the sclera is thinner in these category of patients. Pourjavan et al. and Cseke et al. selected also refractory glaucoma cases to conventional glaucoma treatments for their clinical studies [4, 6]. Cseke et al. even performed the implantation of STARflo in two patients with decompensated neovascular glaucoma with satisfactory lowering of the IOP and retaining the remaining visual acuity in one of the two candidates [4].

Our study shows an IOP reduction of 28.8% after 12 months follow-up compared to the preoperative condition. The average IOP reduction documented in the study of Cseke et al. and in the study of Pourjavan et al. was superior, respectively 32 and 61.35% [4, 6]. Possible explanations include the small amount of patients in these two studies and the severity of open-angle glaucoma of the selected cases of our series. Nevertheless, the IOP reduction, which is achieved in our study, is significant at the 12 months follow-up.

The reduction of the medications at 12 months in our series is superior to the one of Cseke et al.: 66.7 and 48.8%, respectively [4]. The series of four patients with refractory open-angle glaucoma of Pourjavan et al. needed a mean number of glaucoma eye drops of 1.5 after 12 months in comparison to 3.25 preoperatively [6]. We additionally report the admission of the systemic therapy with acetazolamide in five patients of our series (15.2%) after the first postoperative month due to an expected mild IOP increase. According to the STARflo instruction for use such transient, mild IOP peaks are expected between the 4 and 12 postoperative weeks. In this period, oral therapy with acetazolamide is even recommended. At the end of the 12 months, no cases were still under the systemic therapy with acetazolamide. There are no clues in the previous two studies concerning this issue [4, 6].

It is important to mention that 78.6% of the eyes that received the STARflo implant 1 year ago reached the qualified success criterion. The rest 21.4% of the eyes received a secondary glaucoma surgery by decompensated and not regulated IOP under glaucoma eye drops.

Intraoperative complications or severe inflammatory reactions were not observed in none of the three studies. The two previous studies showed transient ocular hypotonia as early postoperative complication that was even combined with choroidal detachment. The ocular hypotonia presented in our clinical study in five patients completely resolved in the first 8 weeks. The bleb formation was avoided in all our patients although Pourjavan et al. reported one case of bleb formation, which disappeared between the first and third month [6]. Repositioning of the STARflo head part was performed in two cases in the clinical trial of Cseke et al. due to a too long sclerocorneal tunnel wound and consecutive endothelial touch and corneal decompensation. No cases of revision of the STARflo Implantation were reported in our study or the one of Pourjavan et al. [4, 6]. Only one case of macular edema was presented in our study as well as the one of Pourjavan et al., and we had to treat it with intravitreal injection of triamcinolone as it persisted for 3 months in total [6].

Each of the previous studies reported one case of unresponsiveness to the STARflo implantation with persistent

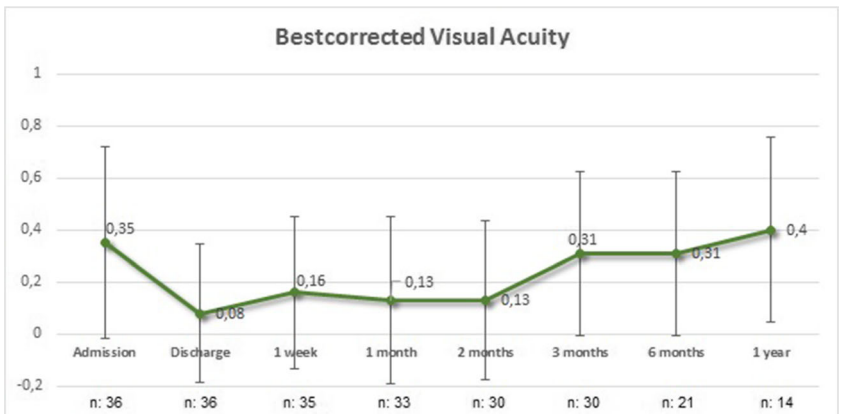

Fig. 7 Graph of the average visual acuity with the standard deviation up to 12 months

Table 2 Postoperative complications after the STARflo implantation. *AC* anterior chamber

Complications							
	Discharge	1 week	1 month	2 months	3 months	6 months	12 months
IOP elevation	0%	25.0%	22.22%	13.89%	30.56%	36.11%	0%
Hypotonia	13.88%	13.-89%	5.56%	0%	0%	0%	0%
Choroid edema	0%	2.78%	0%	0%	0%	0%	0%
Hyphema	8.33%	3.03%	0%	0%	0%	0%	0%
Vitreous hemorrhage	2.78%	2.78%	0%	0%	0%	0%	0%
Fibrin in the AC	2.78%	2.78%	0%	0%	0%	0%	0%
Uveitis	0%	0%	0%	0%	3.03%	0%	0%
Makular edema	0%	0%	0%	0%	3.03%	0%	0%
Expulsive bleeding	2.78%	0%	0%	0%	0%	0%	0%
Corneal decompensation	0%	0%	0%	0%	0%	0%	2.78%

decompensation of the IOP. Pourjavan et al. performed a transscleralcyclophotocoagulation in this candidate in order to stabilize the IOP [6]. We observed also a hypertensive tendency in 30.6% of our cases (11 eyes) after 3 months. In three of them, the IOP could be regulated with glaucoma medications, and in eight patients, a further glaucoma surgical procedure was indicated. Five patients were treated with transscleralcyclophotocoagulation and one patient with trabeculectomy combined with mitomycin and Ologen® implant. Remarkable is the IOP decompensation in one case in the first postoperative month and in another one after 12 months, in which an Ahmed-valve Implantation was inevitable.

We reward the transient rise of the IOP in the early postoperative period (3 months after the STARflo implantation) to a transient presence of fibroblasts in the suprachoroidal space and of multinucleated giant cells (MNGC) in the implant. The retreat of the fibrous tissue and the macrophages in the following postoperative period could explain the gradual stabilization of the IOP in a normoton status. The above hypothesis is even supported from Kammer et al. and Cseke et al. [3–5], who report no encapsulation after 6 months due to the absence of a long-term surrounding fibrous capsule and of the presence of macrophage in experimental studies with rabbits.

Comparing the efficacy and safety of STARflo implant with that of other MIGs and BAGs that are targeting to the lowering of the IOP through the modification of the suprachoroidal space, we noticed that its effectivity is satisfying. STARflo targets to moderate and advanced OAG and achieves a 28.8%reduction of the IOP as well as a 66.7% reduction of the glaucoma medications in the first 12 postoperative months, which is superior to the effectivity of the Cypass implant as a stand-alone treatment in cases with mild to moderate OAG according to the results of CyCLE Study [7]. The studies concerning SOLX Gold implant show a superior lowering effect of the IOP that reaches 35% but fails in

Table 3 Comparison of the efficacy and safety of STARflo with other MIGs and BAGs [3, 7–9]. *IOP* intraocular pressure

Type of suprachoroidal implant	Starflo™	Cypass (alone)	SOLX Gold	iStent Supra	Aquashunt
IOP Reduction	28.84%	26%	32.6–35%	20%	> 20%
Reduction of glaucoma eye drops	66.67%	48%	0%	No data	No data
Serious postoperative adverse events	None	None	None	None	None
Grade of open-angle glaucoma	Moderate to advanced	Mild to moderate	Moderate	Mild to moderate	Mild to moderate

Table 4 Comparison of the efficacy of STARflo with trabeculectomy and tube shunt implants [10, 11]. *IOP* intraocular pressure

Type of glaucoma surgery	Starflo™	Trabeculectomy + mitomycin	Baerveldt implant	Ahmed-valve implant
IOP reduction	28.84%	50.4%	55%	49%
Reduction of glaucoma eye drops	66.67%	83.3%	65%	42%

reducing the number of the local glaucoma medications [8, 9]. The ongoing pilot studies related to iStent Supra and Aquashunt report a reduction of IOP of 20% in patients with mild till moderate OAG without further data concerning the glaucoma eye drops [6] (Table 3).

In comparison to the traditional glaucoma surgeries including the trabeculectomy with mitomycin and the tube shunt implants, the STARflo implant fails to reach their efficacy concerning the reduction of the IOP. The significant drop of the IOP of 28.8% through STARflo remains inferior to 50.4% after a trabeculectomy combined with mitomycin or to 49–55% after a tube shunt implantation [10, 11]. However, the reduction of glaucoma local medication on the 12th month after the implantation of STARflo (66.67%) seems to be more satisfactory than the one after the implantation of an Ahmed-valve shunt (42%) [11]. The remarkable advantage of STARflo is the avoidance of persistent postoperative complications such as ocular hypotonia with choroidal detachment that can potentially lead to permanent reduction of the visual acuity. The possibility of postoperative expulsive choroidal bleeding seems also to be lower, although in our study, one case of expulsive bleeding in the early postoperative period is reported [10, 11] (Table 4).

In conclusion, the STARflo implantation succeeded in stabilizing the IOP and showing a significant reduction of glaucoma medications in the majority of the cases with refractory OAG and achieved similar results when compared to glaucoma medication as well as traditional glaucoma surgeries. Eight patients failed to respond to the effect of the STARflo implant, and glaucoma surgery including transscleralcyclophotocoagulation, trabeculectomy, and Ahmed-valve implantation was required to manage the uncontrolled IOP. The efficacy of this surgical procedure seems to be superior to that of other MIGs that target to the remodeling of the suprachoroidal space. According to the 12-month results, the STARflo fails to present a comparable reduction of the IOP and the glaucoma eye drops like trabeculectomy and tube shunt implants but seems to be a safer procedure for the management of refractory cases of OAGs with limited possibility of vision-threatening complications. Therefore, the STARflo implantation is an important alternative surgical option in patients with refractory open-angle glaucoma when compared to conventional glaucoma surgery including trabeculectomy with mitomycin and canaloplasty.

According to our early experience, an IOP rise can be expected between 2 and 6 weeks following the implantation of the STARflo device. This should be taken into account before indicating additional glaucoma surgical procedures, and we advise to wait at least 3 months.

It is very important to be mentioned that the total number of the STARflo devices that were implanted at different time points in this follow-up of 12 months in this prospective study is included. Consequently, the study is still ongoing, and till now, 14 eyes have completed the 12-month follow-up. Although the number of the follow-ups after 12 months is still limited, the preliminary results help us to demonstrate already a significant efficacy of the STARflo implant.

In conclusion, the early results of the STARflo implant met a sufficient safety standard and showed a satisfactory reduction of IOP, but no patient had reached a complete success so far (after 12 months). Whether this promising suprachoroidal implant for bleb-free IOP reduction in cases with refractory open-angle glaucoma represents a competent alternative to conventional glaucoma surgeries is to be supported from long-term results.

Acknowledgements There is no support, including pharmacological and industry support.

Compliance with ethical standards

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee of St. Johannes Hospital in Dortmund, Germany, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Abbreviations BAGS, blebless ab-externo glaucoma surgery; CyCLE, CyPass clinical experience study; IOP, intraocular pressure; MIGS, micro-invasive glaucoma surgery; MNGC, multinucleated giant cells; OAG, open-angle glaucoma; PEX, pseudoexfoliation; POAG, primary open-angle glaucoma; YAG, Neodym-dotierter Yttrium-Aluminum-Granat Laser

References

1. Pourjavan S, Collignon NJM (2014) STARflo. In: Samples, John R, Ahmed, Iqbal Ike K (eds) Surgical Innovations in Glaucoma. Springer Science+Business Media, New York, pp 235–251
2. Gigon A, Shaarawy T (2016) The suprachoroidal route in glaucoma surgery. J Curr Glaucoma Pract 10:13–20
3. Kammer JA, Mundy KM (2015) Suprachoroidal devices in glaucoma surgery. Middle East Afr J Ophthalmol 22:45–52
4. Cseke I, Vámosi P, Bausz M (2016) STARflo glaucoma implant: early experience in Hungary. Rom J Ophthalmol 60:14–17
5. Vanbrabant M (2012) STARflo. http://www.istarmed.com/products/STARflo/. Accessed 20 June 2017
6. Pourjavan S, Collignon N, De Groot V (2013) STARflo glaucoma implant 12 month clinical results. Acta Ophthalmol 91:252
7. Garcia-Feijoo J, Rau M, Ahmed I, Antonio A, Grabner G, Ianchulev T (2012) Safety and efficacy of CyPass micro-stent as a stand-alone treatment for open angle glaucoma: worldwide clinical experience. European Society of Cataract and Refractive Surgery Annual Meeting Sep 8-12, 2012; Milan, Italy
8. Ichhpujani P, Moster MR (2014) SOLX suprachoroidal shunt. In: Samples JR, Ahmed II (eds) Surgical innovations in glaucoma. Springer Science+Business Media, New York, pp 253–256
9. Melamed S, Ben Simon GJ, Goldenfeld M, Simon G (2009) Efficacy and safety of gold micro shunt implantation to the supraciliary space in patients with glaucoma: a pilot study. Arch Ophthalmol 127:264–269
10. Gedde SJ, Schiffman JC, Feuer WJ, Herndon LW, Brandt JD, Budenz DL, Tube Versus Trabeculectomy Study Group (2012) Treatment outcomes in the tube versus trabeculectomy (TVT) study after five years of follow-up. Am J Ophthalmol 153:789–803
11. Christakis PG, Tsai JC, Kalenak JW, Zurakowski D, Cantor LB, Kammer JA, Ahmed II (2013) The Ahmed versus Baerveldt study: three-year treatment outcomes. Ophthalmology 120:2232–2240