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A Variant of Micro-Invasive Glaucoma Surgery: Calibrated Reverse Meridional Cyclodialysis *ab interno* Involving Implantation of a Non-Absorbable Collagen Implant



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ABSTRACT

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Purpose. To assess safety and effectiveness of calibrated cyclodialysis *ab interno* involving implantation of a non-absorbable collagen implant in the suprauveal space in decreasing IOP in glaucoma patients. **Methods.** Forty-three patients (43 eyes; 16 male and 27 females; average age — 70.4 ± 10.0 years) were included in this pilot study. A 6 mm long and 2.0 mm wide cyclodialysis cleft was created *ab interno* in one of the lower quadrants of the eye using a specially designed spatula followed by insertion of a strip of implant in the cleft. In 19 eyes (44.3 %) the procedure was performed as standalone procedure and in 24 eyes (55.7 %) along with cataract surgery. Outcome measures were IOP change, use of hypotensive medication(s), complications, and need for a second surgery. Decrease in IOP by >20 % and IOP between 6 and 21 mmHg without hypotensive medication(s) constituted complete success; similar changes in IOP with medication(s) constituted partial success. Need for second surgery constituted failure. **Results.** At 6 months, baseline IOP decreased from 20.6 ± 7.4 mmHg to 12.9 ± 4.9 mmHg (a decrease by 37.4 %; $p < 0.001$) and hypotensive medication use reduced from 2.6 ± 0.8 to 1.0 ± 1.1 (a reduction by 57.7 %; $p < 0.001$). Complete success was achieved in 19 eyes (44.2 %), partial in — 15 eyes (34.9 %). Nine eyes had unsuccessful outcomes (20.9 %); among these, seven eyes (78 %) had severe glaucoma and five eyes (55 %) had undergone previously glaucoma surgeries. Hemorrhaging at the cleft site was the most common intraoperative complication — 18 eyes (41.9 %). Postoperative complications included hyphema, which was completely resorbed within one week. **Conclusion.** Calibrated cyclodialysis *ab interno* procedure involving implantation of a non-absorbable collagen implant in the suprauveal is safe and easy to perform. It effectively decreases IOP in patients with moderate glaucoma but is less effective in patients with severe glaucoma and in patients with previously failed glaucoma surgeries. Complications were found to be minimal.

Keywords: glaucoma, calibrated cyclodialysis *ab interno*, non-absorbable collagen implant, glaucoma surgery, suprachoroidal drainage, uveoscleral outflow, glaucoma implant

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Вариант микроинвазивной хирургии глаукомы: дозированный обратный меридиональный циклодиализ *ab interno* с имплантацией нерассасывающегося коллагенового импланта

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РЕЗЮМЕ

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Цель. Оценить безопасность и эффективность дозированного обратного меридионального циклодиализа *ab interno* с имплантацией нерассасывающегося коллагенового импланта в супраувеальное пространство при открытоугольной глаукоме. **Пациенты и методы.** В данное пилотное исследование были включены 43 пациента (43 глаза; 16 мужчин и 27 женщин; средний возраст — 70,4 ± 10 лет). Всем пациентам с помощью специально сконструированного шпателя в одном из нижних квадрантов глаза провели дозированный циклодиализ *ab interno* шириной 2,0 и глубиной 6,0 мм с последующей установкой имплантата. В 19 случаях (44,2 %) выполняли только антиглаукомную операцию, в 24 случаях (55,8 %) провели комбинированную операцию совместно с факоэмульсификацией и имплантацией интраокулярной линзы. Критериями эффективности проведенной операции являлись динамика ВГД, потребность в дополнительной гипотензивной терапии, необходимость повторного хирургического вмешательства и наличие осложнений. Успех считался полным, если снижение ВГД достигало более 20 % и ВГД было в пределах от 6 до 21 мм рт. ст. без применения гипотензивных средств, признанным успех считался при необходимости применения дополнительной гипотензивной терапии. Неудачей считалась необходимость повторного хирургического вмешательства. **Результаты.** Через 6 месяцев после операции ВГД снизилось с 20,6 ± 7,4 до 12,9 ± 4,9 мм рт. ст. (снижение на 37,4 %; $p < 0,001$). Применение гипотензивных препаратов сократилось с 2,6 ± 0,8 до 1,0 ± 1,1 (снижение на 57,7 %; $p < 0,001$). Полного успеха удалось достигнуть в 19 случаях (44,2 %), признанного успеха в 15 случаях (34,9 %). Неудачный исход имел место в девяти случаях (20,9 %), из них семь глаз были с далеко зашедшей стадией глаукомы и пять глаз — с ранее проведанными антиглаукомными операциями. Геморрагия на месте циклодиализа была наиболее частым осложнением — 18 случаев (41,9 %). В послеоперационном периоде наблюдали гифему, которая резорбировалась самостоятельно в течение одной недели. **Заключение.** Дозированный циклодиаз *ab interno* с имплантацией нерассасывающегося коллагенового импланта в супраувеальное пространство является безопасной и легковыполнимой операцией. Данное хирургическое вмешательство эффективно снижает ВГД у пациентов с развитой стадией глаукомы, но менее эффективно у пациентов с далеко зашедшей стадией глаукомы и у пациентов с ранее проведанными антиглаукомными операциями. Осложнения были минимальными.

Ключевые слова: глаукома, дозированный циклодиализ *ab interno*, нерассасывающийся коллагеновый имплантат, хирургия глаукомы, супрахориоидальное дренирование, увеосклеральный отток, глаукомный имплантат

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INTRODUCTION

Open-angle glaucoma (OAG) is a multifactorial surgical disease. Increased intraocular pressure (IOP) is the only factor that can be affected by medication, laser or by surgery. Aqueous humor (AH) flows from anterior chamber (AC) through the trabecular pathway and the uveoscleral pathway. Both generally play an equal role in AH outflow [1], though there is evidence of the uveoscleral pathway carrying up to 60 % of the AH outflow in young people [2].

Previous surgical methods in management of glaucoma focused on creating an artificial pathway for AH outflow. A classic example is trabeculectomy. Trabeculectomy effectively decreases IOP for a substantial period but is accompanied by a number of serious complications such as hypotonia, hypotonic maculopathy, a shallow AC, choroidal effusion, hyphema, bleb leakage, and endophthalmitis [3, 4]. Deep sclerectomy, a non-penetrating surgery for glaucoma, is safer and risks fewer complications, but it has short-term hypotensive effect [5].

Minimally invasive glaucoma surgery (MIGS) is a new development for restoring AH outflow along natural pathways in glaucoma patients. A variety of devices have been proposed and developed for this purpose [6]: trabecular devices allow AH to bypass resistance in the trabecular zone and flows directly from AC to Schlemm's canal and then through the collection canals to the episcleral veins; subconjunctival devices create an additional *ab interno* pathway from AC to

the subconjunctival space [7]; suprachoroidal devices create a direct path from AC to the suprachoroidal space (SCS).

A variant of MIGS has been developed featuring creation of a calibrated reverse meridional cyclodialysis performed *ab interno* (Cai) with the help of a specially designed and calibrated cyclodialysis spatula followed by implantation of a biologically inert non-absorbable bone-collagen implant (CI) in the suprauveal space as space holder and uveoscleral-outflow enhancer.

A pilot study was carried out with the aim to assess safety and effectiveness of Cai involving implantation of CI in the suprauveal space in decreasing IOP in glaucoma patients.

PATIENTS AND METHODS

A total of 43 patients (43 eyes) were included in this study. Every patient underwent Cai involving implantation of CI in the suprauveal space. One surgeon (VK) conducted all the operations between August 2018 and January 2019. The study was approved by Institutional Review Board and Ethics Committee. The study adhered to Declaration of Helsinki. Written informed consent was obtained from all participants in the study.

Patient inclusion criteria were OAG; refractory glaucoma (RG); medically uncontrolled IOP; non-compliance with prescribed hypotensive medication; informed consent provided; postoperative follow-up not less than 6 months; visually significant cataract; decompensated IOP after previous glaucoma and cataract surgery. Exclusion criteria were narrow-angle glaucoma; closed-angle glaucoma; acute attack of glaucoma; neovascular glaucoma; congenital and phacomorphic glaucoma.

Before surgery, a comprehensive ophthalmological examination was carried out. IOP was measured by either Maklakov's method or an iCare tonometer (ic100, Icare Finland Oy). For statistical purposes IOP values obtained by Maklakov's method were converted to P_0 using the conversion table. When measuring IOP using the iCare tonometer, the median of three consecutive measurements was taken into consideration [8].

The CI (Xenoplast, Dubna-Biofarm, Russia), made from a material containing bone collagen type I, isolated from the spongy bone of farm animals and saturated with bone sulfate glycosaminoglycans was selected for the purpose for the following reasons: the architecture of the CI mimics the structure of the human trabecula; it is biologically inert with a porous structure; it is not dissolved in tissue fluids or encapsulated in ocular tissue; the CI had been successfully used to improve the effectiveness of anti-glaucoma operations [9].

The calibrated cyclodialysis spatula made from stainless steel and titanium was curved and followed the natural contour of the potential space between the sclera and the ciliary body (Fig. 1a) with a working distal end measuring 6.0 mm long, 2.0 mm wide and 0.5mm thick. Only one eye per patient was eligible for surgery. After retrobulbar anesthesia and insertion of a lid speculum, a clear corneal incision (2.2 mm) was made at the 10–11 o'clock position. The AC was irrigated with 0.3 ml of 0.01 % solution of carbachol (Appasamy Ocular Devices, Pvt., Ltd., Chennai, India) to constrict the pupil and pull the iris away from the angle. The AC was filled with cohesive viscoelastic device (1.4 % solution of sodium hyaluronate, Beaver Visitec International, Inc., Waltham, MA, USA). Further, two paracenteses were made 180 degrees apart for irrigation and aspiration purposes. To visualize the angle structures, the patient's head was turned approximately 30 degrees away from the surgeon and the optical head of the operating microscope tilted 30 degrees toward the surgeon. A surgical goniolens was placed on the cornea. The cyclodialysis spatula was inserted into the AC through the main incision, and, under visual control, a part of the ciliary body was gently detached from the scleral spur at 16.00–16.30 o'clock position. Through this cleft, the spatula was meridionally advanced until a 6 to 6.5-mm long and 2.0 to 2.5-mm wide tunnel was created (Figs. 1b–d). The spatula and goniolens were withdrawn. If hemorrhage occurred at the cyclodialysis site, a wait-and-watch strategy was used. Next, the CI was captured using an angled suture tying forceps and its fore end was inserted into the AC through the corneal incision (Figs. 1e). The CI was pushed into the AC until it was completely inside the chamber. Using the goniolens again, the CI was inserted into the suprauveal cleft with the help of either forceps or a pusher (Figs. 1f–h). The viscoelastic device was aspirated from the AC. Finally, all incisions were hydrated. For eyes with coexisting pathologies, first ultrasound phacoemulsification (phaco) was performed with implantation of a foldable IOL followed by removal of all viscoelastic from behind the IOL before Cai. The Cai procedure involving CI implantation was performed according to the technique described.

Preoperatively, patients' ocular hypotensive medications were not washed out. Patients discontinued IOP-lowering medications 1 day before surgery and oral acetozolamide 0.25g (Diacarb, Polpharma, Starogard Gdański, Poland) was prescribed twice daily for 1 day. Postoperatively, patients were instructed to resume IOP-lowering medications only if the investigator determined that additional IOP lowering was needed. Patients were evaluated daily during their hospital stay, and then again at 1 week, 1 month, 3 months and 6 months after surgery. Postoperative assessment included visual acuity (VA) assessment, tonometry, biomicroscopy, ophthalmoscopy, and gonioscopy. Wherever possible, findings were documented via photography and videography.

For VA assessment Snellen's chart was used. For analysis purposes VA was converted to LogMAR (minimum-angle-of-resolution logarithm). VA changes were assessed separately for patients who underwent the standalone procedure and for patients who underwent combined interventions.

The Cai procedure involving implantation of CI as a standalone procedure was performed on 19 patients (19 eyes, 44.3 % of total sample). Of these, ten patients had previously undergone various glaucoma surgeries. For 24 patients (24 eyes, 55.7 %) with visually significant cataracts, a combined procedure was conducted; cataract surgery was followed by the Cai procedure. Among these patients, glaucoma surgery had previously been performed in seven eyes. There was one patient with a dislocated IOL-capsule bag complex;

this was removed via 5.5 mm scleral tunnel and an iris-claw IOL was fixed at the back of iris followed by Cai procedure.

At each follow-up visit, consultants noted IOP, the number of different types of hypotensive drugs being used, adverse events, if any, and the need for repeat surgery. Paired t-tests were used to analyze IOP change and the use of hypotensive medications. An IOP decrease of more than 20 % and an IOP measurement between 6 and 21 mmHg without any hypotensive medication was considered a complete success; if additional hypotensive drugs were required, the surgery was considered a partial success. Unsuccessful outcomes included an IOP measurement of less than 6 mmHg or more than 21 mmHg, an IOP decrease of less than 20 %, and the need for repeat surgery. Cases with medically controlled glaucoma before operation were evaluated as follows: the surgery was considered a complete success if the patient didn't require hypotensive medication and IOP was less than 21 mmHg; the surgery was considered a partial success if additional hypotensive medication(s) were required and their number was less than before operation. Treatment was considered unsuccessful if the IOP measured above 21 mmHg, irrespective of hypotensive medication use.

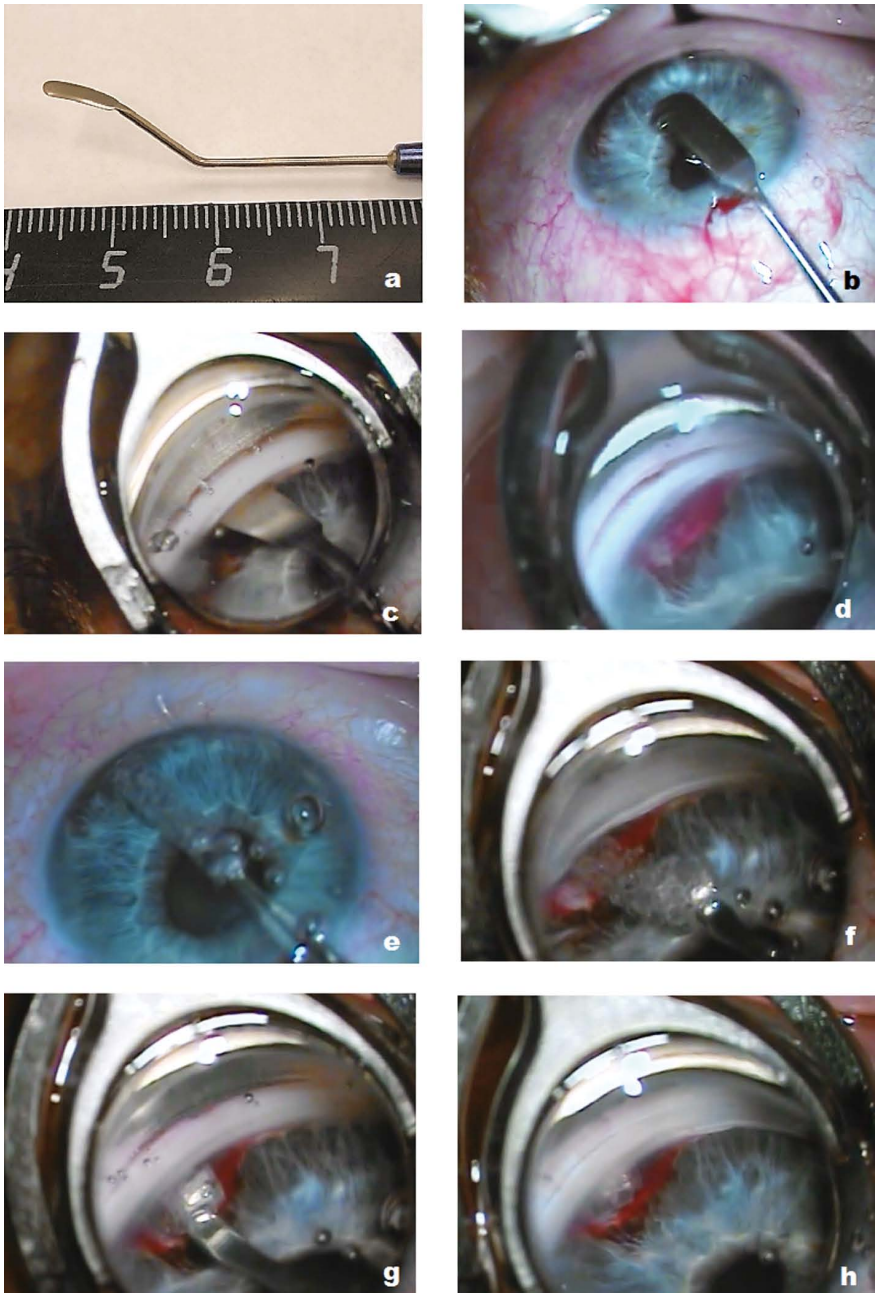

Fig. 1: a) side view of the spatula for calibrated reverse meridional cyclodialysis *ab interno*; b–d) show steps to create calibrated reverse meridional cyclodialysis *ab interno* with the help of cyclodialysis spatula; e–h) show steps to implant collagen implant in the cyclodialysis cleft

Рис. 1: a) шпатель для проведения дозированного обратного меридионального циклодиализа *ab interno* — вид сбоку; b–d) этапы формирования дозированного обратного меридионального циклодиализа *ab interno* с помощью циклодиализного шпателя; e–h) этапы имплантации коллагенового импланта в циклодиализную щель

Gonioscopic assessment of the cyclodialysis cleft and the CI position were carried out as follows: if a part of the implant's distal end was visible in the AC angle and cyclodialysis cleft could be identified from both sides of the implant and inner scleral surface was visible, then the CI's positioning was considered correct and the cleft was open (fig. 2a); if the implant's distal end was identifiable in the AC and cleft was visible on both sides but the inner surface of the sclera was not visible through it, then the opening was considered as semi-closed (fig. 2b); if the CI's distal end was not visible or was engulfed by uveal tissue and no cleft and no details of the inner scleral surface were visible, it was considered as complete closure of the cyclodialysis cleft (fig. 2c). SPSS Statistics (IBM) 22.0 (StatSoft; USA) software for Windows 10 was used for statistical processing. The differences were statistically significant for $p < 0.05$.

RESULTS

Demographic data of the patients and preoperative characteristics of the eyes are presented in table 1.

The average postoperative observation period was 31.0 ± 11.1 weeks (95 % CI 27.7–34.3).

At 6 months, mean baseline IOP decreased from 20.6 ± 7.4 mmHg (95 % CI 18.3–22.8) to 12.9 ± 4.9 (95 % CI 11.4–14.4) ($p < 0.001$), which constituted a decrease by 37.4 %. Figure 3 demonstrates IOP values after surgery at different follow up periods. The number of hypotensive medications used by patients reduced

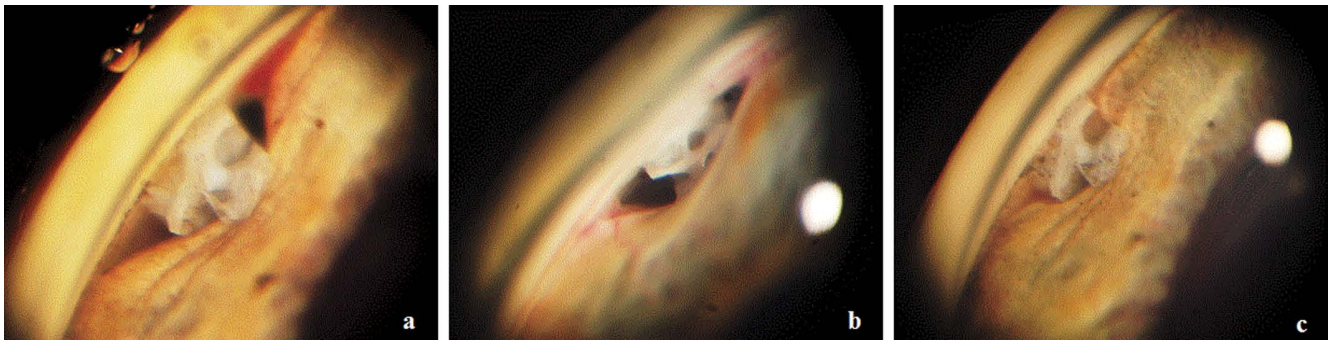

Fig. 2. Gonioscopic assessment of collagen implant positioning and cyclodialysis cleft: a) shows an open cleft, where the implant's distal end is visible from the anterior chamber angle, the cyclodialysis cleft is seen from both sides and inner scleral surface is identifiable; b) shows semi-closed cleft, where the implant's distal end is visible in the anterior chamber and cleft is visible on both sides but the inner surface of the sclera is not visible; c) shows complete closure of the cleft, where the implant's distal end is completely surrounded by uveal tissue, no cleft is seen and inner scleral surface could not be identified

Рис. 2. Гониоскопическая оценка расположения коллагенового имплантата и состояния циклодиализной щели: a) открытая щель, в углу передней камеры визуализируется дистальный конец имплантата, циклодиализная щель просматривается с двух сторон от имплантата, просматривается внутренняя поверхность склеры; b) полузакрытая циклодиализная щель, в углу передней камеры визуализируется дистальный конец имплантата, циклодиализная щель просматривается с двух сторон имплантата, через щель не просматривается внутренняя поверхность склеры; c) полностью закрытая циклодиализная щель, дистальный конец имплантата полностью окружен увеальной тканью, отсутствует циклодиализная щель и не просматривается внутренняя поверхность склеры

Table 1. Demographic data of patients and preoperative characteristics of the eyes

Таблица 1. Демографические данные пациентов и основные характеристики глаз

	Number of patients (%) Mean ± standard deviation (95 % confidence interval) **Кол-во пациентов (%) Среднее ± стандартное отклонение (95 % доверительный интервал)**
Sex: male / female / Пол: мужчины / женщины	16 (37.2) / 27 (62.8)
Average age / Средний возраст male / мужчины female / женщины	70.4 ± 10.0 (95 % CI 67.4–73.4) 66.9 ± 10.9 (95 % CI 61.6–72.3) 72.4± 9.10 (95 % CI 69.0–75.9)
Eye: right / left / Глаз: правый / левый	19 (44.2) / 24 (55.8)
Glaucoma type / Тип глаукомы primary open angle / первичная открытоугольная refractive / рефрактерная secondary / вторичная	 23 (53.5) 17 (39.5) 3 (7)
Severity of glaucoma: moderate / severe / Стадия глаукомы: развитая / далеко зашедшая	11 (25.6) / 32 (74.4)
IOP: baseline / ВГД: исходное	20.6±7.4 (95 % CI 18.3–22.8)
IOP > 21 mmHg / IOP < 21 mmHg / ВГД >21 мм рт. ст. / ВГД < 21 мм рт. ст.	18 (41.8) / 25 (58.2)
Mean number of hypotensive medications used / Среднее количество используемых гипотензивных препаратов 1 type of hypotensive medication / 1 вид гипотензивных препаратов 2 types of hypotensive medications / 2 вида гипотензивных препаратов 3 types of hypotensive medications / 3 вида гипотензивных препаратов 4 types of hypotensive medications / 4 вида лекарственных препаратов	2.8±0.8 (95 % CI 2.4–2.9) 2 (4.7) 16 (37.2) 19 (44.2) 6 (14)
Number of patients with previously failed glaucoma surgeries / Количество пациентов, ранее оперированных по поводу глаукомы Glaucoma surgery performed 1 time / Оперирован 1 раз по поводу глаукомы Glaucoma surgery performed 2 times / Оперирован 2 раза по поводу глаукомы	17 (39.5) 12 (27.9) 5 (11.6)
Previously performed glaucoma surgery (eyes) / Ранее проведенная антиглаукомная операция (глаза) Trabeculectomy / Трабекулэктомия Segmental dilation of Schlemm's canal / Сегментарная дилятация шлеммова канала Deep sclerectomy / Непроникающая глубокая склерэктомия Laser iridotomy / Лазерная иридотомия Cyclodialysis *ab interno* / Циклодиализ *ab interno* Selective laser trabeculoplasty / Селективная лазерная трабекулопластика	 7 6 4 2 2 1
Lens condition / Состояние хрусталика: cataract / катаракта pseudophakia (including 1 case of IOL subluxation) / псевдофакия (в том числе 1 пациент с дислокацией ИОЛ) phakic eyes / факичные глаза	 24 (55.8) 12 (27.9) 7 (16.3)

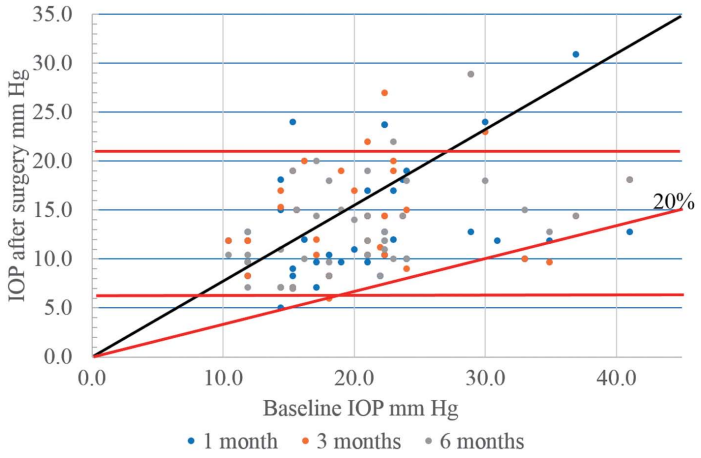

Fig. 3. Scattergram showing IOP values after surgery at different follow up periods. Each dot represents one eye of the patient. Red lines, oblique and horizontal ones represent success criteria

Рис. 3. Скатерограмма, демонстрирующая значение ВГД после операции на различные сроки послеоперационного наблюдения. Каждая точка на диаграмме представляет один глаз пациента. Критерии успеха обозначены красными линиями

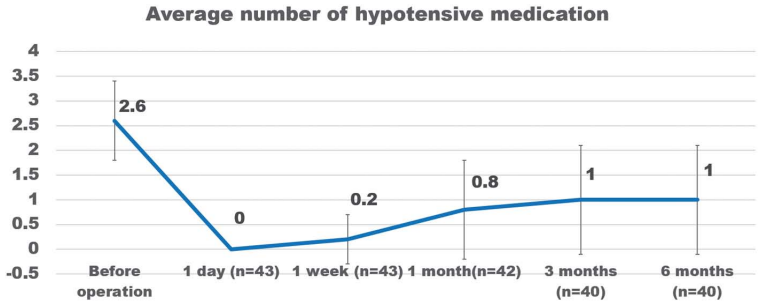

Fig. 4. Graph of hypotensive medication use after surgery

Рис. 4. Графическое изображение изменения в количестве использованных гипотензивных препаратов после операции

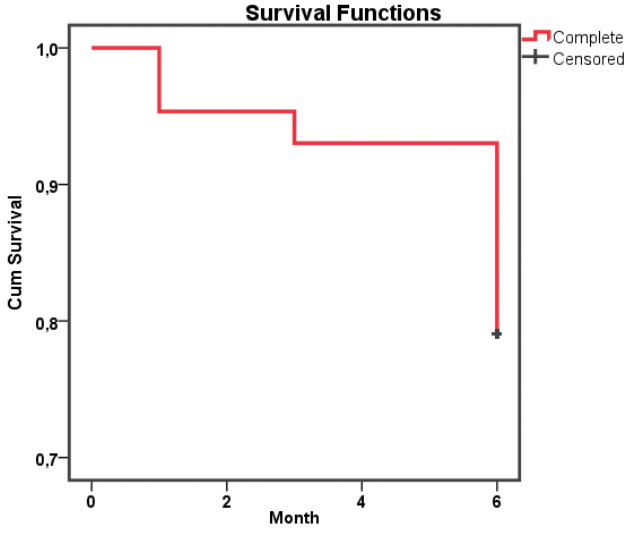

Fig. 5. The Kaplan-Meyer survival curve after calibrated reverse meridional cyclodialysis *ab interno* involving implantation of a collagen implant

Рис. 5. Кривая выживаемости Kaplan—Meyer после проведения дозированного меридионального циклодиализа *ab interno* с имплантацией коллагенового имплантата

from 2.6 ± 0.8 (95 % CI 2.4–2.9) to 1.0 ± 1.1 (95 % CI 0.7–1.3), which constituted a reduction by 57.7 % ($p < 0.001$). Changes in hypotensive medication(s) use after surgery are presented in figure 4.

A success-rate analysis depending upon various predisposing factors is presented in table 2. The analysis allowed to identify several predisposing factors influencing surgical outcomes. The factors were as follows: coexisting patholgies (failure rate = 20.8 % among such cases); pseudophakic eyes (failure rate = 25 %); severe glaucoma (failure rate = 21.9 %) and previously failed glaucoma surgeries (failure rate = 29.4 %).

The Kaplan—Meyer survival curve following the Cai procedure is presented in figure 5.

There were no cases of hypotony or shallow AC during the follow-up. At 6 months, IOP was between 6.1 and 10.0 mmHg in 12 eyes (27.9 %), between 10.1 and 15.0 mmHg in 19 eyes (44.2 %), between 15.1 and 18.0 mmHg in three eyes (7.0 %), and between 18.1 and 21 mmHg in four eyes (9.3 %). In two eyes (4.7 %), IOP was above 21mmHg. There was no change in IOP for three eyes (7.0 %) and an increase in IOP was noted in another three eyes. IOP decreased by less than 20 % in six eyes (14 %), by more than 20 % but less than 30 % in four eyes (9.3 %), and by more than 30 % but less than 40 % in three eyes (7 %). For 21 eyes (48.7 %), the decrease was greater than 40 %. Three patients (7 %) required a second hypotensive surgery within 6 months after operation.

Average VA before surgery was 0.7 ± 0.8. For patients who underwent the standalone procedure, VA was unchanged in eight patients (44.4 %), improved by two lines in one patient (5.6 %), by four lines in two patients (11.1 %), by eight lines in one patient (5.6 %); VA worsened by two lines in one patient (5.6 %), by three lines in two patients (11.1 %), and by six lines in one patient (5.6 %). For the patient with the dislocated IOL-capsule complex, VA improved by four lines after surgery. For patients who underwent combined procedures, VA was unchanged in eight patients (33.3 %), improved by one line in one patient (4.2 %), by two lines — four (16.7 %), by three lines in two patients (8.3 %), by five lines in one patient (8.3 %), by six lines in two patients (8.3 %), and by ten lines in one patient (4.2 %). One patient demonstrated VA worsened by two lines (4.2 %) and two patients by four lines (8.3 %). It was observed that for both groups, postsurgical VA deterioration was not related to previously performed glaucoma surgeries. However, there was a correlation with the severity of the glaucoma: six out of the seven patients whose VA worsened after surgery had advanced glaucoma. Changes in VA after surgery are shown in figure 6.

Table 2. Success rate at six months depending upon various predisposing factors

Таблица 2. Успех через шесть месяцев в зависимости от предрасполагающих факторов

Preoperative predisposing factors / Предрасполагающие факторы до операции	Success, number of eyes (%) / Успех, количество глаз (%)		
	complete / полный	partial / признанный	failure / неудача
all eyes / Все глаза (*n* = 43)	19 (44.2)	15 (34.9)	9 (20.9)
Cataract / Катаракта (*n* = 24)	9 (37.5)	10 (41.7)	5 (20.8)
Pseudophakic eyes / Псевдофакичные глаза (*n* = 12)	5 (41.7)	4 (33.3)	3 (25.0)
Phakic eyes / Факичные глаза (*n* = 7)	5 (71.4)	1 (14.3)	1 (14.3)
Severity of glaucoma / Стадия развития глаукомы			
Severe glaucoma / Далеко зашедшая стадия развития (*n* = 32)	12 (37.5)	13 (40.6)	7 (21.9)
Moderate glaucoma / Развитая стадия (*n* = 11)	7 (63.6)	2 (18.2)	2 (18.2)
Baseline IOP / Исходное ВГД			
>21 mmHg (*n* = 18)	5 (27.8)	9 (50.0)	4 (22.2)
< 21 mmHg (*n* = 25)	14 (56.0)	6 (24.0)	5 (20.0)
Previously failed glaucoma surgery / Ранее оперированные глаза по поводу глаукомы (*n* = 17)	5 (29.4)	7 (41.2)	5 (29.4)
Number of hypotensive medications used / Количество используемых гипотензивных препаратов			
<=2 types of medication / <=2 вида лекарственных препаратов (*n* = 18)	6 (33.3)	6 (33.3)	6 (33.3)
>2 types of medication / >2 вида лекарственных препаратов (*n* = 25)	13 (20.0)	9 (52.0)	3 (12.0)

It was possible to perform Cai and implantation of CI in all cases. During the learning phase, some difficulty in inserting the CI through corneal incision was encountered in four cases (9.3 %). Hemorrhaging at the cleft site, requiring prolonged irrigation of the AC was the most common intraoperative complication, being observed in 18 cases (41.9 %).

In the early postoperative period, hyphema was prevalent in nine cases (20.9 %), but reabsorbed spontaneously within one week. There were four cases of positive Tindal phenomenon, all of which responded satisfactorily to medical therapy.

At last follow up, gonioscopy could be performed in 28 eyes (65 % of total eyes). It was noted that the CI was appropriately located in 25 eyes (89.3 %). In two eyes (7.1 %), only the end of the distal part of CI was visible in AC angle; in one eye (3.6 %), the CI could not be located. The cyclodialysis cleft was open in 19 eyes (67.8 %), partially closed in one eye (3.6 %) and completely closed in eight eyes (28.6 %).

Upon ultrasound biomicroscopy, the CI with its porous structure and an extended space behind it could be easily identified (fig. 7).

DISCUSSION

MIGS features a high safety profile and is designed to restore the natural outflow pathways of AH, but, technically and practically, it is not possible to bypass all the resistance points in the AH outflow pathway [7].

Uveoscleral outflow involves the bulk flow of AH through the ciliary muscle into the SCS, from where it flows into the choroid and suprachoroidal clefts, subsequently exiting the eye through permeable scleral collagen bundles or the perivascular spaces of the emissarial scleral channels. There is a possible connection between the uveoscleral outflow pathway and the lymphatic system, which maintains tissue fluid balance [10]; a gradient of negative pressure within the SCS serves as the conduit for this aqueous flow pathway [11].

Cyclodialysis is the surgical procedure which creates a direct pathway for AH to flow from AC to suprauveal space. The most common cause of cyclodialysis failure is the fibrosis of the cleft. Various devices have been developed to maintain the cyclodialysis cleft patent, including CyPass Micro-Stent (Transcend Medical, USA), iStent Supra (Glaukos, USA), Gold Shunt (SOLX, USA), STAR (iSTAR Medical, Belgium), and Aquashunt (OPKO HealthInc.USA). Of these, only two implants are implanted *ab interno* — the CyPass Micro-Stent and the iStent Supra. The CyPass has been studied in detail

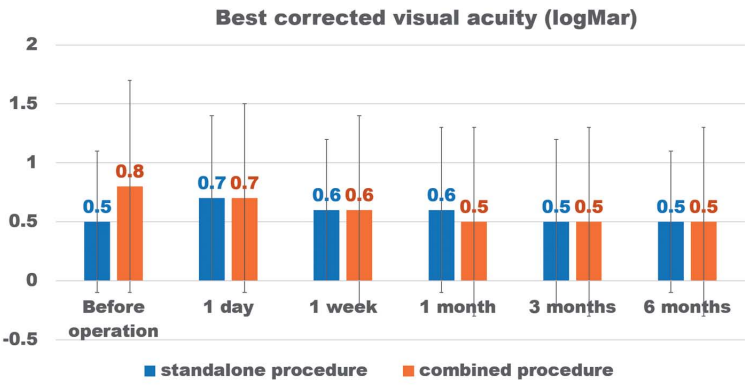

Fig. 6. Diagram showing average best-corrected visual acuity over 6 months for patients who underwent standalone procedure and for patients who underwent combined procedures

Рис. 6. Диаграмма распределения средней наилучшей корригированной остроты зрения у пациентов, которым была выполнена только антиглаукомная операция, и у пациентов, которым антиглаукомная операция была выполнена вместе с хирургией катаракты

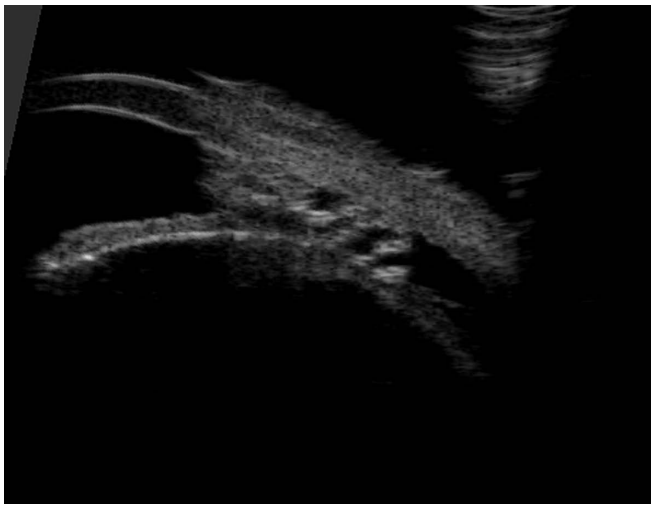

Fig. 7. Ultrasound biomicroscopy assessment of cyclodialysis cleft and the location and position of the CI. The CI is in place, its porous structure adequately defined and identifiable. An extended space can be seen behind the implant

Рис. 7. Оценка состояния циклодиализной щели и коллагенового имплантата с помощью ультразвуковой биомикроскопии. Коллагеновый имплантат расположен правильно, его пористая структура хорошо визуализируется. За имплантатом расположено пространство с жидкостью

and its long-term results regarding endothelial cell loss are not favorable. The loss of endothelial cells is statistically higher for patients with the CyPass than those without it. It is assumed that the loss of endothelial cells is associated with direct contact between the implant and the cornea's endothelium [12]. Presently this device has been withdrawn by the manufacturers and is not available commercially. Aquashunt and iStent Supra have not been fully investigated nor have results of investigations been widely published. In our study we did not encounter any case with corneal decompensation.

Szurman P et al. described suprachoroidal drainage with a collagen sheet implant, a novel technique for non-penetrating glaucoma surgery [13]. After exposing Schlemm's canal, followed by its deroofing, the peeling of juxtacanalicular meshwork and the creation of a window into Descemet's membrane, suprachoroidal space was enlarged by viscodialation followed by insertion of an Ologen implant to keep the drainage pathway open. Sixty-five eyes were operated upon, achieving a reduction of IOP by 35.1 % at one year. The number of topical IOP-reducing medications decreased significantly from 3.5 ± 0.7 to 0.6 ± 0.9 and to 0.9 ± 1.1 at 3 and 12 months, respectively ($p < 0.01$), with no serious complications. According to the authors, inserting Ologen into the suprachroidal space kept it open for aqueous drainage, making this surgery suitable for sufficient IOP reduction in eyes unsuitable for canaloplasty.

Endoviscocanalostomy with local cyclodialysis and implantation of Xenoplast in patients with coexisting pathology has also been proposed [14]. There was a significant decrease in IOP (from 29.6 ± 5.0 mmHg to 19.2 ± 2.4; IOP was measured using the Maklakov's method) and improvement in the outflow coefficient (from 0.12 ± 0.04 to 0.21 ± 0.03). Technically, authors first destroyed the trabecular network at the 6 o'clock position with a spatula, then performed hydro dissection of the SCS followed by viscodialysis of the ciliary body. Next, the collagen device was implanted in the SCS. This technique has some significant limitations: the size of the cyclodialysis cleft is not standardized, thus hydro dissection and viscodialysis may produce cyclodialysis clefts of different sizes and shapes; the inferior location of cyclodialysis at the 6 o'clock position may become the reason for its closure by blood elements. In our study we used a specially designed and calibrated spatula of a specified shape and size which allowed performance of calibrated meridional cyclodialysis in every case. As a result, all surgical steps were standardized, facilitating comparison of results in the postoperative period. In addition, the inserted device's length guaranteed creation of a passage between the AC and the SCS.

In the case of cycodialysis, surgeons are worried about two complications: hemorrhaging during cleft creation and postoperative hypotony [15]. The latter could result from atrophy of the ciliary body due to impaired blood supply. However, throughout this study, not a single case of hypotony was observed. Intraoperative hemorrhaging, which occurred in 42 % of patients, in some cases required prolonged irrigation of AC, which, in turn, increased surgery time, resulting in trauma to the iris and the cornea's endothelial cells. This could be a reason for the development of postoperative inflammation of the AC, which occurred in 9 % of cases (four eyes). Despite an attempt to completely remove blood from the AC during surgery, hyphema was observed on the first day after operation in 21 % of cases. This did not require any specific intervention and was completely resorbed within one week.

In the presented series, unsuccessful cases constituted 20.9 % of all cases (table 2). To establish a relationship, the success rate was analyzed according to various predisposing factors. The failure rate was high — 22 % and success rate low — 37.5 % for patients with advanced glaucoma, whereas for patients with moderate glaucoma, the proportions were 18 % and 64 % respectively. A higher success rate of 56 % was recorded for patients with preoperatively medically controlled glaucoma, whereas the rate was 28 % for patients with uncontrolled IOP. These data indicate the effectiveness of the proposed technique at early stages of the disease, when compensatory mechanisms are still in functional state.

It was also established that previously failed glaucoma surgeries with exhausted compensatory mechanisms played a definite role in the treatment's success. In this study, of nine unsuccessful cases, five cases (55.5 %) had previously been operated for glaucoma. In a study, Jordon JF et al. investigated IOP-decreasing effect of cyclodialysis *ab interno* in patients who had previously undergone multiple surgeries for glaucoma [15]. A total of 28 eyes were operated upon. The average number of previously performed anti-glaucoma surgical manipulations was 4.4 ± 2.4. Postoperatively, IOP decreased from 34.3 ± 10.5 mmHg to 14.6 ± 12.4 mmHg. However, after 60 days, 75 % of the eyes required a second operation. In our

opinion, the results of Jordon's study were expected ones. The eyes included in the study were suffering from refractive glaucoma and had been operated for glaucoma multiple times. It was unlikely to presume that there were any functioning compensatory mechanisms left. The reported short-term decrease in IOP could have resulted from the temporary shutdown of the ciliary body. Those results, additionally, are confirmed by the results of this paper's study.

The intraocular tissues well tolerated the CI, as evidenced by there being no reaction in the AC. Explantation of the CI was not required during the entire postoperative observation period for any case. Furthermore, there were no observations of the dislocation of the CI.

There were several limitations to this study: the nonrandomized nature of the study, the small sample size, and the short follow-up period. Further studies will require a larger sample of patients with longer follow-up periods to confirm the findings reported here.

CONCLUSION

From the results of this pilot study it is concluded that *ab interno* cyclodialysis procedure involving implantation of collagen implant in the suprauveal is an easy to perform procedure and is safe. Like other MIGS procedures, it effectively decreases IOP in patients with moderate glaucoma but is less effective in patients with severe glaucoma and in patients with previously failed glaucoma surgeries. Complications were found to be minimal.

AUTHOR CONTRIBUTIONS:

Vinod Kumar: conception, design, data collection, analysis and interpretation, writing and editing, overall responsibility; Ahmad S. Shradqa: conception, design and data collection; Kamal A. Abo Zaalan: data collection.

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