Telemetric Intraocular Pressure Monitoring after Boston Keratoprosthesis Surgery Using the Eyemate-IO Sensor: Dynamics in the First Year

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• **PURPOSE:** **To analyze the dynamics of telemetrically measured intraocular pressure (IOP) during the first year after implantation of a Boston keratoprosthesis type I (BI-KPro) cornea and to compare agreement of telemetric IOP measurements with finger palpations.**

• **DESIGN:** **Prospective, open-label, multicenter, single-arm clinical trial.**

• **METHODS:** **In the ARGOS (NCT02945176) study, 12 individuals underwent implantation of an Eyemate-IO intraocular system. Follow-up after surgery took place 12 months later with 13 visits planned per patient. During BI-KPro surgery, an electromagnetic induction sensor ring enabling telemetric IOP data transfer to a hand-held reading device outside the eye was implanted into the ciliary sulcus with or without trans-scleral suture fixation. Comprehensive ophthalmic examinations and IOP assessments through the telemetric system were compared to IOP assessed by finger palpation by 2 experts.**

• **RESULTS:** **Preoperative IOP measured by Goldmann tonometry was 13.4 ± 6.2 mm Hg. Telemetric IOP peaked at 23.1 ± 16.5 mm Hg at the first postoperative day. On day 5, mean IOP was 16.0 ± 5.2 mm Hg and 20.95 ± 6.5 mm Hg after 6-12 months. IOP estimation by finger palpation was grouped in 4 categories: normal, A; soft/hypotonic, B; borderline, C; and hypertonic, D. Mean telemetric IOP was 18.2 ± 6.1 mm Hg in category A, 8.9 ± 2.8 mm Hg in B, 22.4 ± 4.9 mm Hg in C, and 34.3 ± 11.0 mm Hg in D. Differences in mean telemetric IOPs per category were statistically significant ($P < .001$). Daily IOP fluctuations and peaks could be identified.**

• **CONCLUSIONS:** **Telemetric IOP assessment seems to be able to identify postoperative IOP peaks and a longitudinal increase of IOP after BI-KPro surgery. IOP measurements using the telemetric Eyemate-IO sensor showed a satisfactory agreement with those of finger palpations by 2 experts.** **(Am J Ophthalmol 2019;206: 256–263. © 2019 Elsevier Inc. All rights reserved.)**

KERATOPROSTHESIS (KPRO) SURGERY TO RESTORE vision represents a significant milestone in the treatment of corneal blindness.[1–14] It is especially those patients with severe corneal opacification who have no realistic prognosis for success of an allogeneic corneal transplant who can benefit from this treatment.

Surgical outcome of the Boston KPro type I (BI-KPro) cornea has improved over the years with increasing experience and published evidence. Recent meta-analyses have found retention rates ranging from 65% to 100% and an improvement of best-corrected Snellen visual acuity ranging from 20/20 to 20/200 in 45% to 89% of eyes.[1,5] Analyses from centers in Germany and Austria show comparable results.[15,16] The most common reasons for loss of vision after BI-KPro implantation include secondary glaucoma, sterile and infectious corneal melts, retinal detachment, and endophthalmitis.[5,15,17]

After BI-KPro surgery, development of secondary glaucoma is a frequent complication. On average, almost every third patient is affected (mean, 27.5 ± 18.1%; range, 2.4%–64.0%).[18] Secondary glaucoma is the most frequent reason for long-term vision loss.[18] Other studies have found an onset or progression of glaucoma in 26% of 113 patients after BI-KPro surgery and a significantly better preservation of vision in glaucoma patients with early surgical intervention than in patients with late or no intervention. The manufacturer of BI-KPro (Massachusetts Eye and Ear Infirmary, Boston, Massachusetts, USA) advises that patients should undergo concurrent or pre-emptive glaucoma surgical intervention with BI-KPro implantation if glaucoma is not well controlled and receive prophylactic local therapy if there is no glaucoma.[11,19]

Measurement of intraocular pressure (IOP) by Goldmann applanation tonometry or other corneal tonometry methods (eg, rebound tonometry) is not feasible after BI-KPro surgery due to the physical and technical properties of the implant.[20] IOP in these patients, therefore, can only be estimated by finger palpation. Even in an

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expert setting with a highly experienced examiner, this technique is prone to high intra- and interindividual variability.[21] Sclera-based approaches have also been proposed.[22]

The concept of continuous IOP measurement with an implantable sensor is not new.[23] Different approaches have been made by several work groups; however, until now, no system has reached clinical applicability, mainly due to technical difficulties.[24–26] The telemetric IOP sensor (Eyemate-IO, Implandata Ophthalmic Products GmbH, Hannover, Germany) combines an implantable intraocular pressure sensor ring consisting of a microelectromechanical system application-specific integrated circuit (MEMS-ASIC) with a hand-held reading device. The technical details of the device have been published previously.[27] An animal study demonstrated good tolerability and a close agreement with manometric IOP measurements.[28–30] More recently, 1-year and long-term results (2-4 years of follow-up) after implantation of a previous version of the device during cataract surgery in 6 glaucoma patients indicated promising results.[27,31]

In a recent first publication, promising safety and efficacy results could be shown in a prospective, open-label, multicenter, single-arm clinical trial aimed to assess safety, tolerability and performance of the Eyemate-IO telemetric IOP sensor implanted in eyes undergoing BI-KPro surgery.[32] Regarding the efficacy of the implanted sensor, telemetric and intracameral IOP measurements obtained by surgical manometry showed a correlation (r) of 0.68 ($P < .001$) for all measurements. If 3 events of presumed measurement errors were excluded, both modalities correlated with $r = 0.87$ ($P < .001$). Safety, adverse events, and serious adverse events in this study were in line with the expected prevalence of complications after BI-KPro surgery. Most frequent complications were formation of a retroprosthetic membrane and hypertonic or hypotonic IOP. An additional multicenter study using the sensor implanted in patients with primary open angle glaucoma has been completed, pending publication of the clinical results (Safety and Performance Study of the ARGOS-IO [Intraocular] System in Patients With Primary Open Angle Glaucoma [POAG] [ARGOS-IO]; NCT02434692). The data from this additional cohort of 22 patients is expected to further allow evaluation of the validity of the telemetric IOP measurements.

The current paper presents additional unpublished data from the ARGOS KPro clinical trial (Safety and Performance Study of the ARGOS-IO System in Patients Undergoing Boston Keratoprosthesis Implantation; NCT02945176). The main objective of this paper was to analyze the dynamics of telemetrically measured IOP during the first year after BI-KPro implantation. A secondary objective was to compare agreement of telemetric IOP measurements with finger palpation and to discuss the potential of home self-tonometry in BI-KPro patients.

METHODS

• **STUDY DESIGN:** This prospective, open-label, multicenter, single-arm clinical trial was conducted at 2 study sites in Germany (Cologne and Munich) between February 2015 and June 2017. The study protocol was reviewed and approved by the responsible institutional ethics committees at each site and was conducted in accordance with the Declaration of Helsinki tenets (ICH-GCP, ISO 14155:2011). All patients provided written informed consent before enrollment and were between 18 and 80 years of age.

• **INCLUSION AND EXCLUSION CRITERIA:** Inclusion criteria were indications and informed consent for KPro surgery, axial length >21 mm, and the ability and willingness to attend all scheduled visits and comply with all study procedures. Exclusion criteria, defined in the study protocol, were reasonable chance of success with conventional keratoplasty, current retinal detachment, connective tissue diseases, history or evidence of severe inflammatory eye diseases, history of ocular or periocular malignancy, history of extensive keloid formation; any known intolerance or hypersensitivity to topical anesthetics, mydriatics, or silicone; presence of another active medical eye implant and/or other electrically active medical implants in the head and neck region; signs of current infection, including fever and current treatment with antibiotics; severe generalized disease that resulted in a life expectancy shorter than a year; any clinical evidence that the investigator felt would place the subject at increased risk with the placement of the device; current pregnancy or breastfeeding; participation in any study involving an investigational drug or device within the previous 30 days or ongoing participation in a study with an investigational drug or device; intraoperative complication precluding implantation of the study device; affiliation with the site, the sponsor, or the contract research organization; or previous or concurrent enrollment of the contralateral eye in this clinical study.

• **SAMPLE SIZE AND PATIENT ENROLLMENT:** This exploratory study was planned to enroll a minimum of 10 and a maximum of 15 patients. The sample size was chosen pragmatically by the sponsor based on the number of patients expected to undergo BI-KPro implantation at the study sites during a 12-month period. It was anticipated that provision of an initial estimate of common safety events and assessment of performance would be sufficient. A total of 13 patients with an indication for BI-KPro implantation were successfully screened and initially enrolled, 12 of whom successfully received the Eyemate-IO implant (4 in Cologne and 8 in Munich). In 1 patient, significant capsular bag instability in a pseudophakic eye was seen during surgery, leading to the surgeon's decision not to implant the Eyemate-IO device.

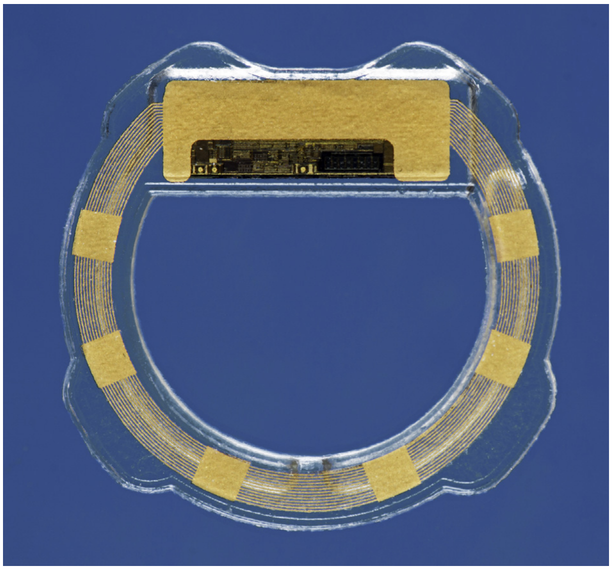

FIGURE 1. The Eyemate-IO telemetric IOP sensor (Implandata, Hannover, Germany) for direct intraocular pressure assessment. The sensor is placed in the ciliary sulcus and consists of a microelectromechanical system application-specific integrated circuit bonded to a gold microcoil and encapsulated in silicone.

• **SURGICAL INTERVENTION AND IMPLANTATION OF THE STUDY DEVICE:** After hospitalization of enrolled, subjects' eligibility requirements were reassessed. Subjects continuing to meet all eligibility requirements underwent BI-KPro implantation with concomitant implantation of the Eyemate-IO. The surgical approach was initiated with the typical trephination of the central recipient cornea of adequate size and cataract extraction with nuclear and cortical removal by an open sky approach where indicated (Videos 1 and 2 [supplemental material is available at AJO.com]).[15,16] In a case where pseudophakia was present, the study protocol allowed performing the site's customary keratoprosthesis implantation protocol. In subjects with adequate capsular support, the device was placed in the ciliary sulcus. In subjects with inadequate capsular support, the implant was fixated by suture to the sclera in the ciliary sulcus. Sutures were attached around the silicone-imbedded antenna of the implant in a girth-hitch manner at opposite positions, using a technique from within the eye. After adequate positioning of the Eyemate-IO implant, the BI-KPro implant was fixated with 12-16 single nylon 10-0 sutures. The Eyemate-IO was calibrated by using direct intracameral manometry in the anterior chamber to measure current IOP as the reference. A device previously developed at the University of Duesseldorf was used for intracameral manometry.[33] It consists of an invasive blood pressure monitor (G-19235 model; Geuder AG, Heidelberg, Germany) connected to a specially designed transducer (model G-19237 monitoring kit; Geuder) and a specialized needle for intracameral measurements (model G-19238; Geuder). The needle was placed in the anterior chamber for about 10 seconds until the readings on the monitor were stable.[34]

TABLE. Baseline Characteristics of Patients and Details of Surgery

Patients	n = 12
Eye n (%)	
Right	4 (33.3)
Left	8 (66.6)
Underlying ocular disease or condition n(%)	
Aniridia	6 (50.0)
Injury (mechanical or chemical)	3 (25.0)
Autoimmune disease	2 (16.7)
Congenital glaucoma	1 (8.3)
Age (y)	
Mean ± SD	39.0 ± 16.0
Range	18-62
Sex	
Females	6 (50.0)
Males	6 (50.0)
Axial length (mm)	
Mean ± SD	23.43 ± 1.6
Range	21.2-27.0
IOP at screening (mm Hg)	
Mean ± SD	12.2 ± 5.0
Range	7-22
Presence of GDD n(%)	
GDD already in place	3 (25.0)
No GDD present or no GDD implanted during the study intervention	9 (75.0)
Lens status before intervention n(%)	
Pseudophakic	9 (75.0)
Phakic	1 (8.3)
Aphakic	2 (16.7)
Fixation of ARGOS implant n(%)	
Supported by ciliary sulcus	7 (58.3)
Sutured to sclera	4 (33.3)
Not documented	1 (8.3)

ARGOS = ARGOS-IO; Implandata Ophthalmic Products GmbH, Hannover, Germany); GDD = glaucoma drainage device; IOP = intraocular pressure.

• **SPECIFICATIONS OF THE TELEMETRIC IOP SENSOR:** The Eyemate-IO telemetric IOP sensor (Figure 1) combines an implantable intraocular pressure sensor ring (4 haptics at the outer edges of the implant; diameter is available in three sizes, 11.3, 11.7, and 12.1 mm; inner diameter, 7 mm; thickness, 0.5 mm on the edges of the device, tapering to a 0.1 mm rounded outer haptics) with a hand-held reading device (Mesograph) to measure IOP. The ring consists of a MEMS-ASIC system bonded to a gold microcoil and encapsulated in silicone-rubber. An

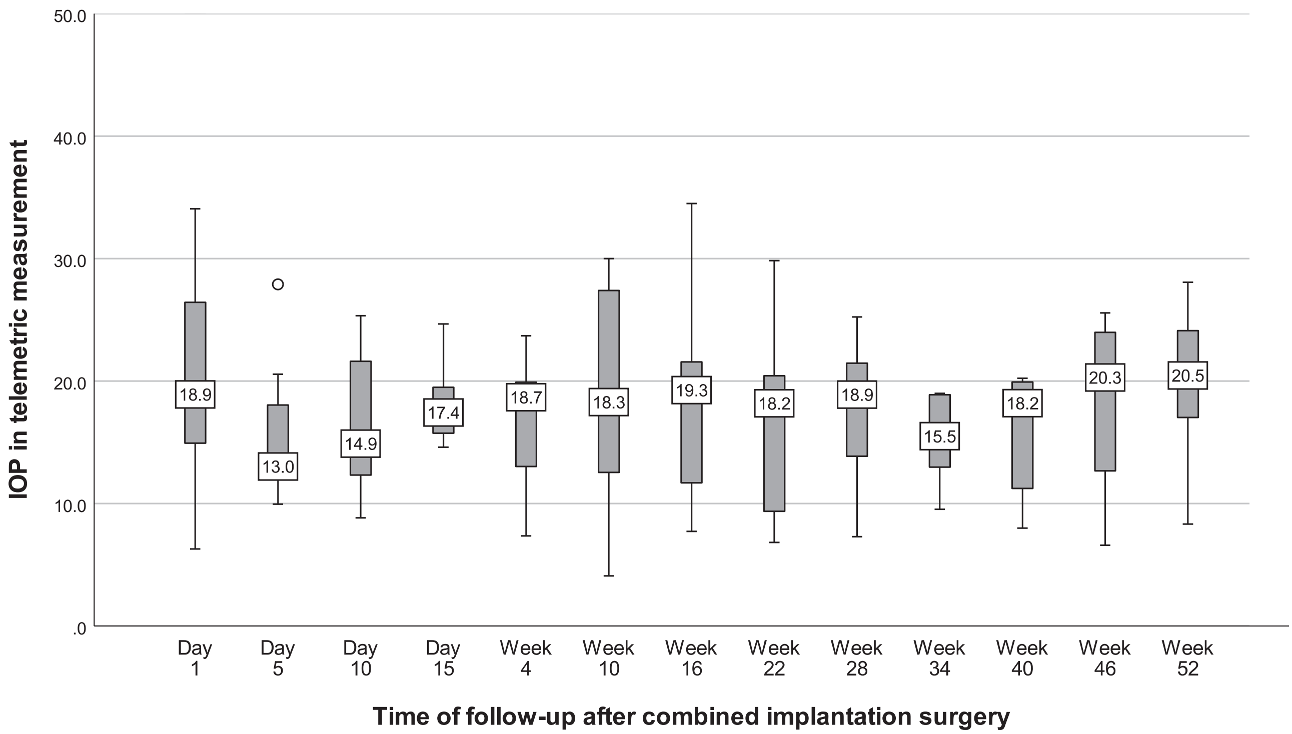

FIGURE 2. Boxplot graph of telemetric IOP measurements with the Eyemate-IO sensor during follow-up after keratoprosthesis surgery. Numbers in boxplots refer to median IOP. Postoperative study visits were at days 1, 5, 10, and 15 and on weeks 4, 10, 16, 22, 28, 34, 40, 46, and 52. IOP = intraocular pressure.

electromagnetic inductive connection between the coil of the sensor and the activated reader powers the ASIC, thereby initiating a pressure reading and enabling telemetric data transfer. During IOP measurements (duration, <2 s), the reader unit is held at a short distance in front of the eye. The wireless IOP transducer has shown biocompatibility in rabbit eyes for up to 25 months with no signs of toxicity. In those studies,[35-37] concordance with manometry data demonstrated transducer drift over time, thereby necessitating recalibration. Once recalibrated, the device showed a strong concordance with intraocular manometry over a wide range of pressures.

• KEY PERFORMANCE INDICATORS AND STATISTICS: Telemetric IOP was assessed in 3 consecutive measurements. Manual IOP palpation by the principal investigators (C.C., T.N.) was performed at every visit without knowledge of the telemetric result. IOP estimates by finger palpation were divided into 4 categories: normal, A; soft/hypotonic, B; borderline, C; and hypertonic, D. Telemetric IOP levels were compared to finger palpation category levels. Baseline characteristics of the study cohort were analyzed with descriptive statistics. Kruskal-Wallis and Wilcoxon tests were used to compare IOP data obtained from both modalities. Spearman correlation analysis was used to test for possible correlations between baseline parameters and IOP outcome.

RESULTS

A TOTAL OF 12 PATIENTS WERE ENROLLED IN THE STUDY and successfully underwent implantation of the Eyemate-IO system. At enrollment, the patients' median age was 41.0 years (range, 18-62 years old). Seven of the 12 subjects had already been treated medically for elevated IOP or glaucoma. Three patients had a glaucoma drainage device in place before undergoing BI-KPro surgery. Study eyes had a mean axial length of 23.5 ± 1.5 mm. Baseline characteristics of patients and details of surgery are shown in Table.

• COURSE OF IOP DYNAMICS AFTER BI-KPRO SURGERY: Telemetric IOP assessment by the Eyemate-IO implant was conducted in every patient at every study follow-up visit; the recorded IOP was obtained by averaging 3 consecutive measurements.

During screening, patients showed normal IOP levels, as measured by Goldmann applanation tonometry, under treatment with a mean IOP of 13.42 ± 6.24 mm Hg. Mean IOP peaked at 23.14 ± 16.53 mm Hg in telemetric measurement at the first postoperative day after BI-KPro implantation. On Day 5, mean IOP was 16.01 ± 5.22 mm Hg. In the last study visit per patient (minimum >20 weeks), mean telemetric IOP was 20.95 ± 6.53 mm Hg with a mean follow-up interval after surgery of 43.8 ± 12.9 weeks. Changes of IOP between

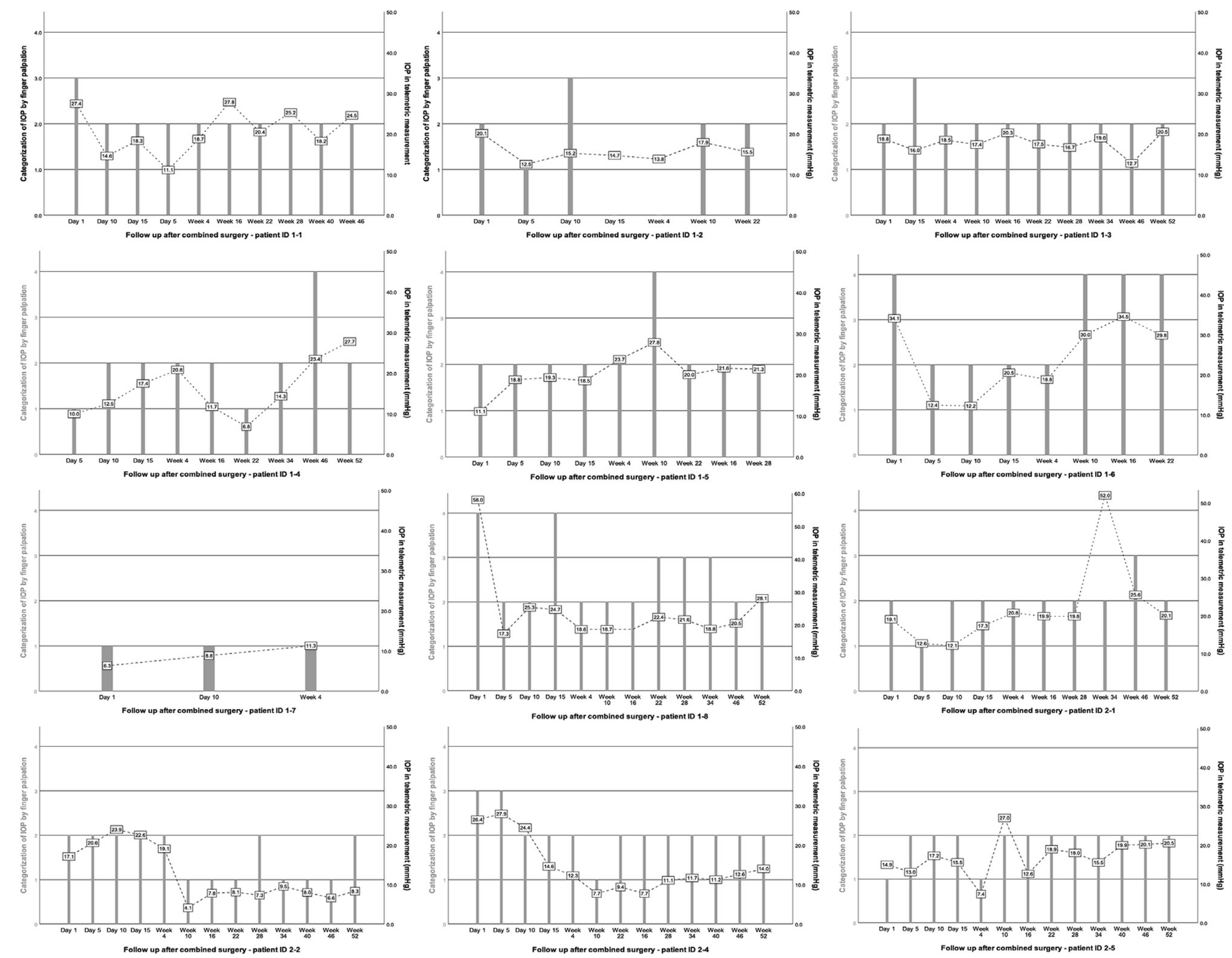

FIGURE 3. Individual IOP follow-up during study period per patient after keratoprosthesis surgery. Line graphs display individual telemetric IOP measurements using the Eyemate-IO sensor in a patient at scheduled visits. Categories for IOP assessment by finger palpation: 1, soft; 2, normal; 3, borderline; and 4, hypertonic. Postoperative study visits were on days 1, 5, 10, and 15 and on weeks 4, 10, 16, 22, 28, 34, 40, 46, and 52. IOP = intraocular pressure.

visits during the follow-up time did not reach a statistical level of significance ($P > .05$). Graphic trend analysis indicated a postoperative IOP peaking on the day and a slow increase of IOP during the course of follow-up. Figure 2 shows a boxplot that displays the aggregated telemetric IOP recordings of all patients during the follow-up period. The individual course of IOP dynamics measured telemetrically per patient is demonstrated in Figure 3. This figure additionally shows the categorized IOP estimations obtained by finger palpation.

• COMPARISON BETWEEN TELEMETRIC IOP MEASUREMENTS AND FINGER PALPATION MEASUREMENTS: IOP by finger palpation was assessed at every study visit. On 82 visits, IOP by finger palpation was judged as "normal"; mean telemetric IOP in these visits was 18.2 ± 6.1 mm Hg, ranging from 7.3 to 52.0 mm Hg. On 16 visits, patients' eyes were rated soft or hypotonic in finger palpation, whereas the mean Eyemate-IO measurement was 8.9 ± 2.8 mm Hg (range, 4.1–14.9 mm Hg). On 9 visits, palpated IOP was classified as borderline, whereas mean IOP assessed by the Eyemate-IO system was 22.4 ± 4.9 mm Hg (range, 15.2–27.9 mm Hg). On 8 visits, eyes were judged as hypertonic with finger palpation. In these cases, mean telemetric IOP was 34.3 ± 11.0 mm Hg, ranging from 23.4 to 58.0 mm Hg. Kruskal-Wallis test results showed a statistically significant difference between telemetric IOP measurements and finger palpation categories ($P < .001$).

• HOME SELF-MONITORING OF IOP: According to the protocol of this study, every patient performed an average 97 ± 46 home measurements between 2 consecutive visits, resulting in 2.8 measurements per day. Figure 4 displays 3 examples of IOP curves obtained by home self-monitoring

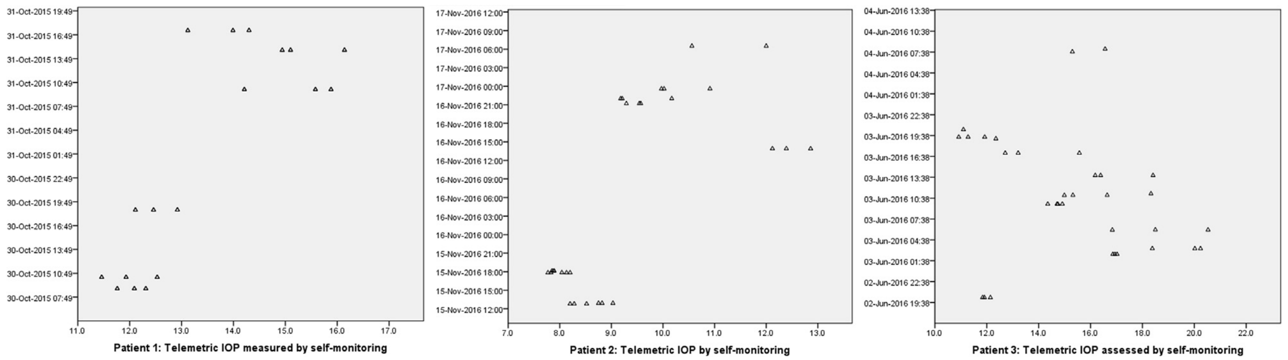

FIGURE 4. Three examples of home self-monitoring of IOP using the Eyemate-IO telemetric sensor performed by 3 different patients. Scatter plots display self-monitoring of IOP in 3 patients over a short period of time (up to 48 h). According to study protocol, the patients were asked to perform 3 repeated measurements at 3 times during the day. In these examples, the patients performed additional measurements. IOP = intraocular pressure.

of patients. Results were stored electronically in the reading device and uploaded to a remote database.

DISCUSSION

IN A RECENTLY PUBLISHED STUDY BY THE CURRENT AUthors, all 12 patients who underwent BI-KPro implantation of the Eyemate-IO system for intraocular telemetric IOP measurement showed good safety and tolerability as well as promising performance results. Comparison between telemetric and intracameral IOP measurements showed good comparability, an adverse events and serious adverse events in this study were in line with the expected prevalence of complications after BI-KPro surgery. The detailed results of safety and adverse events that occurred within the clinical trial can be obtained elsewhere.[32] This report focuses on the clinical course of IOP dynamics in patients who underwent BI-KPro after surgery and the performance of the system in comparison to the clinical standard of IOP estimation by finger palpation.

The concept of continuous monitoring of IOP with an intraocular device was proposed decades ago. Earlier attempts of development failed to reach clinical application due mainly to technical problems.[23,27,38,35,36,39] Recent technological advancements have led to a reduction in size and improved reliability of these devices.[30,37,40] Although earlier developments required a hard-wired connection to the exterior of the eye, Walter and associates[41] described a completely biocompatible encapsulated telemetric pressure sensor. Paschalis and associates[29] proposed an autonomous IOP measurement technique using an implantable wireless transducer that provided reproducible results in conscious rabbits.

The course of IOP dynamics assessed using the telemetric implant could confirm the suspected IOP dynamics after major intraocular surgery. On the first postoperative day, an increase in IOP compared to baseline measurements could be seen. Comparability of measurements is certainly limited due to different methods for IOP measurement. On day 5 after surgery, mean IOP decreased to levels comparable to preoperative values. During the 6- to 12-month follow-up period, an increase of IOP could be seen, although comparisons were not statistically significantly different due to this studies' small sample size.

Mean IOP in telemetric measurements corresponded well to the state of the globe categorized by finger palpation. Between different categories of finger palpation, telemetrically obtained mean IOP levels differed with statistical significance. Finger palpation was performed by 2 experienced surgeons in the study (T.N., C.C.). Results of IOP estimation by finger palpation are highly dependent on the experience of the examiner and are prone to significant intraindividual variations. However, presently, lacking a reliably better alternative, this technique remains the clinical standard. In their comprehensive review of outcomes and complications after BI-KPro surgery, Lee and associates[1] identified 12 studies that found glaucoma was a frequent complication. Measurement of IOP in those studies was based solely on finger palpation, and evaluation of glaucomatous damage was therefore primarily focused on assessment of the optic nerve head and of visual field function. Although those studies also reported findings of increased IOP at different timepoints after surgery, the granularity of the data for the IOP dynamics in the first year of follow-up limits the comparability to our study results.

The user interface of the Eyemate-IO system allows self-monitoring by the patients at home. On average, every patient used the device almost 3 times a day in the present study. This continuing collection of IOP data can allow the physician to detect IOP fluctuations as seen in the exemplary patient 3 of our study. A follow-up project studying further comprehensive analysis and evaluation of all home-self measurements obtained in this study is desirable.

Another finding of the study was that Nd:YAG laser membranotomy to treat retroprosthetic membrane formation can lead to a malfunctioning of the telemetric systems. After completion of the laser procedure, telemetric values were measured out of range. After recalibration of the device by surgical manometry, functionality of the systems was able to be restored in 2 eyes. As retroprosthetic membrane formation is a frequent side effect after BI-KPro surgery, the potential limitation to the use of Nd:YAG laser treatment needs to be taken into account. Although invasive manometry reflects the gold standard for calibration of the intraocular pressure sensor, finger palpation by an expert could be considered to recalibrate the telemetric sensor in case of an offset, for example, after Nd:YAG laser membranotomy in BI-KPro or Nd:YAG laser capsulotomy as indicated. This is especially the case if operative trauma of surgical manometry needs to be avoided or a surgical manometer is not available. On the other hand, the reliability problem of palpation must be taken into account, especially when making it the basis of calibration.

The present ARGOS-IO keratoprosthesis study shows satisfactory performance and safety of the Eyemate-IO system sufficient to allow telemetric IOP measurement in patients undergoing BI-KPro surgery. According to the protocol of this clinical trial, to ensure patient safety and to avoid unnecessary surgery, removal of the sensor is planned only in case of severe complications requiring surgical intervention. Long-term follow-up of these clinical trials will be necessary to assess long-term safety. We found that the use of Nd:YAG laser treatment triggers the need for recalibration of the telemetric systems. Assessment of calibration frequency also needs to be addressed in a longer-term setup. The Eyemate-IO system requires a significant amount of space in the posterior chamber. Induction of glaucoma, although not seen in the first year, is a potential side effect which needs to be studied further.

Overall, further miniaturization of the intraocular sensor is desirable to facilitate implantation and to minimize ocular side effects caused by the system. The expected results of the ARGOS-IO study in primary open angle glaucoma will contribute to generate additional insight.

Patients treated with BI-KPro for corneal blindness face a significant risk to consecutively lose vision due to undetected IOP peaks and subsequently uncontrolled glaucoma. Continual and reliable IOP monitoring by a telemetric sensor system is an important additional tool for the management of secondary glaucoma in these patients. The results of this prospective study demonstrate that the Eyemate-IO system enables reliable continual IOP monitoring in patients undergoing BI-KPro surgery.

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