Abstract

Objective: To analyse the dynamics of telemetrically measured intraocular pressure (IOP) during year one after implantation of a Boston Keratoprosthesis Type I (BI-KPro) and to compare agreement of telemetric IOP measurements with finger palpation.

Study design: Prospective, open-label, multicenter, single-arm clinical trial

Methods: In this clinical trial (ClinicalTrials.gov Identifier: NCT02945176) twelve individuals received implantation of an EYEMATE-IO system. Follow-up after surgery was 12 months 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 transscleral suture fixation. Comprehensive ophthalmic examinations and IOP assessment via the telemetric system were compared to IOP assessed via finger palpation by two experts.

Results: Preoperative IOP measured by Goldmann tonometry was 13.4±6.2 mmHg. Telemetric IOP peaked at 23.1±16.5 mmHg at the first postoperative day. On day 5, mean IOP was 16.0±5.2 mmHg and 20.95±6.5 mmHg after 6-12 months. IOP estimation by finger palpation was grouped in four categories: normal (A), soft/hypotonic (B), borderline (C), hypertonic (D). Mean telemetric IOP was 18.2±6.1 mmHg in category A, 8.9±2.8 mmHg in B, 22.4±4.9 mmHg in C, 34.3±11.0 mmHg in D. Differences in mean telemetric IOP per category were statistically significant (P<0.001). 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 BKPro surgery. IOP measurements with the telemetric EYEMATE-IO sensor showed a satisfactory agreement with finger palpation by two experts.
Enders et al: Telemetric IOP monitoring in Boston Keratoprosthesis
(ARGOS-IO KP study): first year results

Telemetric Intraocular Pressure Monitoring after Boston Keratoprosthesis surgery with
the Eyemate-IO Sensor: Dynamics in the first year

Philip Enders¹, Jonathan Hall², Marco Bornhauser², Kaweh Mansouri³, Lebriz Altay¹, Stefan
Schrader⁴, Thomas S. Dietlein¹, Bjoern O. Bachmann¹, Thomas Neuhann², Claus Cursiefen¹

¹Department of Ophthalmology, University Hospital of Cologne, Kerpener Strasse 62,
50924 Cologne, Germany
²MVZ Prof. Neuham mit Augenabteilung, Rotkreuzklinikum München, Nymphenburger Str. 163,
80634 Munich, Germany
³Glaucoma Research Center, Montchoisi Clinic, Swiss Vision Network, Chemin des Allinges 10,
1006 Lausanne, Switzerland
⁴Department of Ophthalmology, Pius Hospital of the University of Oldenburg, Georgstraße 12
26121 Oldenburg, Germany

Corresponding author and address for reprints:
Philip Enders, MD, FEBO, FICO
Department of Ophthalmology, University of Cologne
Kerpener Strasse 62, 50924 Cologne, Germany
Fon: +49 221 478 4300, Fax: + 49 221 478 5094; Email: philip.enders@uk-koeln.de

Word count: 2.439

Short title: Telemetric IOP monitoring in Boston Keratoprosthesis: first year results

Electronic content: Supplemental Material available at AJO.com. The following should appear
online-only: clip 1 and clip 2.

Key words: BI-KPro, Boston type I keratoprosthesis; KPro, keratoprosthesis; IOP, intraocular
pressure; EYEMATE-IO; telemetric intraocular pressure monitoring
Introduction:

Keratoprosthesis surgery to restore vision represents a significant milestone in treatment of corneal blindness.\textsuperscript{1-14} Especially patients with severe corneal opacification who have no realistic prognosis for success of an allogeneic corneal transplant can benefit from this treatment. Surgical outcome of the Boston Keratoprosthesis Type I (BI-KPro) 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 (BCSVA) ranging from 20/20 to 20/200 in 45% to 89% of eyes.\textsuperscript{1,15} Analyses from centers in Germany and Austria show comparable results.\textsuperscript{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.\textsuperscript{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%).\textsuperscript{18} Secondary glaucoma is the most frequent reason for long-term vision loss.\textsuperscript{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 compared to patients with late or no intervention. The manufacturer of BI-KPro (Massachusetts Eye & Ear Infirmary, Boston, USA) advises that patients should undergo concurrent or preemptive glaucoma surgical intervention with BI-KPro implantation if glaucoma is not well controlled and receive prophylactic local therapy if there is no glaucoma.\textsuperscript{11,19}

Measurement of intraocular pressure (IOP) by Goldmann applanation tonometry (GAT) or other corneal tonometry methods (i.e. rebound tonometry) is not feasible after BI-KPro surgery due to the physical and technical properties of the implant.\textsuperscript{20} IOP in these patients can therefore only be estimated by finger palpation. Even in an expert setting with a highly experienced examiner, this
technique is prone to high intra- and inter-individual variability. Sclera-based approaches have also been proposed.

The concept of continuous IOP measurement with an implantable sensor is not new. Different approaches have been made by several work groups; however, until now, no system has reached clinical applicability, mainly due to technical difficulties. The telemetric IOP sensor (EYEMATE-IO; rebranded from formerly ARGOS-IO; Implantata 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 handheld reading device. The technical details of the device have been published previously. An animal study demonstrated good tolerability and a close agreement with manometric IOP measurements. 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 six glaucoma patients indicated promising results.

In a first publication, we could recently show promising results on safety and efficacy of 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. Regarding the efficacy of the implanted sensor, telemetric and intracameral IOP measurements obtained by surgical manometry showed a correlation of $r=0.68$ (P<0.001) for all measurements. If three events of presumed measuring errors were excluded, both modalities correlated with $r=0.87$ (P<0.001). Regarding 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 implanted sensor in patients with primary open angle glaucoma (POAG) has been completed, pending publication of the clinical
results (ClinicalTrials.gov Identifier: NCT02434692). The data of this additional cohort of twenty-two patients is expected to further allow evaluation of the validity of the telemetric IOP measurements.

This manuscript aims to present additional unpublished data from the ARGOS-KP clinical trial. Our main objective was to analyse the dynamics of telemetrically measured IOP during year one 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 two 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 of all sites and was conducted in accordance with the Declaration of Helsinki (ICH-GCP, ISO 14155:2011). All patients provided written informed consent before enrollment and were between 18 and 80 years of age. The study was registered on ClinicalTrials.gov (Identifier: NCT02945176).

**Inclusion and Exclusion criteria**

Inclusion criteria were indication and informed consent for keratoprosthesis 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 traditional 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/neck region, signs of current infection, including
fever and current treatment with antibiotics, severe generalized disease that results in a life
expectancy shorter than a year, any clinical evidence that the investigator feels 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 past 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, 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 months period. It was
anticipated to be sufficient to provide an initial estimate of common safety events and
assessment of performance. 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 one patient significant capsular bag
instability in a pseudophacic eye was seen during surgery leading to the surgeon’s decision not
to implant the EYEMATE-IO.

Surgical intervention and implantaion 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 (Video clips 1 and 2,
supplemental material available at AJO.com). In case of presence of pseudophakia, 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 suture-fixated 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 an ab interno technique. 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 reference. A device previously developed at the
University of Duesseldorf was used for intracameral manometry. It consists of an invasive
blood pressure monitor (Geuder G- 19235, Geuder AG, Heidelberg, Germany) connected to a
specially designed transducer (Monitoring Kit; Geuder G-19237) and a special needle for
intracameral measurements (Geuder G-19238). The needle was placed in the anterior chamber
for about 10 seconds until the readings on the monitor were stable.

Specifications of the telemetric IOP Sensor

The EYEMATE-IO telemetric IOP sensor combines an implantable intraocular pressure sensor
ring (four 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 microelectromechanical system application specific integrated circuit
(MEMS-ASIC) bonded to a gold micro-coil and encapsulated in silicone-rubber. An
electromagnetic inductive connection between the coil of the sensor and the activated reader
Enders et al: Telemetric IOP monitoring in Boston Keratoprosthesis (ARGOS-IO KP study): first year results

powers the ASIC, thereby initiating a pressure reading and enabling telemetric data transfer. During IOP measurements (duration: < 2 seconds), 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 these studies, 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 three consecutive measurement. Manual IOP palpation by the principal investigator (CC, TN) was performed at every visit without knowledge of the telemetric result. IOP estimation by finger palpation was grouped in four categories: normal, soft/hypotonic, borderline (C), definitively hypertonic (D). Telemetric IOP levels were compared to categories of finger palpation. 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 with successful implantation of the EYEMATE-IO system were enrolled in the study. At enrollment, the patients' median age was 41.0 years (range, 18 to 62 years). Seven out of 12 subjects were already medically treated for elevated IOP or glaucoma. Three patients received had a glaucoma drainage device (GDD) in place before 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 1.

**Course of IOP dynamics after BI-KPro surgery**

Telemetric IOP assessment by the EYEMATE-IO implant was conducted at every study visit of every patient; the recorded IOP was obtained by averaging three consecutive measurements. During screening, patients showed normal IOP levels measured by GAT under treatment with a mean IOP of 13.42 ± 6.24 mmHg. Mean IOP peaked at 23.14 ± 16.53 mmHg in telemetric measurement at the first postoperative day after BI-KPro implantation. On Day 5, mean IOP was 16.01 ± 5.22 mmHg. In the last available study visit per patient (minimum > 20 weeks), mean telemetric IOP was 20.95 ± 6.53 mmHg with a mean follow-up interval after surgery of 43.8 ± 12.9 weeks. Changes of IOP between visits during the follow-up time did not reach the statistically level of significance (p > 0.05). Graphical trend analysis indicated a postoperative IOP peaking on day and a slow increase of IOP during the course of follow-up. Figure 2 is a boxplot graph and displays the aggregated telemetric IOP recordings of all patients included 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 of telemetric IOP measurements to finger palpation**

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 mmHg, ranging from 7.3 to 52.0 mmHg. On 16 visits, patients’ eyes were rated soft/hypotonic in finger palpation, while mean EYEMATE-IO measurement was 8.9 ± 2.8 mmHg (range, 4.1 – 14.9 mmHg). On nine visits, palpated IOP was classified as borderline, mean IOP assessed by the EYEMATE-IO
system was 22.4 ± 4.9 mmHg (range, 15.2 – 27.9 mmHg). On eight visits, eyes were seen hypertonic in palpation. In these cases, mean telemetric IOP was 34.3 ± 11.0 mmHg, ranging from 23.4 to 58.0 mmHg. Kruskal Wallis test showed a statistically significant difference of telemetric IOP measurements between finger palpation categories with P < 0.001.

Home self-monitoring of IOP

According to the protocol of this study, every patient performed in average 97 ± 46 home measurements between two consecutive visits, resulting in 2.8 measurements per day. Figure 4 displays three examples of IOP curves obtained by home self-monitoring of patients. Results were stored electronically in the reading device and uploaded to a remote database.

Discussion

As we have recently published, in all twelve patients undergoing BI-KPro surgery implantation of the EYEMATE-IO system for intraocular telemetric IOP measurement showed good safety and tolerability as well as promising performance results. Comparison of telemetric and intracameral IOP measurements showed a good comparability, 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 on safety and adverse events that occurred within the clinical trial can be obtained elsewhere. This reports focuses on the clinical course of IOP dynamics in BI-KPro patients 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 has been proposed decades ago, earlier attempts of development failed to reach clinical application mostly due to technical problems. Recent technological advancements have led to a reduction of size and improved reliability of these devices. While earlier developments
required a hard-wired connection to the exterior of the eye, Walter et al. described a completely biocompatible encapsulated telemetric pressure sensor.41 Paschalis et al. proposed an autonomous IOP measurement technique using an implantable wireless transducer that provided reproducible results in conscious rabbits.29

The course of IOP dynamics assessed with the telemetric implant could confirm the suspected IOP dynamics after major intraocular surgery. On the first postoperative day, an increase of IOP compared to baseline measurements could be seen. Comparability of measurements is certainly limited due to different methods for IOP measurement. On day five after surgery, mean IOP decreases to levels comparable to preoperative values. During the six to twelve months 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 two very experienced surgeons in our study (TN, CC). Results of IOP estimation by finger palpation are highly dependent on experience of the examiner and are prone to significant intraindividual variations. However, at present, lacking a reliably better alternative, this technique remains the clinical standard. In their comprehensive review on outcomes and complications after BI-KPro surgery, Lee and associates identified twelve studies that found development of glaucoma being a frequent complication.1 Measurement of IOP in these studies was only based on finger palpation, evaluation of glaucomatous damage was therefore primarily focused on assessment of the optic nerve head and of visual field function. While the studies also report findings of increased IOP at different timepoints after surgery, the granularity of the data on 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 home-self monitoring by the patients. In average, every patient used the device almost three times a day in our 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 following project on further comprehensive analysis and evaluation of all home-self measurements obtained in this study is desirable.

Another finding of the study was that YAG 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 could be restored in two eyes. As retroprosthetic membrane formation is a frequent side effect after BI-KPro surgery, this potential limitation in the use of the YAG-Laser needs to be taken into account. While 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 off-set for example after YAG membranotomy in BI-KPro or YAG capsulotomy in after indication. 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 could show satisfactory performance and safety of the Eyemate-IO system 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 sugery, 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 YAG laser triggers need for recalibration of the telemetric systems. Assessment of calibration frequency needs also 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, while not seen in the first year, is a potential side effect, which needs to be studied further on. 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 via a telemetric sensor system, is an important addition to 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 keratoprothesis surgery with BI-KPro.

Acknowledgements:
Funding/Support: Supported by Implandata Ophthalmic Products GmbH, Hannover, Germany.
Financial disclosures: K. Mansouri: Consultant (Implandata GmbH), all other authors declare no financial or competing interests or relationships
Other Acknowledgements: We thank FOR 2240 “(Lymph-) Angiogenesis and Cellular Immunity in Inflammatory Diseases of the Eye” (www.for2240.de) as well as all employees of the Centers for Clinical Trials in Ophthalmology in Munich and Cologne for their support.
References


Enders et al: Telemetric IOP monitoring in Boston Keratoprosthesis (ARGOS-IO KP study): first year results

Figure titles and legends

Figure 1: The EYEMATE-IO telemetric IOP sensor

Note: EYEMATE-IO intraocular sensor 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 micro-coil and encapsulated in silicone.

Figure 2: Boxplot graph of telemetric IOP measurements with the EYEMATE-IO sensor during follow-up after keratoprosthesis surgery

Note: Numbers in boxplots refer to median IOP; post-operative study visits were at Day 1, 5, 10, 15 and Week 4, 10, 16, 22, 28, 34, 40, 46, 52.; IOP, intraocular pressure.

Figure 3: Individual IOP follow up during study period per patient after keratoprosthesis surgery

Note: Line graphs display individual telemetric IOP measurements with the EYEMATE-IO sensor per patient at scheduled visits. Categories for IOP assessment by finger palpation: 1, soft; 2, normal; 3, borderline; 4, hypertonic; Post-operative study visits were at Day 1, 5, 10, 15 and Week 4, 10, 16, 22, 28, 34, 40, 46, 52.; IOP, intraocular pressure.

Figure 4: Three examples of home self-monitoring of IOP with the EYEMATE-IO telemetric sensor performed by three different patients

Note: Scatter plots display self-monitoring of IOP in three patients over a short period of time (up to 48h). Per study protocol, the patients were asked to perform three repeated measurements at three times during the day. In these examples, the patients performed additional measurements. IOP, intraocular pressure.

Electronic content: video clips

Clip 1: BI-KPro surgery and implantation of EYEMATE-IO telemetric IOP sensor in ciliary sulcus

Note: BI-KPro, Boston Keratoprosthesis Type I; IOP, intraocular pressure.

Clip 2: BI-KPro surgery and implantation of EYEMATE-IO telemetric IOP sensor with transsleral suture fixation

Note: BI-KPro, Boston Keratoprosthesis Type I; IOP, intraocular pressure.
Table 1: Baseline characteristics of patients and details of surgery

<table>
<thead>
<tr>
<th></th>
<th>n  = 12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>Left</td>
<td>8 (66.6)</td>
</tr>
<tr>
<td><strong>Underlying ocular disease / condition</strong></td>
<td></td>
</tr>
<tr>
<td>Aniridia</td>
<td>6 (50.0)</td>
</tr>
<tr>
<td>Injury (mechanical or chemical)</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>Autoimmune disease</td>
<td>2 (16.7)</td>
</tr>
<tr>
<td>Congenital glaucoma</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>39.0 ± 16.0</td>
</tr>
<tr>
<td>Range</td>
<td>18 - 62</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>6 (50.0)</td>
</tr>
<tr>
<td>Male</td>
<td>6 (50.0)</td>
</tr>
<tr>
<td><strong>Axial length (mm)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>23.43 ± 1.6</td>
</tr>
<tr>
<td>Range</td>
<td>21.2 – 27.0</td>
</tr>
<tr>
<td><strong>IOP at screening (mmHg)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>12.2 ± 5.0</td>
</tr>
<tr>
<td>Range</td>
<td>7 - 22</td>
</tr>
<tr>
<td><strong>Presence of glaucoma drainage device (GDD)</strong></td>
<td></td>
</tr>
<tr>
<td>GDD already in place</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>No GDD present / no GDD implanted during study intervention</td>
<td>9 (75.0)</td>
</tr>
<tr>
<td><strong>Lens status before intervention</strong></td>
<td></td>
</tr>
<tr>
<td>Pseudophakic</td>
<td>9 (75.0)</td>
</tr>
<tr>
<td>Phakic</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Aphakic</td>
<td>2 (16.7)</td>
</tr>
<tr>
<td><strong>Fixation of ARGOS implant</strong></td>
<td></td>
</tr>
<tr>
<td>Supported by ciliary sulcus</td>
<td>7 (58.3)</td>
</tr>
<tr>
<td>Sutured to sclera</td>
<td>4 (33.3)</td>
</tr>
<tr>
<td>Not documented</td>
<td>1 (8.3)</td>
</tr>
</tbody>
</table>

Note: IOP, intraocular pressure