AMERICAN ACADEMY OF OPHTHALMOLOGY®

Report

# Telemetric Intraocular Pressure Monitoring after Boston Keratoprosthesis Surgery

The use of the Boston keratoprosthesis Type I (BI-KPro) implantation to restore vision in corneal blindness has considerably increased worldwide.[1,2] Patients with severe corneal opacification without realistic prognosis for success of a corneal transplant can benefit from this treatment. Secondary glaucoma has been identified as one of the 2 most common complications after BI-KPro surgery occurring on average in almost every third patient and being the most frequent reason for long-term vision loss.[3]

Because of the physical properties of the BI-KPro, measurement of intraocular pressure (IOP) by established methods is not feasible after surgery. Therefore, IOP can be estimated only by finger palpation. This technique is prone to high variability, resulting in an unmet clinical need for new concepts to reliably monitor IOP after keratoprosthesis surgery.

Continuous IOP measurement with an implantable sensor was described decades ago. Despite different approaches, no system has reached clinical applicability until now, mainly because of technical difficulties.

The telemetric ARGOS-IO IOP sensor (Implandata Ophthalmic Products GmbH, Hanover, Germany) combines an implantable IOP sensor ring consisting of a microelectromechanical system application−specific integrated circuit with a handheld reading device to measure IOP (Fig 1). An electromagnetic inductive connection between the coil of the sensor and the activated reader powers the circuit, initiating a pressure reading and enabling telemetric data transfer.

We report the 1-year results of a prospective, open-label, multicenter, single-arm clinical trial aimed to assess the safety, tolerability, and performance of the ARGOS-IO telemetric IOP sensor implanted in eyes undergoing BI-KPro surgery.

This clinical trial was conducted in full accordance with the Declaration of Helsinki (ICH-GCP, ISO14155:2011). All patients provided written informed consent before enrollment. (ClinicalTrials.gov identifier: NCT02945176).

A total of 13 patients with an indication for BI-KPro implantation were successfully screened and initially enrolled, 12 of whom successfully received the implant (Table S1, available at www.aaojournal.org). The surgical approach consisted of the typical open sky approach for BI-KPro implantation. Dependent on adequate capsular support, the sensor was placed in the ciliary sulcus with or without additional suture fixation to the sclera. The pressure sensor was calibrated using direct intracameral manometry in the anterior chamber to measure current IOP as reference.[4]

To assess safety of the implant, the study analyzed all serious adverse events during the first 12 months after implantation, as well as adverse events and severe adverse device events occurring in enrolled patients.

The primary objective to evaluate the performance of the study device was the comparison of telemetric IOP measurement to invasive IOP measurement using intracameral manometry.

Eight of 12 enrolled patients completed the study with the sensor implanted in the eye. One patient voluntary withdrew from the study with the sensor left in place. In 3 patients, the sensor was explanted, either after dislocation in a patient with aniridia (n = 1) or after necessity for multiple additional ocular surgeries (n = 2). In these 2 cases, the sensor was removed to avoid potential additional complications, not because the sensor device caused or was thought to cause the surgical revision.

Of 168 adverse events, 16 adverse events in 4 patients were rated as possibly related to the medical device by the investigators. Those potential (severe) adverse device events were anterior chamber cells, cystoid macular edema, hypotony, iris adhesion, pigment dispersion, vitritis, increased IOP, and formation of a retroprosthetic membrane (Table S2, available at www.aaojournal.org).

Surgical intracameral manometry was performed in a total of 24 visits in 9 patients. The study protocol entailed manometry in 4 visits in every patient, when the investigators rated the study eye sufficiently stable to undergo surgical manometry. Mean telemetric IOP, representing the averaged value of 3 repeated measurements, was 22.8±11.7 mmHg. Mean invasive IOP by manometry was 19.0±8.4 mmHg. Mean difference of IOP measurements by both modalities was 3.9±8.6 mmHg. The IOP measurements by both modalities had a correlation of $r = 0.68$ ($P < 0.001$) for all measurements and $r = 0.87$ ($P < 0.001$) if 3 events of presumed measuring errors were excluded.

The 1-year results of this prospective clinical trial demonstrate good safety, tolerability, and promising performance of a new intraocular telemetric IOP sensor in 12 patients undergoing BI-KPro surgery. A first clinical trial showed promising results for the implantation of the ARGOS-IO device in 6 patients with glaucoma undergoing cataract surgery.[5] Despite overall good tolerability, a sterile anterior chamber inflammation and anterior segment distress were major concerns in this study thought to be caused by the implant. In this study using a modified smaller implant version in BI-KPro recipients, we did not observe significant anterior segment inflammation. The comparability of the 2 studies is limited by a higher threshold for significance of inflammation after keratoprosthesis compared with cataract surgery.

Adverse events and serious adverse events in this study were in line with the expected prevalence of complications after BI-KPro surgery.[1,2] Most frequent complications were formation of a retroprosthetic membrane and hypertonic or hypotonic IOP. Although it is not possible to clearly differentiate causality between those 2 potential causes, all observed complications are also well known to occur in stand-alone BI-KPro implantation. Performance data acquired in this study showed overall good consistency between manometric and telemetric IOP results.

The results of this prospective study show a promising potential to achieve continuous IOP monitoring and self-tonometry using telemetric systems with an intraocular sensor in patients requiring corneal keratoprosthesis with BI-KPro. Future miniaturization of the system is desirable. With an open-sky corneal trephination for BI-KPro surgery, the current version of the implant could already be usable clinically.

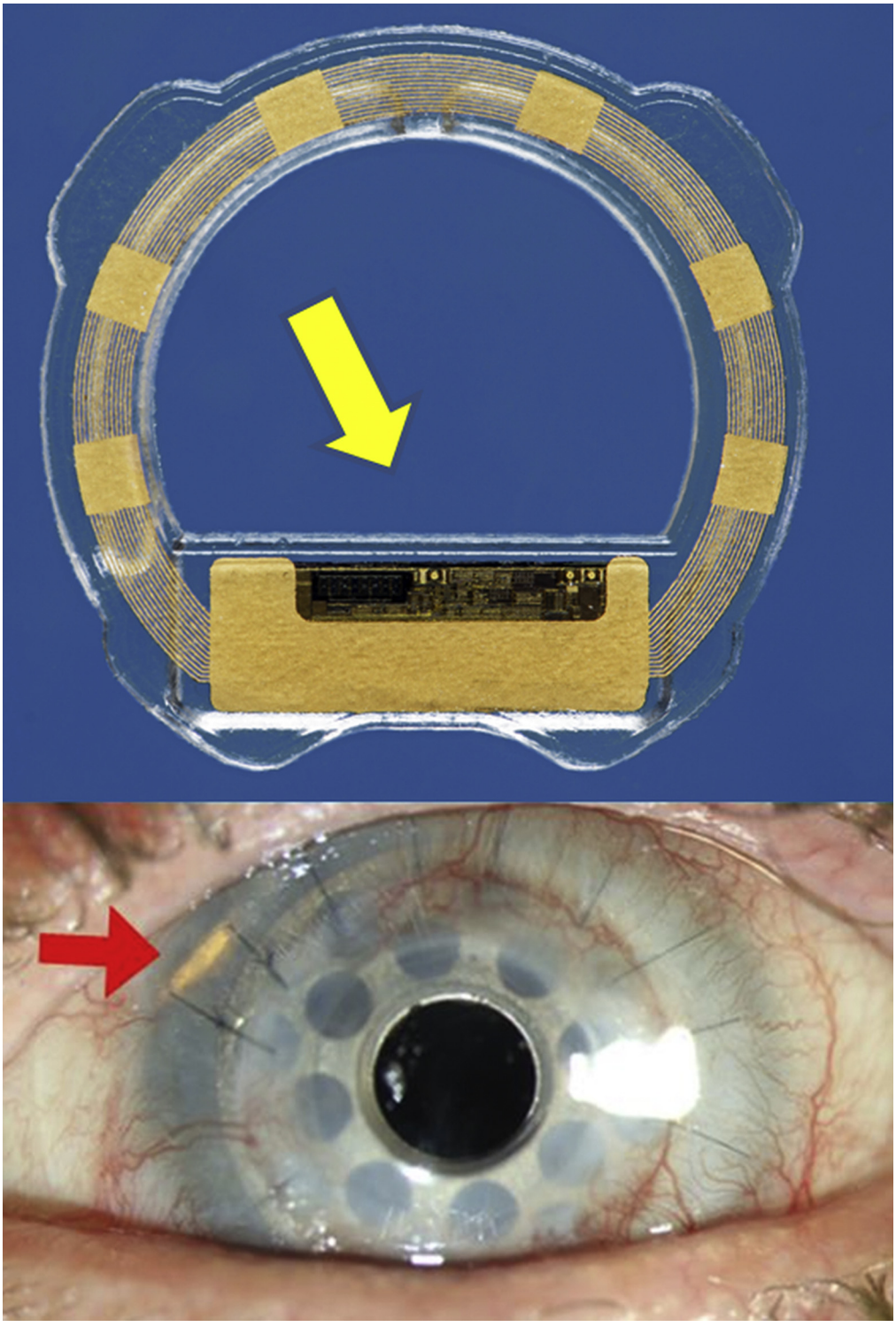

**Figure 1.** The ARGOS-IO (Implandata Ophthalmic Products GmbH, Hanover, Germany) telemetric intraocular pressure (IOP) sensor. The ARGOS-IO is an intraocular sensor for direct IOP assessment. The sensor is placed in the ciliary sulcus and consists of a microelectromechanical system application–specific integrated circuit (*yellow arrow*) bonded to a gold micro-coil and encapsulated in silicone **(top)**. **Bottom:** An implanted ARGOS sensor visible adjacent to the titanium backplate of the Boston keratoprosthesis at the 10 o'clock position of a left eye.

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No animal subjects were used in this study.

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