

# Comparison of three measurement methods of intraocular pressure in patients with keratoconus undergoing MyoRing implantation

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## Abstract

*Purpose:* This study aimed to assess intraocular pressure (IOP) before and after MyoRing implantation in keratoconus patients.

*Methods:* IOP was measured in 13 eyes before and six months after MyoRing implantation using Goldmann applanation (as the gold standard), iCare, and Corvis ST (uncorrected, corrected, and biomechanically corrected).

*Results:* Preoperatively, IOP levels were overestimated using iCare and Corvis (biomechanically corrected). However, uncorrected Corvis measurements were associated with underestimation. Postoperatively, iCare and Corvis (biomechanically corrected) continued to show overestimation, whereas uncorrected Corvis measurements resulted in underestimating IOP.

*Conclusion:* The Goldmann applanation tonometer proves to be a reliable gold standard for obtaining consistent IOP readings in keratoconus patients undergoing MyoRing implantation. Conversely, using iCare and Corvis before and after surgery yielded inconsistent results.

*Keywords:* intraocular pressure, keratoconus, MyoRing, tonometers

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# Perbandingan tiga kaedah pengukuran tekanan mata pesakit keratokonus yang menjalani implantasi Myoring

## Abstrak

*Tujuan:* Kajian ini bertujuan menilai tekanan mata sebelum dan selepas implantasi MyoRing dalam pesakit keratokonus.

*Kaedah kajian:* Tekanan mata 13 pesakit diukur sebelum dan selepas enam bulan implantasi MyoRing menggunakan alat Goldmann tonometer (sebagai piawaian emas), iCare dan Corvis ST (tidak diselaraskan, diselaraskan dan diselaraskan secara biomekanik).

*Keputusan:* Sebelum pembedahan, tahap tekanan mata yang diukur lebih tinggi menggunakan alat iCare dan Cirvis (diselaraskan secara biomekanik). Walaubagaimanapun, ukuran Corvis yang tidak diselaraskan dikaitkan dengan bacaan tekanan mata terlalu rendah. Selepas pembedahan, iCare dan Corvis (yang diselaraskan secara biomekanik) masih menunjukkan bacaan ukuran tekanan mata terlebih tinggi, malah ukuran Corvis yang tidak diselaraskankan pula menghasilkan bacaan tekanan mata terlalu rendah.

*Kesimpulan:* Alat Goldmann tonometer terbukti sebagai tonometer yang boleh dipercayai bagi menghasilkan ukuran tekanan mata yang konsisten dalam pesakit keratoconus yang menjalani implantasi MyoRing. Sebaliknya, menggunakan iCare dan Corvis sebelum dan selepas pembedahan ini menghasilkan bacaan tekanan mata yang tidak konsisten.

*Kata kunci:* keratoconus, MyoRing, tekanan intraokular, tonometer

## Introduction

Keratoconus, characterised by progressive corneal thinning and shape alterations leading to a bulging cornea, irregular astigmatism, and compromised vision, poses a significant challenge. Intrastromal corneal ring segments (ICRSs) have emerged as a corrective measure to address these deformities, reducing asymmetric astigmatism and enhancing visual acuity.<sup>1-3</sup> ICRS implantation has shown promise in delaying or circumventing the need for penetrating keratoplasty (PK). Immediate improvements in refraction and visual acuity post-implantation underscore its clinical significance.<sup>4</sup>

Corneal biomechanics and intraocular pressure (IOP) often undergo changes in corneal disorders, e.g., keratoconus, and following surgeries, e.g., PK.<sup>5-7</sup> Studies

indicate that Goldmann applanation tonometry (GAT) can lead to a significant underestimation of IOP levels after alterations in corneal structure and thickness, such as those resulting from refractive surgeries or PK.<sup>8-10</sup> Recent advancements have introduced tonometers designed to mitigate the impact of corneal changes, such as variations in thickness, on IOP measurements.<sup>11,12</sup>

The effect of corneal structural factors on IOP levels in patients with corneal ectasia or undergoing PK have been discussed in some studies on the Pascal dynamic contour tonometer, the iCare Pro rebound tonometer, and the Tono Pen XL.<sup>13-17</sup> However, few studies have investigated the role of corneal factors in IOP changes among individuals undergoing ICRS implantation.<sup>18</sup> This pilot study seeks to clinically investigate the utility of GAT (AT900, Haag Streit, Koniz, Switzerland; as the gold standard), iCare Pro (iCare Finland Oy, Helsinki, Finland), and Corvis ST (OCULUS Optikgeräte GmbH, Wetzlar, Germany; uncorrected, corrected, and biomechanically corrected) tonometry in patients who had undergone MyoRing (DIOPTEx GmbH, Linz, Austria) implantation. MyoRing, a corneal management device for keratoconus, is similar to other commercially available ICRSs as it flattens the corneal surface, a characteristic dependent on the implant thickness.<sup>19-22</sup> By comparing these instruments with GAT regarding IOP levels, we aim to contribute valuable insights to understanding IOP dynamics in this specific clinical context.

## Methods

This prospective, observational, cross-sectional pilot study involved 13 eyes of 13 subjects (7 males and six females) with a mean age of  $30 \pm 11$  years (ranging from 18 to 42 years), all diagnosed with keratoconus and having undergone MyoRing implantation. The study received approval from the Ethics Committee of Bina Eye Hospital in Tehran, Iran, and all procedures adhered to the principles outlined in the Declaration of Helsinki. Informed consent was obtained from each subject before enrolment in the study.

Before the study, all subjects underwent a comprehensive assessment, including best-corrected visual acuity, slit-lamp examination, fundus biomicroscopy, and Pentacam corneal topography (Orbscan II, Bausch + Lomb, Bridgewater, New Jersey, USA). Pentacam was utilised to confirm the presence of keratoconus in the subjects topographically. Inclusion criteria comprised poor visual acuity even with glasses, intolerance to contact lenses, clear central cornea, corneal thickness  $\geq 360 \mu\text{m}$ , and keratometry readings between 45 D and 52 D. Subjects had undergone MyoRing implantation in the keratoconic eye at least six months before the study initiation.

Exclusion criteria encompassed corneal opacities (e.g., scars, oedema, hydrops), topical ocular treatment, pregnancy, breastfeeding, use of immunosuppressive drugs, a history of keratorefractive surgery on the candidate's eye, a

history of vernal or atopic keratoconjunctivitis or a corneal stromal disorder, dry eye syndrome, nystagmus, hyperopia, and severe ocular (*e.g.*, herpes keratitis, glaucoma, cataracts, diabetic retinopathy, age-related macular degeneration) or systemic disease (*e.g.*, autoimmune disease or systemic connective tissue disease). Only the first treated eye was enrolled in cases where both eyes had a history of MyoRing implantation.

### **Surgical technique**

MyoRing implantation was uniformly conducted in all selected eyes by the same surgeon (MN) under sterile conditions a minimum of 6 months before the commencement of the study. Topical anaesthesia (0.5% proparacaine hydrochloride solution) was induced using the Pocket Maker microkeratome (DIOPTEx GmbH), as previously described.<sup>23,24</sup> In brief, a 9-mm (length) x 300- $\mu$ m (depth) incision was meticulously crafted to create a pocket. The MyoRing was delicately implanted into the pocket using forceps, followed by adjustment with a keratoscope. Notably, the self-sealing nature of the pocket obviated the need for sutures.<sup>21</sup>

Post-implantation, the cornea was shielded with a PureVision silicone hydrogel bandage contact lens (Bausch & Lomb), which was removed after one day with no reported complications. After the procedure, patients were administered betamethasone and chloramphenicol drops (Sinadarou Laboratories, Tehran, Iran) four times daily, along with lubricant tears (Artelac Rebalance, Bausch & Lomb) every four hours. Chloramphenicol use was discontinued after one week, and the dosage of betamethasone was gradually tapered over four to six weeks.

### **Postoperative IOP examination**

All patients underwent a series of ophthalmologic examinations. Initially, a slit lamp examination was conducted on the study's eyes. Subsequently, IOP measurements were obtained with the patient sitting using a Corvis ST-iCare Pro-GAT sequence. All instruments were regularly calibrated following the manufacturer's instructions to ensure accuracy. A 10-minute interval was implemented between different tonometers to minimise potential after-measurement fluctuations. All measurements were conducted between 2 PM and 4 PM to mitigate the impact of daily fluctuation.

Three consecutive IOP measurements were taken for each eye, differing by no more than two mmHg. If discrepancies exceeded two mmHg, an additional measurement was acquired, and the average of the three final measurements was utilised for analysis. For the iCare Pro (iCare Finland Oy, Helsinki, Finland) measurement, a disposable, single-use probe was inserted into the device, aligned 4–8 mm perpendicular to the central cornea, and six consecutive measurements were recorded. The software automatically discarded the highest and lowest values, calculating IOP from the remaining four values, with only proper measurements (indicated by a green background) accepted.

GAT (AT900, Haag Streit, Koniz, Switzerland) was performed using the AT900 device mounted on a slit-lamp biomicroscope. After the instillation of a drop of 0.25% fluorescein with 0.5% proparacaine hydrochloride (Alcaine, Alcon, Couvreur, Belgium) in each eye, three sequential measurements were conducted. If the results were within two mmHg, no further testing was performed, and the final IOP was the average of the three measurements.

Three measurements were taken for each tonometer, with a minimum 3-minute interval between measurements. A 10-minute break was also implemented between using different tonometers to ensure accuracy. Following IOP measurements, central corneal thickness (CCT) was measured using ultrasonic pachymetry (Dicon P55, Paradigm Medical Industries Inc., Salt Lake City, UT, USA). After installing a drop of 0.5% proparacaine hydrochloride, 3 CCT measurements were obtained, and the average of the three values was used for statistical analysis. The same observer conducted all measurements. IOP measurements were carried out by experienced ophthalmologists (MN), and CCT measurements were performed by a skilled optometrist (FK) in separate rooms to ensure independence. Cross-masking was employed during the measurement process to eliminate bias.

### **The Corvis ST tonometer**

The Corvis ST device was used to measure IOP with 3 different corrections: biomechanically corrected IOP (Corvis B), corrected IOP (Corvis C), and uncorrected IOP (Corvis U). Each correction method was applied to ensure a comprehensive analysis of IOP measurements. The Corvis ST tonometer (CST) is a noncontact tonometer (NCT) that employs an ultra-high-speed Scheimpflug camera to monitor corneal deformities during air pulse application. By evaluating the cornea's viscoelastic properties, CST measures IOP. The principles of CST have been detailed previously.<sup>25,26</sup> In the current study, CST measurements were taken 24 hours before surgery, with concurrent determination of head postures.

### **iCare Pro**

The iCare Pro is a portable tonometer featuring a small metal probe with a plastic tip suspended in a solenoid chamber. Voltage is induced in the solenoid by the movement of a magnet within the probe. Utilising rebound tonometry with a 1-mm contact surface between the probe and corneal apex, the probe hits the cornea, rebounds, and induces a voltage in the solenoid.<sup>27-28</sup> This signal is amplified to a microprocessor, and a 6-time reading through this procedure is used to calculate IOP, with the highest and lowest readings automatically excluded.

iCare Pro measurements offer advantages such as minimised damage to the cornea, the absence of a requirement for topical anaesthesia, and a reduced risk of infection.<sup>29</sup> However, corneal anaesthesia was induced in our study to mitigate the risk of bias associated with the order of the three tonometers. Three measure-

ments were taken with high reliability, each being the average of 6 readings. The average of the three measurements was used for statistical analysis. To minimise the impact of daily IOP fluctuations, measurements were consistently performed in the afternoon, with a 5-minute rest interval provided to each subject between readings.

### Statistical analysis

Data analysis was conducted using SPSS version 20. The normality of the data distribution was assessed using the Kolmogorov-Smirnov test. The significance level was set at  $\leq 0.05$ . For comparisons, the Chi-squared test was employed.

## Results

The details of the participants are presented in Table 1. A total of 13 eyes from 13 patients were included. The normality of continuous research variables was assessed using the Kolmogorov/Smirnov test, revealing that none of the variables followed a normal distribution ( $p < 0.05$ ). Both uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) showed significant improvement post-surgery (Table 1). The mean UDVA changed from 1.14 logMAR preoperatively to 0.44 logMAR postoperatively ( $p < 0.001$ ). Similarly, mean CDVA improved from 0.67 logMAR preoperatively to 0.22 logMAR postoperatively ( $p < 0.001$ ). Furthermore, the spherical equivalent decreased from -6.08 D preoperatively to -2.82 D postoperatively, demonstrating a statistically significant reduction ( $p < 0.001$ ).

Table 2 examines preoperative and postoperative IOP measurements using the three tonometers using paired t-tests. A statistically significant difference was observed between preoperative and postoperative measurements with the Corvis C device (bold). Additionally, when comparing preoperative and postoperative IOP measurements across all instruments, all devices exhibited a statistically significant difference (bold).

Bland-Altman plots (Fig. 1) were used to assess the agreement of preoperative IOP measurements among devices. The iCare, Corvis B, and Corvis C performed similarly to GAT, while only the Corvis U exhibited a significant difference from GAT.

Figure 2 presents Bland-Altman plots assessing the agreement of postoperative IOP measurements among devices. In general, iCare and Corvis B performed similarly to GAT, while Corvis U and Corvis C showed a significant difference from GAT.

Table 1. Descriptive statistics of the study patients

Variables	Mean $\pm$ SD		p-value
	Preoperative	Postoperative	
UDVA (logMAR)	1.14 $\pm$ 0.31	0.44 $\pm$ 0.29	< 0.001
CDVA (logMAR)	0.67 $\pm$ 0.23	0.22 $\pm$ 0.15	< 0.001
Sphere (D)	-4.72 $\pm$ 3.19	-1.16 $\pm$ 2.36	< 0.001
Cylinder (D)	-5.45 $\pm$ 1.85	-2.04 $\pm$ 1.29	< 0.001
Spherical equivalent (D)	-6.08 $\pm$ 3.42	-2.82 $\pm$ 2.58	< 0.001
Mean K (D)	51.16 $\pm$ 3.14	46.07 $\pm$ 4.36	< 0.001
CCT ( $\mu$ m)	433 $\pm$ 56	429.8 $\pm$ 42.6	< 0.001

CCT: central corneal thickness; CVDA: corrected distance visual acuity; D: diopters; logMAR: logarithm minimum angle of the resolution; K: keratometry; Max: maximum; Min: minimum; SD; standard deviation; UDVA: uncorrected distance visual acuity

\*Significances are based on Friedman test

Table 2. Comparison of IOP measurements (mmHg) using iCare, GAT, and Corvis before and after MyoRing implantation

IOP (mmHg)	Goldmann	iCare	Corvis U	Corvis C	Corvis B	p-value
<b>Preoperative</b> Mean $\pm$ SD	12.37 $\pm$ 1.45	13 $\pm$ 2.07	11 $\pm$ 1.13	15 $\pm$ 2.84	14 $\pm$ 2.45	< 0.001
<b>Postoperative</b> Mean $\pm$ SD	13.78 $\pm$ 1.73	14 $\pm$ 1.96	11 $\pm$ 1.64	15 $\pm$ 2.49	13 $\pm$ 1.77	< 0.001
<b>p-value</b>	0.08	0.8	0.14	0.014	0.42	

Corvis U: Corvis uncorrected; Corvis C: Corvis corrected; Corvis B: Corvis biomechanically corrected

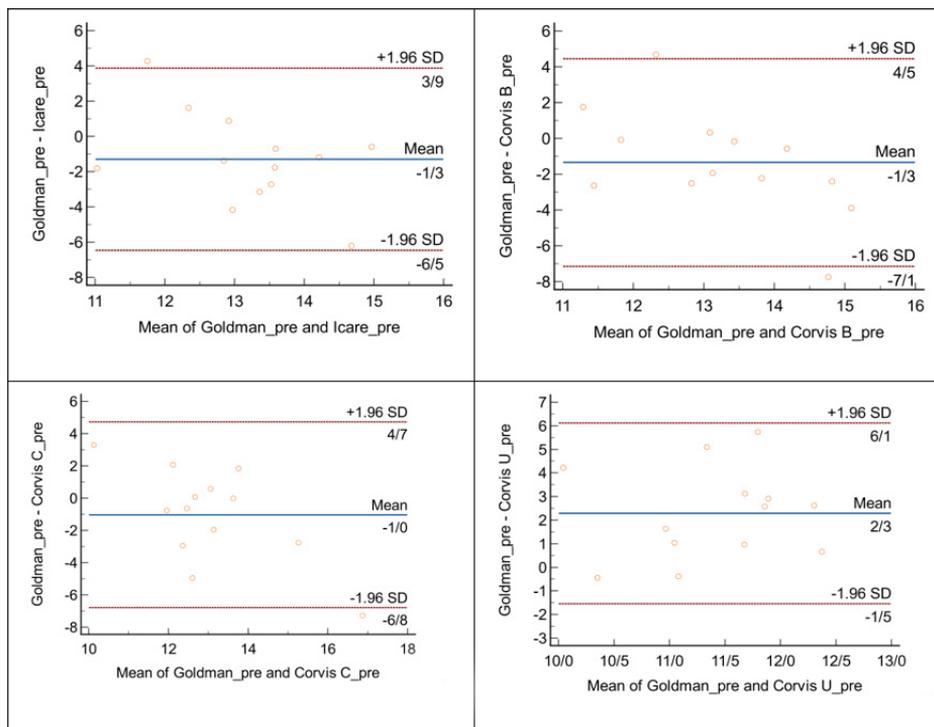


Fig. 1. Bland-Altman plots presenting preoperative agreement between IOP measurements obtained with GAT, iCare Pro, and Corvis ST.

## Discussion

IOP measurement plays a pivotal role in the quest to modify the ocular surface, mainly through ICRS procedures. ICRSs, made of polymethylmethacrylate contact lenses, are utilised to fortify and reshape the cornea, instigating changes to its biomechanical parameters. The evolution of new tonometry techniques strives to discover non-invasive tonometers unaffected by operator bias, CCT, corneal topography, and rigidity. This study scrutinised IOP measurements in subjects who underwent ICRS implantation for keratoconus, comparing IOP measurements from the Corvis ST and iCare Pro tonometers against those from GAT.

While GAT is the gold standard for IOP measurement, it is not recommended in corneal pathology or abnormal corneal thickness cases.<sup>30,31</sup> Recently introduced tonometers aim to bypass corneal parameters that influence IOP measurement.<sup>11,12</sup> In other words, these noninvasive devices mitigate biases caused by the surgeon, CCT, corneal topography, and rigidity.<sup>32</sup> This study assessed the clinical utilisation

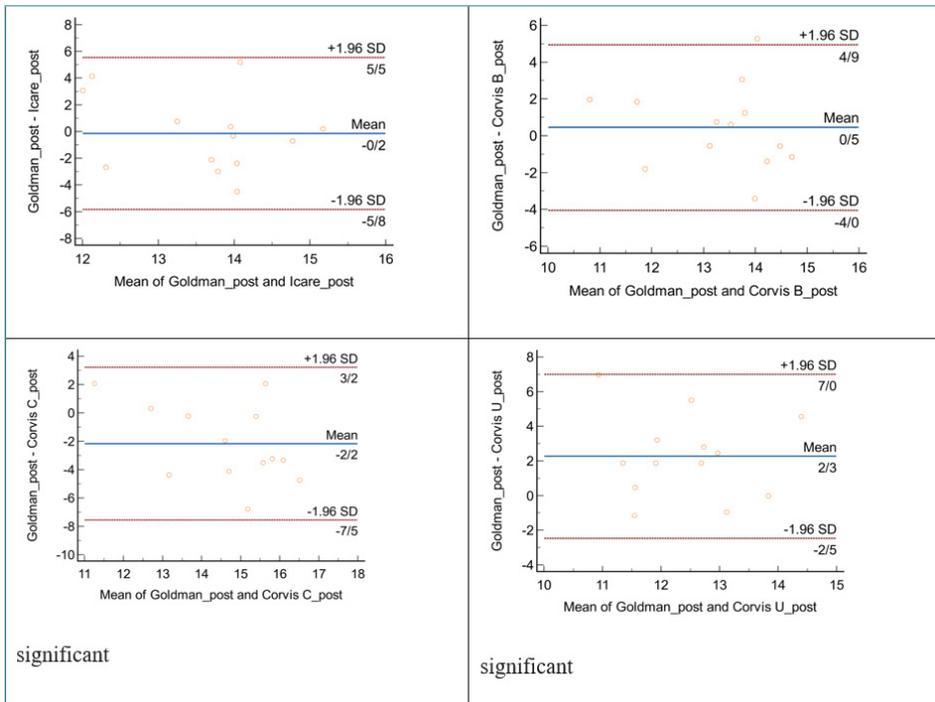


Fig. 2. Bland-Altman plots presenting postoperative agreement between IOP measurements obtained with GAT, iCare Pro, and Corvis ST.

and accuracy of the Corvis ST (with Corvis B, Corvis C, and Corvis U corrections) and iCare Pro by comparing their IOP measurements with readings obtained from the reference standard of the GAT. The study evaluated the agreement between Corvis ST (Corvis B, Corvis C, and Corvis U), iCare Pro, and GAT in patients who had undergone MyoRing implantation for keratoconus 6 months before the study onset. The tonometers were randomly utilised to prevent applanation biases.

Keratoconus is characterised by a thinner, steeper, or more astigmatic cornea than average.<sup>33</sup> ICRS implantation is primarily performed to minimise astigmatism and corneal steepness, stabilising and strengthening the ectatic cornea.<sup>34,35</sup> Gorgun *et al.* reported a decrease in corneal resistance factor over time, with no changes in corneal hysteresis in the first days after the implantation of femtosecond laser-assisted ICRSs, while preoperative corneal hysteresis and corneal resistance factors remained similar. Ring segments affect the cornea and subsequently improve visual acuity within six months; hence, this was considered the follow-up period in our study.<sup>36</sup> Different tonometers have been evaluated in subjects with healthy corneas,<sup>37</sup> corneal deformities such as keratoconus,<sup>38</sup> and those who have undergone PK<sup>39</sup> and deep lamellar keratoplasty.<sup>40</sup>

A prospective study on GAT showed lower IOP levels after ICRS implantation.<sup>42</sup> In the current study, the most significant difference was observed between IOP levels obtained with GAT and iCare Pro (1 mmHg). In comparison, the least significant difference was found between GAT and Corvis U (0 mmHg). Compared with GAT, iCare Pro overestimated IOP while Corvis U underestimated IOP. Mean IOP was one mmHg lower using Corvis U than GAT, although the difference was not statistically significant.

Roberts *et al.*<sup>43</sup> found that procedures biomechanically altering corneal integrity affect IOP levels obtained by CST. The present study found that MyoRing implantation biomechanically alters corneal capacity; these results are consistent with other previous studies.<sup>43,44</sup> The reason can be attributed to energy absorption or dissipation in the cornea after MyoRing implantation.

The present study results indicate that IOP measurements taken with iCare Pro, Corvis B and U, and GAT are influenced by similar parameters in ectatic corneas.<sup>13</sup> However, the minor mean differences among the provided readings may emphasise GAT's reliability. We did not observe signs that postoperative corneal astigmatism or corneal curvature influenced IOP measurements obtained by the tonometers used in this study. Future studies in terms of preoperative values of the studied variables are required.

In summary, it can be concluded that IOP measurements obtained by GAT, iCare Pro, and Corvis ST tonometry are clinically similar in patients undergoing ICRS implantation. A good agreement was observed between IOP measurements obtained by the iCare Pro and Corvis and those measured by GAT; corneal factors did not influence the Corvis C tonometer. A long-term multicentre study with a larger sample size is required to provide conclusive results on the effect of ICRS implantation on IOP levels.

## Declarations

### **Ethics approval and informed consent**

The study received approval from the Ethics Committee of Bina Eye Hospital in Tehran, Iran, and all procedures adhered to the principles outlined in the Declaration of Helsinki. Informed consent was obtained from each subject before enrolment in the study. The medical team/IRB takes full responsibility for the patient data. All data and images in this article have been rigorously anonymised.

### **Competing interests**

The authors declare no competing interests.

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