Assessing Efficacy of Canaloplasty Using Continuous 24-Hour Monitoring of Ocular Dimensional Changes

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Primary open-angle glaucoma (POAG) is one of the most common causes of visual loss encountered in clinical practice and a dominant contributor to blindness.1 Glaucoma causes continuous progressive damage of the optic nerve and it usually is associated with IOP.2

Canaloplasty is one of the modern surgical interventions suitable for treating POAG.3–5 It uses a microcatheter to improve outflow through the patient’s own natural drainage system via viscodilation and tensioning of the Schlemm canal.4 It is particularly suitable for patients with mild optic nerve damage and those who can tolerate a higher target IOP, as well as for patients for whom other surgical techniques, such as trabeculectomy, are associated with high probability of failure.3 Canaloplasty produces a significant and sustained long-term IOP reduction in open-angle glaucoma patients.4,6,7 The adjustment of IOP values by minimal invasive ocular surgery has been shown to be more effective than the use of hypotensive drugs for long periods of follow-up.8–11 However, technical solutions to monitor long-term efficacy of canaloplasty, beyond static evaluation of IOP12–16 seem to be limited.

Dynamic nature of the eye reveals itself in cyclic expansion and contraction of the eye globe known as the ocular pulse and manifests itself in variations of many anatomic and physiologic parameters. However, the ocular pulse is not the only characteristic of the eye’s dynamic nature, which also undergoes longer-term processes associated with the circadian (24-hour) rhythm. Diurnal changes were found mainly in parameters, such as IOP, in normal and glaucomatous eyes, corneal thickness, corneal topography, axial length, anterior chamber depth, and choroidal thickness.

The consequence of ocular volume changes are pulsatile displacements of eye tissues and the corneoscleral limbus area (CSLA) (Lindell J, et al. IOVS 2014;55:ARVO E-Abstract 153). Hence, monitoring those displacements at CSLA may provide additional information on eye dynamics and give more insight for the assessment of ocular pulsation abnormalities in glaucoma. In particular, the characteristics of ocular pulse signal at the CSLA of glaucomatous eyes may reflect obstruction of the outflow of aqueous humour, increased IOP, the pulsation of blood flow in the ciliary muscle, and thereby changes in the tension of the eyeball in that place. Hence, registering biomechanical responses of the eye to chronically elevated IOP at the CSLA may support assessing the effectiveness of
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ophthalmic surgeries focusing on reduction of IOP in glaucomatous eyes.

Recently, a number of studies reported continuous 24-hour circumferential changes at the CLSA with a new promising Triggerfish contact lens sensor (CLS; SENSIMED Triggerfish; Sensimed, Lausanne, Switzerland) with an attempt to link them to changes in IOP.11,12 The aim of this study was to ascertain whether 24-hour continuous monitoring of CLSA with the CLS can be used clinically for assessing midterm efficacy of canaloplasty. An additional aim of this study was to assess the relationships of such continuous monitoring with the heart activity.

METHODS

Study Design

The study was approved by the Bioethics Committee of the Military Institute of Medicine in Warsaw and adhered to the tenets of the Declaration of Helsinki. A written consent was obtained from all participants after they had been informed about the study character of the intervention and the surgical alternatives, and after declaring their participation in the study for at least 12 months.

Primary open-angle glaucoma and pseudoexfoliation glaucoma (PEG) with a possible coexisting cataract was an indication for surgery. Additional inclusion criteria encompassed unsatisfying IOP control despite maximally tolerated medication, well-documented progression of the visual field, noncompliance in antiglaucoma therapy, and allergy to topical medication. Exclusion criteria included unwillingness to participate, dry eye syndrome, intolerance to contact lenses wear, any previous surgical procedure within the eye, poorly controlled diabetes mellitus with diabetic retinopathy, advanced macular degeneration, active inflammatory disease, atrial fibrillation, and patients with cardiac pacemakers.

Preoperative Protocol and Surgical Technique

At the time of qualification, a review of medical history of previous ophthalmic treatment and surgical procedures was performed. Before surgical intervention, all patients underwent a baseline examination, which was performed after a washout period, and included determination of IOP following AGIS recommendations,13 uncorrected (UCVA) and corrected distance visual acuity (CDVA), gonioscopy, and examination of the anterior and posterior segment of the eye. In addition, biometric measurements were taken of central corneal thickness, axial length, and keratometric values. For patients requiring phacoemulsification, IOL was calculated on the basis of the SRK T formula.

After a washout period, simultaneous continuous 24-hour monitoring of ocular dimensional changes and electrical heart activity was performed with Triggerfish CLS and LifeCard CF digital Holter recorder (Del Mar Reynolds Medical, Spacelabs Healthcare Ltd., Hertford, UK), respectively. After the CLS and electrocardiographic (ECG) monitors were fitted, patients were discharged and came back after 24 hours.

Details of the surgical procedures have been reported recently.16 All surgical procedures were performed with the use of retrobulbar anesthesia (2% xylocaine and 0.5% bupivacaine) by one surgeon (M.R.) following the works of Lewis et al.4 and Bellucci and Morseli.44

Postoperative Protocol

Corrected distance visual acuity was measured with an Early Treatment Diabetic Retinopathy Study (ETDRS) chart, and IOP was measured with a Goldmann applanation tonometer at follow-up examinations. The anterior chamber, iridocorneal angle, and fundus were examined. The postoperative course was analyzed, including complications as well as the number of antiglaucoma medications. Follow-up examinations were conducted on days 1 and 7, and 1, 3, 6, and 12 months after surgery. At the 3- and 12-month visit, patients were examined again and simultaneous continuous 24-hour monitoring of ocular dimensional changes and electrical heart activity was performed with Triggerfish CLS and Holter recorder, respectively.

Surgical success was defined as IOP ≤ 18 mm Hg with no antiglaucoma medications. A procedure was considered to be a failure when IOP was >18 mm Hg with or without glaucoma medication or when an eye required further glaucoma drainage surgery. All patients received a topical steroid and antibiotic combination for 4 weeks after surgery.

Monitoring 24-Hour Ocular Dimensional Changes and Heart Activity

The Triggerfish CLS provides an automated recording of 24-hour continuous circumferential changes at the CLSA.45 It is in a form of a silicone contact lens embedded with a microsensor. The CLS examination was conducted according to producer manual and clinical practice.46–47 The device was safe and tolerable for healthy and glaucoma subjects.48 Any eventual adverse effects associated with CLS were noted. The type of the contact lens (flat, medium, or steep) was selected for each patient according to keratometric values. The data from the contact lens are continuously transmitted wirelessly from the antenna, patched around the orbit, to a portable recorder worn by a patient. The 24-hour monitoring with the CLS gives 288 data periods (every 5 minutes) of ocular volume changes taking 30 seconds each at sampling frequency of 10 Hz provided in arbitrary units.

Simultaneously with the Triggerfish CLS, 24-hour ECG monitoring was performed with the Holter recorder. Before the CLS application, three electrodes were attached at designated locations on the patient’s chest. The ECG was registered continuously with the sampling frequency of 128 Hz.

Data Analysis

All signal analyses were performed using custom written algorithms in Matlab (MathWorks, Natick, MA, USA). Raw Triggerfish CLS data were considered for the analysis, which included estimating the median signal level in each packet (so called burst) sampled at 10 Hz for a period of 30 seconds at 5-minute intervals, concatenating the median signal levels into a time series with a corresponding hourly timeline, detrending and partial shifting the time series (to allow comparison of washout and postop measurements), signal variance estimation, and best-sine wave fitting. Estimation of the median signal level in each packet has been performed in a way to exclude sudden signal changes corresponding to blinks and other artefacts (Fig. 1). This was achieved with a filter that examines the derivative of the signal.

Examples of estimated time-series of medians for one of the subjects are shown in Figure 2 (top). Monitoring for this subject did not start at one set time and their mean amplitudes are different. Hence, to compare the three considered measurements, one must detrend the signals (i.e., remove the mean amplitude) and perform partial circular shifting of those records that start earlier than that acquired at the latest time to ensure that all considered records have the same hourly
timeline. Figure 2 (bottom) shows the same records of data as in Figure 2 (top) but detrended and circularly shifted.

The final step in the analysis included estimation of detrended signal temporal variance (VAR) and fitting the best-fit sine circadian changes model,

\[ y = a \sin \left( \frac{2\pi \text{time}}{24} + c \right), \]

where \( a \) is the signal amplitude and \( c \) is the phase. Parameters \( a \) and \( c \) have been estimated using the following linear in-parameters least-squares method. For the discrete pair of variables \((t_n, y_n), n = 1, 2, \ldots, N\), we form two column vectors \( t = [t_1, t_2, \ldots, t_N] \) and \( y = [y_1, y_2, \ldots, y_N] \) and a matrix:

\[ H = \begin{bmatrix} \sin \left( \frac{2\pi t}{24} \right) & \cos \left( \frac{2\pi t}{24} \right) \end{bmatrix}. \]

Using least squares procedure we estimate a two-parameter vector

\[ \hat{\Theta} = (H^T H)^{-1} H^T y, \]

from which we derive the estimators of the parameter \( c \) and \( a \) using

\[ \hat{c} = \tan^{-1}(\hat{\Theta}_1/\hat{\Theta}_2) \quad \text{and} \quad \hat{a} = \hat{\Theta}_1 / \cos(\hat{c}). \]

Parameters VAR and \( \hat{a} \) describe short-term 24-hour variability of CSLA signal. Further signal analysis was used to compare the activity of the rhythm of the heart with continuous 24-hour monitoring of CSLA. For each extracted CSL signal packet a corresponding time period of the Holter ECG recording was assigned. For that, raw data contained in Channel 1 of the 3-channel ECG records were used. Using a peak-detector a series of RR intervals and corresponding changes in time intervals between any two successive maxima (peak-peak) of the Triggerfish CSL packet, were determined. They then were used as the two estimators of heart rhythm within the 30-second packet. Subsequently, the medians of those estimators were calculated and used as an indicator for the given packet. Then, up to 288 such estimates were determined for each recording of Triggerfish CSL signal and Holter ECG.

Power spectral density (PSD) analysis of each extracted signal packet and the corresponding Holter ECG interval was performed to assess the correspondence between dimensional changes at the CSLA and the activity of heart. An example of a packet from the CSL signal acquired at the resting time of a subject is shown in Figure 3 along the acquisition of the Holter.
ECG signal. It is evident that both signals have similar spectral characteristics, particularly around the principal and second harmonics of the ECG signal. However, such a close correspondence is not that evident during active time of a subject where the Triggerfish signal becomes noisier than in the case of the resting time.

**Statistical Analysis**

Statistical analysis included standard descriptive statistics, Wilcoxon signed-rank test, correlation analysis, and Bland-Altman plot. Nonparametric statistical hypothesis testing was favored because of the small sample size ($n/C20\leq10$). A $P$ value of 0.05 or less was considered to be significant. Calculations were performed using Statistica 10.0.

**RESULTS**

There were 10 patients recruited into the study (6 females and 4 males; aged mean $\pm$ SD, 69.3 $\pm$ 11.4), including 4 patients who underwent canaloplasty and 6 who underwent combined canaloplasty and phacoemulsification. The mean follow-up period taken for the statistical analysis was 11.4 $\pm$ 2.8 months. Details of patient’s demographic data are summarized in Table 1.

**IOP and Medicines**

Preoperatively, the mean IOP was 19.1 $\pm$ 3.4 and after washout increased to 20.6 $\pm$ 4.7 mm Hg (Wilcoxon test, $P = 0.225$). After 12 months of observation, IOP decreased by approximately 31% and was 14.2 $\pm$ 3.0 mm Hg (Wilcoxon test, $P = 0.008$; see Table 2 and Fig. 4). Success rate with the criterion of IOP $\leq$ 18 mm Hg was reached in approximately 88% (eight of nine subjects remaining in the study). Preoperatively, the mean number of antiglaucoma medications was 2.2 $\pm$ 1.1, and decreased to 0.1 $\pm$ 0.3 at the end of observation (Wilcoxon test, $P < 0.001$). One patient was administered one medication at the end of follow-up (Table 2).

**Corrected Distance Visual Acuity**

Mean CDVA was 0.18 $\pm$ 0.22 preoperatively and changed after 12 months to 0.08 $\pm$ 0.09 logMAR (Wilcoxon test, $P = 0.236$). In patients after phacoemulsification and canaloplasty mean CDVA was 0.27 $\pm$ 0.20 preoperatively and it improved to 0.10 $\pm$ 0.09 logMAR (Wilcoxon test, $P = 0.138$), whereas for canaloplasty it was 0.0 $\pm$ 0.0 logMAR preoperatively and changed to 0.03 $\pm$ 0.02 (Wilcoxon test, $P = 0.179$). In all phaco-canaloplasty patients, CDVA improved or was stable at the end of observation when compared to initial values, whereas after canaloplasty alone CDVA was stable in two patients, and in two others it decreased one Snellen line. No decline of two or more Snellen lines was noted.

**Complications**

No serious adverse effects associated with Triggerfish CLS were observed. After removal of the device from the eye conjunctival hyperemia was noted, four of the patients had punctate epitheliopathy, which resolved within 1 day. We noted one serious intraoperative complication- hemorrhagic Descemet membrane detachment, which involved the visual axis. It was managed immediately within the same procedure, and the patient regained full visual acuity. The complication and surgical technique for its management have been reported previously.15

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**Table 1. Patients’ Demographic Data**

<table>
<thead>
<tr>
<th>Data</th>
<th>Mean ± SD, Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up, mo</td>
<td>11.4 ± 2.8</td>
</tr>
<tr>
<td>Age, y</td>
<td>69.3 ± 11.4</td>
</tr>
<tr>
<td>Sex, female/male</td>
<td>6/4</td>
</tr>
<tr>
<td>Eye, right/left</td>
<td>5/5</td>
</tr>
<tr>
<td>Canaloplasty/phacoemulsification and canaloplasty</td>
<td>4/6</td>
</tr>
<tr>
<td>Glaucoma type: POAG/PEX</td>
<td>9/1</td>
</tr>
<tr>
<td>Visual field mean deviation, dB</td>
<td>$-4.97\pm5.50$</td>
</tr>
<tr>
<td>Visual field pattern standard deviation, dB</td>
<td>$3.77\pm3.57$</td>
</tr>
</tbody>
</table>
Triggerfish CLS and 24-Hour Electrocardiography Monitoring

Data from 10 canaloplasty patients (including 6 with phacoemulsification) were considered. They consisted of 10 washout records of 24-hour monitoring of changes in ocular dimensions, measured with CLS along with Holter ECG, corresponding 10 records of 3-month postop 24-hour monitoring, and 6 records of 12-month postop monitoring. One patient did not report to 12-month follow-up, and records of three other patients were of low quality and could not be included in the analysis.

A representative example of the best-fit sine model to the considered earlier Triggerfish records of subject No 3 is shown in Figure 5.

A postop decrease in the variations of the ocular pulse is observed. The trend is stronger for the 12-month than for the 3-month postop data. Estimates of the signal variance together with the estimates of diurnal changes in Triggerfish signal amplitude, assumed to be equivalent to changes in the variations of the ocular pulse and represented by the estimator of the parameter \( \hat{a} \) in Equation 1, are collated in Table 3 and Figure 6. In the case of subject 8, at washout the data did not follow typical sine-wave profile due to substantial subject’s movements and were excluded from the analysis.

Decrease trends in the group median signal variance (VAR) and the group median parameter \( \hat{a} \) were observed postop. There are statistically significant differences between the washout and 3-month postop visit for VAR and \( \hat{a} \) (Wilcoxon test, \( P = 0.014 \) and \( P = 0.027 \), respectively) as well as between the washout and the 12-month postop result for \( \hat{a} \) (Wilcoxon test, \( P = 0.051 \)) but not for VAR (Wilcoxon test, \( P = 0.094 \)). No statistically significant differences were found between the 3- and 12-month postop results for VAR and \( \hat{a} \) (Wilcoxon test, \( P = 0.313 \) and \( P = 0.094 \), respectively).

An example of the median CLS values recorded over 24-hour period and the corresponding estimates of RR interval (Holter ECG) and peak-peak interval (CLS) are shown in Figure 7. When examining the raw Triggerfish signal (Fig. 1), it is noted that a better correspondence between those estimates is evident in resting periods of the subject. Figure 8 shows the correlation between the considered two estimators, which was statistically significant (Pearson correlation coefficient, \( R^2 = 0.448, P < 0.001 \)), and the corresponding Bland-Altman plot.

**DISCUSSION**

To our knowledge this study represents the first simultaneous 24-hour recording of CSLA morphology changes and ECG in patients with glaucoma, treated with canaloplasty surgery.

In the subsequent analysis we used the raw Triggerfish signals to guarantee adequate median signal characteristics. Two key signal characteristics were studied. The variance of a detrended signal determines the energy of the CLS signal while the amplitude of the sinusoidal function fitted to the CLS signal

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**TABLE 2.** Mean Values, Median Number, SDs, Ranges of IOP and Number of Medications at Specific Times After Surgery

<table>
<thead>
<tr>
<th>Time</th>
<th>IOP, mm Hg</th>
<th>Medications, n</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean, SD</td>
<td>Median, Range</td>
</tr>
<tr>
<td>Preop</td>
<td>19.1 ± 3.4</td>
<td>19, 14–24</td>
</tr>
<tr>
<td>Washout</td>
<td>20.6 ± 4.7</td>
<td>19.5, 14–29</td>
</tr>
<tr>
<td>First d</td>
<td>10.8 ± 4.8</td>
<td>9.5, 5–21</td>
</tr>
<tr>
<td>Seventh d</td>
<td>16.3 ± 3.1</td>
<td>15.5, 13–22</td>
</tr>
<tr>
<td>First mo</td>
<td>13.6 ± 3.2</td>
<td>14.5, 8–18</td>
</tr>
<tr>
<td>3rd Mo</td>
<td>13.2 ± 3.4</td>
<td>14, 8–17</td>
</tr>
<tr>
<td>Sixth mo</td>
<td>14.1 ± 3.1</td>
<td>14, 10–18</td>
</tr>
<tr>
<td>12th mo</td>
<td>14.2 ± 3.0</td>
<td>15, 11–19</td>
</tr>
</tbody>
</table>

\( n \), number of medications.

* Wilcoxon signed-rank test (washout versus 1 and 7 days, and 1, 3, 6, and 12 months).

![Figure 4. Box-plots of IOP at specific time before and after surgery.](http://iovs.arvojournals.org/pdfaccess.ashx?url=/data/Journals/IOVS/935270/ on 07/12/2016)
describes the diurnal cycle. The smaller the signal variance the smaller changes occur at the CSLA. Similarly, the smaller the amplitude of the sine wave, the flatter is the diurnal cycle. Our approach is in agreement with the works of Agnifili et al.49 and Read et al.19 who also used a sine function model in their research and Mansouri et al.45 who used a modified cosinor rhythmometry model (having sine and cosine components). A different approach was applied by Tan et al.50 who smoothed the signal by the B-spline function and analyzed the variability of the signal for every clock hour independently. The two parameters that we chose to describe the recordings enabled us to compare the signals and perform the subsequent statistical analysis of the whole sample of patients. We believe that the derived parameters are useful to investigate two phenomena that occur in the eye: ocular pulse and diurnal cycle, but more research is needed to explore their potential application in clinical practice.

In our study we found that the parameters VAR and $\hat{a}$ decreased at 3 and 12 months postop comparing to the washout assessment. That decrease, in most cases, was statistically significant. Diurnal curve was flatter with minor nocturnal rise and the signal fluctuations diminished with time. The lack of significance of the difference between postop months 3 and 12 could be explained by the type of patients that have been included in this study (with not very advanced glaucoma and who could benefit most from the canaloplasty procedure). Those patients heal better than patients with longstanding, advanced glaucoma, it is possible that they experienced the improvement faster and exhibited most of the positive effect of the surgery in the early postop period.

In 2007, Lewis et al.4 published their promising interim clinical study analysis, which showed decreasing trend of mean IOP at 3, 6, and 12 months after canaloplasty. Since then, researchers have investigated the efficacy and safety of the canaloplasty procedure.4,16,51–57 The more recent studies have offered a comparison of canaloplasty and other types of glaucoma surgeries, like trabeculectomy or nonpenetrating deep sclerectomy.56,57 It has been confirmed that canaloplasty is effective in decreasing IOP and has a very favorable safety profile although the decrease of IOP is moderate and, therefore, canaloplasty is suitable for patients with not very advanced glaucoma and with higher target IOP.3,58

In terms of IOP reduction, our study results are comparable to those of Matlach et al.56 and Thederan et al.57 Since the postsurgical result is in agreement with previous research we can assume that our group is representative to the typical subset of glaucoma patients that are good candidates for a canaloplasty procedure.

The eye is a dynamic organ undergoing constant changes. In our research we investigated two different types of short-term variability. One associated with the circadian rhythm and the other caused by many different factors, such as ocular pulsation, blinking, eye movements or noise. Interestingly,
Mansouri et al.42 showed that in particular conditions, such as during the sleep period, the Triggerfish CLS has the ability to accurately detect ocular pulsation.

To the great extent the dynamic nature of the eye can be attributed to the complexity of its circulatory system, which is unique due to the presence of two distinct vascular systems, namely retinal and choroidal, and additionally the factor of the aqueous humor hemodynamic, is greatly adding to the complexity. Regulation of these three systems is highly complex; involving the autonomous nervous system, paracrine, and endocrine factors and their interplay is crucial for maintaining the eye homeostasis. Despite the vast body of research, many aspects of this complicated interplay still remain elusive. The changes that occur at the CSLA might be especially relevant for the glaucoma pathogenesis since the changes of the signal registered at the CSLA may reflect changes in the aqueous humour production and outflow rate, fluctuations of the IOP, and changes in the circulatory system of the choroid. Recently, an association was found between the parameters of the CSLA signal with the rate of visual progression in glaucomatous eyes.59

Our study revealed that the CSLA circadian rhythm pattern morphology after the canaloplasty, although being decreased in its amplitude, is not entirely flattened and still is identifiable after the surgery. The maintenance of the diurnal rhythm amplitude could be a potential advantage of the canaloplasty, which the main goal of is to reestablish the natural trabeculo-canalicular outflow, since circadian changes may have an important role in maintaining eye homeostasis. Kara et al.60 have found choroidal thickening at 1 month after trabeculectomy, measured with enhanced depth imaging - optical coherence tomography; they also reported that choroid change was correlated negatively with the change in IOP and axial length. Although until now there has been no study on CSLA changes after trabeculectomy, but according to our hypothesis we may speculate that a large decrease in IOP and no restoration of natural aqueous outflow pathway or even reduction of Schlemm’s canal due to underperfusion,61 accompanying filtration surgery could affect circadian rhythm of choroidal changes and may result with atypical flattened CSLA morphology.

Tan et al.50 have been able to link the increased variability in the CSLA signal in certain time frames, while falling asleep and waking, with faster progression rate of the visual field index. On the other hand, it has been reported by Tojo et al.62 that a typical circadian pattern of the Triggerfish CLS signal with a nocturnal rise was found in all healthy patients in a control group from their study. This raises the question how much

**Figure 7.** An example of the median Triggerfish CLS signal values recorded over a 24-hour period (top) and the corresponding estimates of RR interval (Holter recorder) and peak-peak interval (CLS; bottom).

**Figure 8.** Correlation between the estimator of the RR interval (Holter recorder) and peak-peak interval (Triggerfish CLS) of a signal from Figure 7 (left) and the corresponding Bland-Altman plot (right).
variability is physiologic and whether the preservation of the diurnal rhythm amplitude could be a potential advantage of canaloplasty.

Unlike typical estimation of the heart rate variability (HRV), in our study we used an algorithm to estimate the RR-intervals of Holter ECG signal and corresponding peak–peak intervals of the Triggerfish CLS signal. This was done because HRV parameters are routinely obtained from longer than 30-second periods of time. The median peak–peak intervals recorded over 24-hour period and the corresponding estimates of RR intervals have shown a good correlation. This concordance was seen in the resting time and supine positions (at night) when the balance of heart rate was stable and CLS signal became less noisy. It may suggest that similar correlation appears also during daytime but is undetectable because of noisy signal related to patient’s activity.

It was shown previously that ocular pulse, measured either by pneumotonometry or pneumoplethysmography, or as a corneal pulse was highly correlated with the parameters of reproducible results, and showed a good safety profile, its output signal still is challenging to interpret. Also, a noisy signal related to patient’s activity.

when the balance of heart rate was stable and CSLA signal became less noisy. It may suggest that similar correlation appears also during daytime but is undetectable because of noisy signal related to patient’s activity.

The pathophysiology of glaucoma still is not completely understood and it is of interest to find out how biomechanical effects may have a role in glaucomatous optic nerve head damage. One of the main reasons of increased IOP fluctuations in the elderly is loss of elasticity of the sclera, due to, among others, natural “cross-linking” phenomenon, related to the increased stiffness of the extracellular matrix and collagen fibers. Rigid sclera limits the filling of the vortex veins, increases the resistance of venous outflow, which leads to compensation of the choroidal venous system, particularly in the posterior pole and may result in the degeneration of the Bruch’s membrane, choriocapillaries and RPE. Changes in the outflow facility, following IOP reduction after canaloplasty may affect several parameters of ocular function by alterations in the biomechanical properties in ocular matrix tissues, such as sclera, cornea, and choroid, which contribute the increase in aqueous humor outflow and filling of the choroid.

When interpreting our findings some aspects and limitations of the study should be considered. Although Triggerfish CLS system has been validated, found to produce reproducible results, and showed a good safety profile, its output signal still is challenging to interpret. Also, a small number of patients participating in a study and four dropouts at the 12-month visit, result in the need to verify our findings on a larger group of patients.

In our study, we attempted to answer the question if continuous monitoring of CSLA can be clinically useful for assessing mid-term efficacy of canaloplasty. To date, a gold standard for assessing the efficacy of anti-glaucoma procedures is an IOP measurement. It is worth noting, that the Triggerfish CLS device provides an automated recording of continuous circumferential changes at the CSLA, not the estimates of IOP over 24 hours. In our study, we demonstrated that short-term variability of CSLA changes is decreasing after the canaloplasty and that this change is stable over the course of time. We hypothesized that analysis of the Triggerfish CLS signal could provide additional parameters that in the future may give us much finer criteria to assess the outcome of the glaucoma surgery, than static IOP measurement. Further studies are required to establish the relationship between CSLA changes with choroid thickness measurements after canaloplasty and to investigate CSLA changes following other methods of glaucoma surgery. Also, further studies designed to explore the diurnal effects of topical prostaglandins on IOP reduction and on biomechanical properties in ocular matrix, measured by the CLS signal are needed. Evaluating how a particular medical or surgical intervention modifies the CLS variability throughout the day and night may facilitate the choice of an appropriate, individualized treatment strategy for the glaucoma patients.

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